EASA

European Union Aviation Safety Agency

Part-21

(IR + AMC & GM)

eRules

Easy Access Rules for Airworthiness and Environmental Certification (Regulation (EU) No 748/2012)

EASA eRules: aviation rules for the 21st century

Rules are the core of the EU civil aviation system. The aim of the **EASA eRules** project is to make them **accessible** to stakeholders in an efficient and reliable way.

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The **EASA eRules** system is developed and implemented in close cooperation with the Member States and aviation industry to ensure that all its capabilities are relevant and effective.

Published May 2022[1]

[1] The published date represents the date when the consolidated version of the document was generated.

[1] Euro-Lex, Important Legal Notice: http://eur-lex.europa.eu/content/legal-notice/legal-notice.html.

DISCLAIMER

This version is issued by the European Union Aviation Safety Agency (EASA, referred to as both 'EASA' and 'the Agency') in order to provide its stakeholders with an updated, consolidated, and easy-to-read publication. It has been prepared by putting together the officially published regulations (including the amendments) adopted so far. However, this is not an official publication and EASA accepts no liability for damage of any kind resulting from the risks inherent in the use of this document.

LIST OF REVISIONS

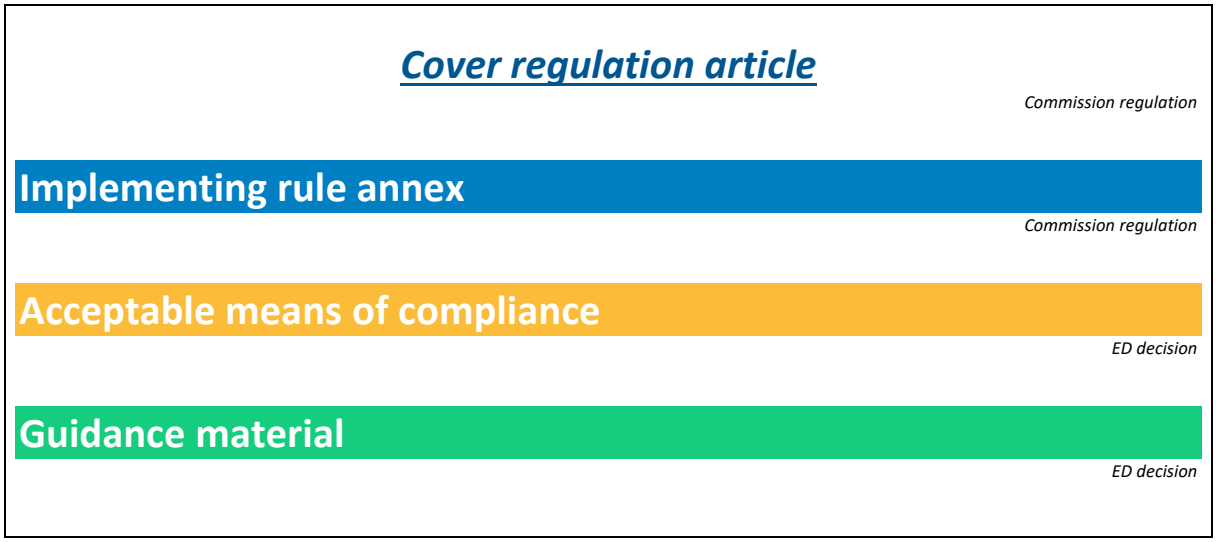
Published	Reason for revision
February 2018	First Easy Access Rules document powered by eRules.
December 2019	To incorporate ED Decision 2019/003/R introducing AMC/GM to Annex I (Part-21) to Regulation (EU) No 748/2012 for proportionality and simplification of airworthiness and environmental certification regulations for small aircraft.
	To incorporate Commission Delegated Regulation (EU) 2019/897 of 12 March 2019 amending Regulation (EU) No 748/2012 as regards the inclusion of risk-based compliance verification in Annex I (Part 21) thereto and the implementation of requirements for environmental protection, and the associated ED Decision 2019/018/R amending the AMC and GM to Part 21 — Issue 2, Amendment 9.
June 2020	To incorporate Commission Delegated Regulation (EU) 2020/570 of 28 January 2020 amending and correcting Regulation (EU) No 748/2012 as regards the alignment of rules for continuing airworthiness of aircraft and aeronautical products, parts and appliances with Regulation (EU) No 1321/2014.
November 2020	To incorporate ED Decision 2020/006/R amending the AMC and GM to Part 21 — Issue 2, Amendment 10, as regards 'Aircraft cybersecurity'.
March 2021	To incorporate ED Decision 2021/001/R amending the AMC and GM to Annex I (Part 21) — Issue 2, Amendment 11.
September 2021	To incorporate the following: — Commission Delegated Regulation (EU) 2021/699 of 21 December 2020 amending and correcting Regulation (EU) No 748/2012 as regards the instructions for continued airworthiness, the production of parts to be used during maintenance and the consideration of ageing aircraft aspects during certification, as well as ED Decision 2021/007/R issuing Amendment 12 to Issue 2 of the AMC and GM to Part 21 to support the implementation of the amendments introduced in Part 21 through Regulation (EU) 2021/699; — Commission Delegated Regulation (EU) 2021/1088 of 7 April 2021 amending Regulation (EU) No 748/2012 as regards updating the references to the environmental protection requirements, as well as ED Decision 2021/011/R issuing Amendment 13 to Issue 2 of the AMC and GM to Part 21 to support the application of Regulation (EU) 2021/1087 amending Article 9(2) of Regulation (EU) 2018/1139 and the application of Regulation (EU) 2021/1088; and — the Corrigendum to Decision 2021/011/R to correct errors in references and listings and change the order of some text in the AMC and GM to Part 21.
May 2022	To incorporate the following: — Commission Delegated Regulation (EU) 2022/201 of 10 December 2021 amending Regulation (EU) No 748/2012 as regards management systems and occurrence-reporting systems to be established by design and production organisations, as well as procedures applied by the Agency, and correcting that Regulation; — Commission Implementing Regulation (EU) 2022/203 of 14 February 2022 amending Regulation (EU) No 748/2012 as regards management systems and occurrence-reporting systems to be established by competent authorities, and

	correcting Regulation (EU) No 748/2012 as regards the issuance of airworthiness review certificates.

NOTE FROM THE EDITOR

The content of this document is arranged as follows: the cover regulation (recitals and articles) of the implementing rule (IR) appear first, then the IR annex points, followed by the related acceptable means of compliance (AMC) and guidance material (GM) paragraph(s).

All elements (i.e. cover regulation, IR annex, AMC, and GM) are colour-coded and can be identified according to the illustration below. The Commission regulation or EASA Executive Director (ED) decision through which the point or paragraph was introduced or last amended is indicated below the point or paragraph title(s) *in italics*.



Note: Amendments introduced by Regulation (EU) 2022/201 and Regulation (EU) 2022/203 with the applicability date in the future are marked with a different colour with the respective applicability date.

This document will be updated regularly to incorporate further amendments.

The format of this document has been adjusted to make it user-friendly and for reference purposes. Any comments should be sent to erules@easa.europa.eu.

INCORPORATED AMENDMENTS

IMPLEMENTING RULES (IRS) (COMMISSION REGULATIONS)

Incorporated Commission Regulation	Regulation amendment	Applicability date[1]
Regulation (EU) No 748/2012	Recast	10/9/2012
Regulation (EU) No 7/2013	First amendment	29/1/2013
Regulation (EU) No 69/2014	Second amendment	17/2/2014
Regulation (EU) 2015/1039	Third amendment	21/7/2015
Regulation (EU) 2016/5	Fourth amendment	26/1/2016
Regulation (EU) 2019/897	Fifth amendment	23/3/2020
Regulation (EU) 2020/570	Sixth amendment	24/3/2020
Regulation (EU) 2021/699	Seventh amendment	18/5/2021 18/5/2022
Regulation (EU) 2021/1088	Eight amendment	25/7/2021
Regulation (EU) 2022/201	Ninth amendment	7/3/2022 7/3/2023
Regulation (EU) 2022/203	Tenth amendment	7/3/2022 7/3/2023

AMC/GM TO IRS (ED DECISIONS)

Incorporated ED Decision	AMC/GM Issue No, Amendment No	Applicability date
ED Decision 2012/020/R	Recast	6/11/2012
ED Decision 2013/001/R	Part-21 / AMC Amendment 1 / GM Amendment 1	29/1/2013
ED Decision 2014/007/R	Part-21 / AMC Amendment 2 / GM Amendment 2	31/1/2014
ED Decision 2015/016/R	AMC/GM to Part 21 — Issue 2, Amendment 3	10/7/2015
ED Decision 2015/026/R	AMC/GM to Part-21 — Issue 2, Amendment 4	11/11/2015
ED Decision 2016/003/R	AMC/GM Part-21 — Issue 2, Amendment 5	26/1/2016
ED Decision 2016/007/R	AMC/GM to Part-21 — Issue 2, Amendment 6	19/12/2016
ED Decision 2017/024/R	AMC/GM to Part-21 — Issue 2, Amendment 7	15/12/2017
ED Decision 2019/003/R	AMC/GM to Part-21 — Issue 2, Amendment 8	14/2/2019

[1] This is the date of application (i.e. the date from which an act or a provision in an act produces its full legal effects) as defined in the relevant cover regulation article. Some provisions of the regulations though may be applicable at a later date (deferred applicability). Besides, there may be some opt-outs (derogations from certain provisions) notified by the Member States.

ED Decision 2019/018/R	AMC/GM to Part-21 — Issue 2, Amendment 9	30/8/2019
ED Decision 2020/006/R	AMC/GM to Part-21 — Issue 2, Amendment 10	1/1/2021
ED Decision 2021/001/R	AMC and GM to Part 21 — Issue 2, Amendment 11	3/3/2021
ED Decision 2021/007/R	AMC and GM to Part 21 — Issue 2, Amendment 12	29/5/2021 18/5/2022
ED Decision 2021/011/R	AMC and GM to Part 21 — Issue 2, Amendment 13	25/7/2021

Note: To access the official versions, please click on the hyperlinks provided above.

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COVER REGULATION

COMMISSION REGULATION (EU) No 748/2012

of 3 August 2012

laying down implementing rules for the airworthiness and environmental certification of aircraft and related products, parts and appliances, as well as for the certification of design and production organisations

(recast)

Regulation (EU) No 748/2012

THE EUROPEAN COMMISSION,

Having regard to the Treaty on the Functioning of the European Union,

Having regard to Regulation (EC) No 216/2008 of the European Parliament and of the Council of 20 February 2008 on common rules in the field of civil aviation and establishing a European Aviation Safety Agency, and repealing Council Directive 91/670/EEC, Regulation (EC) No 1592/2002 and Directive 2004/36/EC[1], and in particular Articles 5(5) and 6(3) thereof,

Whereas:

(1) Commission Regulation (EC) No 1702/2003 of 24 September 2003 laying down implementing rules for the airworthiness and environmental certification of aircraft and related products, parts and appliances, as well as for the certification of design and production organisations[2] has been substantially amended several times[3]. Since further amendments are to be made, it should be recast in the interests of clarity.

(2) Regulation (EC) No 216/2008 establishes common essential requirements to provide for a high uniform level of civil aviation safety and environmental protection. It requires the Commission to adopt the necessary implementing rules to ensure their uniform application. It establishes the 'European Aviation Safety Agency' (hereinafter referred to as the 'Agency') to assist the Commission in the development of such implementing rules.

(3) It is necessary to lay down common technical requirements and administrative procedures to ensure the airworthiness and environmental compatibility of aeronautical products, parts and appliances, subject to Regulation (EC) No 216/2008. Such requirements and procedures should specify the conditions to issue, maintain, amend, suspend or revoke the appropriate certificates.

(4) Organisations involved in the design and production of products, parts and appliances should be required to comply with certain technical requirements in order to demonstrate their capability and means to discharge their obligations and associated privileges. The Commission is required to lay down measures to specify conditions to issue, maintain, amend, suspend or revoke certificates attesting such compliance.

(5) In laying down measures for the implementation of common essential requirements in the field of airworthiness, the Commission must take care that they reflect the state of the art and the best practices, take into account worldwide aircraft experience and scientific and technical

[1] OJ L 79, 19.3.2008, p. 1.

[2] OJ L 243, 27.9.2003, p. 6.

[3] See Annex II.

progress and allow for immediate reaction to established causes of accidents and serious incidents.

(6) The need to ensure uniformity in the application of common airworthiness and environmental requirements for aeronautical products, parts and appliances requires that common procedures be followed by the competent authorities of the Member States and, where applicable, the Agency to assess compliance with these requirements. The Agency should develop certification specifications and guidance material to facilitate the necessary regulatory uniformity.

(7) It is necessary to recognise the continuing validity of certificates issued before the entry into force of Regulation (EC) No 1702/2003, in accordance with Article 69 of Regulation (EC) No 216/2008.

(8) In order to maintain a high uniform level of aviation safety in Europe, it is necessary to introduce changes to requirements and procedures for the certification of aircraft and related products, parts and appliances and of design and production organisations, in particular to elaborate the rules related to the demonstration of compliance with the type-certification basis and environmental protection requirements and to introduce the possibility to choose to comply with later standards for changes to type-certificates.

(9) The concept and complexity of auxiliary power units (APU) resembles that of aircraft engines and in some cases APU designs are even derived from engine designs. Changes to provisions for repairs to APU are therefore needed to restore consistency with repairs process to engines.

(10) In order to subject non-complex motor-powered aircraft, recreational aircraft and related products, parts and appliances to measures that are proportionate to their simple design and type of operation, while maintaining a high uniform level of aviation safety in Europe, it is necessary to introduce changes to requirements and procedures for the certification of those aircraft and related products, parts and appliances and of design and production organisations and in particular, for the owners of European Light Aircraft below 2 000 kg (ELA2) or below 1 200 kg (ELA1), to introduce the possibility to accept certain not safety critical parts for installation without an EASA Form 1.

(11) The Agency prepared draft implementing rules and submitted them as opinions No 01/2009 on 'Possibility to deviate from airworthiness code in case of design changes', No 02/2009 on 'Repair and design changes to European Technical Standard Order', No 01/2010 on 'SubPart J DOA' and Opinion No 01/2011 on 'ELA Process and "standard changes and repairs" ' to the Commission in accordance with Article 19(1) of Regulation (EC) No 216/2008.

(12) The measures provided for in this Regulation are in accordance with the opinion of the European Aviation Safety Agency Committee established by Article 65(1) of Regulation (EC) No 216/2008,

HAS ADOPTED THIS REGULATION:

Article 1 Scope and definitions

Regulation (EU) 2020/570

1. This Regulation lays down, in accordance with Article 5(5) and Article 6(3) of Regulation (EC) No 216/2008, common technical requirements and administrative procedures for the airworthiness and environmental certification of products, parts and appliances specifying:

   (a) the issue of type-certificates, restricted type-certificates, supplemental type-certificates and changes to those certificates;

   (b) the issue of certificates of airworthiness, restricted certificates of airworthiness, permits to fly and authorised release certificates;

   (c) the issue of repair design approvals;

   (d) the showing of compliance with environmental protection requirements;

   (e) the issue of noise certificates;

   (f) the identification of products, parts and appliances;

   (g) the certification of certain parts and appliances;

   (h) the certification of design and production organisations;

   (i) the issue of airworthiness directives.

2. For the purpose of this Regulation, the following definitions shall apply:

   (a) 'JAA' means the 'Joint Aviation Authorities';

   (b) 'JAR' means 'Joint Aviation Requirements';

   (c) 'Part 21' means the requirements and procedures for the certification of aircraft and related products, parts and appliances, and of design and production organisations laid down in Annex I to this Regulation;

   (d) [*deleted*]

   (e) 'principal place of business' means the head office or registered office of the undertaking within which the principal financial functions and operational control of the activities referred to in this Regulation are exercised;

   (f) 'article' means any part and appliance to be used on civil aircraft;

   (g) 'ETSO' means European Technical Standard Order. The European Technical Standard Order is a detailed airworthiness specification issued by the European Aviation Safety Agency (the 'Agency') to ensure compliance with the requirements of this Regulation as a minimum performance standard for specified articles;

   (h) 'EPA' means European Part Approval. European Part Approval of an article means the article has been produced in accordance with approved design data not belonging to the type-certificate holder of the related product, except for ETSO articles;

   (i) 'ELA1 aircraft' means the following manned European Light Aircraft:

      (i) an aeroplane with a Maximum Take-off Mass (MTOM) of 1 200 kg or less that is not classified as complex motor-powered aircraft;

      (ii) a sailplane or powered sailplane of 1 200 kg MTOM or less;

(iii) a balloon with a maximum design lifting gas or hot air volume of not more than 3 400 m^3 for hot air balloons, 1 050 m^3 for gas balloons, 300 m^3 for tethered gas balloons;

(iv) an airship designed for not more than 4 occupants and a maximum design lifting gas or hot air volume of not more than 3 400 m^3 for hot air airships and 1 000 m^3 for gas airships;

(j) 'ELA2 aircraft' means the following manned European Light Aircraft:

(i) an aeroplane with a Maximum Take-off Mass (MTOM) of 2 000 kg or less that is not classified as complex motor-powered aircraft;

(ii) a sailplane or powered sailplane of 2 000 kg MTOM or less;

(iii) a balloon;

(iv) a hot air airship;

(v) a gas airship complying with all of the following characteristics:

— 3% maximum static heaviness,

— Non-vectored thrust (except reverse thrust),

— Conventional and simple design of: structure, control system and ballonet system,

— Non-power assisted controls;

(vi) a Very Light Rotorcraft.

(k) "Operational Suitability Data (OSD)" means data, which are part of an aircraft type-certificate, restricted type- certificate or supplemental type-certificate, consisting of all of the following:

(i) the minimum syllabus of pilot type rating training, including determination of type rating;

(ii) the definition of scope of the aircraft validation source data to support the objective qualification of simulators or the provisional data to support their interim qualification;

(iii) the minimum syllabus of maintenance certifying staff type rating training, including determination of type rating;

(iv) determination of type or variant for cabin crew and type specific data for cabin crew;

(v) the master minimum equipment list.

Article 2 Products, parts and appliances certification

Regulation (EU) No 748/2012

1. Products, parts and appliances shall be issued certificates as specified in Annex I (Part 21).

2. By way of derogation from point 1, aircraft, including any installed product, part and appliance, which are not registered in a Member State shall be exempted from the provisions of Subparts H and I of Annex I (Part 21). They shall also be exempted from the provisions of Subpart P of Annex I (Part 21) except when aircraft identification marks are prescribed by a Member State.

Article 3 Continued validity of type-certificates and related certificates of airworthiness

Regulation (EU) No 69/2014

1. With regard to products which had a type-certificate, or a document allowing the issuing of a certificate of airworthiness, issued before 28 September 2003 by a Member State, the following provisions shall apply:

(a) the product shall be deemed to have a type-certificate issued in accordance with this Regulation when:

(i) its type-certification basis was:

— the JAA type-certification basis, for products that have been certificated under JAA procedures, as defined in their JAA data sheet, or

— for other products, the type-certification basis as defined in the type-certificate data sheet of the State of design, if that State of design was:

— a Member State, unless the Agency determines, taking into account, in particular, certification specifications used and service experience, that such type-certification basis does not provide for a level of safety equivalent to that required by Regulation (EC) No 216/2008 and this Regulation, or

— a State with which a Member State had concluded a bilateral airworthiness agreement or similar arrangement under which such products have been certificated on the basis of the certification specifications of that State of design, unless the Agency determines that such certification specifications or service experience or the safety system of that State of design do not provide for a level of safety equivalent to that required by Regulation (EC) No 216/2008 and this Regulation.

The Agency shall make a first evaluation of the implication of the provisions of the second indent in view of producing an opinion to the Commission including possible amendments to this Regulation;

(ii) the environmental protection requirements were those laid down in Annex 16 to the Chicago Convention, as applicable to the product;

(iii) the applicable airworthiness directives were those of the State of design.

(b) The design of an individual aircraft, which was on the register of a Member State before 28 September 2003, shall be deemed to have been approved in accordance with this Regulation when:

(i) its basic type design was part of a type-certificate referred to in point (a);

(ii) all changes to this basic type design, which were not under the responsibility of the type-certificate holder, had been approved; and

(iii) the airworthiness directives issued or adopted by the Member State of registry before 28 September 2003 were complied with, including any variations to the airworthiness directives of the State of design agreed by the Member State of registry.

2. With regard to products for which a type-certification process was proceeding through the JAA or a Member State on 28 September 2003, the following shall apply:

   (a) if a product is under certification by several Member States, the most advanced project shall be used as the reference;

   (b) points 21.A.15(a), (b) and (c) of Annex I (Part 21) shall not apply;

   (c) by way of derogation from point 21.A.17A of Annex I (Part 21), the type-certification basis shall be that established by the JAA or, where applicable, the Member State at the date of application for the approval;

   (d) compliance findings made under JAA or Member State procedures shall be deemed to have been made by the Agency for the purpose of complying with points 21.A.20(a) and (d) of Annex I (Part 21).

3. With regard to products that have a national type-certificate, or equivalent, and for which the approval process of a change carried out by a Member State was not finalised at the time when the type-certificate had to be in accordance with this Regulation, the following shall apply:

   (a) if an approval process is being carried out by several Member States, the most advanced project shall be used as the reference;

   (b) point 21.A.93 of Annex I (Part 21) shall not apply;

   (c) the applicable type-certification basis shall be that established by the JAA or, where applicable, the Member State at the date of application for the approval of change;

   (d) compliance findings made under JAA or Member State procedures shall be deemed to have been made by the Agency for the purpose of complying with points 21.A.103(a)(2) and (b) of Annex I (Part 21).

4. With regard to products that had a national type-certificate, or equivalent, and for which the approval process of a major repair design carried out by a Member State was not finalised at the time when the type-certificate had to be determined in accordance with this Regulation, compliance findings made under JAA or Member State procedures shall be deemed to have been made by the Agency for the purpose of complying with point 21.A.433(a) of Annex I (Part 21).

5. A certificate of airworthiness issued by a Member State attesting conformity with a type-certificate determined in accordance with point 1 shall be deemed to comply with this Regulation.

Article 4 Continued validity of supplemental type-certificates

Regulation (EU) No 748/2012

1. With regard to supplemental type-certificates issued by a Member State under JAA procedures or applicable national procedures and with regard to changes to products proposed by persons other than the type-certificate holder of the product, which were approved by a Member State under applicable national procedures, if the supplemental type-certificate, or change, was valid on 28 September 2003, the supplemental type-certificate, or change shall be deemed to have been issued under this Regulation.

2. With regard to supplemental type-certificates for which a certification process was being carried out by a Member State on 28 September 2003 under applicable JAA supplemental type-certificate procedures and with regard to major changes to products, proposed by persons other than the type-certificate holder of the product, for which a certification process was being carried out by a Member State on 28 September 2003 under applicable national procedures, the following shall apply:

   (a) if a certification process was being carried out by several Member States, the most advanced project shall be used as the reference;

   (b) point 21.A.113 (a) and (b) of Annex I (Part 21) shall not apply;

   (c) the applicable certification basis shall be that established by the JAA or, where applicable, the Member State at the date of application for the supplemental type-certificate or the major change approval;

   (d) the compliance findings made under JAA or Member State procedures shall be deemed to have been made by the Agency for the purpose of complying with point 21.A.115(a) of Annex I (Part 21).

Article 5

Regulation (EU) No 69/2014

(deleted by Regulation (EU) No 69/2014, 27.01.2014)

Article 6 Continued validity of parts and appliances certificates

Regulation (EU) No 748/2012

1. Approvals of parts and appliances issued by a Member State and valid on 28 September 2003 shall be deemed to have been issued in accordance with this Regulation.

2. With regard to parts and appliances for which an approval or authorisation process was being carried out by a Member State on 28 September 2003, the following shall apply:

   (a) if an authorisation process was being carried out by several Member States, the most advanced project shall be used as the reference;

   (b) point 21.A.603 of Annex I (Part 21) shall not apply;

   (c) the applicable data requirements laid down in point 21.A.605 of Annex I (Part 21) shall be those established by the relevant Member State, at the date of application for the approval or authorisation;

   (d) compliance findings made by the relevant Member State shall be deemed to have been made by the Agency for the purpose of complying with point 21.A.606(b) of Annex I (Part 21).

Article 7 Permit to fly

Regulation (EU) No 748/2012

The conditions determined before 28 March 2007 by the Member States for permits to fly or other airworthiness certificate issued for aircraft which did not hold a certificate of airworthiness or restricted certificate of airworthiness issued under this Regulation, are deemed to have been determined in accordance with this Regulation, unless the Agency has determined before 28 March 2008 that such conditions do not provide for a level of safety equivalent to that required by Regulation (EC) No 216/2008 or this Regulation.

Article 7a Operational suitability data

Regulation (EU) No 69/2014

1. The holder of an aircraft type-certificate issued before 17 February 2014 intending to deliver a new aircraft to an EU operator on or after 17 February 2014 shall obtain approval in accordance with point 21.A.21(e) of Annex I (Part 21) except for the minimum syllabus of maintenance certifying staff type rating training and except for aircraft validation source data to support the objective qualification of simulator(s). The approval shall be obtained not later than 18 December 2015 or before the aircraft is operated by an EU operator, whichever is the latest. The operational suitability data may be limited to the model which is delivered.

2. The applicant for an aircraft type-certificate for which the application was filed before 17 February 2014 and for which a type-certificate is not issued before 17 February 2014 shall obtain approval in accordance with point 21.A.21(e) of Annex I (Part 21) except for the minimum syllabus of maintenance certifying staff type rating training and for aircraft validation source data to support the objective qualification of simulator(s). The approval shall be obtained not later than 18 December 2015 or before the aircraft is operated by an EU operator, whichever is the latest. Compliance findings made by the authorities in Operational Evaluation Board processes conducted under the responsibility of the JAA or the Agency before the entry into force of this Regulation shall be accepted by the Agency without further verification.

3. Operational Evaluation Board reports and master minimum equipment lists issued in accordance with JAA procedures or by the Agency before the entry into force of this Regulation shall be deemed to constitute the operational suitability data approved in accordance with point 21.A.21(e) of Annex I (Part 21) and shall be included in the relevant type-certificate. Before 18 June 2014 the relevant type-certificate holders shall propose the Agency a division of the operational suitability data in mandatory data and non-mandatory data.

4. Holders of a type-certificate including operational suitability data shall be required to obtain approval of an extension of the scope of their design organisation approval or procedures alternative to design organisation approval, as applicable, to include operational suitability aspects before 18 December 2015.

Article 8 Design organisations

Regulation (EU) No 748/2012

1. An organisation responsible for the design of products, parts and appliances or for changes or repairs thereto shall demonstrate its capability in accordance with Annex I (Part 21).

2. By way of derogation from point 1, an organisation whose principal place of business is in a non-member State may demonstrate its capability by holding a certificate issued by that State for the product, part and appliance for which it applies, provided:

   (a) that State is the State of design; and

   (b) the Agency has determined that the system of that State includes the same independent level of checking of compliance as provided by this Regulation, either through an equivalent system of approvals of organisations or through direct involvement of the competent authority of that State.

3. Design organisation approvals issued or recognised by a Member State in accordance with the JAA requirements and procedures and valid before 28 September 2003 shall be deemed to comply with this Regulation.

4. By way of derogation from points 21.B.433(d)(1) and (2) of Annex I (Part 21), a design organisation that holds a valid approval certificate issued in accordance with Annex I (Part 21) may correct, until 7 March 2025, any findings of non-compliance related to the Annex I requirements introduced by Commission Delegated Regulation (EU 2022/2011.

   Where after 7 March 2025, the organisation has not closed such findings, the approval certificate shall be revoked, limited or suspended in whole or in part.

   [applicable from 7 March 2023 — Regulation (EU) 2022/201]

Article 9 Production organisations

Regulation (EU) 2021/699

1. An organisation responsible for the manufacture of products, parts and appliances shall demonstrate its capability in accordance with the provisions of Annex I (Part 21). This demonstration of capability is not required for the parts or appliances that an organisation manufactures which, in accordance with the provisions of Annex I (Part 21), are eligible for installation in a type-certified product without the need to be accompanied by an authorised release certificate (i.e. EASA Form 1).

2. By way of derogation from point 1, a manufacturer whose principal place of business is in a non-member State may demonstrate its capability by holding a certificate issued by that State for the product, part and appliance for which it applies, provided:

   (a) that State is the State of manufacture; and

   (b) the Agency has determined that the system of that State includes the same independent level of checking of compliance as provided by this Regulation, either through an equivalent system of approvals of organisations or through direct involvement of the competent authority of that State.

3. Production organisation approvals issued or recognised by a Member State in accordance with the JAA requirements and procedures and valid before 28 September 2003 shall be deemed to comply with this Regulation.

4. By way of derogation from paragraph 1, the production organisation may apply to the competent authority for exemptions from the environmental protection requirements referred to in the first subparagraph of Article 9(2) of Regulation (EU) 2018/1139.

5. By way of derogation from points 21.B.225(d)(1) and (2) of Annex I (Part 21), a production organisation that holds a valid approval certificate issued in accordance with Annex I (Part 21) may correct, until 7 March 2025, any findings of non-compliance related to the Annex I requirements introduced by Commission Implementing Regulation (EU) 2022/203[2].

   Where after 7 March 2025the organisation has not closed those findings, the approval certificate shall be revoked, limited or suspended in whole or in part.

1 Commission Delegated Regulation (EU) 2022/201 of 10 December 2021 amending Regulation (EU) No 748/2012 as regards management systems and occurrence-reporting systems to be established by design and production organisations, as well as procedures applied by the Agency, and correcting that Regulation (OJ L 33, …, p. 7)

2 Commission Implementing Regulation (EU) 2022/203 of 14 February 2022 amending Regulation (EU) No 748/2012 as regards management systems and occurrence-reporting systems to be established by competent authorities, and correcting Regulation (EU) No 748/2012 as regards the issuance of airworthiness review certificates (OJ L 33, 15.2.2022, p. 46

6. By way of derogation from points 21.B.125(d)(1) and (2) of Annex I (Part 21), an organisation that produces products, parts or appliances without an approval certificate and that holds a valid letter of agreement issued in accordance with Annex I (Part 21) may correct, until 7 March 2025, any findings of non-compliance related to the Annex I requirements introduced by Implementing Regulation (EU) 2022/203.

   Where after 7 March 2025the organisation has not closed those findings, the letter of agreement shall be revoked, limited or suspended in whole or in part.

   [points (5) and (6) applicable from 7 March 2023 - Regulation (EU) 2022/203]

Article 10 Agency measures

Regulation (EU) No 748/2012

1. The Agency shall develop acceptable means of compliance (hereinafter called "AMC") that competent authorities, organisations and personnel may use to demonstrate compliance with the provisions of the Annex I (Part 21) to this Regulation.
2. The AMC issued by the Agency shall neither introduce new requirements nor alleviate the requirements of the Annex I (Part 21) to this Regulation.
3. Without prejudice to Articles 54 and 55 of Regulation (EC) No 216/2008, when the acceptable means of compliance issued by the Agency are used, the related requirements of the Annex I (Part 21) to this Regulation shall be considered as met without further demonstration.

Article 11 Repeal

Regulation (EU) No 748/2012

Regulation (EC) No 1702/2003 is repealed.

References to the repealed Regulation shall be construed as references to this Regulation and shall be read in accordance with the correlation table in Annex III.

Article 12 Entry into force

Regulation (EU) No 748/2012

This Regulation shall enter into force on the twentieth day following that of its publication in the *Official Journal of the European Union*.

This Regulation shall be binding in its entirety and directly applicable in all Member States.

Regulation (EU) No 748/2012

Done at Brussels, 3 August 2012

For the Commission

The President

José Manuel BARROSO

Selected articles[1] of related regulations amending to the content of Regulation No 748/2012

Article 2 of EU 69/2014 on Operational Suitability Data (published on 27 January 2014) – Transitional Provisions

This Regulation shall enter into force on the twentieth day following that of its publication in the Official Journal of the European Union.

Points 16 – 34 and point 43 of the Annex[2] shall apply to applicants for the approval of a change to a type-certificate as well as applicants for a supplemental type-certificate from 19 December 2016.

Article 2 of EU 2015/1039 on Flight Testing (published on 30 June 2015) – Transitional Provisions

1. Member States that at […] [The Publication Office will insert the date of the entry into force] issued national licences for flight test crew members other than pilots may continue to do so in accordance with their national law until 31 December 2017. The holders of those licences may continue to exercise their privileges until that date.
2. After 31 December 2017, applicants for or holders of a permit to fly may continue to use the services of pilots engaged in Category Three or Four flight tests referred to in Appendix XII to Annex I to Regulation (EU) No 748/2012 and of flight test engineers that were conducting flight test activities in accordance with the applicable rules of national law before that date. Any such use shall remain limited to the scope of functions of the flight test crew members as established before 31 December 2017.

The scope of functions of the flight test crew member shall be established by the applicant for or holder of a permit to fly that uses or plans to use their services, based on the flight test crew members' flight test experience and training, and on the relevant records of the applicant for or the holder of a permit to fly. That scope of functions of a flight test crew member shall be made available to the competent authority.

Any addition or any other amendment to the scope of the functions established for these flight test crew members by the applicant for or holder of a permit to fly that uses or plans to use their services shall comply with the requirements of Appendix XII to Annex I to Regulation (EU) No 748/2012.

Article 3 of EU 2015/1039 on Flight Testing – Entry into Force and Application

This Regulation shall enter into force on the twentieth day following that of its publication in the Official Journal of the European Union.

It shall apply from (…) [The Publication Office will insert the date of the entry into force]

[1] These selected articles concern transitional provisions and dates of entry into force and application. All other amending articles have been included in the consolidation, mainly in the Annex, and - for EU 69/2014 – additionally also in the cover regulation

[2] For the content of points 16-34 and 43 consult the Annex to Regulation EU 69/2014.

However:

(a) point 5 of the Annex shall apply from 1 July 2015;

(b) points 2 and 3 of the Annex shall apply from 1 January 2016 to the extent reference is made to Appendix XII to Annex I of Commission Regulation (EU) 748/2012, point (c) of this Article applies.

(c) point 6 of the Annex as regards point D of Appendix XII shall apply from 1 January 2018, without prejudice to requirements already resulting from the Annex I (Part-FCL) to Regulation (EU) No 1178/2011.

ANNEX I

21.1 General [applicable until 6 March 2023] / 21.1. Competent authority [applicable from 7 March 2023 - Regulation (EU) 2022/203]

Regulation (EU) No 748/2012

For the purpose of this Annex I (Part 21), 'competent authority' shall be:

(a) for organisations having their principal place of business in a Member State, the authority designated by that Member State; or the Agency if so requested by that Member State; or

(b) for organisations having their principal place of business in a non-member State, the Agency.

[applicable until 6 March 2023]

For the purpose of this Annex, the 'competent authority' shall be:

(a) for Section A, Subpart A,

1. for design organisations, the Agency;

2. for production organisations that have their principal place of business in a territory for which a Member State is responsible under the Convention on International Civil Aviation, signed in Chicago on 7 December 1944('the Chicago Convention'), the authority designated by that Member State or by another Member State in accordance with Article 64 of Regulation (EU) 2018/1139, or the Agency if the responsibility has been reallocated to the Agency in accordance with Article 64 or 65 of Regulation (EU) 2018/1139;

3. for production organisations that have their principal place of business outside a territory for which a Member State is responsible under the Chicago Convention, the Agency;

(b) for Section A, Subparts B, D, E, J, K, M, O and Q, the Agency;

(c) for Section A, Subparts F and G:

1. for natural or legal persons that have their principal place of business in a territory for which a Member State is responsible under the Chicago Convention, the authority designated by that Member State or by another Member State in accordance with Article 64 of Regulation (EU) 2018/1139, or the Agency if the responsibility has been reallocated to the Agency in accordance with Article 64 or, as regards Subpart G, Article 65 of Regulation (EU) 2018/1139;

2. for natural or legal persons that have their principal place of business outside a territory for which a Member State is responsible under the Chicago Convention, the Agency;

(d) for Section A, Subpart H and I, the authority designated by the Member State where the aircraft is registered or will be registered:

(e) for Section A, Subpart P:

1. for aircraft registered in a Member State, the authority designated by the Member State of registry;
2. for unregistered aircraft, the authority designated by the Member State which prescribed the identification marks;
3. for the approval of the flight conditions related to the safety of the design, the Agency.

[applicable from 7 March 2023 - Regulation (EU) 2022/203]

21.2 Scope

Regulation (EU) 2022/203

Section A of this Annex establishes the provisions that lay down the rights and obligations of the applicant for, and holder of, any certificate issued or to be issued in accordance with this Annex.

Section B of this Annex establishes the conditions for conducting the certification oversight and enforcement tasks as well as the administrative and management system requirements to be complied with by the competent authority that is responsible for the implementation of Section A of this Annex.

[applicable from 7 March 2023 - Regulation (EU) 2022/203]

SECTION A — TECHNICAL REQUIREMENTS

SUBPART A — GENERAL PROVISIONS

21.A.1 Scope

Regulation (EU) No 748/2012

This Section establishes general provisions governing the rights and obligations of the applicant for, and holder of, any certificate issued or to be issued in accordance with this Section.

[applicable until 6 March 2023]

This Subpart establishes the general rights and obligations of the applicant for, and holder of, any certificate that has been issued or is to be issued in accordance with this Annex.

[applicable from 7 March 2023 — Regulation (EU) 2022/201]

21.A.2 Undertaking by another person than the applicant for, or holder of, a certificate

Regulation (EU) No 748/2012

The actions and obligations required to be undertaken by the holder of, or applicant for, a certificate for a product, part or appliance under this Section may be undertaken on its behalf by any other natural or legal person, provided the holder of, or applicant for, that certificate can show that it has made an agreement with the other person such as to ensure that the holder's obligations are and will be properly discharged.

21.A.3A Failures, malfunctions and defects [applicable until 6 March 2023] / 21.A.3A Reporting system [applicable from 7 March 2023 — Regulation (EU) 2022/201]

Regulation (EU) No 748/2012

(a) System for Collection, Investigation and Analysis of Data.

The holder of a type-certificate, restricted type-certificate, supplemental type-certificate, European Technical Standard Order (ETSO) authorisation, major repair design approval or any other relevant approval deemed to have been issued under this Regulation shall have a system for collecting, investigating and analysing reports of and information related to failures, malfunctions, defects or other occurrences which cause or might cause adverse effects on the continuing airworthiness of the product, part or appliance covered by the type-certificate, restricted type-certificate, supplemental type-certificate, ETSO authorisation, major repair design approval or any other relevant approval deemed to have been issued under this Regulation. Information about this system shall be made available to all known operators of the product, part or appliance and, on request, to any person authorised under other associated implementing Regulations.

(b) Reporting to the Agency

1. The holder of a type-certificate, restricted type-certificate, supplemental type-certificate, ETSO authorisation, major repair design approval or any other relevant approval deemed to have been issued under this Regulation shall report to the Agency any failure, malfunction, defect or other occurrence of which it is aware related to a product, part, or appliance covered by the type-certificate, restricted type-certificate, supplemental type-certificate, ETSO authorisation, major repair design approval or any other relevant approval deemed to have been issued under this Regulation, and which has resulted in or may result in an unsafe condition.

2. These reports shall be made in a form and manner established by the Agency, as soon as practicable and in any case dispatched not later than 72 hours after the identification of the possible unsafe condition, unless exceptional circumstances prevent this.

(c) Investigation of Reported Occurrences

1. When an occurrence reported under point (b), or under points 21.A.129(f)(2) or 21.A.165(f)(2) results from a deficiency in the design, or a manufacturing deficiency, the holder of the type-certificate, restricted type-certificate, supplemental type-certificate, major repair design approval, ETSO authorisation, or any other relevant approval deemed to have been issued under this Regulation, or the manufacturer as appropriate, shall investigate the reason for the deficiency and report to the Agency the results of its investigation and any action it is taking or proposes to take to correct that deficiency.

2. If the Agency finds that an action is required to correct the deficiency, the holder of the type-certificate, restricted type-certificate, supplemental type-certificate, major repair design approval, ETSO authorisation, or any other relevant approval deemed to have been issued under this Regulation, or the manufacturer as appropriate, shall submit the relevant data to the Agency.

[applicable until 6 March 2023]

(a) Without prejudice to Regulation (EU) No 376/2014 of the European Parliament and of the Council[1] and its delegated and implementing acts, all natural or legal persons that have applied for or hold a type-certificate, restricted type-certificate, supplemental type-certificate, European Technical Standard Order (ETSO) authorisation, major repair design approval or any other relevant approval deemed to have been issued under this Regulation shall:

1. establish and maintain a system for collecting, investigating and analysing occurrence reports in order to identify adverse trends or to address deficiencies and to extract occurrences whose reporting is mandatory in accordance with point 3 and those which are reported voluntarily. When the principal place of business is located in a Member State, a single system may be established to meet the requirements of Regulation (EU) No 376/2014 of of the European Parliament and of the Council and its implementing acts and of Regulation (EU) 2018/1139 and its delegated and implementing acts. The reporting system shall include:

[1] Regulation (EU) No 376/2014 of the European Parliament and of the Council of 3 April 2014 on the reporting, analysis and follow-up of occurrences in civil aviation, amending Regulation (EU) No 996/2010 of the European Parliament and of the Council and repealing Directive 2003/42/EC of the European Parliament and of the Council and Commission Regulations (EC) No 1321/2007 and (EC) No 1330/2007 (OJ L 122, 24.4.2014, p. 18).

(i) reports of and information related to failures, malfunctions, defects or other occurrences which cause or might cause adverse effects on the continuing airworthiness of the product, part or appliance covered by the type-certificate, restricted type-certificate, supplemental type-certificate, ETSO authorisation, major repair design approval or by any other relevant approval deemed to have been issued under this Regulation;

(ii) errors, near misses and hazards that do not fall under point (i);

2. make available to known operators of the product, part or appliance and, on request, to any person authorised under other implementing or delegated acts the information about the system established in accordance with point 1, and on how to provide reports of and information related to failures, malfunctions, defects or other occurrences referred to in point 1(i);

3. report to the Agency any failure, malfunction, defect or other occurrence of which it is aware and is related to a product, part or appliance covered by the type-certificate, restricted type-certificate, supplemental type- certificate, ETSO authorisation, major repair design approval or by any other relevant approval deemed to have been issued under this Regulation, and which has resulted or may result in an unsafe condition.

(b) Without prejudice to Regulation (EU) No 376/2014 of the European Parliament and of the Council and its delegated and implementing acts, any natural or legal person that holds or has applied for a production organisation approval certificate under Subpart G of this Section, or that produces a product, part or appliance under Subpart F of this Section, shall:

1. establish and maintain a system for collecting and assessing occurrence reports, including reports on errors, near misses and hazards, in order to identify adverse trends or to address deficiencies and extract occurrences whose reporting is mandatory in accordance with points 2 and 3 and those which are reported voluntarily. For organisations that have their principal place of business in a Member State, a single system may be established to meet the requirements of Regulation (EU) No 376/2014 of the European Parliament and of the Council and its implementing acts and of Regulation (EU) 2018/1139 and its delegated and implementing acts;

2. report to the responsible design approval holder all the cases where products, parts or appliances have been released by the production organisation and possible deviations from the applicable design data have been subsequently identified, and investigate with the design approval holder to identify those deviations which could lead to an unsafe condition;

3. report to the competent authority of the Member State responsible in accordance with point 21.1 and the Agency the deviations that have been identified in accordance with point 21.A.3A(b)2 and which could lead to an unsafe condition;

4. if the production organisation acts as a supplier to another production organisation, also report to that other organisation all the cases where it has released products, parts or appliances to that organisation and possible deviations from the applicable design data have been subsequently identified.

(c) Without prejudice to Regulation (EU) No 376/2014 of the European Parliament and of the Council and its delegated and implementing acts, any natural or legal person, when reporting in accordance with points (a)(3), (b)(2), (b)(3) and (b)(4), shall appropriately protect the confidentiality of the person who reports and of the person(s) mentioned in the report.

(d) Without prejudice to Regulation (EU) No 376/2014 of the European Parliament and of the Council and its delegated and implementing acts, any natural or legal person shall make the reports referred to in points (a)(3) and (b)(3) in a form and manner established by the Agency or the competent authority, respectively, and dispatch them as soon as practicable and in any case not later than 72 hours after the natural or legal person has identified that the occurrence may lead to a possible unsafe condition, unless exceptional circumstances prevent this.

(e) Without prejudice to Regulation (EU) No 376/2014 of the European Parliament and of the Council and its delegated and implementing acts, if an occurrence reported under point (a)(3) or under point (b)(3) results from a deficiency in the design or a production deficiency, the holder of the type-certificate, restricted type-certificate, supplemental type-certificate, major repair design approval, ETSO authorisation or any other relevant approval deemed to have been issued under this Regulation, or the production organisation as appropriate, shall investigate the reason for the deficiency and report to the competent authority of the Member State responsible in accordance with point 21.1 and to the Agency the results of its investigation and any action it intends to take or proposes to be taken to correct that deficiency.

(f) If the competent authority finds that action is required to correct the deficiency, the holder of the type-certificate, restricted type-certificate, supplemental type-certificate, major repair design approval, ETSO authorisation or any other relevant approval deemed to have been issued under this Regulation, or the production organisation as appropriate, shall submit the relevant data to the competent authority upon its request.

[applicable from 7 March 2023 — Regulation (EU) 2022/201]

AMC No 1 to 21.A.3A(a) Collection, investigation and analysis of data related to Flammability Reduction Means (FRM) reliability

ED Decision 2012/020/R

Holders of a type-certificate, restricted type-certificate, supplemental type-certificate or any other relevant approval deemed to have been issued under Part 21 and which have included a FRM in their design should assess on an on-going basis the effects of aeroplane component failures on FRM reliability. This should be part of the system for collection, investigation and analysis of data required by 21.A.3A(a). The applicant/holder should do the following:

(a) Demonstrate effective means to ensure collection of FRM reliability data. The means should provide data affecting FRM reliability, such as component failures.

(b) Unless alternative reporting procedures are approved by the Agency, provide a report to the Agency every six months for the first five years after service introduction. After that period, continued reporting every six months may be replaced with other reliability tracking methods found acceptable to the Agency or eliminated if it is established that the reliability of the FRM meets, and will continue to meet, the exposure specifications of paragraph M25.1 of Appendix M to CS-25.

(c) Develop service instructions or revise the applicable aeroplane manual, according to a schedule approved by the Agency, to correct any failures of the FRM that occur in service that could increase any fuel tank's Fleet Average Flammability Exposure to more than that specified by paragraph M25.1 of Appendix M to CS-25.

AMC No 2 to 21.A.3A(a) Collection, investigation and analysis of data related to ETOPS significant occurrences

ED Decision 2012/020/R

(1) Holders of a type-certificate, restricted type-certificate, supplemental type-certificate or any other relevant approval deemed to have been issued under Part 21 and which includes extended range operation with two-engined aeroplane (ETOPS) capability should implement a specific tracking, reporting and resolution system for ETOPS significant occurrences, suitable to ensure the initial and continued fleet compliance with the applicable ETOPS reliability objectives. This system should be part of the system for collection, investigation and analysis of data required by 21.A.3A(a).

Appropriate coordination should exist between engine TC holder, propeller TC holder and APU ETSO authorisation holder with the aircraft TC holder to ensure compliance with the ETOPS reliability objectives.

(2) For tracking, reporting and resolution of ETOPS significant occurrences refer to the latest edition of AMC 20-6 (see AMC-20 document).

AMC3 21.A.3A(a) Failures, malfunctions and defects

ED Decision 2021/001/R

INVESTIGATION AND ANALYSIS

The ‘collection’, ‘investigation’ and ‘analysis’ functions of the system should include specific means to analyse the collected failures, malfunctions, defects or other occurrences, and the related available information, to identify adverse trends, to investigate the associated root cause(s), and to establish any necessary corrective action(s). It should also allow the determination of reportable occurrences as required under point 21.A.3A(b) — see GM 21.A.3A(b).

In addition, for parts whose failure could lead to an unsafe condition, the ‘analysis’ function of the system should ensure that reports and information sent, or available, to the design approval holder are fully investigated so that the full nature of any damage, malfunction, or defect and its effect on continuing airworthiness is understood. This may then result in changes to the design, to the instructions for continued airworthiness (ICAs), and/or in establishing a mitigation plan to prevent or minimise such occurrences in the future, as necessary, and is not limited to those requiring the involvement of EASA under point 21.A.3A(c).

GM 21.A.3A(a) Failures, malfunctions and defects

ED Decision 2021/001/R

GENERAL

The word ‘collection’ means the setting up of systems and procedures which will enable relevant failures, malfunctions and defects, or other occurrences, to be properly reported when they occur.

Considerations for the collection of information related to failures, malfunctions and defects, or other occurrences, should include the analysis of failure rates, the early rejection of parts from service, and comparison with the certification assumptions.

In the context of point 21.A.3A(a), the phrase ‘[…] or any other relevant approval deemed […]’ refers to ‘grandfathered’ design approvals under Part 21, as defined in Article 3 of Regulation (EU) No 748/2012.

Approval holders of minor changes and minor repairs do not have to comply with the requirements in point 21.A.3A(a), since according to the classification criteria for design changes and repairs (see points 21.A.91 and 21.A.435), minor changes and minor repairs have no appreciable effect on the characteristics affecting the airworthiness of the product.

GM 21.A.3A(b) Failures, malfunctions and defects

ED Decision 2021/001/R

OCCURRENCE REPORTING

For guidance on the reporting of failures, malfunctions, defects or other occurrences which have resulted or may result in an unsafe condition, refer to the latest edition of AMC 20-8. The GM available to determine an unsafe condition in accordance with 21.A.3B(b) could be considered to the extent that 21.A.3A(b)(1) also requires the reporting of occurrences that may result in an unsafe condition.

AMC 21.A.3A(b)(2) Reporting to the Agency

ED Decision 2012/020/R

Within the overall limit of 72 hours the degree of urgency for submission of a report should be determined by the level of hazard judged to have resulted from the occurrence.

Where an occurrence is judged by the person identifying the possible unsafe condition to have resulted in an immediate and particularly significant hazard the Agency (or the competent authority of the Member State as required) expects to be advised immediately and by the fastest possible means (telephone, fax, email, telex, etc.) of whatever details are available at that time. This initial report must be followed up by a full written report within 72 hours. A typical example would be an uncontained engine failure resulting in damage to aircraft primary structure.

Where the occurrence is judged to have resulted in a less immediate and less significant hazard, report submission may be delayed up to the maximum of three days in order to provide more details.

21.A.3B Airworthiness directives

Regulation (EU) No 748/2012

(a) An airworthiness directive means a document issued or adopted by the Agency which mandates actions to be performed on an aircraft to restore an acceptable level of safety, when evidence shows that the safety level of this aircraft may otherwise be compromised.

(b) The Agency shall issue an airworthiness directive when:

1. an unsafe condition has been determined by the Agency to exist in an aircraft, as a result of a deficiency in the aircraft, or an engine, propeller, part or appliance installed on this aircraft; and

2. that condition is likely to exist or develop in other aircraft.

(c) When an airworthiness directive has to be issued by the agency to correct the unsafe condition referred to in point (b), or to require the performance of an inspection, the holder of the type-certificate, restricted type-certificate, supplemental type-certificate, major repair design approval, ETSO authorisation or any other relevant approval deemed to have been issued under this Regulation, shall:

1. propose the appropriate corrective action or required inspections, or both, and submit details of these proposals to the Agency for approval;

2. following the approval by the Agency of the proposals referred to under point (1), make available to all known operators or owners of the product, part or appliance and, on request, to any person required to comply with the airworthiness directive, appropriate descriptive data and accomplishment instructions.

(d) An airworthiness directive shall contain at least the following information:

1. an identification of the unsafe condition;
2. an identification of the affected aircraft;
3. the action(s) required;
4. the compliance time for the required action(s);
5. the date of entry into force.

AMC1 21.A.3B(b) Failures, malfunctions and defects

ED Decision 2021/001/R

UNSAFE CONDITION

An unsafe condition exists if there is factual evidence (from service experience, analysis or tests) that:

(a) An event may occur that would result in fatalities, usually with the loss of the aircraft, or reduce the capability of the aircraft or the ability of the crew to cope with adverse operating conditions to the extent that there would be:

(i) A large reduction in safety margins or functional capabilities, or

(ii) Physical distress or excessive workload such that the flight crew cannot be relied upon to perform their tasks accurately or completely, or

(iii) Serious or fatal injury to one or more occupants

unless it is shown that the probability of such an event is within the limit defined by the applicable certification specifications, or

(b) There is an unacceptable risk of serious or fatal injury to persons other than occupants, or

(c) Design features intended to minimise the effects of survivable accidents are not performing their intended function.

Note 1: Non-compliance with applicable certification specifications is generally considered as an unsafe condition, unless it is shown that possible events resulting from this non-compliance do not constitute an unsafe condition as defined under paragraphs (a), (b) and (c).

Note 2: An unsafe condition may exist even though applicable airworthiness requirements are complied with.

Note 3: The above definition covers the majority of cases where the Agency considers there is an unsafe condition. There may be other cases where overriding safety considerations may lead the Agency to issue an airworthiness directive.

Note 4: There may be cases where events can be considered as an unsafe condition if they occur too frequently (significantly beyond the applicable safety objectives) and could eventually lead to consequences listed in paragraph (a) in specific operating environments. Although having less severe immediate consequences than those listed in paragraph (a), the referenced events may reduce the capability of the aircraft or the ability of the crew to cope with adverse operating conditions to the extent that there would be, for example, a significant reduction in safety margins or functional capabilities, a significant increase in crew workload, or in conditions impairing crew efficiency, or discomfort to occupants, possibly including injuries.

GM1 21.A.3B(b) Failures, malfunctions and defects

ED Decision 2021/001/R

DETERMINATION OF AN UNSAFE CONDITION

It is important to note that these guidelines are not exhaustive. However, this material is intended to provide guidelines and examples that will cover most cases, taking into account the applicable certification requirements.

1. INTRODUCTION

Certification or approval of a product, part or appliance is a demonstration of compliance with requirements which are intended to ensure an acceptable level of safety. This demonstration, however, includes certain accepted assumptions and predicted behaviours, such as:

— fatigue behaviour is based on analysis supported by test,

— modelling techniques are used for Aircraft Flight Manual performances calculations,

— the systems safety analyses give predictions of what the systems failure modes, effects and probabilities may be,

— the system components' reliability figures are predicted values derived from general experience, tests or analysis,

— the crew is expected to have the skills to apply the procedures correctly, and

— the aircraft is assumed to be maintained in accordance with the prescribed instructions for continued airworthiness (ICAs) (or maintenance programme).

In service experience, additional testing, further analysis, etc., may show that certain initially accepted assumptions are not correct. Thus, certain conditions initially demonstrated as safe, are revealed by experience as unsafe. In this case, it is necessary to mandate corrective actions in order to restore a level of safety consistent with the applicable certification requirements.

To support the determination of an unsafe condition, the investigation may need to include examinations of worn, damaged and time-expired parts / analysis / certification demonstration / tests / statistical analysis, and comparison with the certification assumptions.

See AMC1 21.A.3B(b) for the definition of 'unsafe condition' used in 21.A.3A(b).

2. GUIDELINES FOR ESTABLISHING IF A CONDITION IS UNSAFE

The following paragraphs give general guidelines for analysing the reported events and determining if an unsafe condition exists, and are provided for each type of product, part or appliance subject to a specific airworthiness approval: type-certificates (TC) or supplemental type-certificates (STC) for aircraft, engines or propellers, or European Technical Standard Orders (ETSO).

This analysis may be qualitative or quantitative, i.e. formal and quantitative safety analyses may not be available for older or small aircraft. In such cases, the level of analysis should be consistent with that required by the certification specifications and may be based on engineering judgement supported by service experience data.

2.1 Analysis method for aircraft

2.1.1 Accidents or incidents without any aircraft, engines, system, propeller or part or appliance malfunction or failure

When an accident/incident does not involve any component malfunction or failure but when a crew human factor has been a contributing factor, this should be assessed from a man-machine interface standpoint to determine whether the design is adequate or not. Paragraph 2.5 gives further details on this aspect.

2.1.2 Events involving an aircraft, engines, system, propeller or part or appliance failure, malfunction or defect

The general approach for analysis of in-service events caused by malfunctions, failures or defects will be to analyse the actual failure effects, taking into account previously unforeseen failure modes or improper or unforeseen operating conditions revealed by service experience.

These events may have occurred in service, or have been identified during maintenance, or been identified as a result of subsequent tests, analyses, or quality control.

These may result from a design deficiency or a production deficiency (non-conformity with the type design), or from improper maintenance. In this case, it should be determined if improper maintenance is limited to one aircraft, in which case an airworthiness directive may not be issued, or if it is likely to be a general problem due to improper design and/or maintenance procedures, as detailed in paragraph 2.5.

2.1.2.1 Flight

An unsafe condition exists if:

— There is a significant shortfall of the actual performance compared to the approved performance (taking into account the accuracy of the performance calculation method), or

— The handling qualities, although having been found to comply with the applicable certification specifications at the time of initial approval, are subsequently shown by service experience not to comply.

2.1.2.2 Structural or mechanical systems

An unsafe condition exists if the deficiency may lead to a structural or mechanical failure which:

— Could exist in a Principal Structural Element that has not been qualified as damage tolerant. Principal Structural Elements are those which contribute significantly to carrying flight, ground, and pressurisation loads, and whose failure could result in a catastrophic failure of the aircraft.

Typical examples of such elements are listed for large aeroplanes in AMC 25.571(a) 'Damage tolerance and fatigue evaluation of structure', and in the equivalent material for rotorcraft.

— Could exist in a Principal Structural Element that has been qualified as damage tolerant, but for which the established inspections, or other procedures, have been shown to be, or may be, inadequate to prevent catastrophic failure.

— Could reduce the structural stiffness to such an extent that the required flutter, divergence or control reversal margins are no longer achieved.

— Could result in the loss of a structural piece that could damage vital parts of the aircraft, cause serious or fatal injuries to persons other than occupants.

— Could, under ultimate load conditions, result in the liberation of items of mass that may injure occupants of the aircraft.

— Could jeopardise proper operation of systems and may lead to hazardous or catastrophic consequences, if this effect has not been taken adequately into account in the initial certification safety assessment.

2.1.2.3 Systems

The consequences of reported systems components malfunctions, failures or defects should be analysed.

For this analysis, the certification data may be used as supporting material, in particular systems safety analyses.

The general approach for analysis of in-service events caused by systems malfunctions, failures or defects will be to analyse the actual failure effects.

As a result of this analysis, an unsafe condition will be assumed if it cannot be shown that the safety objectives for hazardous and catastrophic failure conditions are still achieved, taking into account the actual failure modes and rates of the components affected by the reported deficiency.

The failure probability of a system component may be affected by:

— A design deficiency (the design does not meet the specified reliability or performance).

— A production deficiency (non-conformity with the certified type design) that affects either all components, or a certain batch of components.

— Improper installation (for instance, insufficient clearance of pipes to surrounding structure).

— Susceptibility to adverse environment (corrosion, moisture, temperature, vibrations etc.).

— Ageing effects (failure rate increase when the component ages).

— Improper maintenance.

When the failure of a component is not immediately detectable (hidden or latent failures), it is often difficult to have a reasonably accurate estimation of the component failure rate since the only data available are usually results of maintenance or flight crew checks. This failure probability should therefore be conservatively assessed.

As it is difficult to justify that safety objectives for the following systems are still met, a deficiency affecting these types of systems may often lead to a mandatory corrective action:

— back up emergency systems, or

— fire detection and protection systems (including shut off means).

Deficiencies affecting systems used during an emergency evacuation (emergency exits, evacuation assist means, emergency lighting system ...) and to locate the site of a crash (Emergency Locator Transmitter) will also often lead to mandatory corrective action.

2.1.2.4 Others

In addition to the above, the following conditions are considered unsafe:

— There is a deficiency in certain components which are involved in fire protection or which are intended to minimise/retard the effects of fire/smoke in a survivable crash, preventing them to perform their intended function (for instance, deficiency in cargo liners or cabin material leading to non-compliance with the applicable flammability requirements).

— There is a deficiency in the lightning or High Intensity Radiated Fields protection of a system which may lead to hazardous or catastrophic failure conditions.

— There is a deficiency which could lead to a total loss of power or thrust due to common mode failure.

If there is a deficiency in systems used to assist in the enquiry following an accident or serious incident (e.g., Cockpit Voice Recorder, Flight Data Recorder), preventing them to perform their intended function, the Agency may take mandatory action.

2.2 Engines

The consequences and probabilities of engine failures have to be assessed at the aircraft level in accordance with paragraph 2.1, and also at the engine level for those failures considered as Hazardous in CS E-510.

The latter will be assumed to constitute unsafe conditions, unless it can be shown that the consequences at the aircraft level do not constitute an unsafe condition for a particular aircraft installation.

2.3 Propellers

The consequences and probabilities of propeller failures have to be assessed at the aircraft level in accordance with paragraph 2.1, and also at the propeller level for those failures considered as hazardous in CS P-70.

The latter will be assumed to constitute unsafe conditions, unless it can be shown that the consequences at the aircraft level do not constitute an unsafe condition for a particular aircraft installation.

2.4 Parts and appliances

The consequences and probabilities of equipment failures have to be assessed at the aircraft level in accordance with paragraph 2.1.

2.5 Human factors aspects in establishing and correcting unsafe conditions

This paragraph provides guidance on the way to treat an unsafe condition resulting from a maintenance or crew error observed in service.

It is recognised that human factors techniques are under development. However, the following is a preliminary guidance on the subject.

Systematic review should be used to assess whether the crew or maintenance error raises issues that require regulatory action (whether in design or other areas), or should be noted as an isolated event without intervention. This may need the establishment of a multidisciplinary team (designers, crews, human factors experts, maintenance experts, operators etc.)

The assessment should include at least the following:

— Characteristics of the design intended to prevent or discourage incorrect assembly or operation;

— Characteristics of the design that allow or facilitate incorrect operation,

— Unique characteristics of a design feature differing from established design practices;

— The presence of indications or feedback that alerts the operator to an erroneous condition;

— The existence of similar previous events, and whether or not they resulted (on those occasions) in unsafe conditions;

— Complexity of the system, associated procedures and training (has the crew a good understanding of the system and its logic after a standard crew qualification programme?);

— Clarity/accuracy/availability/currency and practical applicability of manuals and procedures;

— Any issues arising from interactions between personnel, such as shift changeover, dual inspections, team operations, supervision (or lack of it), or fatigue.

Apart from a design change, the corrective actions, if found necessary, may consist of modifications of the manuals, inspections, training programmes, and/or information to the operators about particular design features. The Agency may decide to make mandatory such corrective action if necessary.

GM 21.A.3B(d)(4) Defect correction – Sufficiency of proposed corrective action

ED Decision 2012/020/R

This GM provides guidelines to assist in establishing rectification campaigns to remedy discovered defects.

1. STATUS

This document contains GM of a general nature for use in conjunction with engineering judgement, to aid airworthiness engineers in reaching decisions in the state of technology at the material time.

While the main principles of this GM could be applied to small private aeroplanes, helicopters, etc. the numerical values chosen for illustration are appropriate to large aeroplanes for public transport.

2. INTRODUCTION

2.1 Over the years, target airworthiness risk levels underlying airworthiness requirements have developed on the basis of traditional qualitative airworthiness approaches; they have been given more precision in recent years by being compared with achieved airworthiness levels (judged from accident statistics) and by the general deliberations and discussions which accompanied the introduction of rational performance requirements, and more recently, the Safety Assessment approach in requirements. Although the target airworthiness risk level tends to be discussed as a single figure (a fatal accident rate for airworthiness reasons of not more than 1 in 10 000 000 flights/flying hours for large aeroplanes) it has to be recognised that the requirements when applied to particular aircraft types will result in achieved airworthiness levels at certification lying within a band around the target level and that thereafter, for particular aircraft types and for particular aircraft, the achieved level will vary within that band from time to time.

2.2 The achieved airworthiness risk levels can vary so as to be below the target levels, because it is difficult if not impossible to design to the minimum requirements without being in excess of requirements in many areas; also because aircraft are not always operated at the critical conditions (e.g., aircraft weight, CG position and operational speeds; environmental conditions - temperature, humidity, degree of turbulence). The achieved level may vary so as to be above the target level because of undetected variations in material standards or build standards, because of design deficiencies, because of encountering unforeseen combinations of failures and/or combinations of events, and because of unanticipated operating conditions or environmental conditions.

2.3 There is now a recognition of the need to attempt to monitor the conditions which tend to increase the level and to take appropriate corrective action when the monitoring indicates the need to do so in order to prevent the level rising above a predetermined ‘ceiling’.

2.4 The Agency also has a duty in terms of providing the public with aviation services and therefore should consider the penalties associated with curtailment or even removal (by ‘grounding’) of aviation services when establishing the acceptability of any potential variation in airworthiness level.

2.5 Thus, the purpose of this GM is:

(a) To postulate basic principles which should be used to guide the course of actions to be followed so as to maintain an adequate level of airworthiness risk after a defect has occurred which, if uncorrected, would involve a potential significant increase of the level of risk for an aircraft type.

(b) For those cases where it is not possible fully and immediately to restore an adequate level of airworthiness risk by any possible alleviating action such as an inspection or limitation, to state the criteria which should be used in order to assess the residual increase in risk and to limit it to an appropriate small fraction of the mean airworthiness through life risk.

3. DISCUSSION

3.1 Several parameters are involved in decisions on safety matters. In the past the cost of proposed action has often been compared with the notional 'risk cost', i.e. the cost of a catastrophe multiplied by its probability of occurrence.

3.2 This can be a useful exercise, but it should be held within the constraint of acceptable airworthiness risk levels, i.e., within airworthiness risk targets which represent the maximum levels of risk with which an aircraft design must comply, i.e., in the upper part of the 'band'. Currently for large aeroplanes the mean airworthiness risk level is set at a catastrophe rate for airworthiness reasons of not more than one in every ten- million flights/flying hours. The constraint is overriding in that any option, which could be permitted on risk cost considerations, or other grounds, is unacceptable if it leads to significant long-term violation of this safety requirement.

3.3 While it should clearly be the objective of all to react to and eliminate emergency situations, i.e., those involving a potentially significant increase of airworthiness risk levels, without unreasonable delay, the Agency should be able finally to rule on what is a minimum acceptable campaign programme. It has therefore seemed desirable to devise guidelines to be used in judging whether a proposed campaign of corrective actions is sufficient in airworthiness terms, and clearly this ought to be based on determining the summation of the achieved airworthiness risk levels for the aircraft and passengers during any periods of corrective action and comparing them with some agreed target.

3.4 As the period of corrective action will not be instantaneous (unless by grounding), there is potentially an increase in the achieved airworthiness risk level possibly to and, without controls, even above the higher part of the 'band', and the amount by which the level is above the mean target figure, and the period for which it should be allowed to continue, has been a matter of some arbitrary judgement.

3.5 It would appear desirable to try to rationalise this judgement. For example, if an aircraft were to spend 10 % of its life at a level such that the risk of catastrophe was increased by an order of magnitude, the average rate over its whole life would be doubled which may not be in the public interest. A more suitable criterion is perhaps one which would allow an average increase in risk of, say one third on top of the basic design risk when spread over the whole life of the aircraft an amount which would probably be acceptable within the concept (See Figure 1). It would then be possible to regard the 'through life' risk to an aircraft - e.g., a mean airworthiness target of not more than one airworthiness catastrophe per 10 million (107) hours, as made up of two parts, the first being 3/4 of the total and catering for the basic design risk and the other being 1/4 of the total, forming

an allowance to be used during the individual aircraft's whole life for unforeseen campaign situations such as described above.

3.6 Investigation has shown that a total of ten such occasions might arise during the life of an individual aircraft.

3.7 Using these criteria, there could then be during each of these emergency periods (assumed to be ten in number) a risk allowance contributed by the campaign alone of:

1×10^{-7} for 2.5% of the aircraft's life; or

5×10^{-7} for 0.5% of the aircraft's life; or

1×10^{-6} for 0.25% of the aircraft's life; or

1×10^{-5} for 0.025% of the aircraft's life, etc.

without exceeding the agreed 'allowance' set aside for this purpose.

3.8 Thus a 'reaction table' can be created as indicated in Table 1 (the last two columns assuming a typical aircraft design life of 60,000 hours and an annual utilisation of 3 000 hours per annum) showing the flying or calendar time within which a defect should be corrected if the suggested targets are to be met.

Estimated catastrophe rate to aircraft due to the defect under consideration (per a/c hour)	Average reaction time for aircraft at risk (hours)	On a calendar basis
4 x 10-8	3 750	15 months
5 x 10-8	3 000	12 months
1 x 10-7	1 500	6 months
2 x 10-7	750	3 months
5 x 10-7	300	6 weeks
1 x 10-6	150	3 weeks
1 x 10-5	15	Return to base

Table 1

3.9 These principles may be applied to a single aircraft or a number of aircraft of a fleet but in calculating risk, all the risk should be attributed to those aircraft which may carry it, and should not be diluted by including other aircraft in the fleet which are known to be free of risk. (It is permissible to spread the risk over the whole fleet when a source is known to exist without knowing where). Where a fleet of aircraft is involved Column 2 may be interpreted as the mean time to rectification and not the time to the last one.

3.10 There is one further constraint. However little effect a situation may have on the 'whole life' risk of an aircraft, the risk should not be allowed to reach too high a level for any given flight. Thus while a very high risk could be tolerated for a very short period without unacceptable degradation of the overall airworthiness target, the few flights involved would be exposed to a quite unacceptable level of risk. It is therefore proposed that the Table 1 should have a cut-off at the 2×10^{-6} level so that no flight carries a risk greater than 20 times the target. At this level the defect is beginning to contribute to a greater likelihood of catastrophe than that from all other causes, including non-airworthiness causes, put together. If the situation is worse than this, grounding appears to be the only alternative with possibly specially authorised high-risk ferry flights to allow the aircraft to return to base empty. Figures 2 and 3 show a visualisation chart equivalent to Table 1, giving average rectification time (either in flight hours or months) based on probability of defect that must be corrected.

3.11 It will be seen that the above suggestions imply a probability of catastrophe from the campaign alone of 1.5/10 000 per aircraft during each separate campaign period (i.e., p = 0.015 per 100 aircraft fleet).

3.12 In addition, in order to take into account large fleet size effect, the expected probability of the catastrophic event during the rectification period on the affected fleet shall not exceed 0.1. See Figure 4.

3.13 It should also be noted that in assessing campaign risks against 'design risk', an element of conservatism is introduced, since the passenger knows only 'total risk' (i.e. airworthiness plus operations risks) and the fatal accident rate for all reasons is an order of magnitude greater than that for airworthiness reasons only (i.e., 10^{-6} as against 10^{-7}). The summated campaign risk allowance proposed by this GM is therefore quite a small proportion of the total risk to which a passenger is subject. When operating for short periods at the limit of risk proposed (2 x 10^{-6} per hour) the defect is however contributing 100 % more risk than all other causes added together.

3.14 A similar approach is proposed to cover the case of defects associated to hazardous failure conditions for which the safety objectives defined by the applicable certification specifications are not met. According to CS 25.1309, the allowable probability for each hazardous failure condition is set at 10^{-7} per flight hour compared to 10^{-9} per flight hour for a catastrophic failure condition. Figure 5 is showing a visualisation chart giving average rectification time based on probability of defect that should be corrected. This is similar to Figure 2 but with lower and upper boundaries adapted to cover the case of hazardous failure conditions (probabilities of 10^{-7} and $2x10^{-4}$ respectively).

3.15 In addition, in order to take into account large fleet size effect, the expected probability of the hazardous event during the rectification period on the affected fleet shall not exceed 0.5. See Figure 6.

4. GUIDELINES

4.1 The above would lead to the following guidelines for a rectification campaign to remedy a discovered defect associated to a catastrophic failure condition without grounding the aircraft:

(i) Establish all possible alleviating action such as inspections, crew drills, route restrictions, and other limitations.

(ii) Identify that part of the fleet, which is exposed to the residual risk, after compliance has been established with paragraph (i).

(iii) Using reasonably cautious assumptions, calculate the likely catastrophic rate for each aircraft carrying the risk in the affected fleet.

(iv) Compare the speed with which any suggested campaign will correct the deficiency with the time suggested in Figure 2. The figure should not be used beyond the $2x10^{-6}$ level, except for specially authorised flights.

(v) Also ensure that the expected probability of the catastrophic event during the rectification period on the affected fleet is in accordance with Figure 4.

4.2 Similarly, the following guidelines would be applicable for a rectification campaign to remedy a discovered defect associated to a hazardous failure condition without grounding the aircraft:

(i) Establish all possible alleviating action such as inspections, crew drills, route restrictions, and other limitations.

(ii) Identify that part of the fleet, which is exposed to the residual risk, after compliance has been established with paragraph (i).

(iii) Using reasonably cautious assumptions, calculate the likely hazardous rate for each aircraft carrying the risk in the affected fleet.

(iv) Compare the speed with which any suggested campaign will correct the deficiency with the time suggested in Figure 5.

(v) Also ensure that the expected probability of the hazardous event during the rectification period on the affected fleet is in accordance with Figure 6.

4.3 It must be stressed that the benefit of these guidelines will be to form a datum for what is considered to be the theoretically maximum reaction time. A considerable amount of judgement will still be necessary in establishing many of the input factors and the final decision may still need to be tempered by non-numerical considerations, but the method proposed will at least provide a rational 'departure point' for any exercise of such judgement.

4.4 It is not intended that the method should be used to avoid quicker reaction times where these can be accommodated without high expense or disruption of services.

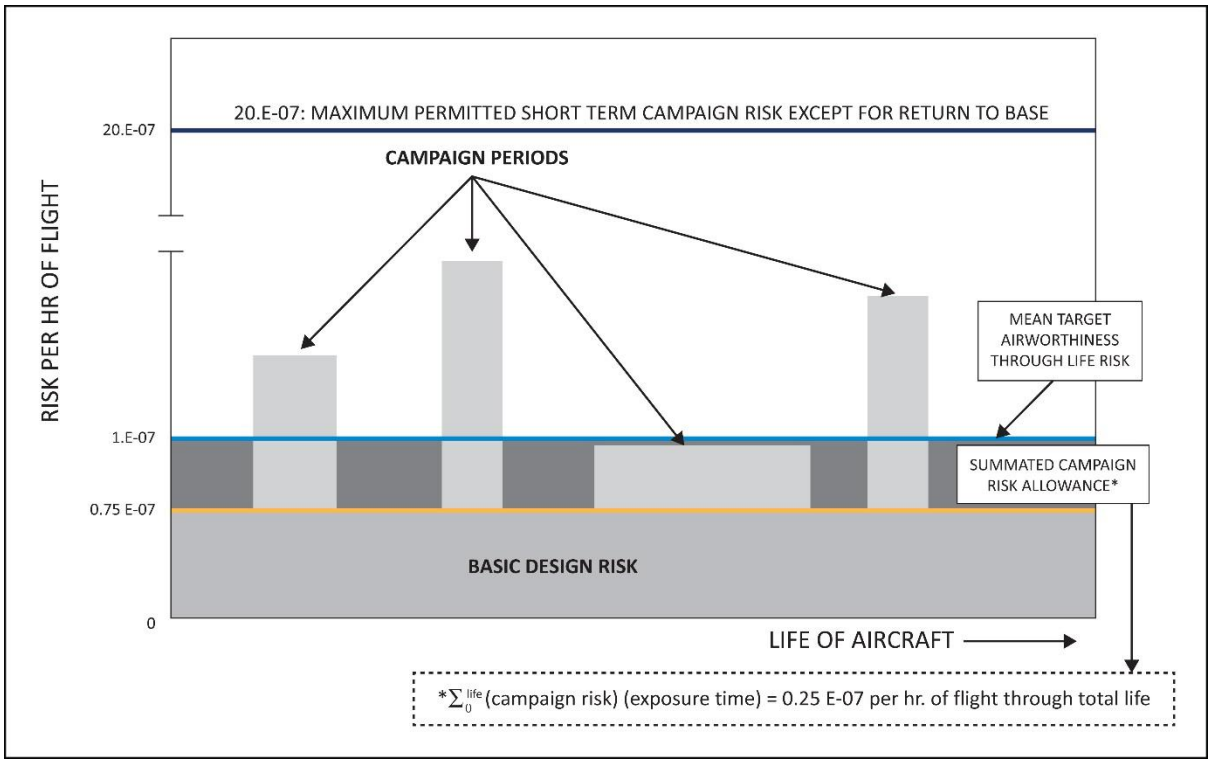


Figure 1 - Visualisation Chart for CS-25

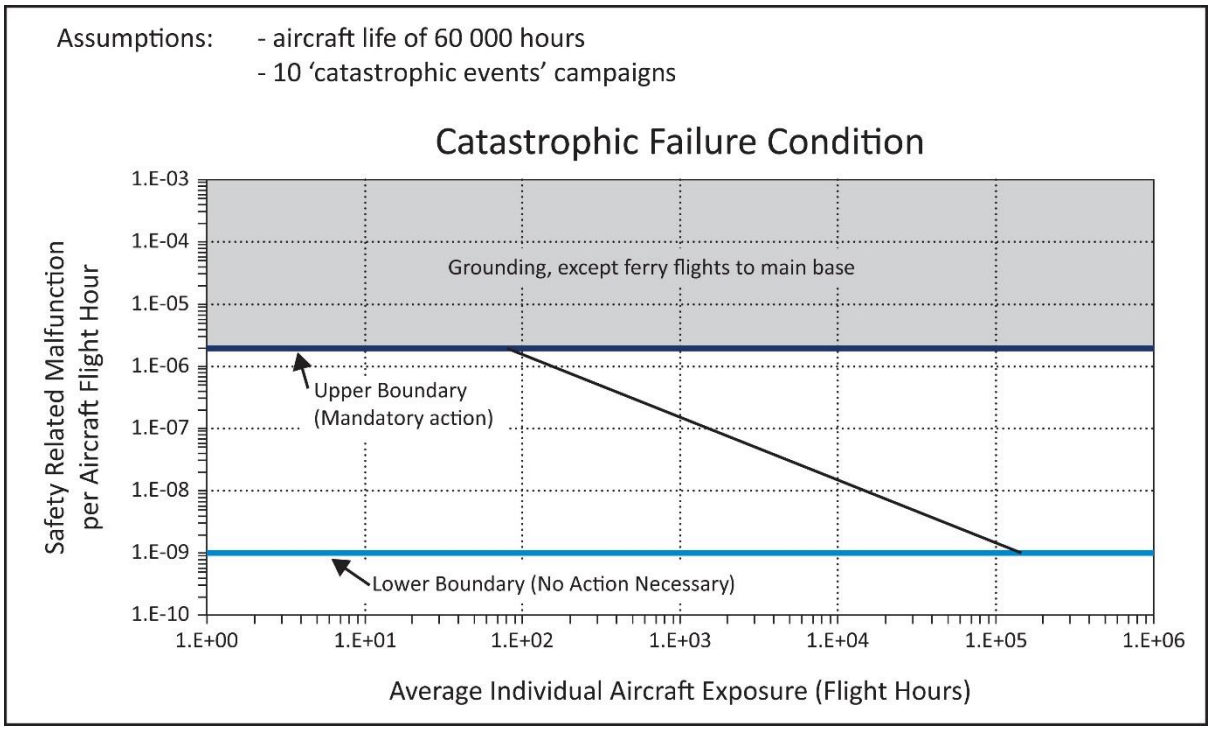


Figure 2 - Visualisation Chart for CS-25 (Flight hours)

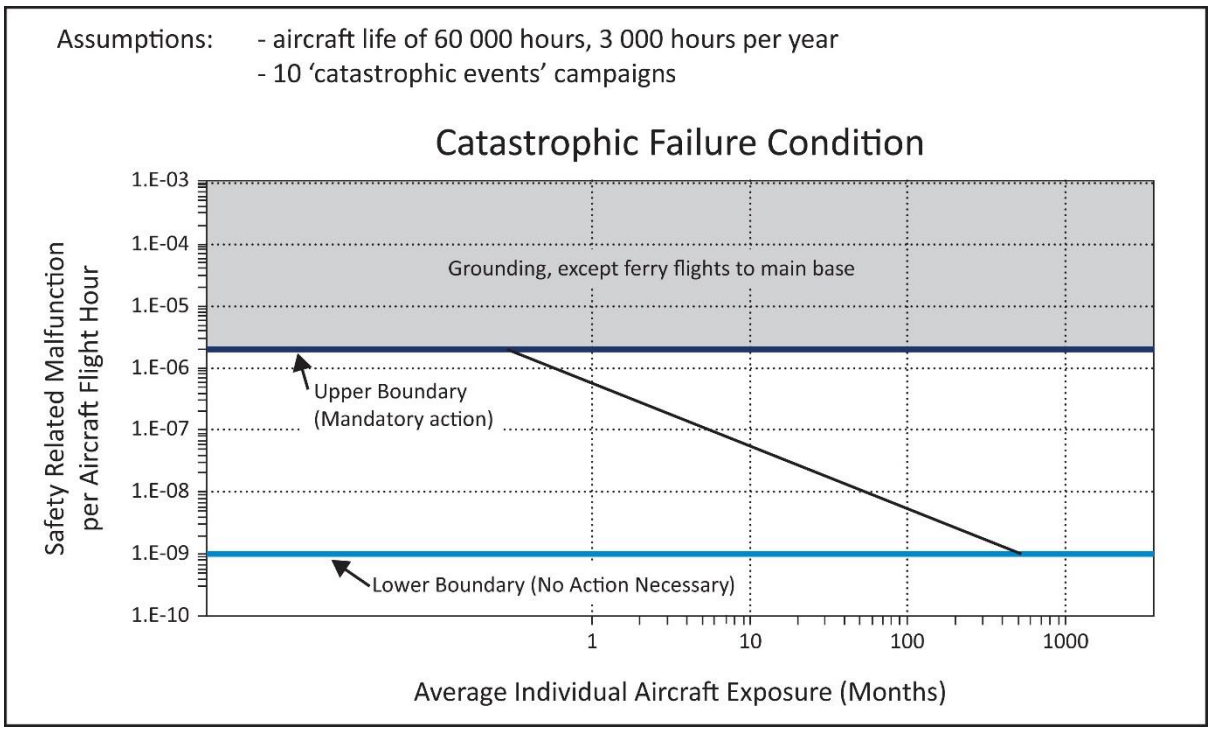


Figure 3 - Visualisation Chart for CS-25 (Calendar basis)

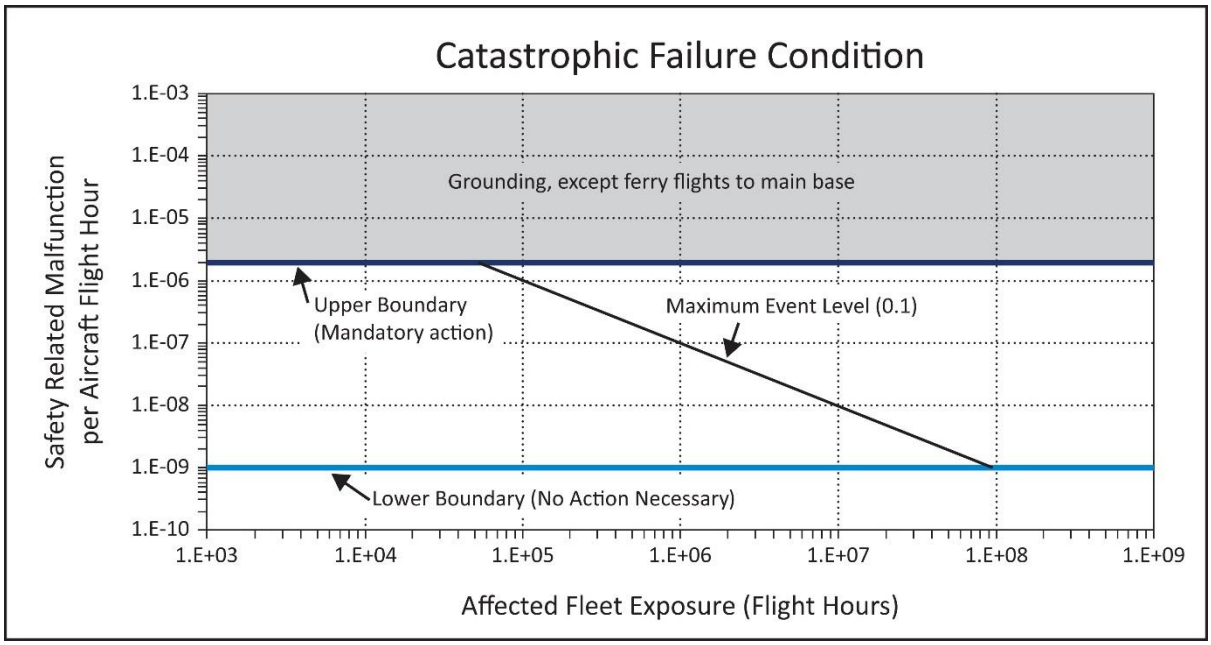


Figure 4 - Visualisation Chart for CS-25 (Flight Hours)

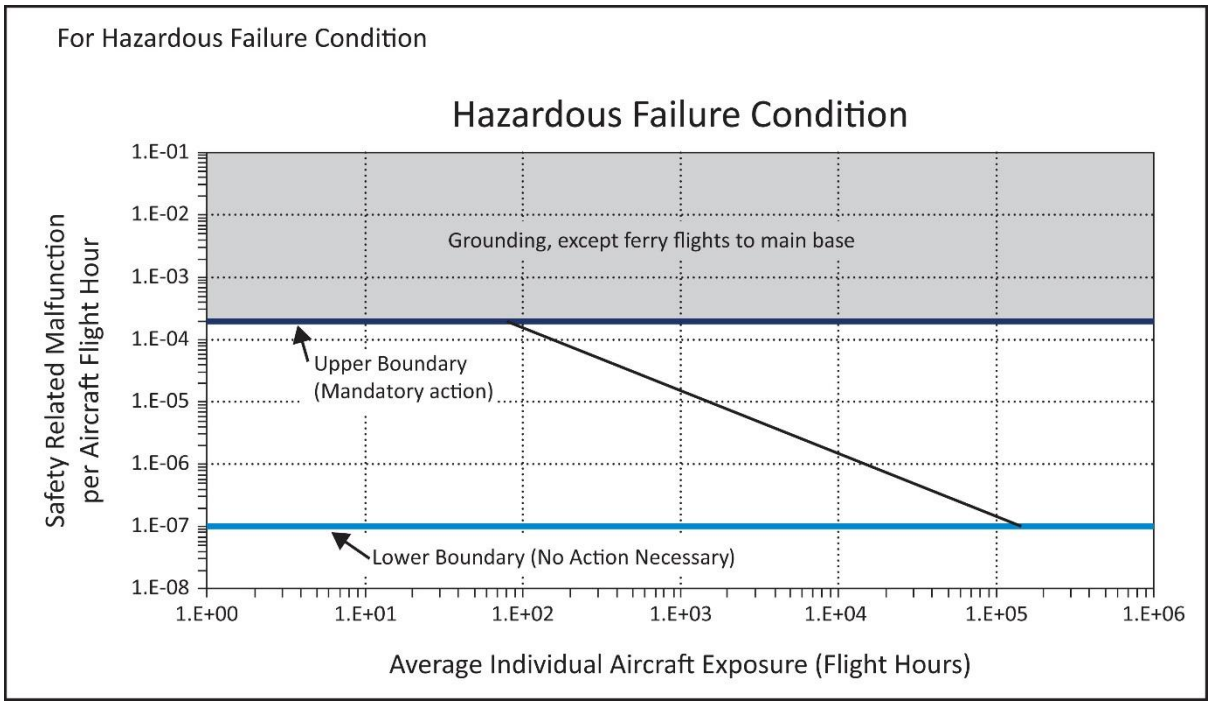


Figure 5 - Visualisation Chart for CS-25 (Flight hours)

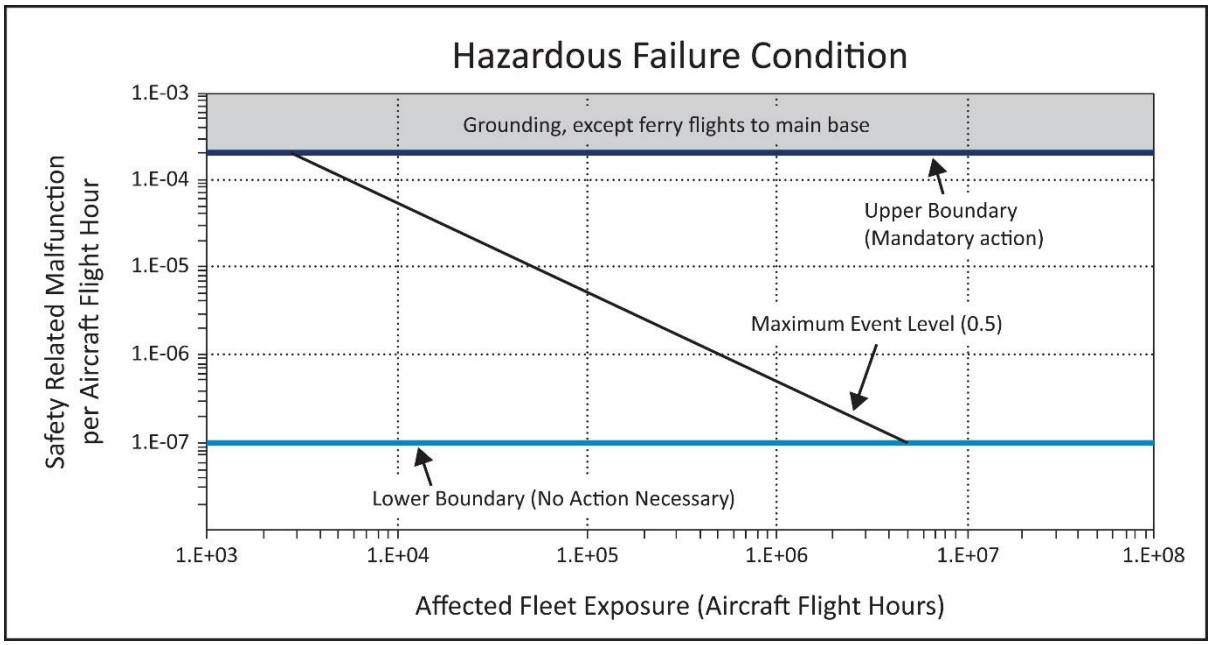


Figure 6 - Visualisation Chart for CS-25 (Flight hours)

21.A.4 Coordination between design and production

Regulation (EU) No 69/2014

Each holder of a type-certificate, restricted type-certificate, supplemental type-certificate, ETSO authorisation, approval of a change to type-certificate or approval of a repair design, shall collaborate with the production organisation as necessary to ensure:

(a) the satisfactory coordination of design and production required by 21.A.122, 21.A.130(b)(3) and (4), 21.A.133 and 21.A.165(c)(2) and (3) as appropriate; and

(b) the proper support of the continued airworthiness of the product, part or appliance.

AMC 21.A.4 Transferring of information on eligibility and approval status from the design holder to production organisations

ED Decision 2014/007/R

Where there is a need to provide (normally outside the design organisation) a visible statement of approved design data or airworthiness, operational suitability or environmental protection data associated with the approved design data, the following minimum information must be provided. The need for a visible statement may be in relation to Company holding a production organisation approval (POA) in relation to 21.A.163(c).

The procedures related to the use of forms or other electronic means to provide this information must be agreed with the Agency.

Information to be provided:

Company Name: the name of the responsible design organisation (TC, STC, approval of repair or minor change design, ETSO authorisation holder) issuing the information.

Date: the date at which the information is released.

Eligibility: indicate the specific products or articles, in case of ETSO authorisation, for which data have been approved.

Identification: the part number of the part or appliance. Preference should be given to the use of the Illustrated Parts Catalogue (IPC) designation. Alternatively the reference to the instruction for continued airworthiness (e.g., SB, AMM, etc.) could be stated. Marking requirements of Part 21 Section A Subpart Q should be taken into account.

Description: the name or description of the part or document should be given. In the case of a part or appliance preference should be given to use of IPC designation. The description is to include reference to any applicable ETSO authorisation or EPA marking, or previous national approvals still valid.

Purpose of data: the reason for the provision of the information should be stated by the design approval holder.

Examples:

a) Provision of approved design data to a production organisation to permit manufacture (AMC No 1 to 21.A.133(b) and (c))

b) Information regarding eligibility for installation (replacement parts, repair, modification, etc.)

c) Direct Delivery Authorisation (AMC No 1 to 21.A.133(b) and (c))

If the data is in support of a change or repair, then reference to the aircraft level approval should be given (make reference to the approved STC, change or repair).

Limitations/Remarks: state any information, either directly or by reference to supporting documentation that identifies any particular data or limitations (including specific importing requirements) needed by a production organisation to complete Block 12 of the EASA Form 1.

Approval: provide reference information related to the approval of the data (Agency document or DOA privilege).

Authorised signature: name and hand-written normal or electronic signature of a person who has written authority from the design organisation, as indicated in the procedures agreed with the Agency.

21.A.5 Record-keeping

Regulation (EU) 2021/699

All relevant design information, drawings and test reports, including inspection records for the product or article tested for the purpose of certification, shall be held by the holder of a type-certificate, restricted type-certificate, supplemental type-certificate, design change or repair design approval or of an ETSO authorisation at the disposal of the Agency and shall be retained in order to provide the information necessary to ensure the continued airworthiness, continued validity of the operational suitability data and the compliance with the applicable environmental protection requirements of the product or the article.

[applicable until 6 March 2023]

All natural or legal persons that hold or have applied for a type-certificate, restricted type-certificate, supplemental type-certificate, ETSO authorisation, design or repair approval, permit to fly, production organisation approval certificate or letter of agreement under this Regulation shall:

(a) when they design a product, part or appliance or changes or repairs thereto, establish a record-keeping system and maintain the relevant design information/data; that information/data shall be made available to the Agency in order to provide the information/data that is necessary to ensure the continued airworthiness of the product, part or appliance, the continued validity of the operational suitability data, and compliance with the applicable environmental protection requirements;

(b) when they produce a product, part or appliance, record the details of the production process relevant to the conformity of the product, part or appliances with the applicable design data, and the requirements imposed on their partners and suppliers, and make that data available to their competent authority in order to provide the information that is necessary to ensure the continuing airworthiness of the product, part or appliance;

(c) with regard to permits to fly:

1. maintain the documents that are produced to establish and justify the flight conditions, and make them available to the Agency and to their competent authority of the Member State in order to provide the information that is necessary to ensure the continued airworthiness of the aircraft;

2. when they issue a permit to fly under the privilege of approved organisations, maintain the documents associated with it, including inspection records and documents that support the approval of the flight conditions and the issuance of the permit to fly itself, and make them available to the Agency and to their competent authority of the Member State responsible for the oversight of the organisation in order to provide the information that is necessary to ensure the continued airworthiness of the aircraft;

(d) retain records of the competence and qualifications, referred to in points 21.A.139(c), 21.A.145(b), 21.A.145(c), 21.A.239(c), 21.A.245(a) or 21.A.245(e)(1), of the personnel that are involved in the following functions:

1. design or production;

2. independent monitoring of the compliance of the organisation with the relevant requirements;

3. safety management;

(e) retain records of the authorisation of personnel, when they employ personnel that:

1. exercise the privileges of the approved organisation pursuant to points 21.A.163 and/or 21.A.263, as appropriate;

2. carry out the independent function to monitor the compliance of the organisation with the relevant requirements pursuant to points 21.A.139(e) and/or 21.A.239(e), as appropriate;

3. carry out the independent verification function of the demonstration of compliance pursuant to point 21. A.239(d)(2).

[applicable from 7 March 2023 — Regulation (EU) 2022/201]

GM1 21.A.5 Repair designs and record keeping

ED Decision 2021/007/R

For repair designs, the record-keeping requirement of point 21.A.5 applies to the data described in AMC 21.A.433(a).

21.A.6 Manuals

Regulation (EU) 2021/699

The holder of a type-certificate, restricted type-certificate, or supplemental type-certificate shall produce, maintain and update master copies of all manuals or variations in the manuals required by the applicable type-certification basis, the applicable operational suitability data certification basis and the environmental protection requirements for the product or article, and provide copies, on request, to the Agency.

21.A.7 Instructions for continued airworthiness

Regulation (EU) 2021/699

(a) The holder of a type-certificate, restricted type-certificate, supplemental type-certificate, design change or repair design approval shall develop or reference the instructions which are necessary for ensuring that the airworthiness standard related to the aircraft type and any associated part is maintained throughout the operational life of the aircraft, when demonstrating compliance with the applicable type-certification basis established and notified by the Agency in accordance with point 21.B.80.

(b) At least one set of complete instructions for continued airworthiness shall be provided by the holder of:

1. a type-certificate or restricted type-certificate to each known owner of one or more products upon its delivery or upon the issuance of the first certificate of airworthiness or restricted certificate of airworthiness for the affected aircraft, whichever occurs later,

2. a supplemental type-certificate or design change approval to all known operators of the product affected by the change upon the release to service of the modified product,

3. a repair design approval to all known operators of the product affected by the repair upon the release to service of the product in which the repair design is embodied. The repaired product, part or appliance may be released into service before the related instructions for continued airworthiness have been completed, but this shall be for a limited service period, and in agreement with the Agency.

Thereafter, those design approval holders shall make those instructions available on request to any other person required to comply with those instructions.

(c) By way of derogation from point (b), the type-certificate holder or restricted type-certificate holder may delay the availability of a part of the instructions for continued airworthiness, dealing with long lead accomplishment instructions of a scheduled nature, until after the product or modified product has entered into service, but shall make those instructions available before the use of this data is required for the product or modified product.

(d) The design approval holder, who is required to provide instructions for continued airworthiness in accordance with point (b), shall also make available changes to those instructions to all known operators of the product affected by the change and, on request, to any other person required to comply with those changes. That design approval holder shall demonstrate to the Agency, on request, the adequacy of the process of making changes to the instructions for continued airworthiness available in accordance with this point.

AMC1 21.A.7(a) ICA contents

ED Decision 2021/007/R

(a) The instructions for continued airworthiness (ICA) should identify the following, in accordance with the applicable certification specifications:

(1) any limitations that are necessary for the continued airworthiness of the product or article;

(2) the means to determine when the product or article has deteriorated to the extent that it is no longer airworthy;

(3) the minimum actions required to restore the airworthiness of the product or article before the limitations (as per point (1)) have been exceeded or before their deterioration (as per point (2)), as an alternative to the withdrawal of the product or article from service.

(b) The ICA should, therefore, include, in accordance with the applicable certification specifications:

(1) any limitations determined through the certification of the product or article, and instructions on how to determine that the limitations have been exceeded;

(2) any inspection, servicing or maintenance actions determined to be necessary by the certification process;

(3) any inspection or troubleshooting actions determined to be necessary to establish the nature of faults and the necessary remedial actions;

(4) sufficient general information on the operation of the product or article to enable the understanding of the instructions in (a)(1) to (a)(3) above.

AMC2 21.A.7(a) Identification of ICA

ED Decision 2021/007/R

The instructions for continued airworthiness (ICA) may be provided together with other, additional or optional, maintenance information, as described in point 21.A.6, or in another acceptable format as per GM1 21.A.7(a), with the following conditions:

(a) The information that is necessary for the continued airworthiness is clearly identified (refer to AMC1 21.A.7(b)).

(b) The ICA may reference additional instructions for continued airworthiness in separate publications, where necessary (for example, those produced by suppliers).

If the product ICA reference the use of supplier's data (e.g. component maintenance manual (CMM) or section of it) as the appropriate location for the ICA, those applicable instructions are incorporated by reference and become part of the complete set of the ICA for the product.

(c) Additional or optional maintenance information not considered as ICA but referenced by the design approval holder (DAH) together with the ICA should be evaluated appropriately by the DAH in order to ensure that its use will not compromise the continued airworthiness of the product or article.

(d) If the maintenance data made available by a DAH includes data from an operator (i.e. in order to customise the data for the operator, and created under the authority of the operator), the operator's data should be identified as such, and the DAH is not required to additionally evaluate it.

AMC3 21.A.7(a) DAH responsibility to check the supplier data which is part of the ICA or referenced with the ICA

ED Decision 2021/007/R

The DAH may carry out a complete check of the supplier data, or may choose to rely, in whole or in part, on the supplier's process. In the latter case, the DAH will propose a means to validate the supplier's process. Supplier data may also be issued by the supplier to the DAH under a contract or an arrangement, addressing the following:

(a) the accuracy and the adequacy of the technical documentation, which should be checked through a verification processes (e.g. component workshop verification);

(b) evidence showing that workshop verification was performed should be kept by the supplier and a clear statement should be given in the introduction to the supplier data as a confirmation that component verification is complete;

(c) evidence that the supplier has taken into account all justified feedback and changes to data requested by any person required to use the ICA; typical examples would be the correction of reported errors, or mistakes.

In addition, some validation activities may be decided by the DAH, depending on the articles and the capability level of the supplier.

For articles subject to an ETSO authorisation, the validation of the supplier's process is not needed. This is also valid for other national TSO authorisations (e.g. FAA TSOs) accepted by EASA as stipulated in related bilateral agreements.

GM1 21.A.7(a) Scope of ICA, their publication format and typical ICA data

ED Decision 2021/007/R

(a) ICA can be published in documents or in a manner other than the traditional understanding of a document — for example, as a series of web pages, or Information Technology (IT) tools, or in a publishing format linked to tasks or data modules rather than pages.

(b) The design approval holder (DAH) can decide — within the framework provided by point 21.A.7 and its acceptable means of compliance and guidance material — to publish the ICA in the most suitable location as part of all the information published to support the airworthiness of an aircraft. Publications typically produced by DAHs (e.g. for the demonstration of compliance with a certification basis established on the basis of CS-25), and which may therefore include ICA, consist of:

- aircraft maintenance manuals (AMMs);
- scheduled maintenance requirements (e.g. MRBRs);
- off-wing component maintenance or overhaul manuals;
- parts catalogues;
- tooling manuals;
- wiring diagram manuals;
- weight and balance manuals;
- electrical loads analyses;

— extended range operations (ETOPS) configuration maintenance programs/plans;

— supplemental structural inspection documentation;

— certification maintenance requirements;

— Airworthiness Limitations items;

— ageing aircraft maintenance requirements;

— fuel tank safety related limitations (e.g. critical design configuration control limitation (CDCCL));

— electrical wiring interconnection system instructions;

— corrosion prevention and control programmes;

— troubleshooting manuals.

Note: The above is only an example of the publications that may contain ICA according to CS-25; the list is not exhaustive, nor does it represent a minimum list of ICA.

(c) The requirement for ICA is not intended to ensure that all products or articles may be restored to an airworthy condition. A certain level of deterioration may require a product or an article to be permanently withdrawn from service, and restoration may not be reasonably achievable. Notwithstanding the above, the existence of an MRBR task other than 'Discard (DS or DIS)' should be a clear indication of the necessity/obligation to produce a corresponding ICA.

Certain deteriorations or levels of deterioration may require specific instructions (e.g. inspection or restoration) that will only be developed and provided on a case-by-case basis, as needed, for a given product or article, and as such, will not be included in the ICA.

In some exceptional cases, product ICA may ultimately instruct the user to contact the DAH in order to define the specific instructions on a case-by-case basis. This typically happens when the definition of generic instructions covering all possible cases is not possible. For example, following an aircraft hard landing, a detailed analysis may have to be carried out by the DAH to determine the specific instructions to be followed, which depends on the touchdown loads, recalculated postflight, based on recorded flight data.

GM2 21.A.7(a) Determination of which supplier data is part of the ICA

ED Decision 2021/007/R

Note 1: For the purpose of this GM, the term 'supplier data' also applies to similar types of data when issued directly by the DAH (e.g. component maintenance manuals issued by the DAH).

Note 2: For the purpose of this GM, the term 'supplier data' has to be understood as data coming from the supplier and related to either a full CMM or to part of a CMM.

Note 3: The link between the aircraft ICA and the engine/propeller CMM, as detailed below, is similar to the link between engine/propeller ICA and the CMM of equipment fitted to the engine/propeller.

Note 4: If the supplier is also the DAH (for instance, an engine or propeller manufacturer), then the ICA for these items will be made available by virtue of the DAH obligations as type-certificate holder (TCH) and need not be included in the aircraft ICA.

(a) When determining whether a supplier data is part of the ICA, the following should be considered:

(1) Supplier data related to the Airworthiness Limitations Section (ALS) of the ICA is part of the ICA. A typical CS-25 example is critical design configuration control limitation (CDCCL) items that are included in CMMs.

(2) Supplier data related to instructions on how to accomplish the scheduled maintenance part of the aircraft ICA (such as MRBR) are part of the aircraft ICA. A typical case is the periodical removal of a component to perform a workshop task.

Example: Escape slide removal for restoration in accordance with the supplier data instructions.

(3) Supplier data related to scheduled maintenance on the component should be endorsed by the DAH before becoming part of the aircraft ICA, to define and confirm that the supplier data is applicable and effective.

(4) If the ICA are defined at aircraft level, the following principles apply to the other supplier data that is not related to the ALS nor to scheduled maintenance:

(i) If the supplier data includes a maintenance instruction for an action identified in the aircraft-level ICA, including an engine or propeller, this supplier data should be referenced in the aircraft-level ICA and should be made available like any other ICA.

As an alternative to linking such supplier data to the aircraft-level ICA (e.g. with cross references), it is possible to include the relevant data directly into the aircraft ICA. In such a case, the supplier data is not part of the aircraft ICA since the aircraft ICA already contain all the required information.

(ii) If an aircraft ICA task only requires a replacement task for an engine, propeller, part or appliance (i.e. 'remove and replace' or 'discard') and does not refer to the supplier data for further maintenance of the removed engine, propeller, part or appliance, this means that the aircraft airworthiness may only be maintained by replacement action, and that the supplier data is not part of the ICA for the aircraft. In such cases, the supplier data does not need to be referenced in the aircraft ICA.

Example: If supplier data provides off-aircraft maintenance instructions for an engine, propeller, or other article (i.e. workshop maintenance), then this data may not be considered as part of the complete set of ICA for the aircraft, but may be considered as part of the complete set of ICA for the engine or propeller. However, the procedure for removal from / installation on the aircraft is necessarily part of the aircraft ICA.

(b) However, for the above cases, aircraft-level ICA can provide, as additional or optional maintenance information, the references to the supplier data even if it is not considered part of the ICA. In such cases, it should be made clear that the supplier data references are provided as additional or optional maintenance information and is not part of the product ICA. Besides, it should be ensured that the use of additional or optional maintenance information not considered as ICA but referenced together with the ICA will not compromise the continued airworthiness of the product or article.

(b) For the supplier data identified as part of the ICA, the DAH should:

(1) identify the supplier data that is part of the ICA; this can be achieved either by creating a listing or by any other acceptable means that allow to identify which data is part of the ICA and which data is not part of the ICA (refer to AMC1 21.A.7(b));

(2) just as for any other ICA, ensure the publication of the supplier data;

(3) ensure the accuracy and the adequacy of the technical content of the supplier data (refer to GM No. 1 to 21.A.239(a), point 3.1.5)

GM3 21.A.7(a) Non-ICA supplier data (e.g. component maintenance manuals (CMMs))

ED Decision 2021/007/R

(a) Non-ICA supplier data referenced together with the ICA

Supplier data, or parts of the supplier data, which is not considered to be part of the ICA but is additional or optional maintenance information referenced together with the product-level ICA, may be issued by the supplier to the DAH under a contract or an arrangement, using the methodology proposed in AMC3 21.A.7(a).

(b) Other non-ICA supplier data

Non-ICA supplier data, which is not referenced together with the ICA, but which can be used for the maintenance of components approved for installation by the DAH, should be acceptable to the DAH. This non-ICA supplier data may be documented in a list.

AMC1 21.A.7(b) Identification of a complete set of instructions for continued airworthiness (ICA)

ED Decision 2021/007/R

The design approval holder (DAH) should identify the complete set of ICA according to point 21.A.7(b) in such a way that the complete set can be:

(a) directly listed in the product TCDS; or

(b) indirectly referenced in the TCDS through other means, which allow the complete list of the ICA to be obtained (e.g. a complete listing of ICA contained in a 'principal manual' or a reference to a DAH's website); or

(c) directly listed in the product STC; or

(d) indirectly referenced in the STC through other means, which allow the obtainment of the complete list of the ICA; or

(e) if direct reference is made to the ICA in the TCDS or the STC, no reference to the revision level of the ICA should be made; in this case, the revision level should be available elsewhere (e.g. on the DAH's website).

For changes to type certificates and repairs, the identification of 'a complete set of the changes to the instructions for continued airworthiness' should be performed by the DAH by a statement to provide this information, or by confirmation that there are no changes to the ICA. This statement can also be made in the accomplishment document (e.g. embodiment instructions).

For products and articles for which the DAH holds a design organisation approval (DOA), the ICA are considered to be issued under the authority of the DOA and, therefore, the approval of the ICA should be made explicit to the reader in accordance with point 21.A.265(h), unless otherwise agreed with EASA.

GM1 21.A.7(b) Other persons required to comply

ED Decision 2021/007/R

For the purpose of this GM, 'any other person required to comply' means:

— any independent certifying staff who performs maintenance on a product or article, in accordance with Regulation (EU) No 1321/2014, in the framework of a contract (or work order) with the person or organisation responsible for the aircraft continuing airworthiness;

— any maintenance organisation approved to maintain a product or article, in accordance with Regulation (EU) No 1321/2014, in the framework of a contract (or work order) with the owner of the engine or article, or the person or organisation responsible for the aircraft continuing airworthiness;

— any organisation approved to manage the aircraft continuing airworthiness in accordance with Regulation (EU) No 1321/2014, in the framework of a contract with the aircraft owner or aircraft operator.

GM2 21.A.7(b) ICA — format

ED Decision 2021/007/R

ICA can be furnished or made available by various means (including paper copies, electronic documents, or web-based access). Regardless of the format, the design approval holder (DAH) is expected to furnish or make ICA available in a means that is readily accessible for and useable by the owner and any person required to comply with the ICA. Service documents, such as service information letters, may be used for transmitting ICA information and updates.

(a) Formatting standards

Applicants may use the latest ATA, AECMA/ASD or GAMA formatting standards such as:

(1) AeroSpace and Defence Industries Association of Europe (ASD), ASD-S1000D, *International Specification for Technical Publications Utilizing a Common Source Data Base*, version 4 or higher;

(2) the Air Transport Association's (ATA) iSpec 2200, *Information Standards for Aviation Maintenance*, latest edition (ATA is now known as Airlines for America (A4A) but the standard is still listed as ATA); or

(3) General Aviation Manufacturers Association (GAMA) Specification No. 2, *Specification for Manufacturers Maintenance Data*, latest edition.

In regard to scheduled maintenance, applicants may also refer to the glossary of the ATA MSG-3 standard, latest revision, for standardised task definitions and designations.

(b) General considerations

ICA should be easy to read and to follow. All ICA should include a means to identify their applicability (model, type, etc.), and the associated revision status. Refer to sample formats in the Air Transport Association's iSpec 2200, *Information Standards for Aviation Maintenance*, latest edition, or AECMA/ASD standards. There is no requirement for any specific format or arrangement of the ICA in document or documents. However, the specific format selected by the applicant should be used and applied in a uniform manner. Empty pages in a document should contain a statement like 'Intentionally left blank' or similar.

At the beginning of each procedure, the ICA should contain cautions and warnings regarding possible mistakes that can be made when following the instructions.

Abbreviations, acronyms and symbolisation should be either avoided or explained as part of the ICA documentation.

ICA contain units of measurement. Measurements could be, for instance, instrument readings, temperatures, pressures, torque values with tolerances, limits, and ranges when applicable. If the ICA contain units of measurement of a system other than the metric, the ICA should include a conversion to the metric system for each measurement, tolerance, or torque value. A general conversion table alone should not be provided, as it may introduce an additional source of error.

The DAH should use a means to indicate changes to the ICA directly in relation to each item of the information/data of the ICA, e.g. using a vertical change bar in the margin next to the line.

(c) Publication of ICA in multiple documents

DAHs may prepare ICA as a document, or several documents, depending on how much data is necessary to provide a complete set of ICA.

If there are multiple documents, there should be a principal document that describes the general scope of all other documents, in order to provide an overview of the multiple document structure.

According to different standards, the Airworthiness Limitations Section (ALS) needs to be included in the principal document as a dedicated section. However, EASA may also accept a separate Airworthiness Limitations document, when it is at least referenced as such in the principal document.

DAHs who decide to segregate information dedicated to a specific subject from a principal document into a separate document, e.g. 'Fuel Pipe Repair Manual', 'Cable Fabrication Manual', 'Duct Repair Manual' or 'Instrument Display Manual', should declare these documents to be ICA.

DAHs may decide to integrate certain information in a principal document (as, for example, troubleshooting information as part of the aircraft maintenance manual (AMM) instead of a separate troubleshooting manual (TSM)).

(d) Language

ICA should be provided in any of the official language(s) of the European Union which is (are) acceptable to the competent authority.

Note: In certain countries, such as the USA, English is required for ICA. EASA, therefore, recommends that DAHs include a version of the ICA in simplified technical English (e.g. in accordance with ASD Specification STE100).

(e) Electronic media

ICA may be provided in an electronic format (e.g. CDs, via the internet, etc.) instead of paper copies or microfilms (refer to AMC1 21.A.7(b)).

When an electronic format is used, the DAH should consider aspects such as the traceability of updates, keeping previous versions (record keeping), data security and the obligations of the person(s) or organisation(s) responsible for the aircraft continuing airworthiness, considering that the ICA form the basis of the data used for continuing airworthiness activities.

GM3 21.A.7(b) Approval status of the manual for a component or article

ED Decision 2021/007/R

When the ICA refer to a document for a specific component or article, it is possible that this document is used for products from more than one DAH. In such cases, instead of placing approval statements from each DAH in the same manual, it may be more practical to identify the approved status of the relevant document through its inclusion in lists managed by the DAH in accordance with the AMC1 21.A.7(b).

GM4 21.A.7(b) Integration of ICA between products (aircraft, engines, propellers)

ED Decision 2021/007/R

The aircraft/engine/propeller type-certificate holder (TCH) should ensure the availability of ICA to allow maintenance of the aircraft, including engines/propellers when installed on the aircraft.

When referring to engine/propeller ICA directly in the aircraft ICA, the aircraft TCH should not perform additional verification and validation. However, the integration and interface aspects between the aircraft and the engine/propeller are still under the responsibility of the aircraft TCH.

If the ICA published by the aircraft TCH include some engine/propeller ICA developed by the engine/propeller TCH, the engine/propeller TCH should make an arrangement with the aircraft TCH setting out engine/propeller TCH and aircraft TCH shared responsibilities with respect to the ICA under point 21.A.7.

This arrangement should:

— define the part of the engine/propeller ICA which is published in the aircraft ICA; and

— address the development, publication and update processes of these ICA, including completeness and timely availability aspects.

The incorporated engine/propeller data content remains under the responsibility of the engine/propeller TCH, and the publication is under the responsibility of the aircraft TCH. Therefore, the aircraft TCH must coordinate with the engine/propeller TCH regarding any modification or alteration of the incorporated data.

AMC1 21.A.7(c) Completeness and timely availability of the ICA

ED Decision 2021/007/R

COMPLETENESS AND TIMELY AVAILABILITY OF THE ICA FOR TYPE-CERTIFICATE (TC) AND RESTRICTED TYPE-CERTIFICATE (RTC) APPLICANTS

(a) An applicant may wish to choose among the three options described below. Once the certification programme starts, it may be necessary to modify the initially selected option to accommodate programme changes. All such changes should be coordinated with EASA.

(1) Option 1: Complete ICA are available at the time of the design approval (TC/RTC)

(i) The ICA will be made available at the time of the design approval. This option minimises the risk of incomplete ICA, especially for changes.

(ii) With all ICA available at the time of the design approval, they should also be furnished / made available to the aircraft operator / aircraft owner and made available to any other person required to comply with any of those instructions in accordance with points 21.A.21(c)(4), 21.A.44 and 21.A.7, without using the provision to delay certain parts of the ICA after the entry into service.

(iii) Frequently, there is only a short period of time between the design approval and the entry into service. Nevertheless, applicants/holders may still wish to apply Option 2 or 3 for a part of their ICA as stated below.

(2) Option 2: Complete ICA are available at entry into service (TC/RTC)

If an applicant plans to make part of the ICA available to EASA at entry into service, the following approach is acceptable:

(i) For the ALS, as part of the type design, notwithstanding the selection of Option 2: the applicant submits the ALS for approval prior to the design approval. Any ALS content that is incomplete, not yet demonstrated for compliance, or delayed beyond the design approval, requires to be compensated through an interim limitation to establish compliance within this limitation. The interim limitation is notified to the aircraft operator(s) concerned as a temporary operational limitation in a manner agreed with EASA.

In this context, ALS content is understood as the task method (e.g. a detailed inspection), including its reference, title and applicability, and the associated threshold / interval / life-limit. The accomplishment procedure itself, i.e. how to carry out the task, is usually described in other parts of the ICA (e.g. in the AMM or NDT manual). However, the feasibility study of the accomplishment procedure is required for compliance with specific requirements (e.g. CS 25.611).

(A) This may typically apply when the aircraft structural full-scale fatigue testing required for compliance with the fatigue- and damage-tolerance requirements, considering the expected operational life, will not be completed prior to the type certificate being issued. In this case, a temporary operational limitation is assigned and stated in the ALS, dependent on the aircraft full-scale fatigue testing progress. The ALS is effectively incomplete beyond this temporary operational limitation, as the required justification and the resulting ICA are not yet available to support the safe operation of the aircraft beyond this limitation.

(B) A TCDS notation is not necessary, since the product is provided with complete ALS content up to the established temporary operational limitation.

(ii) A compliance plan identifying those parts of the ICA that are only to be made available at entry into service is produced, submitted to EASA and agreed between the applicant and EASA prior to the design approval (refer also to (iv) for ICA considered to be necessary at the time of the design approval.

(iii) A commitment is provided to produce, verify and submit (when requested) to EASA the relevant ICA prior to entry into service. This commitment should be provided in a certification document (e.g. the compliance plan) and should also be addressed in a more general manner in a DOA procedure for EU holders/applicants in accordance with points 21.A.239 and 21.A.263. If the respective DOA holder has not previously exercised the practice of delaying the ICA beyond the design approval in order for the DOA to demonstrate this capability in its design assurance system (DAS), the required procedural changes need to be addressed via a significant change to the DAS in accordance with point 21.A.247.

(iv) ICA considered to be necessary at the time of design approval are provided or made available in a format that adequately defines the data. Furthermore, the way the data is presented at the time of the design approval offers the same understanding of the data as in the final published format.

The applicant should agree with the Agency, in a compliance plan, on all ICA necessary at the time of design approval. The Agency investigation may vary from no involvement or evaluating a limited sample of the ICA to performing a thorough review of specific parts of the ICA.

(v) In cases where the AgencyEASA has doubts as to whether the applicant/holder can fulfil the applicable requirements of point 21.A.44 to control and support delaying the ICA beyond the design approval, or TC/RTC, and until entry into service, EASA can decide to assign a condition for entry into service for non-ALS ICA.

As a condition for the entry into service, a note should be included in the type certificate data sheet (TCDS) as a result of these pending issues under the ICA paragraph as follows:

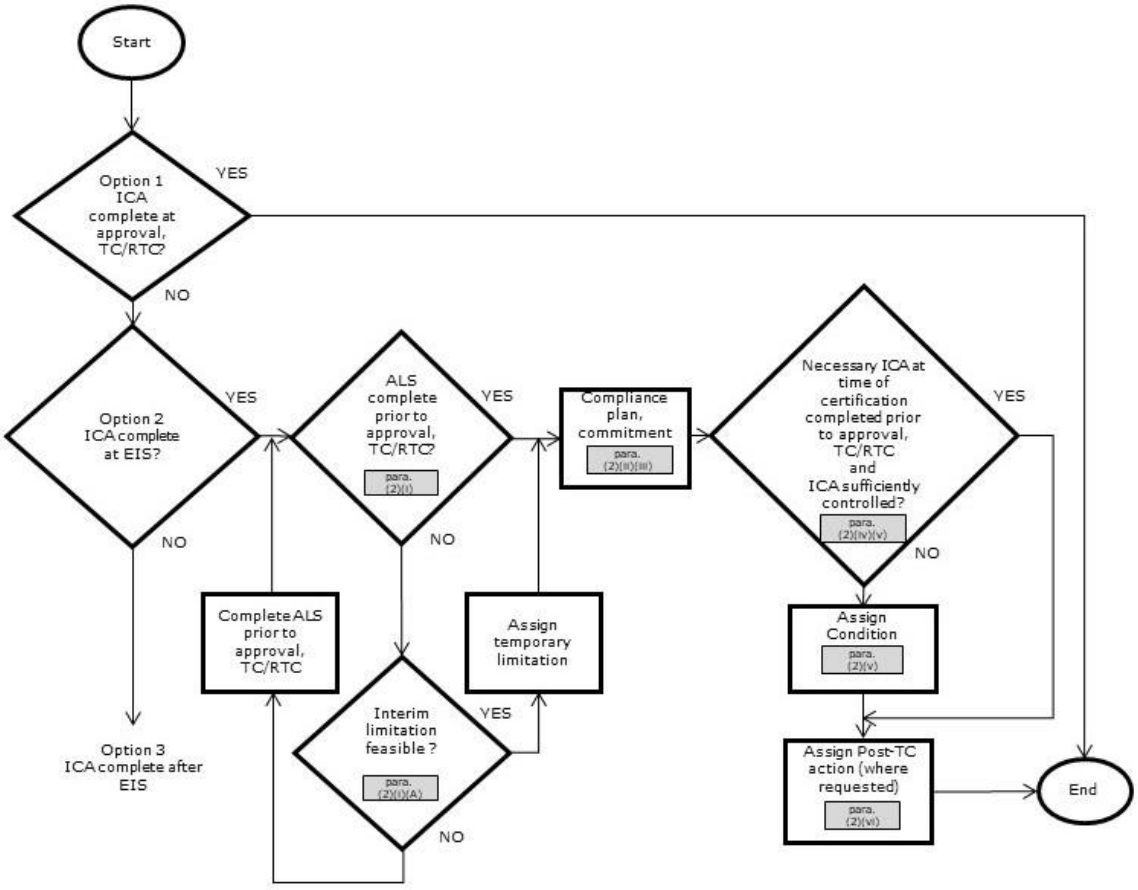
'Note: The ICA are not complete. As per point 21.A.7 of Commission Regulation (EU) No 748/2012, they must be completed before the entry into service of the aircraft. Contact EASA for information on the status.'

The decision to assign a condition may be based on the applicant's performance, e.g. if the applicant has already demonstrated in previous projects that it provided the complete set of ICA before the entry into service, if the applicant has already experienced difficulties in providing the ICA considered necessary at the time of the design approval, or has previously failed on a different project to meet its commitment to complete the ICA prior to entry into service, or if the applicant/holder has no previous experience with the practice of delaying the ICA beyond the design approval.

(vi) Post-TC action is established together with EASA (if EASA requests such a review) to review the ICA status at entry into service.

(vii) If all ICA are made available to EASA at the time of entry into service, they should also be furnished at this time to the aircraft operator / aircraft owner and made available to any other person(s) required to comply with any of those instructions in accordance with points 21.A.21(c)(4), 21.A.44 and 21.A.7, without using the provision to delay certain parts of the ICA beyond the entry into service. For an EU holder/applicant, this should be supported as part of the DOA/ADOA procedure.

Flow chart A — 'Completeness of ICA', Option 1 and 2



(3) Option 3: Complete ICA are available after the entry into service (TC/RTC)

As per point 21.A.7(c), certain ICA dealing with the 'overhaul or other forms of heavy maintenance' may be delayed until after the aircraft entry into service. Although there is no definition of what is meant by 'overhaul or other forms of heavy maintenance', the intention of the rule is to provide flexibility to applicants/holders for long-lead ICA of a scheduled nature.

If an applicant plans to make part of the ICA available only after the entry into service, the following is acceptable for the complete set of ICA:

(i) for the ALS, as it cannot be delayed until after the entry into service, point (i) of Option 2 applies;

(ii) for ICA considered to be necessary at the time of the design approval, point (iv) of Option 2 applies.

(iii) a detailed compliance plan identifying those parts of the ICA that are to be provided prior to and after the entry into service. For ICA made available after the entry into service, the plan should account for when the ICA are needed so that they can be complied with. This approach may only be used for scheduled maintenance accomplishment procedures, where threshold / interval / life-limit requirements of the related scheduled tasks are established. In that respect, the following aspects should be considered:

(A) The majority of the ICA are of an unscheduled nature; therefore, these items should be available at entry into service at the latest.

(B) Consideration should be given to the fact that a number of tasks are used for both scheduled and unscheduled maintenance (e.g. an operational check of a system is planned as a scheduled task at a certain point in time, but is also required as part of the installation procedure to determine the operational status of the system).

(C) For ICA to be made available after entry into service, the detailed plan should contain threshold(s) controlled by the applicant/holder, stating the maximum value in flight hours (FH) / flight cycles (FC) or calendar time (CT), or a combination of them as applicable, by which point in time the delayed ICA should be made available.

(D) This detailed plan should be available prior to the time of the design approval and should be either directly integrated or cross-referenced in a compliance plan.

(E) Information on the format in which the ICA delayed until after entry into service will be made available in time (e.g. regular revisions or temporary revisions (TRs) or service information (SBs, SIL, etc.).

(iv) A procedure/programme that ensures a detailed plan is produced and implemented in the applicant's organisation in order to ensure the timely availability (to the aircraft operator / aircraft owner and to any other person required to comply with any of those instructions and to the Agency, if involved and when requested). For an EU holder/applicant, this should be part of the design organisation approval (DOA) procedure in accordance with points 21.A.239 and 21.A.263.

(v) A commitment is made to produce, verify and provide the relevant ICA in accordance with the detailed plan. This commitment should be provided in a certification document (e.g. a compliance plan) and should also be addressed in a more general manner in a DOA procedure for EU holders/applicants in accordance with points 21.A.239 and 21.A.263. If the respective DOA holder has not previously exercised the practice of delaying the ICA beyond the design approval in order for the DOA to demonstrate this capability in its design assurance system (DAS), the

required procedural changes need to be addressed via a significant change to the DAS in accordance with point 21.A.247.

(vi) In order to ensure that the applicant/holder can meet their obligations as set out in point 21.A.44 to control and support delaying the ICA, EASA may decide:

(A) for ICA delayed until entry into service, to assign a condition/notation for the entry into service to be included in the TCDS as a result of these pending issues under the ICA paragraph, as per point (v) of Option 2;

(B) for ICA delayed until after entry into service, to assign an interim limitation to be published and included in the ALS as a temporary operational limitation, also for non-ALS ICA, to compensate for the delayed ICA; this approach may only be used for scheduled maintenance accomplishment procedures, where task and interval requirements are available.

The decision to assign a condition/limitation may be based on the applicant's performance, e.g. if the applicant has already demonstrated in previous projects that it provided the complete set of ICA before the entry into service, if the applicant had already difficulties in providing the ICA considered necessary at the time of the design approval, or has failed before in a different project to control and support delaying the ICA, or if the applicant/holder has not previously exercised the practice of delaying the ICA beyond the design approval.

(vii) Post-TC action should be established with EASA to regularly review the ICA status, if EASA requests such a review, taking into account the DOA oversight activities.

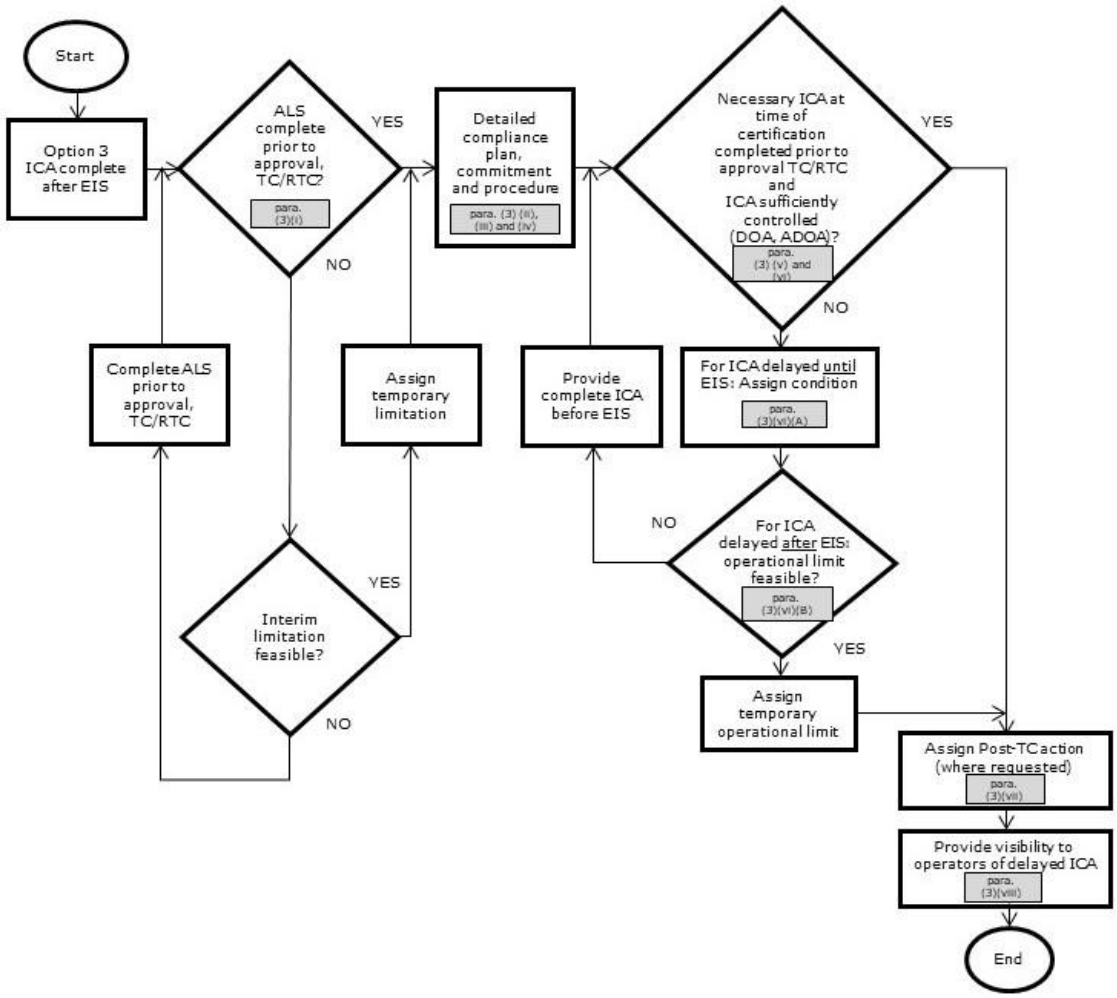
(viii) An applicant/holder should provide visibility, regarding the ICA that are delayed beyond entry into service, to the aircraft operator / aircraft owner and to any other person(s) required to comply with any of those instructions. This can be achieved by providing this information, for example, on a website or in a document, such as an MPD or AMM, preferably in the principal ICA manual. This visibility information is then itself considered to be ICA information.

(ix) It is assumed that for those ICA that are made available to EASA at the time of entry into service, they are also at the same time furnished to the aircraft operator / aircraft owner and made available to any other person(s) required to comply with any of those instructions in accordance with points 21.A.21(c)(4), 21.A.44 and 21.A.7.

This is to satisfy EASA that such a delayed publication will not have an adverse effect on the continuing airworthiness of any individual aircraft.

To allow the timely review and incorporation of a delayed part of the ICA into continuing airworthiness activities and processes (e.g. amendment of the aircraft Maintenance Programme) by the person or organisation responsible for the aircraft continuing airworthiness or for performing maintenance, the Agency considers that the delayed ICA should typically be made available two years before the actual ICA has to be used, when using normal revisions as a format. However, shorter time margins may be acceptable, provided that the format used ensures the prompt notification of the availability of the delayed ICA or the ICA itself, but they should not be less than 1 year before the ICA has to be used.

Flow chart B — 'Completeness of ICA', Option 3



(b) Completeness and timely availability of changes to the ICA (TC/RTC)

Point 21.A.7(d) regulates the distribution of changes to the ICA required from the TC/RTC holder. Those changes to the ICA could result from the design change process (minor and major changes), in-service experience, corrections, and others.

For an EU TC/RTC holder/applicant, a programme showing how changes to the ICA are distributed is part of the respective procedures (e.g. design organisation procedures, or alternative procedures used to demonstrate capabilities). For changes to the ICA triggered by design changes, typically these procedures follow the same principles as those available for TC/RTC, Options 1 to 3, while taking into account the relevant privileges, e.g. that a DOA may approve minor changes in accordance with point 21.A.263(c)(2).

21.A.9 Access and investigation

Regulation (EU) 2022/201

Any natural or legal person that holds or has applied for a type-certificate, restricted type-certificate, supplemental type-certificate, ETSO authorisation, design change or repair approval, certificate of airworthiness, noise certificate, permit to fly, design organisation approval, production organisation approval certificate or letter of agreement under this Regulation, shall:

(a) grant the competent authority access to any facility, product, part and appliance, document, record, data, process, procedure or to any other material in order to review any report, make any inspection, or perform or witness any flight and ground test, as necessary, in order to verify the initial and continued compliance of the organisation with the applicable requirements of Regulation (EU) 2018/1139 and its delegated and implementing acts;

(b) make arrangements to ensure the competent authority has access, as provided for in point (a), also in respect of the natural or legal person's partners, suppliers and subcontractors.

[applicable from 7 March 2023 — Regulation (EU) 2022/201]

SUBPART B — TYPE-CERTIFICATES AND RESTRICTED TYPE-CERTIFICATES

21.A.11 Scope

Regulation (EU) No 748/2012

This Subpart establishes the procedure for issuing type-certificates for products and restricted type-certificates for aircraft, and establishes the rights and obligations of the applicants for, and holders of, those certificates.

21.A.13 Eligibility

Regulation (EU) No 748/2012

Any natural or legal person that has demonstrated, or is in the process of demonstrating, its capability in accordance with point 21.A.14 shall be eligible as an applicant for a type-certificate or a restricted type-certificate under the conditions laid down in this Subpart.

21.A.14 Demonstration of capability

Regulation (EU) 2019/897

(a) An applicant for a type-certificate or restricted type-certificate shall demonstrate its capability by holding a design organisation approval, issued by the Agency in accordance with Subpart J.

(b) By way of derogation from point (a), as an alternative procedure to demonstrate its capability, an applicant may seek the agreement of the Agency for the use of procedures setting out the specific design practices, resources and sequence of activities necessary to comply with this Annex I (Part 21), when the product is one of the following:

1. an ELA2 aircraft;
2. an engine or propeller installed in ELA2 aircraft;
3. a piston engine;
4. a fixed or adjustable pitch propeller.

(c) By way of derogation from point (a), an applicant may demonstrate its capability by obtaining the Agency's acceptance of its certification programme established in accordance with point 21.A.15(b), where the product to be certified is:

1. an ELA1 aircraft; or
2. an engine or propeller installed in ELA1 aircraft.

AMC to 21.A.143, 21.A.243, 21.A.14(b), 21.A.112B(b) and 21.A.432B(b) Flight Test Operations Manual (FTOM)

ED Decision 2017/024/R

1. General

   a. Scope: The FTOM covers flight test operations.

   The FTOM complexity should be proportionate to the aircraft and the organisation complexity.

   b. Format

   The FTOM may:

   — be included in the Design Organisation Approval (DOA)/Production Organisation Approval (POA)/Alternative Procedure to DOA (APDOA) documents, or

   — be a separate manual.

   The FTOM may make reference to other documents to cover the contents listed below, e.g. for record-keeping.

   c. Use by contractors or sub-contractors:

   When flight tests are performed by contractors or sub-contractors, they should comply with the FTOM of the primary organisations, unless they have established an FTOM in compliance with Part-21, the use of which has been agreed between the two organisations.

2. The FTOM should contain the following elements:

   a. Exposition (not applicable in the case of APDOA):

   If the FTOM is presented as a separate document, it should include a chart indicating the structure of the organisation and, more specifically, the functional links of the people in charge of flight test activities. It should also mention the coordination between all departments affecting flight test, e.g. Design Office, Production and Maintenance, in particular coordination for the establishment and update of a Flight Test Programme.

   b. Risk and safety management:

   The FTOM should describe the organisation's policy in relation to risk and safety assessment, mitigation and associated methodologies.

   c. Crew members:

   According to the flight test category, the FTOM should describe the organisation's policy on the composition of the crew (including the need to use a Lead Flight Test Engineer (LFTE)) and the competence and currency of its flight test crew members, including procedures for appointing crew members for each specific flight.

   All crew members should be listed in the FTOM.

   A flight time limitation policy should be established.

   d. Carriage of persons other than crew members:

   According to the flight test category, the FTOM should describe the organisation's policy in relation to the presence and safety on-board, of people other than crew members (i.e. with no flying duties).

People other than crew members should not be allowed on board for Category 1 flight tests.

e. Instruments and equipment:

The FTOM should list, depending on the nature of the flight, the specific safety-related instruments and equipment that should be available on the aircraft or carried by people on board.

The FTOM should contain provisions to allow flights to take place in case of defective or missing instruments or equipment.

f. Documents:

The FTOM should list the documents to be produced for flight test, and include (or refer to) the procedures for their issue, update and follow-up to ensure the documents' configuration control:

(i) documents associated with a Flight Test Programme:

— Flight Order for a given flight, which should include:

— a list of the tests to be performed and associated conditions;

— safety considerations relevant to the flight;

— category of the flight (e.g. Category 1);

— composition of the crew;

— names of persons other than crew members;

— aircraft configuration items relevant to the test to be highlighted to the crew;

— loading of the aircraft;

— reference to approved flight conditions; and

— restrictions relevant to the flight to be highlighted to the crew.

— Flight crew report.

(ii) documentation and information to be carried on the aircraft during flight test;

(iii) record-keeping: the FTOM should describe the policy relative to record-keeping.

g. Permit to fly:

The FTOM should describe the involvement of the flight test organisation or flight test team (as appropriate) in the process for the approval of flight conditions and the issue of permits to fly in accordance with Subpart P.

h. Currency and training:

The FTOM should describe how training for flight test is organised.

Currency of the flight test crew may be ensured either through recent experience or refresher training.

For aircraft for which Appendix XII is applicable, minimum flight experience by year should be:

— for pilots: 50 hours. In addition:

  — for pilots with a flight test rating, the 50 hours should include 20 flight test hours in any flight test category.

  — for pilots performing a Category 3 flight test, the flight test experience should be expressed in terms of a number of flights leading to the issue of a Certificate of Airworthiness (CofA) (e.g. first flights).

  — for pilots performing a Category 4 flight test, the minimum flight test experience should be proportionate to the activity envisaged.

— for LFTEs: 10 flight test hours in any flight test category.

The FTOM should specify the requirements for a refresher training in order to ensure that crew members are sufficiently current to perform the required flight test activity.

A system should be established to record the currency of the flight test crew's training.

A valid national document (i.e. licence), issued by an EASA Member State under its national regulations and ensuring compliance with the agreed currency requirements, is an acceptable means of compliance to demonstrate currency for a pilot that holds a flight test rating and for an LFTE.

AMC1 21.A.14(b) Demonstration of capability

ED Decision 2021/001/R

ALTERNATIVE PROCEDURES FOR THE DEMONSTRATION OF DESIGN CAPABILITY

The availability of procedures that state the specific design practices, resources and sequence of activities is an acceptable means to demonstrate design capability in the cases described in points 21.A.14(b), 21.A.112B(b) or 21.A.432B(b). This concept is that the implementation, in the context of specific projects, of the procedures required for a Subpart J DOA, will ensure that the applicant performs the relevant activities, but without the requirements on the organisation itself. The setting up of those procedures may be seen as a starting phase for a design organization to develop into a Subpart J DOA by the addition of the missing elements.

1. Scope

  1.1 A manual of procedures should be provided that sets out the specific design practices, resources and the sequence of activities that are relevant for the specific projects, taking the Part 21 requirements into account.

  1.2 These procedures should be concise and limited to the information that is needed for the quality and proper control of activities by the applicant/holder, and by EASA.

2. Management of the (supplemental) type-certification process

  2.1 Certification programme: see AMC 21.A.15(b) for type certification and AMC 21.A.93(b) for supplemental type certification.

  2.2 Compliance demonstration: see GM 21.A.20.

  2.3 Reporting: see GM 21.A.20(b).

  2.4 Compliance documentation: see AMC 21.A.20(c).

2.5 Declaration of compliance: see GM 21.A.20(d).

3. Management of changes to type certificates, repair designs and production deviations

3.1 Management of changes to a type certificate or supplemental type certificate (hereinafter referred to as 'changes'), repair designs and production deviations from the approved design data.

The applicant should provide procedures that are acceptable to EASA for the classification and approval of changes (see paragraphs 3.2 and 3.3), repair designs and production deviations from the approved design data.

3.2 Classification

3.2.1 *Content*

The procedure should address the following points:

— the identification of the product configuration(s) to which the change is to be made,

— the identification of the areas of the product that are changed or affected by the change,

— the identification of any reinvestigations that are necessary (see point 21.A.93(b)(2)), including the identification of the applicable certification specifications or environmental protection requirements and means of compliance,

— changes initiated by subcontractors,

— documents to justify the classification,

— authorised signatories,

— the criteria used for classification must be in compliance with 21.A.91 and the corresponding interpretations.

3.2.2 *Identification of changes*

The procedure should indicate how the following are identified:

— major changes,

— those minor changes where additional work is necessary to demonstrate compliance with the certification specifications,

— other minor changes that require no further demonstration of compliance.

3.2.3 *Considerations of effects of the change*

The procedure should show how the effects on airworthiness, operational suitability or environmental protection are analysed, from the very beginning, by reference to the applicable certification specifications.

If no specific certification specifications are applicable to the change, the above review should be carried out at the level of the part or system where the change is integrated and where specific certification specifications are applicable.

3.2.4 *Control of changes initiated by subcontractors*

The procedure should indicate, directly or by cross reference to written procedures, how changes initiated by subcontractors are controlled.

3.2.5 Documents to justify the classification

All decisions of classification of changes should be documented and approved by EASA. The document may be in the format of meeting notes or a register.

3.2.6 *Authorised signatories*

The procedure should identify the persons authorised to sign the proposed classification before release to EASA for approval.

3.3 Approval of changes

3.3.1 *Content*

The procedure should address the following points:

— compliance documentation,

— the internal approval process,

— authorised signatories.

3.3.2 *Compliance documentation*

For major changes and those minor changes where additional work to demonstrate compliance with the applicable type-certification basis, operational suitability data certification basis, and environmental protection requirements (hereinafter referred to as the 'certification basis') is necessary, compliance documentation should be established in accordance with AMC 21.A.20(c).

3.3.3 *Approval process*

A) For the approval of major changes, a certification programme as defined in AMC 21.A.93(b) must be established.

B) For major changes and those minor changes where additional work to demonstrate compliance with the applicable certification basis is necessary, the procedure should define a document to support the approval process.

This document should include at least:

— identification and a brief description of the change and its classification,

— references to the applicable certification basis,

— reference to the compliance documents,

— effects, if any, on limitations and on the approved design data,

— the name of the authorised signatory.

C) For the other minor changes, the procedure should define a means:

— to identify the change,

— to present the change to EASA for approval.

3.3.4 *Authorised signatories*

The procedure should identify the persons authorised to sign the change before release to EASA for approval.

3.4 Repair designs and production deviations from the approved design data

A procedure following the principles of paragraphs 3.2 and 3.3 should be established for the classification and approval of repair designs and unintentional deviations from the approved design data occurring in production (concessions or non-conformances). For repair designs, the procedure should be established in accordance with Part 21, Section A, Subpart M and the associated acceptable means of compliance (AMC) or guidance material (GM).

4. Issue of data and information (including instructions) to owners, operators or others required to use the data and information

4.1 General

Data and information include the operational suitability data.

4.2 Data related to changes

The data and information (including instructions) issued by the holder of a design approval (a TC, STC, approval of a change, approval of a repair design) are intended to provide the owners of a product with all the necessary data and information to embody a change or a repair on the product, or to inspect it.

The data and information (including instructions) may be issued in a format of a service bulletin as defined in ATA 100 system, or in structural repair manuals, maintenance manuals, engine and propeller manuals, etc.

The preparation of this data involves design, production and inspection. The three aspects should be properly addressed and a procedure should exist.

4.3 Procedure

The procedure should address the following points:

— Preparation;

— verification of technical consistency with corresponding approved change(s), repair design(s) or approved data, including effectivity, description, effects on airworthiness or operational suitability, especially when limitations are changed;

— verification of the feasibility in practical applications; and

— approval for the release of data and information.

The procedure should include the information (including instructions) prepared by subcontractors or vendors, and declared applicable to its products by the holder of the TC, STC, approval of changes or approval of repair designs.

4.4 Statement

The data and information should include a statement:

— confirming that the documentation has been produced by the design approval holder in accordance with the associated procedures accepted by EASA; and

— containing a reference to EASA approvals of related changes or repairs, when applicable[1].

5. Obligations addressed in 21.A.44 (TC holder), 21.A.118A (STC holder) or 21.A.451 (major repair design approval holder)

The applicant for alternative procedures to demonstrate their design capabilities should establish the necessary procedures to show to EASA how it will fulfil the obligations that are required under 21.A.44, 21.A.118A or 21.A.451, as appropriate.

6. Control of design subcontractors

The applicant for alternative procedures to demonstrate their design capabilities should establish the necessary procedures to show to EASA how it will control design subcontractors and ensure the acceptability of the parts or appliances that are designed, or the design tasks that are performed.

GM 21.A.14(b) Eligibility for alternative procedures

ED Decision 2012/020/R

Design organisations approved under Part 21 Section A Subpart J ('Subpart J DOA') should be the normal approach for type certification, supplemental type certification, approval of major changes to type design or approval of major repair design, except when agreed otherwise by the Agency in accordance with 21.A.14, 21.A.112B and 21.A.432B.

The acceptance of alternative procedures, as defined in AMC 21.A.14(b), should be limited where the Agency finds it more appropriate for the conduct of type certification, supplemental type certification, approval of changes to type design, approval of repair design.

21.A.15 Application

Regulation (EU) 2021/699

(a) An application for a type-certificate or restricted type-certificate shall be made in a form and manner established by the Agency.

(b) An application for a type-certificate or restricted type-certificate shall include, as a minimum, preliminary descriptive data of the product, the intended use of the product and the kind of operations for which certification is requested. In addition, it shall include, or be supplemented after the initial application by, a certification programme for the demonstration of compliance in accordance with point 21.A.20, consisting of:

1. a detailed description of the type design, including all the configurations to be certified;
2. the proposed operating characteristics and limitations;
3. the intended use of the product and the kind of operations for which certification is requested;
4. a proposal for the initial type-certification basis, operational suitability data certification basis and environmental protection requirements, prepared in accordance with the requirements and options specified in points 21.B.80, 21.B.82 and 21.B.85;

[1] EASA does not directly approve information or instructions. These are approved as part of the TC, STC, change approval or repair design approval. When stand-alone changes (i.e. not related to a TC change or repair design) to the issued information or instructions (e.g. to take in-service experience into account) are needed, these should be prepared, verified and approved according to the agreed procedures (see above).

5. a proposal for a breakdown of the certification programme into meaningful groups of compliance demonstration activities and data, including a proposal for the means of compliance and related compliance documents;

6. a proposal for the assessment of the meaningful groups of compliance demonstration activities and data, addressing the likelihood of an unidentified non-compliance with the type-certification basis, operational suitability data certification basis or environmental protection requirements and the potential impact of that non-compliance on product safety or environmental protection. The proposed assessment shall take into account at least the elements set out in subpoints (1) to (4) of point 21.B.100(a). Based on this assessment, the application shall include a proposal for the Agency's involvement in the verification of the compliance demonstration activities and data; and

7. a project schedule including major milestones.

(c) After its initial submission to the Agency, the certification programme shall be updated by the applicant when there are changes to the certification project affecting any of the points 1 to 7 of point (b).

(d) An application for a type-certificate or restricted type-certificate for an aircraft shall include, or be supplemented after the initial application by, an application supplement for approval of the operational suitability data.

(e) An application for a type-certificate or restricted type-certificate for a large aeroplane or a large rotorcraft shall be valid for five years and an application for any other type-certificate or restricted type-certificate shall be valid for three years, unless the applicant demonstrates at the time of application that its product requires a longer time period to demonstrate and declare compliance and the Agency agrees to that longer time period.

(f) In the case where a type-certificate or restricted type-certificate has not been issued, or it is evident that it will not be issued, within the time limit provided for in point (e), the applicant may:

1. submit a new application and comply with the type-certification basis, operational suitability data certification basis and environmental protection requirements, as established and notified by the Agency in accordance with points 21.B.80, 21.B.82 and 21.B.85 for the date of the new application; or

2. apply for an extension of the time period provided for in point (e) and propose a new date for the issuance of the type-certificate or restricted type-certificate. In that case, the applicant shall comply with the type-certification basis, operational suitability data certification basis and environmental protection requirements, as established and notified by the Agency in accordance with points 21.B.80, 21.B.82 and 21.B.85 for a date to be selected by the applicant. However, that date shall not precede the new date proposed by the applicant for the issuance of the type-certificate or restricted type-certificate by more than five years for an application for a type-certificate or restricted type-certificate for a large aeroplane or a large rotorcraft, and by more than three years for an application for any other type-certificate or restricted type certificate.

AMC 21.A.15(a) Form and manner

ED Decision 2019/018/R

The applicant should file an application using the web-based 'EASA Applicant Portal'[1] or the application form for a type certificate or restricted type certificate (FO.CERT.00030)[2], which may be downloaded from the EASA website.

The form should be completed in accordance with the instructions embedded at the bottom of the application form, and sent to EASA by fax, email or regular mail following the information provided on the EASA website[3].

AMC 21.A.15(b) Content of the certification programme

ED Decision 2019/018/R

The certification programme is a document that allows the applicant and EASA to manage and control the evolving product type design or OSD, as well as the process of compliance demonstration by the applicant and its verification by EASA when required.

The certification programme may be based on modules that may be updated independently.

The level of detail in the certification programme depends on the complexity of the product and its intended use.

In particular, the following information should typically be expected:

General

— Identification of the relevant personnel who make decisions affecting airworthiness, operational suitability and environmental protection, and who will interface with EASA, unless otherwise identified to EASA (e.g. within the DOA procedures).

— A project schedule including major milestones.

— Subcontracting arrangements for design, operational suitability, environmental protection and/or production as well as design organisation approval (DOA) responsibility sharing.

21.A.15(b)(1) 'a detailed description of the type design, including all the configurations to be certified'

An overview of the:

— architecture, functions, systems;

— dimensions, design weights, payloads, design speeds;

— engines and power/thrust rating;

— materials and technologies;

— maximum passenger seating capacity, minimum flight and cabin crew;

— cabin configuration aspects;

[1] https://ap.easa.europa.eu (changes to the link provided may not be reflected in this document).

[2] http://www.easa.europa.eu/document-library/application-forms/focert00030 (changes to the link provided may not be reflected in this document).

[3] https://www.easa.europa.eu/document-library/application-forms/certificates-and-approvals (changes to the link provided may not be reflected in this document).

— options (e.g. weight variants, power/thrust rating variants, optional avionics equipment items, auxiliary power unit (APU) choices, brake options, tire options, floats, skids);

— noise/emissions level; and

— other items, if considered to be more appropriate, that address the specific aeronautical product.

21.A.15(b)(2) 'proposed operating characteristics and limitations'

— Operating speed limitations.

— Service ceiling, maximum airfield elevation.

— Cabin pressure.

— Limit load factors.

— Number of passengers, minimum crew, payload, range.

— Weight and centre-of-gravity (CG) envelope and fuel loading.

— Performance.

— Environmental envelope.

— Runway surface conditions.

— Other items, if considered to be more appropriate, that address the specific aeronautical product.

21.A.15(b)(3) 'the intended use of the product and the kind of operations for which certification is requested'

— Category A or B (relevant for CS-27 and CS-29), ditching, take-off and landing on water, emergency floatation equipment.

— Extended overwater operation, high-altitude operation (above 41 000 ft).

— High-airfield operation, steep approach, short take-off and landing, extended-range twin-engine operations (ETOPS), all-weather operations (AWO), visual flight rules (VFR)/instrument flight rules (IFR), reduced vertical separation minimum (RVSM), required navigation performance (RNP) type, increased bank angles, single-pilot operation, flight into known icing conditions.

— Flight in ice crystal icing.

— Engine operations in ice-forming conditions, helicopter hoist operations, operation on unpaved runway, operation on narrow runway.

— Take-off and landing in tailwind.

— Volcanic-ash operation (limitation or operation as per CS 25.1593 and CS-E 1050).

— Design service goal (DSG)/limit of validity targets.

— Fatigue missions (general description of assumptions for flight durations, main phases, and parameters, as appropriate).

— Other items, if considered to be more appropriate, that address the specific aeronautical product.

21.A.15(b)(4) 'a proposal for the initial type-certification basis, operational suitability data certification basis, where applicable, and environmental protection requirements, considering the requirements and options specified in 21.B.80, 21.B.82 and 21.B.85'

The proposed certification basis should include applicable certification specifications, proposed special conditions, proposed equivalent safety findings, as well as a proposed 'elect to comply' and proposed deviations, as applicable.

21.A.15(b)(5) 'a proposal for a breakdown of the certification programme into meaningful groups of compliance demonstration activities and data, hereinafter referred as "compliance demonstration items" (CDIs), including references to their proposed means of compliance and related compliance documents'

See AMC 21.A.15(b)(5) for the determination of the compliance demonstration items (CDIs).

21.A.15(b)(6) on information relevant for the determination of the level of involvement (LoI)

The applicant should provide sufficient detailed information about the novelty, complexity, and criticality aspects of each proposed CDI.

It is recommended to provide this information at the level of each EASA panel or discipline affected by a proposed CDI. Further interpretative material on the necessary level of details is provided in AMC 21.B.100(a) and 21.A.15(b)(6).

The applicant should provide detailed information about the proposed means of compliance with the applicable requirements identified under 21.A.15(b)(4). The information provided should be sufficient for EASA to determine its (initial) LoI. This should include the following, as far as this information is available at the time of submission to EASA:

— a compliance checklist addressing each requirement, the proposed means of compliance (see Appendix A to AMC 21.A.15(b) below for the relevant codes), and the related compliance document(s);

— identification of industry standards (Society of Automotive Engineers (SAE), American Society for Testing and Materials (ASTM), European Organisation for Civil Aviation Equipment (EUROCAE), AeroSpace and Defence Industries Association of Europe (ASD), etc.), methodology documents, handbooks, technical procedures, technical documents and specifications specified in the type certificate data sheet, certification memoranda, policy statements, guidance material, etc., that should be followed in the demonstration of compliance;

— when the compliance demonstration involves testing, a description of the ground and flight test article(s), test method(s), test location(s), test schedule, test house(s), test conditions (e.g. limit load, ultimate load), as well as of the intent/objective(s) of the testing; and

— when the compliance demonstration involves analyses/calculations, a description/identification of the tools (e.g. name and version/release of the software programs) and methods used, the associated assumptions, limitations and/or conditions, as well as of the intended use and purpose; furthermore, the validation and verification of such tools and methods should be addressed.

For every aspect mentioned above, the applicant should clearly identify whether the demonstration of compliance involves any method (analysis or test) which is novel or unusual for the applicant. This should include any deviations from the published AMC to the relevant CS.

Appendix A to AMC 21.A.15(b) Means of compliance codes

ED Decision 2019/018/R

Type of compliance	Means of compliance	Associated compliance documents
Engineering evaluation	MC0: (a) compliance statement (b) reference to design data (c) election of methods, factors, etc. (d) definitions	(a) Design data (b) Recorded statements
	MC1: design review	(c) Descriptions (d) Drawings
	MC2: calculation/analysis	(e) Substantiation reports
	MC3: safety assessment	(f) Safety analysis
Tests	MC4: laboratory tests	(g) Test programmes (h) Test reports (i) Test interpretations
	MC5: ground tests on related product(s)	
	MC6: flight tests	
	MC8: simulation	
Inspection	MC7: design inspection/audit	(j) Inspection or audit reports
Equipment qualification	MC9: equipment qualification	Note: Equipment qualification is a process that may include all previous means of compliance at equipment level.

AMC 21.A.15(b)(5) Breakdown of the certification programme into compliance demonstration items (CDIs)

ED Decision 2019/018/R

1. What is a CDI?

   A CDI is a meaningful group of compliance demonstration activities and data identified in the certification programme which can be considered in isolation for the purpose of performing the risk assessment that allows EASA to determine its level of involvement (LoI) using a risk-based approach.

   The possibility to create this grouping of compliance demonstration activities and data is intended to facilitate the risk assessment. However, there may be cases in which the risk assessment may also be performed at the level of the compliance demonstration activity or data, or at the level of the whole certification project.

   The chosen breakdown into CDIs may affect the resulting risk classes (please refer to AMC 21.B.100(a) and 21.A.15(b)(6)), but should not have any effect on the compliance demonstration itself or on EASA's LoI.

2. The grouping of compliance demonstration activities and data

   The compliance demonstration activities and data grouped in a CDI may demonstrate compliance with a requirement, a group of requirements, or even a part of a requirement. In this context, 'requirement' means any element of the type-certification basis or operational suitability data (OSD) certification basis as specified in 21.B.80 and 21.B.82, or the environmental protection requirements as specified in 21.B.85.

   A CDI may comprise any of the means of compliance listed in Appendix A to AMC 21.A.15(b).

CDIs may be tailored to the scope and size of the project. On simple projects, a CDI may address all the compliance demonstration activities within a given technical area (e.g. avionics, flight, structures, hydromechanical systems, OSD-cabin crew data (CCD), etc.) or of the whole project.

A CDI should not be too large, by combining completely unrelated compliance demonstration activities or data, so that it becomes meaningless, but neither should it be so small that it might not be considered in isolation from some other related compliance demonstration activities or data.

A way of meaningfully grouping compliance demonstration activities and data, for example, is to select some activities and data and group them into a single CDI, as the certification programme must already contain the applicable requirements, the proposed means of compliance for each requirement, as well as the associated compliance documents for each means of compliance.

Another way to meaningfully group the data is to do it at the level of the technically related compliance demonstration activities and data. This may facilitate the assessment of those activities and data against the novelty, complexity, and criticality criteria (see AMC 21.B.100(a) and 21.A.15(b)(6)). The resultant CDI may encompass various means of compliance.

3. Description of CDIs

Each CDI should be sufficiently described in the certification programme, and should detail the following:

— the scope of the CDI; and

— the information on the novelty, complexity, and criticality of the item being certified.

However, in cases where the rationale of the assessment is obvious, it is considered to be sufficient to indicate whether or not a CDI is novel or complex, and whether or not the impact is critical.

Note: Obvious cases are cases for which the classification is straightforward and does not require additional clarifications. In general, applicant explanations/notes regarding the proposed classification should be provided, since this will also facilitate the acceptance of the LOI proposal. Nevertheless, to avoid unnecessary additional effort, these explanations can be omitted if they are obvious.

Additionally, it is recommended to identify the EASA panel(s)/discipline(s) affected by each CDI, as this will support the determination of the novelty, complexity, and criticality, and finally identify the performance of the design organisation approval (DOA) holder.

GM No 1 to 21.A.15(d) Application for the approval of operational suitability data – MMEL for ELA1 and ELA2

ED Decision 2019/018/R

For ELA1 and ELA2, the applicant may develop a list of the required equipment to be included in the TCDS and/or AFM/POH. This list, in combination with the equipment required for the flight by the applicable implementing rules for a given type of operations, establishes the list of equipment that must be operative for all flights. The list of the other installed equipment that may be inoperative constitutes the MMEL.

GM No 2 to 21.A.15(d) Determination of type or variant

ED Decision 2016/007/R

The criteria for the determination whether an aircraft with a new type certificate (TC) is considered a new type or is a variant with reference to another aircraft type from the same TC holder for the purpose of the specific OSD constituent are provided in the applicable certification specifications for maintenance certifying staff data, flight crew data and cabin crew data.

GM No 3 to 21.A.15(d) OSD content

ED Decision 2016/007/R

The OSD will typically consist of elements that are required to be included by the TC applicant and elements that can be added at the request of the TC applicant. (See also GM No 4 to 21.A.15(d)).

Both the required elements and the additional elements will have a part that is mandatory to be used by the operator or training organisation (status of rule) and a part which is not mandatory to the operator or training organisation (status of AMC). For illustration of this concept, Figure 1 below is included.

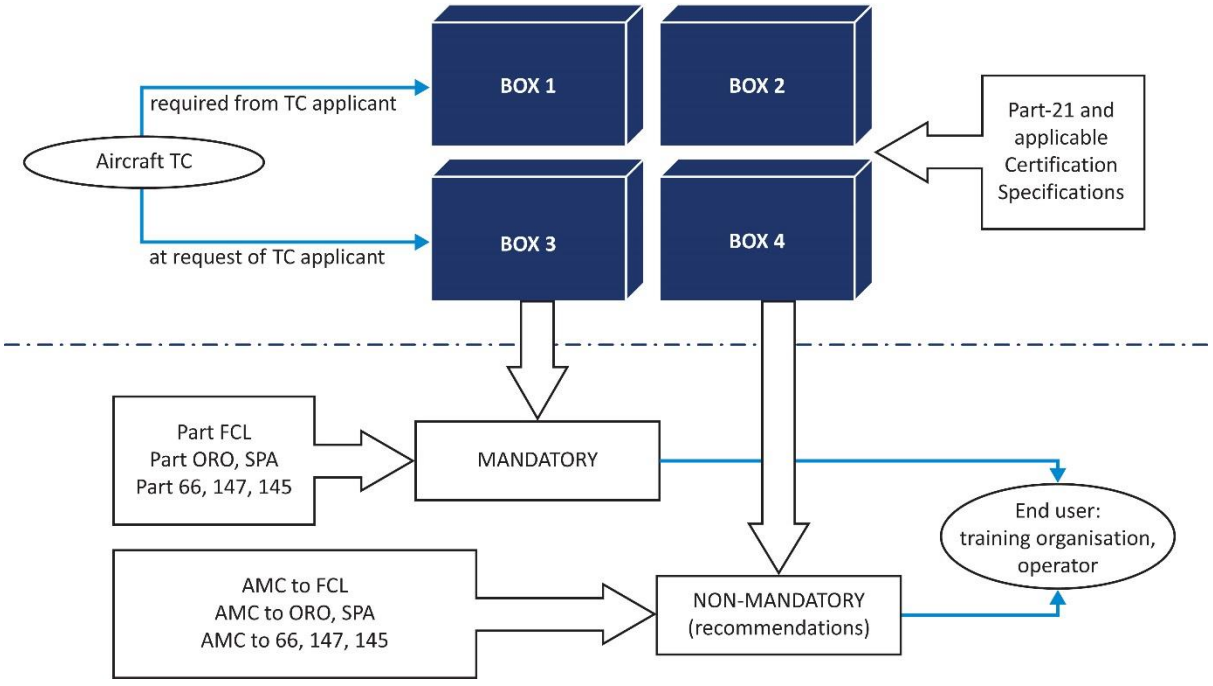


Figure 1: OSD boxes concept

Box 1: required from TC holder; mandatory for end-users.

Box 2: required from TC holder; not mandatory (recommendations) for end-users.

Box 3: at request of TC holder; mandatory for end-users.

The TC applicant may wish to apply for the approval of differences training between variants or types to reduce training, checking or currency requirements for operations of more than one type or variant. This is regarded as an optional element in addition to the required elements of Box 1 and 2.

Box 4: at request of TC holder; not mandatory (recommendations) for end-users.

The exact content of the four boxes in the above figure is determined by the certification specification that is applicable to the specific OSD constituent or the special condition in case of an 'other type-related operational suitability element'.

The status the data will have on the side of the operator or training organisation should be indicated in the OSD by segregating the data in a section called 'Mandatory' and a section called 'Non-mandatory (recommendations)'.

GM4 21.A.15(d) Application

ED Decision 2021/001/R

SCOPE OF OPERATIONAL SUITABILITY DATA

In the application for the approval of operational suitability data, the TC applicant may apply for the approval of different types of operations. If the aircraft is certified for certain types of operations (e.g. ETOPS, RNP, LVO), the impact on the OSD constituents of 21.A.15(d) should be addressed.

The five defined OSD constituents are listed in paragraph (2)(k) of Article 1 of Regulation (EU) No 748/2012. As explained in GM No 1 to 21.A.15(d), they may not all be applicable to all aircraft types. The content of each OSD constituent is defined in the relevant certification specification (CS) and will be approved under a type certificate (TC), supplemental type certificate (STC) or change to those certificates. As explained in GM No 3 to 21.A.15(d), each OSD constituent can have a part that is mandatory for the end user (operator, training organisation, etc.) and a part that is not mandatory (recommendation) for the end user. However, both the mandatory and the non-mandatory part together are the OSD constituent. Furthermore, the OSD constituent always includes the element required from the TC/STC applicant, as specified in the CS, and may include additional elements at the request of the TC/STC applicant, but still as defined in the CS.

GM 21.A.15(c) Updates to the certification programme

ED Decision 2019/018/R

Point 21.A.15(b) recognises that the initial submission of the certification programme may not be fully complete, e.g. due to schedule constraints of the design, analysis and testing activities.

Furthermore, even if the initial submission of the certification programme is complete, it may be necessary to amend it throughout the duration of the project.

The certification programme should be updated and resubmitted to EASA. In particular, updates to the following elements should be provided:

— any complementary information that was not included in the initial submission of the certification programme;

— any change in the intended use or kind of operations of the product itself, or of the aircraft on which the product is installed;

— a change in the key characteristics of the product such as but not limited to any declared limits that are intended to be recorded in the type certificate data sheet (TCDS);

— any change in the product design or its characteristics that may affect the criteria used to assess the likelihood of an unidentified non-compliance with the type-certification basis, operational suitability data (OSD) certification basis or the environmental protection requirements, including the potential impact of that non-compliance on product safety or environmental protection, as defined in 21.A.15(b)(6) and 21.B.100(a)(1) to (4);

Note: An update of the DOA dashboard after the first issuance of the certification programme only needs to be considered if there is a significant change in the performance.

— any change to the initial type-certification basis, OSD certification basis or environmental protection requirements, as applicable to the product, regardless whether the change is initiated by EASA or by the applicant;

— any change in the breakdown of the certification programme into compliance demonstration items (CDIs) or in the content of those CDIs;

— any change in the proposed means of compliance, including its/their methodology;

— any change in the structure of compliance documents that may affect the determination of EASA's level of involvement (LoI), as defined in 21.B.100;

— any relevant change to the design organisation approval (DOA) holder's personnel (and design organisation (DO) suppliers) who are involved in the project; and

— any changes to the schedule that impact on the EASA LoI.

Following each update to the certification programme as submitted by the applicant, EASA may update the determination of its LoI in accordance with 21.B.100(c).

GM 21.A.15(e) and (f) Period of validity for the application for a type certificate (TC) or restricted type certificate (RTC)

ED Decision 2019/018/R

Point 21.A.15(e) establishes a maximum period of validity for an application for a TC or an RTC. During this period, the type-certification basis, operational suitability data (OSD) certification basis, and the environmental protection requirements (hereinafter referred to as the 'certification basis'), established and notified by EASA in accordance with points 21.B.80, 21.B.82 and 21.B.85, remain effective. However, the period of validity of the certification basis is limited so that the standards notified as part of the certification basis at the time of application do not become outdated.

For various reasons (e.g. development, business, commercial, etc.), the applicant may not be able to complete the certification within the established time limit. In this case, the applicant has the following two options (see 21.A.15(f)(1) and (2)):

1. Submit a new application In this case, EASA establishes and notifies a new certification basis in accordance with points 21.B.80, 21.B.82 and 21.B.85, considering the standards that are available at the date of the new application.

   In accordance with point 21.A.15(e), the new application has a maximum period of validity that is equal to the first one, corresponding to the product category. Beyond this period of validity, the applicant may need to choose again between the two options of either submitting a new application or applying for an extension of the initial application.

2. Apply for an extension of the initial application

   In this case, the applicant proposes a 'new target date' to EASA for the issuance of the certificate, and selects a date that becomes the reference date for the establishment of the certification basis by EASA. For the purposes of this GM, the selected reference date is referred to as the 'new effectivity date' of the initial application.

   The 'new effectivity date' of the initial application may be any date in the past between the following time limits:

   — the 'new target date' for a TC proposed by the applicant minus the time limit used under 21.A.15(e) (e.g. 5 years for large aeroplanes and large rotorcraft, 3 years for the other products); and

— the date on which the applicant applies for the extension of the initial application.

This calculation is visualised in Figure 1 below:

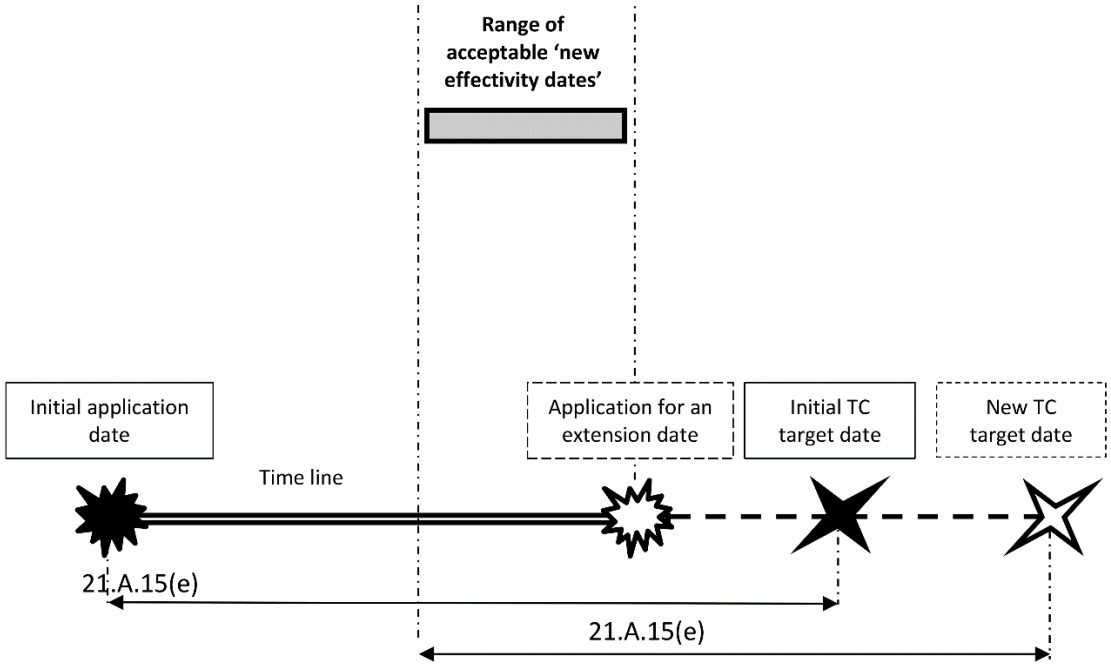


Figure 1

This ensures that the standards used to establish the certification basis are never older than the ones available at the start of the period of validity required by point 21.A.15(e).

If the applicant is not able to complete the product certification by the new target date, the applicant may choose again between the two options of either submitting a new application or applying for a new extension of the initial application.

21.A.19 Changes requiring a new type-certificate

Regulation (EU) No 748/2012

Any natural or legal person proposing to change a product shall apply for a new type-certificate if the Agency finds that the change in design, power, thrust, or mass is so extensive that a substantially complete investigation of compliance with the applicable type-certification basis is required.

21.A.20 Demonstration of compliance with the type certification basis, operational suitability data certification basis and environmental protection requirements

Regulation (EU) 2019/897

(a) Following the acceptance of the certification programme by the Agency, the applicant shall demonstrate compliance with the type certification basis, operational suitability data certification basis and environmental protection requirements, as established and notified to the applicant by the Agency in accordance with points 21.B.80, 21.B.82, 21.B.85, and shall provide the Agency with the means by which such compliance has been demonstrated.

(b) The applicant shall report to the Agency any difficulty or event encountered during the process of demonstration of compliance that may have an appreciable effect on the risk assessment under point 21.A.15(b)(6) or on the certification programme, or may otherwise necessitate a change to the level of involvement of the Agency previously notified to the applicant in accordance with point 21.B.100(c).

(c) The applicant shall record justifications of compliance within the compliance documents as referred to in the certification programme.

(d) After completion of all demonstrations of compliance in accordance with the certification programme, including any inspections and tests in accordance with point 21.A.33, and after all flight tests in accordance with point 21.A.35, the applicant shall declare that:

1. it has demonstrated compliance with the type-certification basis, operational suitability data certification basis and environmental protection requirements, as established and notified by the Agency, following the certification programme as accepted by the Agency; and

2. no feature or characteristic has been identified that may make the product unsafe for the uses for which certification is requested.

(e) The applicant shall submit to the Agency the declaration of compliance provided for in point (d). Where the applicant holds an appropriate design organisation approval, the declaration of compliance shall be made in accordance with Subpart J and submitted to the Agency.

GM 21.A.20 Compliance demonstration process

ED Decision 2019/018/R

Point 21.A.20 applies to the compliance demonstration process for a type certificate (TC) (or a restricted type certificate (RTC)) and, by cross references to Part 21 Subpart D and E, to compliance demonstration processes for major changes to a TC (see point 21.A.97(b)(3)) and an STC (see point 21.A.115(b)(4)).

Applicants for a TC (or an RTC) should apply point 21.A.20 in full. Applicants for a major change to a TC (or an STC) are required (see points 21.A.97(b)(3) and 21.A.115(b)(4)) to apply point 21.A.20 as applicable to the change.

'As applicable to the change' means that:

— the certification programme to be followed is the one prepared for the major change or STC in accordance with point 21.A.93, as accepted by EASA; and

— the certification basis (consisting of the type-certification basis, operational suitability data (OSD) certification basis, and the environmental protection requirements) is the one established by EASA

in accordance with point 21.A.101 and notified to the applicant in accordance with point 21.B.105 (for a major change to a TC) or point 21.B.109 (for an STC).

Point 21.A.20 also applies to major changes to a TC or an STC approved by design organisation approval (DOA) holders under their privilege as per point 21.A.263(c)(8) or (9) (see also points 21.A.97(b)(3) and 21.A.115(b)(4)). As in this case there is no application and no EASA involvement, point 21.A.20 should be applied with the following adaptions:

— the certification programme to be followed, including the certification basis and the detailed means of compliance, should be almost identical to the one accepted by EASA for a major change or an STC when approved for the scope of the privilege as per point 21.A.263(c)(8) or (9); it may differ in some aspects (e.g. the detailed description of the changes), but it should be shown to remain in the frame of the corresponding justification document; and

— the means by which such compliance has been demonstrated (see point 21.A.20(a)) and the final declaration of compliance (see point 21.A.20(e)) should be kept on record and submitted to EASA only if EASA requests them during its DOA continued surveillance process.

GM 21.A.20(b) Reporting on the compliance demonstration process

ED Decision 2019/018/R

The applicant should report to EASA any unexpected difficulty or event encountered during the compliance demonstration that invalidates or appreciably affects the assumptions previously made, for example:

— an increase in the severity of the consequences of a certain condition (e.g. failure mode) of the product;

— significantly reduced margin(s) for the 'pass–fail' criteria of the compliance demonstration;

— changes to the test sequences and conditions that are not in line with the certification specifications or guidance;

— an unusual interpretation of the results of the compliance demonstration; and

— any significant failure or finding resulting from the tests performed as per points 21.A.33 or 21.A.35.

The applicant should also evaluate whether the unexpected difficulty or event encountered will impact on the certification programme and, if necessary, amend it as per point 21.A.15(c).

AMC 21.A.20(c) Compliance documentation

ED Decision 2019/018/R

1. Compliance documentation comprises one or more test or inspection programmes/plans, reports, drawings, design data, specifications, calculations, analyses, etc., and provides a record of the means by which compliance with the applicable type-certification basis, the operational suitability certification basis and environmental protection requirements is demonstrated.

2. Each compliance document should normally contain:

    — the reference of the certification specifications, special conditions or environmental protection requirements addressed by the document;

    — substantiation data demonstrating compliance (except test or inspection programmes/plans);

— a statement by the applicant declaring that the document provides the proof of compliance for which it has been created; and

— the appropriate authorised signature.

3. Each compliance document should be unequivocally identified by its reference and issue date. The various issues of a document should be controlled and comply with point 21.A.55.

GM 21.A.20(d) Final statement

ED Decision 2019/018/R

All compliance demonstrations in accordance with the certification programme, including all the inspections and tests in accordance with point 21.A.33 and all flight tests in accordance with point 21.A.35, should be completed before the issuance of the final statement of compliance required by point 21.A.20(d).

If so agreed by EASA, some compliance documentation may be produced after the issuance of the final statement of compliance required by 21.A.20(d).

'No feature or characteristics' in point 21.A.20(d)2 means the following: while every effort is made to address in the applicable certification basis all the risks to product safety or to the environment that may be caused by the product, experience shows that safety-related events may occur with products in service, even though compliance with the certification basis is fully demonstrated. One of the reasons may be that some existing risks are not properly addressed in the certification basis. Therefore, the applicant has to declare that they have not identified any such features or characteristics.

Point 21.A.20 also applies by reference to minor changes, in which case the risk to product safety or to environmental protection is quite low. Nevertheless, minor changes should not be approved if either the applicant/design organisation approval (DOA) holder approving minor changes under their privileges, or EASA, is aware of a feature or characteristic that may make the product unsafe for the uses for which certification is requested.

21.A.21 Requirements for the issuance of a type certificate or restricted type certificate

Regulation (EU) 2019/897

(a) In order to be issued a product type certificate or, when the aircraft does not meet the essential requirements of Annex II to Regulation (EU) 2018/1139 an aircraft restricted type certificate, the applicant shall:

1. demonstrate its capability in accordance with point 21.A.14;

2. comply with point 21.A.20;

3. demonstrate that the engine and propeller, if installed in the aircraft:

(A) have a type-certificate issued or determined in accordance with this Regulation; or

(B) have been demonstrated to be in compliance with the aircraft type-certification basis established and the environmental protection requirements designated and notified by the Agency as necessary to ensure the safe flight of the aircraft.

(b) By derogation from point (a)(2), at the applicant's request included in the declaration referred to in point 21.A.20(d), the applicant is entitled to have the aircraft type-certificate or restricted type-certificate issued before the applicant has demonstrated compliance with the operational suitability data certification basis, provided that the applicant demonstrates such compliance before the date at which those data are to be actually used.

GM 21.A.21(a)(3)(i) Clarification of the term 'determined'

ED Decision 2021/011/R

A type certificate 'determined' in accordance with Part 21 means a type certificate, or a document that allows the issuance of a certificate of airworthiness, issued before 28 September 2003 by a Member State complying with Article 3(1)(a) of Regulation (EU) No 748/2012.

GM 21.A.21(b), 21.A.95(c), 21.A.97(c), 21.A.115(c), 21.B.103(b), 21.B.107(b) and 21.B.111(b) Approval of operational suitability data (OSD)

ED Decision 2019/018/R

It is acknowledged that it may not always be possible to have the OSD available on the date of the issue of the (restricted) type certificate ((R)TC), change approval or supplemental type certificate (STC). The derogation provided by 21.A.21(b), 21.A.95(c), 21.A.97(c), 21.A.115(c), 21.B.103(b), 21.B.107(b) and 21.B.111(b) is intended for that case. The (R)TC, change approval or STC can be issued before compliance with the OSD certification basis has been demonstrated.

However, the OSD needs to be approved before the data is used by a training organisation for the purpose of obtaining a European Union (EU) licence, rating or attestation, or by an EU operator. This is normally done before the entry into service of the first aircraft by an EU operator but it could also be done later for some of the OSD constituents, such as the definition of the scope of validation source data to support the objective qualification of a simulator, which should only be available when a simulator has to be qualified.

The derogation provided in points 21.A.97(c), 21.A.115(c), 21.B.103(b), 21.B.107(b), and 21.B.111(b) is applicable to all major changes to a TC, so it is also applicable to minor design changes when triggering a major master minimum equipment list (MMEL) change, as well as to changes in which at least one of the OSD constituent changes is major.

21.A.31 Type design

Regulation (EU) 2019/897

(a) The type design shall consist of:

1. the drawings and specifications, and a listing of those drawings and specifications, necessary to define the configuration and the design features of the product shown to comply with the applicable type-certification basis and environmental protection requirements;
2. information on materials and processes and on methods of manufacture and assembly of the product necessary to ensure the conformity of the product;
3. an approved airworthiness limitations section of the instructions for continued airworthiness as defined by the applicable certification specifications; and

4. any other data allowing by comparison the determination of the airworthiness and, if relevant, the environmental characteristics of later products of the same type.

(b) Each type design shall be adequately identified.

21.A.33 Inspections and tests

Regulation (EU) 2019/897

(a) (Reserved)

(b) Before each test is undertaken during the demonstration of compliance required by point 21.A.20, the applicant shall have verified:

1. for the test specimen, that:

(i) the materials and processes adequately conform to the specifications for the proposed type design;

(ii) the parts of the products adequately conform to the drawings in the proposed type design; and

(iii) the manufacturing processes, construction and assembly adequately conform to those specified in the proposed type design; and

2. for the test and measuring equipment to be used for the test, that those are adequate for the test and appropriately calibrated.

(c) On the basis of the verifications carried out in accordance with point (b), the applicant shall issue a statement of conformity listing any potential non-conformity, together with a justification that this will not affect the test results, and shall allow the Agency to make an inspection it considers necessary to check the validity of that statement.

(d) The applicant shall allow the Agency to:

1. review any data and information related to the demonstration of compliance; and

2. witness or carry out any test or inspection conducted for the purpose of the demonstration of compliance.

(e) For all the tests and inspections witnessed or carried out by the Agency in accordance with point (d)(2):

1. the applicant shall submit to the Agency a statement of conformity provided for in point (c); and

2. no change that affects the validity of the statement of conformity shall be made to the test specimen, or the test and measuring equipment, between the time the statement of conformity provided for in point (c) was issued and the time the test specimen is presented to the Agency for test.

AMC 21.A.33 Inspections and tests

ED Decision 2019/018/R

Use of the term 'applicant': point 21.A.33 is applicable to type certification, major changes, major repairs and supplemental type certificates (STCs), and through reference in point 21.A.604 to ETSO for auxiliary power units (APUs). Despite using the word 'applicant', it is also applicable to major changes, major repairs and STCs approved under DOA privileges (see point 21.A.263(c)(5), (8) or (9)).

Proposed type design: this term defines the type design (or the portion of the type design) as it is determined at the time when the inspection or test is undertaken.

Statement of conformity: for each certification inspection or test, the statement of conformity issued in accordance with point 21.A.33(c) must address the conformity of the test specimen (see point 21.A.33(b)(1)) as well as of the test equipment and measuring equipment (see point 21.A.33(b)(2)).

Conformity of the test specimen: the statement of conformity required by point 21.A.33(c) is intended to ensure that the manufactured test specimen adequately represents the proposed type design. Possible types of non-conformity may be the following:

— Non-conformity between the design of the test specimen and the proposed type design at the time of the test. These are typically identified in the early stage of the test planning, and should be addressed as early as possible (e.g. in the test plan). There may be several reasons for such a non-conformity: to account for interfaces with the test equipment, to conservatively cover several or future design configurations, etc.

— Non-conformity between the manufactured test specimen and the design of the test specimen. Such a non-conformity may be the result of the manufacturing of the test specimen.

While it is convenient to define any possible non-conformity in (a) as early as possible, the applicant does not need to make the distinction between the two types of non-conformity above as long as they are explicitly addressed and justified in the statement of conformity or by cross reference to the test plan or other documents.

Type certification is typically an iterative process in which the design is under continuous evolution. If the type design evolves after the time of the inspection or test, then the final type design should be checked against the proposed type design (as it was at the time of the inspection or test), and the differences (if any) should be analysed to ensure that the inspection or test results are representative of the final configuration. However, such changes made to the type design may lead to the invalidation of the inspection or test results and a need to repeat the inspection or test. It is recommended that the design organisation should have a thorough configuration management process to track the evolving type design.

Conformity of test and measuring equipment: the configuration of the test and measuring equipment should be defined in the test plan and include the following:

— definition/design of the test equipment (relevant tools, mechanical parts, electronic components used to execute the test); and

— definition of the measuring equipment:

    — type/model of sensors, together with their technical characteristics;

    — position and orientation of exciters and sensors; and

    — electronic measuring equipment (in some cases, this may also include the acquisition and post-processing of data).

The configuration of the test and measuring equipment should be defined and controlled through certification test plans and supporting documentation, according to the design assurance system, if applicable. The test plan should also include the following elements:

— the test cases, methods, and procedures for test execution;

— the pass–fail criteria; and

— pre-, during- and post-test inspections.

The statement of conformity of point 21.A.33(c) should confirm that the test and measuring equipment conform to its purpose, and that the sensors and measuring system are appropriately calibrated. Any non-conformity should be assessed, and it should be justified that it will not compromise the test purpose and results. This can be done either in the statement of conformity or by cross reference to other documents (test minutes of meetings, test notes, etc.).

Use of the term 'adequate': the test specimen, as well as the test and measuring equipment, are considered to be 'adequate' as long as the test execution on the manufactured test specimen (including any non-conformity) and the use of the installed test set-up does not compromise the test purpose and results (for example, by providing better performance than the proposed type design, or masking any potential failure mode or behaviour).

Changes that affect the validity of the statement of conformity (see point 21.A.33(e)(2)): if changes need to be introduced to the test specimen or to the test and measurement equipment after the statement of conformity is issued (and before the test is undertaken), the statement of conformity must be updated. The updated statement of conformity must be made available to EASA before the test if EASA has informed the applicant that it will witness or carry out the tests.

Development versus certification tests: sometimes, tests of specimens that conform to a preliminary design, but are not intended for certification (known as development tests), are performed as part of a risk control strategy and to develop knowledge of a subject. Problems and failures found during development are part of the process of increasing the understanding of the design, including its failure modes and the potential for optimisation. Such development tests do not need to meet the requirements of point 21.A.33.

Any planned test event should be classified in advance as either a development test or a certification test. Tests that support the compliance demonstration should be classified as certification tests.

Nevertheless, if agreed by EASA, it is acceptable for a development test to finally form part of the compliance demonstration, and it may be declared afterwards to be a certification test as long as it meets the requirements of point 21.A.33. For this reason, it is important to keep the configuration of such tests under the control of the design organisation.

In addition to this, the level of involvement (LoI) notified by EASA as per 21.B.100(c) should be taken into account: if EASA has determined that it will witness or conduct a certain test, this test may need to be repeated so that EASA can witness or conduct the test.

If the test specimen used for a certification test has already undergone a series of previous tests that may affect or ultimately invalidate its acceptance as required by point 21.A.33(b), this aspect should be considered when issuing the statement of conformity required by point 21.A.33(c), and specific analyses or inspections may be required to support such a statement.

Because of the above aspects, EASA advises applicants to inform EASA if they intend to conduct a campaign of development tests that may eventually be used as certification tests.

Availability of compliance data (see point 21.A.33(d)(1)): data and information requested from the applicant for review should be made available in a reliable and efficient way that is agreed between the applicant and EASA.

Point 21.A.33(d)(1) refers to any data or information related to compliance data; the scope of that requirement is therefore not limited to inspections and tests. In particular, point 21.A.33(d)(1) is not limited to data and information related to compliance demonstration items (CDIs) in which EASA is involved.

GM 21.A.33(d) Inspections and tests

ED Decision 2019/018/R

The applicant should inform EASA sufficiently in advance about the execution of inspections and tests that are used for compliance demonstration purposes unless EASA has explicitly excluded these inspections and tests from its involvement according to 21.B.100.

Additionally, the applicant may propose to EASA to perform or witness flight or other tests of particular aspects of the product during its development and before the type design is fully defined. However, before EASA performs or witnesses any flight test, the applicant should have performed these tests already before EASA and should ensure that no features of the product preclude the safe conduct of the evaluation requested.

EASA may require any such tests to be repeated once the type design is fully defined to ensure that subsequent changes have not adversely affected the conclusions from any earlier evaluation.

A statement of conformity as per point 21.A.33(c) is also required for the above tests.

21.A.35 Flight Tests

Regulation (EU) No 748/2012

(a) Flight testing for the purpose of obtaining a type-certificate shall be conducted in accordance with conditions for such flight testing specified by the Agency.

(b) The applicant shall make all flight tests that the Agency finds necessary:

1. to determine compliance with the applicable type-certification basis and environmental protection requirements; and

2. to determine whether there is reasonable assurance that the aircraft, its parts and appliances are reliable and function properly for aircraft to be certificated under this Annex I (Part 21), except for,

(i) sailplanes and powered sailplanes,

(ii) balloons and airships defined in ELA1 or ELA2,

(iii) aeroplanes of 2 722 kg or less maximum take-off mass (MTOM).

(c) (Reserved)

(d) (Reserved)

(e) (Reserved)

(f) The flight tests prescribed in point (b)(2) shall include:

1. for aircraft incorporating turbine engines of a type not previously used in a type-certificated aircraft, at least 300 hours of operation with a full complement of engines that conform to a type-certificate; and

2. for all other aircraft, at least 150 hours of operation.

GM 21.A.35 Flight Tests

ED Decision 2012/020/R

Detailed material on flight testing is included in the applicable CS and GM.

GM 21.A.35(b)(2) Objective and Content of Function and Reliability Testing

ED Decision 2012/020/R

1. OBJECTIVE

The objective of this testing is to expose the aircraft to the variety of uses, including training, that are likely to occur when in routine service to provide an assurance that it performs its intended functions to the standard required for certification and should continue to do so in service.

2. CONTENT OF FUNCTION AND RELIABILITY TESTING

The testing should cover both routine operations and some simulation of abnormal conditions. The details of the programme should be agreed with the Agency prior to commencement of testing.

It may be possible to combine this testing with any required to demonstrate compliance with the applicable CS. This will be agreed on a case-by-case basis with the Agency.

Where possible, testing conditions should be defined with the co-operation of an operator.

A substantial proportion of the flying should be on a single aircraft. The flying should be carried out to a continuous schedule on an aircraft that is very close to the final type design, operated as though it were in service and should include a range of representative ambient operating conditions and airfields.

GM 21.A.35(f)(1) Flying Time for Function and Reliability Testing

ED Decision 2012/020/R

All flying carried out with engines and associated systems not significantly different from the final type-certificate standard may count towards the 300 hours airframe flight time required by 21.A.35(f)(1). At least 150 of the 300 flying hours should be conducted on a dedicated production configured aircraft. The requirement for 300 hours relevant flight time whenever a new turbine engine is incorporated applies regardless of whether the airframe/engine combination is subject to a new type-certificate or is to be certificated as a change or supplement to an existing type-certificate.

GM 21.A.35(f)(2) Flying Time for Function and Reliability Testing

ED Decision 2012/020/R

All flying carried out on an aircraft not significantly different from the final type design may count towards the 150 hours airframe flight time required by 21.A.35(f)(2).

21.A.41 Type-certificate

Regulation (EU) 2021/699

The type-certificate and restricted type-certificate shall include the type design, the operating limitations, the instructions for continued airworthiness, the type-certificate data sheet for airworthiness and emissions, the applicable type-certification basis and environmental protection requirements with which the Agency records compliance, and any other conditions or limitations prescribed for the product in the applicable certification specifications and environmental protection requirements. The aircraft type-certificate and restricted type-certificate shall include in addition the applicable operational suitability data certification basis, the operational suitability data and the type-certificate data sheet for noise. The aircraft type-certificate and restricted type-certificate data sheet shall include the record of CO_2 emissions compliance and the engine type-certificate data sheet shall include the record of exhaust emissions compliance.

21.A.44 Obligations of the holder

Regulation (EU) 2021/699

Each holder of a type-certificate or restricted type-certificate shall:

(a) undertake the obligations laid down in points 21.A.3A, 21.A.3B, 21.A.4, 21.A.5, 21.A.6, 21.A.7, 21.A.62 and 21.A.65; and, for this purpose, shall continue to meet the qualification requirements for eligibility under point 21.A.14; and

[applicable until 6 March 2023]

(a) undertake the obligations laid down in points 21.A.3A, 21.A.3B, 21.A.4, 21.A.5, 21.A.6, 21.A.7, 21.A.9, 21.A.62 and 21.A.65, and, for this purpose, shall continue to meet the qualification requirements for eligibility under point 21.A.13; and

[applicable from 7 March 2023 — Regulation (EU) 2022/201]

(b) specify the marking in accordance with Subpart Q.

21.A.47 Transferability

Regulation (EU) No 748/2012

Transfer of a type-certificate or restricted type-certificate may only be made to a natural or legal person that is able to undertake the obligations under point 21.A.44, and, for this purpose, has demonstrated its ability to qualify under the criteria of point 21.A.14.

[applicable until 6 March 2023]

The transfer of a type-certificate or a restricted type-certificate or an ETSO authorisation for an auxiliary power unit may only be made to a natural or legal person that is able to undertake the obligations laid down in point 21.A.44, and, for this purpose, has demonstrated its capability in accordance with point 21.A.14.

[applicable from 7 March 2023 — Regulation (EU) 2022/201]

21.A.51 Duration and continued validity

Regulation (EU) No 748/2012

(a) A type-certificate and restricted type-certificate shall be issued for an unlimited duration. They shall remain valid subject to:

1. the holder remaining in compliance with this Annex 1 (Part 21); and
2. the certificate not being surrendered or revoked under the applicable administrative procedures established by the Agency.

(b) Upon surrender or revocation, the type-certificate and restricted type-certificate shall be returned to the Agency.

21.A.62 Availability of operational suitability data

Regulation (EU) No 69/2014

The holder of the type-certificate or restricted type-certificate shall make available:

(a) at least one set of complete operational suitability data prepared in accordance with the applicable operational suitability certification basis, to all known EU operators of the aircraft, before the operational suitability data must be used by a training organisation or an EU operator; and

(b) any change to the operational suitability data to all known EU operators of the aircraft; and

(c) on request, the relevant data referred to in points (a) and (b) above, to:

1. the competent authority responsible for verifying conformity with one or more elements of this set of operational suitability data; and
2. any person required to comply with one or more elements of this set of operational suitability data.

GM to 21.A.62, 21.A.108 and 21.A.120B Availability of Operational Suitability Data

ED Decision 2014/007/R

(a) When making data available, the holder of the design approval (TC, change approval, STC) should take into account the applicable security laws.

(b) When making data available, the holder of the design approval can impose conditions addressing the intellectual property nature of the data.

21.A.65 Continuing structural integrity for aeroplanes structures

Regulation (EU) 2021/699

The holder of the type-certificate or restricted type-certificate for a large aeroplane shall ensure that the continuing structural integrity programme remains valid throughout the operational life of the aeroplane, taking into account service experience and current operations.

AMC1 21.A.65 Continuing structural integrity programme for aeroplane structures

ED Decision 2021/007/R

Type-certificate (TC) or restricted type-certificate (RTC) holders for large aeroplanes should implement a process to ensure the continuing structural integrity of the aeroplane's structures following its entry into service.

For those large aeroplanes subject to point 26.300 of Part-26, compliance with point 21.A.65 of Part 21 is demonstrated by complying with point 26.305 of Part-26 within the timescale indicated therein.

For other large aeroplanes, the process should be established considering the points described below:

(a) Overall objectives

The objective of point 21.A.65 of Part 21 is to ensure that the continuing structural integrity programme remains valid throughout the operational life of the aeroplane and will preclude unsafe levels of fatigue cracking and other forms of structural degradation.

The intent is for (R)TC holders for large aeroplanes to monitor the continued validity of the assumptions upon which the ICA related to the aeroplane structures are based, and to ensure that unsafe levels of fatigue cracking or other structural deterioration will be precluded in service.

To achieve this objective, (R)TC holders are expected to work together with aircraft operators.

The process should apply to all structures whose failure could contribute to a catastrophic failure, and it is not limited to metallic structures or fatigue cracking, but should also encompass composite and hybrid structures and associated failure modes.

(b) Description of the process to maintain the validity of the continuing structural integrity programme

The process to maintain the validity of the continuing structural integrity programme is either continuous with each service finding, or is a regular review following several findings, or a combination of both. It should include the following:

(1) a plan to audit and report to EASA the effectiveness of the continuing structural integrity programme, including the continuing validity of the assumptions upon which it is based, prior to reaching any significant point in the life of the aeroplane;

(2) criteria for summarising findings of fatigue, environmental or accidental damage and their causes, and recording them in a way that allows any potential interaction to be evaluated;

(3) criteria to assess and record the relevance of each potential contributing factor to the finding, including operational usage, fatigue load spectra, environmental conditions, material properties, manufacturing processes and the fatigue- and damage-tolerance analytical methods of analysis and their implementation;

(4) criteria for establishing and revising sampling programmes to supplement the inspections and other procedures established in compliance with the applicable fatigue- and damage-tolerance requirements;

(5) criteria for establishing when structures should be modified, or the inspection programme revised, in the light of in-service damage findings;

(6) sunset criteria: the extent to which the above elements of the process require definition may be tailored to the size of the fleet and its expected useful remaining life.

(7) Additional means of compliance may be found in paragraph 5 and Appendix 5 to AMC 20-20B.

(SUBPART C — NOT APPLICABLE)

SUBPART D — CHANGES TO TYPE-CERTIFICATES AND RESTRICTED TYPE-CERTIFICATES

21.A.90A Scope

Regulation (EU) No 69/2014

This Subpart establishes the procedure for the approval of changes to type-certificates, and establishes the rights and obligations of the applicants for, and holders of, those approvals. This Subpart also defines standard changes that are not subject to an approval process under this Subpart. In this Subpart, references to type-certificates include type-certificate and restricted type-certificate.

GM 21.A.90A Scope

ED Decision 2019/018/R

The term 'changes to the type certificate' is consistently used in Part 21 Subpart D and E, as well as in the related AMC and GM. This term does not refer to changing the document that reflects the type certificate (TC) but to the elements of the TC as defined in 21.A.41. It means that the processes for the approval of changes, as described in the said two Subparts, do not only apply to changes to the type design, but may also apply to changes to:

— the operating limitations;

— the type certificate data sheet (TCDS) for airworthiness and emissions;

— the applicable type-certification basis and environmental protection requirements with which the applicant has to demonstrate compliance;

— any other conditions or limitations prescribed for the product by EASA;

— the applicable operational suitability data (OSD) certification basis;

— the OSD; and

— the TCDS for noise.

NOTE: OSD is only applicable to aircraft TCs and not to engine or propeller TCs. Therefore, changes to OSD are only relevant for changes to aircraft TCs.

21.A.90B Standard changes

Regulation (EU) 2021/699

(a) Standard changes are changes to a type-certificate:

1. in relation to:

(i) aeroplanes of 5 700 kg Maximum Take-Off Mass (MTOM) or less;

(ii) rotorcraft of 3 175 kg MTOM or less;

(iii) sailplanes, powered sailplanes, balloons and airships, as defined in ELA1 or ELA2,

2. that follow design data included in the certification specifications issued by the Agency, containing acceptable methods, techniques and practices for carrying out and identifying standard, including the associated instructions for continued airworthiness; and

3. that are not in changes conflict with TC holders data.

(b) Points 21.A.91 to 21.A.109 are not applicable to standard changes.

GM 21.A.90B Standard changes — Certification Specifications

ED Decision 2015/016/R

CS-STAN contains the certification specifications referred to in 21.A.90B(a)2. Guidance on the implementation of Standard Changes and Standard Repairs can be found in AMC M.A.801 of the AMC to Part-M.

21.A.90C Stand-alone changes to the Instructions for Continued Airworthiness

Regulation (EU) 2021/699

(a) Stand-alone changes to the instructions for continued airworthiness are changes that are not directly prepared as a result of a change to the type design or repair design.

(b) Stand-alone changes to the instructions for continued airworthiness can only be made by the holder of the design approval for which those instructions have been established.

(c) Points 21.A.91 to 21.A.109 shall not apply to stand-alone changes to the instructions for continued airworthiness that:

1. do not affect the airworthiness limitations section of the instructions for continued airworthiness, and

2. do not require the design approval holder to perform any additional demonstration of compliance with the certification basis.

(d) Stand-alone changes to the instructions for continued airworthiness referred to in point (c) shall be approved by the design approval holder under procedures agreed with the Agency.

GM1 21.A.90C Stand-alone changes

ED Decision 2021/007/R

Changes to the ICA are considered to be stand-alone changes when they are not directly prepared together with a change to the type design. Stand-alone changes to the ICA are usually prepared and issued, for example, for the purpose of making corrections, improvements, to include feedback from users, or to provide alternatives.

Also, when the ICA are completed after the product (or change to the product) was approved, this is considered to be a stand-alone change to the ICA.

When a non-ALS ICA change is triggered by a change to the type design, this does not affect the overall classification of the type certificate change as per point 21.A.91.

Stand-alone changes are usually straightforward changes, and are not considered to require additional work in order to show compliance. However, they must be managed in accordance with a process accepted by EASA under point 21.A.239 or point 21.A.14(b), for discharging the obligation to keep the ICA up to date.

Examples of changes that may require additional activities in order to show compliance are changes to the CDCCL, and EWIS ICA.

21.A.91 Classification of changes to a type-certificate

Regulation (EU) 2019/897

Changes to a type-certificate are classified as minor and major. A "minor change" has no appreciable effect on the mass, balance, structural strength, reliability, operational characteristics, operational suitability data, or other characteristics affecting the airworthiness of the product or its environmental characteristics. Without prejudice to point 21.A.19, all other changes are "major changes" under this Subpart. Major and minor changes shall be approved in accordance with points 21.A.95 or 21.A.97, as appropriate, and shall be adequately identified.

GM 21.A.91 Classification of changes to a type certificate (TC)

ED Decision 2019/018/R

1. PURPOSE OF CLASSIFICATION

Classification of changes to a type certificate (TC) into MAJOR or MINOR is to determine the approval route to be followed in Part-21 Subpart D, i.e., either 21.A.95 or 21.A.97, or alternatively whether application and approval has to be made in accordance with Part-21 Subpart E.

2. INTRODUCTION

2.1 21.A.91 proposes criteria for the classification of changes to a TC as minor or major.

(a) This GM is intended to provide guidance on the term 'appreciable effect' affecting the airworthiness of the product or affecting any of the other characteristics mentioned in 21.A.91, where 'airworthiness' is interpreted in the context of a product in conformity with type design and in condition for safe operation. It provides complementary guidelines to assess a change to the TC in order to fulfil the requirements of 21.A.91 and 21.A.117 where classification is the first step of a procedure.

Note: For classification of Repairs see GM 21.A.435(a).

(b) Although this GM provides guidance on the classification of major changes, as opposed to minor changes as defined in 21.A.91, the GM and 21.A.91 are deemed entirely compatible.

2.2 For an ETSO authorisation, 21.A.611 gives specific requirements for design changes to ETSO articles.

For APU, this GM 21.A.91 should be used.

3. ASSESSMENT OF A CHANGE FOR CLASSIFICATION

3.1 Changes to the TC

21.A.91 addresses all changes to any of the aspects of a TC. This includes changes to a type design, as defined in 21.A.31, as well as to the other constituents of a TC, as defined in 21.A.41.

3.2 Reserved

3.3 Classification process (see also the flow chart 'Classification process' in Appendix A to GM 21.A.91)

21.A.91 requires all changes to be classified as either major or minor, using the criteria of 21.A.91.

Wherever there is doubt as to the classification of a change, EASA should be consulted for clarification.

When the strict application of the paragraph 3.4 criteria results in a major classification, the applicant may request reclassification, if justified, and EASA could take the responsibility for reclassifying the change.

A simple design change planned to be mandated by an airworthiness directive may be reclassified as minor due to the involvement of EASA in the continued airworthiness process when this is agreed between EASA and the DOA holder.

The reasons for a classification decision should be recorded.

3.4 Complementary guidance for classification of changes

A change to the TC is judged to have an 'appreciable effect on the mass, balance, structural strength, reliability, operational characteristics, noise, fuel venting, exhaust emission, operational suitability or other characteristics affecting the airworthiness, environmental protection or operational suitability of the product' and, therefore, should be classified as major, in particular but not only, when one or more of the following conditions are met:

(a) where the change requires an adjustment of the type-certification basis or the OSD certification basis (special conditions or equivalent safety findings) other than elect to comply with later certification specifications;

(b) where the applicant proposes a new interpretation of the certification specifications used for the type certification basis or the OSD certification basis that has not been published as AMC material or otherwise agreed with the Agency;

(c) where the demonstration of compliance uses methods that have not been previously accepted as appropriate for the nature of the change;

(d) where the extent of new substantiation data necessary to comply with the applicable certification specifications and the degree to which the original substantiation data has to be re-assessed and re-evaluated is considerable;

(e) where the change alters the airworthiness limitations or the operating limitations;

(f) where the change is made mandatory by an airworthiness directive or the change is the terminating action of an airworthiness directive (ref. 21.A.3B), see Note 1; and

(g) where the design change introduces or affects functions where the failure effect is classified as catastrophic or hazardous.

Note 1: A change previously classified as minor and approved prior to the airworthiness directive issuance decision needs no reclassification. However, EASA retains the right to review the change and reclassify/reapprove it if found necessary.

Note 2: The conditions listed in (a) through (g) above are an explanation of the criteria noted in 21.A.91.

For an understanding of how to apply the above conditions, it is useful to take note of the examples given in Appendix A to GM 21.A.91

3.5 Complementary guidance on the classification of changes to OSD

This paragraph provides firstly general guidance on minor OSD change classification, and secondly additional guidance specific to each OSD constituent.

Changes to OSD are considered minor when they:

— incorporate optional information (representing improvements/enhancements);

— provide clarifications, interpretations, definitions or advisory text; or

— do not change the intent of the OSD document, e.g. changes to:

  — titles, numbering, formatting, applicability;

  — order, sequence, pagination; or

  — sketches, figures, units of measurement, and correction of editorial mistakes such as:

    — spelling; or

    — reference numbers.

Given the structure and individual intent of the separate OSD constituents, the interpretation of 'appreciable' is also affected by the specific nature of the applicable certification specifications (CS) for that constituent. Therefore, specific guidance on each of the OSD constituents is provided hereafter.

(a) Master minimum equipment list (MMEL)

(1) A change to the MMEL is judged to have an 'appreciable effect on the operational suitability of the aircraft' and, therefore, should be classified as major, in particular but not only when one or more of the following conditions are met:

(i) where the change requires an adjustment of the OSD certification basis;

(ii) where the applicant proposes changes to the means of compliance with the requirements used for the OSD certification basis (i.e. MMEL safety methodology);

(iii) where the extent of substantiation data and the degree to which the substantiation data has to be assessed and evaluated is considerable, in particular but not only when:

(A) the substantiation data involving the review of failure conditions that are classified as hazardous or catastrophic has to be evaluated;

(B) the assessment of the failure effects (including next worst failure/event effects) on crew workload and the applicable crew procedures has to be evaluated; or

(C) the capability of the aircraft to perform types of operation (e.g. extended-range twin operations (ETOPS), instrument flight rules (IFR)) under MMEL is extended.

(2) A change to the MMEL is judged not to have an 'appreciable effect on the operational suitability of the aircraft' and, therefore, should be classified as minor, in particular but not only when one or more of the following conditions are met:

Modifications to an existing item when:

(i) the change only corresponds to the applicability of an item for configuration management purposes;

(ii) the change corresponds to the removal of an item;

(iii) the change corresponds to the increase in the number of items required for dispatch; and

(iv) the change corresponds to a reduction in the rectification interval of an item.

Addition of a new item when:

(v) it is considered as non-safety-related (refer to CS-MMEL, GM2 MMEL.110); or

(vi) it is indicated as eligible for minor change classification in 1 to GM1 CS-MMEL-145.

(b) Flight crew data (FCD)

(1) FCD change related to change to the type design

When classifying the FCD change as minor or major, the method of CS-FCD, Subpart D should be used.

(i) An analysis should be performed to assess the change impact on the FCD through the allocation of difference levels realised with operator difference requirement (ODR) tables as per CS FCD.400. In this case, the base aircraft is the aircraft without the type design change, whereas the candidate aircraft is the aircraft which includes the type design change.

(A) If a no more than level B difference is assigned for training, checking and currency for the candidate aircraft, the related FCD change should be classified as minor.

(B) If a difference level C, D or E for training, checking and currency is assigned to the candidate aircraft, the related FCD change should be classified as major.

(ii) Notwithstanding the above, the change to FCD should be classified as major when a T1 or T2 test is found necessary by the applicant to confirm that the aircraft with the type design change is not a new type for pilot type rating.

(2) Stand-alone changes to FCD are not related to any type design changes. They may be triggered for example by in-service experience or by the introduction of data at the request of the applicant after type certification.

(i) Introduction of credits in training, checking or currency should be classified as major. Example: addition of further-differences training, common take-off and landing credits, etc.

(ii) Stand-alone changes to FCD that correspond to a change of the intent of a data should be classified as major. Example: addition of a training area of special emphasis (TASE) or prerequisite, expansion of a TASE.

(c) Cabin crew data (CCD)

(1) OSD change related to change to the type design

When classifying the OSD CCD change as minor or major, the method from CS-CCD, Subpart B should be used.

(i) An analysis should be performed to assess the change impact on the OSD CCD through the identification of the difference and its impact on operation in the aircraft difference table (ADT) as per CS CCD.200. In this case, the base aircraft is the aircraft without the type design change, whereas the candidate aircraft is the aircraft which includes the type design change.

(A) If the difference has no impact on the operation of an element of the ADT for the candidate aircraft, the related OSD CCD change should be classified as minor.

(B) If the difference has an impact on the operation of an element of the ADT for the candidate aircraft, the related OSD CCD change should be classified as major.

(ii) Notwithstanding the above, the change to OSD CCD should be classified as major when an ADT analysis is found necessary by the applicant to confirm that the aircraft with the type design change is not a new type for cabin crew.

(2) Stand-alone changes to OSD CCD are not related to any type design changes. They may be triggered for example by in-service experience or by the introduction of data at the request of the applicant after type certification.

(i) Stand-alone changes to cabin aspects of special emphasis (CASE) should be classified as major. Example: addition of further CASE, expansion of CASE.

(ii) When classifying stand-alone changes to type-specific data for cabin crew the method from CS-CCD, Subpart B should be used. An analysis should be performed to assess the change impact on the type-specific data through the identification of the difference and its impact on operation in the ADT as per CS CCD.200.

(A) If the change does not concern a determination element of CS CCD.205, the stand-alone change should be classified as minor.

(B) If the change has no impact on the operation of an element of the ADT, the stand-alone change should be classified as minor.

(C) If the change has an impact on the operation of an element of the ADT, the stand-alone change should be classified as major.

(d) Simulator data (SIMD)

The OSD constituent 'simulator data' does not include the data package that is necessary to build the simulator. It includes only the definition of the scope of validation source data to support the objective qualification of a simulator. So, when this guidance discusses changes to 'simulator data', this concerns only changes to the 'definition of scope of validation source data' and not changes to the data package.

(1) A change to the SIMD should be classified as major, in particular but not only when one or more of the following conditions are met:

(i) when a change to the SIMD introduces validation source data from an engineering platform where the process to derive such data has not been audited by the Agency in the initial SIMD approval; or

(ii) when the process to derive validation source data from an engineering platform is changed.

(2) A change to the SIMD could be classified as minor, in particular but not only when one or more of the following conditions are met:

(i) changes to engineering validation data independent of the aircraft due to improvements or corrections in simulation modelling (e.g. aerodynamics, propulsion);

(ii) configuration changes to the aircraft where the process to derive validation source data from an engineering platform is unchanged;

(iii) changes to validation source data by using better, more applicable flight test data; or

(iv) editorial changes to the validation data roadmap (VDR).

(e) Maintenance certifying staff data (MCSD)

[Reserved]

3.6 Complementary guidance for the classification of changes to aircraft flight manuals (AFMs)

The following changes to the AFM are deemed to be minor:

(a) revisions to the AFM associated with changes to the type design that are classified as minor in accordance with point 21.A.91;

(b) revisions to the AFM that are not associated with changes to the type design (also identified as stand-alone revisions) which fall into one of the following categories:

(1) changes to limitations or procedures that remain within already certified limits (e.g. weight, structural data, noise, etc.);

(2) consolidation of two or more previously approved and compatible AFMs into one, or the compilation of different parts taken from previously approved

and compatible AFMs that are directly applicable to the individual aircraft (customisation); and

(3) the introduction into a given AFM of compatible and previously approved AFM amendments, revisions, appendices or supplements; and

(c) administrative revisions to the AFM, defined as follows:

(1) for the AFMs issued by the TC holder:

(i) editorial revisions or corrections to the AFM;

(ii) changes to parts of the AFM that do not require approval by EASA;

(iii) conversions of previously Federal Aviation Administration (FAA)- or EASA-approved combinations of units of measurement added to the AFM in a previously approved manner;

(iv) the addition of aircraft serial numbers to an existing AFM where the aircraft configuration, as related to the AFM, is identical to the configuration of aircraft already covered by that AFM;

(v) the removal of references to aircraft serial numbers no longer applicable to that AFM; and

(vi) the translation of an EASA-approved AFM into the language of the State of design or State of registration;

(2) for AFM supplements issued by STC holders:

(i) editorial revisions or corrections to the AFM supplement;

(ii) changes to parts of the AFM supplement that are not required to be approved by EASA;

(iii) conversions of previously FAA- or EASA-approved combinations of units of measurement added to the AFM supplement in a previously approved manner;

(iv) the addition of aircraft serial numbers to an existing AFM supplement where the aircraft configuration, as related to the AFM supplement, is identical to that of the aircraft already in that AFM supplement; 'identical' means here that all the aircraft have to belong to the same type and model/variant;

(v) the addition of a new STC to an existing AFM supplement, when this supplement is fully applicable to the new STC;

(vi) the removal of references to aircraft serial numbers that are no longer applicable to that AFM supplement;

(vii) the translation of an EASA-approved AFM supplement into the language of the State of design or the State of registration.

3.7 Complementary guidance for classification of changes to environmental protection characteristics See Section 8 of Appendix A to GM 21.A.91.

Appendix A to GM 21.A.91 Examples of Major Changes per discipline

ED Decision 2021/007/R

The information below is intended to provide a few major change examples per discipline, resulting from application of 21.A.91 and paragraph 3.3 conditions. It is not intended to present a comprehensive list of all major changes. Examples are categorised per discipline and are applicable to all products (aircraft, engines and propellers). However a particular change may involve more than one discipline, e.g., a change to engine controls may be covered in engines and systems (software).

Those involved with classification should always be aware of the interaction between disciplines and the consequences this will have when assessing the effects of a change (i.e., operations and structures, systems and structures, systems and systems, etc.; see example in paragraph 2 (ii).

Specific rules may exist which override the guidance of these examples.

In the Part 21 a negative definition is given of minor changes only. However in the following list of examples it was preferred to give examples of major changes.

Where in this list of examples the words 'has effect' or 'affect(s)' are used, they have always to be understood as being the opposite of 'no appreciable effect' as in the definition of minor change in 21.A.91. Strictly speaking the words 'has appreciable effect' and 'appreciably affect(s)' should have been used, but this has not been done to improve readability.

1. Structure

   (i) changes such as a cargo door cut-out, fuselage plugs, change of dihedral, addition of floats;

   (ii) changes to materials, processes or methods of manufacture of primary structural elements, such as spars, frames and critical parts;

   (iii) changes that adversely affect fatigue or damage tolerance or life limit characteristics;

   (iv) changes that adversely affect aeroelastic characteristics.

2. Cabin Safety

   (i) changes which introduce a new cabin layout of sufficient change to require a re-assessment of emergency evacuation capability or which adversely affect other aspects of passenger or crew safety.

   Items to consider include, but are not limited to, :

   — changes to or introduction of dynamically tested seats.

   — change to the pitch between seat rows.

   — change of distance between seat and adjacent obstacle like a divider.

   — changes to cabin lay outs that affect evacuation path or access to exits.

   — installation of new galleys, toilets, wardrobes, etc.

   — installation of new type of electrically powered galley insert.

   (ii) changes to the pressurisation control system which adversely affect previously approved limitations.

3. Flight

Changes which adversely affect the approved performance, such as high altitude operation, brake changes that affect braking performance.

Changes which adversely affect the flight envelope.

Changes which adversely affect the handling qualities of the product including changes to the flight controls function (gains adjustments, functional modification to software) or changes to the flight protection or warning system.

4. Systems

For systems assessed under CS 25.1309, the classification process is based on the functional aspects of the change and its potential effects on safety.

(i) Where failure effect is 'Catastrophic' or 'Hazardous', the change should be classified as major.

(ii) Where failure effect is 'major', the change should be classified as major if:

— aspects of the compliance demonstration use means that have not been previously accepted for the nature of the change to the system; or

— the change affects the pilot/system interface (displays, controls, approved procedures); or

— the change introduces new types of functions/systems such as GPS primary, TCAS, Predictive windshear, HUD.

The assessment of the criteria for software changes to systems also needs to be performed.

When software is involved, account should be taken also of the following guidelines:

Where a change is made to software produced in accordance with the guidelines of the latest edition of AMC 20-115 (see AMC-20 document) the change should be classified as major if either of the following apply, and the failure effect is Catastrophic, Hazardous or Major:

(i) the executable code for software, determined to be Level A or Level B in accordance with the guidelines, is changed unless that change involves only a variation of a parameter value within a range already verified for the previous certification standard; or

(ii) the software is upgraded to or downgraded from Level A, Level B or Level C; or

(iii) the executable code, determined to be level C, is deeply changed, e.g., after a software re-engineering process accompanying a change of processor.

For software developed to guidelines other than the latest edition of AMC 20-115, the applicant should assess changes in accordance with the foregoing principles.

For other codes the principles noted above may be used. However, due consideration should be given to specific certification specifications/interpretations.

In the context of a product information security risk assessment (PISRA), a change that may introduce the potential for unauthorised electronic access to product systems should be considered to be ‘major’ if there is a need to mitigate the risks for an identified unsafe condition. The following examples do not provide a complete list of conditions to classify a modification as major, but rather they present the general interactions between security domains. Examples of modifications that should be classified as ‘major’ are when any of the following changes occur:

— A new digital communication means, logical or physical, is established between a more closed, controlled information security domain, and a more open, less controlled security domain.

— For example, in the context of large aircraft, a communication means is established between the aircraft control domain (ACD) and the airline information services domain (AISD), or between the AISD and the passenger information and entertainment services domain (PIESD) (see ARINC 811).

As an exception, new simplex digital communication means (e.g. ARINC 429) from a controlled domain to a more open domain is not considered as major modification, if it has been verified that the simplex control cannot be reversed by any known intentional unauthorised electronic interaction (IUEI).

— A new service is introduced between a system of a more closed, controlled information security domain and a system of a more open, less controlled security domain, which allows the exploitation of a vulnerability of the service that has been introduced, creating a new attack path.

For example:

— opening and listening on a User Datagram Protocol (UDP) port in an end system of an already certified topology;

— activating a protocol in a point-to-point communication channel.

— The modification of a service between a system of a more closed, controlled security domain and a system of a more open, less controlled security domain.

— The modification of a security control between a system of a more closed, controlled information security domain and a system of a more open, less controlled security domain.

5. Propellers

Changes to:

— diameter

— airfoil

— planform

— material

— blade retention system, etc.

6. Engines

Changes:

(i) that adversely affect operating speeds, temperatures, and other limitations.

(ii) that affect or introduce parts identified by CS E-510 where the failure effect has been shown to be hazardous.

(iii) that affect or introduce engine critical parts (CS E-515) or their life limits.

(iv) to a structural part which requires a re-substantiation of the fatigue and static load determination used during certification.

(v) to any part of the engine which adversely affects the existing containment capability of the structure.

(vi) that adversely affect the fuel, oil and air systems, which alter the method of operation, or require reinvestigation against the type-certification basis.

(vii) that introduce new materials or processes, particularly on critical components.

7. Rotors and drive systems

Changes that:

(i) adversely affect fatigue evaluation unless the service life or inspection interval are unchanged. This includes changes to materials, processes or methods of manufacture of parts, such as

— rotor blades

— rotor hubs including dampers and controls

— gears

— drive shafts

— couplings

(ii) affect systems the failure of which may have hazardous or catastrophic effects. The design assessment will include:

— cooling system

— lubrication system

— rotor controls

(iii) adversely affect the results of the rotor drive system endurance test, the rotor drive system being defined in CS 27/29.917.

(iv) adversely affect the results of the shafting critical speed analysis required by CS 27/29.931.

8. Environment

The introductory text to Appendix A to GM 21.A.91 describes how in Part 21 a negative definition is given of minor changes only. This philosophy is similar to the manner in which the ICAO Standards and Recommended Practices for environmental protection (ICAO Annex 16) and the associated Guidance Material (ICAO Environmental Technical Manual) define changes affecting a product's environmental characteristics in terms of 'no-acoustical changes', 'no-emissions changes' and 'no-CO_2 changes' (i.e. changes which do not appreciably affect the product's environmental characteristics).

Following the general philosophy of this Appendix, however, it is preferred to give examples of changes which might have an appreciable effect on a product's environmental characteristics (i.e. the effect might be greater than the no-acoustic change, no-emissions change and no-CO_2 change criteria) and might therefore lead to a 'major change' classification.

Where a change is made to an aircraft or aircraft engine, the effect of the change on the product's environmental characteristics should be taken into account. Examples of changes that might have an appreciable effect on the product's environmental characteristics, and might therefore be classified as major changes, are listed below. The examples are not exhaustive and will not, in every case, result in an appreciable change to the product's environmental

characteristics, and therefore, will not per se and in every case result in a 'major change' classification.

An appreciable effect is considered to be one which exceeds the ICAO criteria for a no-acoustical change, a no-emissions change or a no-CO_2 change. For the definition of a no-acoustical change refer to the section of the ICAO Environmental Technical Manual, Volume I (ICAO Doc 9501, Volume I – Procedures for the Noise Certification of Aircraft) concerning changes to aircraft type designs involving no-acoustical changes (see also the definitions of a 'derived version' in ICAO Annex 16, Volume I). For the definition of a no-emissions change, refer to the section of the ICAO Environmental Technical Manual, Volume II (ICAO Doc 9501, Volume II – Procedures for the Emissions Certification of Aircraft Engines) concerning no-emissions changes. For the definition of a no-CO_2 change, refer to ICAO Doc 9501 'Environmental Technical Manual', Volume III 'Procedures for the CO_2 Emissions Certification of Aeroplanes', 1st Edition 2018, concerning no-CO_2 changes.

(i) Noise: A change that introduces either:

— an increase in the noise certification level(s); or

— a reduction in the noise certification level(s) for which the applicant wishes to take credit.

Examples of noise-related changes that might lead to a major change classification are:

(1) For jet and heavy (maximum take-off mass greater than 8 618 kg) propeller-driven aeroplanes:

— A change that might affect the aircraft's take-off performance including:

— a change to the maximum take-off mass;

— a change to V2 ('take-off safety speed'); or

— a change to the lift augmentation devices, including their configuration under normal take-off operating conditions.

— A change that might affect the aircraft's landing performance including:

— a change to the maximum landing mass;

— a change to VREF (reference landing speed); or

— a change to the lift augmentation devices, including their deployment under normal landing operating conditions.

— A change to the Centre of Gravity (CG) limits;

— A change that increases the aircraft's drag;

— A change that alters the external profile of the aircraft, including the installation or change of shape or size of any item on the external surface of the aircraft that might protrude into the airflow such as winglets and vortex generators; generally the installation of small antennas does not represent an acoustical change;

— A change that introduces an open-ended hollow cavity at more or less right angles to the airflow (e.g. hollow pins in undercarriage assemblies);

— A change of engine or, if fitted, propeller type;

— A change in engine thrust rating;

— A change to the engine rotating parts or stators, such as geometry, blade profile or blade number;

— A change to the aerodynamic flow lines through the engine;

— A change that affects the engine thermodynamic cycle, including a change to the engine's bypass ratio;

— A change to the engine nacelle, including a change to the acoustic liners;

— A change to the engine exhaust;

— A change to the engine bleed valves, including bleed valve scheduling;

— A change in the operation of engine power off-takes (e.g. the operation of the Environmental Control System (ECS) during a normal take-off or approach);

— A change to the Auxiliary Power Unit (APU), including associated operating limitations (e.g. a change that allows the APU to be operated during a normal approach when previously it was not allowed);

— A change to the propeller pitch and/or propeller speed during a normal take-off or approach;

— A change that causes a change to the angle at which air flows into the propeller.

(2) For light (maximum take-off mass 8 618 kg or less) propeller-driven aeroplanes:

— A change that might affect the aircraft's take-off performance including:

  — a change to the maximum take-off mass;

  — a change to the take-off distance;

  — a change to the rate of climb; or

  — a change to Vy (best rate of climb speed).

— A change that increases the aircraft's drag (e.g. the installation of external cargo pods, external fuel tanks, larger tyres to a fixed undercarriage, floats etc.);

— A change of engine or propeller type;

— A change in take-off power including a change in engine speed (tachometer 'red line') or, for piston engines, a change to the manifold pressure limitations;

— A change to the highest power in the normal operating range ('top of green arc');

— In the case of an aircraft where take-off power/engine speed is time limited, a change in the period over which take-off power/engine speed may be applied;

— A change to the engine inlet or exhaust including, if fitted, the inlet or exhaust muffler;

— A change in propeller diameter, tip shape, blade thickness or the number of blades;

— The installation of a variable or adjustable pitch propeller in place of a fixed pitch propeller and vice versa;

— A change that causes a change to the angle at which air flows into the propeller.

(3) For helicopters:

— A change that might affect the take-off and/or landing performance, including a change in take-off mass and VY (best rate of climb speed);

— A change to VNE (never-exceed airspeed) or to VH (airspeed in level flight obtained using the torque corresponding to minimum engine installed, maximum continuous power available for sea level pressure, 25°C ambient conditions at the relevant maximum certificated mass);

— A change to the maximum take-off engine power or maximum continuous power;

— A change to the gearbox torque limits;

— A change of engine type;

— A change to the engine intake or exhaust;

— A change to the maximum normal operating rpm of the main or tail rotors;

— A change to the main or tail rotors, including a change in diameter, blade thickness or blade tip profile.

Note: The effect on the helicopter's noise characteristics of either carrying external loads or the installation of external equipment need not be considered.

(ii) Emissions: A change that introduces an increase or decrease in the emissions certification levels. Examples of smoke and gaseous engine emission-related changes that might lead to a major change classification are:

— A change in engine thrust rating;

— A change to the aerodynamic flow lines through the engine;

— A change that affects the engine thermodynamic cycle, specifically relevant engine cycle parameters (e.g. combustor pressure P3, combustor entry temperature T3, Air Fuel Ratio (AFR));

— A change to the compressor that might influence the combustor inlet conditions and engine overall pressure ratio;

— A change to the combustor design (geometry);

— A change to the cooling of the combustor;

— A change to the air mass flow through the combustor;

— A change that affects the fuel spray characteristics.

(iii) CO_2: a change that introduces either:

— an increase in the CO_2 emissions certification level; or

— a decrease in the CO_2 emissions certification level for which an applicant wishes to take credit.

Examples of CO_2 emission-related changes that may lead to a 'major change' classification are:

— a change to the maximum take-off mass;

— a change that may affect the aeroplane's specific air range performance, including one or several of the following:

  — a change that increases the aircraft's drag;

  — a change of engine or, if fitted, propeller type;

  — a change in the engine design that affects the engine specific fuel consumption in cruise.

— a change to the aeroplane's reference geometric factor (RGF).

9. Power plant Installation

Changes which include:

(i) control system changes which affect the engine/propeller/airframe interface;

(ii) new instrumentation displaying operating limits;

(iii) modifications to the fuel system and tanks (number, size and configuration);

(iv) change of engine/propeller type.

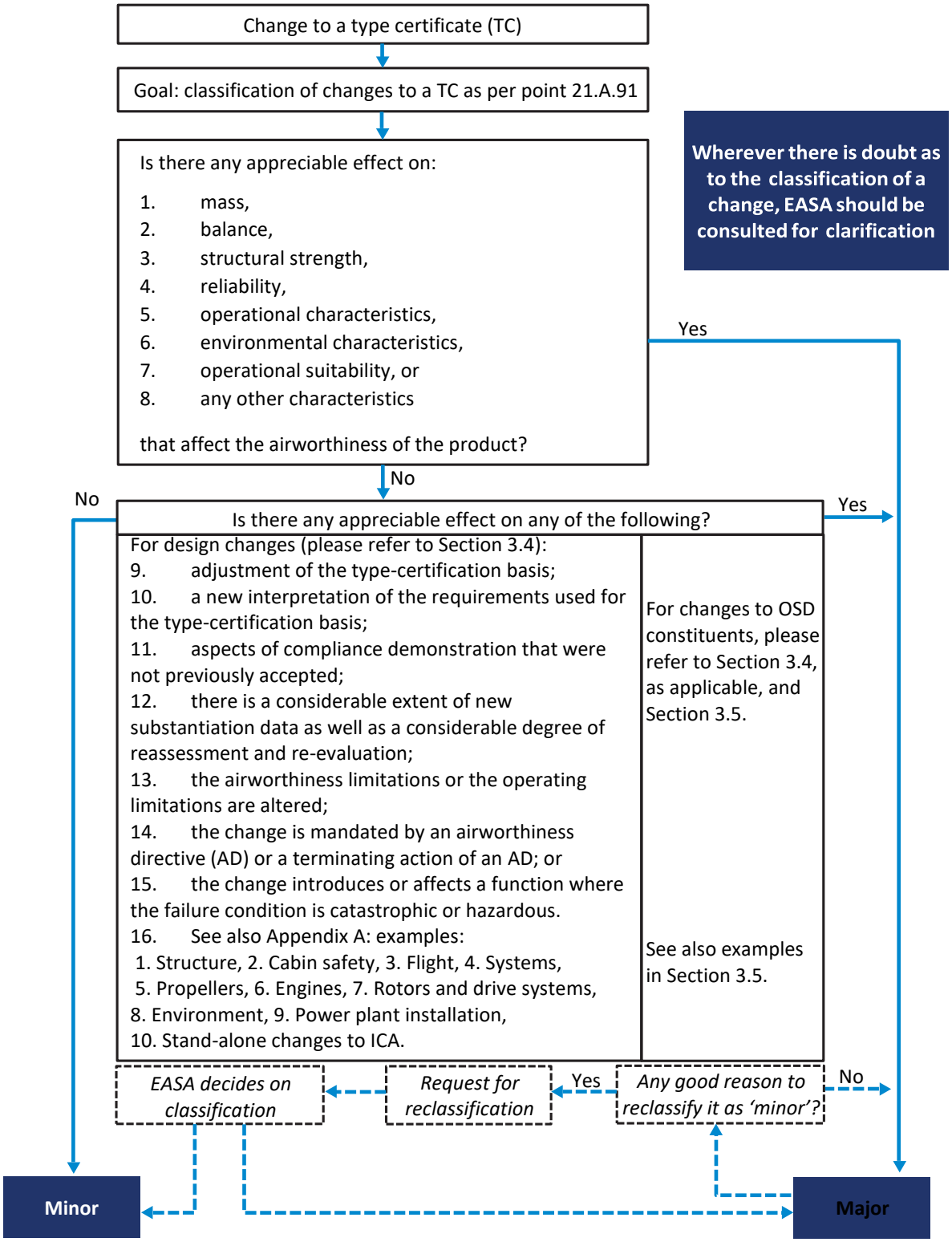
10. Stand-alone changes to non-ALS ICA that require additional work to demonstrate compliance with the applicable certification basis as follows:

(i) changes related to accomplishment instructions (e.g. to the aircraft maintenance manual) related to the CDCCL, or the EWIS ICA, for which the technical content (e.g. gaps, steps) of the procedures is changed;

(ii) the introduction of novel technology for inspection purposes related to an ALS task;

(iii) changes that adversely affect the certification assumptions: e.g. some specific inspection procedures, such as inspection procedures for use after a hard landing, may include a decision-making chart based on the level of exceedance of the load in comparison with the certified limit loads; such criteria, and adverse changes, need to be agreed with EASA.

Classification Process



21.A.92 Eligibility

Regulation (EU) No 69/2014

(a) Only the type-certificate holder may apply for approval of a major change to a type-certificate under this Subpart; all other applicants for a major change to a type-certificate shall apply under Subpart E.

(b) Any natural or legal person may apply for approval of a minor change to a type-certificate under this Subpart.

21.A.93 Application

Regulation (EU) 2021/699

(a) An application for approval of a change to a type-certificate shall be made in a form and manner established by the Agency.

(b) An application shall include, or be supplemented after the initial application by, a certification programme for the demonstration of compliance in accordance with point 21.A.20, consisting of:

1. a description of the change identifying:

   (i) the configuration(s) of the product in the type certificate upon which the change is to be made;

   (ii) all areas of the product in the type-certificate, including the approved manuals, that are changed or affected by the change; and

   (iii) when the change affects the operational suitability data, any necessary changes to the operational suitability data;

2. an identification of any reinvestigations necessary to demonstrate compliance of the change and areas affected by the change with the type-certification basis, operational suitability data certification basis and environmental protection requirements; and

3. for a major change to a type-certificate:

   (i) a proposal for the initial type-certification basis, operational suitability data certification basis and environmental protection requirements, prepared in accordance with the requirements and options specified in point 21.A.101;

   (ii) a proposal for a breakdown of the certification programme into meaningful groups of compliance demonstration activities and data, including a proposal for the means of compliance and related compliance documents;

   (iii) a proposal for the assessment of the meaningful groups of compliance demonstration activities and data, addressing the likelihood of an unidentified non-compliance with the type-certification basis, operational suitability data certification basis or environmental protection requirements and the potential impact of that non-compliance on product safety or environmental protection. The proposed assessment shall take into account at least the elements set out in subpoints (1)–(4) of point 21.B.100(a). Based on this assessment, the application shall include a proposal for the Agency's involvement in the verification of the compliance demonstration activities and data; and

   (iv) a project schedule including major milestones.

(c) An application for a change to a type-certificate of a large aeroplane or a large rotorcraft shall be valid for five years and an application for a change to any other type-certificate shall be valid for three years. In the case where the change has not been approved, or it is evident that it will not be approved, within the time limit provided for in this point, the applicant may:

1. submit a new application for a change to the type-certificate and comply with the type-certification basis, operational suitability data certification basis and environmental protection requirements, as established by the Agency in accordance with point 21.A.101 and notified in accordance with point 21.B.105 for the date of the new application; or

2. apply for an extension of the time period provided for in the first sentence of point (c) for the original application and propose a new date for the issuance of the approval. In that case, the applicant shall comply with the type-certification basis, operational suitability data certification basis and environmental protection requirements, as established by the Agency in accordance with point 21.A.101 and notified in accordance with point 21.B.105, for a date to be selected by the applicant. However, that date shall not precede the new date proposed by the applicant for the issuance of the approval by more than five years for an application for a change to type-certificate or restricted type-certificate for a large aeroplane or a large rotorcraft, and by more than three years for an application for a change to any other type-certificate or restricted type certificate.

AMC 21.A.93(a) Form and manner

ED Decision 2019/018/R

The applicant should file an application using the web-based 'EASA Applicant Portal'[1] or the application forms for the approval of major changes/major repair designs (FO.CERT.00031)[2] or for the approval of minor changes/minor repair designs (FO.CERT.00032)[3], which may be downloaded from the EASA website.

The forms should be completed in accordance with the instructions embedded at the bottom of the application forms, and sent to EASA by fax, email or regular mail following the information provided on the EASA website[4].

AMC 21.A.93(b) Certification programme for a change to a TC or an STC

ED Decision 2019/018/R

The description of the change should include an explanation of the purpose of the change, the pre-modification and post-modification configuration(s) of the product, schematics/pictures, and any other detailed features and boundaries of the physical change (this may be supplemented by drawings or outlines of the design, if this helps to understand the design change), as well as the identification of the changes in areas of the product that are functionally affected by the change, and the

[1] https://ap.easa.europa.eu (changes to the link provided may not be reflected in this document).

[2] https://www.easa.europa.eu/document-library/application-forms/focert00031 (changes to the link provided may not be reflected in this document).

[3] https://www.easa.europa.eu/document-library/application-forms/focert00032 (changes to the link provided may not be reflected in this document).

[4] https://www.easa.europa.eu/document-library/application-forms/certificates-and-approvals (changes to the link provided may not be reflected in this document).

identification of any changes to the approved manuals. Guidance on areas that are changed and affected by the change is found in GM 21.A.101, Section 3.9.1.

Identification of reinvestigations referred to in point 21.A.93(b)(2), necessary to demonstrate compliance, does not mean the demonstration of compliance itself, but the list of affected items of the applicable certification basis for which a new demonstration is necessary, together with the means (e.g. calculation, test or analysis) by which it is proposed to demonstrate compliance.

Before submitting the application for a change, the analysis and classification activities of points 21.A.91 and 21.A.101 should be performed using the corresponding GM. For repair designs, the analysis of point 21.A.91 should be performed using GM 21.A.435(a).

For a major change, AMC 21.A.15(b) should be used as applicable to the change.

GM No 1 to 21.A.93(b)(1)(iii) Interaction of changes to the type design and changes to operational suitability data (OSD)

ED Decision 2019/018/R

In general, it has to be assumed that changes to the type design can have an effect on the OSD.

Due to the alleviating nature of the OSD constituent master minimum equipment list (MMEL), the impact of design changes on the MMEL can be treated differently from the impact on other OSD constituents. Therefore, a separate GM No 2 to 21.A.93(b)(1)(iii) is available to explain the interaction between design changes and the MMEL. The following guidance is, therefore, only applicable to the other OSD constituents: flight crew data (FCD), cabin crew data (CCD), simulator data (SIMD), and maintenance certifying staff data (MCSD).

In assessing the interactions between the changes to the type design and to the OSD, the following can be taken into consideration (see Figure 1):

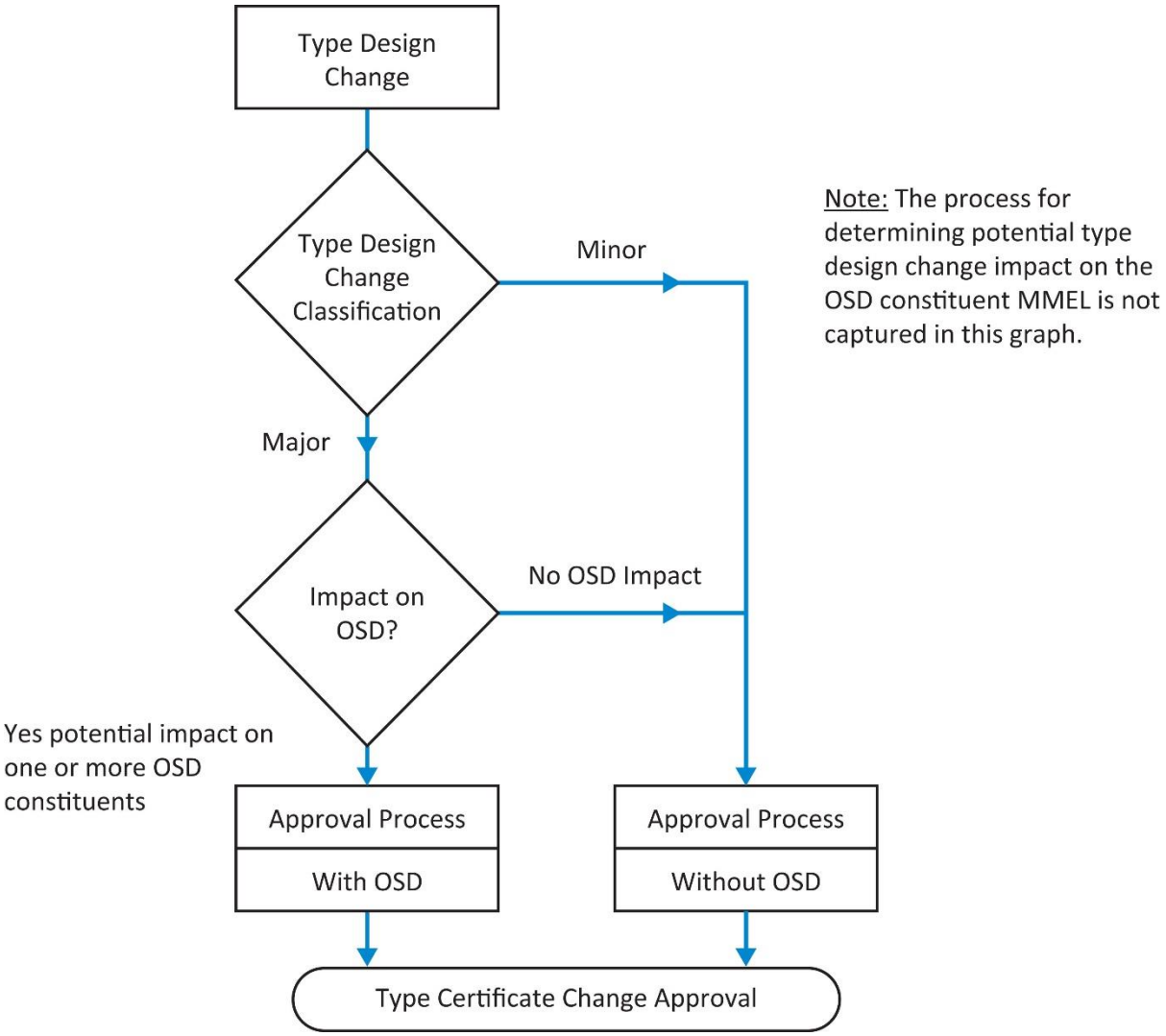


Figure 1

(a) Changes to the type certificate (TC) that only include a minor change to the type design ('stand-alone' type design changes) do not have an effect on the OSD. No dedicated assessment of the effects of the minor type design change on the OSD is needed in this case.

(b) TC changes that only include a major type design change do not need to be assessed for their effect on the OSD in case the experience of the applicant has demonstrated that similar changes do not have an effect on the OSD. Examples of major type design changes and their expected effect on OSD constituents are identified in Table 1 below.

Table 1: Examples of major type design changes and their expected impact on OSD constituents

Discipline	Example of major type design change	Expected impact on OSD constituent			
		FCD	SIMD	CCD	MCSD
Structure	(i) Changes such as a cargo door cut-out, fuselage plugs, change to dihedral, addition of floats.	No	No	No	tbd[1]
	(ii) Changes to material, processes or methods of manufacture, or to primary structural elements such as spars, frames and critical parts.	No	No	No	tbd
	(iii) Changes that adversely affect fatigue or damage tolerance or life limit characteristics.	No	No	No	tbd
	(iv) Changes that adversely affect aeroelastic characteristics.	No	No	No	tbd
	(v) Aircraft weight changes such as maximum zero fuel weight (MZFW) changes or reduction in maximum take-off weight (MTOW) for operational considerations.	No	No	No	No
Cabin safety	(i) Changes which introduce a new cabin layout of a sufficient extent to require a reassessment of the emergency evacuation capability, or which adversely affect other aspects of passenger or crew safety in aeroplanes with more than 19 passenger seats.	No	No	Yes, potential impact	No
	(ii) Changes which introduce new cabin layout of a sufficient extent to require a reassessment of the emergency evaluation capability, or which adversely affect other aspects of passenger or crew safety in aeroplanes with 19 or less passenger seats.	No	No	No (unless assessment identifies need for CCD	No
	(iii) Installation of observer seat.	No	No	Yes, potential impact	No
Flight	(i) Software changes that do not affect the pilot interface.	No	No	No	No
	(ii) Software changes that affect the pilot interface.	Yes, potential impact	No	No	No
Systems	(i) Updating the aircraft cockpit voice recorder (CVR) or flight data recorder (FDR) to meet a later standard.	No	No	No	No

[1] To be determined under rulemaking task RMT.0106 (21.039(e)).

Discipline	Example of major type design change	Expected impact on OSD constituent			
		FCD	SIMD	CCD	MCSD
Propellers	(i) Changes to: — diameter, — aerofoil, — planform, — material, and — blade retention system.	No	No	No	No
Engines	(i) Power limit change	No	No	No	No
Rotors and drive systems	*[Reserved]*				
Environment	(i) A change that introduces either an increase in the noise certification level(s) or a reduction in the noise certification level(s) for which the applicant wishes to take credit.	No	No	No	No
Power plant installation	(i) Modifications to the fuel system and tanks (number, size, or configuration)	No	No	No	tbd
Avionics	Comprehensive flight deck upgrade, such as conversion from entirely-federated, independent electromechanical flight instruments to highly-integrated and combined electronic display systems with extensive use of software and/or complex electronic hardware	Yes, potential impact	No	No	tbd

(c) Design changes to aircraft for which OSD is not required in accordance with Article 7(a)(2) of Regulation (EU) No 748/2012, as amended by Regulation (EU) No 69/2014, cannot trigger the need to establish OSD.

(d) The OSD constituents SIMD and MCSD were not required to be included in the 'catch-up' OSD in accordance with Article 7(a)(2) of Regulation (EU) No 748/2012, as amended by Regulation (EU) No 69/2014. No design change can trigger the need to add that constituent.

(e) When the design change makes an OSD constituent applicable (see GM No 1 to 21.A.15(d) – Clarification of the applicability of operational suitability data (OSD) constituents) where it was not applicable before, that OSD constituent should be added to the application for the approval of the change to the TC.

GM No 2 to 21.A.93(b)(1)(iii) Interaction of changes to the type design and changes to the master minimum equipment list (MMEL)

ED Decision 2019/018/R

In general, it has to be assumed that changes to the type certificate (TC) that affect the type design can have an effect on the MMEL.

Due to its alleviating nature, the MMEL is developed to improve aircraft use, thereby providing a more convenient and economical air transportation for the public.

Therefore, not introducing MMEL relief for new equipment, system or function has no effect on the safety of the operation. The introduction of MMEL relief for new equipment can, therefore, be treated as a stand-alone MMEL change, separately from the design change, and can be processed at a later date than the date of entry into service of the aircraft including the design change.

Not modifying an MMEL item whose validity is altered by a type design modification may, however, have an effect on the safety of the operation. The applicant for a change to the TC that changes the type design should, therefore, identify whether this change needs to be supplemented by a change to the MMEL. However, the update of an MMEL relief for an already addressed equipment, system or function can be treated at a later date than the date of entry into service of the aircraft including the design change, provided that the change to the MMEL is of an alleviating nature. When the change to the MMEL is not of an alleviating nature, it has to be approved according to point 21.A.97(b)(2) and (c).

It may be assumed that a change to the type design requires a change to the MMEL if any of the following conditions are fulfilled:

(a) the change affects an existing MMEL item in a more restrictive manner: there is a change to equipment, system or function linked to an MMEL item, or a change to the operational limitations and procedures linked to an MMEL item;

(b) the change invalidates the assumptions used to justify an existing MMEL item, and requires a more restrictive MMEL item; and

(c) the change invalidates any dispatch conditions of the MMEL.

Examples of the above three conditions, where no change to the MMEL is required:

(a) introduction of new equipment, system or function in the type design;

(b) the change has no adverse impact on the qualitative and quantitative assessment used to justify an MMEL item; and

(c) the dispatch conditions do not need to be more restrictive if the current intent of (o) or (m) procedures (as referred in CS MMEL.125) is not impacted.

The following diagram summarises the interaction between type design changes and changes to MMEL (see Figure 1).

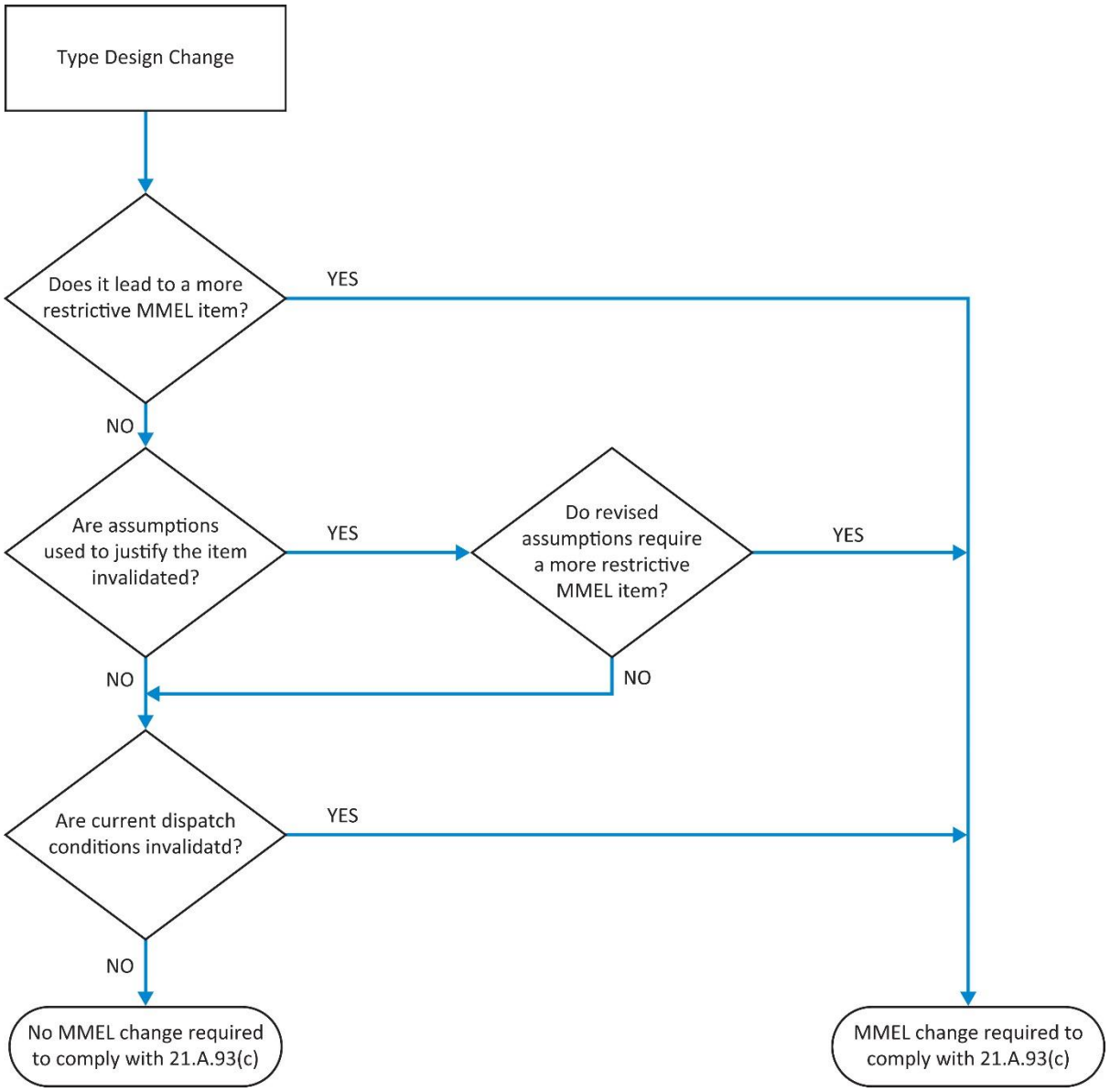


Figure 1

GM 21.A.93(c) Period of validity for the application

ED Decision 2019/018/R

For guidance on the determination of the period of validity for the application, refer to GM 21.A.15(e) and (f).

21.A.95 Requirements for approval of a minor change

Regulation (EU) 2019/897

(a) Minor changes to a type-certificate shall be classified and approved by:

1. the Agency; or
2. an approved design organisation within the scope of its privileges provided for in points (1) and (2) of point 21.A.263(c), as recorded in the terms of approval.

(b) A minor change to a type-certificate shall only be approved:

1. when it has been demonstrated that the change and areas affected by the change comply with the type-certification basis and the environmental protection requirements incorporated by reference in the type-certificate;
2. in the case of a change affecting the operational suitability data, when it has been demonstrated that the necessary changes to the operational suitability data comply with the operational suitability data certification basis incorporated by reference in the type-certificate;
3. when compliance with the type-certification basis that applies in accordance with point (1) has been declared and the justifications of compliance have been recorded in the compliance documents; and
4. when no feature or characteristic has been identified that may make the product unsafe for the uses for which certification is requested.

(c) By derogation from point (1) in point (b), certification specifications which became applicable after those incorporated by reference in the type-certificate can be used for approval of a minor change, provided they do not affect the demonstration of compliance.

(d) By derogation from point (a), at the applicant's request included in the declaration referred to in point 21.A.20(d), a minor change to an aircraft type-certificate may be approved before compliance with the operational suitability data certification basis has been demonstrated, provided that the applicant demonstrates such compliance before the date at which those data are actually used.

(e) The applicant shall submit to the Agency the substantiation data for the change and a statement that compliance has been demonstrated in accordance with point (b).

(f) An approval of a minor change to a type-certificate shall be limited to the specific configuration(s) in the type-certificate to which the change relates.

AMC 21.A.95 Requirements for the approval of a minor change

ED Decision 2019/018/R

(a) Applicability of point 21.A.95

Point 21.A.95 has to be complied with by applicants for the approval of a minor change to a type certificate (TC), and by design organisation approval (DOA) holders that approve minor changes under their own privileges.

Point 21.A.95(e), however, only applies to projects for which an application is submitted to EASA. For DOA holders that approve minor changes under their privileges, the substantiating data and the statement of compliance required by point 21.A.95(e) should be produced but do not need to be submitted to EASA. They should be, however, kept on record and submitted to EASA on request during its DOA continued surveillance process.

(b) The approval process

The approval process comprises the following steps:

Note: Steps 1, 2 and 5 should be followed only by applicants for minor changes approved by EASA. DOA holders that approve minor changes under their privileges should refer to AMC No 1 to 21.A.263(c)(2) or AMC No 2 to 21.A.263(c)(2), as applicable to their approval process.

(1) Application

When the minor change is approved by EASA, an application should be submitted to EASA as described in point 21.A.93(a) and (b) and in AMC 21.A.93(a).

(2) Certification programme

The certification programme should consist of the information defined in points 21.A.93(b)(1) and 21.A.93(b)(2). Please refer to AMC 21.A.93(b) for further information.

(3) Certification basis

(4) Demonstration of compliance

(5) Statement of compliance

(c) Certification basis

The certification basis for a minor change consists of a subset of the elements of the product's certification basis 'incorporated by reference in the type certificate' (see also the additional guidance below on the meaning of certification specifications that became applicable after those 'incorporated by reference in the type certificate'), which have been identified in accordance with point 21.A.93(b)(2) due to a reinvestigation of compliance being necessary because compliance was affected by the minor change (see also additional guidance below on the meaning of 'specific configurations').

The certification basis 'incorporated by reference in the type certificate' is the certification basis for the product as recorded in the type certificate data sheet (TCDS) for the product type/model in the configuration(s) identified in accordance with point 21.A.93(b)(1)(i).

The certification basis contains the applicable airworthiness and (for aircraft only) operational suitability data certification specifications (CS-OSD), environmental protection requirements specified by reference to their amendment level, as complemented by special conditions, equivalent safety findings, deviations, an 'elect to comply', etc., as applicable. See also the additional guidance below on the meaning of 'Minor changes affecting OSD constituents'.

By derogation from the above, CSs that became applicable after those incorporated by reference in the TC may be used for the approval of a minor change (see the guidance below on certification specifications that became applicable after those 'incorporated by reference in the type certificate').

If other changes are required for the embodiment of the minor change, the certification basis corresponding to the product modified by these other changes should also be considered when determining the certification basis for the minor change.

(d) Demonstration of compliance required by point 21.A.95(b)(1) and (2)

The applicant needs to demonstrate compliance with the certification basis established for the minor change for all areas that are either physically changed or functionally affected by the minor change.

(1) Means of compliance: the applicant should define and record the means (calculation, test or analysis, etc.) by which compliance is demonstrated. Appendix A to AMC 21.A.15(b) may be used to describe how compliance is demonstrated.

(2) Compliance documents: the compliance demonstration should be recorded in compliance documents. For minor changes, one comprehensive compliance document may be sufficient, provided that it contains evidence of all aspects of the compliance demonstration. AMC 21.A.20(c) can also be used, where applicable.

See also the additional guidance in item (e).

(3) Aircraft manuals: where applicable, supplements to manuals (e.g. aircraft flight manual (AFM), aircraft maintenance manual (AMM), etc.) may be issued.

See also additional guidance below on embodiment/installation instructions (item (f)).

(e) Definition of the change to the type certificate

The change to the type certificate should be defined in accordance with GM 21.A.90A.

(f) Embodiment/installation instructions

The instructions for the embodiment/installation of the change (e.g. service bulletin, modification bulletin, production work order, etc.) should be defined. This may include the installation procedure, the required material, etc.

(g) Minor changes affecting OSD constituents (i.e. master minimum equipment list (MMEL))

Some minor changes to the type design may only have an effect on the MMEL (see GM No 1 to 21.A.93(b)(1)(iii)). In such cases, GM No 2 to 21.A.93(b)(1)(iii) is also applicable. This also means that a dedicated assessment of the effects of the minor type design change on the other OSD constituents is not needed.

(h) Meaning of 'specific configurations' in point 21.A.95(f)

These 'specific configurations' are defined as the combination of the product type/model (on which the minor change will be installed) with (if applicable) the list of those already approved changes (minor, major, supplemental type certificate (STC)) that are required for the installation of the minor change.

(i) Certification specifications that became applicable after those incorporated by reference in the type certificate

(1) Minor changes are those changes that do not affect the airworthiness of the product and thus are, by definition, non-significant as per point 21.A.101. This means that the certification basis for the minor change may consist of the items of the certification basis incorporated by reference in the TCDS of the product type/model, and normally it should not be necessary for a minor change to use certification specifications that became applicable after those that are incorporated by reference in the type certificate.

(2) On the other hand, the applicant may elect to use later amendments of the affected certification specifications for the compliance demonstration. This does not affect the classification of the change; however, the applicant should also comply with any other certification specifications that EASA considers to be directly related.

(3) If other changes are required for the installation of the minor change (as explained in 'specific configurations'), the certification basis for the minor change should also take into account the corresponding certification basis.

(j) Meaning of 'no feature or characteristics' in point 21.A.95(b)(4)

See GM 21.A.20(d).

GM 21.A.95(b) Requirements for the approval of a minor change

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The level of detail of the documents that are referred to in 21.A.93(b) should be the same regardless of whether the change is approved by EASA or under a design organisation approval (DOA) privilege, to allow the change to be assessed in the frame of the DOA surveillance.

GM 21.A.21(b), 21.A.95(c), 21.A.97(c), 21.A.115(c), 21.B.103(b), 21.B.107(b) and 21.B.111(b) Approval of operational suitability data (OSD)

ED Decision 2019/018/R

It is acknowledged that it may not always be possible to have the OSD available on the date of the issue of the (restricted) type certificate ((R)TC), change approval or supplemental type certificate (STC). The derogation provided by 21.A.21(b), 21.A.95(c), 21.A.97(c), 21.A.115(c), 21.B.103(b), 21.B.107(b) and 21.B.111(b) is intended for that case. The (R)TC, change approval or STC can be issued before compliance with the OSD certification basis has been demonstrated.

However, the OSD needs to be approved before the data is used by a training organisation for the purpose of obtaining a European Union (EU) licence, rating or attestation, or by an EU operator. This is normally done before the entry into service of the first aircraft by an EU operator but it could also be done later for some of the OSD constituents, such as the definition of the scope of validation source data to support the objective qualification of a simulator, which should only be available when a simulator has to be qualified.

The derogation provided in points 21.A.97(c), 21.A.115(c), 21.B.103(b), 21.B.107(b), and 21.B.111(b) is applicable to all major changes to a TC, so it is also applicable to minor design changes when triggering a major master minimum equipment list (MMEL) change, as well as to changes in which at least one of the OSD constituent changes is major.

21.A.97 Requirements for approval of a major change

Regulation (EU) 2019/897

(a) Major changes to a type-certificate shall be classified and approved by:

1. the Agency; or
2. an approved design organisation within the scope of its privileges provided for in points (1) and (8) of point 21.A.263(c), as recorded in the terms of approval.

(b) A major change to a type-certificate shall only be approved:

1. when it has been demonstrated that the change and areas affected by the change comply with the type-certification basis and environmental protection requirements, as established by the Agency in accordance with point 21.A.101;

2. in the case of a change affecting the operational suitability data, when it has been demonstrated that the necessary changes to the operational suitability data meet the operational suitability data certification basis, as established by the Agency in accordance with point 21.A.101; and

3. when compliance with points (1) and (2) has been demonstrated in accordance with point 21.A.20, as applicable to the change.

(c) By derogation from points (2) and (3) of point (b), at the applicant's request included in the declaration referred to in point 21.A.20(d), a major change to an aircraft type-certificate may be approved before compliance with the operational suitability data certification basis has been demonstrated, provided that the applicant demonstrates such compliance before the date at which those data are actually used.

(d) An approval of a major change to a type-certificate shall be limited to the specific configuration(s) in the type-certificate to which the change relates.

AMC 21.A.97 Requirements for the approval of a major change

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1. For major changes approved by EASA, the applicant should use all the AMC 21.A.20(c), as well as the GM 21.A.20.

2. For the application of point 21.A.97(c), see GM 21.A.21(b), 21.A.95(c), 21.A.97(c), 21.A.115(c), 21.B.103(b), 21.B.107(b) and 21.B.111(b).

3. In accordance with point 21.A.97(c), the compliance demonstration process always takes into account the specific configuration(s) in the type certificate (TC) to which the major change under approval is applied. These configurations may be defined by type models/variants or by design changes to the type design. The demonstration of compliance covers these applicable specific configurations. Consequently, the approval of the major change excludes any other configurations, in particular those that already exist but are not considered in the compliance demonstration process, as well as those that may be certified in future.

4. For major changes approved by the design organisation approval (DOA) holder on the basis of their privilege as per point 21.A.263(c)(8), the process described under AMC No 2 to 21.A.263(c)(5), (8) and (9) applies.

GM 21.A.97(b) Requirements for the approval of a major change

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The level of detail of the documents that are referred to in 21.A.93(b) should be the same regardless of whether the change is approved by EASA or under a design organisation approval (DOA) privilege, to allow the change to be assessed in the frame of the DOA surveillance.

GM 21.A.21(b), 21.A.95(c), 21.A.97(c), 21.A.115(c), 21.B.103(b), 21.B.107(b) and 21.B.111(b) Approval of operational suitability data (OSD)

ED Decision 2019/018/R

It is acknowledged that it may not always be possible to have the OSD available on the date of the issue of the (restricted) type certificate ((R)TC), change approval or supplemental type certificate (STC). The derogation provided by 21.A.21(b), 21.A.95(c), 21.A.97(c), 21.A.115(c), 21.B.103(b), 21.B.107(b) and 21.B.111(b) is intended for that case. The (R)TC, change approval or STC can be issued before compliance with the OSD certification basis has been demonstrated.

However, the OSD needs to be approved before the data is used by a training organisation for the purpose of obtaining a European Union (EU) licence, rating or attestation, or by an EU operator. This is normally done before the entry into service of the first aircraft by an EU operator but it could also be done later for some of the OSD constituents, such as the definition of the scope of validation source data to support the objective qualification of a simulator, which should only be available when a simulator has to be qualified.

The derogation provided in points 21.A.97(c), 21.A.115(c), 21.B.103(b), 21.B.107(b), and 21.B.111(b) is applicable to all major changes to a TC, so it is also applicable to minor design changes when triggering a major master minimum equipment list (MMEL) change, as well as to changes in which at least one of the OSD constituent changes is major.

21.A.101 Type-certification basis, operational suitability data certification basis and environmental protection requirements for a major change to a type-certificate

Regulation (EU) 2022/201

(a) A major change to a type-certificate and areas affected by the change shall comply with either the certification specifications applicable to the changed product on the date of the application for the change or certification specifications which became applicable after that date in accordance with point (f) below. The validity of the application shall be determined in accordance with point 21.A.93(c). In addition, the changed product shall comply with the environmental protection requirements designated by the Agency in accordance with point 21.B.85.

(b) Except as provided in point (h), by derogation from point (a), an earlier amendment to a certification specification referred to in point (a) and to any other certification specification which is directly related may be used in any of the following situations, unless the earlier amendment became applicable before the date at which the corresponding certification specifications incorporated by reference in the type-certificate became applicable:

1. a change that the Agency finds not to be significant. In determining whether a specific change is significant, the Agency shall consider the change in the context of all previous relevant design changes and all related revisions to the applicable certification specifications incorporated by reference in the type-certificate for the product. Changes meeting one of the following criteria shall automatically be considered significant:

   (i) the general configuration or the principles of construction are not retained;

   (ii) the assumptions used for certification of the product to be changed do not remain valid;

2. each area, system, part or appliance that the Agency finds not affected by the change;

3. each area, system, part or appliance that is affected by the change for which the Agency finds that compliance with the certification specifications referred to in point (a) does not contribute materially to the level of safety of the changed product or is impractical.

(c) By derogation from point (a), in the case of a change to an aircraft other than a rotorcraft of 2 722 kg (6 000 lb) or less maximum weight, or to a non-turbine rotorcraft of 1 361 kg (3 000 lb) or less maximum weight, the change and areas affected by the change shall comply with the type-certification basis incorporated by reference in the type-certificate. However, if the Agency finds that the change is significant in an area, the Agency may require that the change and areas affected by the change comply with an amendment to a certification specification of the type-certification basis incorporated by reference in the type-certificate and with any other certification specification which is directly related, unless the Agency also finds that compliance with that amendment does not contribute materially to the level of safety of the changed product or is impractical.

(d) If the Agency finds that the certification specifications applicable on the date of the application for the change do not provide adequate standards with respect to the proposed change, the change and areas affected by the change shall also comply with any special conditions, and amendments to those special conditions, prescribed by the Agency in accordance with point 21.B.75, to provide a level of safety equivalent to that established by the certification specifications applicable on the date of the application for the change.

(e) By derogation from points (a), (b) and (c), the change and areas affected by the change may comply with an alternative to a certification specification designated by the Agency if proposed by the applicant, provided that the Agency finds that the alternative provides a level of safety which is:

1. in the case of a type-certificate:

   (i) equivalent to that of the certification specifications designated by the Agency under (a), (b) or (c) above; or

   (ii) compliant with the essential requirements of Annex II to Regulation (EU) 2018/1139;

2. in the case of a restricted type-certificate, adequate with regard to the intended use.

(f) If an applicant chooses to comply with a certification specification set out in an amendment that becomes applicable after submitting the application for a change to a type-certificate, the change and areas affected by the change shall also comply with any other certification specification which is directly related.

(g) When the application for a change to a type-certificate for an aircraft includes, or is supplemented after the initial application to include, changes to the operational suitability data, the operational suitability data certification basis shall be established in accordance with points (a)-(f).

(h) For large aeroplanes subject to point 26.300 of Annex I to Commission Regulation (EU) 2015/640[1], the applicant shall comply with certification specifications that provide at least an equivalent level of safety to points 26.300 and 26.330 of Annex I to Regulation (EU) 2015/640, except for applicants for supplemental type-certificates who are not required to take into account point 26.303.

GM 21.A.101 Establishing the certification basis of changed aeronautical products

ED Decision 2019/018/R

Foreword

This guidance material (GM) provides guidance for the application of the 'Changed Product Rule (CPR)', pursuant to point 21.A.101, *Designation of the applicable certification specifications and environmental protection requirements*, and 21.A.19, *Changes requiring a new type certificate*, for changes made to type-certified aeronautical products.

1. INTRODUCTION

1.1. Purpose.

This GM provides guidance for establishing the certification basis for changed aeronautical products pursuant to point 21.A.101, *Designation of the applicable certification specifications and environmental protection requirements*. The guidance is also intended to help applicants and approved design organisations to determine whether it will be necessary to apply for a new type certificate (TC) under point 21.A.19, *Changes requiring a new type certificate*. The guidance describes the process for establishing the certification basis for a change to a TC, for a supplemental type certificate (STC), or for a change to an STC, detailing the requirements (evaluations, classifications, and decisions) throughout the process.

1.2. Applicability.

1.2.1 This GM is for an applicant that applies for changes to TCs under Subpart D, for STCs, or changes to STCs under Subpart E, or for changes to European Technical Standard Order Authorisations (ETSOAs) for auxiliary power units (APUs) under Subpart O. This GM is also for approved design organisations that classify changes and approve minor changes under their 21.A.263(c)(1) and (2) privileges.

1.2.2 This GM applies to major changes under point 21.A.101 for aeronautical products certified under Part 21, and the certification specifications (CSs) applicable to the changed product (CS-23, CS-25, CS-27, CS-29, CS-MMEL, CS-FCD, CS-CCD, etc.). References to 'change' include the change and areas affected by the change pursuant to point 21.A.101.

1.2.3 Minor changes are within the scope of 21.A.101 and this GM but are automatically considered to not be significant under the 'does not contribute materially to the level of safety' provision of point 21.A.101(b).

1.2.4 This GM also applies to changes to restricted type certificates.

[1] Commission Regulation (EU) 2015/640 of 23 April 2015 on additional airworthiness specifications for a given type of operations and amending Regulation (EU) No 965/2012 (OJ L 106, 24.4.2015, p. 18).

1.2.5 The term ‘aeronautical product’, or ‘product’, means a type-certified aircraft, aircraft engine, or propeller and, for the purpose of this GM, an ETSOA’d APU.

1.2.6 This GM primarily provides guidance for the designation of applicable airworthiness certification specifications and other airworthiness standards for the type-certification basis for the changed product. However, portions of this GM, as specified in GM1 21.A.101(g), can be applied by analogy to establish the operational suitability data (OSD) certification basis for the changed product. This GM is not intended to be used to determine the applicable environmental protection requirements (aircraft noise, fuel venting, and engine exhaust emissions and aeroplane CO_2 emissions requirements) for changed products, as they are designated through point 21.B.85.

1.2.7 This GM is not mandatory and is not an EU regulation. This GM describes an acceptable means, but not the only means, to comply with point 21.A.101. However, an applicant who uses the means described in this GM must follow it entirely.

1.3. Reserved.

1.4. GM Content

This GM contains 5 chapters and 10 appendices.

1.4.1 This chapter clarifies the purpose of this GM, describes its content, specifies the intended audience affected by this GM, clarifies which changes are within the scope of this GM, and references the definitions and terminology used in this GM.

1.4.2 Chapter 2 provides a general overview of points 21.A.101 and 21.A.19, clarifies the main principles and safety objectives, and directs an applicant to the applicable guidance contained in subsequent chapters of this GM.

1.4.3 Chapter 3 contains guidance for the implementation of point 21.A.101(b) to establish the certification basis for changed aeronautical products. It describes in detail the various steps for developing the certification basis, which is a process that applies to all changes to aeronautical products. Chapter 3 also addresses the point 21.A.19 considerations for identifying the conditions under which an applicant for a change is required to submit an application for a new TC, and it provides guidance regarding the stage of the process at which this assessment is performed.

1.4.4 Chapter 4 provides guidance about products excepted from the requirement of point 21.A.101(a).

1.4.5 Chapter 5 contains considerations for:

— design-related operating requirements,

— defining a baseline product,

— predecessor standards,

— using special conditions under point 21.A.101(d),

— documenting revisions to the TC basis,

— incorporating STCs into the type design,

— removing changes,

— determining a certification basis after removing an approved change, and

— sequential changes.

1.4.6 Appendix A contains examples of typical type design changes for small aeroplanes, large aeroplanes, rotorcraft, engines, and propellers. The European Union Aviation Safety Agency (EASA) has categorised these examples into individual tables according to the classifications of design change: 'substantial', 'significant', and 'not significant'.

1.4.7 Appendix B contains application charts for applying the point 21.A.101 process, including the excepted process.

1.4.8 Appendix C contains one method for determining the changed and affected areas of a product.

1.4.9 Appendix D contains additional guidance on affected areas that is not discussed in other parts of this GM.

1.4.10 Appendix E provides detailed guidance with examples for evaluating the 'impracticality' exception in the rule.

1.4.11 Appendix F provides guidance with examples on the use of relevant service experience in the certification process as one way to demonstrate that a later amendment may not contribute materially to the level of safety, allowing the use of earlier certification specifications.

1.4.12 Appendix G provides an example CPR decision record.

1.4.13 Appendix H provides examples of documenting a proposed certification basis list.

1.4.14 Appendix I lists the Part 21 points related to this GM.

1.4.15 Appendix J lists the definitions and terminology applicable for the application of the rule.

1.5. Terms Used in this GM.

1.5.1 The following terms are used interchangeably and have the same meaning: 'specifications', 'standards', 'certification specifications' and 'certification standards'. They refer to the elements of the type-certification basis for airworthiness or OSD certification basis.

1.5.2 The term 'certification basis' refers to the type-certification basis for airworthiness provided for in point 21.B.80 and the operational suitability data (OSD) certification basis provided for in point 21.B.82.

For more terms, consult Appendix J.

2. OVERVIEW OF POINTS 21.A.19 AND 21.A.101

2.1. Point 21.A.19.

2.1.1 Point 21.A.19 requires an applicant to apply for a new TC for a changed product if EASA finds that the change to the design, power, thrust, or weight is so extensive that a substantially complete investigation of compliance with the applicable type-certification basis is required.

2.1.2 Changes that require a substantial re-evaluation of the compliance findings of the product are referred to as 'substantial changes'. For guidance, see paragraph 3.3 in Chapter 3 of this GM. Appendix A of this GM provides examples of changes that will require a new TC.

2.1.3 If EASA determines through point 21.A.19 that a proposed change does not require a new TC, see point 21.A.101 for the applicable requirements to develop the certification basis for the proposed change. For guidance, see Chapter 3 and the examples in Appendix A of this GM.

2.2. Point 21.A.101.

2.2.1 Point 21.A.101(a).

Point 21.A.101(a) requires a change to a TC, and the areas affected by the change to comply with the certification specifications that are applicable to the changed product and that are in effect on the date of application for the change (i.e. the latest certification standards in effect at the time of application), unless the change meets the criteria for the exceptions identified in point 21.A.101(b) or (c), or unless an applicant chooses to comply with the certification specifications of later effective amendments* in accordance with point 21.A.101(f). The intent of point 21.A.101 is to enhance safety by incorporating the latest requirements into the certification basis for the changed product to the greatest extent practicable.

*NOTE: Certification specifications that were amended after the date of application.

2.2.2 Point 21.A.101(b).

Point 21.A.101(b) pertains to when an applicant may show that a changed product complies with an earlier amendment of a certification specification, provided that the earlier amendment is considered to be adequate and meets the criteria in point 21.A.101(b)(1), (2), or (3). When changes involve features or characteristics that are novel and unusual in comparison with the airworthiness standard at the proposed amendment, more recent airworthiness standards and/or special conditions will be applied for these features.

An applicant is considered to comply with the earlier amendment of the certification specifications consistent with point 21.A.101(b), when:

(a) a change is not significant (see point 21.A.101(b)(1));

(b) an area, system, part or appliance is not affected by the change (see point 21.A.101(b)(2));

(c) compliance with a later amendment for a significant change does not contribute materially to the level of safety (see point 21.A.101(b)(3)); or

(d) compliance with the latest amendment would be impractical (see point 21.A.101(b)(3)).

Earlier amendments may not precede the amendment level of the certification basis of the identified baseline product.

Points 21.A.101(b)(1)(i) and (ii) pertain to changes that meet the automatic criteria where the change is significant.

2.2.3 Point 21.A.101(c).

Point 21.A.101(c) provides an exception from the requirements of point 21.A.101(a) for a change to certain aircraft with less than the specified maximum weight. An applicant who applies for a change to an aircraft (other than rotorcraft) of 2 722 kg (6 000 lb) or less maximum weight, or to a non-turbine-powered rotorcraft of 1 361 kg (3 000 lb) or less maximum weight, can show that the changed product complies with the standards incorporated by reference in the type certificate. An applicant can also elect to comply or may be required to comply with the later standards. See paragraph 4.1 of this GM for specific guidance on this provision.

2.2.4 Point 21.A.101(d).

Point 21.A.101(d) provides for the use of special conditions, under 21.B.75, when the proposed certification basis and any later certification specifications do not provide adequate standards for the proposed change because of a novel or unusual design feature.

2.2.5 Point 21.A.101(e).

Point 21.A.101(e) provides the legal basis under which an applicant may propose to certify a change and the areas affected by the change against alternative requirements to the certification specifications established by EASA.

2.2.6 Point 21.A.101(f).

Point 21.A.101(f) requires that if an applicant chooses (elects) to comply with a certification specification or an amendment to the certification specifications that is effective after the filing of the application for a change to a TC, the applicant shall also comply with any other certification specifications that EASA finds are directly related. The certification specifications which are directly related must be, for the purpose of compliance demonstration, considered together at the same amendment level to be consistent.

2.2.7 Point 21.A.101(g).

Point 21.A.101(g) pertains to the designation of the applicable OSD certification basis when the application for a change to a type certificate for an aircraft includes, or is supplemented after the initial application to include, changes to the OSD. It implies that the same requirements of paragraphs (a) and (f) that are applicable to the establishment of the airworthiness type-certification basis also apply to the establishment of the OSD certification basis. For specific guidance, see GM1 21.A.101(g).

3. PROCESS FOR ESTABLISHING THE CERTIFICATION BASIS FOR CHANGED PRODUCTS

3.1. Overview.

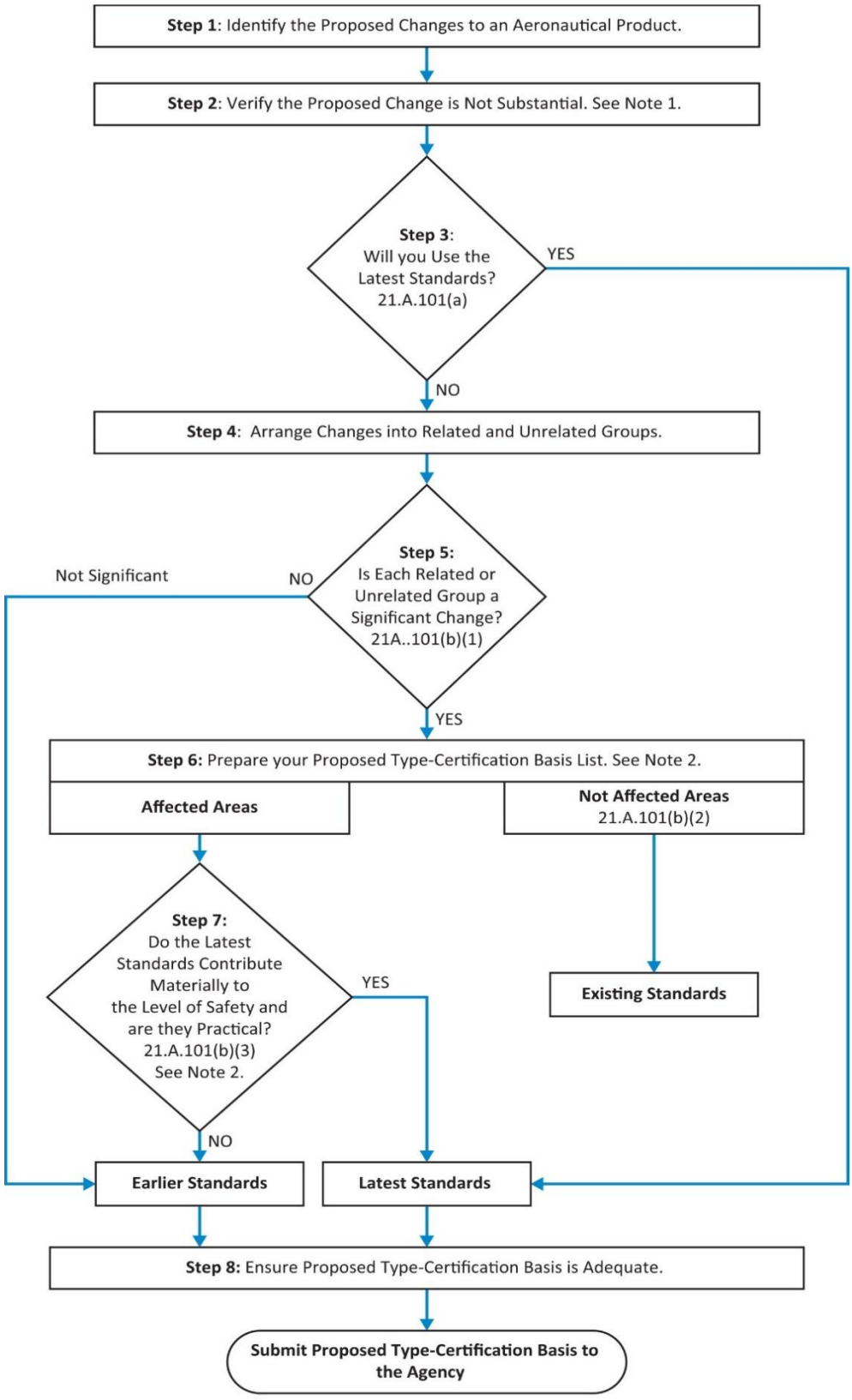
3.1.1 The applicant and EASA both have responsibilities under point 21.A.101(a) and (b). As an applicant for the certification of a change, the applicant must demonstrate that the change and areas affected by the change comply with the latest applicable certification specifications unless the applicant proposes exception(s) under point 21.A.101(b). An applicant proposing exception(s) should make a preliminary classification whether the change is ‘significant’ or ‘not significant’, and propose an appropriate certification basis. EASA is responsible for determining whether the applicant’s classification of the change, and proposal for the certification basis, are

consistent with the applicable rules and their interpretation. The EASA determination does not depend on whether the TC holder or applicant for an STC is originating the change. The certification basis can vary depending on the magnitude and scope of the change. The steps below present a streamlined approach for making this determination.

3.1.2 The tables in appendix A of this GM are examples of classifications of typical type design changes. See paragraph 3.6.3 of this chapter for instructions on how to use those tables.

3.1.3 If a proposed change is not in the examples provided in appendix A, the applicant may use the following steps in conjunction with the flow chart in Figure 3-1 of this GM to develop the appropriate certification basis for the change. For clarification, the change discussed in the flow chart also includes areas affected by the change. See paragraph 3.9.1 of this GM for guidance about affected areas.

Figure 3-1. Developing a Proposed Certification Basis for a Changed Product Pursuant to point 21.A.101



Notes:
1. Changed products that are substantially changed do not follow this flowchart. Refer to 21.A19.
2. Process and propose each applicable standard individually. If Standards are linked together, then they should be assessed together.

3.2. Step 1. Identify the proposed changes to an aeronautical product.

— Identify the type design being changed (the baseline product).

— Identify the proposed change.

— Use high-level descriptors.

3.2.1 **Identify the type design being changed (the baseline product)**.

Prior to describing the proposed change(s), it is important to clearly identify the specific type design configuration being changed.

Note: For additional guidance on the baseline product, see paragraph 5.3 of this GM.

3.2.2 **Identify the proposed change**.

3.2.2.1 The purpose of this process step is to identify and describe the change to the aeronautical product. Changes to a product can include physical design changes and functional changes (e.g. operating envelope or performance changes). An applicant must identify all changes and areas affected by the change, including those where they plan to use previously approved data. EASA considers all of these changes and areas affected by the change to be part of the entire proposed type design and they are considered as a whole in the classification of whether the proposed change is substantial, significant, or not significant. The change can be a single change or a collection of changes. In addition to the proposed changes, an applicant should consider the cumulative effect of previous relevant changes incorporated since the last time the certification basis was upgraded. An applicant for a change must consider all previous relevant changes and the amendment level of the certification specifications in the certification basis used for these changes.

3.2.2.2 When identifying the proposed changes, an applicant should consider previous relevant changes that create a cumulative effect, as these may influence the decisions regarding the classification of the change later in the process. By 'previous relevant changes,' EASA means changes where effects accumulate, such as successive thrust increases, incremental weight increases, or sectional increases in fuselage length. An applicant must account for any previous relevant changes to the area affected by the proposed change that did not involve an upgrade of the certification basis in the proposed change.

3.2.2.3 Example:

An applicant proposes a 5 per cent weight increase, but a previous 4 per cent and another 3 per cent weight increase were incorporated into this aircraft without upgrading the existing certification basis. In the current proposal for a 5 per cent weight increase, the cumulative effects of the two previous weight increases that did not involve an upgrade of the certification basis will now be accounted for as an approximate 12 per cent increase in weight. Note that the cumulative effects the applicant accounts for are only those incremental increases since the last time the airworthiness certification

specifications in the type-certification basis applicable to the area affected by the proposed change were upgraded.

3.2.3 Use High-Level Descriptors.

To identify and describe the proposed changes to any aeronautical product, an applicant should use a high-level description of the change that characterises the intent of, or the reason for, the change. No complex technical details are necessary at this stage. For example, a proposal to increase the maximum passenger-carrying capacity may require an addition of a fuselage plug, and as such, a 'fuselage plug' becomes one possible high-level description of this change. Similarly, a thrust increase, a new or complete interior, an avionics system upgrade, or a passenger-to-cargo conversion are all high-level descriptions that characterise typical changes to the aircraft, each driven by a specific goal, objective, or purpose.

3.2.4 Evolutionary changes that occur during the course of a certification program may require re-evaluation of the certification basis, and those changes that have influence at the product level may result in re-classification of the change.

3.3. Step 2. Verify the proposed change is not substantial.

3.3.1 Point 21.A.19 requires an applicant to apply for a new TC for a changed product if the change to design, power, thrust, or weight is so extensive that a substantially complete investigation of compliance with the applicable regulations is required. A new TC could be required for either a single extensive change to a previously type-certified product or for a changed design derived through the cumulative effect of a series of design changes from a previously type-certified product.

3.3.2 A 'substantially complete investigation' of compliance is required when most of the existing substantiation is not applicable to the changed product. In other words, an applicant may consider the change 'substantial' if it is so extensive (making the product sufficiently different from its predecessor) that the design models, methodologies, and approaches used to demonstrate a previous compliance finding could not be used in a similarity argument. EASA considers a change 'substantial' when these approaches, models, or methodologies of how compliance was shown are not valid for the changed product.

3.3.3 If it is not initially clear that a new TC is required, appendix A of this GM provides some examples of substantial changes to aid in this classification. A substantial change requires an application for a new TC. See points 21.B.80, 21.B.82, 21.B.85 and 21.A.19. If the change is not substantial, proceed to step 3.

3.4. Step 3. Will the applicant use the latest standards?

An applicant can use the latest certification specifications for their proposed change and the area affected by the change. If they use the latest certification specifications, they will have met the intent of point 21.A.101 and no further classification (significant or not significant) and justification is needed. Even though an applicant elects to use the latest certification specifications, the applicant will still be able to apply point 21.A.101 for future similar changes, and use the exceptions under point 21.A.101(b). However, the decision to comply with the latest certification specifications sets a new basis for all future related changes to the same affected area for that amended TC.

— If using the latest certification specifications, an applicant should proceed to Step 6 (in paragraph 3.9 of this GM).

— If not using the latest certification specifications, an applicant should proceed to Step 4 below.

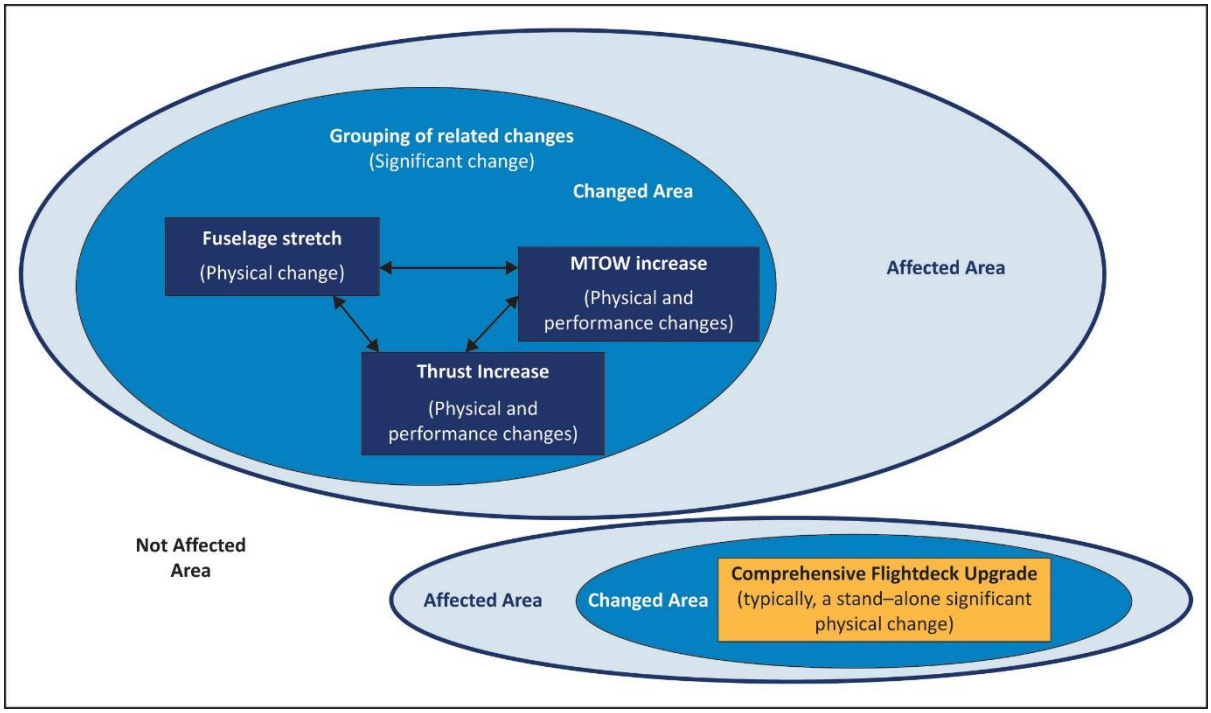
3.5. Step 4. Arrange changes into related and unrelated groups.

3.5.1 An applicant should now determine whether any of the changes identified in Step 1 are related to each other. Related changes are those that cannot exist without another, are co-dependent, or a prerequisite of another. For example, a need to carry more passengers could require the addition of a fuselage plug, which will result in a weight increase, and may necessitate a thrust increase. Thus, the fuselage plug, weight increase, and thrust increase are all related, high-level changes needed to achieve the goal of carrying more passengers. A decision to upgrade the flight deck to more modern avionics at the same time as these other changes may be considered unrelated, as the avionics upgrade is not necessarily needed to carry more passengers (it has a separate purpose, likely just modernisation). The proposed avionics upgrade would then be considered an unrelated (or a stand-alone) change. However, the simultaneous introduction of a new cabin interior is considered related since occupant safety considerations are impacted by a cabin length change. Even if a new cabin interior is not included in the product-level change, the functional effect of the fuselage plug has implications on occupant safety (e.g. the dynamic environment in an emergency landing, emergency evacuation, etc.), and thus the cabin interior becomes an affected area. Figure 3-2 below illustrates the grouping of related and unrelated changes using the example of increasing the maximum number of passengers.

Note: An applicant who plans changes in sequence over time should refer to the discussion on ‘sequential design changes’ in paragraph 5.13 of this GM.

Figure 3-2. Related and Unrelated Changes for Example of Increasing the Maximum Number of Passengers

The Aeronautical Product



3.5.2 Once the change(s) is (are) organised into groupings of those that are related and those that are unrelated (or stand-alone), an applicant should proceed to Step 5 below.

3.6. Step 5. Is each group of related changes or each unrelated (stand-alone) change a significant change?

3.6.1 The applicant is responsible for proposing the classification of groups of related changes or unrelated changes as 'significant' or 'not significant'. Significant changes are product-level changes that could result from an accumulation of changes, or occur through a single significant change that makes the changed product distinct from its baseline product. The grouping of related and unrelated changes is particularly relevant to EASA's significant Yes/No decision (point 21.A.101(b)(1)) described in Step 1 of Figure 3-1. EASA evaluates each group of related changes and each unrelated (stand-alone) change on its own merit for significance. Thus, there may be as many evaluations for significance as there are groupings of related and unrelated changes. Step 1 of Figure 3-1 explains the accumulation of changes that an applicant must consider. Additionally, point 21.A.101(b)(1) defines a change as 'significant' when at least one of the three automatic criteria applies:

3.6.1.1 Changes where the general configuration is not retained (significant change to general configuration).

A change to the general configuration at the product level is one that distinguishes the resulting product from other product models, for example, performance or interchangeability of major components. Typically, for these changes, an applicant will designate a new product model, although this is not required. For examples, see appendix A of this GM.

3.6.1.2 Changes where the principles of construction are not retained (significant change to principles of construction).

A change at the product level to the materials and/or construction methods that affects the overall product's operating characteristics or inherent strength and would require extensive reinvestigation to demonstrate compliance is one where the principles of construction are not retained. For examples, see appendix A of this GM.

3.6.1.3 Product-level changes that invalidate the assumptions used for certification of the baseline product.

Examples include:

— change of an aircraft from an unpressurised to pressurised fuselage,

— change of operation of a fixed-wing aircraft from land-based to water-based, and

— operating envelope expansions that are outside the approved design parameters and capabilities.

For additional examples, see appendix A of this GM.

3.6.2 The above criteria are used to determine whether each change grouping and each stand-alone change is significant. These three criteria are assessed at the product level. In applying the automatic criteria and the examples in appendix A of this GM, an applicant should focus on the change and how it impacts the existing product (including its performance, operating envelope, etc.). A change cannot be classified or reclassified as a significant change on the basis of the importance of a later amendment.

3.6.3 Appendix A of this GM includes tables of typical changes (examples) for small aeroplanes, transport aeroplanes, rotorcraft, engines, and propellers that meet the criteria for a significant design change. The Appendix also includes tables of typical design changes that EASA classifies as not significant. The tables can be used in one of two ways:

3.6.3.1 To identify the classification of a proposed design change listed in the table, or

3.6.3.2 In conjunction with the three automatic criteria, to help classify a proposed design change not listed in the table by comparison to determinations made for changes with similar type and magnitude.

3.6.4 In many cases, a significant change may involve more than one of these criteria and will be obvious and distinct from other product improvements or production changes. There could be cases where a change to a single area, system, component, or appliance may not result in a product-level change. There could also be other cases where the change to a single system or component might result in a significant change due to its effect on the product overall. Examples may include the addition of winglets or leading-edge slats, or a change to primary flight controls of a fly-by-wire system.

3.6.5 If an unrelated (stand-alone) change or a grouping of related changes is classified as —

Significant (point 21.A.101(a)):

You must comply with the latest airworthiness standards for certification of the change and areas affected by change, unless you justify use of one of the exceptions provided in point 21.A.101(b)(2) or (3) to show compliance with earlier amendment(s). The final certification basis may consist of a combination of the requirements recorded in the certification basis ranging from the original aircraft certification basis to the most current regulatory amendments

Not Significant (point 21.A.101(b)(1)):

You may comply with the existing certification basis unless the standards in the proposed certification basis are deemed inadequate. In cases where the existing certification basis is inadequate or no regulatory standards exist, later requirements and/or special conditions will be required. See paragraph 3.11 of this GM for a detailed discussion.

3.6.6 A new model designation to a changed product is not necessarily indicative that the change is significant under point 21.A.101. Conversely, retaining the existing model designation does not mean that the change is not significant. Significance is determined by the magnitude of the change.

3.6.7 EASA determines the final classification of whether a change is significant or not significant. To assist an applicant in its assessment, EASA has predetermined the classification of several typical changes that an applicant can use for reference, and these examples are listed in appendix A of this GM.

3.6.8 At this point, the determination of significant or not significant for each of the groupings of related changes and each stand-alone change is completed. For significant changes, an applicant that proposes to comply with an earlier certification specification should use the procedure outlined in paragraph 3.7 below. For changes identified as not significant, see paragraph 3.8 below.

3.7. Proposing an amendment level for a significant change.

3.7.1 Without prejudice to the exceptions provided for in point 21.A.101(b) or (c), if the classification of a group of related changes or a stand-alone unrelated change is significant, all areas, systems, components, parts, or appliances affected by the change must comply with the certification specifications at the amendment level in effect on the date of application for the change, unless the applicant elects to comply with certification specifications that have become effective after that date (see point 21.A.101(a)).

3.7.2 In certain cases, an applicant will be required by EASA to comply with certification specifications that have become effective after the date of application (see point 21.A.101(a)):

3.7.2.1 If an applicant elects to comply with a specific certification specification or a subset of certification specifications at an amendment which has become effective after the date of application, the applicant must comply with any other certification specification that EASA finds is directly related (see point 21.A.101(f)).

3.7.2.2 In a case where the change has not been approved, or it is clear that it will not be approved under the time limit established, the applicant will be required to comply with an upgraded certification basis established according to points 21.B.80, 21.B.82 and 21.B.85 from the certification specifications that have become effective since the date of the initial application.

3.7.3 Applicants can justify the use of one of the exceptions in point 21.A.101(b)(2) or (3) to comply with an earlier amendment, but not with an amendment introduced earlier than the existing certification basis. See paragraphs 3.9 and 3.10 of this GM. Applicants who elect to comply with a specific certification specification or a subset of certification specifications at an earlier amendment will be required to comply with any other certification specification that EASA finds are directly related.

3.7.4 The final certification basis may combine the latest, earlier (intermediate), and existing certification specifications, but cannot contain certification specifications preceding the existing certification basis.

3.8. Proposing an amendment level for a not significant change.

3.8.1 When EASA classifies the change as not significant, the point 21.A.101(b) rule allows compliance with earlier amendments, but not prior to the existing certification basis. Within this limit, the applicant may propose an amendment level for each certification specification for the affected area. However, each applicant should be aware that EASA will review their proposals for the certification basis to ensure that the certification basis is adequate for the proposed change under Step 8. (See paragraph 3.11 of this GM.)

3.8.2 Even for a not significant change, an applicant may elect to comply with certification specifications which became applicable after the date of application. Applicants may propose to comply with a specific certification specification or a subset of certification specifications at a certain amendment of their choice. In such a case, any other certification specifications of that amendment that are directly related should be included in the certification basis for the change.

3.9. Step 6. Prepare the proposed certification basis list.

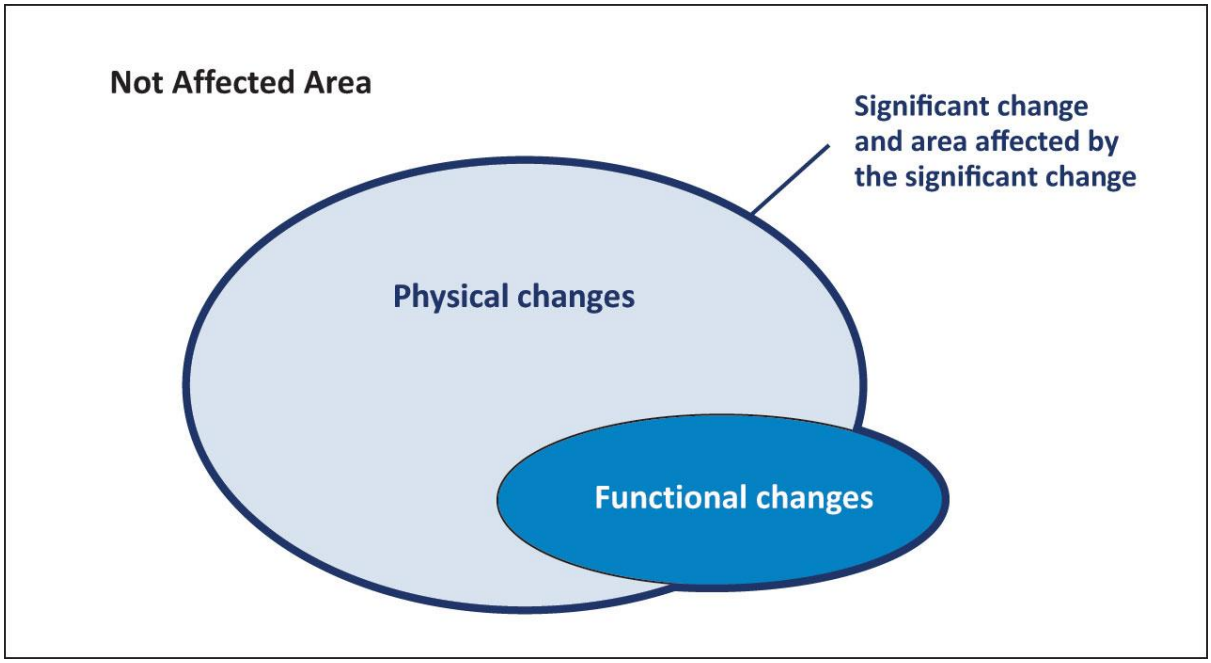
As part of preparing the proposed certification basis list, an applicant must identify any areas, systems, parts or appliances of the product that are affected by the change and the corresponding certification specifications associated with these areas. For each group, the applicant must assess the physical and/or functional effects of the change on any areas, systems, parts or appliances of the product. The characteristics affected by the change are not only physical changes, but also functional changes brought about by the physical changes. Examples of physical aspects are structures, systems, parts and appliances, including software in combination with the affected hardware. Examples of functional characteristics are performance, handling qualities, aeroelastic characteristics, and emergency egress. The intent is to encompass all aspects where there is a need for re-evaluation, that is, where the substantiation presented for the product being changed should be updated or rewritten. Appendix H of this GM contains two examples of how to document a proposed certification basis list.

3.9.1 An area affected by the change is any area, system, component, part, or appliance of the aeronautical product that is physically and/or functionally changed.

3.9.2 Figure 3-33 of this GM illustrates concepts of physical and functional changes of an affected area. Appendix C of this GM contains a method used to define the change and areas affected by the change. This Appendix is meant to assist applicants when they propose large, complex changes. For each change, it is important for the applicant to properly assess the effects of such change on any areas, systems, parts or appliances of the product because areas that have not been physically changed may still be considered part of the affected area. If a new compliance finding is required, regardless of its amendment level, it is an affected area.

Figure 3-3. Affected Areas versus Not Affected Areas

The Aeronautical Product



3.9.3 An area not affected by a change can remain at the existing certification basis, provided that the applicant presents to EASA an acceptable justification that the area is not affected.

3.9.4 For sample questions to assist in determining affected areas, see paragraph D.1 of appendix D of this GM.

3.9.5 Consider the following aspects of a change: **Physical aspects**.

The physical aspects include direct changes to structures, systems, equipment, components, and appliances, and may include software/airborne electronic hardware changes and the resulting effects on systems functions.

3.9.5.1 Performance/functional characteristics.

The less obvious aspect of the word ‘areas’ covers general characteristics of the type-certified product, such as performance features, handling qualities, emergency egress, structural integrity (including load carrying), aeroelastic characteristics, or crashworthiness. A product-level change may affect these characteristics. For example, adding a fuselage plug could affect performance and handling qualities, and thus the certification specifications associated with these aspects would be considered to be part of the affected

area. Another example is the addition of a fuel tank and a new fuel conditioning unit. This change affects the fuel transfer and fuel quantity indication system, resulting in the aircraft's unchanged fuel tanks being affected. Thus, the entire fuel system (changed and unchanged areas) may become part of the affected area due to the change to functional characteristics. Another example is changing turbine engine ratings and operating limitations, affecting the engine rotors' life limits.

3.9.6 All areas affected by the proposed change must comply with the latest certification specifications, unless the applicant shows that demonstrating compliance with the latest amendment of a certification specification would not contribute materially to the level of safety or would be impractical. Step 7 below provides further explanation.

3.9.7 The applicant should document the change and the area affected by the change using high-level descriptors along with the applicable certification specifications and their proposed associated amendment levels. The applicant proposes this change to the certification basis that EASA will consider for documentation in the type certificate data sheet (TCDS) or STC, if they are different from that recorded for the baseline product in the TCDS.

3.10. Step 7. Do the latest standards contribute materially to the level of safety and are they practical?

Pursuant to point 21.A.101(a), compliance with the latest certification specifications is required. However, exceptions may be allowed pursuant to point 21.A.101(b)(3). The applicant must provide justification to support the rationale for the application of earlier amendments for areas affected by a significant change in order to document that compliance with later standards in these areas would not contribute materially to the level of safety or would be impractical. Such a justification should address all the aspects of the area, system, part or appliance affected by the significant change. See paragraphs 3.10.1 and 3.10.1.4 of this GM.

3.10.1 Do the latest standards contribute materially to the level of safety?

Applicants could consider compliance with the latest standards to 'not contribute materially to the level of safety' if the existing type design and/or relevant experience demonstrates a level of safety comparable to that provided by the latest standards. In cases where design features provide a level of safety greater than the existing certification basis, applicants may use acceptable data, such as service experience, to establish the effectiveness of those design features in mitigating the specific hazards by a later amendment. Applicants must provide sufficient justification to allow EASA to make this determination. An acceptable means of compliance is described in appendix E of this GM. Justification is sufficient when it provides a summary of the evaluation that supports the determination using an agreed evaluation method, such as that in appendix E of this GM. This exception could be applicable in the situations described in the paragraphs below.

Note: Compliance with later standards is not required where the amendment is of an administrative nature and made only to correct inconsequential errors or omissions, consolidate text, or to clarify an existing requirement.

3.10.1.1 Improved design features.

Design features that exceed the existing certification basis standards, but do not meet the latest certification specifications, can be used as a basis for granting an exception under point 21.A.101(b)(3) since complying with the latest amendment of the certification specifications would not contribute materially to the level of safety of the product. If EASA accepts these design features as justification for an exception, the applicant must incorporate them in the amended type design configuration and record them, where necessary, in the certification basis. The description of the design feature would be provided in the TCDS or STC at a level that allows the design feature to be maintained, but does not contain proprietary information. For example[1], an applicant proposes to install winglets on a Part 25 aeroplane, and part of the design involves adding a small number of new wing fuel tank fasteners. Assuming that the latest applicable amendment of § 25.981 is Amendment 25-102, which requires structural lightning protection, the applicant could propose an exception from these latest structural lightning protection requirements because the design change uses new wing fuel tank fasteners with cap seals installed. The cap seal is a design feature that exceeds the requirement of § 25.981 at a previous amendment level, but does not meet the latest Amendment 25-102. If the applicant can successfully substantiate that compliance with Amendment 25-102 would not materially increase the level of safety of the changed product, then this design feature can be accepted as an exception to compliance with the latest amendment.

3.10.1.2 Consistency of design.

This provision gives the opportunity to consider the consistency of design. For example, when a small fuselage plug is added, additional seats and overhead bins are likely to be installed, and the lower cargo hold extended. These components may be identical to the existing components. The level of safety may not materially increase by applying the latest certification specifications in the area of the fuselage plug. Compliance of the new areas with the existing certification basis may be acceptable.

3.10.1.3 Service experience.

3.10.1.3.1 Relevant service experience, such as experience based on fleet performance or utilisation over time (relevant flight hours or cycles), is one way of showing that the level of safety will not materially increase by applying the latest amendment, so the use of earlier certification specifications could be appropriate. Appendix F of this GM provides additional guidance on the use of service experience, along with examples.

3.10.1.3.2 When establishing the highest practicable level of safety for a changed product, EASA has determined that it is appropriate to assess the service history of a product, as well as the later airworthiness standards. It makes little sense to mandate changes to well-

[1] This example is taken from the FAA experience gained prior to EASA's start, therefore the references to the FAA sections and amendments are kept.

understood designs, whose service experience has been acceptable, merely to comply with new standards. The clear exception to this premise is if the new standards were issued to address a deficiency in the design in question, or if the service experience is not applicable to the new standards.

3.10.1.3.3 There may be cases for rotorcraft and small aeroplanes where relevant data may not be sufficient or not available at all because of the low utilisation and the insufficient amount and type of data available. In such cases, other service history information may provide sufficient data to justify the use of earlier certification specifications, such as: warranty, repair, and parts usage data; accident, incident, and service difficulty reports; service bulletins; airworthiness directives; or other pertinent and sufficient data collected by the manufacturers, authorities, or other entities.

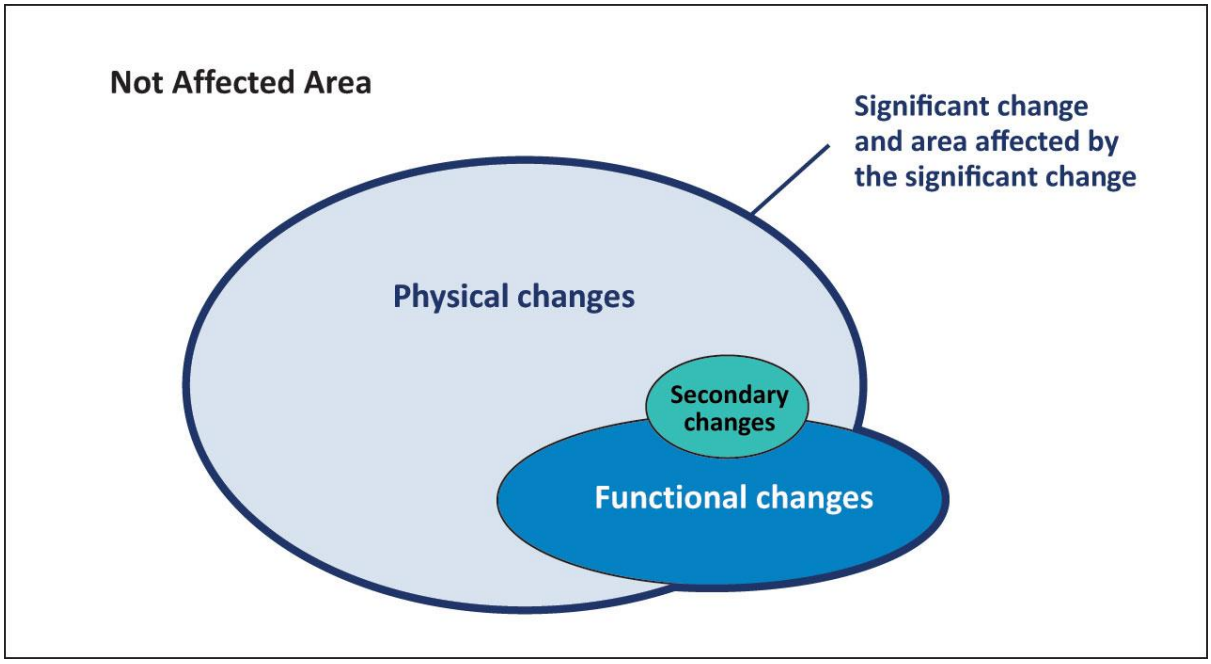
3.10.1.3.4 EASA will determine whether the proposed service experience levels necessary to demonstrate the appropriate level of safety as they relate to the proposed design change are acceptable.

3.10.1.4 Secondary changes.

3.10.1.4.1 The change proposed by the applicant can consist of physical and/or functional changes to the product. See Figure 3-4 below. There may be aspects of the existing type design of the product that the applicant may not be proposing to change directly, but that are affected by the overall change. For example, changing an airframe's structure, such as adding a cargo door in one location, may affect the frame or floor loading in another area. Further, upgrading engines with new performance capabilities could require additional demonstration of compliance for minimum control speeds and aeroplane performance certification specifications. For many years, EASA has required applicants to consider these effects, and this practice is unchanged under the procedures of point 21.A.101.

Figure 3-4. Change-Affected Areas with Secondary Changes

The Aeronautical Product



3.10.1.4.2 For each change, it is important that the effects of the change on other systems, components, equipment, or appliances of the product are properly identified and assessed. The intent is to encompass all aspects where there is a need for re-evaluation, that is, where the substantiation presented for the product being changed should be reviewed, updated, or rewritten.

3.10.1.4.3 In assessing the areas affected by the change, it may be helpful to identify secondary changes. A secondary change is a change to physical and/or functional aspects that is part of, but consequential to, a significant physical change, whose only purpose is to restore, and not add or increase, existing functionality or capacity. The term 'consequential' is intended to refer to:

— a change that would not have been made by itself; it achieves no purpose on its own;

— a change that has no effect on the existing functionality or capacity of areas, systems, structures, components, parts, or appliances affected by the change; or

— a change that would not create the need for: (1) new limitations or would affect existing limitations; (2) a new aircraft flight manual (AFM) or instructions for continued airworthiness (ICA) or a change to the AFM or ICA; or (3) special conditions, equivalent safety findings, or deviations.

3.10.1.4.4 A secondary change is not required to comply with the latest certification specifications because it is considered to be 'not contributing materially to the level of safety' and, therefore, eligible for an exception under point 21.A.101. Determining whether a change meets the description for a secondary change, and is thus eligible for an exception, should be straightforward. Hence, the substantiation or justification need only be minimal. If this determination is not straightforward, then the proposed change is not a secondary change.

3.10.1.4.5 In some cases, a secondary area of change that restores functionality may in fact contribute materially to the level of safety by meeting a later amendment. If this is the case, it is not considered a secondary change.

3.10.2 Are the latest specifications practical?

The intent of point 21.A.101 is to enhance safety by applying the latest certification specifications to the greatest extent practicable. The concepts of contributing materially and practicality are linked. If compliance with the latest certification specifications does contribute materially to the level of safety, then the applicant may assess the incremental costs to see whether they are commensurate with the increase in safety. The additional resource requirements could include those arising from changes required for compliance and the effort required to demonstrate compliance, but excluding resource expenditures for prior product changes. The cost of changing compliance documentation and/or drawings is not an acceptable reason for an exception.

3.10.2.1 Applicants should support their position that compliance is impractical with substantiating data and analyses. While evaluating that position and the substantiating data regarding impracticality, EASA may consider other factors (e.g. the costs and safety benefits for a comparable new design).

3.10.2.2 A review of large aeroplane projects showed that, in certain cases where EASA allowed an earlier amendment of applicable certification specifications, the applicants made changes that nearly complied with the latest amendments. In these cases, the applicants successfully demonstrated that full compliance would require a substantial increase in the outlay or expenditure of resources with a very small increase in the level of safety. These design features can be used as a basis for granting an exception under point 21.A.101(b)(3) on the basis of 'impracticality.'

3.10.2.3 Appendix E of this GM provides additional guidance and examples for evaluating the impracticality of applying the latest certification specifications to a changed product for which compliance with the latest certification specifications would contribute materially to the level of safety of the product.

3.10.2.3.1 The exception of impracticality is a qualitative and quantitative cost–safety benefit assessment for which it is difficult to specify clear criteria. Experience to date with applicants has shown that a justification of impracticality is more feasible when both the applicant and EASA agree during a discussion at an early stage that the effort (in terms of cost, changes to manufacturing, etc.) required to comply would not be commensurate with a small incremental safety gain. This

would be clear even without the need to perform any detailed cost–safety benefit analysis (although an applicant could always use cost analysis to support an appropriate amendment level). However, there should be enough detail in the applicant's rationale to justify the exception.

Note: An applicant should not base an exception due to impracticality on the size of the applicant's company or their financial resources. The applicant must evaluate the costs to comply with a later amendment against the safety benefit of complying with the later amendment.

3.10.2.3.2 For example, a complex redesign of an area of the baseline aircraft may be required to comply with a new requirement, and that redesign may affect the commonality of the changed product with respect to the design and manufacturing processes of the existing family of models. Relevant service experience of the existing fleet of the baseline aircraft family would be required to show that there has not been a history of problems associated with the hazard that the new amendment in question was meant to address. In this way, the incremental cost/impact to the applicant is onerous, and the incremental safety benefit realised by complying with the later amendment would be minimal. This would be justified by demonstrated acceptable service experience in relation to the hazard that the new rule addresses.

3.11. Step 8. Ensure the proposed certification basis is adequate.

EASA considers a proposed certification basis for any change (whether it is significant or not significant) to be adequate when:

— the certification standards provide an appropriate level of safety for the intended change, and

— the change and the areas affected by the change do not result in unsafe design features or characteristics for the intended use.

3.11.1 For a change that contains new design features that are novel and unusual for which there are no later applicable certification specifications at a later amendment level, EASA will designate special conditions pursuant to point 21.B.75. EASA will impose later certification specifications that contain adequate or appropriate safety standards for this feature, if they exist, in lieu of special conditions. An example is adding a flight-critical system, such as an electronic air data display on a CS-25 large aeroplane whose existing certification basis does not cover protection against lightning and high-intensity radiated fields (HIRF). In this case, EASA will require compliance with the certification specifications for lightning and HIRF protection, even though EASA determined that the change is not significant.

3.11.2 For new design features or characteristics that may pose a potential unsafe condition for which there are no later applicable certification specifications, new special conditions may be required to address points 21.B.107(a)(3) or 21.B.111(a)(3).

3.11.3 In cases where inadequate or no standards exist for the change to the existing certification basis, but adequate standards exist in a later amendment of the applicable certification specifications, the later amendment will be made part of the certification basis to ensure the adequacy of the certification basis.

3.11.4 EASA determines the final certification basis for a product change. This may consist of a combination of those standards ranging from the existing certification basis of the baseline product to the latest amendments and special conditions.

4. Excepted Products under point 21.A.101(c)

4.1. Excepted products.

For excepted products as defined in paragraph 4.1.1 below, the starting point for regulatory analysis is the existing certification basis for the baseline product.

4.1.1 Point 21.A.101(c) provides an exception to the compliance with the latest certification specifications required by point 21.A.101(a) for aircraft (other than rotorcraft) of 2 722 kg (6 000 lb) or less maximum weight, or to a non-turbine rotorcraft of 1 361 kg (3 000 lb) or less maximum weight. In these cases, the applicant may elect to comply with the existing certification basis. However, the applicant has the option of applying later, appropriate certification specifications.

4.1.2 If EASA finds that the change is significant in an area, EASA may require the applicant to comply with a later certification specification and with any certification specification that EASA finds is directly related. Starting with the existing certification basis, EASA will progress through each later certification specification to determine the amendment appropriate for the change. However, if an applicant proposes, and EASA finds, that complying with the later amendment or certification specification would not contribute materially to the level of safety of the changed product or would be impractical, EASA may allow the applicant to comply with an earlier amendment appropriate for the proposed change. The amendment may not be earlier than the existing certification basis. For excepted products, changes that meet one or more of the following criteria, in the area of change, are automatically considered significant:

4.1.2.1 The general configuration or the principles of construction are not retained.

4.1.2.2 The assumptions used for certification of the area to be changed do not remain valid.

4.1.2.3 The change contains new features (not foreseen in the existing certification basis and for which appropriate later certification specifications exist). In this case, EASA will designate the applicable certification specifications, starting with the existing certification basis and progressing to the most appropriate later amendment level for the change.

4.1.2.4 The change contains a novel or unusual design feature. In this case, EASA will designate the applicable special conditions appropriate for the change, pursuant to point 21.A.101(d).

4.1.3 The exception for products under point 21.A.101(c) applies to the aircraft only. Changes to engines and propellers installed on these excepted aircraft are assessed as separate type-certified products using point 21.A.101(a) and (b).

5. Other Considerations

5.1. Design-related requirements from other aviation domains.

Some implementing rules in other aviation domains (air operations, ATM/ANS) (e.g. Commission Regulation (EU) No 965/2012 on air operations or Commission Regulation (EU) 2015/640 on additional airworthiness specifications for a given type of operations (Annex I (Part-26)) impose airworthiness standards that are not required for the issue of a TC or STC (e.g. CS-26, CS-ACNS, etc.). If not already included in the certification basis, any such applicable airworthiness standard may be added to the type certification basis by mutual agreement between the applicant and EASA. The benefit of adding these airworthiness standards to the type certification basis is to increase awareness of these standards, imposed by other implementing rules, during design certification and future modifications to the aircraft. The use of exceptions under point 21.A.101(b) is not intended to alleviate or preclude compliance with operating regulations.

5.2. Reserved.

5.3. Baseline product.

A baseline product consists of one unique type design configuration, an aeronautical product with a specific, defined, approved configuration and certification basis that the applicant proposes to change. As mentioned in paragraph 3.2.1 of this GM, it is important to clearly identify the type design configuration to be changed. EASA does not require an applicant to assign a new model name for a changed product. Therefore, there are vastly different changed products with the same aircraft model name, and there are changed products with minimal differences that have different model names. Since the assignment of a model name is based solely on an applicant's business decision, the identification of the baseline product, for the purposes of point 21.A.101, is, as defined below.

The baseline product is an approved type design that exists at the date of application and is representative of:

— a single certified build configuration, or

— multiple approvals over time (including STC(s) or service bulletins) and may be representative of more than one product serial number.

Note: The type design configuration, for this purpose, could also be based on a proposed future configuration that is expected to be approved at a later date but prior to the proposed changed product.

5.4. Predecessor standards.

The certification specifications in effect on the date of application for a change are those in CS-22, CS-23, CS-25, CS-27, CS-29, CS-CCD, CS-FCD, CS-MMEL, etc., issued by EASA after 2003. However, the type-certification basis of some 'grandfathered' products, i.e. those with a pre-EASA TC deemed to have been issued in accordance with Commission Regulation (EU) No 748/2012 (see Article 3), may consist of other standards issued by or recognised in the EU Member States. These standards may include Joint Aviation Requirements (JARs) issued by the Joint Aviation Authorities (JAA) or national regulations of an EU Member State (e.g. BCARs) or national regulations of a non-EU State of Design with which an EU Member State had concluded a bilateral airworthiness agreement (e.g. US FARs, CARs etc.). Consequently, when using one of the exception routes allowing

electing to comply with earlier standards, the predecessor standards may be applicable. Such predecessor standards are not recognised under point 21.A.101(a), but may be allowed under point 21.A.101(b) or (c).When choosing the amendment level of a standard, all related standards associated with that amendment level would have to be included.

5.5. Special conditions, point 21.A.101(d).

Point 21.A.101(d) allows for the application of special conditions, or for changes to existing special conditions, to address the changed designs where neither the proposed certification basis nor any later certification specifications provide adequate standards for an area, system, part or appliance related to the change. The objective is to achieve a level of safety consistent with that provided for other areas, systems, parts or appliances affected by the change by the other certification specifications of the proposed certification basis. The application of special conditions to a design change is not, in itself, a reason to classify it as either a substantial change or a significant change. Whether the change is significant, with earlier certification specifications allowed through exceptions, or not significant, the level of safety intended by the special conditions must be consistent with the agreed certification basis.

5.6. Reserved.

5.7. Reserved.

5.8. Reserved.

5.9. Documentation.

5.9.1 Documenting the proposal.

In order to efficiently determine and agree upon a certification basis with EASA, the following information is useful to understand the applicant's position:

— The current certification basis of the product being changed, including the amendment level.

— The amendment level of all the applicable certification specifications at the date of application.

— The proposed certification basis, including the amendment levels.

— Description of the affected area.

— Applicants who propose a certification basis that includes amendment levels earlier than what was in effect at the date of application should include the exception as outlined in point 21.A.101(b) and their justification if needed.

Please see appendix H for examples of optional tools an applicant can use to document your proposed certification basis.

5.9.2 Documenting the significant/not significant decision.

5.9.2.1 EASA determines whether the changes are significant or not significant, and this decision is documented in the Certification Review Item(s). However, EASA provides an optional decision record for the applicant to make a predetermination to facilitate EASA decision. This form is provided in appendix G of this GM and follows the flow chart in Figure 3-1 of this GM. If it is used, the applicant should submit it along with the certification plan.

5.9.2.2 Changes that are determined to be significant changes under point 21.A.101, the exceptions, and the agreement of affected and unaffected areas is typically documented through the Certification Review Item (CRI) A-01 process. An example tool is provided in appendix H of this GM.

5.9.3 Documenting the certification basis.

5.9.3.1 EASA will amend the certification basis for all changes that result in a revision to the product's certification basis on the amended TCDS or STC. In case of a significant change, EASA will document the resulting certification basis in CRI A-01.

5.9.3.2 EASA will document the certification basis of each product model on all STCs, including approved model list STCs.

5.10. Incorporation of STCs into the Type Design.

The incorporation of STCs into the product type design may generate an additional major change when that change is needed to account for incompatibility between several STCs that were initially not intended to be applied concurrently.

5.10.1 If the incorporation of the STC(s) does not generate an additional major change, the incorporation is not evaluated pursuant to point 21.A.101. The existing certification basis should be updated to include the later amendments of the STC(s) being incorporated.

5.10.2 If the incorporation of the STC(s) generates an additional major change, the change must be evaluated pursuant to point 21.A.101, and the existing certification basis should be updated to include the amendments resulting from the application of point 21.A.101.

5.11. Removing changes.

Approved changes may be removed after incorporation in an aeronautical product. These changes will most commonly occur via an STC or a service bulletin kit.

5.11.1 The applicant should identify a product change that they intend at its inception to be removable as such, and should develop instructions for its removal during the initial certification. EASA will document the certification basis for both the installed and removed configuration separately on the TCDS or STC.

5.11.2 If specific removal instructions and a certification basis corresponding to the removed condition are not established at the time of the initial product change certification, the removal of changes or portions of those changes may constitute a significant change to type design. A separate STC or an amended TC may be required to remove the modifications and the resulting certification basis established for the changed product.

5.12. The certification basis is part of the change.

A new change may be installed in a product during its production or via a service bulletin or STC. In terms of point 21.A.101, each of the approved changes has its own basis of certification. If an applicant chooses to remove an approved installation (e.g. an interior installation, avionics equipment) and install a new installation, a new certification basis may be required for the new installation, depending on whether the change associated with the new installation is considered significant compared to the baseline configuration that the applicant chooses. If the new installation is a not significant change, the

unmodified product's certification basis may be used (not the previous installation certification basis), provided the certification basis is adequate. For example, a large aeroplane is certified in a 'green' configuration. The aeroplane certification basis does not include CS 25.562. An interior is installed under an STC, and the applicant elects to include CS 25.562 (dynamic seats) in the certification basis to meet specific operational requirements. At a later date, the aeroplane is sold to another operator who does not have the same operational requirements. A new interior is installed; there will be no requirement for CS 25.562 to be included in the new certification basis.

5.13. Sequential changes — cumulative effects.

5.13.1 Any applicant who intends to accomplish a product change by incorporating several changes in a sequential manner should identify this to EASA up front when the first application is made. In addition, the cumulative effects arising from the initial change, and from all of the follow-on changes, should be included as part of the description of the change in the initial proposal. The classification of the intended product change will not be evaluated solely on the basis of the first application, but rather on the basis of all the required changes needed to accomplish the intended product change. If EASA determines that the current application is a part of a sequence of related changes, then EASA will re-evaluate the determination of significance and the resulting certification basis as a group of related changes.

5.13.2 Example: Cumulative effects — advancing the certification basis.

The type certificate for aeroplane model X lists three models, namely X-300, X-200, and X-100. The X-300 is derived from the X-200, which is derived from the original X-100 model. An applicant proposes a change to the X-300 aeroplane model. During the review of the X-300 certification basis and the certification specifications affected by the proposed change, it was identified that one certification specification, CS 25.571 (damage tolerance requirements), remained at the same amendment level as the X-100 original certification basis (exception granted on the X-200). Since the amendment level for this particular certification specification was not changed for the two subsequent aeroplane models (X-200 and X-300), the applicant must now examine the cumulative effects of these two previous changes that are related to the proposed change and the damage tolerance requirements to determine whether the amendment level needs to advance.

Appendix A to GM 21.A.101 Classification of design changes

ED Decision 2017/024/R

The following tables of 'substantial', 'significant', and 'not significant' changes are adopted by the FAA, Agência Nacional de Aviação Civil (ANAC), the European Aviation Safety Agency (EASA), and Transport Canada Civil Aviation (TCCA) through international collaboration. The classification may change due to cumulative effects and/or combinations of individual changes.

A.1 Examples of Substantial, Significant, and Not Significant Changes for Small Aeroplanes (CS-23).

A.1.1 Table A-1 contains examples of changes that are 'substantial' for small aeroplanes (CS-23).

Table A-1. Examples of Substantial Changes for Small Aeroplanes (CS-23)

Example	Description of Change	Notes
1.	Change to wing location (tandem, forward, canard, high/low).	Proposed change to design is so extensive that a substantially complete investigation of compliance with the applicable certification basis is required.
2.	Fixed wing to tilt wing.	Proposed change to design is so extensive that a substantially complete investigation of compliance with the applicable certification basis is required.
3.	A change to the number of engines.	Proposed change to design is so extensive that a substantially complete investigation of compliance with the applicable certification basis is required.
4.	Replacement of piston or turboprop engines with turbojet or turbofan engines.	Proposed change to design is so extensive that a substantially complete investigation of compliance with the applicable certification basis is required.
5.	Change to engine configuration (tractor/pusher).	Proposed change to design is so extensive that a substantially complete investigation of compliance with the applicable certification basis is required.
6.	Increase from subsonic to supersonic flight regime.	
7.	Change from an all-metal to all-composite aeroplane.	Proposed change to design is so extensive that a substantially complete investigation of compliance with the applicable certification basis is required.
8.	Certifying a CS-23 (or predecessor basis, such as JAR-23) aeroplane into another certification category, such as CS-25.	—

A.1.2 Table A-2 contains examples of changes that are 'significant' for small aeroplanes (CS-23).

Table A-2. Examples of Significant Changes for Small Aeroplanes (CS-23)					
Example	Description of change	Is there a change to the general configuration? 21.A.101(b)(1)(i)	Is there a change to the principles of construction? 21.A.101(b)(1)(i)	Have the assumptions used for certification been invalidated? 21.A.101(b)(1)(ii)	Notes
1.	Conventional tail to T-tail or V-tail, or vice versa.	Yes	No	Yes	Change to general configuration. Requires extensive, structural flying qualities and performance reinvestigation. Requires new aeroplane flight manual (AFM) to address performance and flight characteristics.

Table A-2. Examples of Significant Changes for Small Aeroplanes (CS-23)					
Example	**Description of change**	**Is there a change to the general configuration? 21.A.101(b)(1)(i)**	**Is there a change to the principles of construction? 21.A.101(b)(1)(i)**	**Have the assumptions used for certification been invalidated? 21.A.101(b)(1)(ii)**	**Notes**
2.	Changes to wing configuration, such as change to dihedral, changes to wing span, flap or aileron span, addition of winglets, or increase of more than 10 per cent of the original wing sweep at the quarter chord.	Yes	No	Yes	Change to general configuration. Likely requires extensive changes to wing structure. Requires new AFM to address performance and flight characteristics. Note: Small changes to the wingtip or winglet are not significant changes. See table for 'not significant' changes.
3.	Changes to tail configuration, such as the addition of tail strakes or angle of incidence of the tail.	Yes	No	Yes	Change to general configuration. Likely requires extensive changes to tail structure. Requires new AFM to address performance and flight characteristics. Note: Small changes to tail are not significant changes.
4.	Tricycle/tail wheel undercarriage change or addition of floats.	Yes	No	No	Change to general configuration. Likely, at aeroplane level, general configuration and certification assumptions remain valid.
5.	Passenger-to-freighter configuration conversion that involves the introduction of a cargo door or an increase in floor loading of more than 20 per cent, or provision for carriage of passengers and freight together.	Yes	No	Yes	Change to general configuration affecting load paths, aeroelastic characteristics, aircraft-related systems, etc. Change to design assumptions.
6.	Replace reciprocating engines with the same number of turbo-propeller engines.	Yes	No	No	Requires extensive changes to airframe structure, addition of aircraft systems, and new AFM to address performance and flight characteristics.
7.	Addition of a turbo-charger that changes the power envelope, operating range, or limitations.	No	No	Yes	Invalidates certification assumptions due to changes to operating envelope and limitations. Requires new AFM to address performance and flight characteristics.
8.	The replacement of an engine of higher rated power or increase thrust would be considered significant if it would invalidate the existing substantiation, or would change the primary structure, aerodynamics, or operating envelope sufficiently to invalidate the assumptions of certification.	No	Yes	Yes	Invalidates certification assumptions. Requires new AFM to address performance and flight characteristics. Likely changes to primary structure. Requires extensive construction reinvestigation.

Table A-2. Examples of Significant Changes for Small Aeroplanes (CS-23)					
Example	**Description of change**	**Is there a change to the general configuration? 21.A.101(b)(1)(i)**	**Is there a change to the principles of construction? 21.A.101(b)(1)(i)**	**Have the assumptions used for certification been invalidated? 21.A.101(b)(1)(ii)**	**Notes**
9.	A change to the type of material, such as composites in place of metal, or one composite fibre material system with another (e.g. carbon for fiberglass), for primary structure would normally be assessed as a significant change.	No	Yes	Yes	Change to principles of construction and design from conventional practices. Likely change to design/certification assumptions.
10.	10. A change involving appreciable increase in design speeds V^D, V^B, V^{MO}, V^C, or V^A.	No	No	Yes	Certification assumptions invalidated. Requires new AFM to address performance and flight characteristics.
11.	Installation of a short take-off and landing (STOL) kit.	No	No	Yes	Certification assumptions invalidated. Requires new AFM to address performance and flight characteristics.
12.	A change to the rated power or thrust could be a significant change if the applicant is taking credit for increased design speeds per example 10 of this table.	No	No	Yes	Certification assumptions invalidated. Requires new AFM to address performance and flight characteristics.
13.	Fuel state, such as compressed gaseous fuels or fuel cells. This could completely alter the fuel storage and handling systems and possibly affect the aeroplane structure.	No	No	Yes	Changes to design/certification assumptions. Extensive alteration of fuel storage and handling systems.
14.	A change to the flight control concept for an aircraft, e.g. to fly-by-wire (FBW) and side-stick control, or a change from hydraulic to electronically actuated flight controls, would in isolation normally be regarded as a significant change.	No	No	Yes	Changes to design and certification assumptions. Requires extensive systems architecture and integration reinvestigation. Requires new AFM.
15.	Change to aeroplane's operating altitude, or cabin operating pressure greater than 10 per cent in maximum cabin pressure differential.	No	No	Yes	This typically invalidates certification assumptions and the fundamental approach used in decompression, structural strength, and fatigue. May require extensive airframe changes affecting load paths, fatigue evaluation, aeroelastic characteristics, etc. Invalidates design assumptions.
16.	Addition of a cabin pressurisation system.	No	Yes	Yes	Extensive airframe changes affecting load paths, fatigue evaluation, aeroelastic characteristics, etc. Invalidates design assumptions.

Table A-2. Examples of Significant Changes for Small Aeroplanes (CS-23)					
Example	**Description of change**	**Is there a change to the general configuration? 21.A.101(b)(1)(i)**	**Is there a change to the principles of construction? 21.A.101(b)(1)(i)**	**Have the assumptions used for certification been invalidated? 21.A.101(b)(1)(ii)**	**Notes**
17.	Changes to types and number of emergency exits or an increase in maximum certified passenger capacity.	Yes	No	Yes	Emergency egress certification specifications exceed those previously substantiated. Invalidates assumptions of certification.
18.	A change to the required number of flight crew that necessitates a complete flight deck rearrangement, and/or an increase in pilot workload.	No	No	Yes	Extensive changes to avionics and aircraft systems. Invalidates certification assumptions. Requires new AFM.
19.	Expansion of an aircraft's operating envelope.*	No	No	Yes* *Some changes may be deemed 'not significant' depending on the extent of the expansion.	An expansion of operating capability is a significant change (e.g. an increase in maximum altitude limitation, approval for flight in icing conditions, or an increase in airspeed limitations).
20.	Replacement of an aviation gasoline engine with an engine of approximately the same horsepower utilising, e.g. diesel, hybrid, or electrical power.	No	No	Yes	A major change to the aeroplane. The general configuration and principles of construction will usually remain valid; however, the assumptions for certification are invalidated.
21.	Comprehensive flight deck upgrade, such as conversion from entirely federated, independent electromechanical flight instruments to highly integrated and combined electronic display systems with extensive use of software and/or complex electronic hardware.	No	No	Yes	Affects avionics and electrical systems integration and architecture concepts and philosophies. This drives a reassessment of the human–machine interface, flight-crew workload, and re-evaluation of the original design flight deck assumptions.
22.	Introduction of autoland.	No	No	Yes	Invalidates original design assumptions.
23.	Conversion from a safe life design to a damage-tolerance-based design.	No	No	Yes	Where the airframe-established safe life limits change to damage-tolerance principles, then use of an inspection program in lieu of the safe life design limit invalidates the original assumptions used during certification.
24.	Extensive structural airframe modification, such as a large opening in the fuselage.	Yes	No	No	Requires extensive changes to fuselage structure, affects aircraft systems, and requires a new AFM to address performance and flight characteristics.

Table A-2. Examples of Significant Changes for Small Aeroplanes (CS-23)					
Example	**Description of change**	**Is there a change to the general configuration? 21.A.101(b)(1)(i)**	**Is there a change to the principles of construction? 21.A.101(b)(1)(i)**	**Have the assumptions used for certification been invalidated? 21.A.101(b)(1)(ii)**	**Notes**
25.	Fuselage stretch or shortening in the cabin or pressure vessel.	Yes	No	Yes	Cabin interior changes are related changes since occupant safety considerations are impacted by a cabin length change. Even if a new cabin interior is not included in the product-level change, the functional effect of the fuselage plug has implications on occupant safety (e.g. the dynamic environment in an emergency landing, emergency evacuation, etc.), and thus the cabin interior becomes an affected area.
26.	Conversion from normal category to commuter category aeroplane.	Yes	No	Yes	Requires compliance with all commuter regulatory standards. In many cases, this change could be considered a substantial change to the type design. Therefore, a proposed change of this nature would be subject to EASA determination under 21.A.19.
27.	Installation of a full authority digital engine control (FADEC) on an aeroplane that did not previously have a FADEC installed.	No	No	Yes	—

A.1.3 Table A-3 contains examples of changes that are 'not significant' for small aeroplanes (CS-23).

Table A-3. Examples of Not Significant Changes for Small Aeroplanes (CS-23)					
Example	**Description of change**	**Is there a change to the general configuration? 21.A.101(b)(1)(i)**	**Is there a change to the principles of construction? 21.A.101(b)(1)(i)**	**Have the assumptions used for certification been invalidated? 21.A.101(b)(1)(ii)**	**Notes**
1.	Addition of wingtip modifications (not winglets).	No	No	No	A major change to the aeroplane. Likely, the original general configuration, principles of construction, and certification assumptions remain valid.
2.	Installation of skis or wheel skis.	No	No	No	Although a major change to the aeroplane, likely the original general configuration, principles of construction, and certification assumptions remain valid.
3.	Forward looking infrared (FLIR) or surveillance camera installation.	No	No	No	Additional flight or structural evaluation may be necessary, but the change does not alter basic aeroplane certification.

Table A-3. Examples of Not Significant Changes for Small Aeroplanes (CS-23)					
Example	Description of change	Is there a change to the general configuration? 21.A.101(b)(1)(i)	Is there a change to the principles of construction? 21.A.101(b)(1)(i)	Have the assumptions used for certification been invalidated? 21.A.101(b)(1)(ii)	Notes
4.	Litter, berth, and cargo tie down device installation.	No	No	No	Not an aeroplane-level change.
5.	Not an aeroplane-level change.	No	No	No	Not an aeroplane-level change.
6.	Replacement of one propeller type with another (irrespective of increase in number of blades).	No	No	No	Although a major change to the aeroplane, likely the original general configuration, principles of construction, and certification assumptions remain valid.
7.	Addition of a turbo-charger that does not change the power envelope, operating range, or limitations (e.g. a turbo-normalised engine, where the additional power is used to enhance high-altitude or hot-day performance).	No	No	No	Not an aeroplane-level change.
8.	Substitution of one method of bonding for another (e.g. change to type of adhesive).	No	No	No	Not an aeroplane-level change.
9.	Substitution of one type of metal for another.	No	No	No	Not an aeroplane-level change.
10.	Any change to construction or fastening not involving primary structure.	No	No	No	Not an aeroplane-level change.
11.	A new fabric type for fabric-skinned aircraft.	No	No	No	Not an aeroplane-level change.
12.	Increase in flap speed or undercarriage limit speed.	No	No	No	Although a major change to the aeroplane, likely the original general configuration, principles of construction, and certification assumptions remain valid.
13.	Structural strength increases.	No	No	No	Although a major change to the aeroplane, likely the original general configuration, principles of construction, and certification assumptions remain valid.

Table A-3. Examples of Not Significant Changes for Small Aeroplanes (CS-23)					
Example	Description of change	Is there a change to the general configuration? 21.A.101(b)(1)(i)	Is there a change to the principles of construction? 21.A.101(b)(1)(i)	Have the assumptions used for certification been invalidated? 21.A.101(b)(1)(ii)	Notes
14.	Instrument flight rules (IFR) upgrades involving installation of components (where the original certification does not indicate that the aeroplane is not suitable as an IFR platform, e.g. special handling concerns).	No	No	No	Not an aeroplane-level change.
15.	Fuel tanks where fuel is changed from gasoline to diesel fuel and tank support loads are small enough that an extrapolation from the previous analysis would be valid. Chemical compatibility would have to be substantiated.	No	No	No	Not an aeroplane-level change.
16.	Limited changes to a pressurisation system, e.g. number of outflow valves, type of controller, or size of pressurised compartment, but the system must be re-substantiated if the original test data are invalidated.	No	No	No	Although a major change to the aeroplane, likely the original general configuration, principles of construction, and certification assumptions remain valid.
17.	Install a different exhaust system.	No	No	No	Not an aeroplane-level change.
18.	Changes to engine cooling or cowling.	No	No	No	Not an aeroplane-level change.
19.	Changing fuels of substantially the same type, such as AvGas to AutoGas, AvGas (80/87) to AvGas (100LL), ethanol to isopropyl alcohol, Jet B to Jet A.	No	No	No	Although a major change to the aeroplane, likely the original general configuration, principles of construction, and certification assumptions remain valid.

Table A-3. Examples of Not Significant Changes for Small Aeroplanes (CS-23)					
Example	Description of change	Is there a change to the general configuration? 21.A.101(b)(1)(i)	Is there a change to the principles of construction? 21.A.101(b)(1)(i)	Have the assumptions used for certification been invalidated? 21.A.101(b)(1)(ii)	Notes
20.	Fuels that specify different levels of 'conventional' fuel additives that do not change the primary fuel type. Different additive levels (controlled) of MTBE, ETBE, ethanol, amines, etc., in AvGas would not be considered a significant change.	No	No	No	Although a major change to the aeroplane, likely the original general configuration, principles of construction, and certification assumptions remain valid.
21.	A change to the maximum take-off weight of less than 5 per cent, unless assumptions made in justification of the design are thereby invalidated.	No	No	No	Although a major change to the aeroplane, likely the original general configuration, principles of construction, and certification assumptions remain valid.
22.	An additional aileron tab (e.g. on the other wing).	No	No	No	Although a major change to the aeroplane, likely the original general configuration, principles of construction, and certification assumptions remain valid.
23.	Larger diameter flight control cables with no change to routing, or other system design.	No	No	No	Not an aeroplane-level change.
24.	Autopilot installation (for IFR use, unless the original certification indicates that the aeroplane is not suitable as an IFR platform).	No	No	No	Although a major change to the aeroplane, likely the original general configuration, principles of construction, and certification assumptions remain valid.
25.	Increased battery capacity or relocate battery.	No	No	No	Not an aeroplane-level change.
26.	Replace generator with alternator.	No	No	No	Not an aeroplane-level change.
27.	Additional lighting (e.g. navigation lights, strobes).	No	No	No	Not an aeroplane-level change.
28.	Higher capacity brake assemblies.	No	No	No	Not an aeroplane-level change.
29.	Increase in fuel tank capacity.	No	No	No	Not an aeroplane-level change.
30.	Addition of an oxygen system.	No	No	No	Not an aeroplane-level change.

Table A-3. Examples of Not Significant Changes for Small Aeroplanes (CS-23)					
Example	Description of change	Is there a change to the general configuration? 21.A.101(b)(1)(i)	Is there a change to the principles of construction? 21.A.101(b)(1)(i)	Have the assumptions used for certification been invalidated? 21.A.101(b)(1)(ii)	Notes
31.	Relocation of a galley.	No	No	No	Not an aeroplane-level change.
32.	Passenger-to-freight (only) conversion with no change to basic fuselage structure.	No	No	No	Although a major change to the aeroplane, likely the original general configuration, principles of construction, and certification assumptions remain valid. Requires certification substantiation applicable to freighter certification specifications.
33.	New cabin interior with no fuselage length change.	No	No	No	—
34.	Installation of new seat belt or shoulder harness.	No	No	No	Not an aeroplane-level change.
35.	A small increase in centre of gravity (CG) range.	No	No	No	At aeroplane level, no change to general configuration, principles of construction, and certification assumptions.
36.	Auxiliary power unit (APU) installation that is not flight-essential.	No	No	No	Although a major change to the aeroplane level, likely the original general configuration, principles of construction, and certification assumptions remain valid. Requires certification substantiation applicable to APU installation certification specifications.
37.	An alternative autopilot.	No	No	No	Not an aeroplane-level change.
38.	Addition of Class B terrain awareness and warning system (TAWS).	No	No	No	Not an aeroplane-level change.
39.	Extending an established life limit.	No	No	No	This extension may be accomplished by various methods, such as ongoing fatigue testing, service life evaluation, component level replacement, and inspections based on damage-tolerance principles.

Table A-3. Examples of Not Significant Changes for Small Aeroplanes (CS-23)					
Example	Description of change	Is there a change to the general configuration? 21.A.101(b)(1)(i)	Is there a change to the principles of construction? 21.A.101(b)(1)(i)	Have the assumptions used for certification been invalidated? 21.A.101(b)(1)(ii)	Notes
40.	Flight deck replacement of highly integrated and combined electronic display systems with other highly integrated and combined electronic display systems.	No	No	No	Not significant if the architecture concepts, design philosophies, human–machine interface, or flight-crew workload assumptions are not impacted.
41.	Interior cabin reconfigurations are generally considered not significant. This includes installation of in-flight entertainment (IFE), new seats, and rearrangement of furniture.	No	No	No	—
42.	Modification to ice protection systems.	No	No	No	Recertification required, but certification basis should be evaluated for adequacy.

A.2 Examples of Substantial, Significant, and Not Significant Changes for Large Aeroplanes (CS-25).

A.2.1 Table A-4 contains examples of changes that are ‘substantial’ for large aeroplanes (CS-25).

Table A-4. Examples of Substantial Changes for Large Aeroplanes (CS-25)

Example	Description of Change	Notes
1.	Change to the number or location of engines, e.g. four to two wing-mounted engines or two wing-mounted to two body-mounted engines.	Proposed change to design is so extensive that a substantially complete investigation of compliance with the applicable certification basis is required.
2.	Change from a high-wing to low-wing configuration.	Proposed change to design is so extensive that a substantially complete investigation of compliance with the applicable certification basis is required.
3.	Change from an all-metal to all-composite aeroplane.	Proposed change to design is so extensive that a substantially complete investigation of compliance with the applicable certification basis is required.
4.	Change of empennage configuration for larger aeroplanes (cruciform vs ‘T’ or ‘V’ tail).	Proposed change to design is so extensive that a substantially complete investigation of compliance with the applicable certification basis is required.
5.	Increase from subsonic to supersonic flight regime.	Proposed change to design is so extensive that a substantially complete investigation of compliance with the applicable certification basis is required.

A.2.2 Table A-5 contains examples of changes that are 'significant' for large aeroplanes (CS-25).

Table A-5. Examples of Significant Changes for Transport Large Aeroplanes (CS-25)

Example	Description of change	Is there a change to the general configuration? 21.A.101(b)(1)(i)	Is there a change to the principles of construction? 21.A.101(b)(1)(i)	Have the assumptions used for certification been invalidated? 21.A.101(b)(1)(ii)	Notes
1.	Reduction in the number of flight crew (in conjunction with flight deck update).	No	No	Yes	Extensive changes to avionics and aircraft systems. Impact to flight-crew workload and human factors, pilot type rating.
2.	Modify an aeroplane to add certification for flight in icing conditions by adding systems, such as ice detection and ice protection.	Yes	No	Yes	New aircraft operating envelope. Requires major new systems installation and aircraft evaluation. Operating envelope changed.
3.	Conversion — passenger or combination freighter/passenger to all-freighter, including cargo door, redesign floor structure and 9g net or rigid barrier.	Yes	No	Yes	Extensive airframe changes affecting load paths, aeroelastic characteristics, aircraft-related systems for fire protection, etc. Design assumptions changed from passenger to freighter.
4.	Conversion from a cargo to passenger configuration.	Yes	No	Yes	Completely new floor loading and design. Redistribution of internal loads, change to cabin safety certification specifications, system changes.
5.	Increase in cabin pressurisation greater than 10 per cent.	No	No	Yes	A change greater than 10 per cent in operational cabin pressure differential is a significant change since it requires extensive airframe changes affecting load paths, fatigue evaluation, or aeroelastic characteristics, invalidating the certification assumptions.
6.	Addition of leading-edge slats.	Yes	No	Yes	The addition of leading-edge slats is significant since it requires extensive changes to wing structure, adds aircraft systems, and requires a new AFM to address performance and flight characteristics.

Table A-5. Examples of Significant Changes for Transport Large Aeroplanes (CS-25)					
Example	**Description of change**	**Is there a change to the general configuration? 21.A.101(b)(1)(i)**	**Is there a change to the principles of construction? 21.A.101(b)(1)(i)**	**Have the assumptions used for certification been invalidated? 21.A.101(b)(1)(ii)**	**Notes**
7.	Fuselage stretch or shortening in the cabin or pressure vessel.	Yes	No	Yes	Cabin interior changes are related changes since occupant safety considerations are impacted by a cabin length change. Even if a new cabin interior is not included in the product-level change, the functional effect of the fuselage plug has implications on occupant safety (e.g. the dynamic environment in an emergency landing, emergency evacuation, etc.), and thus the cabin interior becomes an affected area.
8.	Extensive structural airframe modification, such as installation of a large telescope with large opening in the fuselage.	Yes	No	No	These types of structural modifications are significant since they require extensive changes to fuselage structure, affect aircraft systems, and require a new AFM to address performance and flight characteristics.
9.	Changing the number of axles or number of landing gear done in context with a product change that involves changing the aeroplane's gross weight.	Yes	No	No	This type of landing gear change with an increase in gross weight is significant since it requires changes to aircraft structure, affects aircraft systems, and requires AFM changes, which invalidate the certification assumptions.
10.	Primary structure changes from metallic material to composite material.	No	Yes	No	Change to principles of construction and design from conventional practices.
11.	An increase in design weight of more than 10 per cent.	No	No	Yes	Design weight increases of more than 10 per cent result in significant design load increase that invalidates the assumptions used for certification, requiring re-substantiation of aircraft structure, aircraft performance, and flying qualities and associated systems.

Table A-5. Examples of Significant Changes for Transport Large Aeroplanes (CS-25)					
Example	**Description of change**	**Is there a change to the general configuration? 21.A.101(b)(1)(i)**	**Is there a change to the principles of construction? 21.A.101(b)(1)(i)**	**Have the assumptions used for certification been invalidated? 21.A.101(b)(1)(ii)**	**Notes**
12.	Installation of winglets, modification of existing winglets, or other changes to wing tip design.	Yes	No	Yes	Significant if it requires extensive changes to wing structure or aircraft systems, or if it requires a new AFM to address performance and flight characteristics. It may also affect the wing fuel tanks, including fuel tank lightning protection, fuel tank ignition source prevention, and fuel tank flammability exposure.
13.	Changes to wing span, chord, or sweep.	Yes	No	Yes	Significant if it requires extensive changes to wing structure or aircraft systems, or if it requires a new AFM to address performance and flight characteristics. It may also affect the wing fuel tanks, including fuel tank lightning protection, fuel tank ignition source prevention, and fuel tank flammability exposure.
14.	A change to the type or number of emergency exits or an increase in the maximum certified number of passengers.	Yes	No	Yes	—
15.	A comprehensive avionics upgrade that changes a federated avionics system to a highly integrated avionics system.	No	No	Yes	This change refers to the avionics system that feeds the output to displays and not the displays themselves.
16.	An avionics upgrade that changes the method of input from the flight crew, which was not contemplated during the original certification.	No	No	Yes	A change that includes touchscreen technology typically does not invalidate the assumptions used for certification. A change that incorporates voice-activated controls or other novel human–machine interface would likely invalidate the assumptions used for certification.

Table A-5. Examples of Significant Changes for Transport Large Aeroplanes (CS-25)					
Example	**Description of change**	**Is there a change to the general configuration? 21.A.101(b)(1)(i)**	**Is there a change to the principles of construction? 21.A.101(b)(1)(i)**	**Have the assumptions used for certification been invalidated? 21.A.101(b)(1)(ii)**	**Notes**
17.	Change to primary flight controls to FBW system. (Some aeroplanes have some degree of FBW. Achieving full FBW may be a not significant change on some aeroplanes.)	No	No	Yes	When the degree of change is so extensive that it affects basic aircraft systems integration and architecture concepts and philosophies. This drives a complete reassessment of flight-crew workload, handling qualities, and performance evaluation, which are different from the original design assumptions.
18.	Replace reciprocating with turbo-propeller engines.	Yes	No	No	Requires extensive changes to airframe structure, addition of aircraft systems, and new AFM to address performance and flight characteristics.
19.	Maximum continuous or take-off thrust or power increase of more than 10 per cent or, for turbofans, an increase of the nacelle diameter.	No	No	Yes	A thrust or power increase of more than 10 per cent is significant because it does have a marked effect on aircraft performance and flying qualities, or requires re-substantiation of powerplant installation. An increase of the nacelle diameter as a result of an increase in the bypass ratio is significant because it results in airframe-level effects on aircraft performance and flying qualities. However, a small increase of the nacelle diameter would not have such an airframe-level effect and would not be considered a significant change.
20.	Initial installation of an autoland system.	No	No	Yes	Baseline aeroplane not designed for autoland operation, potential flight-crew workload, and systems compatibility issues.

Table A-5. Examples of Significant Changes for Transport Large Aeroplanes (CS-25)					
Example	**Description of change**	**Is there a change to the general configuration? 21.A.101(b)(1)(i)**	**Is there a change to the principles of construction? 21.A.101(b)(1)(i)**	**Have the assumptions used for certification been invalidated? 21.A.101(b)(1)(ii)**	**Notes**
21.	Installation of a new fuel tank, e.g. installation of an auxiliary fuel tank in a cargo bay or installation of an auxiliary fuel tank that converts a dry bay into a fuel tank (such as a horizontal stabiliser tank).	No	No	Yes	Requires changes to airframe, systems, and AFM. Results in performance changes. These changes typically affect fuel tank lightning protection, fuel tank ignition source prevention, and fuel tank flammability exposure.
22.	Main deck cargo door installation.	Yes	No	No	Redistribution of internal loads, change to aeroelastic characteristics, system changes.
23.	Expansion of an aircraft's operating envelope.*	No	No	Yes* *Some changes may be deemed 'not significant' depending on the extent of the expansion.	An expansion of operating capability is a significant change (e.g. an increase in maximum altitude limitation, approval for flight in icing conditions, or an increase in airspeed limitations).
24.	Changing the floor from passenger-carrying to cargo-carrying capability.	Yes	No	Yes	Completely new floor loading and design. Redistribution of internal loads, change to cabin safety certification specifications, system changes. If a cargo handling system is installed, it would be a related change.
25.	Initial installation of an APU essential for aircraft flight operation.	No	No	Yes	Changes to emergency electrical power certification specifications, change to aircraft flight manual and operating characteristics.
26.	Conversion from hydraulically actuated brakes to electrically actuated brakes.	No	No	Yes	Assumptions of certification for aeroplane performance are changed.
27.	Installation of engine thrust reversers.	Yes	No	Yes	

Table A-5. Examples of Significant Changes for Transport Large Aeroplanes (CS-25)					
Example	**Description of change**	**Is there a change to the general configuration? 21.A.101(b)(1)(i)**	**Is there a change to the principles of construction? 21.A.101(b)(1)(i)**	**Have the assumptions used for certification been invalidated? 21.A.101(b)(1)(ii)**	**Notes**
28.	Request for extended-range operations (ETOPS) type design approval for: (a) aeroplanes without an existing ETOPS type design approval, and (b) extension of an aeroplane's diversion time.	No	No	Yes	An expansion of diversion capability for ETOPS would normally be a significant change. However, expanding the diversion capability for which it was originally designed is generally not a significant change. In this case, the assumptions used for certification of the basic product remain valid, and the results can be applied to cover the changed product with predictable effects or can be demonstrated without significant physical changes to the product.
29.	Installation of an engine with a FADEC on an aeroplane that did not previously have a FADEC engine installed.	No	No	Yes	A change from a mechanical control engine to a FADEC engine may be so extensive that it affects basic aircraft systems integration and architecture concepts and philosophies. This drives a complete reassessment of flight-crew workload, handling qualities, and performance evaluation, which are different from the original design assumptions.

A.2.3 Table A-6 contains examples of changes that are 'not significant' for large aeroplanes (CS-25).

Table A-6. Examples of Not Significant Changes for Large Aeroplanes (CS-25)					
Example	**Description of change**	**Is there a change to the general configuration? 21.A.101(b)(1)(i)**	**Is there a change to the principles of construction? 21.A.101(b)(1)(i)**	**Have the assumptions used for certification been invalidated? 21.A.101(b)(1)(ii)**	**Notes**
1.	Alternate engine installation or hush kit at same position.	No	No	No	It is not significant so long as there is less than a 10 per cent increase in thrust or there is not a change to the principles of propulsion. A change to position to accommodate a different engine size could influence aeroplane performance and handling qualities and result in a significant change.
2.	A small change to fuselage length due to re-fairing the aft body or radome.	No	No	No	For cruise performance reasons, where such changes do not require extensive structural, systems, aerodynamic, or AFM changes.

Table A-6. Examples of Not Significant Changes for Large Aeroplanes (CS-25)					
Example	Description of change	Is there a change to the general configuration? 21.A.101(b)(1)(i)	Is there a change to the principles of construction? 21.A.101(b)(1)(i)	Have the assumptions used for certification been invalidated? 21.A.101(b)(1)(ii)	Notes
3.	Re-fairing of wing tip caps (for lights, fuel dump pipes) and addition of splitter plates to the trailing edge thickness of the cruise aerofoil.	No	No	No	Does not require extensive structural, AFM, or systems changes.
4.	Additional power used to enhance high-altitude or hot-day performance.	No	No	No	Usually no change to basic operating envelope. Existing certification data can be extrapolated. Could be significant product change if the additional power is provided by installation of a rocket motor or additional, on demand engine due to changes to certification assumptions.
5.	Installation of an autopilot system.	No	N/A	See notes	It may be possible that the modification is adaptive in nature, with no change to original certification assumptions. However, in certain cases the installation of an autopilot may include extensive changes and design features that change both the general configuration and the assumptions for certification (i.e. installation of the autopilot may introduce a number of additional mechanical and electronic failure modes and change the hazard classification of given aircraft-level failures).
6.	Change from assembled primary structure to monolithic or integrally machined structure.	No	No	No	Method of construction must be well understood.
7.	Modification to ice protection systems.	No	No	No	Recertification required, but certification basis is adequate.
8.	Brakes: design or material change, e.g. steel to carbon.	No	No	No	Recertification required, but certification basis is adequate.

Table A-6. Examples of Not Significant Changes for Large Aeroplanes (CS-25)					
Example	**Description of change**	**Is there a change to the general configuration? 21.A.101(b)(1)(i)**	**Is there a change to the principles of construction? 21.A.101(b)(1)(i)**	**Have the assumptions used for certification been invalidated? 21.A.101(b)(1)(ii)**	**Notes**
9.	Redesign floor structure.	No	No	No	By itself, not a significant product change. It is significant if part of a cargo conversion of a passenger aeroplane.
10.	New cabin interior with no fuselage length change.	No	No	No	A new cabin interior includes new ceiling and sidewall panels, stowage, galleys, lavatories, and seats. Novel or unusual design features in the cabin interior may require special conditions. Many interior-related certification specifications are incorporated in operational rules. Even though the design approval holder may not be required to comply with these certification specifications, the operator may be required to comply.
11.	A rearrangement of an interior (e.g. seats, galleys, lavatories, closets, etc.).	No	No	No	—
12.	Novel or unusual method of construction of a component.	No	No	No	The component change does not rise to the product level. Special conditions could be required if there are no existing certification specifications that adequately address these features.
13.	Initial installation of a non-essential APU.	No	No	No	A stand-alone initial APU installation on an aeroplane originally designed to use ground- or airport-supplied electricity and air conditioning. In this case, the APU would be an option to be independent of airport power.

Table A-6. Examples of Not Significant Changes for Large Aeroplanes (CS-25)					
Example	Description of change	Is there a change to the general configuration? 21.A.101(b)(1)(i)	Is there a change to the principles of construction? 21.A.101(b)(1)(i)	Have the assumptions used for certification been invalidated? 21.A.101(b)(1)(ii)	Notes
14.	Increasing the life limit as CS 25.571 fatigue testing progresses for a recently type-certified aeroplane.	No	No	No	For example, a recently type-certified aeroplane may undergo fatigue testing as part of compliance with CS 25.571. In this case, the TC holder may specify an initial life limit in the airworthiness limitations section (ALS) and gradually increase that life limit as fatigue testing progresses. Such change to the ALS is considered not significant.
15.	Extending limit of validity (LOV)	No	No	No	Extending an LOV without any other change to the aeroplane is not a significant change. However, if extending the LOV requires a physical design change to the aeroplane, the design change is evaluated to determine the level of significance of the design change.
16.	Airframe life extension.	No	No	No	This does not include changes that involve changes to design loads, such as pressurisation or weight increases. Also, this does not include changing from safe life to damage tolerance.
17.	Changes to the type or number of emergency exits by de-rating doors or deactivating doors with corresponding reduction in passenger capacity.	No	No	No	The new emergency egress does not exceed that previously substantiated because the certified number of passengers is reduced.

Table A-6. Examples of Not Significant Changes for Large Aeroplanes (CS-25)					
Example	Description of change	Is there a change to the general configuration? 21.A.101(b)(1)(i)	Is there a change to the principles of construction? 21.A.101(b)(1)(i)	Have the assumptions used for certification been invalidated? 21.A.101(b)(1)(ii)	Notes
18.	Request for ETOPS type design approval for a type design change of a product with an existing ETOPS type design approval.	No	No	No	A change to a product with an existing ETOPS type design approval without a change to diversion capability would normally not be significant. However, if the existing ETOPS type design approval was based on policy prior to the adoption of transport category ETOPS airworthiness standards, then there is not an adequate certification basis to evaluate the type design change for ETOPS. In this case, the change is still not significant, and the appropriate transport category ETOPS airworthiness standards would apply.
19.	An avionics change from federated electromechanical displays to federated electronic displays.	No	No	No	Changing an electromechanical display to an electronic display is not considered significant.
20.	An avionics change replacing an integrated avionics system with another integrated avionics system.	No	No	No	The assumptions used to certify a highly integrated avionics system should be the same for another highly integrated avionics system.

A.3 Examples of Substantial, Significant, and Not Significant Changes for Rotorcraft (CS-27 and CS-29).

A.3.1 Table A-7 contains examples of changes that are 'substantial' for rotorcraft (CS-27 and CS-29).

Table A-7. Examples of Substantial Changes for Rotorcraft (CS-27 and 29)

Example	Description of Change	Notes
1.	Change from the number and/or configuration of rotors (e.g. main & tail rotor system to two main rotors).	Proposed change to design is so extensive that a substantially complete investigation of compliance with the applicable certification basis is required.
2.	Change from an all-metal rotorcraft to all-composite rotorcraft.	Proposed change to design is so extensive that a substantially complete investigation of compliance with the applicable certification basis is required.

A.3.2 Table A-8 contains examples of changes that are 'significant' for rotorcraft (CS-27 and CS-29).

Table A-8. Examples of Significant Changes for Rotorcraft (CS-27 and CS-29)

Example	Description of change	Is there a change to the general configuration? 21.A.101(b)(1)(i)	Is there a change to the principles of construction? 21.A.101(b)(1)(i)	Have the assumptions used for certification been invalidated? 21.A.101(b)(1)(ii)	Notes
1.	Comprehensive flight deck upgrade, such as conversion from entirely federated, independent electromechanical flight instruments to highly integrated and combined electronic display systems with extensive use of software and/or complex electronic hardware.	No	No	Yes	Affects avionics and electrical systems integration and architecture concepts and philosophies. This drives a reassessment of the human–machine interface, flight-crew workload, and re-evaluation of the original design flight deck assumptions.
2.	Certification for flight into known icing conditions.	No	No	Yes	
3.	(Fixed) flying controls from mechanical to fly-by-wire.	No	No	Yes	This drives a complete reassessment of the rotorcraft controllability and flight control failure.
4.	Addition of an engine; e.g. from single to twin or reduction of the number of engines; e.g. from twin to single.	Yes	Yes	Yes	—
5.	A change of the rotor drive primary gearbox from a splash-type lubrication system to a pressure-lubricated system due to an increase in horsepower of an engine or changing from a piston engine to turbine engine.	No	Yes	Yes	—
6.	A fuselage or tail boom modification that changes the primary structure, aerodynamics, and operating envelope sufficiently to invalidate the certification assumptions.	Yes	No	Yes	—
7.	Application of an approved primary structure to a different approved model (e.g. installation on a former model of a main rotor that has been approved on a new model, and that results in increased performance).	No	Yes	Yes	—

Table A-8. Examples of Significant Changes for Rotorcraft (CS-27 and CS-29)					
Example	**Description of change**	**Is there a change to the general configuration? 21.A.101(b)(1)(i)**	**Is there a change to the principles of construction? 21.A.101(b)(1)(i)**	**Have the assumptions used for certification been invalidated? 21.A.101(b)(1)(ii)**	**Notes**
8.	Emergency medical service (EMS) configuration with primary structural changes sufficient to invalidate the certification assumptions.	No	No	Yes	Many EMS configurations will not be classified as significant. Modifications made for EMS are typically internal, and the general external configuration is normally not affected. These changes should not automatically be classified as significant. Note: Door addition or enlargement involving structural change would be significant.
9.	Skid landing gear to wheel landing gear or wheel landing to skid.	Yes	No	Yes	—
10.	Change of the number of rotor blades.	Yes	No	Yes	—
11.	Change of tail anti-torque device (e.g. tail rotor, ducted fan, or other technology).	Yes	Yes	No	—
12.	Passenger-configured helicopter to a firefighting-equipment-configured helicopter.	Yes	No	Yes	Depends on the firefighting configuration.
13.	Passenger-configured helicopter to an agricultural-configured helicopter.	Yes	No	Yes	Depends on the agricultural configuration.
14.	An initial Category A certification approval to an existing configuration.	No	No	Yes	—
15.	IFR upgrades involving installation of upgraded components for new IFR configuration.	No	No	Yes	Changes to architecture concepts, design philosophies, human-machine interface, or flight-crew workload.
16.	Human external cargo (HEC) certification approval.	No	No	Yes	Must comply with the latest HEC certification specifications in order to obtain operational approval. Assumptions used for certification are considered invalidated when this leads to a significant re-evaluation, for example, of fatigue, quick-release systems, HIRF, one-engine-inoperative (OEI) performance, and OEI procedures.
17.	Reducing the number of pilots for IFR from two to one.	No	No	Yes	—
18.	An avionics upgrade that changes a federated avionics system to a highly integrated avionics system.	No	No	Yes	This change refers to the avionics system that feeds the output to displays and not the displays themselves.

Table A-8. Examples of Significant Changes for Rotorcraft (CS-27 and CS-29)					
Example	**Description of change**	**Is there a change to the general configuration? 21.A.101(b)(1)(i)**	**Is there a change to the principles of construction? 21.A.101(b)(1)(i)**	**Have the assumptions used for certification been invalidated? 21.A.101(b)(1)(ii)**	**Notes**
19.	An avionics upgrade that changes the method of input from the flight crew, which was not contemplated during the original certification.	No	No	Yes	A change that includes touchscreen technology typically does not invalidate the assumptions used for certification. A change that incorporates voice-activated controls or other novel human-machine interface would likely invalidate the assumptions used for certification.

A.3.3 Table A-9 contains examples of changes that are 'not significant' changes for rotorcraft (CS-27 and CS-29).

Table A-9. Examples of Not Significant Changes for Rotorcraft (CS-27 and CS-29)					
Example	**Description of change**	**Is there a change to the general configuration? 21.A.101(b)(1)(i)**	**Is there a change to the principles of construction? 21.A.101(b)(1)(i)**	**Have the assumptions used for certification been invalidated? 21.A.101(b)(1)(ii)**	**Notes**
1.	Emergency floats.	No	No	No	Must comply with the specific applicable certification specifications for emergency floats. This installation, in itself, does not change the rotorcraft configuration, overall performance, or operational capability. Expanding an operating envelope (such as operating altitude and temperature) and mission profile (such as passenger-carrying operations to external-load operations, flight over water, or operations in snow conditions) are not by themselves so different that the original certification assumptions are no longer valid at the type-certified-product level.
2.	Forward looking infrared (FLIR) or surveillance camera installation.	No	No	No	Additional flight or structural evaluation may be necessary but the change does not alter the basic rotorcraft certification.
3.	Helicopter terrain awareness warning system (HTAWS) for operational credit.	No	No	No	Certified under rotorcraft HTAWS AMC guidance material and ETSO-C194. Does not alter the basic rotorcraft configuration.
4.	Health usage monitoring system (HUMS) for maintenance credit.	No	No	No	Certified under rotorcraft HUMS GM guidance material. Does not alter the basic rotorcraft configuration.

Table A-9. Examples of Not Significant Changes for Rotorcraft (CS-27 and CS-29)					
Example	**Description of change**	**Is there a change to the general configuration? 21.A.101(b)(1)(i)**	**Is there a change to the principles of construction? 21.A.101(b)(1)(i)**	**Have the assumptions used for certification been invalidated? 21.A.101(b)(1)(ii)**	**Notes**
5.	Expanded limitations with minimal or no design changes, following further tests/justifications or different mix of limitations (CG limits, oil temperatures, altitude, minimum/maximum weight, minimum/ maximum external temperatures, speed, engine ratings).	No	No	No	Changes to an operating envelope (such as operating altitude and temperature) and mission profile (such as passenger-carrying operations to external-load operations, flight over water, or operations in snow conditions) that are not so different that the original certification assumptions remain valid.
6.	Change from a single-channel FADEC to a dual-channel FADEC.				Change does not change the overall product configuration or the original certification assumptions.
7.	Installation of a new engine type, equivalent to the former one, leaving aircraft installation and limitations substantially unchanged.	No	No	No	Refer to AMC 27 or AMC 29 for guidance. Does not alter the basic rotorcraft configuration, provided there is no additional capacity embedded in the new design.
8.	Windscreen installation.	No	No	No	Does not change the rotorcraft overall product configuration.
9.	Snow skis, 'Bear Paws.'	No	No	No	Must comply with specific certification specifications associated with the change. Expanding an operating envelope (such as operating altitude and temperature) and mission profile (such as passenger-carrying operations to external-load operations, flight over water, or operations in snow conditions) are not by themselves so different that the original certification assumptions are no longer valid at the type-certified-product level.

Table A-9. Examples of Not Significant Changes for Rotorcraft (CS-27 and CS-29)					
Example	**Description of change**	**Is there a change to the general configuration? 21.A.101(b)(1)(i)**	**Is there a change to the principles of construction? 21.A.101(b)(1)(i)**	**Have the assumptions used for certification been invalidated? 21.A.101(b)(1)(ii)**	**Notes**
10.	External cargo hoist.	No	No	No	Must comply with the specific applicable certification specifications for external loads. This installation, in itself, does not change the rotorcraft configuration, overall performance, or operational capability. Expanding an operating envelope (such as operating altitude and temperature) and mission profile (such as passenger-carrying operations to external-load operations (excluding HEC), flight over water, or operations in snow conditions) are not by themselves so different that the original certification assumptions are no longer valid at the type-certified-product level.
11.	IFR upgrades involving installation of upgraded components to replace existing components.	No	No	No	Not a rotorcraft-level change.
12.	An avionics change from federated electromechanical displays to federated electronic displays.	No	No	No	Changing an electromechanical display to an electronic display on a single avionics display is not considered significant.
13.	An avionics change replacing an integrated avionics system with another integrated avionics system.	No	No	No	The assumptions used to certify a highly integrated avionics system should be the same for another highly integrated avionics system.
14.	Flight deck replacement of highly integrated and combined electronic display systems with other highly integrated and combined electronic display systems.	No	No	No	Not significant if the architecture concepts, design philosophies, human–machine interface, flight-crew workload design and flight-deck assumptions are not impacted.
15.	IFR upgrades involving installation of upgraded components for new IFR configuration.	No	No	No	No changes to architecture concepts, design philosophies, human–machine interface, or flight-crew workload.
16.	Flight deck replacement or upgrade of avionics systems in non-Appendix ‘B’ (IFR) or non-CAT ‘A’ rotorcraft that can enhance safety or pilot awareness.	No	No	No	—
17.	Modifications to non-crashworthy fuel systems intended to improve its crashworthiness.	No	No	No	—

Table A-9. Examples of Not Significant Changes for Rotorcraft (CS-27 and CS-29)					
Example	Description of change	Is there a change to the general configuration? 21.A.101(b)(1)(i)	Is there a change to the principles of construction? 21.A.101(b)(1)(i)	Have the assumptions used for certification been invalidated? 21.A.101(b)(1)(ii)	Notes
18.	Changing the hydraulic system from one similar type of fluid to another, e.g. a fluid change from a highly flammable mineral oil-based fluid (MIL-H-5606) to a less flammable synthetic hydrocarbon-based fluid (MIL-PRF-87257)	No	No	No	—
19.	An ETSO C-127 dynamic seat installed in a helicopter with an existing certification basis prior to addition of CS 29.562, Emergency landing dynamic conditions.	No	No	No	

A.4 Examples of Substantial, Significant, and Not Significant Changes for Engines (CS-E)

A.4.1 Table A-10 contains examples of changes that are 'substantial' for engines (CS-E).

Table A-10. Examples of Substantial Changes for Engines (CS-E)

Example	Description of Change	Notes
Turbine Engines		
1.	Traditional turbofan to geared-fan engine.	Proposed change to design is so extensive that a substantially complete investigation of compliance with the applicable certification basis is required.
2.	Low-bypass ratio engine to high-bypass ratio engine with an increased inlet area.	Proposed change to design is so extensive that a substantially complete investigation of compliance with the applicable certification basis is required.
3.	Turbojet to turbofan.	Proposed change to design is so extensive that a substantially complete investigation of compliance with the applicable certification basis is required.
4.	Turboshaft to turbo-propeller.	Proposed change to design is so extensive that a substantially complete investigation of compliance with the applicable certification basis is required.
5.	Conventional ducted fan to unducted fan.	Proposed change to design is so extensive that a substantially complete investigation of compliance with the applicable certification basis is required.
6.	Turbine engine for subsonic operation to afterburning engine for supersonic operation.	Proposed change to design is so extensive that a substantially complete investigation of compliance with the applicable certification basis is required.

A.4.2 Table A-11 contains examples of changes that are 'significant' for engines (CS-E).

Table A-11. Examples of Significant Changes for Engines (CS-E)					
Example	**Description of change**	**Is there a change to the general configuration? 21.A.101(b)(1)(i)**	**Is there a change to the principles of construction? 21.A.101(b)(1)(i)**	**Have the assumptions used for certification been invalidated? 21.A.101(b)(1)(ii)**	**Notes**
Turbine Engines					
1.	Increase/decrease in the number of compressor/turbine stages with resultant change to approved operational limitations.	Yes	No	Yes	Change is associated with other changes that would affect the rating of the engine and the engine dynamic behaviour, such as backbone bending, torque spike effects on rotors and casing, surge and stall characteristics, etc.
2.	New design fan blade and fan hub, or a bladed fan disk to a blisk, or a fan diameter change, that could not be retrofitted.	Yes	No	Yes	Change is associated with other changes to the engine thrust/power, ratings, and operating limitations; engine dynamic behaviour in terms of backbone bending, torque spike effects on casing, foreign object ingestion behaviour (birds, hail, rain, ice slab); blade-out test and containment; induction system icing capabilities; and burst model protection for the aircraft. If there is a diameter change, installation will be also affected.
3.	Hydromechanical control to FADEC/electronic engine control (EEC) without hydromechanical backup.	Yes	No	No	Change to engine control configuration. Not interchangeable. Likely fundamental change to engine operation.
4.	A change to the containment case from hard-wall to composite construction or vice versa that could not be retrofitted without additional major changes to the engine or restricting the initial limitations or restrictions in the initial installation manual.	No	Yes	Yes	Change to methods of construction that have affected inherent strength, backbone bending, blade-to-case clearance retention, containment wave effect on installation, effect on burst model, torque spike effects.
5.	A change to the gas generator (core, turbine/compressor/ combustor) in conjunction with changes to approved operating limitations.	No	No	Yes	Change is associated with other changes that would affect engine thrust/power and operating limitations, and have affected the dynamic behaviour of the engine, foreign object ingestion behaviour (birds, hail storm, rain, ice shed), induction system icing capabilities. Assumptions used for certification may no longer be valid.

Table A-11. Examples of Significant Changes for Engines (CS-E)					
Example	**Description of change**	**Is there a change to the general configuration? 21.A.101(b)(1)(i)**	**Is there a change to the principles of construction? 21.A.101(b)(1)(i)**	**Have the assumptions used for certification been invalidated? 21.A.101(b)(1)(ii)**	**Notes**
6.	A change from traditional metal to composite materials on an assembly or structure that provides a load path for the engine affecting the engine dynamic behaviour and/or the engine inherent strength.	No	Yes	Yes	Change to principles of construction and design.
Piston Engines					
7.	Convert from mechanical to electronic control system.	Yes	Yes	No	Change to engine configuration: installation interface of engine changed. Changes to principles of construction: digital controllers and sensors require new construction techniques and environmental testing.
8.	Add turbocharger that increases performance and changes to overall product.	Yes	No	Yes	Change to general configuration: installation interface of engine changed (exhaust system). Certification assumptions invalidated: change to operating envelope and performance.
9.	Convert from air-cooled cylinders to liquid-cooled cylinders.	Yes	No	Yes	Change to general configuration: installation interface of engine changed (cooling lines from radiator, change to cooling baffles). Certification assumptions invalidated: change to operating envelope and engine temperature certification specifications.
10.	A change from traditional metal to composite materials on an assembly or structure that provides a load path for the engine affecting the engine dynamic behaviour and/or the engine inherent strength.	No	Yes	Yes	Change to principles of construction and design.
11.	Convert from spark-ignition to compression-ignition.	Yes	No	Yes	Change to general configuration: installation interface of engine changed (no mixture lever). Certification assumptions invalidated: change to operating envelope and performance.

A.4.3 Table A-12 contains examples of changes that are 'not significant' for engines (CS-E).

Table A-12. Examples of Not Significant Changes for Engines (CS-E)

Example	Description of change	Is there a change to the general configuration? 21.A.101(b)(1)(i)	Is there a change to the principles of construction? 21.A.101(b)(1)(i)	Have the assumptions used for certification been invalidated? 21.A.101(b)(1)(ii)	Notes
		Turbine Engines			
1.	Change to the material from one type of metal to another type of metal of a compressor drum.	No	No	No	No change to performance. Assumptions are still valid.
2.	Increase/decrease in the number of compressor/turbine stages without resultant change to operational performance envelope.	No	No	No	No change to performance. Assumptions are still valid.
3.	Hardware design changes to the FADEC/EEC, the introduction of which does not change the function of the system.	No	No	No	No change to configuration. Retrofitable. Assumptions used for certification are still valid. Possible changes to principles of construction are insignificant.
4.	Software changes.	No	No	No	—
5.	Rub-strip design changes.	No	No	No	Component-level change.
6.	A new combustor that does not change the approved limitations or dynamic behaviour.* (*Exclude life limits.)	No	No	No	Component-level change.
7.	Bearing changes.	No	No	No	Component-level change.
8.	New blade designs with similar material that can be retrofitted.	No	No	No	Component-level change.
9.	Fan blade redesign that can be retrofitted.	No	No	No	Component-level change.
10.	Oil tank redesign.	No	No	No	Component-level change.
11.	Change from one hydromechanical control to another hydromechanical control.	No	No	No	Component-level change.
12.	Change to limits on life-limited components supported by data that became available after certification.	No	No	No	Extending or reducing the life limits. For example, extending life limits based on credits from service experience or new fatigue data.
13.	Changes to limits on exhaust gas temperature.	No	No	No	

Table A-12. Examples of Not Significant Changes for Engines (CS-E)					
Example	**Description of change**	**Is there a change to the general configuration? 21.A.101(b)(1)(i)**	**Is there a change to the principles of construction? 21.A.101(b)(1)(i)**	**Have the assumptions used for certification been invalidated? 21.A.101(b)(1)(ii)**	**Notes**
14.	Changes to the Airworthiness Limitations section with no configuration changes.	No	No	No	—
15.	Bump ratings within the product's physical capabilities that may be enhanced with gas path changes, such as blade re-staggering, cooling hole patterns, blade coating changes, etc.	No	No	No	—
Piston Engines					
16.	New or redesigned cylinder head, valves, or pistons.	No	No	No	—
17.	Changes to crankshaft.	No	No	No	Component-level change.
18.	Changes to crankcase.	No	No	No	Component-level change.
19.	Changes to carburettor.	No	No	No	Component-level change.
20.	Changes to mechanical fuel injection system.	No	No	No	
21.	Changes to mechanical fuel injection pump.	No	No	No	Component-level change.
22.	Engine model change to accommodate new aircraft installation. No change to principles of operation of major subsystems; no significant expansion in power or operating envelopes or in limitations.	No	No	No	—
23.	A simple mechanical change, or a change that does not affect the basic principles of operation. For example, change from dual magneto to two single magnetos on a model.	No	No	No	—

Table A-12. Examples of Not Significant Changes for Engines (CS-E)					
Example	Description of change	Is there a change to the general configuration? 21.A.101(b)(1)(i)	Is there a change to the principles of construction? 21.A.101(b)(1)(i)	Have the assumptions used for certification been invalidated? 21.A.101(b)(1)(ii)	Notes
24.	Subsystem change produces no changes to base engine input parameters, and previous analysis can be reliably extended. For example, a change to turbocharger where induction system inlet conditions remain unchanged, or if changed, the effects can be reliably extrapolated.	No	No	No	—
25.	Change to material of secondary structure or not highly loaded component. For example, a change from metal to composite material in a non-highly loaded component, such as an oil pan that is not used as a mount pad.	No	No	No	Component-level change.
26.	Change to material that retains the physical properties and mechanics of load transfer. For example, a change to trace elements in a metal casting for ease of pouring or to update to a newer or more readily available alloy with similar mechanical properties.	No	No	No	Component-level change.

A.5 Examples of Substantial, Significant, and Not Significant Changes for Propellers (CS-P).

A.5.1 Table A-13 contains an example of a change that is 'substantial' for propellers (CS-P).

Table A-13. Example of a Substantial Change for Propellers (CS-P)

Example	Description of Change	Notes
1.	Change to the number of blades.	Proposed change to design is so extensive that a substantially complete investigation of compliance with the applicable type-certification basis is required.

A.5.2 Table A-14 contains examples of changes that are 'significant' for propellers (CS-P).

Table A-14. Examples of Significant Changes for Propellers (CS-P)

Example	Description of change	Is there a change to the general configuration? 21.A.101(b)(1)(i)	Is there a change to the principles of construction? 21.A.101(b)(1)(i)	Have the assumptions used for certification been invalidated? 21.A.101(b)(1)(ii)	Notes
1.	Principle of pitch change, such as a change from single acting to dual acting.	Yes	Yes	Yes	Requires extensive modification of the pitch change system with the introduction of backup systems. The inherent control system requires re-evaluation.
2.	Introduction of a different principle of blade retention, such as a single row to a dual row bearing.	Yes	Yes	No	Requires extensive modification of the propeller hub and blade structure. The inherent strength requires re-evaluation.
3.	A hub configuration change, such as a split hub to a one-piece hub.	Yes	Yes	No	Requires extensive modification of the propeller hub structure. The inherent strength requires re-evaluation.
4.	Changing the method of mounting the propeller to the engine, such as a spline to a flange mount.	Yes	Yes	No	Requires extensive modification of the propeller hub structure. The inherent strength requires re-evaluation.
5.	Change to hub material from steel to aluminium.	Yes	Yes	No	Requires extensive modification of the propeller hub structure and change to method of blade retention. The inherent strength requires re-evaluation.
6.	Change to blade material from metal to composite.	Yes	Yes	Yes	Requires extensive modification of the propeller blade structure and change to method of blade retention. Composite construction methods required. The inherent strength requires re-evaluation.
7.	Change from hydromechanical to electronic control.	Yes	Yes	Yes	Electronic manufacturing and design methods required. Assumptions used for certification are no longer valid or not addressed in the original certification, i.e. HIRF and lightning protection, fault tolerance, software certification, and other aspects.

A.5.3 Table A-15 contains examples of changes that are 'not significant' for propellers (CS-P).

Table A-15. Examples of Not Significant Changes for Propellers (CS-P)					
Example	**Description of change**	**Is there a change to the general configuration? 21.A.101(b)(1)(i)**	**Is there a change to the principles of construction? 21.A.101(b)(1)(i)**	**Have the assumptions used for certification been invalidated? 21.A.101(b)(1)(ii)**	**Notes**
1.	Change to the material of a blade bearing.	No	No	No	Component-level change.
2.	Change to a component in the control system.	No	No	No	Component-level change.
3.	Change to a propeller de-icer boot.	No	No	No	Component-level change.
4.	Changes to the operational design envelope, such as increase in power.	No	No	No	Propeller's operating characteristics and inherent strength require re-evaluation.
5.	Change to the intended usage, such as normal to acrobatic category.	No	No	No	Propeller's operating characteristics and inherent strength require re-evaluation.

Appendix B to GM 21.A.101 Application charts for changed product rule

ED Decision 2017/024/R

Table A-16. Application Chart for 21.A.101(a) and (b) and 21.A.19

<table>
<tr><th>Substantial
(21.A.19)</th><th colspan="3">Significant
(21.A.101(a) and (b))</th><th colspan="2">Not Significant
(21.A.101)(b)(1))</th></tr>
<tr><td rowspan="3">Substantially changed product
Compliance with all latest CSs required for product certification. Previously approved type design and compliance data may be allowed if valid for the changed product.</td><td colspan="3">Affected area
(Changed and/or affected areas)
New demonstration of compliance is required
Previously approved type design and compliance data may be allowed if valid for the changed product.</td><td rowspan="3">Unaffected area
No new demonstration of compliance is required. Unaffected area continues to comply with the existing certification basis.</td><td rowspan="3">Affected area
(Changed and/or affected areas) New demonstration of compliance is required. The applicant may propose a certification basis using an earlier amendment but not earlier than in the existing TC basis. Previously approved type design and compliance data may be allowed if valid for the changed product.</td><td rowspan="3">Unaffected area
No new demonstration of compliance is required. Unaffected area continues to comply with the existing certification basis.</td></tr>
<tr><td colspan="2">Compliance with the latest amendment materially contributes to safety</td><td>No material contribution to safety</td></tr>
<tr><td>Practical
—</td><td>Impractical
The applicant may propose a certification basis using earlier CS(s), but not earlier than the existing TC basis.</td><td>The applicant may propose a certification basis using earlier CS(s), but not earlier than the existing TC basis.</td></tr>
<tr><td colspan="6">Certification Basis Proposed by the Applicant</td></tr>
<tr><td colspan="2">New certification basis using latest CSs.</td><td colspan="2">CSs at earlier amendments with supporting rationale.</td><td>Existing certification basis.</td><td>Existing certification basis including ‘elects to comply’.</td><td>Existing certification basis.</td></tr>
<tr><td colspan="6">EASA Resultant Type-Certification Basis</td></tr>
<tr><td colspan="2">New certification basis using the latest CSs, and special conditions if required.</td><td colspan="2">New certification basis using the CSs at earlier approved amendments, and special conditions if required.</td><td>Existing certification basis.</td><td>Existing certification basis (if adequate); if not, first appropriate later amendment(s) and/or special conditions including ‘elects to comply’.</td><td>Existing certification basis.</td></tr>
</table>

Table A-17. Application Chart for 21.A.101(c) Excepted Products

<table>
<tr><td colspan="4">Affected area
(Changed areas and/or unchanged but affected)
New demonstration of compliance is required.
Previously approved type design and compliance data may be allowed if valid for the changed product.</td><td>Unaffected area
No new demonstration of compliance is required.
Unaffected area continues to be compliant with the existing TC basis.</td></tr>
<tr><td colspan="5">Type-Certification Basis Proposed by the Applicant</td></tr>
<tr><td colspan="4">The existing TC basis, including ‘elects to comply’.</td><td>The existing TC basis.</td></tr>
<tr><td colspan="3">Found by EASA to be ‘significant in an area’.</td><td>Not ‘significant in an area’.</td><td rowspan="3"></td></tr>
<tr><td colspan="2">Compliance with a later amendment materially contributes to safety.</td><td rowspan="2">No material contribution to safety.</td><td rowspan="2"></td></tr>
<tr><td>Practical</td><td>Impractical</td></tr>
<tr><td colspan="5">EASA Resultant Type-Certification Basis</td></tr>
<tr><td>The latest amendment designated by EASA including special conditions and including ‘elects to comply’.</td><td colspan="3">The existing TC basis. If inadequate, the first appropriate later amendment. If not appropriate, add special conditions, including ‘elects to comply’.</td><td>The existing TC basis.</td></tr>
</table>

Appendix C to GM 21.A.101 A method to determine the changed and affected areas

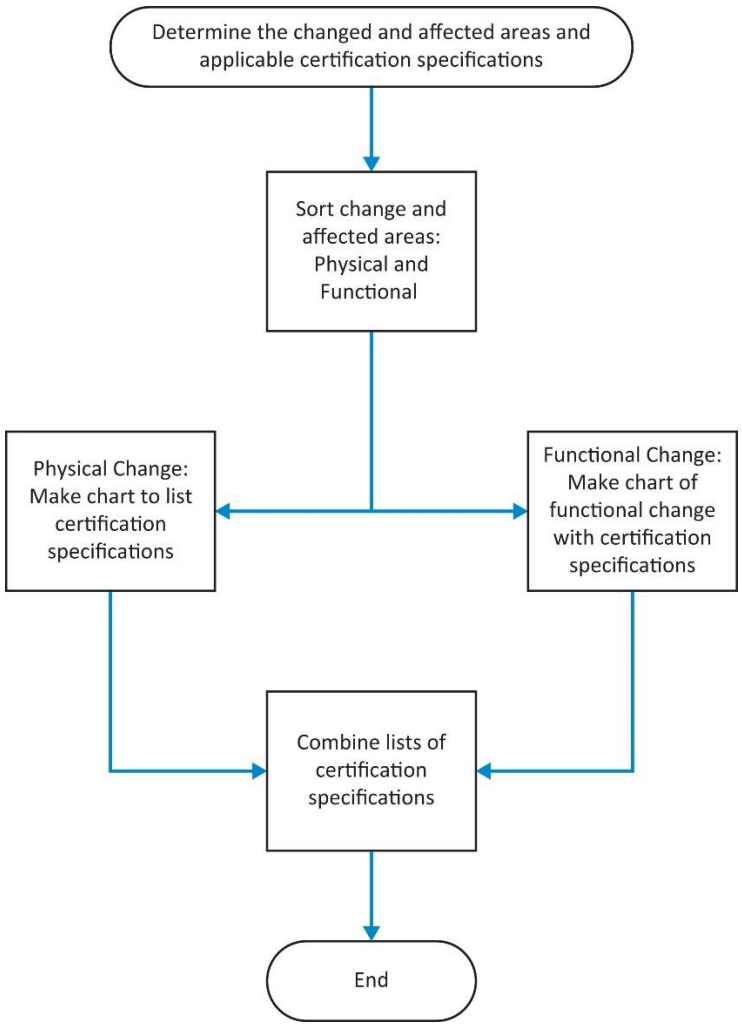
ED Decision 2017/024/R

C.1 Overview.

C.1.1 When a product is changed, some areas may change physically, while others may change functionally. EASA refers to this combination as changed and affected areas. For example, an extension to the wing of a fixed-wing aircraft would physically change the wing tip and likely other wing structure. Some areas of the airframe may have sufficient strength for the increase in load and would change functionally, i.e. they would carry greater load, but they would not change physically. These areas have associated certification specifications, which become part of the certification basis for the change.

C.1.2 Figure C-1 below provides an overview of one method that applicants may use to determine the changed and affected areas and the applicable certification specifications.

Figure C-1. Method to Determine the Changed and Affected Areas



C.2 Physical Changes.

C.2.1 Steps.

- Step 1. Make a list of the physical changes.
- Step 2. List the corresponding certification specifications applicable to the physical changes.
- Step 3. List the amendment level recorded on the existing certification basis of the baseline product and the amendments on the date of application.

C.2.2 Example.

The change is adding a winglet to a fixed-wing aircraft and a change to the leading-edge slats for a performance increase. As part of the change, an electrically driven slat actuator is modified by changing the mounting structure of the actuator used to connect the actuator to the slat. The actuator structure is changed. The electrical system in the actuator is not affected. The applicant would list certification specifications applicable to the actuator. The applicant would not list the certification specifications applicable to the electrical system of the actuator. See Table C-1 below for an example of how to chart a physical change and the associated certification specifications.

Table C-1. Example of Associating a Physical Change with the Applicable Certification Specifications

Physical Change	Applicable Certification Specifications*	Amendment of Existing Certification Basis	Amendment on Application Date
Structural change to slat actuator	25.xxx	25-aaa	25-ddd
	25.yyy	25-bbb	25-eee
	25.zzz	25-ccc	25-fff

* These would be certification specifications related to structural aspects only.

C.3 Functional Changes.

C.3.1 Steps.

- Step 1. Describe each change.
- Step 2. Describe the effects of the change (e.g. structural, performance, electrical, etc.).
- Step 3. List the areas, systems, parts, and appliances that are affected by those effects.
- Step 4. List the certification specifications associated with the effects for each area, system, part, or appliance.
- Step 5. List the amendment level recorded on the existing certification basis of the baseline product and the amendments on the date of application.

C.3.2 Example.

The change is adding a winglet to a fixed-wing aircraft and a change to the leading-edge slats for a performance increase. The wing root bending moment has increased. The loads in the wing box are increased but the wing box has sufficient structural margins to carry the higher loads. Thus, the wing box is not physically changed but its function has changed because it carries greater loads. See Table C-2 below for an example of how to chart a functional change, its effects, and the affected areas (steps 1 through 3 above). See Table C-3 below for an example of how to chart an area affected by a functional change and the associated certification specifications (steps 4 and 5 above).

Table C-2. Example of a Functional Change, Affected Areas, and Associated Effects

Description of Change	Effects	Affected Areas
Installation of winglet	Increased loads in wing structure	Wing spars
		Wing skins
	Effect 2*	Area 1
		Area 2
	Effect 3*	Area 3

* There may be other effects as well.

Table C-3. Example of Associating Affected Areas with the Applicable Certification Specifications

Impacted Area	Applicable Certification Specifications*	Amendment of Existing Certification Basis	Amendment on Application Date
Wing spar	25.xxx	25-aaa	25-ddd
	25.yyy	25-bbb	25-eee
	25.zzz	25-ccc	25-fff

* These would be structural certification specifications only. There could be other certification specifications applicable to the wing box. But since the effect is structural, then only the structural certification specifications are applicable.

C.4 Combine the Lists.

C.4.1 EASA typically presents the certification basis for a product by certification specification and not by area. The next step is to combine these two lists. However, since only a portion of the product is being changed, the changed and affected areas of the new certification basis need to be identified. The unchanged area is not required to comply with the certification specifications in effect at the date of application. (See point 21.A.101(b)(2))

C.4.2 When the change is quite extensive, applicants will save time by listing all the certification specifications applicable to the category of product they are certifying. They can use Table C-4 below in the next step where they will identify any other exceptions that they would like EASA to consider.

C.4.3 Example. If we use the examples above for the combined list for the actuator structural changes and the wing box functional change, then the certification basis would be listed as shown in Table C-4 below.

Table C-4. Example of a Combined List of Physical and Functional Changes with Applicable Certification Specifications

Certification Specification	Amendment Levels		Changed and Affected Area
	Amendment of Existing Certification Basis	Amendment on Application Date	
25.xxx*	25-aaa	25-ddd	- Wing spar - Leading-edge actuator - Wing loads
25.yyy*	25-bbb	25-eee	
25.zzz*	25-ccc	25-fff	

* These represent structural certification specifications.

Appendix D to GM 21.A.101 Other guidance for affected areas

ED Decision 2017/024/R

D.1 Sample Questions in Determining Affected Areas.

Below are sample questions to assist in determining whether an area is affected by the change. If the answer to any of these questions is yes, then the area is considered to be affected.

1. Is the area changed from the identified baseline product?
2. Is the area impacted by a significant product-level change?
3. Is there a functional effect on the unchanged area by a change to the system or system function that it is a part of?
4. Does the unchanged area need to comply with a system or product-level certification specification that is part of the change?
5. Are the product-level characteristics affected by the change?
6. Is the existing compliance for the area invalidated?

D.2 Sub-Areas within an Affected Area.

Within areas affected by a change, there may be 'sub-areas' of the area that are not affected. For those sub-areas, the amendment levels at the existing certification basis remain valid, along with the previous compliance findings. For example, if a passenger seat fitting is changed as part of a significant change, then the structure of the seat is affected. Thus, the amendment level for CS 25.561 and CS 25.562, along with other applicable structural certification specifications, would be at the amendment level on the date of application (unless an exception is granted). However, the seat fabric is not affected, so the amendment level for CS 25.853 (flammability) may remain at the existing certification basis, and a new compliance finding would not be required.

Appendix E to GM 21.A.101 Procedure for evaluating material contribution to safety or impracticality of applying latest certification specifications to a changed product

ED Decision 2019/018/R

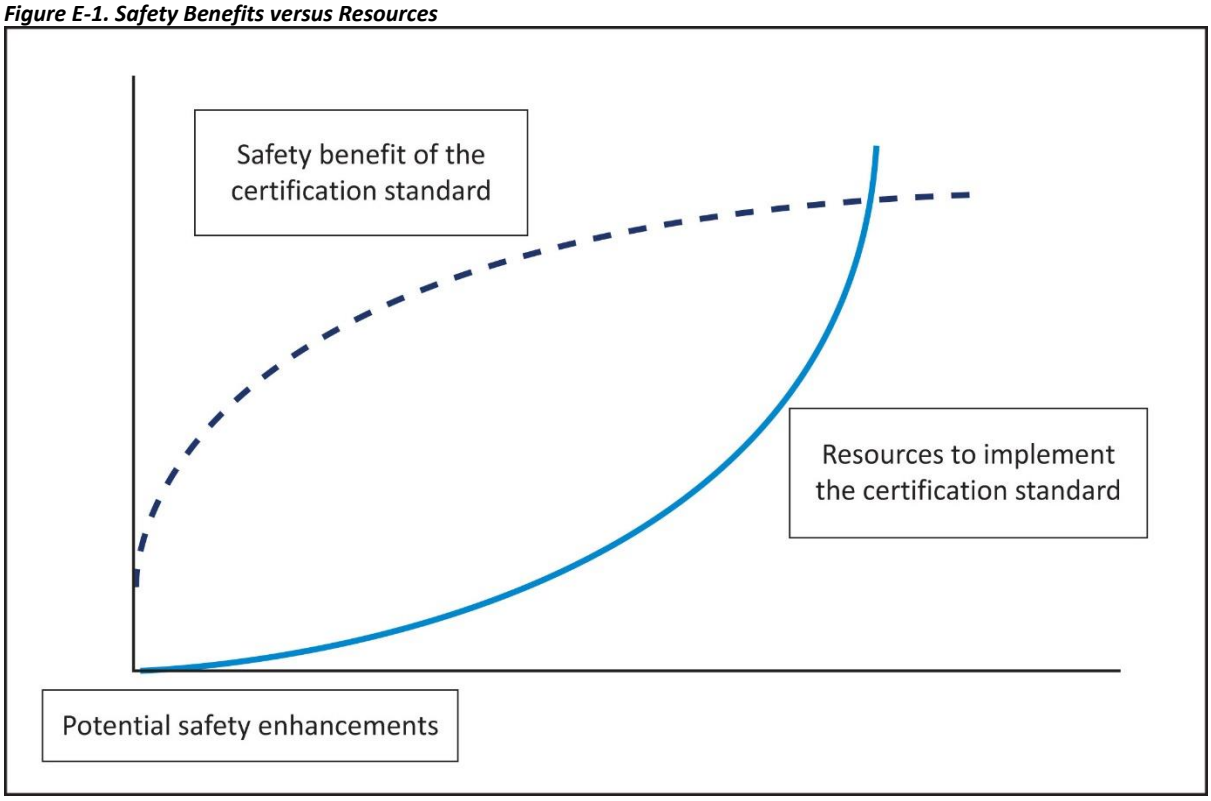
E.1 Introduction.

E.1.1 The basic principle of enhancing the level of safety of changed aeronautical products is to apply the latest certification specifications for significant changes to the greatest extent practical. In certain cases, the cost of complying fully with a later certification specification may not be commensurate with the small safety benefit achieved. These factors form the basis where compliance with the latest standard may be considered impractical, thereby allowing compliance with an earlier certification specification. This Appendix gives one method of determining whether compliance with a later certification specification is impractical; however, it does not preclude the use of other methods for improving the safety of aeronautical products.

E.1.2 EASA recognises that other procedures can be used and have historically been accepted on a case-by-case basis. The acceptance of results through the use of these procedures may vary from state to state. Consequently, they may not be accepted through all bilateral certification processes. Regardless of which method is used, the process must show that a proposed certification basis is able to achieve a positive safety benefit for the overall product.

E.1.3 Regarding impracticality, any method used must encourage the incorporation of safety enhancements that will have the most dramatic impact on the level of safety of the aircraft while considering the effective use of resources. This important point is illustrated graphically in Figure E-1 below. This Figure notionally shows the interrelation between the total resources required for incorporating each potential safety enhancement with the corresponding net increase in safety benefit.

Figure E-1. Safety Benefits versus Resources



E.1.4 Typically, it is found that, for impractical certification basis changes, there are proposals that can achieve a positive safety benefit that are resource-effective. Conversely, there are proposals that may achieve a small safety benefit at the expense of a large amount of resources to implement them. Clearly, there will be a point where a large percentage of the potential safety benefit can be achieved with a reasonable expenditure of resources. The focus of the methods used should be to determine the most appropriate certification standards relative to the respective incremental cost to reach this point.

E.1.5 This Appendix provides procedural guidance for determining the material contribution to the level of safety, or the practicality of applying a certification standard at a particular amendment level to a changed product. The procedure is generic in nature and describes the steps and necessary inputs that may be used on any project to develop a position.

E.1.6 The procedure is intended to be used, along with good engineering judgment, to evaluate the relative merits of a changed product complying with the latest certification standards. It provides a means, but not the only means, for applicants to present their position regarding an exception under point 21.A.101(b)(3).

E.1.7 The certification basis for a change to a product will not be at an amendment level earlier than the existing certification basis.

E.2 Procedure for evaluating the material contribution or impracticality of applying the latest certification specifications to a changed product.

The following are steps to determine the material contribution or impracticality of applying a certification specification at a particular amendment level.

E.2.1 Step 1: Identify the regulatory change being evaluated.

In this step, applicants should document:

E.2.1.1 The specific standard (e.g. CS 25.365),

E.2.1.2 The amendment level of the existing certification basis for the standards, and

E.2.1.3 The latest amendment level of the certification specification.

E.2.2 Step 2: Identify the specific hazard that the certification specification addresses.

E.2.2.1 Each certification specification and its subsequent amendments addresses a hazard or hazards. In this step, the specific hazard(s) is (are) identified. This identification will allow for a comparison of the effectiveness of the amendment levels of the certification specification in addressing the hazard.

E.2.2.2 In many cases, the hazard and the cause of the hazard will be obvious. When the hazard and its related cause are not immediately obvious, it may be necessary to review the explanatory note (EN) and/or the impact assessment (IA) in the ED Decision by which the certification specification or its amendment was adopted. It may also be helpful to discuss the hazard with the responsible EASA team.

E.2.3 Step 3: Review the consequences of the hazard(s).

E.2.3.1 Once the hazard is identified, it is possible to identify the types of consequences that may occur due to the hazard. More than one consequence can be attributed to the same hazard. Typical examples of consequences would include but are not limited to:

— incidents where only injuries occurred,

— accidents where a total hull loss occurred,

— accidents where less than 10 per cent of the passengers died,

— accidents where 10 per cent or more passengers died, and

— engine- and propeller-specific hazards.

E.2.3.2 The explanatory note (EN) and/or the impact assessment (IA) in the ED Decision may provide useful information regarding the consequences of the hazard that the certification specification addresses.

E.2.4 Step 4: Identify the historical and predicted frequency of each consequence.

E.2.4.1 Another source for determining impracticality is the historical record of the consequences of the hazard that led to a certification specification or an amendment to a certification specification. From these data, a frequency of occurrence for the hazard can be determined. It is important to recognise that the frequency of occurrence may be higher or lower in the future. Therefore, it also is necessary to predict the frequency of future occurrences.

E.2.4.2 More than one consequence can be attributed to the same hazard. Therefore, when applicable, the combination of consequences and frequencies of those consequences should be considered together.

E.2.4.3 The explanatory note (EN) and/or the impact assessment (IA) in the ED Decision may provide useful information regarding the frequency of an occurrence.

E.2.5 Step 5: Determine how effective full compliance with the latest amendment of the certification specification would be in addressing the hazard.

E.2.5.1 When each amendment is issued, it is usually expected that compliance with the certification specification would be completely effective in addressing the associated hazard for the designs and technology envisioned at the time. It is expected that the hazard would be eliminated, avoided, or mitigated. However, experience has shown that this may not always be the case. It is also possible that earlier amendment levels may have addressed the hazard but were not completely effective. A product may also contain a design feature(s) that provides a level of safety that approaches that of the latest certification specifications, yet is not fully compliant with the latest certification specifications. Therefore, in comparing the benefits of compliance with the existing certification basis to the latest amendment level, it is useful to estimate the effectiveness of both amendment levels in dealing with the hazard.

E.2.5.2 It is recognised that the determination of levels of effectiveness is normally of a subjective nature. Therefore, prudence should be exercised when making these determinations. In all cases, it is necessary to document the assumptions and data that support the determination.

E.2.5.3 The following five levels of effectiveness are provided as a guideline:

1. Fully effective in all cases. Compliance with the certification specification eliminates the hazard or provides a means to avoid the hazard completely.
2. Considerable potential for eliminating or avoiding the hazard. Compliance with the certification specification eliminates the hazard or provides a means to completely avoid the hazard for all probable or likely cases, but it does not cover all situations or scenarios.
3. Adequately mitigates the hazard. Compliance with the certification specification eliminates the hazard or provides a means to avoid the hazard completely in many cases. However, the hazard is not eliminated or avoided in all probable or likely cases. Usually this action only addresses a significant part of a larger or broader hazard.
4. Hazard only partly addressed. In some cases, compliance with the certification specification partly eliminates the hazard or does not completely avoid the hazard. The hazard is not eliminated or avoided in all probable or likely cases. Usually this action only addresses part of a hazard.
5. Hazard only partly addressed but action has a negative side effect. Compliance with the certification specification does not eliminate or avoid the hazard or may have negative safety side effects. The action is of questionable benefit.

E.2.5.4 If it is determined that compliance with the latest certification specifications does not contribute materially to the product's level of safety, applicants should skip Step 6 of this Appendix and go directly to Step 7 to document the conclusion. If it is determined that complying with the latest amendment of the certification specification contributes materially to the product's level of safety, applicants should continue to Step 6 of this Appendix.

E.2.6 Step 6: Determine the incremental resource costs and cost avoidance.

E.2.6.1 There is always cost associated with complying with a certification specification. This cost may range from minimal administrative efforts to the resource expenditures that support full-scale testing or the redesign of a large portion of an aircraft. However, there are also potential cost savings from compliance with a certification specification. For example, compliance with a certification specification may avoid aircraft damage or accidents and the associated costs to the manufacturer for investigating accidents. Compliance with the latest amendment of a certification specification may also help a foreign authority to certify a product.

E.2.6.2 When determining the impracticality of applying a certification specification at the latest amendment level, only the incremental costs and safety benefits from complying with the existing certification basis should be considered.

E.2.6.3 When evaluating the incremental cost, it may be beneficial for applicants to compare the increase in cost of complying with the latest certification specifications with the cost of incorporating the same design feature in a new aircraft. In many cases, an estimate for the cost of incorporation in a new aircraft is provided by EASA in the regulatory impact assessment, which was presented when the corresponding certification specification was first issued. Incremental costs of retrofit/incorporation on existing designs may be higher than that for production. Examples of costs may include but are not limited to the following:

Costs

The accuracies of fleet size projections, utilisation, etc., may be different from those experienced for derived product designs and must be validated.

— Labour: work carried out in the design, fabrication, inspection, operation, or maintenance of a product for the purpose of incorporating or demonstrating compliance with a proposed action. Non-recurring labour certification specifications, including training, for the applicant supporting development and production of the product, should be considered.

— Capital: construction of new, modified, or temporary facilities for design, production, tooling, training, or maintenance.

— Material: costs associated with product materials, product components, inventory, kits, and spares.

— Operating costs: costs associated with fuel, oil, fees, training, and expendables.

— Revenue/utility loss: costs resulting from earning/usage capability reductions from departure delays, product downtime, and performance loss due to seats, cargo, range, or airport restrictions.

— The cost of changing compliance documentation and/or drawings in itself is not an acceptable reason for an exception.

Cost Avoidance.

— Avoiding costs of accidents, including investigation of accidents, lawsuits, public relations activities, insurance, and lost revenue.

— Foreign certification: conducting a single effort that would demonstrate compliance with the certification specifications of most certifying authorities, thus minimising certification costs.

E.2.7 Step 7: Document the conclusion.

With the information from the previous steps documented and reviewed, the applicant's position and rationale regarding whether complying with the latest certification specifications contributes materially to the product's level of safety or its practicality can be documented. EASA records the determination of whether the conditions for the proposed exception were met. That determination is based on the information and analysis provided by the applicant in the preceding steps. If the determination to grant the exception is based on the product's design features, those features are documented at a high level in the TCDS. Documentation in the TCDS is required so that the features are maintained during subsequent changes to the product, therefore, maintaining the product's agreed level of safety. If the results of this analysis are inconclusive, then further discussions with EASA are warranted.

E.3 Examples of how to certify changed aircraft.

The following examples illustrate the typical process an applicant follows. The process will be the same for all product types.

E.3.1 Example 1: FAR § 25.963, Fuel Tank Access Covers.

NOTE: This example is taken from the FAA's certification experience, so references to FAR sections and amendments are kept.

This example is part of a significant change to a transport aeroplane that increases the passenger payload and gross weight by extending the fuselage by 20 feet (6.1 metres). To accommodate the higher design weights and increased braking requirements and to reduce the runway loading, the applicant will change the landing gear from a two-wheel to four-wheel configuration; this changes the debris scatter on the wing from the landing gear. EASA will require the new model of the aeroplane to comply with the latest applicable certification specifications based on the date of application.

The wing will be strengthened locally at the side of the body and at the attachment points of the engines and the landing gear, but the applicant would not like to alter the wing access panels and the fuel tank access covers. Although the applicant recognises that the scatter pattern and impact loading on the wing from debris thrown from the landing gear will change, the applicant proposes that it would be impractical to redesign the fuel tank access covers.

Note: Points 21.B.107(a)(3) or 21.B.111(a)(3) may be an additional reason why EASA would require compliance with CS 25.963(e), regardless of the 'significant' determination.

E.3.1.1 Step 1: Identify the regulatory change being evaluated.

The existing certification basis of the aeroplane that is being changed is Part 25 prior to Amendment 25-69. Amendment 25-69 added the requirement that fuel tank access covers on transport category aeroplanes be designed to minimise penetration by likely foreign objects, and that they be fire-resistant.

E.3.1.2 Step 2: Identify the specific hazard that the certification specification addresses.

Fuel tank access covers have failed in service due to impact with high-energy objects, such as failed tire tread material and engine debris following engine failures. In one accident, debris from the runway impacted a fuel tank access cover, causing its failure and subsequent fire, which resulted in fatalities and loss of the aeroplane. Amendment 25-69 will ensure that all access covers on all fuel tanks are designed or located to minimise penetration by likely foreign objects, and that they are fire-resistant.

E.3.1.3 Step 3: Review the history of the consequences of the hazard(s).

There have been occurrences with injuries and with more than 10 per cent deaths.

E.3.1.4 Step 4: Identify the historical and predicted frequency of each consequence.

In 200 million departures of large jets, there was:

— 1 occurrence with more than 10 per cent deaths, and

— 1 occurrence with injuries.

There is no reason to believe that the future rate of accidents will be significantly different from the historical record.

E.3.1.5 Step 5: Determine how effective full compliance with the latest amendment of the certification specifications would be in addressing the hazard.

There is considerable potential for eliminating or avoiding the hazard. Compliance with Amendment 25-69 eliminates the hazard or provides a means to avoid the hazard completely for all probable or likely cases. However, it does not cover all situations or scenarios.

E.3.1.6 Step 6: Determine resource costs and cost avoidance.

Costs.

— For a newly developed aeroplane, there would be minor increases in labour resulting from design and fabrication of new fuel tank access covers.

— There would be a negligible increase in costs related to materials, operating costs, and revenue utility loss.

Cost avoidance.

— There were 2 accidents in 200 million departures. The applicant believes that it will manufacture more than 2 000 of these aeroplanes. These aeroplanes would average 5 flights a day. Therefore, statistically there will be accidents in the future if the hazard is not alleviated. Compliance will provide cost benefits related to avoiding lawsuits, accident investigations, and public relations costs.

— There are cost savings associated with meeting a single certification basis for EASA's and foreign standards.

E.3.1.7 Step 7: Document the conclusion.

It is concluded that compliance with the latest certification specification increases the level of safety at a minimal cost to the applicant. Based on the arguments and information presented by the applicant through the certification review item (CRI) process, EASA determined that meeting the latest amendment would be practical. EASA has also found that fuel tank access covers that are not impact-resistant and fire-resistant, and which are located where a strike is likely, are unsafe features or characteristics which preclude the issue of a type certificate under 21.B.107(a)(3).

E.3.2 Example 2: FAR § 25.365, Pressurized Compartment Loads.

NOTE: This example is taken from the FAA's certification experience, so references to FAR sections and amendments are kept.

This example is a passenger-to-freighter conversion STC. This change affects the floor loads on the aeroplane as well as the decompression venting.

E.3.2.1 Step 1: Identify the regulatory change being evaluated.

The existing certification basis of the aeroplane that is being changed includes § 25.365 at Amendment 25-00. The initial release of § 25.365 required the interior structure of passenger compartments to be designed to withstand the effects of a sudden release of pressure through an opening resulting from the failure or penetration of an external door, window, or windshield panel, or from structural fatigue or penetration of the fuselage, unless shown to be extremely remote.

Amendment 25-54 revised § 25.365 to require the interior structure to be designed for an opening resulting from penetration by a portion of an engine, an opening in any compartment of a size defined by § 25.365(e)(2), or the maximum opening caused by a failure that was not shown to be extremely improbable. The most significant change is the 'formula hole size' requirement introduced into § 25.365(e)(2) at Amendment 25-54.

Amendment 25-71/72 (Amendments 25-71 and 25-72 are identical) extended the regulation to all pressurised compartments, not just passenger compartments, and to the pressurisation of unpressurised areas. Pressurisation of unpressurised areas had previously been identified as an unsafe feature under § 21.B.111(a)(3).

Amendment 25-87 redefined the pressure differential load factor that applies above an altitude of 45 000 feet. Compliance with Amendment 25-87 is not affected since the aeroplane does not operate above an altitude of 45 000 feet. The applicant proposes to meet the 'pressurisation into unpressurised areas' requirement introduced in Amendment 25-71/72. The applicant does not propose to comply with the 'formula hole size' requirement introduced in § 25.365(e)(2) at Amendment 25-54.

E.3.2.2 Step 2: Identify the specific hazard that the certification specification addresses.

The hazard is a catastrophic structure and/or system failure produced by a sudden release of pressure through an opening in any compartment in flight. This opening could be caused by an uncontained engine failure, an opening of a prescribed size due to the inadvertent opening of an external door in flight, or an opening caused by a failure not shown to be extremely improbable. The opening could be caused by an event that has yet to be identified.

E.3.2.3 Step 3: Review the history of the consequences of the hazard(s).

There have been occurrences with injuries, with less than 10 per cent deaths and with more than 10 per cent deaths.

E.3.2.4 Step 4: Identify the historical and predicted frequency of each consequence.

In 200 million departures of large jets, there were:

— 2 occurrences with more than 10 per cent deaths,

— 1 occurrence with less than 10 per cent deaths, and

— 1 occurrence with injuries.

There is no reason to believe that the future rate of accidents will be significantly different from the historical record.

E.3.2.5 Step 5: Determine how effective full compliance with the latest amendment of the certification specifications would be at addressing the hazard.

Compliance with the latest amendment eliminates the hazard or provides a means to avoid the hazard completely.

Design changes made to the proposed aeroplane bring it closer to full compliance with § 25.365 at Amendment 25-54. The original aeroplane was shown to meet the requirements for a hole size of 1.1 square feet. Amendment 25-54 would require a hole size of 5.74 square feet, and the current reinforcements for the converted aeroplane can sustain a hole size of 3.65 square feet in the forward area and 2.65 square feet at the aft area. This is 3.1 and 2.4 times, respectively, better than the original design condition of Amendment 25-0 and is a significant improvement over the worldwide passenger fleet in service.

E.3.2.6 Step 6: Determine resource costs and cost avoidance.

Costs.

There would be savings in both labour and capital costs if compliance were shown to Amendment 25-0 instead of Amendment 25-54. Major modifications to the floor beams would be necessary to meet the 'formula hole size' requirement in Amendment 25-54.

Cost avoidance.

There were 4 accidents in 200 million departures. The applicant believes that it will manufacture more than 2 000 of these aeroplanes. These aeroplanes would average 2 flights a day. Therefore, statistically there will be accidents in the future if the hazard is not alleviated. Compliance will provide cost benefits related to avoiding lawsuits, accident investigations, and public relations costs.

There are cost savings associated with meeting a single certification basis for FAA and foreign regulations.

E.3.2.7 Step 7: Document the conclusion regarding practicality.

The design complies with § 25.365 at Amendments 25-0, 25-71/72, and 25-87, and it is nearly in full compliance with Amendment 25-54. The design would adequately address the hazard at an acceptable cost. Therefore, based on arguments of impracticality discussed in an issue paper, the FAA accepts the applicant's proposal to comply with § 25.365 at Amendment 25-0.

E.3.3 Example 3: FAR § 25.981, Fuel Tank Ignition Prevention.

NOTE: This example is taken from the FAA's certification experience, so references to FAR sections and amendments are kept.

This example is part of a significant change to a transport aeroplane that increases passenger payload and gross weight by extending the fuselage by 20 feet (6.1 metres). To accommodate the longer fuselage, the applicant will modify systems wiring installations; this includes changing fuel tank system wiring. The new model of the aeroplane will be required to comply with the latest applicable certification specifications based on the date of application.

E.3.3.1 Step 1: Identify the regulatory change being evaluated.

The existing certification basis of the aeroplane that is being changed is Part 25 prior to Amendment 25-102 but includes Amendment 25-40.

Note: If the original certification basis does not include Amendment 25-40, the certification basis should be considered not adequate for fuel tank ignition prevention.

The 2001 Fuel Tank Safety (FTS) rule adopted Amendment 25-102 to add explicit requirements in § 25.981(a)(3) for demonstrating that the design precludes fuel tank ignition sources. This was required, but had in several cases not been properly applied in demonstrating compliance with §§ 25.901 and 25.1309. Amendment 25-102, § 25.981(b), added a requirement to develop fuel tank system airworthiness limitations to maintain the ignition prevention features of the design. Section H25.4, Amendment 25-102, requires the inclusion of those fuel tank system airworthiness limitations in the Airworthiness Limitations section of the Instructions for Continued Airworthiness (ICA).

Since the FAA policy for performing the failure analysis to demonstrate compliance with §§ 25.901 and 25.1309 at Amendment 25-40 and 25-46 was adopted in the explicit fuel tank ignition prevention failure analysis requirements of § 25.981(a)(3), the incremental requirement for demonstrating compliance with the ignition prevention requirements of Amendment 25-102 is to develop and implement the fuel tank system airworthiness limitations instead of developing Certification Maintenance Requirements in accordance with § 25.901(b)(2) at Amendments 25-40 through 25-46 and AC 25-19A.

E.3.3.2 Step 2: Identify the specific hazard that the certification specification addresses.

The FAA issued the 2001 FTS rule to preclude fuel tank ignition sources because of a history of fuel tank explosions. The catastrophic TWA Flight 800 in-flight fuel tank explosion on July 17, 1996, caused the death of all 230 people on board.

E.3.3.3 Step 3: Review the history of the consequences of the hazard(s).

There have been occurrences with injuries, with more than 10 per cent deaths, less than 10 per cent deaths, and no deaths.

E.3.3.4 Step 4: Identify the historical and predicted frequency of each consequence.

The 1998 Aviation Rulemaking Advisory Committee Fuel Tank Harmonisation Working Group report documented the number of historical fuel tank explosions as 16, which caused a total of 539 fatalities.

There have been 2 additional fuel tank explosions since that report was issued:

— March 3, 2001: Thai Airways International Flight 114 experienced a fuel tank explosion on the ground that caused 1 fatality and 3 serious injuries. The explosion and subsequent fire destroyed the aeroplane.

— May 4, 2006: A Malaysia Airlines Boeing 727 experienced a wing tank low pressure explosion during ground operations. There was no fire and no injuries. The wing structure suffered significant damage.

There is no reason to believe that the future rate of accidents will be significantly different from the historical record if fuel tank system airworthiness limitations are not included in the ICA as is permitted in earlier amendment levels.

E.3.3.5 Step 5: Determine how effective full compliance with the latest amendment of the certification specifications would be at addressing the hazard.

There is considerable potential for eliminating or avoiding the hazard.

In the 2008 Fuel Tank Flammability Reduction (FTFR) rule, the FAA estimated that compliance with the ignition prevention requirements of Amendment 25-102, together with the fuel tank ignition prevention airworthiness directives issued as a result of the Special Federal Aviation Regulation number 88 reviews, resulted in the range of effectiveness in preventing fuel tank explosions between 25 to 75 per cent with a median value of 50 per cent (73 FR 42449).

E.3.3.6 Step 6: Determine resource costs and cost avoidance.

Costs.

— For newly developed designs, there would be minor increases in costs resulting from the identification and implementation of fuel tank system airworthiness limitations.

— There would be no increase in costs related to materials, operating costs, and revenue utility loss.

Cost avoidance.

There were 18 accidents in 200 million departures. The applicant believes that it will manufacture more than 2 000 of these aeroplanes or derivatives of these aeroplanes. These aeroplanes would average 5 flights a day. Therefore, statistically there will be accidents in the future if the hazard is not alleviated. Compliance will provide cost benefits related to avoiding fatalities and injuries.

E.3.3.7 Step 7: Document the conclusion.

It is concluded that compliance with the latest certification specification increases the level of safety at a minimal cost to the applicant. Based on the arguments and information presented by the applicant through the issue paper process, the FAA determined that meeting the latest amendment would be practical.

The following is additional background on the specific hazard that the certification specification addresses:

As stated in the 2001 FTS rule under ‘Changes to Part 25’, § 25.981(a)(3) was adopted because the previous regulations (§§ 25.901 and 25.1309) were not always properly applied.

Section 25.901(b)(2), Amendments 25-40 through 46, requires in part preventative maintenance as necessary to ensure that components of the powerplant installation, which includes the fuel tank system, will safely perform their intended function between inspections and overhauls defined in the maintenance instructions. When demonstrating compliance with the requirements of § 25.901(b) for maintenance of fuel tank ignition prevention features, the policy has been that the applicant identify critical features as critical maintenance requirements using the guidance in AC 25-19A.

Appendix F to GM 21.A.101 The use of service experience in the exception process

ED Decision 2017/024/R

F.1 **Introduction.**

Service experience may support the application of an earlier certification specification pursuant to point 21.A.101(b)(3) if, in conjunction with the applicable service experience and other compliance measures, the earlier certification specification provides a level of safety comparable to that provided by the latest certification specification. The applicant must provide sufficient substantiation to allow EASA to make this determination. A statistical approach may be used, subject to the availability and relevance of data, but sound engineering judgment must be used. For service history to be acceptable, the data must be both sufficient and pertinent. The essentials of the process involve:

— A clear understanding of the certification specification change and the purpose for the change,

— A determination based on detailed knowledge of the proposed design feature,

— The availability of pertinent and sufficient service experience data, and

— A comprehensive review of that service experience data.

F.2 **Guidelines.**

The CRI process (either as a stand-alone CRI or included in the CRI A-01) would be used, and the applicant should provide documentation to support the following:

F.2.1 The identification of the differences between the certification specification in the existing basis and the certification specification as amended, and the effect of the change to the specification.

F.2.2 A description as to what aspect(s) of the latest certification specifications the proposed changed product would not meet.

F.2.3 Evidence showing that the proposed certification basis for the changed product, together with applicable service experience, relative to the hazard, provides a level of safety that approaches the latest certification specification, yet is not fully compliant with the latest certification specifications.

F.2.4 A description of the design feature and its intended function.

F.2.5 Data for the product pertinent to the requirement.

F.2.5.1 Service experience from such data sources, such as:

— Accident reports,

— Incident reports,

— Service bulletins,

— Airworthiness directives,

— Repairs,

— Modifications,

— Flight hours/cycles for fleet leader and total fleet,

— World airline accident summary data,

— Service difficulty reports,

— Accident Investigation Board reports, and

— Warranty, repair, and parts usage data.

F.2.5.2 Show that the data presented represent all relevant service experience for the product, including the results of any operator surveys, and is comprehensive enough to be representative.

F.2.5.3 Show that the service experience is relevant to the hazard.

F.2.5.4 Identification and evaluation of each of the main areas of concern with regard to:

— Recurring and/or common failure modes,

— Cause,

— Probability by qualitative reasoning, and

— Measures already taken and their effects.

F.2.5.5 Relevant data pertaining to aircraft of similar design and construction may be included.

F.2.5.6 Evaluation of failure modes and consequences through analytical processes. The analytical processes should be supported by:

— A review of previous test results,

— Additional detailed testing as required, or

— A review of aircraft functional hazard assessments (FHA) and any applicable system safety assessments (SSA) as required.

F.2.6 A conclusion that draws together the data and the rationale.

F.2.7 These guidelines are not intended to be limiting, either in setting the required minimum elements or in precluding alternative forms of submission. Each case may be different, based on the particulars of the system being examined and the requirement to be addressed.

F.3 **Example: 25.1141(f) for Transport Category Aeroplanes.**

NOTE: This example is taken from the FAA's certification experience, so references to FAR sections and amendments are kept.

F.3.1 The following example, for transport category aeroplanes (§ 25.1141(f), APU Fuel Valve Position Indication System), illustrates the typical process an applicant follows. The process will be the same for all product types.

F.3.2 This example comes from a derived model transport aeroplane where significant changes were made to the main airframe components, engines and systems, and APU. The baseline aeroplane has an extensive service history. The example shows how the use of service experience supports a finding that compliance with the latest certification specifications would not contribute materially to the level of safety and that application of the existing certification basis (or earlier amendment) would be appropriate. The example is for significant derived models of transport aeroplanes with extensive service history. It illustrates the process, following the guidelines in this Appendix, but does not include the level of detail normally required.

F.3.2.1 Determine the differences between the certification specifications applied in the original certification basis and the latest certification specification, and the effect of the change to the certification specifications. The original certification basis of the aeroplane that is being changed is the initial release of Part 25. Amendment 25-40 added requirement §

25.1141(f), which mandates that power-assisted valves must have a means to indicate to the flight crew when the valve is in the fully open or closed position, or is moving between these positions. The addressed hazard would be risk of APU fire due to fuel accumulation caused by excessive unsuccessful APU start attempts.

F.3.2.2 What aspect of the proposed changed product would not meet the latest certification specifications? The proposed APU fuel valve position indication system does not provide the flight crew with fuel valve position or transition indication and, therefore, does not comply with the requirements of § 25.1141(f).

F.3.2.3 The applicant provides evidence that the proposed certification basis for the changed product, together with applicable service experience of the existing design, provide a level of safety that approaches, yet is not fully compliant with, the latest certification specifications. The APU fuel shut-off valve and actuator are unchanged from those used on the current family of aeroplanes, and have been found to comply with the earlier Amendment 25-11 of § 25.1141. The existing fleet has achieved approximately (#) flights during which service experience of the existing design has been found to be acceptable. If one assumes a complete APU cycle, i.e. start-up and shutdown for each flight, the number of APU fuel shut-off valve operations would be over 108 cycles, which demonstrates that the valve successfully meets its intended function and complies with the intent of the certification specification.

F.3.2.4 The applicant provides a description of the design feature and its intended function. The fuel shut-off valve, actuator design, and operation is essentially unchanged with the system design ensuring that the valve is monitored for proper cycling from closed to open at start. If the valve is not in the appropriate position (i.e. closed), then the APU start is terminated, an indication is displayed on the flight deck, and any further APU starts are prevented. Design improvements using the capability of the APU electronic control unit (ECU) have been incorporated in this proposed product change. These design changes ensure that the fuel valve indication system will indicate failure of proper valve operation to the flight crew, and these features increase the level of functionality and safety, but the system does not indicate valve position as required by § 25.1141(f).

F.3.2.5 The FAA and the applicant record this in an issue paper. The FAA can use the G-1 or a technical issue paper for this purpose. An issue paper was coordinated, included data, or referenced reports documenting relevant service experience compiled from incident reports, fleet flight hour/cycle data, and maintenance records. The issue paper also discussed existing and proposed design details, failure modes, and analyses showing to what extent the proposed aeroplane complies with the latest amendment of § 25.1141. Information is presented to support the applicant's argument that compliance with the latest amendment would not materially increase the level of safety. Comparative data pertaining to aircraft of similar design and construction are also presented.

F.3.2.6 The conclusion, drawing together the data and rationale, is documented in the G-1 issue paper. The additional features incorporated in the APU fuel shut-off valve will provide a significant increase in safety to an existing design with satisfactory service experience. The applicant proposes that compliance with the latest amendment would not materially increase the level of safety and that compliance with § 25.1141 at Amendment 25-11 would provide an acceptable level of safety for the proposed product change.

Appendix G to GM 21.A.101 Changed product rule (CPR) decision record

ED Decision 2017/024/R

CHANGED PRODUCT RULE (CPR) DECISION RECORD		
TC/STC No: Click here to enter text.	**Project Number:** Click here to enter text.	
Step 1: Identify the proposed type design changes to the aeronautical product. (See paragraph 3.2 of GM 21.A.101)	The proposed type design changes are identified here or in the following document(s): Click here to enter text.	
Note: The CRI process is used to track/document the decisions at Step 2 and Steps 5 through 8 as required.		
Step 2: Is the proposed type design change substantial? (See paragraph 3.3 of GM 21.A.101)	☐ Yes	**New Type Certificate:** Proceed to point 21.A.19. Point 21.A.101 does not apply. A Certification Review Item CRI A-01 will be used to establish and document the certification basis.
	☐ No	**Proceed to Step 3.**
Step 3: Will you use the latest standards? (See paragraph 3.4 of GM 21.A.101)	☐ Yes	**Latest Standards:** Propose a certification basis using the CSs in effect at the date of application. Proceed to Step 8.
	☐ No	**Proceed to Step 4.**
Step 4: Arrange changes into related and unrelated groups. (See paragraph 3.5 of GM 21.A.101)	**Note:** For multiple groupings, continuation of this process should be split into separate decision records. Groupings may be rationalised and recorded in separate documents: Click here to enter text.	
Step 5: Is each related or unrelated group a significant change? (See paragraph 3.6 of GM 21.A.101)	☐ Yes	**Proceed to Step 6.**
	☐ No	Earlier Standards: Propose a certification basis using the CSs in effect before the date of application but not earlier than the existing certification basis. Certification basis to be defined and documented as indicated (below). **Proceed to Step 8.**
Step 6: Prepare your Certification Basis List. (See paragraph 3.9 of GM 21.A.101) **Affected Areas:**	The Affected Area(s) is (are) detailed here or in the following Certification Basis List document number(s): Click here to enter text. Process and propose each applicable certification specification individually. **Proceed to Step 7.**	
Not Affected Areas:	Existing Standards: You may continue using the existing certification basis.	
Step 7: Do the latest standards contribute materially to the level of safety and are they practical? (See paragraph 3.10 of GM 21.A.101)	☐ Yes	Latest Standards: Propose a certification basis using the CSs in effect on the date of application.
	☐ No	Earlier Standards: You may propose a certification basis using the CSs in effect before the date of application but not earlier than the existing certification basis. Certification basis defined or documented as indicated below.
☐ Continuation Sheet(s) Attached	**Note:** Several CSs may apply to each affected area, and the assessment may differ from specifications to specifications. Indicate '**Yes**' if compliance with any latest standard(s) is required. Indicate '**No**' only if earlier standard(s) is (are) proposed.	
Note:	You may submit a proposal for the decision in Step 7; however, EASA will make the final certification basis determination.	
Step 8: Ensure the proposed certification basis is adequate. (See paragraph 3.11 of GM 21.A.101)	If you deem that the certification basis is adequate, submit the proposed certification basis to EASA. If not, consult EASA. CRI A-01 may be needed to document the certification basis.	
Certification Basis:	The certification basis is detailed here or in the following document(s): Click here to enter text.	
Based on the information provided above, I am proposing the certification basis with the following classification for the type design change. (check one)		
☐ Significant, pursuant to point 21.A.101.	☐ Not significant, pursuant to point 21.A.101.	
Click here to enter text.		Click here to enter text.
Printed Name/Title	Signature	Date

Appendix H to GM 21.A.101 Examples of documenting the proposed certification basis list

ED Decision 2017/024/R

H.1 **Example 1.**

H.1.1 This optional tool may be used to establish the applicable airworthiness and OSD certification specifications that will become part of the type-certification basis for airworthiness or OSD certification basis. For a significant change, the applicant must demonstrate compliance for the change and the area affected by the change with the certification specifications that were in effect at the date of application. However, in some cases earlier or later certification specifications can be used, as allowed in point 21.A.101.

H.1.2 In order to efficiently determine and agree upon a certification basis with EASA, the following information is useful to understand the applicant's position:

H.1.2.1 The scope of the change. This includes a high-level description of the physical and functional changes and performance/functional characteristics, which are changed as a result of the physical or functional change, and the certification specifications for which compliance demonstration is required as a result of the change.

H.1.2.2 The amendment level of all the applicable certification specifications at the date of application.

H.1.2.3 The proposed certification basis, including amendment levels.

H.1.2.4 Applicants who propose a certification basis that includes amendment levels earlier than what was in effect at the date of application should include the exception as outlined in point 21.A.101 and their justification if needed.

H.1.3 Exceptions.

H.1.3.1 Unrelated changes that are not significant (point 21.A.101(b)(1)).

H.1.3.2 Not affected by the change (point 21.A.101(b)(2)).

H.1.3.3 Compliance with the certification specification would not contribute materially to the level of safety (point 21.A.101(b)(3)).

H.1.3.4 Compliance with the certification specification would be impractical (point 21.A.101(b)(3)).

H.1.4 One easy way to document the proposed certification basis is using a tabular form as shown in Table below.

Table H-1. Tabular Form for Documenting a Proposed Certification Basis

CS	Amendment Levels			Applicant Justification for Lower Amendment Level and Comments	Affected Area
	Existing TCDS Amendment	Amendment at Date of Application	Proposed Amendment Level		
Subpart A — General					
Subpart B — Flight					

H.1.5 Best Practices.

H.1.5.1 Account for all certification specifications, even if they are not applicable.

H.1.5.2 Mark certification specifications that are not applicable as ‘N/A’.

H.1.5.3 If more than one amendment level is used depending on the area of the product, list all areas and amendment levels at each area with proper justification.

H.1.5.4 If the justification is long, provide the justification below the table and only place the certification specification reference and note in the comment field.

H.1.5.5 Include airworthiness and OSD standards required by other EU regulations (e.g. Part-26) of affected areas.

H.2 **Example 2.**

Pages 129 through 135 of this Appendix contain another example for documenting a proposed certification basis.

TITLE OF DESIGN CHANGE

Product Name or Change to Type Certificate [XXXX]

Proposed Certification Basis Pursuant to point 21.A.101

1. INTRODUCTION.

1.1 REFERENCE DOCUMENTS.

Reference	Title
[1] Point 21.A.101	Designation of applicable certification specifications and environmental protection requirements
[2] GM 21.A.101-1B	Establishing the Certification Basis of Changed Aeronautical Products
[3] XXXX	Application letter
[4] Type Certificate YYYY	Product type-certification basis
[5] Document ZZZZ	Certification plan
[6]	

<The above-referenced documents are examples. Each applicant should reference documents appropriate to their products and procedures.>

1.2 ACRONYMS.

Acronym	Meaning
AFM	Aircraft Flight Manual
AMC	Acceptable Means of Compliance
CRI	Certification Review Item
ELOS	Equivalent Level of Safety
ESF	Equivalent Safety Finding
GM	Guidance Material
MOC	Means of Compliance
SC	Special Condition
TC	Type Certificate

<This section constitutes a representative list of acronyms. Each applicant should provide an acronym list appropriate for their product and document.>

1.3 PURPOSE OF THE DOCUMENT.

The purpose of this document is to propose the certification basis applicable to [Product Design Change] in accordance with point 21.A.101.

<Note that this optional document is intended to be used for changes to type-certified products for which the change or a portion of the change is significant at the product level pursuant to 21.A.101. Not significant changes being accomplished concurrently with significant changes(s) would also be identified in this document.>

2. DESIGN DEFINITION.

2.1 BASELINE PRODUCT.

The type design to be changed, which is also known as the 'baseline product,' is the Model Series___ (this should be a specific product configuration, such as a specific serial number or line number).

The reference product certification basis is TCDS No. [XXXX], issued on [DATE].

2.2 DESIGN CHANGE AND BASELINE PRODUCT COMPARISON SUMMARY.

<Example table where the product is an aeroplane. This is a representative set of data that may be provided by the applicant.>

Specification	Model Series X	Model Series Y
Max Taxi Weight — MTW (lb)	A1	A2
Max Take-off Weight — MTOW (lb)	B1	B2
Max Landing Weight — MLW (lb)	C1	C2
Max Zero Fuel Weight — MZFW (lb)	D1	D2
Max Length (ft, in)	E1	E2
Max Height (ft, in)	F1	F2
Wing Span (ft, in)	G1	G2
Horizontal Tail Span (ft, in)	H1	H2
Fuel Capacity (gal)	I1	I2
Total Cargo Volume (ft^3)	J1	J2
Max Passenger Limit — one class seating (occupants)	K1	K2
Engine Types	L1 & M1	L2
Maximum Engine Thrust	T1	T2

2.3 DESCRIPTION OF DESIGN CHANGE, GROUPING AND CLASSIFICATION.

2.3.1 SIGNIFICANT CHANGE(S).

<Describe here the stand-alone change(s) and/or change grouping(s) that are part of the proposed changed product and are proposed as significant. Include with each stand-alone change or change grouping the relevant accumulated change(s) and the applicable physical and/or functional effects. Note, the description should be detailed enough to identify why the change or change grouping is proposed as significant.>

The following group of changes is proposed as significant based on [GM 21.A.101-1, Appendix A, '[Description of Change in Appendix A]] or [the general configuration is not retained, principles of construction are not retained, or assumptions for certification of the product to be changed do not remain valid].

Changes Related to [Title of Significant Change X]:

[Title of High-Level Change C1]

The areas of physical change are:

— [design change xx]

— [design change yy]

— [design change zz]

The areas unchanged but affected by the change are:

— [affected area aaa]

— [affected area bbb]

— [affected area ccc]

[Title of High-Level Change C2]

2.3.2 UNRELATED NOT-SIGNIFICANT CHANGES.

<Describe here the not significant stand-alone changes or change groupings that are part of the modification but are unrelated to any of the significant changes described in paragraph 2.3.1.>

[Title of High-Level Change D1]. [Description].

<The description must be just detailed enough to serve its purpose, which is to identify why each of those changes is not significant and unrelated.>

[Title of High-Level Change D2]. [Description]…

3. IDENTIFICATION OF APPLICABLE CERTIFICATION STANDARDS.

3.1 PROPOSED CERTIFICATION BASIS.

Based on the effective application date, [date], under the provisions of 21.A.101, the applicable certification standards for the [Title of Design Change] are proposed as follows. The proposed certification basis includes exceptions to earlier amendments (reversions), deviations, special conditions, and equivalent (level of) safety findings.

3.1.1 Certification specifications effective at the date of application.

Applicable certification specifications in effect on the date of the application are:

<List the applicable parts and amendment levels here.>

Example for large aeroplanes:

A. Airworthiness:

— CS-25,

— CS-AWO.

B. Operational Suitability Data:

— CS-CCD,

— CS-FCD,

— CS-MCSD (to be published),

— CS-MMEL,

— CS-SIMD.

C. Environmental Protection:

— CS-34,

— CS-36.

3.1.2 Point 21.A.101 exception rationale.

The completed rationale for each does not contribute materially to the level of safety (DCMLS) or impracticality exception is provided in this section.

Exception 1: …

Exception 2:…

3.1.3 Optional certification standards

Applicable certification specifications in effect on the date of the application are:

<List the applicable parts and amendment levels here.>

Example for large aeroplanes:

— CS 25.803, *Emergency evacuation*, Amendment 12,

— CS 25.1810, *Emergency egress assisting means and escape routes*, Amendment 17.

3.1.4 Design-related requirements from other aviation domains.

Applicable certification specifications in effect on the date of the application are:

<List the applicable parts and amendment levels here.>

Example for large aeroplanes:

— CS-ACNS Communications, Navigation and Surveillance

— Initial Issue, dated 17 December 2013, Subpart D Sections 2/3,

— CS-26.

3.1.5 Proposed Special Conditions.

Special Condition (or TBD)	Title	Effective Date (or TBD)

3.1.6 Equivalent Safety Findings.

ELOS Memo No (or TBD)	Title	Applicable Standard

3.1.7 Deviations.

Deviation No (or TBD)	Title	Applicable Standard	Date Issued (or TBD)

3.1.8 Elect to comply

Elect to Comply No (or TBD)	Title	Applicable Standard	Date Issued (or TBD)

Proposed Certification Basis

The certification basis is a complete extract from the applicable FAA 14 CFR part **[A]** and it references the certification basis **[B]**. Column **[C]** identifies the amendment level for the specific requirement on the date of application. The changed product's certification basis is proposed in last column **[D]**. References to FAR sections and amendments are kept.

Example for a Part 25 aeroplane:

[A] Requirement	Title (or subparagraph)	[B] Existing Certification Basis Amendment Level	[C] Amendment Level on Application Date	[D] Proposed Amendment for Changed Product	Applicable Area	Notes
25.25	*Weight limits*					
		25-23	25-63	25-63	Product	
25.33	*Propeller speed and pitch limits*					
		N/A	25-72	N/A	—	Not applicable to Changed Product (Jet Aircraft)
25.1309(a)	*Equipment, systems, and installations*					
		25-41	15-123	25-123	Changed and Affected Areas	
		25-41	25-123	25-41	Exception — Not Affected	See example 1 in section 3.1.2
25.1703	*Function and installation: EWIS*					
		N/A	25-124	N/A	Exception — Product	See example 2 in section 3.2.1

Appendix I to GM 21.A.101 Related documents

ED Decision 2019/018/R

I.1 Related Part 21 requirements.

- 21.A.15, *Application*
- 21.B.70, *Certification specifications*
- 21.B.75, *Special conditions*
- 21.B.80, *Type-certification basis for a type-certificate or restricted type-certificate*
- 21.B.82, *Operational suitability data certification basis for an aircraft type certificate or restricted type-certificate*
- 21.A.19, *Changes requiring a new type certificate*
- 21.B.103, *Issuance of a type-certificate or restricted type-certificate*
- 21.A.31, *Type design*
- 21.A.41, *Type certificate*
- 21.A.91, *Classification of changes to a type certificate*
- 21.A.93, *Application*
- 21.A.97, *Requirements for approval of a major change*
- 21.A.101, *Type-certification basis, operational suitability data certification basis and environmental protection requirements for a major change to a type-certificate*
- 21.B.107, *Issuance of an approval of a change to a type-certificate*
- 21.A.113, *Application for a supplemental type-certificate*
- 21.A.115, *Requirements for approval of major changes in the form of a supplemental type-certificate*
- 21.B.111, *Issuance of a supplemental type-certificate*

Appendix J to GM 21.A.101 Definitions and terminology

ED Decision 2019/018/R

J.1 Aeronautical product.

The terms 'aeronautical product' or 'product' used in this guidance material include type-certified aircraft, engines, or propellers and, for the purpose of this GM, an ETSOA'd APU.

J.2 Assumptions used for certification.

The assumptions used for certification are the evaluations and decisions that led to the approval of the baseline product's characteristics. Examples of the product's baseline characteristics include but are not limited to the following:

— Design methodologies, methods of compliance, and standards used to achieve compliance with the certification specifications making up the certification basis;

— Structural, mechanical, electrical, propulsion, aerodynamic, performance, operational, and maintenance characteristics;

— Operational and flight envelopes defining the product performance and capabilities at specified weights, speeds, altitudes, load factors, and centres of gravity;

— Crashworthiness;

— Role or mission;

— Airworthiness and operational limitations; or

— Pilot training, if necessary.

J.3 Baseline product.

It is an aeronautical product with a specific, defined approved configuration and certification basis that the applicant proposes to change.

J.4 Certification basis.

The combination of the:

— airworthiness certification specifications as provided for in point 21.B.80;

— OSD certification specifications as provided for in point 21.B.82; and

— environmental protection requirements, as provided for in point 21.B.85,

and as established for the change according to point 21.A.101, as well as the:

— special conditions;

— equivalent safety findings;

— elects to comply; and

— deviations, applicable to the product to be certified.

J.5 Change.

The term 'change' refers to a change to a product type certificate (as defined in point 21.A.41) approved or to be approved under Subpart D or Subpart E (as a supplemental type certificate) of Part 21, including a change to an STC or a change to the ETSOA for auxiliary power units (APUs) under Subpart O. A change may consist of a single stand-alone change to one TC component or several interrelated changes to different TC components (e.g. the type design,

operating characteristics, OSD, environmental protection characteristics, etc. (see point 21.A.41 and GM to 21.A.90A)).

J.6 Design change.

The term 'design change' refers to a change to the type design (as defined in point 21.A.31) of an aeronautical product. In the context of this document, the terms 'change to the type design', 'modification', 'design change', and 'type design change' are synonymous.

J.7 Earlier standards.

The certification specifications or previous standards in effect prior to the date of application for the change, but not prior to the existing certification basis.

J.8 Existing certification basis.

The certification specifications or previous standards incorporated by reference in the type certificate of the baseline product to be changed.

J.9 Latest standards.

The certification specifications in effect on the date of application for the change.

J.10 Previous relevant design changes.

Previous design changes, the cumulative effect of which could result in a product significantly or substantially different from the original product or model, when considered from the last time the latest standards were applied.

J.11 Product-level change.

A change or combination of changes that makes the product distinct from other models of the product (e.g. range, payload, speed, design philosophy). Product-level change is defined at the aircraft, aircraft engine, or propeller level of change.

J.12 Secondary change.

A change that is part of a significant physical change that does not contribute materially to the level of safety. Guidance is contained in paragraph 3.10.1.4 of this GM.

J.13 Significant change.

A change to the type certificate to the extent that it changes one or more of the following, but not to the extent to be considered a substantial change: the general configuration, principles of construction, or the assumptions used for certification. The significance of the change is considered in the context of all previous relevant design changes and all related revisions to the applicable standards. Not all product-level changes are significant.

J.14 Significant change to area.

For aircraft excepted under point 21.A.101(c) only: a change to an area is significant if the general configuration or the principles of construction in that area are not retained, or the assumptions used for the certification of that area do not remain valid.

J.15 Substantial change.

A change that is so extensive that a substantially complete investigation of compliance with the applicable certification basis is required, and consequently a new type certificate is required pursuant to point 21.A.19.

GM No 1 to 21.A.101(g) Establishment of the operational suitability data (OSD) certification basis for changes to type certificates (TCs)

ED Decision 2019/018/R

This GM provides guidance on the application of point 21.A.101(g) in order to determine the applicable OSD certification basis in accordance with points 21.A.101(a), (b), (c), (d), (e) and (f) for major changes to the OSD of type-certified aircraft.

1. Minor changes

   Minor changes to the OSD are automatically outside the scope of point 21.A.101. See GM 21.A.95 for their certification basis.

2. Major changes

   a. If the design change that triggered the change to the OSD constituent is classified as non-significant, the change to the OSD constituent is also non-significant.

   b. If the design change that triggered the change to the OSD constituent is classified as significant, the change to the OSD constituent should comply with the latest amendment of the applicable CSs, unless the exceptions of 21.A.101(b)(3) apply or unless the OSD change can be classified as minor as per 21.A.91. The guidance of GM 21.A.101 Section 3.10 regarding the exceptions 'impractical' and 'not contributing materially to the level of safety', can be applied by analogy and as far as it is applicable to OSD changes.

   c. Stand-alone changes to an OSD constituent are considered to be non-significant.

   d. When a new OSD constituent is added or required to be added, it should comply with the latest amendment of the applicable CSs.

   e. Reserved.

   f. Reserved.

   g. Point 21.A.101(c) provides an exception from the requirements of 21.A.101(a) for a change to the OSD of certain aircraft below a specified maximum weight. If an applicant applies for a change to the OSD for an aircraft (other than rotorcraft) of 2 722 kg (6 000 lbs) or less maximum weight, or for a non-turbine-powered rotorcraft of 1 361 kg (3 000 lbs) or less maximum weight, the applicant can demonstrate that the changed OSD complies with the OSD certification basis incorporated by reference in the TC. The applicant can also elect to comply, or may be required to comply, with a later amendment. See also Chapter 4 Section 4.1 (GM 21.A.101) for specific guidance on this requirement.

Note: Refer to GM No 1 to 21.A.15(d) for the applicability of the OSD to other-than-complex motor-powered aircraft.

AMC1 21.A.101(h) Type-certification basis for changes to large aeroplanes subject to point 26.300 of Part-26

ED Decision 2021/007/R

Compliance with point 21.A.101(h) is demonstrated through compliance with Amdt 19 to CS 25.571 or subsequent amendments, or with the following:

(a) For turbine-powered large aeroplanes with a certified maximum take-off weight (MTOW) greater than 34 019 kg (75 000 lbs):

(1) For changes that affect or introduce fatigue critical structures susceptible to widespread fatigue damage (WFD), WFD evaluations should substantiate freedom from WFD up to the existing limit of validity (LOV) or a new reduced LOV approved by EASA;

(2) The extension of an existing LOV is a major change.

(3) The extent of the test evidence required in support of the WFD evaluation should be agreed with EASA;

(4) Inspections and other maintenance actions upon which the LOV is dependent are established and submitted to EASA for approval in accordance with point 21.A.7 of Part 21;

(5) AMC 20-20B paragraph 8 contains additional guidance on this subject.

(b) For turbine-powered large aeroplanes certified to carry 30 passengers or more, or with a payload capacity of 3 402 kg (7 500 lbs) or more:

(1) For changes that affect or introduce fatigue critical structures, damage-tolerance evaluations must be performed according to the certification basis of the aeroplane unless it precedes JAR 25.571 Change 7 or 14 CFR §25.571 Amendment 45, in which case the certification basis for the change should be:

(i) JAR 25.571 Change 7 or 14 CFR §25.571 Amendment 45, or later amendments; or

(ii) the specifications used for compliance with the applicable points of Part-26 for the structures affected by the change.

(2) Develop or amend the list of fatigue-critical modified structures (FCMS) as necessary and make it available to aircraft operators as part of the ICA of the change.

(c) For turbine-powered large aeroplanes, the baseline corrosion prevention and control programme is amended or supplemented to address the influence of the change on the effectiveness of the programme, as necessary.

21.A.108 Availability of operational suitability data

Regulation (EU) No 69/2014

In the case of a change affecting the operational suitability data, the holder of the minor change approval shall make available:

(a) at least one set of changes to the operational suitability data prepared in accordance with the applicable operational suitability certification basis, to all known EU operators of the changed aircraft, before the operational suitability data must be used by a training organisation or an EU operator; and

(b) any further change to the affected operational suitability data, to all known EU operators of the changed aircraft; and

(c) on request, the relevant parts of the changes in points (a) and (b) above, to:

1. the competent authority responsible for verifying conformity with one or more elements of the affected operational suitability data; and

2. any person required to comply with one or more elements of this set of operational suitability data.

GM to 21.A.62, 21.A.108 and 21.A.120B Availability of Operational Suitability Data

ED Decision 2014/007/R

(a) When making data available, the holder of the design approval (TC, change approval, STC) should take into account the applicable security laws.

(b) When making data available, the holder of the design approval can impose conditions addressing the intellectual property nature of the data.

21.A.109 Obligations and EPA marking

Regulation (EU) 2021/699

The holder of a minor change approval to a type-certificate shall:

(a) undertake the obligations laid down in points 21.A.4, 21.A.5, 21.A.7 and 21.A.108; and

[applicable until 6 March 2023]

(a) undertake the obligations laid down in points 21.A.4, 21.A.5, 21.A.6, 21.A.7, 21.A.9 and 21.A.108; and

[applicable from 7 March 2023 — Regulation (EU) 2022/201]

(b) specify the marking, including EPA (European Part Approval) letters, in accordance with point 21.A.804(a).

SUBPART E — SUPPLEMENTAL TYPE-CERTIFICATES

21.A.111 Scope

Regulation (EU) 2019/897

This Subpart establishes the procedure for the approval of major changes to the type-certificate under supplemental type-certificate procedures, and establishes the rights and obligations of the applicants for, and holders of, those certificates. In this Subpart, the references to type-certificates include type-certificates and restricted type-certificates.

21.A.112A Eligibility

Regulation (EU) 2019/897

Any natural or legal person that has demonstrated, or is in the process of demonstrating, its capability in accordance with point 21.A.112B may apply for a supplemental type-certificate in accordance with the conditions laid down in this Subpart.

21.A.112B Demonstration of capability

Regulation (EU) 2019/897

(a) An applicant for a supplemental type-certificate shall demonstrate its capability by holding a design organisation approval, issued by the Agency in accordance with Subpart J.

(b) By way of derogation from point (a), as an alternative procedure to demonstrate its capability, an applicant may seek Agency agreement for the use of procedures setting out the specific design practices, resources and sequence of activities necessary to comply with this Subpart.

(c) By way of derogation from point (a), in the case of products referred to in point 21.A.14(c), an applicant may demonstrate its capability by obtaining the Agency's acceptance of its certification programme established in accordance with point 21.A.93(b).

AMC to 21.A.143, 21.A.243, 21.A.14(b), 21.A.112B(b) and 21.A.432B(b) Flight Test Operations Manual (FTOM)

ED Decision 2017/024/R

1. General

   a. Scope: The FTOM covers flight test operations.

      The FTOM complexity should be proportionate to the aircraft and the organisation complexity.

   b. Format

      The FTOM may:

      — be included in the Design Organisation Approval (DOA)/Production Organisation Approval (POA)/Alternative Procedure to DOA (APDOA) documents, or

      — be a separate manual.

      The FTOM may make reference to other documents to cover the contents listed below, e.g. for record-keeping.

c. Use by contractors or sub-contractors:

When flight tests are performed by contractors or sub-contractors, they should comply with the FTOM of the primary organisations, unless they have established an FTOM in compliance with Part-21, the use of which has been agreed between the two organisations.

2. The FTOM should contain the following elements:

a. Exposition (not applicable in the case of APDOA):

If the FTOM is presented as a separate document, it should include a chart indicating the structure of the organisation and, more specifically, the functional links of the people in charge of flight test activities. It should also mention the coordination between all departments affecting flight test, e.g. Design Office, Production and Maintenance, in particular coordination for the establishment and update of a Flight Test Programme.

b. Risk and safety management:

The FTOM should describe the organisation's policy in relation to risk and safety assessment, mitigation and associated methodologies.

c. Crew members:

According to the flight test category, the FTOM should describe the organisation's policy on the composition of the crew (including the need to use a Lead Flight Test Engineer (LFTE)) and the competence and currency of its flight test crew members, including procedures for appointing crew members for each specific flight.

All crew members should be listed in the FTOM.

A flight time limitation policy should be established.

d. Carriage of persons other than crew members:

According to the flight test category, the FTOM should describe the organisation's policy in relation to the presence and safety on-board, of people other than crew members (i.e. with no flying duties).

People other than crew members should not be allowed on board for Category 1 flight tests.

e. Instruments and equipment:

The FTOM should list, depending on the nature of the flight, the specific safety-related instruments and equipment that should be available on the aircraft or carried by people on board.

The FTOM should contain provisions to allow flights to take place in case of defective or missing instruments or equipment.

f. Documents:

The FTOM should list the documents to be produced for flight test, and include (or refer to) the procedures for their issue, update and follow-up to ensure the documents' configuration control:

(i) documents associated with a Flight Test Programme:

— Flight Order for a given flight, which should include:

— a list of the tests to be performed and associated conditions;

— safety considerations relevant to the flight;

— category of the flight (e.g. Category 1);

— composition of the crew;

— names of persons other than crew members;

— aircraft configuration items relevant to the test to be highlighted to the crew;

— loading of the aircraft;

— reference to approved flight conditions; and

— restrictions relevant to the flight to be highlighted to the crew.

— Flight crew report.

(ii) documentation and information to be carried on the aircraft during flight test;

(iii) record-keeping: the FTOM should describe the policy relative to record-keeping.

g. Permit to fly:

The FTOM should describe the involvement of the flight test organisation or flight test team (as appropriate) in the process for the approval of flight conditions and the issue of permits to fly in accordance with Subpart P.

h. Currency and training:

The FTOM should describe how training for flight test is organised.

Currency of the flight test crew may be ensured either through recent experience or refresher training.

For aircraft for which Appendix XII is applicable, minimum flight experience by year should be:

— for pilots: 50 hours. In addition:

— for pilots with a flight test rating, the 50 hours should include 20 flight test hours in any flight test category.

— for pilots performing a Category 3 flight test, the flight test experience should be expressed in terms of a number of flights leading to the issue of a Certificate of Airworthiness (CofA) (e.g. first flights).

— for pilots performing a Category 4 flight test, the minimum flight test experience should be proportionate to the activity envisaged.

— for LFTEs: 10 flight test hours in any flight test category.

The FTOM should specify the requirements for a refresher training in order to ensure that crew members are sufficiently current to perform the required flight test activity.

A system should be established to record the currency of the flight test crew's training.

A valid national document (i.e. licence), issued by an EASA Member State under its national regulations and ensuring compliance with the agreed currency requirements, is an acceptable means of compliance to demonstrate currency for a pilot that holds a flight test rating and for an LFTE.

GM1 to 21.A.112B Demonstration of capability

ED Decision 2021/001/R

DEMONSTRATION OF CAPABILITY FOR SUPPLEMENTAL TYPE CERTIFICATE (STC) CASES

See also AMC 21.A.14(b) for the details of the alternative procedures.

The following examples of major changes to type design (ref.: 21.A.91) are classified in two groups. Group 1 contains cases where a design organisation approved under Part 21 Subpart J ('Subpart J DOA') should be required, and Group 2 cases where the alternative procedure may be accepted. They are typical examples but each STC case should be addressed on its merits and there would be exceptions in practice. This classification is valid for new STCs, not for evolution of STCs, and may depend upon the nature of the STC (complete design or installation).

Product	Discipline	Kind of STC	Group
All aircraft			
	OSD		
		Major stand-alone change to any OSD constituent	1
Products for which an alternative procedure may be accepted according to 21.A.14(b)	**All disciplines**		2
CS-23 (products where a Subpart J DOA is required for TC)			
Notes: 1) An STC which leads to a reassessment of the loads on large parts of the primary structure should be in Group 1. 2) '2/1' means that an assessment of consequences in terms of handling qualities, performance or complexity of demonstration of compliance may lead to classification in Group 1.			
	Aircraft		
		Conversion to tail wheel configuration	1
		Auxiliary fuel tank installations	2/1
		Glass fibre wing tips	2/1
		Fairings: nacelle, landing gear	2
		Gap seals: aileron, flap, empennage, doors	2
		Vortex generators	2/1
		Spoiler installation	1
		Increase in MTOW	1
	Structures		
		Stretcher installation	2
		Change to seating configuration	2
		Windshield replacement (heated, single piece, etc.)	2

Product	Discipline	Kind of STC	Group
		Lightweight floor panels	2
		Ski installations	2/1
	Propulsion		
		Engine model change	1
		Fixed pitch propeller installation	2
		Constant speed propeller installation	2/1
		Installation of exhaust silencer	2
		Installation of graphic engine monitor	2
		Installation of fuel flow meter	2
		Accessory replacement (alternator, magnetos, etc.)	2
		Inlet modifications: oil cooler; induction air	2
	Equipment		
		Avionics upgrades (EFIS, GPS, etc.)	2/1
		Engine instrument replacements	2
		Carburettor ice detection system	2
		Autopilot system installation	1
		Wing tip landing light; recognition lights	2
		WX radar installation	2
		Aeromedical system installations	2
		De-icing and anti-icing system installations	1
		Emergency power supply installations	2
CS-25			
	Cabin Safety		
Note: Basically, all changes related to cabin configuration should be in Group 2.		Cabin layout (installation of seats (16G), galleys, single class or business / economy class, etc.)	2
		Floor path marking	2
		Crew rest compartment	1
		Change of cargo compartment classification (from class D to class C)	1
	Structure		
Note: An STC which leads to a reassessment of the loads on large parts of the primary structure should be in Group 1.		Cargo door	1
		Change from passenger to freighter configuration	1
	Avionics		
Notes: For CS-25 products, the existence of an ETSO is not taken into account for the classification. The impact on aircraft performance, and influence of aircraft performance are criteria to assess the classification. Subjective assessment of human factors is considered for determination of the classification.		CVR	2

Product	Discipline	Kind of STC	Group
		VHF	2
		NAV (ADF, VOR, GPS, BRNAV)	2
		Autopilot, HUD, EFIS, FMS	1
		DFDR	2/1
		Meteo radar	2
		ILS Cat 3	1
		RVSM	1
		TCAS, EGPWS	1
		GPWS	2
	Powerplant		
		Auxiliary fuel tanks	1
		Thrust reverser system	1
		Hushkit	1
		Fire detection	1
		Fuel gauging	1
		Change of engine or propeller	1
CS-27 or CS-29	**All disciplines**		
Note: 2/1 means that an assessment of consequences in terms of handling qualities and performance may lead to classification in Group 1.		Replacement of main rotor or tail rotor blades	1
		Autopilot	1
		Engine type change	1
		GPS installation	2
		Jettisonable overhead raft installation	2
		Utility basket installation	2/1
		Nose or side mount camera installation	2/1
		Passenger access step installation	2/1
		Protection net & handle installation (parachuting)	2
		VIP cabin layout	2
		Navigation system installation	2
		Fuel boost pump automatic switch-on installation	2
		Decrease of maximum seating capacity	2
		Agricultural spray kit installation	2/1
		Long exhaust pipe installation	2
		Flotation gear installation	2/1
		Wipers installation	2
		Engine oil filter installation	2
		Skid gear covering installation	2/1
		Gutter installation (top pilot door)	2
		Cable cutter installation	2
		Auxiliary fuel tank fixed parts installation	2
		Cabin doors windows replacement	2
		Radio altimeter aural warning installation	2
		Standby horizon autonomous power supply	2

Product	Discipline	Kind of STC	Group
		Fire attack system	2/1
		Hoisting system installation	2/1
		External loads hook installation	2
		Emergency flotation gear installation	2/1
		Heating/demisting (P2 supply)	2

21.A.113 Application for a supplemental type-certificate

Regulation (EU) 2019/897

(a) An application for a supplemental type-certificate shall be made in a form and manner established by the Agency.

(b) When applying for a supplemental type-certificate, the applicant shall:

(i) include in the application the information required by point 21.A.93(b);

(ii) specify whether the certification data has been or will be prepared completely by the applicant or on the basis of an arrangement with the owner of the type-certification data.

(c) Point 21.A.93(c) applies to the requirements for the time limits of the application effectivity as well as the requirements related to the need to update the type-certification basis, operational suitability data certification basis and environmental protection requirements, when the change has not been approved or it is evident that it will not be approved within the time limit established.

AMC 21.A.113(a) Form and manner

ED Decision 2019/018/R

The applicant should file an application using the web-based 'EASA Applicant Portal'[1] or the application form for a supplemental type certificate (STC) (FO.CERT.00033)[2], which may be downloaded from the EASA website.

If the form is filled in offline, it should be completed in accordance with the instructions embedded at the bottom of the application form, and sent to EASA by fax, email or regular mail following the information provided on the EASA website[3].

[1] https://ap.easa.europa.eu (changes to the link provided may not be reflected in this document).

[2] https://www.easa.europa.eu/document-library/application-forms/focert00033 (changes to the link provided may not be reflected in this document).

[3] https://www.easa.europa.eu/document-library/application-forms/certificates-and-approvals (changes to the link provided may not be reflected in this document).

21.A.115 Requirements for approval of major changes in the form of a supplemental type-certificate

Regulation (EU) 2019/897

(a) Supplemental type certificates shall be issued by:

1. the Agency; or

2. an approved design organisation within the scope of its privileges provided for in points (1) and (9) of point 21.A.263(c), as recorded in the terms of approval.

(b) A supplemental type-certificate shall only be issued when:

1. the applicant has demonstrated its capability in accordance with point 21.A.112B;

2. it has been demonstrated that the change to a type-certificate and areas affected by the change comply with the type-certification basis and the environmental protection requirements, as established by the Agency in accordance with point 21.A.101;

3. in the case of a supplemental type-certificate affecting the operational suitability data, it has been demonstrated that the necessary changes to the operational suitability data meet the operational suitability data certification basis, as established by the Agency in accordance with point 21.A.101;

4. compliance with points (2) and (3) has been demonstrated in accordance with point 21.A.20, as applicable to the change; and

5. in case the applicant has specified that it provided certification data on the basis of an arrangement with the owner of the type-certification data in accordance with point 21.A.113(b):

   (i) the type-certificate holder has indicated that it has no technical objection to the information submitted under point 21.A.93; and

   (ii) the type-certificate holder has agreed to collaborate with the supplemental type-certificate holder to ensure discharge of all obligations for continued airworthiness of the changed product through compliance with points 21.A.44 and 21.A.118A.

(c) By derogation from points (3) and (4) of point (b), at the applicant's request included in the declaration referred to in point 21.A.20(d), the applicant is entitled to have a supplemental type-certificate for an aircraft issued before the applicant has demonstrated compliance with the operational suitability data certification basis, provided that the applicant demonstrates such compliance before the date at which those data are to be actually used.

(d) A supplemental type-certificate shall be limited to the specific configuration(s) in the type-certificate to which the related major change relates.

AMC 21.A.115 Requirements for the approval of major changes in the form of a supplemental type certificate (STC)

ED Decision 2019/018/R

(a) For STCs approved by EASA, the AMC and GM to point 21.A.20 should be followed by the applicant.

(b) For an application under point 21.A.115(c), see GM 21.A.21(b), 21.A.95(c), 21.A.97(c), 21.A.115(c), 21.B.103(b), 21.B.107(b) and 21.B.111(b).

(c) In accordance with point 21.A.115(d), the compliance demonstration process must always cover the specific configuration(s) in the type certificate (TC) to which the STC under approval is applied. These configurations should be defined by the change to the type certificate considering the type certificate data sheet (TCDS) and the relevant optional installations. The demonstration of compliance should cover these specific applicable configurations. Consequently, the approval of the STC excludes any other configurations, in particular those that already existed, but were not considered in the compliance demonstration process, and those that may be certified in future.

(d) For STCs approved by the design organisation approval (DOA) holder under their privilege as per point 21.A.263(c)(9), the process described under AMC No 2 to 21.A.263(c)(5), (8) and (9) applies.

GM 21.A.21(b), 21.A.95(c), 21.A.97(c), 21.A.115(c), 21.B.103(b), 21.B.107(b) and 21.B.111(b) Approval of operational suitability data (OSD)

ED Decision 2019/018/R

It is acknowledged that it may not always be possible to have the OSD available on the date of the issue of the (restricted) type certificate ((R)TC), change approval or supplemental type certificate (STC). The derogation provided by 21.A.21(b), 21.A.95(c), 21.A.97(c), 21.A.115(c), 21.B.103(b), 21.B.107(b) and 21.B.111(b) is intended for that case. The (R)TC, change approval or STC can be issued before compliance with the OSD certification basis has been demonstrated.

However, the OSD needs to be approved before the data is used by a training organisation for the purpose of obtaining a European Union (EU) licence, rating or attestation, or by an EU operator. This is normally done before the entry into service of the first aircraft by an EU operator but it could also be done later for some of the OSD constituents, such as the definition of the scope of validation source data to support the objective qualification of a simulator, which should only be available when a simulator has to be qualified.

The derogation provided in points 21.A.97(c), 21.A.115(c), 21.B.103(b), 21.B.107(b), and 21.B.111(b) is applicable to all major changes to a TC, so it is also applicable to minor design changes when triggering a major master minimum equipment list (MMEL) change, as well as to changes in which at least one of the OSD constituent changes is major.

21.A.116 Transferability

Regulation (EU) No 748/2012

A supplemental type-certificate shall only be transferred to a natural or legal person that is able to undertake the obligations of point 21.A.118A and for this purpose has demonstrated its ability to qualify under the criteria of point 21.A.112B except for ELA1 aircraft for which the natural or legal person has sought the Agency agreement for the use of procedures setting out its activities to undertake these obligations.

21.A.117 Changes to that part of a product covered by a supplemental type-certificate

Regulation (EU) No 748/2012

(a) Minor changes to that part of a product covered by a supplemental type-certificate shall be classified and approved in accordance with Subpart D.

(b) Each major change to that part of a product covered by a supplemental type-certificate shall be approved as a separate supplemental type-certificate in accordance with this Subpart.

(c) By way of derogation from point (b), a major change to that part of a product covered by a supplemental type-certificate submitted by the supplemental type-certificate holder itself may be approved as a change to the existing supplemental type-certificate.

21.A.118A Obligations and EPA marking

Regulation (EU) 2021/699

Each holder of a supplemental type-certificate shall:

(a) undertake the obligations:

1. laid down in points 21.A.3A, 21.A.3B, 21.A.4, 21.A.5, 21.A.6, 21.A.7, and 21.A.120B;

   [applicable until 6 March 2023]

1. laid down in points 21.A.3A, 21.A.3B, 21.A.4, 21.A.5, 21.A.6, 21.A.7, 21.A.9 and 21.A.120B;

   [applicable from 7 March 2023 — Regulation (EU) 2022/201]

2. implicit in the collaboration with the type-certificate holder under point 21.A.115(d)(2);

and for this purpose continue to meet the criteria of point 21.A.112B;

(b) specify the marking, including EPA letters, in accordance with point 21.A.804(a).

21.A.118B Duration and continued validity

Regulation (EU) No 748/2012

(a) A supplemental type-certificate shall be issued for an unlimited duration. It shall remain valid subject to:

1. the holder remaining in compliance with this Annex I (Part 21); and
2. the certificate not being surrendered or revoked under the applicable administrative procedures established by the Agency.

(b) Upon surrender or revocation, the supplemental type-certificate shall be returned to the Agency.

21.A.120B Availability of operational suitability data

Regulation (EU) No 69/2014

In the case of a change affecting the operational suitability data, the holder of the supplemental type-certificate shall make available:

(a) at least one set of changes to the operational suitability data prepared in accordance with the applicable operational suitability certification basis, to all known EU operators of the changed aircraft, before the operational suitability data must be used by a training organisation or an EU operator; and

(b) any further change to the affected operational suitability data, to all known EU operators of the changed aircraft; and

(c) on request, the relevant parts of the changes in points (a) and (b) above, to:

1. the competent authority responsible for verifying conformity with one or more elements of the affected operational suitability data; and
2. any person required to comply with one or more elements of this set of operational suitability data.

GM to 21.A.62, 21.A.108 and 21.A.120B Availability of Operational Suitability Data

ED Decision 2014/007/R

(a) When making data available, the holder of the design approval (TC, change approval, STC) should take into account the applicable security laws.

(b) When making data available, the holder of the design approval can impose conditions addressing the intellectual property nature of the data.

SUBPART F — PRODUCTION WITHOUT PRODUCTION ORGANISATION APPROVAL

21.A.121 Scope

Regulation (EU) No 748/2012

(a) This Subpart establishes the procedure for demonstrating the conformity with the applicable design data of a product, part and appliance that is intended to be manufactured without a production organisation approval under Subpart G.

(b) This Subpart establishes the rules governing the obligations of the manufacturer of a product, part, or appliance being manufactured under this Subpart.

GM No 1 to 21.A.121 Applicability – Individual product, part or appliance

ED Decision 2012/020/R

In this context, 'demonstrating the conformity with the applicable design data of a product, part and appliance' means that conformity with the applicable design data has to be established and shown for each and every product, part or appliance.

GM No 2 to 21.A.121 Applicability – Applicable design data

ED Decision 2019/018/R

Applicable design data is defined as all the necessary drawings, specifications and other technical information provided by the applicant for, or holder of a design organisation approval, TC, STC, approval of repair or minor change design, or ETSO authorisation (or equivalent when Part 21 Section A Subpart F is used for production of products, parts or appliances, the design of which has been approved other than according to Part 21), and released in a controlled manner to the manufacturer that produces under Part 21 Subpart F. This should be sufficient for the development of production data to enable manufacture in conformity with the design data.

Prior to the issue of the TC, STC, approval of repair or minor change design or ETSO authorisation, or equivalent, design data is defined as 'not approved', but parts and appliances may be released with an EASA Form 1 as a certificate of conformity.

After the issue of the TC, STC, approval of repair or minor change or ETSO authorisation, or equivalent, this design data is defined as 'approved' and items manufactured in conformity are eligible for release on an EASA Form 1 for airworthiness purposes.

For the purpose of Subpart F of Part 21, the term 'applicable design data' includes the information related to the applicable engine exhaust emissions and aeroplane CO_2 emissions production cut-off requirements.

21.A.122 Eligibility

Regulation (EU) No 748/2012

Any natural or legal person may apply to show conformity of individual products, parts or appliances under this Subpart, if:

(a) it holds or has applied for an approval covering the design of that product, part or appliance; or

(b) it has ensured satisfactory coordination between production and design, through an appropriate arrangement with the applicant for, or holder of, an approval of such a design.

AMC No 1 to 21.A.122 Eligibility – Link between design and production

ED Decision 2012/020/R

An 'arrangement' is considered suitable if it is documented and satisfies the competent authority that co-ordination is satisfactory.

To achieve satisfactory co-ordination the documented arrangements must at least define the following aspects irrespective of whether the design organisation and the person producing or intending to produce under Part 21 Subpart F are separate legal entities or not:

1. The responsibilities of a design organisation which assure correct and timely transfer of up-to-date applicable design data (e.g., drawings, material specifications, dimensional data, processes, surface treatments, shipping conditions, quality requirements, etc.);

2. The responsibilities and procedures of the manufacturer for receiving, managing and using the applicable design data provided by the design organisation.

3. The responsibilities and procedures of the manufacturer for developing, where applicable, its own manufacturing data in compliance with the applicable design data package.

4 The responsibilities of the manufacturer to assist the design organisation in dealing with continuing airworthiness matters and for required actions (e.g., traceability of parts in case of direct delivery to users, retrofitting of modifications, traceability of processes' outputs and approved deviations for individual parts as applicable, technical information and assistance, etc.);

5. The scope of the arrangements covering Subpart F requirements, in particular: 21.A.126(a)(4) and 21.A.129(d) and (f) and any associated GM or AMC.

6. The responsibilities of the manufacturer, in case of products prior to type certification to assist a design organisation in demonstrating compliance with CS (access and suitability of production and test facilities for manufacturing and testing of prototype models and test specimen);

7. The procedures to deal adequately with production deviations and non-conforming parts;

8. The means to achieve adequate configuration control of manufactured parts, to enable the manufacturer to make the final determination and identification for conformity or airworthiness release and eligibility status;

9. The identification of responsible persons/offices who controls the above.

10. The acknowledgment by the holder of the TC/STC/repair or change approval/ETSO authorisation that the approved design data provided, controlled and modified in accordance with the arrangement are recognised as approved.

In many cases the person producing or intending to produce under Part 21 Subpart F may receive the approved design data through an intermediate production organisation. This is acceptable provided an effective link between the design approval holder and the production organisation can be maintained to satisfy the intent of 21.A.122.

When the design organisation and the manufacturer are two separate legal entities a Direct Delivery Authorisation should be available for direct delivery to end users in order to guarantee continued airworthiness control of the released parts and appliances.

Where there is no general agreement for Direct Delivery Authorisation, specific permissions may be granted (see AMC 21.A.4).

AMC No 2 to 21.A.122 Eligibility – Link between design and production

ED Decision 2012/020/R

In accordance with AMC No 1 to 21.A.122 the person producing or intending to produce under Part 21 Subpart F should demonstrate to the authority that it has entered into an arrangement with the design organisation. The arrangement must be documented irrespective of whether the two organisations are separate legal entities or not.

The documented arrangement must facilitate the person producing or intending to produce under Part 21 Subpart F to demonstrate compliance with the requirement of 21.A.122 by means of written documents agreed.

In the case where the design organisation and the person producing or intending to produce under Part 21 Subpart F are part of the same legal entity these interfaces may be demonstrated by company procedures accepted by the competent authority.

In all other cases to define such a design/production interface the following sample format is offered:

Arrangement Sample Form

<table>
<tr><td colspan="2">ARRANGEMENT
in accordance with 21.A.122</td></tr>
<tr><td>The undersigned agree on the following commitments:</td><td>Relevant interface procedures</td></tr>
<tr><td>The design organisation [NAME] takes responsibility to:
— assure correct and timely transfer of up-to-date applicable design data (e.g., drawings, material specifications, dimensional data, processes, surface treatments, shipping conditions, quality requirements, etc.) to the person producing under Part 21 Subpart F [NAME]
— provide visible statement(s) of approved design data.</td><td></td></tr>
<tr><td>The person producing under Part 21 Subpart F [NAME] takes responsibility to
— assist the design organisation [Name] in dealing with continuing airworthiness matter and for required actions
— assist the design organisation [NAME] in case of products prior to type certification in demonstrating compliance with certification specifications
— develop, where applicable, its own manufacturing data in compliance with the airworthiness data package.</td><td></td></tr>
<tr><td>The design organisation [NAME] and the person producing under Part 21 Subpart F [NAME] take joint responsibility to:
— deal adequately with production deviations and non-conforming parts in accordance with the applicable procedures of the design organisation and the manufacturer producing under Part 21 Subpart F.
— achieve adequate configuration control of manufactured parts, to enable the manufacturer producing under Part 21 Subpart F to make the final determination and identification for conformity.</td><td></td></tr>
<tr><td colspan="2">The scope of production covered by this arrangement is detailed in [DOCUMENT REFERENCE/ATTACHED LIST]</td></tr>
<tr><td colspan="2">[When the design organisation is not the same legal entity as the manufacturer producing under Part 21 Subpart F]

Transfer of approved design data:
The TC/STC/ETSO authorisation holder [NAME] acknowledges that the approved design data provided, controlled and modified in accordance with the arrangement are recognised as approved by the competent authority and therefore the parts and appliances manufactured in accordance with these data and found in a condition for safe operation may be released certifying that the item was manufactured in conformity to approved design data and is in a condition for safe operation.</td></tr>
<tr><td colspan="2">[When the design organisation is not the same legal entity as the manufacturer producing under Part 21 Subpart F]

Direct Delivery Authorisation:
This acknowledgment includes also [OR does not include] the general agreement for direct delivery to end users in order to guarantee continued airworthiness control of the released parts and appliances.</td></tr>
<tr><td>For the [NAME of the design organisation/DOA holder]

Date:
xx.xx.xxxx

Signature:
([NAME in block letters])</td><td>For the [NAME of the person producing under Part 21 Subpart F]

Date:
xx.xx.xxxx

Signature:
([NAME in block letters])</td></tr>
</table>

Instructions for completion:

Title: The title of the relevant document must clearly indicate that it serves the purpose of a design/production interface arrangement in accordance with 21.A.122.

Commitment: The document must include the basic commitments between the design organisation and the manufacturer producing under Part 21 Subpart F as addressed in AMC 21.A.4 and AMC No 1 to 21.A.122.

Relevant Procedures: Identify an entry point into the documentary system of the organisations with respect to the implementation of the arrangement (for example a contract, quality plan, handbooks, common applicable procedures, working plans etc.).

Scope of arrangement: The scope of arrangement must state by means of a list or reference to relevant documents those products, parts or appliances that are covered by the arrangement.

Transfer of approved design data: Identify the relevant procedures for the transfer of the applicable design data required by 21.A.122 and AMC No 1 to 21.A.122 from the design organisation to the person producing under Part 21 Subpart F. The means by which the design organisation advises the person producing under Part 21 Subpart F whether such data is approved or not approved must also be identified (ref. 21.A.4 / AMC 21.A.4).

Direct Delivery Authorisation: Where the design organisation and the person producing under Part 21 Subpart F are separate legal entities the arrangement must clearly identify whether authorisation for direct delivery to end users is permitted or not.

Where any intermediate production/design organisation is involved in the chain between the original design organisation and the person producing under Part 21 Subpart F, evidence must be available that this intermediate organisation has received authority from the design organisation to grant Direct Delivery Authorisation.

Signature: AMC No 1 to 21.A.122 requests the identification of the responsible persons/offices who control the commitments laid down in the arrangement. Therefore the basic document must be signed mutually by the authorised representatives of the design organisation and the manufacturer producing under Part 21 Subpart F in this regard.

21.A.124 Application

Regulation (EU) No 748/2012

(a) Each application for an agreement to the showing of conformity of individual products, parts and appliances under this Subpart shall be made in a form and manner established by the competent authority.

(b) Such application shall contain:

1. evidence which demonstrates, where applicable, that:

   (i) the issuance of a production organisation approval under Subpart G would be inappropriate; or

   (ii) the certification or approval of a product, part or appliance under this Subpart is needed pending the issuance of a production organisation approval under Subpart G;

2. an outline of the information required in point 21.A.125A(b).

GM 21.A.124(a) Application – Application form

ED Decision 2012/020/R

EASA Form 60 (see AMC 21.B.120(c)(1)) should be obtained from the competent authority and completed by the applicant.

An application may be accepted from:

— An individual applying on his or her own behalf, or

— In the case of an organisation, an individual with the authority to make agreements on behalf of the organisation.

The completed form should be forwarded to the competent authority.

GM 21.A.124(b)(1)(i) Applicability – Inappropriate approval under Subpart G

ED Decision 2012/020/R

The issue of a letter of agreement of production under Part 21 Subpart F may be agreed by the competent authority when:

1. The applicant produces or intends to produce aeronautical products, parts and/or appliances intended for airborne use as part of a type-certificated product (this excludes simulators, ground equipment and tools), and

2. The competent authority determines that Part 21 Section A Subpart G would be inappropriate, and consequently Part 21 Section A Subpart F applies. The main difference between Part 21 Section A Subparts G and F is that Subpart G requires the existence of a Quality System which provides the competent authority with the necessary confidence to grant to the manufacturer the privileges of certifying its own production. There are situations where a Quality System, including independent monitoring and continuous internal evaluation functions, is not justified and /or feasible. In making the determination that Subpart F may apply, the competent authority may take into account one or a combination of parameters such as the following:

    — no flow production (infrequent or low volume of production).

    — simple technology (enabling effective inspection phases during the manufacturing process).

    — very small organisation.

GM 21.A.124(b)(1)(ii) Certification or approval needed in advance of the issue of a POA

ED Decision 2012/020/R

In cases where Part 21 Section A Subpart G is applicable, but when some time is needed for the organisation to achieve compliance with Subpart G, i.e., to establish the necessary documented quality system, the competent authority may agree to use Part 21 Section A Subpart F for a limited period (transient phase).

In cases where Part 21 Section A Subpart G is applicable, such as to produce ETSO articles, a letter of agreement to produce under Part 21 Subpart F should not be given unless an application has been made for organisation approval under Subpart G, and reasonable progress is being made towards compliance with Subpart G. Long-term production under Part 21 Subpart F will not be permitted.

GM 21.A.124(b)(2) Application – Minimum information to include with the application

ED Decision 2012/020/R

At this early stage, provision of the complete manual is not necessary, but at least the following items should be covered:

1. Table of Contents of the Manual (including list of existing inspection system documents or procedures)
2. Description of items to be manufactured (including intended quantities /deliveries)
3. List of possible suppliers
4. General description of facilities
5. General description of production means
6. Human resources

21.A.124A Means of compliance

Regulation (EU) 2022/201

(a) An organisation may use any alternative means of compliance to establish compliance with this Regulation.

(b) If an organisation wishes to use an alternative means of compliance, it shall, prior to using it, provide the competent authority with a full description. The description shall include any revisions to manuals or procedures that may be relevant, as well as an explanation indicating how compliance with this Regulation is achieved.

The organisation may use those alternative means of compliance subject to prior approval from the competent authority.

[applicable from 7 March 2023 — Regulation (EU) 2022/201]

21.A.125A Issue of a letter of agreement [applicable until 6 March 2023] / 21.A.125A Issuance of a letter of agreement [applicable from 7 March 2023]

Regulation (EU) No 748/2012

The applicant shall be entitled to have a letter of agreement issued by the competent authority agreeing to the showing of conformity of individual products, parts and appliances under this Subpart, after:

(a) having established a production inspection system that ensures that each product, part or appliance conforms to the applicable design data and is in condition for safe operation;

(b) having provided a manual that contains:

1. a description of the production inspection system required under point (a);
2. a description of the means for making the determination of the production inspection system;
3. a description of the tests required in points 21.A.127 and 21.A.128, and the names of persons authorised for the purpose of point 21.A.130(a);

(c) demonstrating that it is able to provide assistance in accordance with points 21.A.3A and 21.A.129(d).

GM No 1 to 21.A.125A Letter of agreement – Meaning of individual

ED Decision 2012/020/R

'Individual' means that each part number or type of item (i.e., product, part or appliance) to be produced should be specifically referenced, either directly or through a referenced capability list, in the letter of agreement from the competent authority. The letter may also specify any limitation in the production rate.

GM No 1 to 21.A.125A(b) Letter of agreement – Contents of the Manual

ED Decision 2012/020/R

The manual referred in 21.A.125A(b) should include, at least the following information:

1. Declaration by the applicant of undertaking in respect of
   - 1.1 the requirements defined in Part 21 Section A Subpart F
   - 1.2 the procedures contained in the manual and in the documentation mentioned herein
   - 1.3 every legal provision laid down for the carrying on of the business activities (statutory declaration).
2. Declaration by the applicant certifying the conformity of the manual to the requirements defined in Part 21 Section A Subpart F
3. Jobs, power and responsibilities of the accountable personnel
4. Organisation chart, if required by the competent authority
5. Description of the resources, including human resources, with an indication of the personnel qualification criteria
6. Description of location and equipment
7. Description of the scope of work, the production processes and techniques, and reference to the 'capability list'
8. Communications with the competent authority, and specifically those required by 21.A.125A(c)
9. Assistance and communication with the design approval holder, and the means of compliance with 21.A.125A(c)
10. Amendments to the Manual
11. Description of the Inspection System (including test, see GM No 2 to 21.A.125A(b), and 21.A.127 and 21.A.128), and the procedures to meet 21.A.126 and associated GM
12. List of suppliers
13. Issuing of the Statement of Conformity and competent authority inspection for validation

If the information is listed in the Manual in a different order a cross-reference to the above list should be made available in the Manual.

GM No 2 to 21.A.125A(b) Letter of agreement – Production Inspection System: Functional Tests

ED Decision 2012/020/R

All items produced should be subject to inspection to be carried out at suitable phases which permit an effective verification of conformity with the design data.

These inspections may provide for the execution of tests to measure performances as set out in the applicable design data.

Considerations of complexity of the item and/or its integration in the next level of production will largely determine the nature and time for these tests, for example:

— appliances - will require full functional testing to the specifications

— parts - will at least require basic testing to establish conformity, but due allowance may be made for further testing carried out at the next level of production

— material - will require verification of its stated properties.

GM 21.A.125A(c) Letter of agreement – Assistance

ED Decision 2012/020/R

The competent authority should be provided with material which defines the means of providing assistance as required by 21.A.125A(c). Suitable descriptive material should be included in the Manual, as described in GM No 1 to 21.A.125A(b).

21.A.125B Findings [applicable until 6 March 2023] / 21.A.125B Findings and observations [applicable from 7 March 2023 - Regulation (EU) 2022/201]

Regulation (EU) No 748/2012

(a) When objective evidence is found showing non-compliance of the holder of a letter of agreement with the applicable requirements of this Annex I (Part 21), the finding shall be classified as follows:

1. a level one finding is any non-compliance with this Annex I (Part 21) which could lead to uncontrolled non-compliances with applicable design data and which could affect the safety of the aircraft;

2. a level two finding is any non-compliance with this Annex I (Part 21) which is not classified as level one.

(b) A level three finding is any item where it has been identified, by objective evidence, to contain potential problems that could lead to a non-compliance under point (a).

(c) After receipt of notification of findings according to point 21.B.125:

1. in case of a level one finding, the holder of the letter of agreement shall demonstrate corrective action to the satisfaction of the competent authority within a period of no more than 21 working days after written confirmation of the finding;

2. in case of level two findings, the corrective action period granted by the competent authority shall be appropriate to the nature of the finding but in any case initially shall not be more than three months. In certain circumstances and subject to the nature of the finding, the competent authority may extend the three months period subject to the provision of a satisfactory corrective action plan agreed by the competent authority;

3. a level three finding shall not require immediate action by the holder of the letter of agreement.

(d) In case of level one or level two findings, the letter of agreement may be subject to a partial or full limitation, suspension and revocation under point 21.B.145. The holder of the letter of agreement shall provide confirmation of receipt of the notice of limitation, suspension or revocation of the letter of agreement in a timely manner.

[applicable until 6 March 2023]

(a) After receipt of the notification of findings in accordance with point 21.B.125, the holder of a letter of agreement shall:

1. identify the root cause(s) of, and contributing factor(s) to, the non-compliance;

2. define a corrective action plan;

3. demonstrate the implementation of the corrective action to the satisfaction of the competent authority.

(b) The actions referred to in point (a) shall be performed within the period agreed with that competent authority in accordance with point 21.B.125.

(c) The observations received in accordance with point 21.B.125(e) shall be given due consideration by the holder of the letter of agreement. The organisation shall record the decisions taken in respect of those observations.

[applicable from 7 March 2023 - Regulation (EU) 2022/201]

GM No 1 to 21.A.125B(a) Uncontrolled non-compliance with applicable design data

ED Decision 2012/020/R

An uncontrolled non-compliance with applicable design data is a non-compliance:

a) that cannot be discovered through systematic analysis or

b) that prevents identification of affected products, parts, appliances, or material.

GM No 2 to 21.A.125B(a) Examples for level one findings

ED Decision 2012/020/R

Examples for level 1 findings are non-compliances with any of the following points, that could affect the safety of the aircraft:

21.A.126, 21.A.127, 21.A.128, 21.A.129.

It should be anticipated that a non-compliance with these points is only considered a level one finding when objective evidence has been found that this finding is an uncontrolled non-compliance that could affect the safety of the aircraft.

21.A.125C Duration and continued validity

Regulation (EU) No 748/2012

(a) The letter of agreement shall be issued for a limited duration not exceeding one year. It shall remain valid unless:

1. the holder of the letter of agreement fails to demonstrate compliance with the applicable requirements of this Subpart; or
2. there is evidence that the manufacturer cannot maintain satisfactory control of the manufacture of products, parts, or appliances under the agreement; or
3. the manufacturer no longer meets the requirements of point 21.A.122; or
4. the letter of agreement has been surrendered, revoked under point 21.B.145, or has expired.

(b) Upon surrender, revocation or expiry, the letter of agreement shall be returned to the competent authority.

[applicable until 6 March 2023]

(a) The letter of agreement shall be issued for a limited period of time that in any case shall not exceed 1 year. It shall remain valid subject to the organisation's compliance with all the following conditions:

1. the production organisation continues to comply with the applicable requirements of this Annex;
2. the production organisation or any of its partners, suppliers or subcontractors acknowledges that the competent authority may carry out investigations in accordance with point 21.A.9;
3. the production organisation is able to provide the competent authority with evidence showing that it maintains satisfactory control of the manufacture of products, parts and appliances under the letter of agreement;
4. the letter of agreement has not been revoked by the competent authority under point 21.B.65, has not been surrendered by the production organisation, and its duration has not expired.

(b) Upon surrender, revocation or expiry, the letter of agreement shall be returned to the competent authority.

[applicable from 7 March 2023 - Regulation (EU) 2022/201]

21.A.126 Production inspection system

Regulation (EU) No 748/2012

(a) The production inspection system required under point 21.A.125A(a) shall provide a means for determining that:

1. incoming materials, and bought or subcontracted parts, used in the finished product are as specified in the applicable design data;
2. incoming materials, and bought or subcontracted parts, are properly identified;
3. processes, manufacturing techniques and methods of assembly affecting the quality and safety of the finished product are accomplished in accordance with specifications accepted by the competent authority;
4. design changes, including material substitutions, have been approved under Subpart D or E and controlled before being incorporated in the finished product.

(b) The production inspection system required by point 21.A.125A(a), shall also be such as to ensure that:

1. parts in process are inspected for conformity with the applicable design data at points in production where accurate determinations can be made;
2. materials subject to damage and deterioration are suitably stored and adequately protected;
3. current design drawings are readily available to manufacturing and inspection personnel, and used when necessary;
4. rejected materials and parts are segregated and identified in a manner that precludes installation in the finished product;
5. materials and parts that are withheld because of departures from design data or specifications, and that are to be considered for installation in the finished product, are subjected to an approved engineering and manufacturing review procedure. Those materials and parts determined by this procedure to be serviceable shall be properly identified and reinspected if rework or repair is necessary. Materials and parts rejected by this procedure shall be marked and disposed of to ensure that they are not incorporated in the final product;

   [applicable until 6 March 2023]

5. materials and parts that are withheld because of deviations from type design or production specifications, and that are to be considered for installation in the finished product, are subjected to an approved engineering and manufacturing review procedure. Those materials and parts that have been found in that procedure to be serviceable shall be properly identified and reinspected if it is necessary to be reworked or repaired. Materials and parts rejected in that procedure shall be marked and disposed of to ensure that they are not incorporated in the final product;

   [applicable from 7 March 2023 - Regulation (EU) 2022/201]

6. records produced under the production inspection system are maintained, identified with the completed product or part where practicable, and retained by the manufacturer in order to provide the information necessary to ensure the continued airworthiness of the product.

   [applicable until 6 March 2023]

GM 21.A.126 Production inspection system

ED Decision 2012/020/R

GM 21.A.126(a) and (b) have been developed for persons producing under Part 21 Section A Subpart F on the long term basis as defined in 21.A.124(b)(1)(i).

For those persons producing under Part 21 Section A Subpart F as a transient phase under 21.A.124(b)(1)(ii), compliance with 21.A.126 may also be demonstrated to the satisfaction of the competent authority by using the equivalent Part 21 Section A Subpart G AMC/GM.

GM 21.A.126(a)(1) Production inspection system – Conformity of supplied parts, appliances and material

ED Decision 2012/020/R

1. The person producing under Subpart F is responsible for determining and applying acceptance standards for physical condition, configuration status and conformity, as appropriate, of raw materials, subcontracted works, and supplied products, parts, appliances or material, whether to be used in production or delivered to customers as spare parts. This responsibility also includes BFE (Buyer Furnished Equipment) items.
2. Control may be based upon use of the following techniques, as appropriate:
   - 2.1 first article inspection, including destruction if necessary, to verify that the article conforms to the applicable data for new production line or new supplier,
   - 2.2 incoming inspections and tests of supplied parts or appliances that can be satisfactorily inspected on receipt,
   - 2.3 identification of incoming documentation and data relevant to the showing of conformity to be included in the certification documents,
   - 2.4 any additional work, tests or inspection which may be needed for parts or appliances which are to be delivered as spare parts and which are not subject to the checks normally provided by subsequent production or inspection stages.
3. The person producing under Part 21 Subpart F may rely upon an EASA Form 1 issued in accordance with Part 21 if provided as evidence of conformity with applicable design data

For suppliers not holding a POA the inspection system of the person producing under Part 21 Subpart F should establish a system for control of incoming materials and bought or subcontracted items which provides for inspections and tests of such items by the person producing under Part 21 Subpart F at the supplier's facility, if the item cannot or will not be completely inspected upon receipt.

GM 21.A.126(a)(2) Production inspection system – Identification of incoming materials and parts

ED Decision 2012/020/R

All parts and materials coming from external parties should be identified and inspected to ascertain that they have not been damaged during transport or unpacking, that the incoming parts and materials have the appropriate and correct accompanying documentation and that the configuration and condition of the parts or materials is as laid down in that documentation.

Only on completion of these checks and of any incoming further verifications laid down in the procurement specification, may the part or material be accepted for warehousing and used in production.

This acceptance should be certified by an inspection statement.

A suitable recording system should allow reconstruction at any time of the history of every material or part.

The areas where the incoming checks are carried out and the materials or parts are stored pending completion of the checks should be physically segregated from other departments.

GM No 1 to 21.A.126(a)(3) Production inspection system – List of specifications

ED Decision 2012/020/R

It is the responsibility of:

1. The designer, to define all necessary processes, techniques and methods to be followed during manufacture (21.A.31) and this information will be provided as part of the applicable design data.
2. The manufacturer, to ensure that all processes are carried out strictly in accordance with the specifications provided as part of the applicable design data.

GM No 2 to 21.A.126(a)(3) Production inspection system – Means of checking of the production processes

ED Decision 2012/020/R

The Production Inspection System should be provided with appropriate means of checking that production processes, whether performed by the person producing under Part 21 Subpart F or by sub-contractors under its control, are carried out in accordance with applicable data, including:

1. A system for the control and authorised amendment of data provided for the production, inspection and test to ensure that it is complete and up-to-date at the point of use
2. Availability of personnel with suitable qualification, experience, and training for each required production, inspection, and test task. Special attention should be paid to tasks requiring specialised knowledge and skill, e.g., NDT/NDI, welding...
3. A working area where the working conditions and environment are controlled as appropriate in respect of: cleanliness, temperature, humidity, ventilation, lighting, space/access, protection against noise and pollution
4. Equipment and tools sufficient to enable all specified tasks to be accomplished in a safe and effective manner without detrimental effect on the items under production. Calibration control of equipment and tools which affect critical dimensions and values must demonstrate compliance with, and be traceable to, recognised national or international standards.

GM 21.A.126(a)(4) Production inspection system – Applicable design/production data procedures

ED Decision 2012/020/R

1. When a person producing under Part 21 Subpart F is developing its own manufacturing data from the design data package delivered by a Design holder, procedures should demonstrate the correct transcription of the original design data.
2. Procedures should define the manner in which applicable design data is used to issue and update the production/inspection data, which determines the conformity of products, parts, appliances and materials. The procedure should also define the traceability of such data to each individual product, part, appliance or material for the purpose of stating the condition for safe operation and for issuing a Statement of Conformity.
3. During execution, all works should be accompanied by documentation giving either directly or by means of appropriate references, the description of the works as well as the identification of the personnel in charge of inspection and execution tasks for each of the different work phases.

GM 21.A.126(b)(1) Production inspection system – Inspection of parts in process

ED Decision 2012/020/R

The purpose of the Production Inspection System is to check at suitable points during production and provide objective evidence that the correct specifications are used, and that processes are carried out strictly in accordance with the specification.

During the manufacturing process, each article should be inspected in accordance with a plan which identifies the nature of all inspections required and the production stages at which they occur. The plan should also identify any particular skills or qualification required of person(s) carrying out the inspections (e.g., NDT personnel). A copy of the plan should be included in, or referenced by, the manual required by 21.A.125A(b).

If the parts are such that, if damaged, they could compromise the safety of the aircraft, additional inspections for such damage should be performed at the completion of each production stage.

GM 21.A.126(b)(2) Production inspection system – Suitable storage and protection

ED Decision 2012/020/R

1. Storage areas should be protected from dust, dirt, or debris, and adequate blanking and packaging of stored items should be practised.
2. All parts should be protected from extremes of temperatures and humidity and, where needed, temperature-controlled or full air-conditioned facilities should be provided.
3. Racking and handling equipment should be provided such as to allow storage, handling and movement of parts without damage.
4. Lighting should be such as to allow safe and effective access and handling, but should also cater for items which are sensitive to light e.g., rubber items.

5. Care should be taken to segregate and shield items which can emit fumes (e.g., wet batteries), substances or radiation (e.g., magnetic items) which are potentially damaging to other stored items.

6. Procedures should be in place to maintain and record stored parts identities and batch information.

7. Access to storage areas should be restricted to authorised personnel who are fully trained to understand and maintain the storage control arrangements and procedures.

8. Provisions should be made for segregated storage of non-conforming items pending their disposition (see GM 21.A.126(b)(4)).

GM 21.A.126(b)(3) Production inspection system – Use of derived data instead of original design data

ED Decision 2012/020/R

Where derived data, e.g., worksheets, process sheets, fabrication/inspection instructions, etc., is used instead of original design drawings, documents identification and control procedures should be used to ensure that the documentation in use is always accurate and current.

GM 21.A.126(b)(4) Production inspection system – Segregation of rejected material

ED Decision 2012/020/R

All materials and parts which have been identified at any stage in the manufacturing process as not conforming to the specific working and inspection instructions must be suitably identified by clearly marking or labelling, to indicate their non-conforming status.

All such non-conforming material or parts should be removed from the production area and held in a restricted access segregated area until an appropriate disposition is determined in accordance with 21.A.126(b)(5).

GM 21.A.126(b)(5) Production inspection system – Engineering and manufacturing review procedure

ED Decision 2012/020/R

1. The procedure should permit to record the deviation, to present it to the Design holder under the provisions of 21.A.122, and to record the results of the review and actions taken consequently as regards the part/product.

2. Any unintentional deviation from the manufacturing/inspection data should be recorded and handled in accordance with Part 21 Section A Subpart D or E as changes to the approved design.

GM 21.A.126(b)(6) Production inspection system – Recording and record keeping

ED Decision 2012/020/R

1. Records within a production environment satisfy two purposes. Firstly, they should, during the production process to ensure that products, parts, or appliances are in conformity with the controlling data throughout the manufacturing cycle. Secondly, certain records of milestone events are needed to subsequently provide objective evidence that all prescribed stages of the production process have been satisfactorily completed and that compliance with the applicable design data has been achieved.

   Therefore, the person producing under Part 21 Subpart F should implement a system for the compilation and retention of records during all stages of manufacture, covering short-term and long-term records appropriate to the nature of the product and its production processes.

   The management of such information should be subject to appropriate documented procedures in the Manual required by 21.A.125A(b).

   All forms of recording media are acceptable (paper, film, magnetic ...) provided they can meet the required duration for archiving under the conditions provided.

2. The related procedures should:

   2.1 Identify records to be kept.

   2.2 Describe the organisation of and responsibility for the archiving system (location, compilation, format) and conditions for access to the information (e.g., by product, subject).

   2.3 Control access and provide effective protection from deterioration or accidental damage.

   2.4 Ensure continued readability of the records.

   2.5 Demonstrate to the competent authority proper functioning of the records system.

   2.6 Clearly identify the persons involved in conformity determination.

   2.7 Define an archiving period for each type of data taking into account importance in relation to conformity determination subject to the following:

      a) Data which supports conformity of a product, part, or appliance should be kept for not less than three years from the issue date of the related Statement of Conformity or Authorised Release Certificate.

      b) Data considered essential for continuing airworthiness should be kept throughout the operational life of the product, part or appliance.

   2.8 Data related to supplied parts may be retained by the supplier if the supplier has a system agreed under Part 21 Section A Subpart F by the competent authority. The manufacturer should, in each case, define the archiving period and satisfy himself or herself and the competent authority that the recording media are acceptable.

21.A.127 Tests: aircraft

Regulation (EU) No 748/2012

(a) Each manufacturer of an aircraft manufactured under this Subpart shall establish an approved production ground and flight test procedure and check-off forms, and in accordance with those forms, test each aircraft produced, as a means of establishing relevant aspects of compliance with point 21.A.125A(a).

(b) Each production test procedure shall include at least the following:

1. a check on handling qualities;
2. a check on flight performance (using normal aircraft instrumentation);
3. a check on the proper functioning of all aircraft equipment and systems;
4. a determination that all instruments are properly marked, and that all placards and required flight manuals are installed after flight test;
5. a check of the operational characteristics of the aircraft on the ground;
6. a check on any other items peculiar to the aircraft being tested.

GM 21.A.127 Approved production ground and flight tests

ED Decision 2012/020/R

The production ground and flight tests for new aircraft will be specified by the aircraft design organisation.

21.A.128 Tests: engines and propellers

Regulation (EU) No 748/2012

Each manufacturer of engines, or propellers manufactured under this Subpart shall subject each engine, or variable pitch propeller, to an acceptable functional test as specified in the type-certificate holder's documentation, to determine if it operates properly throughout the range of operation for which it is type-certificated, as a means of establishing relevant aspects of compliance with point 21.A.125A(a).

GM No 1 to 21.A.128 Acceptable functional test – Engines

ED Decision 2012/020/R

The functional test required for a new engine will be specified by the engine design organisation and will normally include at least the following:

1. Break-in runs that include a determination of fuel and oil consumption and a determination of power characteristics at rated maximum continuous power or thrust and, if applicable, at rated take-off power or thrust.
2. A period of operation at rated maximum continuous power or thrust. For engines having a rated take-off power or - thrust, part of that period should be at rated take-off power or - thrust.

The test equipment used for the test run should be capable of output determination of accuracy sufficient to assure that the engine output delivered complies with the specified rating and operation limitations.

GM No 2 to 21.A.128 Acceptable functional test – Variable pitch propellers

ED Decision 2012/020/R

The functional tests required for a new propeller will be specified by the propeller design organisation and should normally include a number of complete cycles of control throughout the propeller pitch and rotational speed ranges. In addition, for feathering and/or reversing propellers, several cycles of feathering operation and reversing operation from the lowest normal pitch to the maximum reverse pitch, should normally be required.

GM No 3 to 21.A.128 Acceptable functional test – Engines and Propellers

ED Decision 2012/020/R

After functional test, each engine or propeller should be inspected to determine that the engine or propeller is in condition for safe operation. Such inspection will be specified by the design organisation and should normally include internal inspection and examination. The degree of internal inspections will normally be determined on the basis of the positive results of previous inspections conducted on the first production engines, and on the basis of service experience.

21.A.129 Obligations of the manufacturer [applicable until 6 March 2023] / 21.A.129 Obligations of the production organisation [applicable from 7 March 2023 - Regulation (EU) 2022/201]

Regulation (EU) No 748/2012

Each manufacturer of a product, part or appliance being manufactured under this Subpart shall:

(a) make each product, part or appliance available for inspection by the competent authority;

(b) maintain at the place of manufacture the technical data and drawings necessary to determine whether the product conforms to the applicable design data;

(c) maintain the production inspection system that ensures that each product conforms to the applicable design data and is in condition for safe operation;

(d) provide assistance to the holder of the type-certificate, restricted type-certificate or design approval in dealing with any continuing airworthiness actions that are related to the products, parts or appliances that have been produced;

(e) establish and maintain an internal occurrence reporting system in the interest of safety, to enable the collection and assessment of occurrence reports in order to identify adverse trends or to address deficiencies, and to extract reportable occurrences. This system shall include evaluation of relevant information relating to occurrences and the promulgation of related information;

[applicable until 6 March 2023]

(e) comply with Subpart A of this Section.

[applicable from 7 March 2023 - Regulation (EU) 2022/201]

(f) 1. report to the holder of the type-certificate, restricted type-certificate or design approval, all cases where products, parts or appliances have been released by the manufacturer and subsequently identified to have deviations from the applicable design data, and investigate with the holder of the type-certificate, restricted type-certificate or design approval to identify those deviations which could lead to an unsafe condition;

2. report to the Agency and the competent authority of the Member State the deviations which could lead to an unsafe condition identified according to point (1). Such reports shall be made in a form and manner established by the Agency under point 21.A.3A(b)(2) or accepted by the competent authority of the Member State;

3. where the manufacturer acts as supplier to another production organisation, report also to that other organisation all cases where it has released products, parts or appliances to that organisation and subsequently identified them to have possible deviations from the applicable design data.

[Point (f) applicable until 6 March 2023]

GM 21.A.129(a) Availability for inspection by the competent authority

ED Decision 2012/020/R

Each product, part or appliance should be made available for inspection at any time at the request of the competent authority.

It is recommended that a pre-defined plan of inspection points be established and agreed with the competent authority to be used as a basis for such inspections.

The manufacturer should provide such documentation, tools, personnel, access equipment etc. as necessary to enable the competent authority to perform the inspections.

AMC No 1 to 21.A.129(c) Obligations of the manufacturer – Conformity of prototype models and test specimens

ED Decision 2012/020/R

21.A.33 requires determination of conformity of prototype models and test specimens to the applicable design data. For a complete aircraft a 'conformity document', that has to be validated by the competent authority, should be provided as part of the assistance to the design approval applicant. For products other than a complete aircraft, and for parts and appliances, an EASA Form 1 validated by the competent authority may be used as a conformity document as part of the assistance to the design approval applicant.

AMC No 2 to 21.A.129(c) Obligations of the manufacturer – Conformity with Applicable Design Data

ED Decision 2012/020/R

Individual configurations are often based on the needs of the customer and improvements or changes which may be introduced by the type-certificate holder. There are also likely to be unintentional divergences (concessions or non-conformances) during the manufacturing process. All these changes are required to have been approved by the design approval applicant/holder, or when necessary by the Agency.

AMC No 3 to 21.A.129(c) Obligations of the manufacturer – Condition for safe operation

ED Decision 2012/020/R

Before issue of the Statement of Conformity to the competent authority the manufacturer under this Subpart should make an investigation so as to be satisfied in respect to each of the items listed below. The documented results of this investigation should be kept on file by the manufacturer. Certain of these items may be required to be provided (or made available) to the operator or owner of the aircraft, and, for validation of the statement of conformity, to the competent authority.

1. Equipment or modifications which do not meet the requirements of the state of manufacture but have been accepted by the competent authority of the importing country.
2. Identification of products, parts or appliances which:
   - 2.1 Are not new
   - 2.2 Are furnished by the buyer or future operator (including those identified in 21.A.801 and 805).
3. Technical records which identify the location and serial numbers of components that have traceability requirements for continued airworthiness purposes including those identified in 21.A.801 and 21.A.805.
4. Log book and a modification record book for the aircraft as required by the Agency.
5. Log books for products identified in 21.A.801 installed as part of the type design as required by the Agency.
6. A weight and balance report for the completed aircraft.
7. A record of missing items or defects which do not affect airworthiness these for example could be furnishing or BFE (Items may be recorded in a technical log or other suitable arrangement such that the operator and Agency are formally aware).
8. Product support information required by other associated implementing rules and CS or GM, such as a Maintenance Manual, a Parts Catalogue, or MMEL all of which are to reflect the actual build standard of the particular aircraft. Also an Electrical load analysis and a wiring diagram.
9. Records which demonstrate completion of maintenance tasks appropriate to the test flight flying hours recorded by the aircraft. These records should show the relationship of the maintenance status of the particular aircraft to the manufacturers recommended maintenance task list and the Maintenance Review Board (MRB) document/report.
10. Details of the serviceability state of the aircraft in respect of, a) the fuel and oil contents, b) provision of operationally required emergency equipment such as life rafts, etc.
11. Details of the approved interior configuration if different from that approved as part of the type design.
12. An approved Flight Manual which conforms to the build standard and modification state of the particular aircraft should be available.
13. Show that inspections for foreign objects at all appropriate stages of manufacture have been satisfactorily performed.
14. The registration has been marked on the exterior of the aircraft as required by national legislation. Where required by national legislation fix a fireproof owners nameplate.

15. Where applicable, there should be a certificate for noise and, for the aircraft radio station.

16. The installed compass and or compass systems have been adjusted and compensated and a deviation card displayed in the aircraft.

17. Software criticality list.

18. A record of rigging and control surface movement measurements.

19. Details of installations which will be removed before starting commercial air transport operations (e.g., ferry kits for fuel, radio or navigation).

20. List of all applicable Service Bulletins and airworthiness directives that have been implemented.

21.A.130 Statement of conformity

Regulation (EU) 2021/1088

(a) Each manufacturer of a product, part or appliance manufactured under this Subpart shall raise a statement of conformity, an EASA Form 52 (see Appendix VIII), for complete aircraft, or EASA Form 1 (see Appendix I), for other products, parts or appliances. This statement shall be signed by an authorised person who holds a responsible position in the manufacturing organisation.

(b) A statement of conformity shall include all of the below:

1. for each product, part or appliance, a statement that the product, part or appliance conforms to the approved design data and is in condition for safe operation;

2. for each aircraft, a statement that the aircraft has been ground- and flight-checked in accordance with point 21.A.127(a);

3. for each engine, or variable pitch propeller, a statement that the engine or variable pitch propeller has been subjected by the manufacturer to a final functional test in accordance with point 21.A.128;

4. additionally, in the case of environmental protection requirements:

(i) a statement that the completed engine is in compliance with the applicable engine exhaust emissions requirements on the date of manufacture of the engine, and

(ii) a statement that the completed aeroplane is in compliance with the applicable CO_2 emissions requirements on the date its first certificate of airworthiness is issued.

(c) Each manufacturer of such a product, part or appliance shall:

1. upon the initial transfer by it of the ownership of such a product, part or appliance; or

2. upon application for the original issue of an aircraft certificate of airworthiness; or

3. upon application for the original issue of an airworthiness release document for an engine, a propeller, a part or appliance,

present a current statement of conformity, for validation by the competent authority.

(d) The competent authority shall validate by counter-signature the statement of conformity if it finds after inspection that the product, part or appliance conforms to the applicable design data and is in condition for safe operation.

GM1 21.A.130, 21.A.163 and 21.A.165 Performance of tasks in real time for the issuance of an 'EASA Form 1' for prototype and new parts, appliances and products other than complete aircraft, using information and communication technologies (ICT)

ED Decision 2021/007/R

This GM provides technical guidance on the use of remote ICT to support the issuance of an 'EASA Form 1' for prototype and newly produced parts, appliances and products other than complete aircraft.

It is the responsibility of the production organisation to assess whether the use of remote ICT constitutes a suitable alternative to the physical inspection of the part, appliance or product in accordance with the applicable requirements. The production organisation that intends to use the remote ICT for such purposes should first discuss the feasibility aspects with its competent authority.

(a) Terminology

In the context of this GM, the following terminology is used:

— 'issue of an EASA Form 1' means the issuance of an EASA Form 1 under Part 21 Subpart G by a certifying staff, raise an EASA Form 1 under Part 21 Subpart F by an authorised person, and the validation of an EASA Form 1 under Part 21 Subpart F by a competent authority inspector, except in the case of issuance of an EASA Form 1 for the correction of error(s) on a previously issued certificate and for the recertification of an item from 'prototype' to 'new' provided that the design data has not changed;

— 'authorised staff' means certifying staff as defined in Part 21 Subpart G, and 'authorised person' and 'competent authority inspector' as defined in Part 21 Subpart F;

— 'item' means any part, appliance or product other than a complete aircraft;

— 'applicable design data' means non-approved design data for a prototype item and approved design data for a newly produced item;

— 'task' means any inspection, test and/or verification, as described in a documented procedure, which is needed to be performed by an authorised staff before signing an EASA Form 1;

— 'remote ICT' means any real-time video and audio communication tools using information and communication technologies (ICT) whose aim is to enable the performance of the task(s) by the authorised staff from a location different from that where the item is located (on-site).

(b) Regulatory context

The following entities may issue an EASA Form 1 for produced items in order to certify their conformity to the applicable design data and, for new items, their condition for safe operation:

— the holder of a letter of agreement (LoA) that is issued in accordance with Part 21 Subpart F (refer to point 21.A.130(a));

— the competent authority in the context of Part 21 Subpart F (refer to point 21.A.130(d));

— the holder of a production organisation approval (POA) in accordance with Part 21 Subpart G (refer to point 21.A.163(c)).

An EASA Form 1 has to be issued by appropriately qualified authorised staff. Part 21 does not require authorised staff to be on-site when issuing an EASA Form 1, nor how the production organisation and the competent authority shall determine whether the part/appliance/product other than a complete aircraft conforms to the applicable design data and, for a new item, is in a condition for safe operation. These should be detailed in a documented procedure accepted by the competent authority.

Part 21 requires:

— in point 21.A.130(d) that the competent authority validate the EASA Form 1 following inspections performed in accordance with 21.B.135(b) if it finds after the inspection that the product, part or appliance conforms to the applicable design data and is in condition for safe operation;

— in point 21.A.165(c) that the POA holder has to determine that:

  — other products, parts or appliances are complete and conform to the approved design data and are in a condition for safe operation before issuing an EASA Form 1;

  — other products, parts or appliances conform to the applicable data before issuing an EASA Form 1.

Typically, compliance with these requirements is ensured through the on-site presence of the authorised staff in order to guarantee they have appropriate access to the item, as needed.

However, compliance with these requirements may be also ensured in certain circumstances, determined as per the considerations described in point (c) below, by remotely conducting the tasks which are needed before the issuance of an EASA Form 1 by the use of remote ICT. The following considerations should be used as guidelines when the on-site presence of the authorised staff is to be replaced by virtual presence, using remote ICT.

(c) The use of remote ICT to support the issuance of an EASA Form 1

Remote ICT may have limitations that could render it unsuitable for some applications. Accordingly, careful consideration and risk management should be applied when determining when to use remote ICT. These considerations, listed below, are however not exhaustive and should not be treated as a checklist.

(1) General considerations

— As an overarching principle, it needs to be determined whether the nature of the tasks to be performed by the authorised staff allows the use of remote ICT.

— The facility where the item is located:

  — should be referred to in EASA Form 65 or EASA Form 55, directly or indirectly by reference to the corresponding section of the manual or production organisation exposition (POE); or

  — for a POA, should be a facility from where a POE procedure related to point 21.A.139(b)(1)(xv) authorises the issuance of an EASA Form 1.

— The complexity, novelty and safety criticality of the item to be released with the EASA Form 1 should be taken into account.

— The level of competence and experience of the personnel in the use of the particular procedures and equipment that will be used to perform the tasks before issuing EASA Form 1.

— Previous experience of the organisation / confidence in the organisation's inspection system / quality system / management system.

— The appropriateness of the inspection and test instruments and/or equipment, especially if used to evaluate qualitative aspects of a product, part or appliance.

(2) Equipment and set-up considerations

— The suitability of video resolution, fidelity, and field of view for the task being performed.

— The need for multiple cameras, imaging systems or microphones, and whether the person that performs or witnesses the tasks can switch between them, or direct them to be switched, and has the possibility to stop the process, ask a question, move the equipment, etc.

— The controllability of viewing direction, zoom, and lighting.

— The appropriateness of audio fidelity for the evaluation being conducted.

— Whether real-time, uninterrupted communication between the person(s) authorised to remotely witness the activity (authorised staff) and the personnel performing it exists at the location where the item is located.

— The need for unique testing devices or equipment (for example, fast-frame cameras, special lighting conditions, sensitive listening devices, mobile phones with cameras for HD video calls).

— Whether personnel have been adequately trained in the proper set-up, validation and use of the technology, tools and/or equipment to be used.

— The need for the recording of audio and video data, as well for its retention or for the retention of other information.

(3) Cybersecurity considerations

There are cases where the facilities where the tasks have to be performed are subject to strict security limitations. When using remote ICT for the tasks needed before issuing an EASA Form 1, it is the responsibility of the organisation to provide an equivalent level of security, therefore the person that is responsible for IT security within the organisation should concur to the ICT technology before proceeding.

(4) Documenting the use of the remote ICT

The documented processes (procedures) developed by the holder of a letter of agreement (LoA) or a POA should be accepted by the competent authority, and should describe the following:

— the risk assessment process required to determine the appropriateness of the remote ICT taking into account the above-mentioned considerations;

— the tasks to be performed, including preparation activities, inspections, tests, verifications to be done, personnel involved in the remote ICT activities and their level of competence;

— that it is necessary to guarantee that authorised staff have access to all necessary data (e.g. drawings, schematics, datasheets, etc.) they require in order to determine that the item conforms to the applicable design data, and how this can be ensured;

— how remote ICT will be used in real time (not pre-recorded) so that authorised staff may direct the performance of the tasks as if it were conducted in-person, on-site, with the aid of the equipment or the personnel supporting the activity at the remote location;

— the procedures for conducting a reinspection in case the equipment malfunctions or the process fails to yield acceptable results; a reinspection using remote ICT may be accomplished after correcting the malfunction or process, or by an actual on-site inspection;

— how authorised staff should record and communicate any difficulties or concerns regarding the process so that the organisation can improve its programme;

— how the use of the remote ICT will be documented in the required records; and

— how the organisation's IT security is ensured throughout the remote ICT process (data protection and intellectual property of the organisation also need to be safeguarded).

AMC No 1 to 21.A.130(b) Statement of conformity for complete aircraft

ED Decision 2019/018/R

1. PURPOSE AND SCOPE

The description under this AMC refers only to the use of the aircraft Statement of Conformity issued under Part 21 Section A Subpart F. Statement of Conformity under Part 21 Subpart F for products other than complete aircraft, and for parts and appliances is described in AMC No 2 to 21.A.130(b).

Use of the aircraft Statement of Conformity issued by an approved production organisation is described in 21.A.163(b) under Part 21 Section A Subpart G and the completion instructions are to be found in the Appendices to Part 21.

The purpose of the aircraft Statement of Conformity (EASA Form 52) issued under Part 21 Section A Subpart F is to present to the competent authority a complete aircraft. The competent authority only validates the Statement of Conformity if it finds, as described in 21.A.130 and its associated GM, that the aircraft conforms with the type design and is in condition for safe operation.

2. GENERAL

The Statement of Conformity must comply with the format attached including block numbers and the location of each Block. The size of each Block may however be varied to suit the individual application, but not to the extent that would make the Statement of Conformity unrecognisable. If in doubt consult the competent authority.

The Statement of Conformity must either be pre-printed or computer generated but in either case the printing of lines and characters must be clear and legible. Pre-printed wording is permitted in accordance with the attached model but no other certification statements are permitted.

Statements of Conformity must be issued in one or more of the official language(s) of the issuing competent authority with translations in English shown below, if required. Completion may be either machine/computer printed or hand-written using block letters to permit easy reading.

A copy of the Statement of Conformity and all referenced attachments are to be retained by the manufacturer. A copy of the validated Statement of Conformity is to be retained by the competent authority.

3. COMPLETION OF THE AIRCRAFT STATEMENT OF CONFORMITY BY THE ORIGINATOR

There must be an entry in all Blocks to make the document a valid Statement.

A Statement of Conformity must not be issued for validation by the competent authority, unless the design of the aircraft and its installed products are approved.

The information required in Blocks 9, 10, 11, 12, 13 and 14 may be by reference to separate identified documents held on file by the manufacturer, unless the competent authority agrees otherwise.

This Statement of Conformity is not intended to provide for the complete equipment fit required by the applicable operational rules. However, some of these individual items may be included in Block 10 or in the approved type design. Operators are therefore reminded of their responsibility to ensure compliance with the applicable operational rules for their own particular operation.

Block 1 Enter name of the State of manufacture.

Block 2 The competent authority under which authority the Statement of Conformity is issued.

Block 3 A unique serial number should be pre-printed in this Block for Statement control and traceability purposes. Except that in the case of a computer generated document the number need not be pre-printed where the computer is programmed to produce and print a unique number.

Block 4 The full name and location address of the manufacturer issuing the statement. This Block may be pre-printed. Logos, etc., are permitted if the logo can be contained within the Block.

Block 5 The aircraft type in full as defined in the type-certificate and its associated data sheet.

Block 6 The type-certificate reference numbers and issue for the subject aircraft.

Block 7 If the aircraft is registered then this mark will be the registration mark. If the aircraft is not registered then this will be such a mark that is accepted by the competent authority of the Member State and, if applicable, by the competent authority of a third country.

Block 8 The identification number assigned by the manufacturer for control and traceability and product support. This is sometimes referred to as a Manufacturers Serial No or Constructors No.

Block 9 The engine and propeller type(s) in full as defined in the relevant type-certificate and its associated data sheet. Their manufacturer identification No and associated location should also be shown.

Block 10 Approved design changes to the Aircraft Definition.

Block 11 A listing of all applicable airworthiness directives (or equivalent) and a declaration of compliance, together with a description of the method of compliance on the subject individual aircraft including products and installed parts, appliances and equipment. Any future compliance requirement time should be shown.

Block 12 Approved unintentional deviation to the approved type design sometimes referred to as concessions, divergences, or non-conformances.

Block 13 Only agreed exemptions, waivers or derogations may be included here..

Block 14 Remarks: Any statement, information, particular data or limitation which may affect the airworthiness of the aircraft. If there is no such information or data, state: 'NONE'. If the competent authority has endorsed a CO_2 emissions production cut-off exemption, make the following record: 'Aeroplane exempted from the applicability of paragraph 2.1.1 [x] as referenced in the 1st Edition of Annex 16, Volume III, Part II, Chapter 2 (July 2017).'

Block 15 Enter 'Certificate of Airworthiness' or 'Restricted Certificate of Airworthiness' for the Certificate of Airworthiness requested.

Block 16 Additional requirements such as those notified by an importing country should be noted in this Block.

Block 17 Validity of the Statement of Conformity is dependent on full completion of all Blocks on the form. A copy of the flight test report together with any recorded defects and rectification details should be kept on file by the manufacturer. The report should be signed as satisfactory by the appropriate certifying staff and a flight crew member, e.g., test pilot or flight test engineer. The flight tests performed are those required by 21.A.127 and GM 21.A.127, to ensure that the aircraft conforms to the applicable design data and is in condition for safe operation.

The listing of items provided (or made available) to satisfy the safe operation aspects of this statement should be kept on file by the manufacturer.

Block 18 The Statement of Conformity may be signed by the person authorised to do so by the manufacturer in accordance with 21.A.130(a). A rubber stamp signature should not be used.

Block 19 The name of the person signing the certificate should be typed or printed in a legible form.

Block 20 The date the Statement of Conformity is signed must be given.

Block 21 For production under Part 21 Subpart F, state 'NOT APPLICABLE'

Additionally, for production under Part 21 Section A Subpart F, this Block must include validation by the competent authority. For this purpose, the validation statement below should be included in the Block 21 itself, and not referred in a separate document. The statement can be pre-printed, computer generated or stamped, and should be followed by the signature of the representative of the competent authority validating the certificate, the name and the position/identification of such representative of the competent authority, and the date of such validation by the competent authority.

VALIDATION STATEMENT:

'After due inspection the *<identify the issuing competent authority>* is satisfied that this document constitutes an accurate and valid Statement of Conformity in accordance with Part 21 Section A Subpart F.'

AMC2 21.A.130(b) Statement of Conformity for Products (other than complete aircraft), parts, appliances and materials — The Authorised Release Certificate (EASA Form 1)

ED Decision 2021/011/R

A. INTRODUCTION

This AMC relates specifically to the use of the EASA Form 1 for manufacturing purposes under Part 21 Subpart F. It can be used as a supplement to the completion instructions in Part 21, Appendix I which covers the use of the EASA Form 1.

1. PURPOSE AND USE

The EASA Form 1 is prepared and signed by the manufacturer. For production under Part 21 Subpart F it is presented for validation by the competent authority.

Under Subpart F the certificate may only be issued by the competent authority.

A mixture of items released under Subpart G and under Subpart F of Part 21 is not permitted on the same certificate.

2. GENERAL FORMAT

Refer to Part 21 Appendix I.

3. COPIES

Refer to Part 21 Appendix I.

The Part 21 Subpart F originator must retain a copy of the certificate in a form that allows verification of original data.

4. ERROR(S) ON THE CERTIFICATE

If an end user finds an error(s) on a certificate, they must identify it/them in writing to the originator. The originator may prepare and sign a new certificate for validation by the competent authority if they can verify and correct the error(s).

The new certificate must have a new tracking number, signature and date.

The request for a new certificate may be honoured without re-verification of the item(s) condition. The new certificate is not a statement of current condition and should refer to the previous certificate in block 12 by the following statement: 'This certificate corrects the error(s) in block(s) [enter block(s) corrected] of the certificate [enter original tracking number] dated [enter original issuance date] and does not cover conformity/condition/release to service.' Both certificates should be retained according to the retention period associated with the first.

5. COMPLETION OF THE CERTIFICATE BY THE ORIGINATOR

Refer to Part 21 Appendix I for completion of the certificate. Specific Part 21 Subpart F instructions that differ from the Part 21 Appendix I are provided below.

Block 1 – Approving competent authority/Country

State the name and country of the competent authority under whose jurisdiction this certificate is issued. When the competent authority is the Agency, 'EASA' must be stated.

Block 12 – Remarks

Examples of conditions which would necessitate statements in Block 12 are:

a) When the certificate is used for prototype purposes, the following statement must be entered at the beginning of Block 12:

'NOT ELIGIBLE FOR INSTALLATION ON IN-SERVICE TYPE-CERTIFICATED AIRCRAFT'.

b) Re-certification of items from 'prototype' (conformity only to non-approved data) to 'new' (conformity to approved data and in a condition for safe operation) once the applicable design data is approved.

The following statement must be entered in Block 12:

RE-CERTIFICATION OF ITEMS FROM 'PROTOTYPE' TO 'NEW':

THIS DOCUMENT CERTIFIES THE APPROVAL OF THE DESIGN DATA [insert TC/STC number, revision level], DATED [insert date if necessary for identification of revision status], TO WHICH THIS ITEM (THESE ITEMS) WAS (WERE) MANUFACTURED.

c) When a new certificate is issued to correct error(s), the following statement must be entered in Block 12:

'THIS CERTIFICATE CORRECTS THE ERROR(S) IN BLOCK(S) [enter block(s) corrected] OF THE CERTIFICATE [enter original tracking number] DATED [enter original issuance date] AND DOES NOT COVER CONFORMITY/CONDITION/RELEASE TO SERVICE'.

d) In case of an engine, when the competent authority has granted an exemption from the environmental protection requirements, the following statement must be entered in block 12:

'ENGINE EXEMPTED FROM [*REFERENCE TO THE TYPE OF EMISSION*] EMISSIONS ENVIRONMENTAL PROTECTION REQUIREMENT'

Additionally, for production under Subpart F, this block must include the Statement of Conformity by the manufacturer under 21.A.130. For this purpose, the appropriate Block 13a statement must be included in the block 12 and not referenced in a separate document. The statement may be pre-printed, computer generated or stamped, and must be followed by the signature of the manufacturer's authorised person under 21.A.130(a), the name and the position/identification of such person and the date of the signature.

Block 13b – Authorised Signature

This space shall be completed with the signature of the competent authority representative validating the Block 12 manufacturer Statement of Conformity, under 21.A.130(d). To aid recognition, a unique number identifying the representative may be added.

Block 13c – Approval/Authorisation Number

Enter the authorisation number reference. This number or reference is given by the competent authority to the manufacturer working under Part 21 Subpart F.

AMC1 21.A.130(b)(4)(i) Applicable engine exhaust emissions requirements

ED Decision 2021/011/R

This determination is made according to the data provided by the engine type-certificate holder. It should be noted that the competent authority has the possibility to grant exemptions from these requirements as noted in Chapter 2, paragraph 2.1.1 and Chapter 4, paragraph 4.1.1 of Part III of Volume II of Annex 16 to the Chicago Convention.

When such an exemption is granted, the competent authority:

— takes into account the number of exempted engines that will be produced and their impact on the environment;

— considers imposing a time limit on the production of such engines; and

— issues an exemption document.

The Agency establishes and maintains a register, containing at least the engine serial number, and makes it publicly available.

ICAO Doc 9501 'Environmental Technical Manual' Volume II provides guidance on the issuing of exemptions.

GM1 21.A.130(b)(4)(i) Definitions of engine type certification date and production date

ED Decision 2021/011/R

Volume II of Annex 16 to the Chicago Convention contains three different references to applicability dates:

1. the 'date of manufacture for the first individual production model', which refers to the date when the type certificate is issued for the engine type or model;
2. the 'date of application for a type certificate', which refers to the application date to the certificating authority of the State of Design of the engine type certification; and
3. the 'date of manufacture for the individual engine', which refers to the production date of a specific engine serial number (date of EASA Form 1).

The third reference refers to the date of the first engine EASA Form 1 issued after the completion of the engine production pass-off test.

The third reference is used in the application of the engine emissions production cut-off requirement, which specifies a date after which all in-production engine models must meet a certain emissions standard.

21.A.130(b)(4)(i) includes the production requirements for engine exhaust emissions.

ICAO Doc 9501 'Environmental Technical Manual' Volume II provides guidance on these applicability dates.

AMC1 21.A.130(b)(4)(ii) Applicable aeroplane CO2 emissions requirements

ED Decision 2021/011/R

This determination is made according to the data provided by the aeroplane type-certificate holder. This data should allow the determination of whether the aeroplane complies with the CO_2 emissions applicability requirements in Chapter 2, paragraph 2.1.1 of Part II of Volume III of Annex 16 to the Chicago Convention.

It should be noted that the competent authority has the possibility to grant exemptions as noted in Chapter 1, paragraph 1.11 and Chapter 2, paragraph 2.1.3 of Part II of Volume III of Annex 16 to the Chicago Convention,.

When such an exemption is granted, the competent authority:

— takes into account the number of exempted aeroplanes that will be produced and their impact on the environment; and

— issues an exemption document.

The Agency establishes and maintains a register, containing at least the aeroplane serial number, and makes it publicly available.

ICAO Doc 9501 'Environmental Technical Manual' Volume III provides guidance on the issuing of exemptions.

AMC 21.A.130(c) Validation of the Statement of Conformity

ED Decision 2012/020/R

It is the responsibility of the applicant to ensure that each and every product, part and appliance conforms to the applicable design data and is in condition for safe operation before issuing and signing the relevant statement of conformity. During manufacture, the applicant is expected to use such facilities, systems, processes and procedures as are described in the Manual and have been previously agreed with the competent authority.

The competent authority must then make such inspection and investigation of records and product, part or appliance as are necessary to determine that the agreed facilities, systems, processes and procedures have been used, and that the statement of conformity may be regarded as a valid document.

To enable timely inspection and investigation by the competent authority, the statement of conformity must be prepared and submitted to the competent authority immediately upon satisfactory completion of final production inspection and test.

AMC 21.A.130(c)(1) Initial transfer of ownership

ED Decision 2012/020/R

Upon transfer of ownership:

a) For a complete aircraft, whether or not an application for a certificate of airworthiness is to be made, an EASA Form 52 must be completed and submitted to the competent authority for validation.

b) For anything other than a complete aircraft an EASA Form 52 is inappropriate, and an EASA Form 1 must be completed and submitted to the competent authority for validation.

NOTE: If there is any significant delay between the last production task and presentation of the EASA Form 52 or EASA Form 1 to the competent authority, then additional evidence relating to the storage, preservation and maintenance of the item since its production must be presented to the competent authority.

SUBPART G — PRODUCTION ORGANISATION APPROVAL

21.A.131 Scope

Regulation (EU) No 748/2012

This Subpart establishes:

(a) the procedure for the issuance of a production organisation approval for a production organisation showing conformity of products, parts and appliances with the applicable design data;

(b) the rules governing the rights and obligations of the applicant for, and holders of, such approvals.

AMC-ELA No 1 to 21.A.131 Scope

ED Decision 2019/003/R

The AMC-ELA in this Subpart provide acceptable means of compliance for the issuance of a production organisation approval for organisations that produce

— aeroplanes that are within the scope of CS-LSA, CS-VLA and CS-23 level 1;

— sailplanes or powered sailplanes that are within the scope of CS-22; or

— balloons, hot-air airships and gas airships that are ELA2 aircraft,

that are not classified as complex motor-powered aircraft, as well as products or parts used on these products.

GM-ELA No 1 to 21.A.131 Scope – General applicability of AMC-ELA and the use of AMC-ELA as a baseline outside its scope

ED Decision 2019/003/R

The AMC indicated with 'AMC-ELA' and the GM related to them (as indicated with 'GM-ELA'), provide an alternative set of AMC and GM to the other available AMC and GM.

The AMC-ELA provide acceptable means to meet the requirements for small, non-complex organisations that produce aircraft as specified in AMC-ELA No 1 to 21.A.131.

If the AMC-ELA are not applicable (for instance for small, non-complex organisations that produce other low-risk products that are outside the scope of AMC-ELA No 1 to 21.A.131, e.g. light rotorcraft, CS-23 Level 2, etc.), the applicant is not obliged to use any other available AMC. Switching to those other available AMC will not necessarily provide a means of compliance that is proportionate. Since AMC are a means, but not the only means, of showing compliance, applicants and approval holders can also propose alternative means of compliance. These alternative means can use the AMC-ELA as a baseline, and complement them by additional or more stringent controls, processes or methods. This allows a gradual increase in the level of detail of the established procedures and the thoroughness of the implemented tools for POA approval. This enables the introduction of a proportionate approach that is commensurate with the kind of product and its associated risk or its production process risks, as a function of the complexity of the organisations and the risk and performance of the product. Using the AMC-ELA as a baseline for POA outside the applicability of the AMC-ELA is therefore considered to be an appropriate starting point.

Complementary elements need to be detailed, documented and recorded to a level at which the occurrence of repetitive non-conformities is mitigated. Applicants and approval holders need to demonstrate to the competent authority in such cases that those additional means meet the requirements that are appropriate for the products being produced.

GM-ELA No 2 to 21.A.131 Scope – AMC-ELA as a complete, self-contained set of AMC

ED Decision 2019/003/R

The AMC-ELA provide an alternative, complete and self-contained set of AMC. Applicants or POA holders that manufacture products or parts within the scope of AMC-ELA can use AMC-ELA instead of the existing AMC to Subpart G.

The AMC-ELA in full determine the acceptable means of compliance with Subpart G. The applicant should implement each of the means defined here on an individual basis. If the specific characteristics of the organisation render individual elements of AMC-ELA impracticable or not applicable, alternative means with a specific resolution should be agreed with the competent authority. A justification needs to be developed to show that the means that are applied meet the requirements of Part-21. A trustful relationship between the typically very compact team of the applicant and the competent authority should be developed. The applicant is strongly encouraged to ask the relevant contact person at the competent authority for mutual clarification of any questionable item, if there is any doubt.

GM-ELA No 3 to 21.A.131 Scope – Applicable design data

ED Decision 2019/003/R

GM 21.A.131 applies.

GM-ELA No 4 to 21.A.131 Scope – Explanation of terms used in AMC-ELA

ED Decision 2019/003/R

'A method needs to be practised'.

When AMC-ELA applies the principle that 'a method needs to be practised', it means that the applicant can show what is actually done in order to comply with a requirement in a practical but systematic way. The applicant is not expected to have an excessively detailed documented procedure. As a baseline, documented procedures for such 'practised methods' can be limited to a declaration of the principles that are considered within the practised method. For example, a declaration such as 'Document control is ensured by the workflow management as part of the IT-based Document Management System (DMS)', may be provided. This is acceptable when evidence is provided by work results, by the demonstration of satisfactory conduct during surveillance activities, or by similar means. When the actions that are continuously performed show that they do not satisfy the needs of the AMC, a more detailed and documented procedure may need to be implemented to rectify the situation.

'Delegation of tasks and responsibilities'

AMC-ELA differentiates between the delegation of tasks and the delegation of responsibilities. For small and simple organisations, the delegation of responsibilities to specific and separate organisational positions can create overly burdensome administrative processes that do not reflect the operational reality. The AMC-ELA accepts that tasks can be delegated, while the responsibility formally remains with the delegator. This can increase efficiency, and it offers the possibility for the

applicant to simplify procedures. A typical example is when the accountable manager delegates tasks, while keeping the responsibility associated with these tasks. If this situation is identified with respect to the individual requirements, this may significantly reduce the effort required for documentation, and it allows streamlined methods to be practised.

'Consolidated team'

AMC-ELA makes reference to companies working in a 'consolidated team', mainly in relation to coordination between the design and production activities. Companies are considered to be working in consolidated teams if the following criteria apply:

— Even when a consolidated team spans across different legal entities, it acts as one organisation;

— A consolidated team is expected to work within one consolidated setup, and under one management, so that a free flow of information is inherently ensured;

— In a consolidated team, functions are not duplicated, so the same person(s) takes care of both the production and design aspects of any one function;

— Responsibilities are defined at the level of the person or the position, not at the level of the legal entity;

— Within consolidated teams, adequate coordination is expected to be present through 'practised methods', without any further written definitions of responsibilities beyond those elements that are explicitly described within AMC-ELA.

GM 21.A.131 Scope – Applicable design data

ED Decision 2019/018/R

Applicable design data is defined as all necessary drawings, specifications and other technical information provided by the applicant for, or holder of a design organisation approval, TC, STC, approval of repair or minor change design, or ETSO authorisation and released in a controlled manner to a production organisation approval holder. This should be sufficient for the development of production data to enable repeatable manufacture to take place in conformity with the design data.

Prior to issue of the TC, STC, approval of repair or minor change design or ETSO authorisation, or equivalent, design data is defined as 'not approved' but parts and appliances may be released with an EASA Form 1 as a certificate of conformity.

After issue of the TC, STC, approval of repair or minor change or ETSO authorisation, or equivalent, this design data is defined as 'approved' and items manufactured in conformity are eligible for release on an EASA Form 1 for airworthiness purposes.

For the purpose of Subpart G of Part 21, the term 'applicable design data' includes the information related to the applicable engine exhaust emissions and aeroplane CO_2 emissions production cut-off requirements.

21.A.133 Eligibility

Regulation (EU) No 748/2012

Any natural or legal person ('organisation') shall be eligible as an applicant for an approval under this Subpart. The applicant shall:

(a) justify that, for a defined scope of work, an approval under this Subpart is appropriate for the purpose of showing conformity with a specific design; and

(b) hold or have applied for an approval of that specific design; or

(c) have ensured, through an appropriate arrangement with the applicant for, or holder of, an approval of that specific design, satisfactory coordination between production and design.

GM 21.A.133(a) Eligibility – Approval appropriate for showing conformity

ED Decision 2012/020/R

'Appropriate' should be understood as follows:

— The applicant produces or intends to produce aeronautical products, parts and/or appliances intended for airborne use as part of a type-certificated product (this excludes simulators, ground equipment and tools).

— The applicant will be required to show a need for an approval, normally based on one or more of the following criteria:

1. Production of aircraft, engines or propellers (except if the competent authority considers a POA inappropriate)
2. Production of ETSO articles and parts marked EPA
3. Direct delivery to users such as owners or operators maintenance organisations with the need for exercising the privileges of issuing Authorised Release Certificates – EASA Form 1
4. Participation in an international co-operation program where working under an approval is considered necessary by the competent authority
5. Criticality and technology involved in the part or appliance being manufactured. Approval in this case may be found by the competent authority as the best tool to exercise its duty in relation to airworthiness control
6. Where an approval is otherwise determined by the competent authority as being required to satisfy the essential requirements of Annex I to the Regulation (EC) No 216/2008.

— It is not the intent of the competent authority to issue approvals to manufacturing firms that perform only sub-contract work for main manufacturers of products and are consequently placed under their direct surveillance.

— Where standard parts, materials, processes or services are included in the applicable design data (see guidance on applicable design data in GM 21.A.131) their standards should be controlled by the POA holder in a manner which is satisfactory for the final use of the item on the product, part or appliance. Accordingly, the manufacturer or provider of the following will not at present be considered for production organisation approval:

  — consumable materials
  — raw materials
  — standard parts
    — parts identified in the product support documentation as 'industry supply' or 'no hazard'
    — non-destructive testing or inspection
    — processes (heat treatment, surface finishing, shot peening, etc.)

AMC No 1 to 21.A.133(b) and (c) Eligibility – Link between design and production organisations

ED Decision 2012/020/R

An arrangement is considered appropriate if it is documented and satisfies the competent authority that co-ordination is satisfactory.

To achieve satisfactory coordination the documented arrangements must at least define the following aspects irrespective of whether the two organisations are separate legal entities or not:

— The responsibilities of a design organisation which assure correct and timely transfer of up-to-date airworthiness data (e.g., drawings, material specifications, dimensional data, processes, surface treatments, shipping conditions, quality requirements, etc.);

— The responsibilities and procedures of a POA holder/applicant for developing, where applicable, its own manufacturing data in compliance with the airworthiness data package;

— The responsibilities of a POA holder/applicant to assist the design organisation in dealing with continuing airworthiness matters and for required actions (e.g., traceability of parts in case of direct delivery to users, retrofitting of modifications, traceability of processes' outputs and approved deviations for individual parts as applicable, technical information and assistance, etc.);

— The scope of the arrangements must cover Part 21 Subpart G requirements and associated AMC and GM, in particular: 21.A.145(b), 21.A.165(c), (f) and (g);

— The responsibilities of a POA holder/applicant, in case of products prior to type certification to assist a design organisation in demonstrating compliance with CS (access and suitability of production and test facilities for manufacturing and testing of prototype models and test specimen);

— The procedures to deal adequately with production deviations and non-conforming parts;

— The procedures and associated responsibilities to achieve adequate configuration control of manufactured parts, to enable the production organisation to make the final determination and identification for conformity or airworthiness release and eligibility status;

— The identification of the responsible persons/offices who control the above;

— The acknowledgment by the holder of the TC/STC/repair or change approval/ETSO authorisation that the approved design data provided, controlled and modified in accordance with the arrangement are recognised as approved.

In many cases the production organisation may receive the approved design data through an intermediate production organisation. This is acceptable provided an effective link between the design approval holder and the production organisation can be maintained to satisfy the intent of 21.A.133.

When the design and production organisations are two separate legal entities a Direct Delivery Authorisation must be available for direct delivery to end users in order to guarantee continued airworthiness control of the released parts and appliances.

Where there is no general agreement for Direct Delivery Authorisation, specific permissions may be granted (refer to AMC 21.A.4).

AMC No 2 to 21.A.133(b) and (c) Eligibility – Link between design and production organisations

ED Decision 2012/020/R

In accordance with AMC No 1 to 21.A.133(b) and (c) the POA holder must demonstrate to the competent authority that it has entered into an arrangement with the design organisation. The arrangement must be documented irrespective of whether the two organisations are separate legal entities or not.

The documented arrangement must facilitate the POA holder to demonstrate compliance with the requirement of 21.A.133(b) and (c) by means of written documents agreed.

In the case where the design organisation and POA holder are part of the same legal entity these interfaces may be demonstrated by company procedures accepted by the competent authority.

In all other cases to define such a design/production interface the following sample format is offered:

Arrangement Sample Form

ARRANGEMENT in accordance with 21.A.133(b) and (c)	
The undersigned agree on the following commitments:	**Relevant interface procedures**
The design organisation *[NAME]* takes responsibility to — assure correct and timely transfer of up-to-date applicable design data (e.g., drawings, material specifications, dimensional data, processes, surface treatments, shipping conditions, quality requirements, etc.) to the production organisation approval holder [NAME] — provide visible statement(s) of approved design data.	
The production organisation approval holder *[NAME]* takes responsibility to — assist the design organisation [NAME] in dealing with continuing airworthiness matter and for required actions — assist the design organisation [NAME] in case of products prior to type certification in demonstrating compliance with certification specifications — develop, where applicable, its own manufacturing data in compliance with the airworthiness data package.	
The design organisation *[NAME]* and the POA holder *[NAME]* take joint responsibility to — deal adequately with production deviations and non-conforming parts in accordance with the applicable procedures of the design organisation and the production organisation approval holder — achieve adequate configuration control of manufactured parts, to enable the POA holder to make the final determination and identification for conformity.	
The scope of production covered by this arrangement is detailed in *[DOCUMENT REFERENCE/ATTACHED LIST]*	
[When the design organisation is not the same legal entity as the production organisation approval holder] **Transfer of approved design data:** The TC/STC/ETSO holder *[NAME]* acknowledges that the approved design data provided, controlled and modified in accordance with the arrangement are recognised as approved by the competent authority and therefore the parts and appliances manufactured in accordance with these data and found in a condition for safe operation may be released certifying that the item was manufactured in conformity to approved design data and is in a condition for safe operation..	
[When the design organisation is not the same legal entity as the production organisation approval holder] **Direct Delivery Authorisation:** This acknowledgment includes also [*OR* does not include] the general agreement for direct delivery to end users in order to guarantee continued airworthiness control of the released parts and appliances.	
For the *[NAME of the design organisation/DOA holder]* **Date:** **Signature:** xx.xx.xxxx [NAME in block letters]	For the *[NAME of the POA holder]* **Date:** **Signature:** xx.xx.xxxx [NAME in block letters]

Instructions for completion:

Title: The title of the relevant document must clearly indicate that it serves the purpose of a design/production interface arrangement in accordance with 21.A.133(b) and (c).

Commitment: The document must include the basic commitments between the design organisation and the POA holder as addressed in AMC 21.A.4 and AMC No 1 to 21.A.133(b) and (c).

Relevant Procedures: Identify an entry point into the documentary system of the organisations with respect to the implementation of the arrangement (for example a contract, quality plan, handbooks, common applicable procedures, working plans etc.).

Scope of arrangement: The scope of arrangement must state by means of a list or reference to relevant documents those products, parts or appliances that are covered by the arrangement.

Transfer of applicable design data: Identify the relevant procedures for the transfer of the applicable design data required by 21.A.131 and GM 21.A.131 from the design organisation to the POA holder. The means by which the design organisation advises the POA holder whether such data is approved or not approved must also be identified (ref. 21.A.4/AMC 21.A.4).

Direct Delivery Authorisation: Where the design organisation and the POA holder are separate legal entities the arrangement must clearly identify whether authorisation for direct delivery to end users is permitted or not.

Where any intermediate production/design organisations are involved in the chain between the original design organisation and the POA holder evidence must be available that this intermediate organisation has received authority from the design organisation to grant Direct Delivery Authorisation.

Signature: AMC No 1 to 21.A.133(b) and (c) requests the identification of the responsible persons/offices who control the commitments laid down in the arrangement. Therefore the basic document must be signed mutually by the authorised representatives of the design organisation and the POA holder in this regard.

AMC-ELA No 1 to 21.A.133(c) Eligibility – Link between design and production

ED Decision 2019/003/R

The link between design and production is appropriately arranged when the organisation responsible for production and the one responsible for design both work within one consolidated team. The following documented arrangement may be used between the production organisation and the applicant for, or the holder of, a type design, in order to record their respective responsibilities.

ARRANGEMENT in accordance with AMC-ELA No 1 to 21.A.133(c)
The undersigned agree on the following commitments:
The design organisation *[NAME]* takes responsibility for — assuring the correct and timely transfer of up-to-date applicable design data (e.g., drawings, material specifications, dimensional data, processes, surface treatments, shipping conditions, quality requirements, etc.) to the production organisation approval holder [NAME]; — providing visible statement(s) of approved design data.
The production organisation approval holder *[NAME]* takes responsibility for — assisting the design organisation *[NAME]* in dealing with continuing airworthiness matters and for required actions;

— assisting the design organisation *[NAME]*, with products prior to type certification, in demonstrating products' compliance with the certification specifications; — developing, where applicable, its own manufacturing data in compliance with the airworthiness data package.
The design organisation *[NAME]* and the POA holder *[NAME]* take joint responsibility for — dealing adequately with production deviations and non-conforming parts in accordance with the applicable procedures of the design organisation and the production organisation approval holder; — achieving adequate configuration control of manufactured parts to enable the POA holder to make the final determination and identification for conformity.
The scope of production that is covered by this arrangement is detailed in the POE
[If the design organisation is not the same legal entity as the production organisation approval holder] **Transfer of approved design data:** The TC/STC/ETSO holder *[NAME]* acknowledges that the approved design data provided, controlled and modified in accordance with this arrangement are recognised as having been approved by the competent authority, and that therefore, the parts and appliances manufactured in accordance with these data and found to be in a condition for safe operation may be released, certifying that the item was manufactured in conformity to approved design data and is in a condition for safe operation.
[If the design organisation is not the same legal entity as the production organisation approval holder] **Direct Delivery Authorisation:** This acknowledgment also includes [*OR* does not include] the general agreement for direct delivery to end users in order to guarantee continued airworthiness control of the released parts and appliances.

For the *[NAME of the design organisation/DOA holder]* **Date: Signature:** xx.xx.xxxx *[NAME in block letters]*	For the *[NAME of the POA holder]* **Date: Signature:** xx.xx.xxxx *[NAME in block letters]*

AMC-ELA No 2 to 21.A.133(c) Eligibility – Link between design and production

ED Decision 2019/003/R

If the approval is held or is applied for by a different entity, and the work is not performed by one consolidated team, an arrangement in accordance with AMC-ELA No 1 to 21.A.133(c) is not sufficient. The roles and responsibilities for the coordination between the design and production staff (in both directions) need to be established. This may be achieved, for example, by simple flow chart definitions supported by strong, self-explanatory forms, or by task descriptions of responsible functions in the organisation, or by equivalent means. IT-based enterprise resource planning (ERP) systems can be used to ensure and to demonstrate that there is a correct flow of information on the basis of defined and visible workflows with assigned roles and release gates, without any further need for written definitions. Further means with a comparable effect are possible. Internal and external audits can verify that the coordination functions properly.

21.A.134 Application

Regulation (EU) No 748/2012

Each application for a production organisation approval shall be made to the competent authority in a form and manner established by that authority, and shall include an outline of the information required by point 21.A.143 and the terms of approval requested to be issued under point 21.A.151.

GM 21.A.134 Application – Application form and manner

ED Decision 2012/020/R

EASA Form 50 (see AMC 21.B.220(c)) should be obtained from the competent authority, and completed by the accountable manager of the organisation.

The completed form, an outline of the production organisation exposition, and details of the proposed terms of approval are to be forwarded to the competent authority.

GM-ELA No 1 to 21.A.134 Scope – Application

ED Decision 2019/003/R

GM 21.A.134 applies.

21.A.134A Means of compliance

Regulation (EU) 2022/201

(a) An organisation may use any alternative means of compliance to establish compliance with this Regulation.

(b) If an organisation wishes to use an alternative means of compliance, it shall, prior to using it, provide the competent authority with a full description. The description shall include any revisions to manuals or procedures that may be relevant, as well as an explanation indicating how compliance with this Regulation is achieved.

The organisation may use those alternative means of compliance subject to prior approval from the competent authority.

[applicable from 7 March 2023 - Regulation (EU) 2022/201]

21.A.135 Issue of production organisation approval [applicable until 6 March 2023] / 21.A.135 Issuance of production organisation approval [applicable from 7 March 2023 - Regulation (EU) 2022/201]

Regulation (EU) No 748/2012

An organisation shall be entitled to have a production organisation approval issued by the competent authority when it has demonstrated compliance with the applicable requirements under this Subpart.

21.A.139 Quality System [applicable until 6 March 2023] / 21.A.139 Production management system [applicable from 7 March 2023 - Regulation (EU) 2022/201]

Regulation (EU) No 748/2012

(a) The production organisation shall demonstrate that it has established and is able to maintain a quality system. The quality system shall be documented. This quality system shall be such as to enable the organisation to ensure that each product, part or appliance produced by the organisation or by its partners, or supplied from or subcontracted to outside parties, conforms to the applicable design data and is in condition for safe operation, and thus exercise the privileges set forth in point 21.A.163.

(b) The quality system shall contain:

1. as applicable within the scope of approval, control procedures for:

(i) document issue, approval, or change;

(ii) vendor and subcontractor assessment audit and control;

(iii) verification that incoming products, parts, materials, and equipment, including items supplied new or used by buyers of products, are as specified in the applicable design data;

(iv) identification and traceability;

(v) manufacturing processes;

(vi) inspection and testing, including production flight tests;

(vii) calibration of tools, jigs, and test equipment;

(viii) non conforming item control;

(ix) airworthiness coordination with the applicant for, or holder of, the design approval;

(x) records completion and retention;

(xi) personnel competence and qualification;

(xii) issue of airworthiness release documents;

(xiii) handling, storage and packing;

(xiv) internal quality audits and resulting corrective actions;

(xv) work within the terms of approval performed at any location other than the approved facilities;

(xvi) work carried out after completion of production but prior to delivery, to maintain the aircraft in a condition for safe operation;

(xvii) issue of permit to fly and approval of associated flight conditions.

The control procedures need to include specific provisions for any critical parts.

2. An independent quality assurance function to monitor compliance with, and adequacy of, the documented procedures of the quality system. This monitoring shall include a feedback system to the person or group of persons referred to in point 21.A.145(c)(2) and ultimately to the manager referred to in point 21.A.145(c)(1) to ensure, as necessary, corrective action.

[applicable until 6 March 2023]

(a) The production organisation shall establish, implement and maintain a production management system that includes a safety management element and a quality management element, with clearly defined accountability and lines of responsibility throughout the organisation.

(b) The production management system shall:

1. correspond to the size of the organisation, and to the nature and complexity of its activities, taking into account the hazards and associated risks inherent in those activities;

2. be established, implemented and maintained under the direct accountability of a single manager appointed pursuant to point 21.A.145(c)(1).

(c) As part of the safety management element of the production management system, the production organisation shall:

1. establish, implement and maintain a safety policy and the corresponding related safety objectives;

2. appoint key safety personnel in accordance with point 21.A.145(c)(2);

3. establish, implement and maintain a safety risk management process to identify safety hazards entailed by its aviation activities, evaluate them and manage associated risks, including taking actions to mitigate the risks and verify their effectiveness;

4. establish, implement and maintain a safety assurance process that includes:

(i) the measurement and monitoring of the organisation's safety performance;

(ii) the management of changes in accordance with point 21.A.147;

(iii) the principles for the continuous improvement of the safety management element;

5. promote safety in the organisation through:

(i) training and education;

(ii) communication;

6. establish an occurrence reporting system in accordance with point 21.A.3A in order to contribute to the continuous improvement of safety.

(d) As part of the quality management element of the production management system, the production organisation shall:

1. ensure that each product, part or appliance produced by the organisation or by its partners, or supplied from or subcontracted to outside parties, conforms to the applicable design data and is in condition for safe operation, thus enabling the exercise of the privileges set out in point 21.A.163;

2. establish, implement and maintain, as appropriate, within the scope of the approval, control procedures for:

(i) document issue, approval or change;

(ii) vendor and subcontractor assessment audit and control;

(iii) verifying that incoming products, parts, materials and equipment, including items supplied new or used by buyers of products, are as specified in the applicable design data;

(iv) identification and traceability;

(v) manufacturing processes;

(vi) inspection and testing, including production flight tests;

(vii) the calibration of tools, jigs, and test equipment;

(viii) non-conforming item control;

(ix) airworthiness coordination with the applicant for, or holder of, the design approval;

(x) the completion and retention of records;

(xi) the competence and qualifications of personnel;

(xii) the issue of airworthiness release documents;

(xiii) handling, storage and packing;

(xiv) internal quality audits and the resulting corrective actions;

(xv) work within the terms of approval performed at any location other than the approved facilities;

(xvi) work performed after the completion of production but prior to delivery, to maintain the aircraft in a condition for safe operation;

(xvii) the issue of a permit to fly and approval of the associated flight conditions;

3. include specific provisions in the control procedures for any critical parts.

(e) The production organisation shall establish, as part of the production management system, an independent monitoring function to verify compliance of the organisation with the relevant requirements of this Annex as well as compliance with and adequacy of the production management system. Monitoring shall include feedback to the person or group of persons referred to in point 21.A.145(c)(2) and to the manager referred to in point 21.A.145(c)(1) to ensure, where necessary, the implementation of corrective action.

(f) If the production organisation holds one or more additional organisation certificates within the scope of Regulation (EU) 2018/1139, the production management system may be integrated with that required under the additional certificate(s) held.

[applicable from 7 March 2023 - Regulation (EU) 2022/201]

GM1 21.A.139, 21.A.157, 21.A.239, 21.A.257, 21.B.120, 21.B.140, 21.B.220, 21.B.235 and 21.B.240 The use of information and communication technologies (ICT) for performing remote audits

ED Decision 2021/007/R

This GM provides technical guidance on the use of remote information and communication technologies (ICT) to support:

— competent authorities when overseeing regulated organisations;

— regulated organisations when conducting internal audits / monitoring compliance of their organisation with the relevant requirements, and when evaluating vendors, suppliers and subcontractors.

In the context of this GM:

— ‘remote audit’ means an audit that is performed with the use of any real-time video and audio communication tools in lieu of the physical presence of the auditor on-site; the specificities of each type of approval / letter of agreement (LoA) need to be considered in addition to the general overview (described below) when applying the ‘remote audit’ concept;

— ‘auditing entity’ means the competent authority or organisation that performs the remote audit;

— ‘auditee’ means the entity being audited/inspected (or the entity audited/inspected by the auditing entity via a remote audit);

It is the responsibility of the auditing entity to assess whether the use of remote ICT constitutes a suitable alternative to the physical presence of an auditor on-site in accordance with the applicable requirements.

The conduct of a remote audit

The auditing entity that decides to conduct a remote audit should describe the remote audit process in its documented procedures and should consider at least the following elements:

— The methodology for the use of remote ICT is sufficiently flexible and non-prescriptive in nature to optimise the conventional audit process.

— Adequate controls are defined and are in place to avoid abuses that could compromise the integrity of the audit process.

— Measures to ensure that the security and confidentiality are maintained throughout the audit activities (data protection and intellectual property of the organisation also need to be safeguarded).

Examples of the use of remote ICT during audits may include but are not limited to:

— meetings by means of teleconference facilities, including audio, video and data sharing;

— assessment of documents and records by means of remote access, in real time;

— recording, in real time during the process, of evidence to document the results of the audit, including non-conformities, by means of exchange of emails or documents, instant pictures, video or/and audio recordings;

— visual (livestream video) and audio access to facilities, stores, equipment, tools, processes, operations, etc.

An agreement between the auditing entity and the auditee should be established when planning a remote audit, which should include the following:

— determining the platform for hosting the audit;

— granting security and/or profile access to the auditor(s);

— testing platform compatibility between the auditing entity and the auditee prior to the audit;

— considering the use of webcams, cameras, drones, etc., when the physical evaluation of an event (product, part, process, etc.) is desired or is necessary;

— establishing an audit plan which will identify how remote ICT will be used and the extent of their use for the audit purposes to optimise their effectiveness and efficiency while maintaining the integrity of the audit process;

— if necessary, time zone acknowledgement and management to coordinate reasonable and mutually agreeable convening times;

— a documented statement of the auditee that they shall ensure full cooperation and provision of the actual and valid data as requested, including ensuring any supplier or subcontractor cooperation, if needed; and

— data protection aspects.

The following equipment and set-up elements should be considered:

— the suitability of video resolution, fidelity, and field of view for the verification being conducted;

— the need for multiple cameras, imaging systems, or microphones, and whether the person that performs the verification can switch between them, or direct them to be switched and has the possibility to stop the process, ask a question, move the equipment, etc.;

— the controllability of viewing direction, zoom, and lighting;

— the appropriateness of audio fidelity for the evaluation being conducted; and

— real-time and uninterrupted communication between the person(s) participating to the remote audit from both locations (on-site and remotely).

When using remote ICT, the auditing entity and the other persons involved (e.g. drone pilots, technical experts) should have the competence and ability to understand and utilise the remote ICT tools employed to achieve the desired results of the audit(s)/assessment(s). The auditing entity should also be aware of the risks and opportunities of the remote ICT used and the impacts they may have on the validity and objectivity of the information gathered.

Audit reports and related records should indicate the extent to which remote ICT have been used in conducting remote audits and the effectiveness of remote ICT in achieving the audit objectives, including any item that it has not been able to be completely reviewed.

GM-ELA No 1 to 21.A.139(a) Quality system

ED Decision 2019/003/R

The focus of the quality system is on the key workflows that are indispensable to ensure conformity to the relevant parameters of the applicable design data. The quality system should include elements to determine that there is conformity to the relevant parameters of the applicable design data and, if applicable, the production process definitions. The quality system should mitigate any repetitive non-conformities found in products or spare parts.

The production organisation should demonstrate that it has established, and will maintain, a quality system via integration or by making use of one of the following, as applicable:

— a valid ISO 9001 certificate;

— a valid EN 9100 certificate;

— compliance with ASTM F2972 for organisations that have only the production of CS-LSA aircraft in their scope of approval; or

— an individual quality system that meets all the definitions of the full set of AMC-ELA.

It should be ensured that the existing quality system covers all the aspects defined in 21.A.139(a). The quality system should be documented in such a way that the documentation can be made easily available to any personnel who need to use the material to perform their duties.

GM-ELA No 2 to 21.A.139(a) Quality system

ED Decision 2019/003/R

The documentation of the quality system can be done by any method that ensures that members of the organisation can obtain the actual and relevant information in a reasonable way. This explicitly includes the provision of such information by electronic means, for example, on the intranet of the organisation, by the use of an electronic database such as DMS, on paper, by illustration, by using workflow definitions within IT based ERP systems, by other means, or by a combination of several such means.

The person responsible for the definition, implementation and maintenance of the quality system should be identified. This person should coordinate the maintenance of the system. For small-sized companies with low (product) complexity, typically the accountable manager bears this responsibility, even if that manager delegates tasks to a quality manager.

GM No 1 to 21.A.139(a) Quality System

ED Decision 2012/020/R

The quality system is an organisational structure with responsibilities, procedures, processes, and resources which implement a management function to determine and enforce quality principles.

The quality system should be documented in such a way that the documentation can be made easily available to personnel who need to use the material for performing their normal duties, in particular:

— procedures, instructions, data to cover the issues of 21.A.139(b)(1) are available in a written form,

— distribution of relevant procedures to offices/persons is made in a controlled manner,

— procedures which identify persons responsible for the prescribed actions are established,

— the updating process is clearly described.

The manager responsible for ensuring that the quality system is implemented and maintained should be identified.

The competent authority will verify on the basis of the exposition and by appropriate investigations that the production organisation has established and can maintain their documented quality system.

GM No 2 to 21.A.139(a) Quality System – Conformity of supplied parts or appliances

ED Decision 2012/020/R

The POA holder is responsible for determining and applying acceptance standards for physical condition, configuration status and conformity of supplied products, parts or appliances, whether to be used in production or delivered to customers as spare parts. This responsibility also includes BFE (Buyer Furnished Equipment) items.

To discharge this responsibility the quality system needs an organisational structure and procedures to adequately control suppliers. Elements of the quality system for the control of suppliers may be performed by other parties provided that the conditions of AMC No 1 or No 2 to 21.A.139(b)(1)(ii) are met.

Control can be based upon use of the following techniques (as appropriate to the system or product orientation necessary to ensure conformity):

— qualification and auditing of supplier's quality system,

— evaluation of supplier capability in performing all manufacturing activities, inspections and tests necessary to establish conformity of parts or appliances to type design,

— first article inspection, including destruction if necessary, to verify that the article conforms to the applicable data for new production line or new supplier,

— incoming inspections and tests of supplied parts or appliances that can be satisfactorily inspected on receipt,

— identification of incoming documentation and data relevant to the showing of conformity to be included in the certification documents,

— a vendor rating system which gives confidence in the performance and reliability of this supplier,

— any additional work, tests or inspection which may be needed for parts or appliances which are to be delivered as spare parts and which are not subjected to the checks normally provided by subsequent production or inspection stages.

The POA holder may rely on inspection/tests performed by supplier if it can establish that:

— personnel responsible in charge of these tasks satisfy the competency standards of the POA quality system,

— quality measurements are clearly identified,

— the records or reports showing evidence of conformity are available for review and audit.

The control of suppliers holding a POA for the parts or appliances to be supplied can be reduced, to a level at which a satisfactory interface between the two quality systems can be demonstrated. Thus, for the purpose of showing conformity, a POA holder can rely upon documentation for parts or appliances released under a suppliers 21.A.163 privileges.

A supplier who does not hold a POA is considered as a sub-contractor under the direct control of the POA quality system.

The POA holder retains direct responsibility for inspections/tests carried out either at its own facilities or at supplier's facilities.

AMC-ELA No 1 to 21.A.139(b)(1) Quality system – Control procedures

ED Decision 2019/003/R

Note: This AMC-ELA is numbered in accordance with the numbering of the subparagraphs of point 21.A.139(b)(1).

These minimum means are considered to be acceptable unless repeated non-conformities show otherwise. The quality system should contain, as applicable, the following structured information that may be provided and embedded in various documents and systems.

(i) Information is provided that shows how control procedures for the issuing, approval, or change of documents are organised and practised. This information also specifies to which documents it is applicable. A practised method describes how the use of invalid or superseded information in production is prevented.

(ii) A practised method describes how and when the assessment and surveillance of any vendors and subcontractors are carried out. This information explains how this is controlled. The assessment and surveillance of vendors and subcontractors are only required in cases where the methods identified in (iii) below or in other production control mechanisms are not able to detect non-conformities with the applicable design data.

(iii) Verification that incoming products, parts, materials, and equipment, including items supplied new or used by buyers of products, are as specified in the applicable design data can be achieved by one or more of the following practised methods:

— inspections of incoming articles;

— assessment and surveillance of vendors and subcontractors;

— other production control mechanisms that are able to detect non-conformities with the applicable design data.

(iv) Information is provided to show that procedures are practised that ensure the identification and traceability of parts and material in stock, in completed parts or in parts in process. Where the applicable design data specifies that parts require specific individual traceability, these parts are identified and records are kept.

(v) Information is provided for the procedures of the manufacturing process for:

— specific manufacturing process information as required in the applicable design data; and/or

— complementary procedures established by the production organisation.

Practised methods that use standard manufacturing processes do not require specific documentation.

If strict adherence to a manufacturing process is required in order to ensure that safety-critical product characteristics are met, this is specified in the manufacturing procedure.

(vi) Information is provided on the scope and sampling rate of production inspections and testing that, as a minimum, covers the inspection and testing that is defined as part of the applicable design data. If needed, it is complemented by inspections and testing as defined by the production organisation.

Information is provided for the flight test plan and flight conditions defined for the purpose of production acceptance flight tests, when applicable.

(vii) Information is provided on the tools, jigs and test equipment on which verification or calibration is performed and recorded. A statement that all other production tooling is controlled via practised methods is acceptable.

(viii) General practised methods are described that prevent the release of non-conforming products and their parts that would have an impact on the safe operation of the aircraft. Non-conformities are recorded in order to control the quality system.

(ix) General practised methods are described for adequate airworthiness coordination with the applicant for, or the holder of, the design approval. The documented DO/PO arrangement is used to define responsibilities.

(x) Information is provided about which production records are kept, and how completed records are kept in an adequately protected environment.

(xi) Information is provided that shows what the required competences and qualifications are for certifying staff, and how records on the certifying staff are kept.

(xii) Information is provided on the procedures to issue airworthiness release documents by the:

— identification of the persons permitted to issue airworthiness release documents; and

— identification of the relevant forms, and instructions for filling in the forms.

(xiii) Information is provided on the handling, storage and packaging methods that are adequate if:

— inappropriate handling, storage or packaging could lead to damage or deterioration;

— standard inspections prior to the use of the component would not detect defects; and

— such damage or deterioration would endanger the airworthiness of a component or a part.

(xiv) Information is provided on how internal quality audits and the resulting corrective action procedure are covered by practised surveillance mechanisms that allow the organisation to verify the efficiency of all the elements of the quality system as per this listing.

(xv) Work conducted in places other than the 'major place of activity' and the premises specified in the POE should be approved by the accountable manager, who must ensure that the critical process parameters for the work conducted, such as the light, temperature, humidity, etc., and adequate tooling, are identified and considered. Work conducted at such a location cannot be of a kind that would be performed at a 'major place of activity'. The information on this kind of work is considered to be a change to the production approval, and it requires approval.

(xvi) Work carried out after the completion of the product, but prior to its delivery, is conducted according to the same definitions and procedures and by the same staff as are relevant for the regular production process. It is the responsibility of the accountable manager to ensure the adherence to this requirement.

(xvii) A workflow is defined that shows how to issue flight conditions and permits to fly (PtFs) for the purpose of the production flight testing of new production aircraft. When the flight test plan, the completed flight conditions and Forms 18a and 20b for the purpose of conducting the flight tests are provided as part of the approved type design, the workflow can be limited to:

- making the required entries in those documents (i.e. the reference to the individual aircraft S/N and the configuration);
- verification that the product configuration conforms with the definitions provided within the flight conditions document (which may be an integral part of the type inspection as part of the production workflow); and
- the issuing of the documents.

As part of the workflow, it should be defined that the production organisation can only issue flight conditions and PtFs for this case, and as long as this flight test plan and flight conditions can be fully adhered to.

When the production organisation issues flight conditions and PtFs for a purpose other than the production flight testing of new production aircraft, a flight test operations manual (FTOM) needs to be put in place, which should define the relevant workflows.

For companies that work as one consolidated team, it is sufficient to have one set of flight test procedures that have been established on the basis of an FTOM within either the design or the production organisation.

GM-ELA No 1 to 21.A.139(b)(1) Quality system – Control procedures

ED Decision 2019/003/R

The documentation of the quality system, and the associated training, is limited to what is necessary to demonstrate that the products that are produced conform to the relevant design definition, and are in a condition for safe operation. If products are repeatedly found that do not conform, or if evidence is available that the products may be or may become unsafe, then enhanced procedures and documentation that go beyond the AMC-ELA may be one of the means, but not the only possible means, to rectify that situation.

The control procedures of a quality system can be defined by flow charts, process cards, or similar means. If enterprise resource planning (ERP) systems or other IT systems that manage workflows are applied, then separate workflow documentation is not necessary, as long as the workflow can be demonstrated on the basis of the IT system that is applied. The quality system methods should cover those aspects for which a failure to control these elements is expected to have a direct impact on the safe operation of the aircraft.

GM-ELA No 2 to 21.A.139(b)(1) Conformity of supplied parts or appliances

ED Decision 2019/003/R

The organisation is responsible for ensuring that the delivered product conforms to the type design. This includes components that are used on the product and that are obtained from outside. To discharge this responsibility, the organisation needs to implement practised methods that ensure that non-conforming products are detected at a suitable point in time, prior to the declaration of conformity of the final product or the delivery of spare parts to the customer.

Organisations that apply AMC-ELA No 1 to 21.A.139(b)(1) should ensure, as a minimum, the conformity of supplied parts to a level that is defined as part of the approved type design by using one or more of the following methods:

— supplier control;

— the inspection of incoming goods;

— inspections conducted at a suitable stage of the production and verification flow;

— verification of the performance and the characteristics of the completed product; or

— other means that have an equivalent purpose.

If methods for the verification of conformity are defined as part of the approved type design, the organisation does not need to go beyond these verification methods in their extent, method or frequency.

If the type design does not determine the conformity criteria, the organisation may need to extend reasonable quality assurance methods to the related supplier if non-conformities of the parts would create a hazard.

GM 21.A.139(b)(1) Quality System – Elements of the quality system

ED Decision 2012/020/R

1. The control procedures covering the elements of 21.A.139(b)(1) should document the standards to which the production organisation intends to work.

2. An organisation having a Quality system designed to meet a recognised Standard such as ISO 9001 (relevant to the scope of approval being requested) should expand it to include at least the following additional topics, as appropriate, in order to demonstrate compliance with the requirements of Part 21 Subpart G:

    — Mandatory Occurrence Reporting and continued airworthiness as required by 21.A.165(e)

    — Control of work occasionally performed (outside the POA facility by POA personnel)

    — Co-ordination with the applicant for, or holder of, an approved design as required by 21.A.133(b) and (c) and 21.A.165(g)

    — Issue of certifications within the scope of approval for the privileges of 21.A.163

    — Incorporation of airworthiness data in production and inspection data as required in 21.A.133(b) and (c) and 21.A.145(b)

    — When applicable, ground test and/or production flight test of products in accordance with procedures defined by the applicant for, or holder of, the design approval

— Procedures for traceability including a definition of clear criteria of which items need such traceability. Traceability is defined as a means of establishing the origin of an article by reference to historical records for the purpose of providing evidence of conformity

— Personnel training and qualification procedures especially for certifying staff as required in 21.A.145(d).

3. An organisation having a quality system designed to meet a recognised aerospace quality standard will still need to ensure compliance with all the requirements of Subpart G of Part 21. In all cases, the competent authority will still need to be satisfied that compliance with Part 21 Subpart G is established.

AMC No 1 to 21.A.139(b)(1)(ii) Vendor and sub-contractor assessment, audit and control – Production Organisation Approval (POA) holder using documented arrangements with other parties for assessment and surveillance of a supplier.

ED Decision 2012/020/R

1. General

Note:
For the purpose of this AMC, vendors and sub-contractors are hereafter referred to as 'suppliers', regardless of whether or not they hold a POA and audit and control is hereafter referred to as 'surveillance'.

The production organisation is required by Part 21 to demonstrate that it has established and maintains a quality system that enables the organisation to ensure that each item produced conforms to the applicable design data and is in a condition for safe operation. To discharge this responsibility, the quality system should have, among other requirements, procedures to adequately carry out the assessment and surveillance of suppliers.

The use of Other Parties (OP), such as a consulting firm or quality assurance company, for supplier assessment and surveillance does not exempt the POA holder from its obligations under 21.A.165. The supplier assessment and surveillance, corrective action and follow-up activity conducted at any of its supplier's facilities may be performed by OP.

The purpose of using an OP cannot be to replace the assessment, audit and control of the POA Holder. It is to allow an element (i.e. the assessment of the quality system) to be delegated to another organisation under controlled conditions.

The use of OP to perform supplier assessments and surveillance should be part of the production organisation quality system and fulfil the conditions of this AMC.

This AMC is applicable to a method whereby a POA holder has a documented arrangement with OP for the purpose of assessing and/or surveying a POA's supplier.

2. Approval by the competent authority

Implementing or changing procedures for using OP for supplier assessment and surveillance is a significant change to the quality system and requires approval in accordance with 21.A.147.

3. Conditions and criteria for the use of OP to perform supplier assessment and surveillance

(a) The POA holder should include the use of OP for supplier assessment and surveillance in the POA holders' quality system to demonstrate compliance with the applicable requirements of Part 21.

(b) Procedures required for using OP for supplier assessment and surveillance should be consistent with other procedures of the POA holders' quality system.

(c) Procedures of the POA holder that uses OP to perform supplier assessment and surveillance should include the following:

(1) Identification of the OP that will conduct supplier assessment and surveillance.

(2) A listing of suppliers under surveillance by the OP. This listing should be maintained by the POA holder and made available to the competent authority upon request.

(3) The method used by the POA holder to evaluate and monitor the OP. The method should include the following as a minimum:

(i) Verification that standards and checklists used by the OP are acceptable for the applicable scope.

(ii) Verification that the OP is appropriately qualified and have sufficient knowledge, experience and training to perform their allocated tasks.

(iii) Verification that the OP surveillance frequency of the suppliers is commensurate with the complexity of the product and with the surveillance frequency established by the POA holder's suppliers control programme.

(iv) Verification that the suppliers' assessment and surveillance is conducted on-site by the OP.

(v) Verification that the OP has access to applicable proprietary data to the level of detail necessary to survey suppliers functions.

Where the POA holder uses an OP accredited by a signatory to the European cooperation for Accreditation (EA) Multilateral Agreement and working in accordance with an aviation standard (e.g. EN 9104 series of requirements) that describes requirements for the other party assessment and surveillance, the items (ii) and (iv) shall be deemed to be complied with.

(4) A definition to what scope the OP will conduct suppliers surveillance on behalf of the POA holder. If the OP replaces surveillance in part, the POA holder should identify the functions that will continue to be surveyed by the POA holder.

(5) The procedures used by the OP to notify the POA holder of non-conformities discovered at the suppliers facility, corrective action and follow-up.

(d) The POA should make arrangements that allow the competent authority to make investigation in accordance with 21.A.157 to include OP activities.

AMC No 2 to 21.A.139(b)(1)(ii) Vendor and sub-contractor assessment, audit and control – Production Organisation Approval (POA) holder using other party supplier certification

ED Decision 2012/020/R

1. General

Note:
For the purpose of this AMC, vendors and sub-contractors are hereafter referred to as 'suppliers', regardless of whether or not they hold a POA and audit and control is hereafter referred to as 'surveillance'.

Other party supplier certification is a method whereby a supplier contracts with an appropriately recognised or accredited Other Party (OP) for the purpose of obtaining a certification from that OP. Certification indicates that the supplier has satisfactorily demonstrated to meet the applicable standard on a continuing basis. OP certification results in placing the supplier on the OP list of certified organisations, or in the supplier receiving a certificate identifying the requirements that have been met. Periodic follow-up evaluations are conducted by the OP to verify continued compliance with the requirements of the applicable standard.

The production organisation is required by Part 21 to demonstrate that it has established and maintains a quality system that enables the organisation to ensure that each item produced conforms to the applicable design data and is in a condition for safe operation. To discharge this responsibility, the quality system should have, among other requirements, procedures to adequately carry out the assessment and surveillance of suppliers.

The assessment and surveillance of suppliers by an OP should be deemed to satisfy the requirements of 21.A.139(b)(1)(ii) when the conditions of this AMC are satisfied. The assessment and surveillance of suppliers by OP as part of supplier certification does not exempt the POA holder from its obligations under 21.A.165. The supplier assessment and surveillance, corrective action and follow-up activity conducted at any of its supplier's facilities may be performed by OP.

The purpose of using an OP cannot be to replace the assessment, audit and control of the POA Holder. It is to allow an element (i.e. the assessment of the quality system) to be delegated to another organisation under controlled conditions.

The use of suppliers that are certified by OP in accordance with this AMC should be part of a production organisation quality system.

2. Approval by the competent authority

Implementing or changing procedures for using suppliers that are certified by an OP is a significant change to the quality system and requires approval in accordance with 21.A.147.

3. Conditions and criteria for using supplier certification for the supplier assessment and surveillance

(a) The POA holder should include the use of supplier certification for the supplier assessment and surveillance in the POA holder's quality system to demonstrate compliance with the applicable requirements of Part 21.

(b) Procedures required for use of supplier certification for the supplier assessment and surveillance should be consistent with other procedures of the POA holders' quality system.

(c) Procedures of the POA holder that uses supplier certification for the supplier assessment and surveillance should include the following:

(1) Listing of the OP that has certified or will certify suppliers and will conduct supplier assessment and surveillance or the scheme under which the accreditation of the OP is controlled. This listing should be maintained by the POA holder and made available to the competent authority upon request.

(2) A listing of the certified suppliers under surveillance by the OP and used by the POA holder. This listing should be maintained by the POA holder and made available to the competent authority upon request.

(3) The method used by the POA holder to evaluate and monitor the certification process of any OP certification body or OP certification scheme used. This applies not only to new suppliers, but also to any decision by the POA holder to rely on OP certification of current suppliers. The method should include the following as a minimum:

(i) Verification that certification standards and checklists are acceptable and applied to the applicable scope.

(ii) Verification that the OP is appropriately qualified and has sufficient knowledge, experience and training to perform its allocated tasks.

(iii) Verification that the OP surveillance frequency of the suppliers is commensurate with the complexity of the product and with the surveillance frequency established by the POA holder's suppliers control programme.

(iv) Verification that the suppliers' surveillance is conducted on-site by the OP.

(v) Verification that the surveillance report will be made available to the competent authority upon request.

(vi) Verification that the OP continues to be recognised or accredited.

(vii) Verification that the OP has access to applicable proprietary data to the level of detail necessary to survey suppliers functions.

Where the POA holder uses an OP accredited by a signatory to the European cooperation for Accreditation (EA) Multilateral Agreement and working in accordance with an aviation standard (e.g. EN 9104 series of requirements) that describes requirements for the OP certification, the items (ii), (iv) and (v) shall be deemed to be complied with:

(4) A definition to what scope the OP will conduct suppliers surveillance on behalf of the POA holder. If the OP replaces surveillance in part, the POA holder should identify the functions that will continue to be surveyed by the POA holder.

(5) Procedures that ensure that the POA is aware of the loss of an existing certification.

(6) Procedures that ensure that the POA holder is aware of non-conformities and has access to detailed information of these non-conformities.

(7) Procedures to evaluate the consequences of non-conformities and take appropriate actions.

(d) The POA should make arrangements that allow the competent authority to make investigation in accordance with 21.A.157 to include OP activities.

AMC-ELA No 1 to 21.A.139(b)(2) Quality system – Independent quality assurance function

ED Decision 2019/003/R

The responsibility for the independent checking that the quality system functions in accordance with point 21.A.139(b)(1)(xiv) is specified within the organisation. The responsible person(s) establish(es) a schedule, which verifies all the elements of the quality system at least once a year. The schedule can be complemented by unplanned audits if needed. The person(s) responsible obtain(s) direct monitoring results and ensure(s) that corrective actions are taken when necessary.

GM-ELA No 1 to 21.A.139(b)(2) Quality system – Independent quality assurance function

ED Decision 2019/003/R

The term 'adequacy of procedures' means that the quality system, through the use of the practised methods or procedures as documented, is capable of meeting the conformity objectives identified in point 21.A.139(a). This can be shown with the results from the implemented quality system, carried out in accordance with point 21.A.139(b)(1)(xiv). Independent quality assurance monitoring can be accomplished by structured experience exchanges, regular quality meetings, brainstorming or lessons-learned sessions, project reviews at appropriate phases of the development, or by other similar means.

The adequacy of the quality system should be assessed on the basis of the continued conformity of the product with the approved type design. If the practised methods and the level of documentation of procedures are not found to be adequate, a more detailed documented procedure may need to be implemented to rectify the situation.

GM No 1 to 21.A.139(b)(2) Quality System – Independent quality assurance function

ED Decision 2012/020/R

The quality assurance function which is part of the organisation is required to be independent from the functions being monitored. This required independence relates to the lines of reporting, authority and access within the organisation and assumes an ability to work without technical reliance on the monitored functions.

GM No 2 to 21.A.139(b)(2) Quality System – Adequacy of procedures and monitoring function

ED Decision 2012/020/R

Adequacy of procedures means that the quality system, through the use of the procedures as set forth, is capable of meeting the conformity objectives identified in 21.A.139(a).

The quality assurance function to ensure the above should perform planned continuing and systematic evaluations or audits of factors that affect the conformity (and, where required, safe operation) of the products, parts or appliances to the applicable design. This evaluation should include all elements of the quality system in order to demonstrate compliance with Part 21 Subpart G.

21.A.143 Exposition [applicable until 6 March 2023] / 21.A.143 Production organisation exposition [applicable from 7 March 2023 - Regulation (EU) 2022/201]

Regulation (EU) 2015/1039

(a) The organisation shall submit to the competent authority a production organisation exposition providing the following information:

[applicable until 6 March 2023]

(a) The production organisation shall establish and maintain a production organisation exposition (POE) that provides directly or by cross reference the following information related to the production management system as described in point 21.A.139:

[applicable from 7 March 2023 - Regulation (EU) 2022/201]

1. a statement signed by the accountable manager confirming that the production organisation exposition and any associated manuals which define the approved organisation's compliance with this Subpart will be complied with at all times;
2. the title(s) and names of managers accepted by the competent authority in accordance with point 21.A.145(c)(2);
3. the duties and responsibilities of the manager(s) as required by point 21.A.145(c)(2) including matters on which they may deal directly with the competent authority on behalf of the organisation;
4. an organisational chart showing associated chains of responsibility of the managers as required by point 21.A.145(c)(1) and (2);
5. a list of certifying staff as referred to in point 21.A.145(d);
6. a general description of man-power resources;
7. a general description of the facilities located at each address specified in the production organisation's certificate of approval;
8. a general description of the production organisation's scope of work relevant to the terms of approval;
9. the procedure for the notification of organisational changes to the competent authority;
10. the amendment procedure for the production organisation exposition;
11. a description of the quality system and the procedures as required by point 21.A.139(b)(1);
12. a list of those outside parties referred to in point 21.A.139(a).

[points 11 and 12 applicable until 6 March 2023]

11. a description of the production management system, the policy, processes and procedures as provided for in point 21.A.139(c);
12. a list of the outside parties referred to in point 21.A.139(d)(1);

[points 11and 12 applicable from 7 March 2023 - Regulation (EU) 2022/201]

13. if flight tests are to be conducted, a flight test operations manual defining the organisation's policies and procedures in relation to flight test. The flight test operations manual shall include:

(i) a description of the organisation's processes for flight test, including the flight test organisation involvement into the permit to fly issuance process;

(ii) crewing policy, including composition, competency, currency and flight time limitations, in accordance with Appendix XII to this Annex I (Part 21), where applicable;

(iii) procedures for the carriage of persons other than crew members and for flight test training, when applicable;

(iv) a policy for risk and safety management and associated methodologies;

(v) procedures to identify the instruments and equipment to be carried;

(vi) a list of documents that need to be produced for flight test.

(b) The production organisation exposition shall be amended as necessary to remain an up-to-date description of the organisation, and copies of any amendments shall be supplied to the competent authority.

[point (b) applicable until 6 March 2023]

(b) The initial issue of the POE shall be approved by the competent authority.

(c) The POE shall be amended as necessary so that it remains an up-to-date description of the organisation. Copies of any amendments shall be supplied to the competent authority.

[points (b) and (c) applicable from 7 March 2023 - Regulation (EU) 2022/201]

AMC to 21.A.143, 21.A.243, 21.A.14(b), 21.A.112B(b) and 21.A.432B(b) Flight Test Operations Manual (FTOM)

ED Decision 2017/024/R

1. General

a. Scope: The FTOM covers flight test operations.

The FTOM complexity should be proportionate to the aircraft and the organisation complexity.

b. Format

The FTOM may:

— be included in the Design Organisation Approval (DOA)/Production Organisation Approval (POA)/Alternative Procedure to DOA (APDOA) documents, or

— be a separate manual.

The FTOM may make reference to other documents to cover the contents listed below, e.g. for record-keeping.

c. Use by contractors or sub-contractors:

When flight tests are performed by contractors or sub-contractors, they should comply with the FTOM of the primary organisations, unless they have established an FTOM in compliance with Part-21, the use of which has been agreed between the two organisations.

2. The FTOM should contain the following elements:

a. Exposition (not applicable in the case of APDOA):

If the FTOM is presented as a separate document, it should include a chart indicating the structure of the organisation and, more specifically, the functional links of the people in charge of flight test activities. It should also mention the coordination between all departments affecting flight test, e.g. Design Office, Production and Maintenance, in particular coordination for the establishment and update of a Flight Test Programme.

b. Risk and safety management:

The FTOM should describe the organisation's policy in relation to risk and safety assessment, mitigation and associated methodologies.

c. Crew members:

According to the flight test category, the FTOM should describe the organisation's policy on the composition of the crew (including the need to use a Lead Flight Test Engineer (LFTE)) and the competence and currency of its flight test crew members, including procedures for appointing crew members for each specific flight.

All crew members should be listed in the FTOM.

A flight time limitation policy should be established.

d. Carriage of persons other than crew members:

According to the flight test category, the FTOM should describe the organisation's policy in relation to the presence and safety on-board, of people other than crew members (i.e. with no flying duties).

People other than crew members should not be allowed on board for Category 1 flight tests.

e. Instruments and equipment:

The FTOM should list, depending on the nature of the flight, the specific safety-related instruments and equipment that should be available on the aircraft or carried by people on board.

The FTOM should contain provisions to allow flights to take place in case of defective or missing instruments or equipment.

f. Documents:

The FTOM should list the documents to be produced for flight test, and include (or refer to) the procedures for their issue, update and follow-up to ensure the documents' configuration control:

(i) documents associated with a Flight Test Programme:

— Flight Order for a given flight, which should include:

— a list of the tests to be performed and associated conditions;

— safety considerations relevant to the flight;

— category of the flight (e.g. Category 1);

— composition of the crew;

— names of persons other than crew members;

— aircraft configuration items relevant to the test to be highlighted to the crew;

— loading of the aircraft;

— reference to approved flight conditions; and

— restrictions relevant to the flight to be highlighted to the crew.

— Flight crew report.

(ii) documentation and information to be carried on the aircraft during flight test;

(iii) record-keeping: the FTOM should describe the policy relative to record-keeping.

g. Permit to fly:

The FTOM should describe the involvement of the flight test organisation or flight test team (as appropriate) in the process for the approval of flight conditions and the issue of permits to fly in accordance with Subpart P.

h. Currency and training:

The FTOM should describe how training for flight test is organised.

Currency of the flight test crew may be ensured either through recent experience or refresher training.

For aircraft for which Appendix XII is applicable, minimum flight experience by year should be:

— for pilots: 50 hours. In addition:

— for pilots with a flight test rating, the 50 hours should include 20 flight test hours in any flight test category.

— for pilots performing a Category 3 flight test, the flight test experience should be expressed in terms of a number of flights leading to the issue of a Certificate of Airworthiness (CofA) (e.g. first flights).

— for pilots performing a Category 4 flight test, the minimum flight test experience should be proportionate to the activity envisaged.

— for LFTEs: 10 flight test hours in any flight test category.

The FTOM should specify the requirements for a refresher training in order to ensure that crew members are sufficiently current to perform the required flight test activity.

A system should be established to record the currency of the flight test crew's training.

A valid national document (i.e. licence), issued by an EASA Member State under its national regulations and ensuring compliance with the agreed currency requirements, is an acceptable means of compliance to demonstrate currency for a pilot that holds a flight test rating and for an LFTE.

AMC-ELA No 1 to 21.A.143 Exposition

ED Decision 2019/003/R

Note: The following provides the information, the acceptable level of detail and the format to be used for the production organisation exposition (POE), and this section is numbered in accordance with the numbering of point 21.A.143(a). If it is needed for completeness, the text of the implementing rule is quoted in italics.

The exposition should contain:

1 *A statement signed by the accountable manager that confirms that the production organisation exposition and any associated manuals, which define the approved organisation's compliance with this Subpart, will be complied with at all times.*

2 *The titles and the names of the managers accepted by the competent authority in accordance with point 21.A.145(c)(2).* The titles and the names of the managers should include the accountable manager (AM), and a statement that this manager is accountable for all the tasks, even if the manager delegates some individual tasks. The delegation of tasks without a delegation of responsibility is not required to be shown within the POE. Persons such as, for example, the quality manager (QM) and the production manager (PM) should only be identified within the POE if responsibilities are delegated to them as outlined by AMC-ELA No 1 to 21.A.145(c).

3 A statement that the AM is the formal point of contact with the competent authority unless other persons under the direct responsibility of the AM are identified.

4 An organisational chart if the AM delegates responsibilities. The organisational chart should identify the positions and the reporting lines of those persons who hold delegated responsibilities. In cases where all the responsibilities remain with the AM, even though individual tasks may be delegated, this delegation should be briefly described, and no organisational chart is necessary.

5 A list of the certifying staff. This may be identified by a reference to a separate source (e.g. a document, listing, intranet, etc.), and should be easily accessible to everyone concerned within the company.

6 A general description of the manpower resources. This can be provided by stating the approximate size of the organisation in full-time equivalents (FTEs).

7 A general description of the facilities. This should identify the addresses of the major places of activity. The 'major places of activity' are those locations where the major activities take place that finally lead to the completion of the product and the issuance of the statement of conformity/release certificate.

8 The general description of the organisation's scope of work should be provided as defined by point 21.A.151 (see GM-ELA No 1 to 21.B.230), on the basis of the product type(s).

9 The procedure for the notification of organisational changes. This can be provided through a reference to that procedure in the company manual (see also GM-ELA No 1 to 21.A.147).

10 The procedure for the notification of organisational changes to the competent authority, which can be provided by a declaration that the POE is kept up to date under the responsibility of the AM, when changes to the organisation occur that affect the POE. Amendments to the POE are released by the AM, and are distributed by following the implemented method for the control of documented information to the locations identified in a generic or document-specific distribution list, including distribution to the competent authority.

11 The description of the quality system and the procedures in the POE, which may use references to the company manual, or to any other document applied in the quality system (e.g. in accordance with ISO 9001, EN 9100, ASTM F2972 or other suitable standards). These references do not need to explicitly include the revision status of these documents.

12 The list of outside parties, which should contain the outside parties that operate under the quality system and the procedures of the manufacturer (i.e. the extended workbench).

13 The flight test operations manual (FTOM). The POE can use a reference to an FTOM that is adequate for the production flight testing of new production aircraft, if this is applicable. If both the design and manufacturing entities work within one consolidated flight test team, it is acceptable to have one set of FTOM procedures defined for the whole team.

GM-ELA No 1 to 21.A.143 Exposition

ED Decision 2019/003/R

The purpose of the production organisation exposition (POE) is to provide in a concise and documented format the organisational relationships, responsibilities, terms of reference, and the associated authority, procedures, means and methods of the organisation.

The POE is not the top-level mechanism for organisational control and oversight, and it therefore does not need to provide revision-controlled links to referenced documents. The POE should provide a high-level summary of the organisation's control and oversight methods, and appropriate cross references that allow access to the manuals, procedures and instructions, if applicable.

The POE should be an accurate definition and description of the production organisation. The document does not require approval in itself, but it will be considered when approving the organisation.

The scope of the production organisation and the oversight is not limited to the locations that are identified in the POE, which only shows the 'major places of activity'.

The sublevel production location(s) does (do) not need to be identified in the POE. To ensure transparency to the authority, and in analogy to the management of external suppliers, at least those sublevel locations where manufacturing processes are exercised that require close process control ('special processes') should be identified, but not necessarily as part of the POE. They may be identified within the company manual or in a separate listing.

The scope of work automatically includes the products and all the spare parts required for the identified products, without any further specifications or details. Capability lists are not required by Subpart G. Separate from the statement of scope itself, a listing is provided that identifies the type(s) produced by the approved production organisation.

Note: A POE template, which may be used for a small company (adapted to the company's specifics), is published by EASA.

When changes to the organisation occur that have an impact on the POE, the POE should be updated in accordance with the agreed procedure. Significant changes to the approved production organisation (as explained in GM-ELA No 1 to 21.A.147) require approval by the competent authority,

and could also change the POE. The POE document, which is amended in accordance with the approved change, is not intended to be approved by the competent authority, and visual evidence of the approval of the POE document is not needed.

GM 21.A.143 Exposition – Production Organisation Exposition (POE)

ED Decision 2012/020/R

The purpose of the POE is to set forth in a concise document format the organisational relationships, responsibilities, terms of reference, and associated authority, procedures, means and methods of the organisation.

The information to be provided is specified in 21.A.143(a). Where this information is documented and integrated in manuals, procedures and instruction, the POE should provide a summary of the information and an appropriate cross-reference.

The competent authority requires the POE to be an accurate definition and description of the production organisation. The document does not require approval in itself, but it will be considered as such by virtue of the approval of the organisation.

When changes to the organisation occur, the POE is required to be kept up to date per a procedure, laid down in the POE. Significant changes to the organisation (as defined in GM 21.A.147(a)) should be approved by the competent authority prior to update of the POE.

When an organisation is approved against any other implementing rule containing a requirement for an exposition, a supplement covering the differences may suffice to meet the requirements of Part 21 Subpart G except that the supplement should have an index identifying where those parts missing from the supplement are covered. Those items then formally become part of the POE. In any combined documents the POE should be easily identifiable.

AMC-ELA No 1 to 21.A.143(a)(13) Exposition – Policies and procedures related to flight test

ED Decision 2019/003/R

The objective of this AMC is to identify the items that need to be considered for a safe flight test, that need to be practised, and, if necessary, defined in the flight test operations manual (FTOM) or related procedures, templates or checklists. Those items are the following:

— A flight test plan, completed flight conditions, and the related Forms 18a and 20b for the purpose of conducting the production flight testing of a new production aircraft that are provided as part of the approved type design. These define:

  — a crewing policy, including its composition, and any competence, currency and flight time limitations;

  — procedures for the carriage of persons other than crew members, and for flight test training;

  — a policy for risk and safety management, and associated methodologies that are adequate for the purpose of the flight;

  — a definition of the instruments and equipment to be carried on board during this test flight; and

  — a list of the records that need to be produced when conducting this flight test.

— This flight test plan constitutes the FTOM for this limited purpose.

AMC-ELA No 2 to 21.A.143(a)(13) Exposition – Policies and procedures related to flight test

ED Decision 2019/003/R

For companies to which AMC-ELA No 1 to 21.A.143(a)(13) is not appropriate, the POA may implement policies and procedures for conducting these activities that include a proportionate and efficient risk and safety management system. This approach is documented either within a separate FTOM or as an integral part of any other valid manual of the organisation, such as the company manual, or any other relevant quality manual. The FTOM, or its equivalent, should be proportionate to the complexity of the aircraft and the organisation.

The risk and safety management system, documented within the FTOM, or its equivalent, covers the following aspects:

— The definition of the key qualifications, responsibilities and accountabilities for the staff involved in conducting the flight test, and should cover at least:

  — The Head of Flight Test (HoFT), who coordinates all the activities related to flight test, and who assumes the responsibility for flight testing (which can be shared with other management positions within the PO);

  — The Flight Test Engineer, who manages the individual flight tests (or campaigns);

  — The Test Pilot, who conducts any flight tests; and

  — The Flight Test Mechanic, who conducts all the maintenance tasks and makes all the configuration changes to the test aircraft.

  One person who has adequate qualifications may act in more than one role. The HoFT should have a direct reporting line to the AM.

— A method that provides practical guidance to conduct a hazard assessment to classify flight tests according to the risks involved. At least two categories should be identified:

  — Category 1: for high-risk flight tests; and

  — Category 2: for medium- and low-risk flight tests.

— Definitions of generic risk mitigation strategies, such as the use of minimum and maximum altitudes or airspeed safety margins, and safety rules to be obeyed for the typical major test phases and missions.

— The identification of the aircraft-related safety equipment that needs to be available, including references to the maintenance requirements of this equipment.

— The policy on how to alert and involve rescue services, such as the fire brigade or emergency physicians, in order to provide sufficiently short reaction times.

— Crew qualifications, including requirements for their qualifications to be current and crew (refresher) training, as required.

— For aircraft with MTOMs of 2 000 kg or more:

  — the provisions of Appendix XII to Part-21 apply;

  — the minimum flight experience per year should be:

    — for pilots: 50 hours. In addition:

- for pilots who have flight test ratings, the 50 hours should include 20 flight test hours in any flight test category;
- for pilots to perform Category 3 flight tests, their flight test experience should be expressed in terms of the number of flights that led to the issuing of a certificate of airworthiness (CofA) (e.g. first flights);
- for pilots to perform Category 4 flight tests, their minimum flight test experience should be proportionate to the activity envisaged.

— Crew composition and duty time limitations that are adequate for the kind of testing and the risk category of the flight tests conducted by the POA.

The procedural aspects, documented within the FTOM, or its equivalent, should cover the following aspects:

— The initiation and planning of a flight test activity, including, for example, but not limited to:
  - hazard analysis;
  - detailed flight test planning;
  - the generation and approval of flight conditions;
  - the definition and verification of the test-aircraft configuration;
  - the preparation of the aircraft;
  - the integration, calibration and verification of any flight test equipment;
  - verification of the fitness of the aircraft for flight;
  - issuing or obtaining a PtF;
  - the preflight briefing, and conducting the flight test; and
  - debriefing and data reporting.

— The identification of all the documents and records that are required to be generated or maintained in relation to the flight test, including the definitions for the authority to sign.

— Identification of how training for flight tests is organised.

The definition of the methods required may be provided in different ways including but not limited to flow charts, process descriptions, forms that are detailed enough to enforce adherence to the required workflow, workflow implementation in IT-based ERP systems, or similar means.

The implementation of the standard FTOM, including its associated process definitions and forms, ensures that there will be adherence to this AMC, and hence that there will be compliance with the relevant requirements of Part-21.

Any flight tests that are subcontracted to a third party should comply with the FTOM of the POA, unless the third party has established an FTOM that is in compliance with Part-21, and its use has been agreed between the two organisations.

21.A.145 Approval requirements [applicable until 6 March 2023] / 21.A.145 Resources [applicable from 7 March 2023 - Regulation (EU) 2022/201]

Regulation (EU) 2021/1088

The production organisation shall demonstrate, on the basis of the information submitted in accordance with point 21.A.143 that:

(a) with regard to general approval requirements, facilities, working conditions, equipment and tools, processes and associated materials, number and competence of staff, and general organisation are adequate to discharge obligations under point 21.A.165;

(b) with regard to all necessary airworthiness and environmental protection data:

1. the production organisation is in receipt of such data from the Agency, and from the holder of, or applicant for, the type-certificate, restricted type-certificate or design approval, including any exemption granted against the environmental protection requirements, to determine conformity with the applicable design data;

2. the production organisation has established a procedure to ensure that airworthiness and environmental data are correctly incorporated in its production data and,

3. such data are kept up to date and made available to all personnel who need access to such data to perform their duties.

(c) with regard to management and staff:

1. a manager has been nominated by the production organisation, and is accountable to the competent authority. His or her responsibilities within the organisation shall consist of ensuring that all production is performed to the required standards and that the production organisation is continuously in compliance with the data and procedures identified in the exposition referred to in point 21.A.143;

2. a person or group of persons have been nominated by the production organisation to ensure that the organisation is in compliance with the requirements of this Annex (Part 21), and are identified, together with the extent of their authority. Such person(s) shall act under the direct authority of the accountable manager referred to in point (1). The person(s) nominated shall be able to show the appropriate knowledge, background and experience to discharge their responsibilities;

3. staff at all levels have been given appropriate authority to be able to discharge their allocated responsibilities and that there is full and effective coordination within the production organisation in respect of airworthiness and environmental data matters.

(d) with regard to certifying staff, authorised by the production organisation to sign the documents issued under point 21.A.163 under the scope or terms of approval:

1. the knowledge, background (including other functions in the organisation), and experience of the certifying staff are appropriate to discharge their allocated responsibilities;

2. the production organisation maintains a record of all certifying staff which shall include details of the scope of their authorisation;

3. certifying staff are provided with evidence of the scope of their authorisation.

[applicable until 6 March 2023]

The production organisation shall demonstrate that:

(a) the facilities, working conditions, equipment and tools, processes and associated materials, number and competence of staff, and the general organisation are adequate to discharge its obligations under point 21.A.165;

(b) with regard to all the necessary airworthiness and environmental protection data:

1. the production organisation holds all data it needs to determine conformity with the applicable design data. Such data may originate from the Agency and from the holder of, or applicant for, the type-certificate, restricted type-certificate or design approval, and may include any exemption granted from the environmental protection requirements;

2. the production organisation has established a procedure to ensure that the airworthiness and environmental protection data are correctly incorporated in its production data;

3. such data are kept up to date and made available to all personnel that need access to such data to perform their duties;

(c) with regard to management and staff:

1. an accountable manager has been appointed by the production organisation with the authority to ensure that, within the organisation, all production is performed to the required standards and that the production organisation is continuously in compliance with the requirements of the production management system referred to in point 21.A.139, and the data and procedures identified in the POE referred to in point 21.A.143;

2. a person or group of persons has/have been nominated by the accountable manager to ensure that the organisation is in compliance with the requirements of this Annex, and are identified, together with the extent of their authority; such person or group of persons shall be responsible to the accountable manager and have direct access to him. The person or group of persons shall have the appropriate knowledge, background and experience to discharge their responsibilities;

3. staff at all levels have been given the appropriate authority to be able to discharge their allocated responsibilities and that there is full and effective coordination within the production organisation in respect of airworthiness and environmental protection data matters;

(d) with regard to certifying staff authorised by the production organisation to sign the documents issued under point 21.A.163 within the scope of the terms of approval:

1. they have the appropriate knowledge, background (including other functions in the organisation) and experience to discharge their allocated responsibilities;

2. they are provided with evidence of the scope of their authorisation.

[applicable from 7 March 2023 - Regulation (EU) 2022/201]

AMC-ELA No 1 to 21.A.145(a) Approval requirements – General

ED Decision 2019/003/R

The adequacy of the infrastructure and staffing may be demonstrated by producing conforming products (on the basis that the type inspection results are part of the production final acceptance process), at the anticipated production rate, and with an adequate staff workload.

GM 21.A.145(a) Approval requirements

ED Decision 2012/020/R

A facility is a working area where the working conditions and the environment are controlled as appropriate in respect of: cleanliness, temperature, humidity, ventilation, lighting, space/access, noise, air pollution.

Equipment and tools should be such as to enable all specified tasks to be accomplished in a repeatable manner without detrimental effect. Calibration control of equipment and tools which affect critical dimensions and values should demonstrate compliance with, and be traceable to, national or international standards.

Sufficient personnel means that the organisation has for each function according to the nature of the work and the production rate, a sufficient quantity of qualified personnel to accomplish all specified manufacturing tasks and to attest the conformity. Their number should be such that airworthiness consideration may be applied in all areas without undue pressure.

An evaluation of the competence of personnel is performed as part of the quality system. This should include, where appropriate, verification that specific qualification standards have been implemented, for example NDT, welding, etc. Training should be organised to establish and maintain the personal competence levels determined by the organisation to be necessary.

AMC-ELA No 1 to 21.A.145(b) Approval requirements – Airworthiness noise fuel venting and exhaust emissions data

ED Decision 2019/003/R

For applicants whose design and production entities operate in one consolidated team, and for which the applicable design data is provided as part of the approved type design data, the availability of all the necessary airworthiness, noise, fuel venting and exhaust emissions data is considered to be met.

In all other cases, in accordance with the practised methods and procedures that were established as part of the quality system, the PO can demonstrate that the production data contains all the necessary data to determine that there is conformity with the applicable design data, and that this data is kept up to date and is available to the relevant personnel.

GM 21.A.145(b)(2) Approval requirements – Airworthiness and environmental protection, production/quality data procedures

ED Decision 2019/018/R

1 When a POA holder/applicant is developing its own manufacturing data, such as computer-based data, from the design data package delivered by a design organisation, procedures are required to demonstrate the right transcription of the original design data.

2 Procedures are required to define the manner in which airworthiness and environmental data is used to issue and update the production/quality data, which determines the conformity of products, parts and appliances. The procedure must also define the traceability of such data to each individual product, part or appliance for the purpose of certifying a condition for safe operation and issuing a Statement of Conformity or EASA Form 1.

AMC-ELA No 1 to 21.A.145(c) Approval requirements – Management and staff

ED Decision 2019/003/R

EASA Form 4 should be used to nominate the accountable manager (AM) to the competent authority. Further management staff members are not required to be nominated if the AM elects to take all the required responsibilities (e.g. including quality manager responsibilities). If the AM delegates any of the responsibilities as defined in 21.A.145(c) to sublevel managers, the sublevel managers who receive this delegation have to be nominated to the competent authority by the use of EASA Form 4, and have to be listed in the POE.

It should be demonstrated that the AM has sufficient power within the company to control the production activity on the basis of the available resources, up to the point of stopping production when adequate resources cannot be provided.

The AM may delegate individual tasks to sublevel managers, while still maintaining his/her responsibilities and the power to make decisions; at the sublevel, in this case, the manager should monitor the sublevel activities. Such delegation of tasks to sublevels is defined internally and does not need to be formally declared to the competent authority.

GM 21.A.145(c)(1) Approval requirements – Accountable manager

ED Decision 2012/020/R

Accountable manager means the manager who is responsible, and has corporate authority for ensuring that all production work is carried out to the required standard. This function may be carried out by the Chief Executive or by another person in the organisation, nominated by him or her to fulfil the function provided his or her position and authority in the organisation permits to discharge the attached responsibilities.

The manager is responsible for ensuring that all necessary resources are available and properly used in order to produce under the production approval in accordance with Part 21 Section A Subpart G.

The manager needs to have sufficient knowledge and authority to enable him or her to respond to the competent authority regarding major issues of the production approval and implement necessary improvements.

The manager needs to be able to demonstrate that he or she is fully aware of and supports the quality policy and maintains adequate links with the quality manager.

GM 21.A.145(c)(2) Approval requirements – Responsible managers

ED Decision 2012/020/R

The person or persons nominated should represent the management structure of the organisation and be responsible for all functions as specified in Part 21 Section A Subpart G. It therefore follows that, depending on the size of the Part 21 Section A Subpart G organisation, the functions may be subdivided under individual managers (and in fact may be further subdivided) or combined in a variety of ways.

The competent authority requires the nominated managers to be identified and their credentials submitted on an EASA Form 4 (see EASA Form 4 for Production Organisations on the EASA website under: http://easa.europa.eu/certification/application-forms.php) to the competent authority in order that they may be seen to be appropriate in terms of relevant knowledge and satisfactory

experience related to the nature of the production activities as performed by the Part 21 Section A Subpart G organisation.

The responsibilities and the tasks of each individual manager are required to be clearly defined, in order to prevent uncertainties about the relations, within the organisation. In the case of organisation structures where staff-members are responsible to more than one person, as for instance in matrix and project organisations, responsibilities of the managers should be defined in such a way that all responsibilities are covered.

Where a Part 21 Section A Subpart G organisation chooses to appoint managers for all or any combination of the identified Part 21 functions because of the size of the undertaking, it is necessary that these managers report ultimately to the accountable manager. In cases where a manager does not directly report to the accountable manager, he or she should have a formally established direct access to the accountable manager.

One such manager, normally known as the quality manager is responsible for monitoring the organisation's compliance with Part 21 Section A Subpart G and requesting remedial action as necessary by the other managers or the accountable manager as appropriate. He or she should have a direct access to the accountable manager.

AMC 21.A.145(d)(1) Approval requirements – Certifying staff

ED Decision 2012/020/R

1. Certifying Staff are nominated by the production organisation to ensure that products, parts and/or appliances qualify for Statements of Conformity or Release Certificates. Certifying Staff positions and numbers are to be appropriate to the complexity of the product and the production rate.
2. The qualification of certifying staff is based on their knowledge, background and experience and a specific training (or testing) established by the organisation to ensure that it is appropriate to the product, part, or appliance to be released.
3. Training must be given to develop a satisfactory level of knowledge of organisation procedures, aviation legislation, and associated implementing rules, CS and GM, relevant to the particular role.
4. For that purpose, in addition to general training policy, the organisation must define its own standards for training, including pre-qualification standards, for personnel to be identified as certifying staff.
5. Training policy is part of the Quality System and its appropriateness forms part of investigation by the competent authority within the organisation approval process and subsequent surveillance of persons proposed by managers.
6. The training must be updated in response to experience gained and changes in technology.
7. A feedback system to ascertain that the required standards are being maintained must be put in place to ensure the continuing compliance of personnel to authorisation requirements.
8. For release of products, parts or appliances, the responsibilities to issue statements of conformity/release certificates (EASA Form 1) or permit to fly including approval of flight conditions are allocated to the certifying staff identified in 21.A.145(d)(2).
9. The competent authority holds the right to reject those personnel, appointed by the organisation, if found to have inappropriate experience or not to otherwise comply with its requirements.

AMC-ELA No 1 to 21.A.145(d)(1) Approval requirements – Certifying staff

ED Decision 2019/003/R

Certifying staff (CS) are nominated by the production organisation to ensure that products qualify for statements of conformity or release certificates. The number of CS and their positions within the organisation should be adequate to perform their duties and commensurate with the complexity of the product and the production rate.

The nomination of the CS is based on their knowledge, background and experience, and specific training (or testing) is established by the organisation to ensure that the CS members are appropriately qualified for the product, part, or appliance to be released. This can be ensured by utilising appropriately qualified Part-66 licence holders as inspectors, or inspectors who are qualified to comparable standards that are agreed with the relevant competent authority.

The training of personnel who support CS at the subcomponent level may be ensured by on-the-job training.

For the release of products, parts or appliances, the responsibilities for issuing statements of conformity or release certificates (EASA Form 52, EASA Form 1), or PtFs and approvals of flight conditions (if applicable), are allocated under the responsibility of the AM to individuals that are nominated as CS.

AMC 21.A.145(d)(2) Approval requirements – Record of certifying staff

ED Decision 2012/020/R

1. The following is the minimum information to be recorded in respect of each certifying person:
   - (a) Name
   - (b) Date of Birth
   - (c) Basic Training and standard attained
   - (d) Specific Training and standard attained
   - (e) If appropriate – Continuation Training
   - (f) Experience
   - (g) Scope of the authorisation
   - (h) Date of first issue of the authorisation
   - (i) If appropriate – expiry date of the authorisation
   - (j) Identification Number of the authorisation
2. The record may be kept in any format and must be controlled by an internal procedure of the organisation. This procedure forms part of the quality system.
3. Persons authorised to access the system must be maintained at a minimum to ensure that records cannot be altered in an unauthorised manner and that confidential records cannot become accessible to unauthorised persons.
4. The certifying person must be given reasonable access on request to his or her own records.

5. Under the provision of 21.A.157 the competent authority has a right of access to the data held in such a system.

6. The organisation must keep the record for at least two years after the certifying person has ceased employment with the organisation or withdrawal of the authorisation, whichever is the sooner.

AMC-ELA No 1 to 21.A.145(d)(2) Approval requirements – Records of certifying staff

ED Decision 2019/003/R

The following data should be recorded for each certifying staff (CS) member:

(a) name;

(b) date of birth;

(c) basic training and the standard attained;

(d) specific training and the standard attained;

(e) if appropriate, continuation training;

(f) experience;

(g) scope of the authorisation;

(h) date of first issue of the authorisation;

(i) if applicable, the expiry date of the authorisation;

(j) identification (number) of the authorisation;

(k) documented acceptance of the nomination.

The above information is deemed to be sufficient to provide the CS with evidence of their scope of authorisation.

The record of this data may be kept in any format. Each CS member should be given reasonable access on request to his or her own records.

The organisation should keep these records for at least 2 years after the CS member has ceased to be employed by the organisation, or 2 years after the withdrawal of their authorisation, whichever occurs first.

AMC 21.A.145(d)(3) Approval requirements – Evidence of authorisation

ED Decision 2012/020/R

1. The authorisation document must be in a style that makes its scope clear to the certifying staff and any authorised person who may require to examine the authorisation. Where codes are used to define scope, an interpretation document should be readily available.

2. Certifying staff are not required to carry the authorisation document at all times but should be able to make it available within a reasonable time of a request from an authorised person. Authorised persons include the competent authority.

AMC-ELA No 1 to 21.A.145(d)(3) Approval requirements – Evidence of authorisation

ED Decision 2019/003/R

Evidence of the scope of the authorisation may be provided in a reasonably accessible way within the company, so that a staff member that needs to be aware of the authorisation can verify their status whenever needed. This can be achieved by the provision of accessible listings of the nominated CS members, or by other means. The issuing of individual badges or passes is not required.

21.A.147 Changes to the approved production organisation [applicable until 6 March 2023] / 21.A.147 Changes in the production management system applicable from 7 March 2023 - Regulation (EU) 2022/201]

Regulation (EU) 2021/1088

(a) After the issue of a production organisation approval, each change to the approved production organisation that is significant to the showing of conformity or to the airworthiness and environmental protection characteristics of the product, part or appliance, particularly changes to the quality system, shall be approved by the competent authority. An application for approval shall be submitted in writing to the competent authority and the organisation shall demonstrate to the competent authority, before implementing the change, that it complies with this Subpart.

(b) The competent authority shall establish the conditions under which a production organisation approved under this Subpart may operate during such changes unless the competent authority determines that the approval should be suspended.

[applicable until 6 March 2023]

After the issue of a production organisation approval certificate, each change in the production management system that is significant for the demonstration of conformity or the airworthiness and environmental protection characteristics of the product, part or appliance, shall be approved by the competent authority before being implemented. The production organisation shall submit an application for approval to the competent authority demonstrating that it will continue to comply with this Annex.

[applicable from 7 March 2023 - Regulation (EU) 2022/201]

GM-ELA No 1 to 21.A.147 Changes to the approved production organisation

ED Decision 2019/003/R

The company should consider whether to verify the classification of changes with the competent authority.

The following changes are considered to be significant and require approval by the competent authority prior to the implementation of the changes:

— significant changes to the production capacity or methods;

— changes in the structure of the organisation, especially those parts of the organisation that are in charge of quality;

— a change of the accountable manager (AM) or of any other person nominated under point 21.A.145(c)(2);

— changes in the production or quality systems that may have an important impact on the conformity/airworthiness of each product, part or appliance;

— changes in the placement or control of significant subcontracted work or supplied parts;

— relocation of the major place of activities to a different geographic location, city, airfield or similar;

— changes in the scope of approval; and

— changes in ownership.

GM 21.A.147(a) Changes to the approved production organisation – Significant changes

ED Decision 2012/020/R

1. Changes to be approved by the competent authority include:

   — Significant changes to production capacity or methods.

   — Changes in the organisation structure especially those parts of the organisation in charge of quality.

   — A change of the accountable manager or of any other person nominated under 21.A.145(c)(2).

   — Changes in the production or quality systems that may have an important impact on the conformity/airworthiness of each product, part or appliance.

   — Changes in the placement or control of significant sub-contracted work or supplied parts.

2. To ensure that changes do not result in non-compliance with Part 21 Section A Subpart G it is in the interest of both the competent authority and the approval holder to establish a relationship and exchange information that will permit the necessary evaluation work to be conducted before the implementation of a change. This relationship should also permit agreement on the need for variation of the terms of approval (ref 21.A.143(a)(9)).

3. Where a change of name or ownership results in the issue of a new approval the investigation will normally take account of the competent authority's knowledge and information from the preceding approval.

4. Changes of location are addressed in 21.A.148 and changes of ownership in 21.A.149, change of scope of approval in 21.A.153.

21.A.148 Changes of location

Regulation (EU) No 748/2012

A change of the location of the manufacturing facilities of the approved production organisation shall be deemed of significance and therefore shall comply with point 21.A.147.

AMC 21.A.148 Changes of location – Management during change of location

ED Decision 2012/020/R

1. The relocation of any work, to an unapproved location, or a location with inappropriate scope of approval, constitutes a change of significance to the organisation and requires approval by the competent authority as prescribed in 21.A.147. An unapproved relocation will invalidate the production organisation approval, and may necessitate re-application for any similar approval required at the new location. However, suitable transitional arrangements may be agreed with the competent authority, in advance of the relocation, which can allow continuation of the approval.

2. When an organisation expands its facility to include a new production location or moves parts of its production to a new location the production organisation approval may continue in force, but the approval does not include the new location until the competent authority has indicated its satisfaction with the arrangements.

3. For a change in location, taking an extended period of time, suitable transitional arrangements would require preparation of a co-ordination plan for the removal. The plan must, at least, identify the following:

   (a) A clearly identified person, or group of persons, responsible for co-ordinating the removal and acting as focal point for communication with all parties, including the competent authority.

   (b) The basis of the co-ordination plan, e.g., whether by product or area.

   (c) Planned timing of each phase of relocation.

   (d) Arrangements for maintaining the standards of the approval up to the point where the production area is closed down.

   (e) Arrangements for verifying continued production quality upon resumption of work at the new location.

   (f) Arrangements for check and/or re-calibration of inspection aids or production tools and jigs before resuming production.

   (g) Procedures which ensure that goods are not released from the new location until their associated production and quality systems have been verified.

   (h) Arrangements for keeping the competent authority informed of progress with the relocation.

4. From the co-ordination plan, the competent authority can determine the points at which it wishes to conduct investigation.

5. If an agreed co-ordination plan is in operation, the competent authority will normally allow the existing approval to remain in force and will, where appropriate, grant an additional approval to cover the new address for the duration of the move.

GM-ELA No 1 to 21.A.148 Changes of location

ED Decision 2019/003/R

A change of location of the major place of activities to a different geographic location, city, airfield or similar is deemed to be of significance, and is treated in line with GM-ELA No 1 to 21.A.147.

No other changes related to the location of the company, including a relocation within one building, or to a neighbouring building on the same premises, or similar, are considered to be of significance, as long as the parameters that are critical to the environment, infrastructure or equipment remain the same, and are under the responsibility of the accountable manager (AM). Any other alterations will be addressed during the subsequent periodical authority oversight.

21.A.149 Transferability

Regulation (EU) No 748/2012

Except as a result of a change in ownership, which is deemed significant for the purposes of point 21.A.147, a production organisation approval is not transferable.

GM 21.A.149 and 21.A.249 Transferability

ED Decision 2021/001/R

GENERAL

A transfer of approval to another production or design organisation is, by default, excluded by points 21.A.149 or 21.A.249 respectively. These points only allow it exceptionally if it is a direct consequence of a transfer of ownership in an approved production or design organisation, which is then considered a significant change to the existing approval (to which point 21.A.147 or 21.A.247 applies).

As a consequence, and in order to apply this exception, the production or design organisation has to demonstrate to the competent authority the existence of a change in ownership which resulted in the fact that a different legal entity is now conducting the approved production or design functions while remaining effectively unchanged.

An example of such an exception is a change of ownership that leads to a re-registration of the organisation (supported by the appropriate certificate from the National Companies Registration Office or equivalent). In order to demonstrate that the organisation remains effectively unchanged, the organisation needs to demonstrate that there are no changes affecting the initial demonstration of compliance of the organisation with Subpart G or Subpart J. If, for instance, the change of ownership would, in addition, lead to a change of address, facilities, type of work, staff, accountable manager or persons nominated under points 21.A.145 or 21.B.245, then it is not an acceptable transfer situation; the exception does not apply in this case. A new investigation by the competent authority would be necessary. The new organisation would have to apply for its own approval. In such a case where the organisation applies for a new approval, the demonstration of compliance in accordance with points 21.A.135 or 21.A.235 may be limited to the demonstration that the changes in the organisation comply with the Subpart G or Subpart J requirements, while referring for the rest to the compliance demonstration of the previous approval holder.

A pure name change, where the ownership does not change, does not require a transfer of the approval. In this case, the natural or legal person that holds the approval remains the same. However, as a consequence of the name change, the approval document needs to be amended to reflect the new company name. This is a significant change, to which point 21.A.147 or 21.A.247 applies.

Another example of a transfer of ownership, which may be exceptionally accepted under points 21.A.149 or 21.A.249, may be the event of receivership (bankruptcy, insolvency or another equivalent

legal process). In this case, there is no change to the production or design organisation, except that the custodial responsibility for its property, including its tangible and intangible assets and rights, is transferred to a receiver or insolvency administrator. The receivership aims to continue the business of the same organisation.

21.A.151 Terms of approval

Regulation (EU) No 748/2012

The terms of approval shall identify the scope of work, the products or the categories of parts and appliances, or both, for which the holder is entitled to exercise the privileges under point 21.A.163.

Those terms shall be issued as part of a production organisation approval.

GM 21.A.151 Terms of approval – Scope and categories

ED Decision 2012/020/R

Terms of approval document(s) will be issued by the competent authority under 21.A.135 to identify the scope of work, the products, and/or categories for which the holder is entitled to exercise the privileges defined in 21.A.163.

The codes shown against each scope of work item are intended for use by the competent authority for purposes such as managing, administering and filing details of approvals. It may also assist in the production and publication of a list of approval holders.

The scope of work, the Products, Parts, or Appliances for which the POA holder is entitled to exercise the privileges defined in 21.A.163 will be described by the competent authority as follows:

FOR PRODUCTS:

1. General area, similar to the titles of the corresponding certification codes.
2. Type of Product, in accordance with the type-certificate.

FOR PARTS AND APPLIANCES:

1. General area, showing the expertise, e.g., mechanical, metallic structure.
2. Generic type, e.g., wing, landing gear, tyres.

SCOPE OF WORK		PRODUCTS/CATEGORIES
A1	Large Aeroplanes	State types
A2	Small Aeroplanes	‘
A3	Large Helicopters	‘
A4	Small Helicopters	‘
A5	Gyroplanes	‘
A6	Sailplanes	‘
A7	Motor Gliders	‘
A8	Manned Balloons	‘
A9	Airships	‘
A10	Light Sport Aeroplanes	‘
A11	Very Light Aeroplanes	‘
A12	Other	‘
B1	Turbine Engines	‘
B2	Piston Engines	‘
B3	APU’s	‘
B4	Propellers	

SCOPE OF WORK		PRODUCTS/CATEGORIES
C1	Appliances:	State appliance generic types (e.g., Tyres, Altimeter, etc.) Examples include: Avionic, Com/Nav/Pulse Computer System, Aircraft/Engine/Avionic Instruments, Mechanical/Electrical/Gyroscopic/Electronic Mechanical/Hydraulic/Pneumatic
C2	Parts:	State part generic types (e.g., Wing, Landing Gear, etc.) Examples include: Structural, Metallic/non-metallic Mechanical/Hydraulic/Pneumatic Electrical Electronic
D1	Maintenance	State aircraft types
D2	Issue of permit to fly	State aircraft types

21.A.153 Changes to the terms of approval

Regulation (EU) No 748/2012

Each change to the terms of approval shall be approved by the competent authority. An application for a change to the terms of approval shall be made in a form and manner established by the competent authority. The applicant shall comply with the applicable requirements of this Subpart.

AMC 21.A.153 Changes to the terms of approval – Application for a change to the terms of approval

ED Decision 2012/020/R

EASA Form 51 (see AMC No 1 to 21.B.240) must be obtained from the competent authority and completed in accordance with the procedures of the POE.

The information entered on the form is the minimum required by the competent authority to assess the need for change of the production organisation approval.

The completed form and an outline of the changed POE, and details of the proposed change to POA terms of approval must be forwarded to the competent authority.

AMC-ELA No 1 to 21.A.153 Changes to the terms of approval – Application for a change to the terms of approval

ED Decision 2019/003/R

EASA Form 51 (see AMC No 1 to 21.B.240) should be obtained from the competent authority and completed in accordance with the instructions provided by the competent authority. The information entered on the form is needed by the competent authority in order to assess whether the production organisation approval is to be amended. The completed form should be forwarded to the competent authority. The applicant and the competent authority can agree on whether the assessment for a change in approval can be completed via a desktop audit or through a surveillance audit.

21.A.157 Investigations

Regulation (EU) No 748/2012

A production organisation shall make arrangements that allow the competent authority to make any investigations, including investigations of partners and subcontractors, necessary to determine compliance and continued compliance with the applicable requirements of this Subpart.

[applicable until 6 March 2023 – Regulation (EU) 2022/201]

GM 21.A.157 Investigations – Arrangements

ED Decision 2012/020/R

The arrangements made by the applicant for, or holder of an approval under Part 21 Section A Subpart G should allow the competent authority to make investigations that include the complete production organisation including partners, sub-contractors and suppliers, whether they are in the State of the applicant or not.

The investigation may include; audits, enquiries, questions, discussions and explanations, monitoring, witnessing, inspections, checks, flight and ground tests and inspection of completed products, parts or appliances produced under the POA.

In order to maintain its confidence in the standards achieved by a POA holder or applicant the competent authority may make an investigation of a sample product part or appliance and its associated records, reports and certifications.

The arrangements should enable the organisation to give positive assistance to the competent authority and co-operate in performing the investigation during both initial assessment and for the subsequent surveillance to maintain the POA.

Co-operation in performing investigation means that the competent authority has been given full and free access to the facilities and to any information relevant to demonstrate compliance to Part 21 Section A Subpart G requirements, and assistance (personnel support, records, reports, computer data, etc., as necessary).

Assistance to the competent authority includes all appropriate means associated with the facilities of the production organisation to allow the competent authority to perform these investigations, such as the availability of a meeting room, office and personnel support, documentation and data, and communication facilities, all properly and promptly available as necessary.

The competent authority seeks to have an open relationship with the organisation and suitable liaison personnel should be nominated to facilitate this, including suitable representative(s) to accompany competent authority staff during visits not only at the organisations own facilities but also at sub-contractors, partners or suppliers.

GM1 21.A.139, 21.A.157, 21.A.239, 21.A.257, 21.B.120, 21.B.140, 21.B.220, 21.B.235 and 21.B.240 The use of information and communication technologies (ICT) for performing remote audits

ED Decision 2021/007/R

This GM provides technical guidance on the use of remote information and communication technologies (ICT) to support:

— competent authorities when overseeing regulated organisations;

— regulated organisations when conducting internal audits / monitoring compliance of their organisation with the relevant requirements, and when evaluating vendors, suppliers and subcontractors.

In the context of this GM:

— 'remote audit' means an audit that is performed with the use of any real-time video and audio communication tools in lieu of the physical presence of the auditor on-site; the specificities of each type of approval / letter of agreement (LoA) need to be considered in addition to the general overview (described below) when applying the 'remote audit' concept;

— 'auditing entity' means the competent authority or organisation that performs the remote audit;

— 'auditee' means the entity being audited/inspected (or the entity audited/inspected by the auditing entity via a remote audit);

It is the responsibility of the auditing entity to assess whether the use of remote ICT constitutes a suitable alternative to the physical presence of an auditor on-site in accordance with the applicable requirements.

The conduct of a remote audit

The auditing entity that decides to conduct a remote audit should describe the remote audit process in its documented procedures and should consider at least the following elements:

— The methodology for the use of remote ICT is sufficiently flexible and non-prescriptive in nature to optimise the conventional audit process.

— Adequate controls are defined and are in place to avoid abuses that could compromise the integrity of the audit process.

— Measures to ensure that the security and confidentiality are maintained throughout the audit activities (data protection and intellectual property of the organisation also need to be safeguarded).

Examples of the use of remote ICT during audits may include but are not limited to:

— meetings by means of teleconference facilities, including audio, video and data sharing;

— assessment of documents and records by means of remote access, in real time;

— recording, in real time during the process, of evidence to document the results of the audit, including non-conformities, by means of exchange of emails or documents, instant pictures, video or/and audio recordings;

— visual (livestream video) and audio access to facilities, stores, equipment, tools, processes, operations, etc.

An agreement between the auditing entity and the auditee should be established when planning a remote audit, which should include the following:

— determining the platform for hosting the audit;

— granting security and/or profile access to the auditor(s);

— testing platform compatibility between the auditing entity and the auditee prior to the audit;

— considering the use of webcams, cameras, drones, etc., when the physical evaluation of an event (product, part, process, etc.) is desired or is necessary;

— establishing an audit plan which will identify how remote ICT will be used and the extent of their use for the audit purposes to optimise their effectiveness and efficiency while maintaining the integrity of the audit process;

— if necessary, time zone acknowledgement and management to coordinate reasonable and mutually agreeable convening times;

— a documented statement of the auditee that they shall ensure full cooperation and provision of the actual and valid data as requested, including ensuring any supplier or subcontractor cooperation, if needed; and

— data protection aspects.

The following equipment and set-up elements should be considered:

— the suitability of video resolution, fidelity, and field of view for the verification being conducted;

— the need for multiple cameras, imaging systems, or microphones, and whether the person that performs the verification can switch between them, or direct them to be switched and has the possibility to stop the process, ask a question, move the equipment, etc.;

— the controllability of viewing direction, zoom, and lighting;

— the appropriateness of audio fidelity for the evaluation being conducted; and

— real-time and uninterrupted communication between the person(s) participating to the remote audit from both locations (on-site and remotely).

When using remote ICT, the auditing entity and the other persons involved (e.g. drone pilots, technical experts) should have the competence and ability to understand and utilise the remote ICT tools employed to achieve the desired results of the audit(s)/assessment(s). The auditing entity should also be aware of the risks and opportunities of the remote ICT used and the impacts they may have on the validity and objectivity of the information gathered.

Audit reports and related records should indicate the extent to which remote ICT have been used in conducting remote audits and the effectiveness of remote ICT in achieving the audit objectives, including any item that it has not been able to be completely reviewed.

GM-ELA No 1 to 21.A.157 Investigations – Arrangements

ED Decision 2019/003/R

The production organisation is encouraged to coordinate with the competent authority on any investigations that focus on issues that could result in unsafe conditions.

The production organisation grants to the competent authority full and free access to the facilities and to any information that is relevant to demonstrate the conformity of the product to the approved type design, and it provides assistance (personnel support, records, reports, computer data, etc., as necessary) to the competent authority during the investigation.

In this context, assistance to the competent authority includes providing all the appropriate means that are necessary to allow the competent authority to perform these investigations, such as making available a meeting room, office and personnel support, documentation and data, and communication facilities, which should all be properly and promptly made available as necessary.

21.A.158 Findings [applicable until 6 March 2023] / 21.A.158 Findings and observations [applicable from 7 March 2023 - Regulation (EU) 2022/201]

Regulation (EU) No 748/2012

(a) When objective evidence is found showing non-compliance of the holder of a production organisation approval with the applicable requirements of this Annex I (Part 21), the finding shall be classified as follows:

1. a level one finding is any non-compliance with this Annex I (Part 21) which could lead to uncontrolled non-compliances with applicable design data and which could affect the safety of the aircraft;

2. a level two finding is any non-compliance with this Annex I (Part 21) which is not classified as level one.

(b) A level three finding is any item where it has been identified, by objective evidence, to contain potential problems that could lead to a non-compliance under point (a).

(c) After receipt of notification of findings according to point 21.B.225,

1. in case of a level one finding, the holder of the production organisation approval shall demonstrate corrective action to the satisfaction of the competent authority within a period of no more than 21 working days after written confirmation of the finding;

2. in case of level two findings, the corrective action period granted by the competent authority shall be appropriate to the nature of the finding but in any case initially shall not be more than three months. In certain circumstances and subject to the nature of the finding the competent authority may extend the three months period subject to the provision of a satisfactory corrective action plan agreed by the competent authority;

3. a level three finding shall not require immediate action by the holder of the production organisation approval.

(d) In case of level one or level two findings, the production organisation approval may be subject to a partial or full limitation, suspension or revocation under point 21.B.245. The holder of the production organisation approval shall provide confirmation of receipt of the notice of limitation, suspension or revocation of the production organisation approval in a timely manner.

[applicable until 6 March 2023]

(a) After receipt of the notification of findings in accordance with point 21.B.225, the holder of the production organisation approval certificate shall:

1. identify the root cause(s) of, and contributing factor(s) to, the non-compliance;
2. define a corrective action plan;
3. demonstrate the implementation of the corrective action to the satisfaction of the competent authority.

(b) The actions referred to in point (a) shall be performed within the period agreed with that competent authority in accordance with point 21.B.225.

(c) The observations received in accordance with 21.B.225(e) shall be given due consideration by the holder of the production organisation approval certificate. The organisation shall record the decisions taken in respect of those observations.

[applicable from 7 March 2023 - Regulation (EU) 2022/201]

GM-ELA No 1 to 21.A.158 Findings

ED Decision 2019/003/R

An uncontrolled non-compliance with the applicable design data is a non-compliance that:

— cannot be discovered through systematic analysis; or

— prevents the identification of the affected products, parts, appliances, or materials.

A finding may only be classified as level 1 if the non-compliance has an effect on the condition of the aircraft.

Any failure to allow the competent authority to have access to facilities to conduct investigations should be classified as a level 1 finding.

It is recommended that the company should reach agreement with the competent authority on the administrative closure of level 2 findings at regular surveillance intervals.

GM No 1 to 21.A.158(a) Uncontrolled non-compliance with applicable design data

ED Decision 2012/020/R

An uncontrolled non-compliance with applicable design data is a non-compliance:

— that cannot be discovered through systematic analysis; or

— that prevents identification of affected products, parts, appliances, or material.

GM No 2 to 21.A.158(a) Examples of level one findings

ED Decision 2012/020/R

Examples of level one findings are non-compliances with any of the following points, that could affect the safety of the aircraft:

21.A.139, 21.A.145, 21.A.147, 21.A.148, 21.A.151, 21.A.163, 21.A.165(b), (c), (d), (e), (f) and (g).

It should be anticipated that a non-compliance with these points is only considered a level one finding when objective evidence has been found that this finding is an uncontrolled non-compliance that could affect the safety of the aircraft.

In addition, the failure to arrange for investigations under 21.A.157, in particular to obtain access to facilities, after denial of one written request should be classified as a level one finding.

21.A.159 Duration and continued validity

Regulation (EU) No 748/2012

(a) A production organisation approval shall be issued for an unlimited duration. It shall remain valid unless:

1. the production organisation fails to demonstrate compliance with the applicable requirements of this Subpart; or
2. the competent authority is prevented by the holder or any of its partners or subcontractors to perform the investigations in accordance with point 21.A.157; or
3. there is evidence that the production organisation cannot maintain satisfactory control of the manufacture of products, parts or appliances under the approval; or
4. the production organisation no longer meets the requirements of point 21.A.133; or
5. the certificate has been surrendered or revoked under point 21.B.245.

(b) Upon surrender or revocation, the certificate shall be returned to the competent authority.

[applicable until 6 March 2023]

(a) A production organisation approval certificate shall be issued for an unlimited period of time. It shall remain valid subject to the production organisation's compliance with all the following conditions:

1. the production organisation continues to comply with the applicable requirements of Regulation (EU) 2018/1139 and its delegated and implementing acts;
2. the competent authority is permitted by the production organisation or by any of its partners, suppliers or subcontractors to perform the investigations in accordance with point 21.A.9;
3. the production organisation is able to provide the competent authority with evidence showing that it maintains satisfactory control of the manufacture of products, parts and appliances under the approval;
4. the production organisation approval certificate has not been revoked by the competent authority under point 21.B.65, or surrendered by the production organisation.

(b) Upon surrender or revocation, the production organisation approval certificate shall be returned to the competent authority.

[applicable from 7 March 2023 - Regulation (EU) 2022/201]

GM 21.A.159(a)(3) Evidence of a lack of satisfactory control

ED Decision 2012/020/R

A positive finding by the competent authority of:

1. an uncontrolled non-compliance with type design data affecting the airworthiness of product part or appliance
2. an incident/accident identified as caused by POA holder
3. non-compliance with the POE and its associated procedures which could affect conformity of manufactured items to design data
4. insufficient competence of certifying staff
5. insufficient resources in respect of facilities, tools and equipment
6. insufficient means to ensure good production work standards
7. a lack of effective and timely response to prevent a recurrence of any of point 1 to 6.

21.A.163 Privileges

Regulation (EU) No 748/2012

Pursuant to the terms of approval issued under point 21.A.135, the holder of a production organisation approval may:

(a) perform production activities under this Annex I (Part 21);

(b) in the case of complete aircraft and upon presentation of a statement of conformity (EASA Form 52) under point 21.A.174, obtain an aircraft certificate of airworthiness and a noise certificate without further showing;

(c) in the case of other products, parts or appliances, issue authorised release certificates (EASA Form 1) without further showing;

(d) maintain a new aircraft that it has produced and issue a certificate of release to service (EASA Form 53) in respect of that maintenance;

(e) under procedures agreed with its competent authority for production, for an aircraft it has produced and when the production organisation itself is controlling under its POA the configuration of the aircraft and is attesting conformity with the design conditions approved for the flight, to issue a permit to fly in accordance with point 21.A.711(c) including approval of the flight conditions in accordance with point 21.A.710(b).

GM1 21.A.130, 21.A.163 and 21.A.165 Performance of tasks in real time for the issuance of an 'EASA Form 1' for prototype and new parts, appliances and products other than complete aircraft, using information and communication technologies (ICT)

ED Decision 2021/007/R

This GM provides technical guidance on the use of remote ICT to support the issuance of an 'EASA Form 1' for prototype and newly produced parts, appliances and products other than complete aircraft.

It is the responsibility of the production organisation to assess whether the use of remote ICT constitutes a suitable alternative to the physical inspection of the part, appliance or product in accordance with the applicable requirements. The production organisation that intends to use the remote ICT for such purposes should first discuss the feasibility aspects with its competent authority.

(a) Terminology

In the context of this GM, the following terminology is used:

— 'issue of an EASA Form 1' means the issuance of an EASA Form 1 under Part 21 Subpart G by a certifying staff, raise an EASA Form 1 under Part 21 Subpart F by an authorised person, and the validation of an EASA Form 1 under Part 21 Subpart F by a competent authority inspector, except in the case of issuance of an EASA Form 1 for the correction of error(s) on a previously issued certificate and for the recertification of an item from 'prototype' to 'new' provided that the design data has not changed;

— 'authorised staff' means certifying staff as defined in Part 21 Subpart G, and 'authorised person' and 'competent authority inspector' as defined in Part 21 Subpart F;

— 'item' means any part, appliance or product other than a complete aircraft;

— 'applicable design data' means non-approved design data for a prototype item and approved design data for a newly produced item;

— 'task' means any inspection, test and/or verification, as described in a documented procedure, which is needed to be performed by an authorised staff before signing an EASA Form 1;

— 'remote ICT' means any real-time video and audio communication tools using information and communication technologies (ICT) whose aim is to enable the performance of the task(s) by the authorised staff from a location different from that where the item is located (on-site).

(b) Regulatory context

The following entities may issue an EASA Form 1 for produced items in order to certify their conformity to the applicable design data and, for new items, their condition for safe operation:

— the holder of a letter of agreement (LoA) that is issued in accordance with Part 21 Subpart F (refer to point 21.A.130(a));

— the competent authority in the context of Part 21 Subpart F (refer to point 21.A.130(d));

— the holder of a production organisation approval (POA) in accordance with Part 21 Subpart G (refer to point 21.A.163(c)).

An EASA Form 1 has to be issued by appropriately qualified authorised staff. Part 21 does not require authorised staff to be on-site when issuing an EASA Form 1, nor how the production organisation and the competent authority shall determine whether the part/appliance/product other than a complete aircraft conforms to the applicable design data and, for a new item, is in a condition for safe operation. These should be detailed in a documented procedure accepted by the competent authority.

Part 21 requires:

- in point 21.A.130(d) that the competent authority validate the EASA Form 1 following inspections performed in accordance with 21.B.135(b) if it finds after the inspection that the product, part or appliance conforms to the applicable design data and is in condition for safe operation;
- in point 21.A.165(c) that the POA holder has to determine that:
  - other products, parts or appliances are complete and conform to the approved design data and are in a condition for safe operation before issuing an EASA Form 1;
  - other products, parts or appliances conform to the applicable data before issuing an EASA Form 1.

Typically, compliance with these requirements is ensured through the on-site presence of the authorised staff in order to guarantee they have appropriate access to the item, as needed.

However, compliance with these requirements may be also ensured in certain circumstances, determined as per the considerations described in point (c) below, by remotely conducting the tasks which are needed before the issuance of an EASA Form 1 by the use of remote ICT. The following considerations should be used as guidelines when the on-site presence of the authorised staff is to be replaced by virtual presence, using remote ICT.

(c) The use of remote ICT to support the issuance of an EASA Form 1

Remote ICT may have limitations that could render it unsuitable for some applications. Accordingly, careful consideration and risk management should be applied when determining when to use remote ICT. These considerations, listed below, are however not exhaustive and should not be treated as a checklist.

(1) General considerations

- As an overarching principle, it needs to be determined whether the nature of the tasks to be performed by the authorised staff allows the use of remote ICT.
- The facility where the item is located:
  - should be referred to in EASA Form 65 or EASA Form 55, directly or indirectly by reference to the corresponding section of the manual or production organisation exposition (POE); or
  - for a POA, should be a facility from where a POE procedure related to point 21.A.139(b)(1)(xv) authorises the issuance of an EASA Form 1.
- The complexity, novelty and safety criticality of the item to be released with the EASA Form 1 should be taken into account.
- The level of competence and experience of the personnel in the use of the particular procedures and equipment that will be used to perform the tasks before issuing EASA Form 1.

— Previous experience of the organisation / confidence in the organisation's inspection system / quality system / management system.

— The appropriateness of the inspection and test instruments and/or equipment, especially if used to evaluate qualitative aspects of a product, part or appliance.

(2) Equipment and set-up considerations

— The suitability of video resolution, fidelity, and field of view for the task being performed.

— The need for multiple cameras, imaging systems or microphones, and whether the person that performs or witnesses the tasks can switch between them, or direct them to be switched, and has the possibility to stop the process, ask a question, move the equipment, etc.

— The controllability of viewing direction, zoom, and lighting.

— The appropriateness of audio fidelity for the evaluation being conducted.

— Whether real-time, uninterrupted communication between the person(s) authorised to remotely witness the activity (authorised staff) and the personnel performing it exists at the location where the item is located.

— The need for unique testing devices or equipment (for example, fast-frame cameras, special lighting conditions, sensitive listening devices, mobile phones with cameras for HD video calls).

— Whether personnel have been adequately trained in the proper set-up, validation and use of the technology, tools and/or equipment to be used.

— The need for the recording of audio and video data, as well for its retention or for the retention of other information.

(3) Cybersecurity considerations

There are cases where the facilities where the tasks have to be performed are subject to strict security limitations. When using remote ICT for the tasks needed before issuing an EASA Form 1, it is the responsibility of the organisation to provide an equivalent level of security, therefore the person that is responsible for IT security within the organisation should concur to the ICT technology before proceeding.

(4) Documenting the use of the remote ICT

The documented processes (procedures) developed by the holder of a letter of agreement (LoA) or a POA should be accepted by the competent authority, and should describe the following:

— the risk assessment process required to determine the appropriateness of the remote ICT taking into account the above-mentioned considerations;

— the tasks to be performed, including preparation activities, inspections, tests, verifications to be done, personnel involved in the remote ICT activities and their level of competence;

— that it is necessary to guarantee that authorised staff have access to all necessary data (e.g. drawings, schematics, datasheets, etc.) they require in order to determine that the item conforms to the applicable design data, and how this can be ensured;

— how remote ICT will be used in real time (not pre-recorded) so that authorised staff may direct the performance of the tasks as if it were conducted in-person, on-site, with the aid of the equipment or the personnel supporting the activity at the remote location;

— the procedures for conducting a reinspection in case the equipment malfunctions or the process fails to yield acceptable results; a reinspection using remote ICT may be accomplished after correcting the malfunction or process, or by an actual on-site inspection;

— how authorised staff should record and communicate any difficulties or concerns regarding the process so that the organisation can improve its programme;

— how the use of the remote ICT will be documented in the required records; and

— how the organisation's IT security is ensured throughout the remote ICT process (data protection and intellectual property of the organisation also need to be safeguarded).

AMC No 1 to 21.A.163(c) Computer generated signature and electronic exchange of the EASA Form 1

ED Decision 2012/020/R

1. Submission to the competent authority

Any POA holder/applicant intending to implement an electronic signature procedure to issue EASA Form 1 and/or to exchange electronically such data contained on the EASA Form 1, should document it and submit it to the competent authority as part of the documents attached with its exposition.

2. Characteristics of the electronic system generating the EASA Form 1

The electronic system should:

— guarantee secure access for each certifying staff;

— ensure integrity and accuracy of the data certified by the signature of the Form and be able to show evidence of the authenticity of the EASA Form 1 (recording and record keeping) with suitable security, safeguards and backups;

— be active only at the location where the part is being released with an EASA Form 1;

— not permit to sign a blank form;

— provide a high degree of assurance that the data has not been modified after signature (if modification is necessary after issuance, i.e. re-certification of a part), a new form with a new number and reference to the initial issuance should be made); and

— provide for a 'personal' electronic signature, identifying the signatory. The signature should be generated only in the presence of the signatory.

An electronic signature means data in electronic form which are attached to or logically associated with other electronic data and which serve as a method of authentication and should meet the following criteria:

— it is uniquely linked to the signatory;

— it is capable of identifying the signatory;

— it is created using means that the signatory can maintain under their sole control.

The electronic signature is defined as an electronically generated value based on a cryptographic algorithm and appended to data in a way to enable the verification of the data's source and integrity.

POA holders/applicants are reminded that additional national and/or European requirements may need to be satisfied when operating electronic systems. 'Directive 1999/93/EC of the European Parliament and of the Council of 13 December 1999 on a Community framework for electronic signatures', as last amended may constitute a reference.

The electronic system should be based on a policy and management structure (confidentiality, integrity and availability), such as:

— administrators, signatories;

— scope of authorisation, rights;

— password and secure access, authentication, protections, confidentiality;

— track changes;

— minimum blocks to be completed, completeness of information;

— archives;

— etc.

The electronic system generating the EASA Form 1 may contain additional data such as:

— manufacturer code;

— customer identification code;

— workshop report;

— inspection results;

— etc.

3. Characteristics of the computer generated signature

To facilitate understanding and acceptance of the EASA Form 1 released with an electronic signature, the following statement should be in Block 13b: 'Electronic Signature on File'.

In addition to this statement, it is accepted to print or display a signature in any form such as a representation of the hand-written signature of the person signing (i.e. scanned signature) or their name.

When printing the electronic form, the EASA Form 1 should meet the general format as specified in Appendix I to Part 21. A watermark-type 'PRINTED FROM ELECTRONIC FILE' should be printed on the document.

When the electronic file contains a hyperlink to data, required to determine the airworthiness of the item(s), the data associated to the hyperlink, when printed, should be in a legible format and be identified as a reference from the EASA Form 1.

Additional information not required by the EASA Form 1 completion instructions may be added to the printed copies of EASA Form 1 as long as the additional data do not prevent a person from filling out, issuing, printing, or reading any portion of the EASA Form 1. This additional data should be provided only in block 12 unless it is necessary to include it in another block to clarify the content of that block.

4. Electronic exchange of the electronic EASA Form 1

The electronic exchange of the electronic EASA Form 1 should be accomplished on a voluntary basis. Both parties (issuer and receiver) should agree on electronic transfer of the EASA Form 1.

For that purpose, the exchange needs to include:

— all data of the EASA Form 1, including data referenced from the EASA Form 1;

— all data required for authentication of the EASA Form 1.

In addition, the exchange may include:

— data necessary for the electronic format;

— additional data not required by the EASA Form 1 completion instructions, such as manufacturer code, customer identification code.

The system used for the exchange of the electronic EASA Form 1 should provide:

— a high level of digital security; the data should be protected, unaltered or uncorrupted;

— traceability of data back to its source should be possible.

Trading partners wishing to exchange EASA Form 1 electronically should do so in accordance with these means of compliance stated in this document. It is recommended that they use an established, common, industry method such as Air Transport Association (ATA) Spec 2000 Chapter 16.

The applicant(s) is/are reminded that additional national and/or European requirements may need to be satisfied when operating the electronic exchange of the electronic EASA Form 1.

The receiver should be capable of regenerating the EASA Form 1 from the received data without alteration; if not the system should revert back to the paper system.

When the receiver needs to print the electronic form, refer to the subparagraph 3 above.

AMC2 21.A.163(c) Completion of EASA Form 1

ED Decision 2021/011/R

EASA Form 1 Block 8 ‘Part Number’

The part number as it appears on the item, is usually defined in the design data; however in the case of a kit of parts, media containing software or any other specific condition of supply may be defined in production data developed from design data. Information about the contents of the kit or media may be given in block 12 or in a separate document cross-referenced from block 12.

EASA Form 1 Block 12 ‘Remarks’

Examples of conditions which would necessitate statements in Block 12 are:

— When the certificate is used for prototype purposes the following statement must be entered at the beginning of block 12:

‘NOT ELIGIBLE FOR INSTALLATION ON IN-SERVICE TYPE-CERTIFICATED AIRCRAFT’.

— Re-certification of items from ‘prototype’ (conformity only to non-approved data) to ‘new’ (conformity to approved data and in a condition for safe operation) once the applicable design data is approved.

The following statement must be entered in block 12:

RE-CERTIFICATION OF ITEMS FROM 'PROTOTYPE' TO 'NEW':

THIS DOCUMENT CERTIFIES THE APPROVAL OF THE DESIGN DATA *[insert TC/STC number, revision level]*, DATED *[insert date if necessary for identification of revision status]*, TO WHICH THIS ITEM (THESE ITEMS) WAS (WERE) MANUFACTURED.

— When a new certificate is issued to correct error(s) the following statement must be entered in block 12:

'THIS CERTIFICATE CORRECTS THE ERROR(S) IN BLOCK(S) *[enter block(s) corrected]* OF THE CERTIFICATE *[enter original tracking number]* DATED *[enter original issuance date]* AND DOES NOT COVER CONFORMITY/ CONDITION/RELEASE TO SERVICE'.

Examples of data to be entered in this block as appropriate:

— For complete engines, a statement of compliance with the applicable emissions requirements current on the date of manufacture of the engine.

— For ETSO articles, state the applicable ETSO number.

— Modification standard.

— Compliance or non-compliance with airworthiness directives or service bulletins.

— Details of repair work carried out, or reference to a document where this is stated.

— Shelf-life data, manufacture date, cure date, etc.

— Information needed to support shipment with shortages or reassembly after delivery.

— References to aid traceability, such as batch numbers.

— In the case of an engine, if the competent authority has granted an exemption from the applicable engine environmental protection requirements, the record: 'ENGINE EXEMPTED FROM [*REFERENCE TO THE TYPE OF EMISSION*] EMISSIONS ENVIRONMENTAL PROTECTION REQUIREMENT'.

AMC-ELA No 1 to 21.A.163(c) Privileges to issue authorised release certificates

ED Decision 2019/003/R

Block 12 on any issued EASA Form 1 is filled with the following statement:

'ELIGIBLE ONLY FOR INSTALLATION ON AIRCRAFT THAT ARE NOT CLASSIFIED AS COMPLEX MOTOR POWERED AIRCRAFT, AND THAT ARE EITHER AEROPLANES WITHIN THE SCOPE OF CS-LSA, CS VLA OR CS-23 LEVEL 1, OR SAILPLANES OR POWERED SAILPLANES WITHIN THE SCOPE OF CS-22, OR BALLOONS, HOT AIR AIRSHIPS OR GAS AIRSHIPS THAT ARE ELA2 AIRCRAFT.'

AMC1 21.A.163(d) Privileges

ED Decision 2021/001/R

MAINTENANCE

The applicant may apply for terms of approval, which cover maintenance of a new aircraft that it has manufactured, as necessary to keep it in an airworthy condition, but not beyond the point at which the applicable operational rules require maintenance to be performed by an approved maintenance organisation. If the production organisation intends to maintain the aircraft beyond that point, it would have to apply for and obtain an appropriate maintenance approval.

When the competent authority is satisfied that the procedures required by 21.A.139 are satisfactory to control maintenance activities so as to ensure that the aircraft is airworthy, this capability will be stated in the terms of approval.

MAINTENANCE OF AIRCRAFT

Examples of such maintenance activities are:

— Preservation, periodic inspection visits, etc.

— Embodiment of a Service Bulletin.

— Application of airworthiness directives.

— Repairs.

— Maintenance tasks resulting from special flights.

— Maintenance tasks to maintain airworthiness during flight training, demo flights and other non-revenue flights.

Any maintenance activities must be recorded in the Aircraft Log Book. It must be signed by certifying staff for attesting the conformity of the work to the applicable airworthiness data.

In some cases the Aircraft Log Book is not available, or the production organisation prefers to use a separate form (for instance for a large work package or for delivery of the aircraft to the customer). In these cases, production organisations must use EASA Form 53 which must subsequently become part of the aircraft maintenance records.

MAINTENANCE OF COMPONENTS OUTSIDE THE POA CAPABILITY

Such a maintenance activity outside the capability of the aircraft POA holder may still be accomplished under the production approval of the original release organisation. In such circumstances, the engine(s), propeller(s), parts and appliances will require re-release in accordance with point 21.A.163(c) (EASA Form 1).

Records relevant to continued airworthiness or retirement lives, such as engine runs, flight hours, landings, etc., which affect part retirement of maintenance schedules must be specified on any re-release.

As an alternative the engine, propeller, part or appliance may be maintained by the holder of an approval in accordance with Part 145, classified and released as ‘used’.

AMC 21.A.163(e) Procedure for the issue of a permit to fly including approval of the flight conditions

ED Decision 2012/020/R

1. INTENT

This acceptable means of compliance provides means to develop a procedure for the issue of a permit to fly including approval of the flight conditions.

Each POA applicant or holder must develop its own internal procedure following this AMC, in order to obtain the privilege of 21.A.163(e) to issue permits to fly for an aircraft under procedures agreed with its competent authority for production, when the production organisation itself is controlling under its POA the configuration of the aircraft and is attesting conformity with the design conditions approved for the flight.

2. PROCEDURE FOR THE ISSUE OF A PERMIT TO FLY

2.1 Content

The procedure must address the following points:

— as relevant, in accordance with 21.A.710(b), the approval of flight conditions;

— conformity with approved conditions;

— issue of the permit to fly under the POA privilege;

— authorised signatories;

— interface with the local authority for the flight.

2.2 Approval of the flight conditions (when relevant)

The procedure must include the process to establish and justify the flight conditions, in accordance with 21.A.708 and how compliance with 21.A.710(c) is established, and include the EASA Form 18B as defined in AMC 21.A.709(b) for the approval under the POA privilege.

2.3 Conformity with approved conditions

The procedure must indicate how conformity with approved conditions is made, documented and attested by an authorised person.

2.4 Issue of the permit to fly under the POA privilege

The procedure must describe the process to prepare the EASA Form 20b and how compliance with 21.A.711(c) and (e) is established before signature of the permit to fly.

2.5 Authorised signatories

The person(s) authorised to sign the permit to fly under the privilege of 21.A.163(e) must be identified (name, signature and scope of authority) in the procedure, or in an appropriate document linked to the Production Organisation Exposition.

2.6 Interface with the local authority for the flight

The procedure must include provisions describing the communication with the local authority for compliance with the local requirements which are outside the scope of the conditions of 21.A.708(b) (see 21.A.711(e)).

21.A.165 Obligations of the holder

Regulation (EU) 2020/570

The holder of a production organisation approval shall:

(a) ensure that the production organisation exposition furnished in accordance with point 21.A.143 and the documents to which it refers, are used as basic working documents within the organisation;

(b) maintain the production organisation in conformity with the data and procedures approved for the production organisation approval;

(c) 1. determine that each completed aircraft conforms to the type design and is in condition for safe operation prior to submitting statements of conformity to the competent authority; or

2. determine that other products, parts or appliances are complete and conform to the approved design data and are in a condition for safe operation before issuing an EASA Form 1 to certify conformity to approved design data and condition for safe operation;

3. Additionally, in the case of environmental requirements determine that:

(i) the completed engine is in compliance with the applicable engine exhaust emissions requirements on the date of manufacture of the engine; and

(ii) the completed aeroplane is in compliance with the applicable CO_2 emissions requirements on the date its first certificate of airworthiness is issued.

4. determine that other products, parts or appliances conform to the applicable data before issuing an EASA Form 1 as a conformity certificate.

(d) record all details of work carried out;

(e) establish and maintain an internal occurrence reporting system in the interest of safety, to enable the collection and assessment of occurrence reports in order to identify adverse trends or to address deficiencies, and to extract reportable occurrences. This system shall include evaluation of relevant information relating to occurrences and the promulgation of related information;

(f) 1. report to the holder of the type-certificate or design approval, all cases where products, parts or appliances have been released by the production organisation and subsequently identified to have possible deviations from the applicable design data, and investigate with the holder of the type-certificate or design approval in order to identify those deviations which could lead to an unsafe condition;

2. report to the Agency and the competent authority of the Member State the deviations which could lead to an unsafe condition identified according to point (1). Such reports shall be made in a form and manner established by the Agency under point 21.A.3A(b)(2) or accepted by the competent authority of the Member State;

3. where the holder of the production organisation approval is acting as a supplier to another production organisation, report also to that other organisation all cases where it has released products, parts or appliances to that organisation and subsequently identified them to have possible deviations from the applicable design data;

(g) provide assistance to the holder of the type-certificate or design approval in dealing with any continuing airworthiness actions that are related to the products parts or appliances that have been produced;

(h) establish an archiving system incorporating requirements imposed on its partners, suppliers and subcontractors, ensuring conservation of the data used to justify conformity of the products, parts or appliances. Such data shall be held at the disposal of the competent authority and be retained in order to provide the information necessary to ensure the continuing airworthiness of the products, parts or appliances;

[points (d) to (h) applicable until 6 March 2023]

(d) provide assistance to the holder of the type-certificate or other design approval in dealing with any continuing airworthiness actions that are related to the products, parts or appliances that have been produced;

(e) where, under its terms of approval, the holder of a production organisation approval intends to issue a certificate of release to service, determine, prior to issuing the certificate, that each completed aircraft has been subjected to necessary maintenance and is in condition for safe operation;

(f) where applicable, under the privilege set out in point 21.A.163(e), determine the conditions under which a permit to fly can be issued;

(g) where applicable, under the privilege set out in point 21.A.163(e), establish compliance with points 21.A.711(c) and (e) before issuing an aircraft with a permit to fly;

(h) comply with Subpart A of this Section.

[points (d) to (h) applicable from 7 March 2023 - Regulation (EU) 2022/201]

(i) where, under its terms of approval, the holder issues a certificate of release to service, determine that each completed aircraft has been subjected to necessary maintenance and is in condition for safe operation, prior to issuing the certificate;

(j) where applicable, under the privilege of point 21.A.163(e), determine the conditions under which a permit to fly can be issued;

(k) where applicable, under the privilege of point 21.A.163(e), establish compliance with points 21.A.711(c) and (e) before issuing a permit to fly to an aircraft.

[points (i), (j) and (k) applicable until 6 March 2023]

GM1 21.A.130, 21.A.163 and 21.A.165 Performance of tasks in real time for the issuance of an 'EASA Form 1' for prototype and new parts, appliances and products other than complete aircraft, using information and communication technologies (ICT)

ED Decision 2021/007/R

This GM provides technical guidance on the use of remote ICT to support the issuance of an 'EASA Form 1' for prototype and newly produced parts, appliances and products other than complete aircraft.

It is the responsibility of the production organisation to assess whether the use of remote ICT constitutes a suitable alternative to the physical inspection of the part, appliance or product in accordance with the applicable requirements. The production organisation that intends to use the remote ICT for such purposes should first discuss the feasibility aspects with its competent authority.

(a) Terminology

In the context of this GM, the following terminology is used:

— 'issue of an EASA Form 1' means the issuance of an EASA Form 1 under Part 21 Subpart G by a certifying staff, raise an EASA Form 1 under Part 21 Subpart F by an authorised person, and the validation of an EASA Form 1 under Part 21 Subpart F by a competent authority inspector, except in the case of issuance of an EASA Form 1 for the correction of error(s) on a previously issued certificate and for the recertification of an item from 'prototype' to 'new' provided that the design data has not changed;

— 'authorised staff' means certifying staff as defined in Part 21 Subpart G, and 'authorised person' and 'competent authority inspector' as defined in Part 21 Subpart F;

— 'item' means any part, appliance or product other than a complete aircraft;

— 'applicable design data' means non-approved design data for a prototype item and approved design data for a newly produced item;

— 'task' means any inspection, test and/or verification, as described in a documented procedure, which is needed to be performed by an authorised staff before signing an EASA Form 1;

— 'remote ICT' means any real-time video and audio communication tools using information and communication technologies (ICT) whose aim is to enable the performance of the task(s) by the authorised staff from a location different from that where the item is located (on-site).

(b) Regulatory context

The following entities may issue an EASA Form 1 for produced items in order to certify their conformity to the applicable design data and, for new items, their condition for safe operation:

— the holder of a letter of agreement (LoA) that is issued in accordance with Part 21 Subpart F (refer to point 21.A.130(a));

— the competent authority in the context of Part 21 Subpart F (refer to point 21.A.130(d));

— the holder of a production organisation approval (POA) in accordance with Part 21 Subpart G (refer to point 21.A.163(c)).

An EASA Form 1 has to be issued by appropriately qualified authorised staff. Part 21 does not require authorised staff to be on-site when issuing an EASA Form 1, nor how the production organisation and the competent authority shall determine whether the part/appliance/product other than a complete aircraft conforms to the applicable design data and, for a new item, is in a condition for safe operation. These should be detailed in a documented procedure accepted by the competent authority.

Part 21 requires:

- in point 21.A.130(d) that the competent authority validate the EASA Form 1 following inspections performed in accordance with 21.B.135(b) if it finds after the inspection that the product, part or appliance conforms to the applicable design data and is in condition for safe operation;
- in point 21.A.165(c) that the POA holder has to determine that:
  - other products, parts or appliances are complete and conform to the approved design data and are in a condition for safe operation before issuing an EASA Form 1;
  - other products, parts or appliances conform to the applicable data before issuing an EASA Form 1.

Typically, compliance with these requirements is ensured through the on-site presence of the authorised staff in order to guarantee they have appropriate access to the item, as needed.

However, compliance with these requirements may be also ensured in certain circumstances, determined as per the considerations described in point (c) below, by remotely conducting the tasks which are needed before the issuance of an EASA Form 1 by the use of remote ICT. The following considerations should be used as guidelines when the on-site presence of the authorised staff is to be replaced by virtual presence, using remote ICT.

(c) The use of remote ICT to support the issuance of an EASA Form 1

Remote ICT may have limitations that could render it unsuitable for some applications. Accordingly, careful consideration and risk management should be applied when determining when to use remote ICT. These considerations, listed below, are however not exhaustive and should not be treated as a checklist.

(1) General considerations

- As an overarching principle, it needs to be determined whether the nature of the tasks to be performed by the authorised staff allows the use of remote ICT.
- The facility where the item is located:
  - should be referred to in EASA Form 65 or EASA Form 55, directly or indirectly by reference to the corresponding section of the manual or production organisation exposition (POE); or
  - for a POA, should be a facility from where a POE procedure related to point 21.A.139(b)(1)(xv) authorises the issuance of an EASA Form 1.
- The complexity, novelty and safety criticality of the item to be released with the EASA Form 1 should be taken into account.
- The level of competence and experience of the personnel in the use of the particular procedures and equipment that will be used to perform the tasks before issuing EASA Form 1.

— Previous experience of the organisation / confidence in the organisation's inspection system / quality system / management system.

— The appropriateness of the inspection and test instruments and/or equipment, especially if used to evaluate qualitative aspects of a product, part or appliance.

(2) Equipment and set-up considerations

— The suitability of video resolution, fidelity, and field of view for the task being performed.

— The need for multiple cameras, imaging systems or microphones, and whether the person that performs or witnesses the tasks can switch between them, or direct them to be switched, and has the possibility to stop the process, ask a question, move the equipment, etc.

— The controllability of viewing direction, zoom, and lighting.

— The appropriateness of audio fidelity for the evaluation being conducted.

— Whether real-time, uninterrupted communication between the person(s) authorised to remotely witness the activity (authorised staff) and the personnel performing it exists at the location where the item is located.

— The need for unique testing devices or equipment (for example, fast-frame cameras, special lighting conditions, sensitive listening devices, mobile phones with cameras for HD video calls).

— Whether personnel have been adequately trained in the proper set-up, validation and use of the technology, tools and/or equipment to be used.

— The need for the recording of audio and video data, as well for its retention or for the retention of other information.

(3) Cybersecurity considerations

There are cases where the facilities where the tasks have to be performed are subject to strict security limitations. When using remote ICT for the tasks needed before issuing an EASA Form 1, it is the responsibility of the organisation to provide an equivalent level of security, therefore the person that is responsible for IT security within the organisation should concur to the ICT technology before proceeding.

(4) Documenting the use of the remote ICT

The documented processes (procedures) developed by the holder of a letter of agreement (LoA) or a POA should be accepted by the competent authority, and should describe the following:

— the risk assessment process required to determine the appropriateness of the remote ICT taking into account the above-mentioned considerations;

— the tasks to be performed, including preparation activities, inspections, tests, verifications to be done, personnel involved in the remote ICT activities and their level of competence;

— that it is necessary to guarantee that authorised staff have access to all necessary data (e.g. drawings, schematics, datasheets, etc.) they require in order to determine that the item conforms to the applicable design data, and how this can be ensured;

— how remote ICT will be used in real time (not pre-recorded) so that authorised staff may direct the performance of the tasks as if it were conducted in-person, on-site, with the aid of the equipment or the personnel supporting the activity at the remote location;

— the procedures for conducting a reinspection in case the equipment malfunctions or the process fails to yield acceptable results; a reinspection using remote ICT may be accomplished after correcting the malfunction or process, or by an actual on-site inspection;

— how authorised staff should record and communicate any difficulties or concerns regarding the process so that the organisation can improve its programme;

— how the use of the remote ICT will be documented in the required records; and

— how the organisation's IT security is ensured throughout the remote ICT process (data protection and intellectual property of the organisation also need to be safeguarded).

AMC-ELA No 1 to 21.A.165(a);(b) Obligations of the holder – Basic working document

ED Decision 2019/003/R

The organisation should ensure that its personnel have access to, and are familiar with, the parts of the organisation's procedures that are applicable to their activities. This may be done, for example, by providing information to the personnel when updates of the documentation become available, or by making the changed documentation available at a location where the information is accessible to all the affected personnel.

Staff members of the production organisation who are involved in the production of products under the POA should be able to demonstrate their awareness of the information that is provided within the POE and the company manual. This can be achieved by any suitable means, and it does not necessarily require training sessions to be provided. Regular internal monitoring should be used to internally verify that the relevant staff members are aware of the relevant definitions.

The organisation should systematically conduct monitoring for compliance with this documentation. This monitoring can be via auditing, structured experience exchanges, regular quality meetings, brainstorming or lessons-learned sessions, project reviews at appropriate phases of the development, or other similar means.

GM 21.A.165(a) Obligations of the holder – Basic working document

ED Decision 2012/020/R

Compliance with the production organisation exposition (POE) is a prerequisite for obtaining and retaining a production organisation approval.

The organisation should make the POE available to its personnel where necessary for the performance of their duties. A distribution list should therefore be established. Where the POE mainly refers to separate manuals or procedures, the distribution of the POE could be limited.

The organisation should ensure that personnel have access to and are familiar with that part of the content of the POE or the referenced documents, which covers their activities.

Monitoring of compliance with the POE is normally the responsibility of the quality assurance function.

GM-ELA No 1 to 21.A.165(c) Obligations of the holder

ED Decision 2019/003/R

GM No 1 to 21.A.165(c) is applicable.

GM No 2 to 21.A.165(c) is applicable.

GM No 3 to 21.A.165(c) is applicable.

GM No 4 to 21.A.165(c) is applicable.

GM No 1 to 21.A.165(c) Obligations of the holder – Conformity of prototype models and test specimens

ED Decision 2012/020/R

21.A.33 requires determination of conformity of prototype models and test specimens to the applicable design data. The EASA Form 1 may be used as a conformity certificate as part of the assistance a POA holder provides to a design approval holder/applicant.

GM No 2 to 21.A.165(c) Obligations of holder – Conformity with type design

ED Decision 2012/020/R

Individual configurations are often based on the needs of the customer and improvements or changes which may be introduced by the type-certificate holder. There are also likely to be unintentional divergencies (concessions or non-conformances) during the manufacturing process. All these changes should have been approved by the design approval holder, or when necessary by the Agency.

GM No 3 to 21.A.165(c) Obligations of the holder – Condition for safe operation

ED Decision 2012/020/R

Before issue of the Statement of Conformity to the competent authority of the Member State of registry, the holder of a production organisation approval should make an investigation so as to be satisfied in respect of each of the items listed below. The documented results of this investigation should be kept on file by the POA holder. Certain of these items may be required to be provided (or made available) to the operator or owner of the aircraft (and in some cases the competent authority of the Member State of registry):

1. Equipment or modifications which do not meet the requirements of the State of manufacture but have been accepted by the competent authority of the importing country.
2. Identification of products, parts or appliances which:
   a) are not new;
   b) are furnished by the buyer or future operator (including those identified in 21.A.801 and 21.A.805).

3. Technical records which identify the location and serial numbers of components that have special traceability requirements for continued airworthiness purposes including those identified in 21.A.801 and 21.A.805.

4. Log book and a modification record book for the aircraft as required by the Agency.

5. Log books for products identified in 21.A.801 installed as part of the type design as required by the Agency.

6. A weight and balance report for the completed aircraft.

7. A record of missing items or defects which do not affect airworthiness these for example could be furnishing or BFE (Items may be recorded in a technical log or other suitable arrangement such that the operator and Agency are formally aware).

8. Product support information required by other implementing rules and associated CS or GM, such as a Maintenance Manual, a Parts Catalogue, or MMEL all of which are to reflect the actual build standard of the particular aircraft. Also an Electrical load analysis and a wiring diagram.

9. Records which demonstrate completion of maintenance tasks appropriate to the test flight flying hours recorded by the aircraft. These records should show the relationship of the maintenance status of the particular aircraft to the manufacturers recommended maintenance task list and the MRB document/report.

10. Details of the serviceability state of the aircraft in respect of a) the fuel and oil contents, b) provision of operationally required emergency equipment such as life rafts, etc.

11. Details of the approved interior configuration if different from that approved as part of the type design.

12. An approved Flight Manual which conforms to the build standard and modification state of the particular aircraft shall be available.

13. Show that inspections for foreign objects at all appropriate stages of manufacture have been satisfactorily performed.

14. The registration has been marked on the exterior of the aircraft as required by national legislation. Where required by national legislation fix a fireproof owners nameplate.

15. Where applicable there should be a certificate for noise and for the aircraft radio station.

16. The installed compass and or compass systems have been adjusted and compensated and a deviation card displayed in the aircraft.

17. Software criticality list.

18. A record of rigging and control surface movement measurements.

19. Details of installations which will be removed before starting commercial air transport operations (e.g., ferry kits for fuel, radio or navigation).

20. Where maintenance work has been performed under the privilege of 21.A.163(d) issue a release to service that includes a statement that the aircraft is in a condition for safe operation.

21. List of all applicable Service Bulletins and airworthiness directives that have been implemented.

GM No 4 to 21.A.165(c) Airworthiness Release or Conformity Certificate

ED Decision 2012/020/R

The EASA Form 1, when used as a release certificate as addressed in 21.A.165(c)(2) and (3), may be issued in two ways:

— As an airworthiness release, only when by virtue of the arrangement described in 21.A.133(b) and (c), it can be determined that the part conforms to the approved design data and is in a condition for safe operation.

— As a conformity certificate, only when by virtue of the arrangement described in 21.A.133(b) and (c), it can be determined that the part conforms to applicable design data which is not (yet) approved, for a reason that is indicated in Block 12. Parts released with an EASA Form 1 as a conformity certificate are not eligible for installation in a type-certificated aircraft.

The EASA Form 1 should only be used for conformity release purposes when it is possible to indicate the reason that prevents its issue as for airworthiness release purposes.

AMC1 21.A.165(c)(3) Applicable engine exhaust emissions requirements

ED Decision 2021/011/R

This determination is made according to the data provided by the engine type-certificate holder. It should be noted that the competent authority has the possibility to grant exemptions from these requirements as noted in Chapter 2, paragraph 2.1.1 and Chapter 4, paragraph 4.1.1 of Part III of Volume II of Annex 16 to the Chicago Convention.

When such an exemption is granted, the competent authority:

— takes into account the number of exempted engines that will be produced and their impact on the environment;

— considers imposing a time limit on the production of such engines; and

— issues an exemption document.

The Agency establishes and maintains a register, containing at least the engine serial number, and makes it publicly available.

ICAO Doc 9501 ‘Environmental Technical Manual’ Volume II provides guidance on the issuing of exemptions.

GM1 21.A.165(c)(3) Definitions of engine type certification date and production date

ED Decision 2021/011/R

Volume II of Annex 16 to the Chicago Convention contains three different references to applicability dates:

1. the ‘date of manufacture for the first individual production model’, which refers to the date when the type certificate is issued for the engine type or model;

2. the ‘date of application for a type certificate’, which refers to the application date to the certificating authority of the State of Design of the engine type certification; and

3. the ‘date of manufacture for the individual engine’, which refers to the production date of a specific engine serial number (date of EASA Form 1).

The third reference refers to the date of the first engine EASA Form 1 issued after the completion of the engine production pass-off test.

The third reference is used in the application of engine emissions production cut-off requirement which specifies a date after which all in-production engine models must meet a certain emissions standard.

21.A.165(c)(3) includes the production requirements for engine exhaust emissions.

ICAO Doc 9501 ‘Environmental Technical Manual’ Volume II provides guidance on these applicability dates.

AMC1 21.A.165(c)(4) Applicable aeroplane CO_2 emissions requirements

ED Decision 2021/011/R

This determination is made according to the data provided by the aeroplane type-certificate holder. This data should allow the determination of whether the aeroplane complies with the CO_2 emissions applicability requirements in Chapter 2, paragraph 2.1.1 of Part II of Volume III of Annex 16 to the Chicago Convention.

It should be noted that the competent authority has the possibility to grant exemptions as noted in Chapter 1, paragraph 1.11 and Chapter 2, paragraph 2.1.3 of Part II of Volume III of Annex 16 to the Chicago Convention.

When such an exemption is granted, the competent authority:

— takes into account the number of exempted aeroplanes that will be produced and their impact on the environment; and

— issues an exemption document.

The Agency establishes and maintains a register, containing at least the aeroplane serial number, and makes it publicly available.

ICAO Doc 9501 ‘Environmental Technical Manual’ Volume III provides guidance on the issuing of exemptions.

GM 21.A.165(d) and (h) Obligations of the holder – Recording and archiving system

ED Decision 2012/020/R

Records within a production environment satisfy two purposes. Firstly, they are required, during the production process to ensure that products, parts, or appliances are in conformity with the controlling data throughout the manufacturing cycle. Secondly, certain records of milestone events are needed to subsequently provide objective evidence that all prescribed stages of the production process have been satisfactorily completed and that compliance with the applicable design data has been achieved.

Therefore, the approved production organisation should implement a system for the compilation and retention of records during all stages of manufacture, covering short-term and long-term records appropriate to the nature of the product and its production processes.

The management of such information should be subject to appropriate procedures in the Quality System required by 21.A.139.

All forms of recording media are acceptable (paper, film, magnetic, ...) provided they can meet the required duration for archiving under the conditions provided.

The related organisation procedures should:

— Identify records to be kept.

— Describe the organisation of and responsibility for the archiving system (location, compilation, format) and conditions for access to the information (e.g., by product, subject).

— Control access and provide effective protection from deterioration or accidental damage.

— Ensure continued readability of the records.

— Demonstrate to the competent authority proper functioning of the records system.

— Clearly identify the persons involved in conformity determination.

— Define an archiving period for each type of data taking into account importance in relation to conformity determination subject to the following:

  a) Data which supports conformity of a product, part, or appliance should be kept for not less than three years from the issue date of the related Statement of Conformity or Authorised Release Certificate.

  b) Data considered essential for continuing airworthiness should be kept throughout the operational life of the product, part or appliance.

— Ensure that the recording and record-keeping system used by the partners, supplier and sub-contractors meet the objective of conformity of the product, part or appliance with the same level of confidence as for their own manufacture. They should define in each case who is to retain the record data (organisation or partner, supplier or sub-contractor). They should also define method for surveillance of the recording/record keeping system of the partners, suppliers or sub-contractors.

AMC-ELA No 1 to 21.A.165(d) Obligations of the holder – Recording and archiving system

ED Decision 2019/003/R

The POA holder should establish (in coordination with the design holder) which details are to be recorded to support the production process and to assist the design holder in dealing with continued airworthiness matters. The level of detail chosen for the production process records can have a substantial impact on the scope of any corrective actions.

AMC-ELA No 1 to 21.A.165(e);(f) Obligations of the holder – Reporting to the design holder

ED Decision 2019/003/R

The production organisation should record and evaluate any occurrences that may affect the safety of the product. Occurrence reports are collected and assessed in order to identify adverse trends, or to address deficiencies, and to extract reportable occurrences.

The production organisation should share all of its information that is related to potential product deficiencies, observed in the field or during or after production and delivery, with the design approval holder. The production and the design organisations should jointly determine any product design and / or corrective actions that may be required in the field.

The production organisation should have procedures in their quality system to determine whether a production-related deficiency results in an 'unsafe condition' in accordance with point 21.A.3B. This may be done by applying the method described in ASTM F2295, as follows:

— any occurrence that is categorised as an 'urgent safety of flight situation' in ASTM F2295 is considered to be an 'unsafe situation'; and

— any occurrence that falls into the category of a 'potential safety of flight bulletin' in ASTM F2295 is considered to have the potential to be an 'unsafe situation'. Further analysis is required, and possibly in coordination with the competent authority or with EASA.

Production deficiencies, in which the assessment leads to a potential 'unsafe situation', should be reported to the competent authority, within the terms and in the manner determined by the competent authority.

If the design and production entities both work within one consolidated team, then it is sufficient for either the design or the production entity to establish and maintain an internal occurrence reporting system that is accessible to both entities.

AMC-ELA No 1 to 21.A.165(g) Obligations of the holder – Continuing airworthiness assistance

ED Decision 2019/003/R

The production organisation should actively communicate with and assist the holder of the type certificate or the design approval when dealing with any continuing airworthiness actions that are related to the products, parts or appliances that have been produced. Compliance with this requirement can be shown by effective coordination regarding the corrective actions.

If the design and production entities both work within one consolidated team, assistance to the type design holder is expected to be provided as an intrinsic function of the cooperation, and no further evidence of the assistance needs to be provided.

AMC-ELA No 1 to 21.A.165(d);(h) Obligations of the holder – Recording and archiving system

ED Decision 2019/003/R

Records of production that have been used to determine conformity with the type design, such as those records mentioned in relation to point 21.A.165(c) and (d), should be archived and preserved using an adequate archiving method that should be defined within the company manual. Those records need to be held at the disposal of the competent authority, and need to be retained in order

to provide the information necessary to ensure the continuing airworthiness of the products, parts or appliances.

All forms of recording media are acceptable (paper, database, etc.), provided that the preservation of the records for the retention period for archiving can be ensured.

The production organisation should:

— define the records to be retained. If the type design defines which data needs to be recorded, the production organisation is not required to go beyond this data;

— implement a structured method of archiving. If IT-based ERP systems with workflow management are used, a detailed description of the system is not required;

— ensure that there is effective protection of the records from deterioration or accidental damage, e.g. by holding hard and soft copies in separate locations;

— ensure the continued readability of the records by selecting an adequate method of archiving;

— define a retention period for each type of data, taking into account that the determination of conformity is subject to the following:

    — data which supports the conformity of a product, part or appliance should be kept for not less than 3 years from the issue date of the related statement of conformity or authorised release certificate;

    — data considered to be essential for continuing airworthiness should be kept throughout the operational life of the product, part or appliance.

If the production organisation has decided that the records of any partner, supplier or subcontractor do not need to be supplied to the production organisation, then the production organisation should extend its requirements for record keeping to that partner, supplier or subcontractor.

SUBPART H — CERTIFICATES OF AIRWORTHINESS AND RESTRICTED CERTIFICATES OF AIRWORTHINESS

21.A.171 Scope

Regulation (EU) No 748/2012

This Subpart establishes the procedure for issuing airworthiness certificates.

21.A.172 Eligibility

Regulation (EU) No 748/2012

Any natural or legal person under whose name an aircraft is registered or will be registered in a Member State ('Member State of registry'), or its representative, shall be eligible as an applicant for an airworthiness certificate for that aircraft under this Subpart.

21.A.173 Classification

Regulation (EU) No 748/2012

Airworthiness certificates shall be classified as follows:

(a) certificates of airworthiness shall be issued to aircraft which conform to a type-certificate that has been issued in accordance with this Annex I (Part 21);

(b) restricted certificates of airworthiness shall be issued to aircraft:

1. which conform to a restricted type-certificate that has been issued in accordance with this Annex I (Part 21); or
2. which have been shown to the Agency to comply with specific airworthiness specifications ensuring adequate safety.

21.A.174 Application

Regulation (EU) 2021/699

(a) Pursuant to point 21.A.172, an application for an airworthiness certificate shall be made in a form and manner established by the competent authority of the Member State of registry.

(b) Each application for a certificate of airworthiness or restricted certificate of airworthiness shall include:

1. the class of airworthiness certificate applied for;
2. with regard to new aircraft:
   (i) a statement of conformity:
   - issued under point 21.A.163(b); or
   - issued under point 21.A.130 and validated by the competent authority; or
   - for an imported aircraft, a statement signed by the exporting authority that the aircraft conforms to a design approved by the Agency;
   (ii) a weight and balance report with a loading schedule and;

(iii) the flight manual, when required by the applicable certification specifications for the particular aircraft.

3. with regard to used aircraft originating from:

(i) a Member State, an airworthiness review certificate issued in accordance with Annex I (Part-M) or Annex Vb (Part-ML) to Commission Regulation (EU) No 1321/2014[1];

(ii) a non-member State:

— a statement by the competent authority of the State where the aircraft is, or was, registered, reflecting the airworthiness status of the aircraft on its register at the time of transfer;

— a weight and balance report with a loading schedule;

— the flight manual when such a manual is required by the airworthiness code for the aircraft;

— historical records to establish the production, modification and maintenance standard of the aircraft, including all limitations associated with a restricted certificate of airworthiness issued in accordance with point 21.B.327;

— a recommendation for the issuance of a certificate of airworthiness or restricted certificate of airworthiness and for an airworthiness review certificate pursuant to an airworthiness review in accordance with Annex I (Part-M) to Regulation (EU) No 1321/2014[2] or an airworthiness review certificate in accordance with Annex Vb (Part-ML) to Regulation (EU) No 1321/2014.

— the date on which the first certificate of airworthiness was issued and, if the standards of Volume III of Annex 16 to the Chicago Convention apply, the CO_2 metric value data

(c) Unless otherwise agreed, the statements referred to in points (b)(2)(i) and (b)(3)(ii) shall be issued no more than 60 days before presentation of the aircraft to the competent authority of the Member State of registry.

21.A.175 Language

Regulation (EU) No 748/2012

The manuals, placards, listings, and instrument markings and other necessary information required by applicable certification specifications shall be presented in one or more of the official language(s) of the European Union acceptable to the competent authority of the Member State of registry.

[1] Commission Regulation (EU) No 1321/2014 of 26 November 2014 on the continuing airworthiness of aircraft and aeronautical products, parts and appliances, and on the approval of organisations and personnel involved in these tasks (OJ L 362, 17.12.2014, p. 1).

[2] Commission Regulation (EU) No 1321/2014 of 26 November 2014 on the continuing airworthiness of aircraft and aeronautical products, parts and appliances, and on the approval of organisations and personnel involved in these tasks (OJ L 362, 17.12.2014, p. 1).

21.A.177 Amendment or modification

Regulation (EU) No 748/2012

An airworthiness certificate may be amended or modified only by the competent authority of the Member State of registry.

21.A.179 Transferability and re-issuance within Member States

Regulation (EU) 2020/570

(a) Where ownership of an aircraft has changed:

1. if it remains on the same register, the certificate of airworthiness, or the restricted certificate of airworthiness conforming to a restricted type-certificate only, shall be transferred together with the aircraft;

2. if the aircraft is registered in another Member State, the certificate of airworthiness, or the restricted certificate of airworthiness conforming to a restricted type-certificate only, shall be issued:

(i) upon presentation of the former certificate of airworthiness and of a valid airworthiness review certificate issued in accordance with Annex I (Part-M) or Annex Vb (Part-ML) of Regulation (EU) No 1321/2014;

(ii) when satisfying point 21.A.175.

(b) Where ownership of an aircraft has changed, and the aircraft has a restricted certificate of airworthiness not conforming to a restricted type-certificate, the airworthiness certificates shall be transferred together with the aircraft provided the aircraft remains on the same register, or issued only with the formal agreement of the competent authority of the Member State of registry to which it is transferred.

21.A.180 Inspections

Regulation (EU) No 748/2012

The holder of the airworthiness certificate shall provide access to the aircraft for which that airworthiness certificate has been issued upon request by the competent authority of the Member State of registry.

[applicable until 6 March 2023 – Regulation (EU) 2022/201]

21.A.181 Duration and continued validity

Regulation (EU) 2021/699

(a) An airworthiness certificate shall be issued for an unlimited duration. It shall remain valid subject to:

1. compliance with the applicable type-design and continued airworthiness requirements; and

[points (a) and (a)(1) applicable until 6 March 2023]

(a) An airworthiness certificate shall be issued for an unlimited period of time. It shall remain valid subject to compliance with all the following conditions:

1. the aircraft continues to comply with the applicable type design and continued airworthiness requirements; and

[points (a) and (a)(1) applicable from 7 March 2023 - Regulation (EU) 2022/201]

2. the aircraft remaining on the same register; and

3. the type-certificate or restricted type-certificate under which it is issued not being previously invalidated under point 21.A.51;

4. the certificate not being surrendered or revoked under point 21.B.330.

[applicable until 6 March 2023]

4. the certificate has not been revoked by the competent authority under point 21.B.65, or surrendered by the certificate holder.

[applicable from 7 March 2023 - Regulation (EU) 2022/201]

(b) Upon surrender or revocation, the certificate shall be returned to the competent authority of the Member State of registry.

21.A.182 Aircraft identification

Regulation (EU) No 748/2012

Each applicant for an airworthiness certificate under this Subpart shall demonstrate that its aircraft is identified in accordance with Subpart Q.

SUBPART I — NOISE CERTIFICATES

21.A.201 Scope

Regulation (EU) No 748/2012

This Subpart establishes the procedure for issuing noise certificates.

21.A.203 Eligibility

Regulation (EU) No 748/2012

Any natural or legal person under whose name an aircraft is registered or will be registered in a Member State (Member State of registry), or its representative, shall be eligible as an applicant for a noise certificate for that aircraft under this Subpart.

21.A.204 Application

Regulation (EU) No 748/2012

(a) Pursuant to point 21.A.203, an application for a noise certificate shall be made in a form and manner established by the competent authority of the Member State of registry.

(b) Each application shall include:

1. with regard to new aircraft:

(i) a statement of conformity:

— issued under point 21.A.163(b); or

— issued under point 21.A.130 and validated by the competent authority; or

— for an imported aircraft, a statement, signed by the exporting authority that the aircraft conforms to a design approved by the Agency; and

(ii) the noise information determined in accordance with the applicable noise requirements;

2. with regard to used aircraft:

(i) the noise information determined in accordance with the applicable noise requirements; and

(ii) historical records to establish the production, modification, and maintenance standard of the aircraft.

(c) Unless otherwise agreed, the statements referred to in point (b)(1) shall be issued no more than 60 days before presentation of the aircraft to the competent authority of the Member State of registry.

21.A.207 Amendment or modification

Regulation (EU) No 748/2012

A noise certificate may be amended or modified only by the competent authority of the Member State of registry.

21.A.209 Transferability and re-issuance within Member States

Regulation (EU) No 748/2012

Where ownership of an aircraft has changed:

(a) if the aircraft remains on the same register, the noise certificate shall be transferred together with the aircraft; or

(b) if the aircraft moves to the register of another Member State, the noise certificate shall be issued upon presentation of the former noise certificate.

21.A.210 Inspections

Regulation (EU) No 748/2012

The holder of the noise certificate shall provide access to the aircraft for which that noise certificate has been issued upon request by the competent authority of the Member State of registry or by the Agency for inspection.

[applicable until 6 March 2023 – Regulation (EU) 2022/201]

21.A.211 Duration and continued validity

Regulation (EU) 2021/699

(a) A noise certificate shall be issued for an unlimited duration. It shall remain valid subject to:

1. compliance with the applicable type-design, environmental protection and continued airworthiness requirements; and

[points (a) and (a)(1) applicable until 6 March 2023]

(a) A noise certificate shall be issued for an unlimited period of time. It shall remain valid subject to compliance with all the following conditions:

1. the aircraft continues to comply with the applicable type design and continued airworthiness requirements; and

[points (a) and (a)(1) applicable from 7 March 2023 - Regulation (EU) 2022/201]

2. the aircraft remaining on the same register; and

3. the type-certificate or restricted type-certificate under which it is issued not being previously invalidated under point 21.A.51;

4. the certificate not being surrendered or revoked under point 21.B.430.

[applicable until 6 March 2023]

(4) the certificate has not been revoked by the competent authority under point 21.B.65, or surrendered by the certificate holder.

[applicable from 7 March 2023 - Regulation (EU) 2022/201]

(b) Upon surrender or revocation, the certificate shall be returned to the competent authority of the Member State of registry.

SUBPART J — DESIGN ORGANISATION APPROVAL

21.A.231 Scope

Regulation (EU) 2019/897

This Subpart establishes the procedure for the approval of design organisations and rules governing the rights and obligations of applicants for, and holders of, such approvals. In this Subpart, the references to type-certificates include type-certificates and restricted type-certificates.

AMC-ELA No 1 to 21.A.231 Scope

ED Decision 2019/003/R

The AMC-ELA in this Subpart provides acceptable means of compliance for a design organisation approval for organisations that design:

— aeroplanes that are within the scope of CS-LSA, CS-VLA and CS-23 level 1;

— sailplanes or powered sailplanes that are within the scope of CS-22; or

— balloons, hot-air airships and gas airships that are ELA2 aircraft,

that are not classified as complex motor-powered aircraft, as well as products or articles that are used on these types of aircraft.

GM-ELA No 1 to 21.A.231 Scope

ED Decision 2019/003/R

The AMC indicated with 'AMC-ELA' and the GM related to them (as indicated with 'GM-ELA') provide an alternative set of AMC and GM to the other available AMC and GM.

The AMC-ELA provide acceptable means to meet the requirements of Subpart J for small, non-complex organisations that make designs for aircraft as specified in AMC-ELA No 1 to 21.A.231.

If the AMC-ELA are not applicable (for instance, for small, non-complex organisations that make designs for other low-risk products outside the scope of AMC-ELA No 1 to 21.A.231, e.g. light rotorcraft, CS 23 Level 2, etc.), the applicant is not obliged to use any other available AMC. Switching to those other available AMC will not necessarily provide a means of compliance that is proportionate. Since AMC are a means, but not the only means of showing compliance, applicants and approval holders can also propose alternative means of compliance. These alternative means may use the AMC ELA as a baseline, and complement them with additional or more stringent controls, processes or methods. This allows a gradual increase in the level of detail of the established procedures and the thoroughness of the implemented tools for DOA approval. This enables the introduction of a proportionate approach that is commensurate with the kind of product and its associated risk as a function of the complexity of the organisation and the risk and performance of the product. The use of AMC-ELA as a baseline for DOA outside the applicability of that AMC-ELA is therefore considered to be an appropriate starting point.

Complementing elements need to be detailed, documented and recorded to a level where the occurrence of any repetitive non-conformities is mitigated. Applicants and approval holders need to demonstrate to the competent authority in such cases that those additional means meet the requirements that are appropriate for the complexity of these designs.

GM-ELA No 2 to 21.A.231 Scope – AMC-ELA as a complete, self-contained set of AMC

ED Decision 2019/003/R

The AMC-ELA provide an alternative, complete and self-contained set of AMC. Small, non-complex organisations that design products or articles within the scope of AMC-ELA can use AMC-ELA instead of the existing AMC to Subpart J.

The AMC-ELA in full determine the acceptable means of compliance with Subpart J. The applicant should implement each of the means defined here on an individual basis. If the specific characteristics of the organisation render individual elements of the AMC-ELA impracticable or not applicable, alternative means with specific resolutions should be agreed with the competent authority. A justification needs to be developed that shows that the means applied meet the requirements of Part-21. A trustful relationship between the typically very compact team of the applicant and the competent authority should be developed. The applicant is strongly encouraged to ask the relevant contact person at the competent authority for mutual clarification of any questionable item, if there is any doubt.

GM-ELA No 3 to 21.A.231 Scope – Explanation of terms used in AMC-ELA

ED Decision 2019/003/R

'A method needs to be practised'

When the AMC-ELA uses the term 'a method needs to be practised', it means that the applicant can show what is actually done in order to comply with a requirement in a practical and systematic way. The applicant is not expected to have an excessively detailed documented procedure. As a baseline, documented procedures for such 'practised methods' can be limited to a 'declaration' of the principles that are considered within the practised method that refers to the system used. For example, a declaration such as 'Document control is ensured by workflow management as part of the IT-based Document Management System (DMS)' may be provided. This is acceptable when evidence is provided by work results, by demonstration of actual behaviour during surveillance activities, or by similar means. When the actual behaviour continuously shows that it does not satisfy the needs of the requirements, a more detailed documented procedure may need to be implemented to rectify the situation.

Delegation of tasks and responsibilities

AMC-ELA differentiates between the delegation of tasks, and the delegation of responsibilities. For small and simple organisations, the delegation of responsibilities to specific and separate organisational positions can create overly burdensome administrative processes that do not reflect the operational reality.

The AMC-ELA accepts that tasks can be delegated, while the responsibility formally stays with the delegator. This can increase efficiency, and it offers the possibility to simplify procedures. A typical example is when the head of the design organisation (HDO) delegates tasks, while keeping the responsibility associated with this task.

If this situation is identified with respect to the individual requirements, this may significantly reduce the effort required for documentation, and it allows streamlined methods to be practised.

21.A.233 Eligibility

Regulation (EU) No 748/2012

Any natural or legal person ('organisation') shall be eligible as an applicant for an approval under this Subpart

(a) in accordance with points 21.A.14, 21.A.112B, 21.A.432B or 21.A.602B; or

(b) for approval of minor changes or minor repair design, when requested for the purpose of obtaining privileges under point 21.A.263.

21.A.234 Application

Regulation (EU) No 748/2012

Each application for a design organisation approval shall be made in a form and manner established by the Agency and shall include an outline of the information required by point 21.A.243, and the terms of approval requested to be issued under point 21.A.251.

AMC-ELA No 1 to 21.A.234 Application

ED Decision 2019/003/R

EASA Form 80 should be obtained from the EASA website and completed by the head of the design organisation (HDO). The completed form should be submitted to EASA, accompanied by a copy of the company's registration.

21.A.235 Issue of design organisation approval

Regulation (EU) No 748/2012

An organisation shall be entitled to have a design organisation approval issued by the Agency when it has demonstrated compliance with the applicable requirements under this Subpart.

21.A.239 Design assurance system [applicable until 6 March 2023] / 21.A.139 Design management system [applicable from 7 March 2023 - Regulation (EU) 2022/201]

Regulation (EU) No 69/2014

(a) The design organisation shall demonstrate that it has established and is able to maintain a design assurance system for the control and supervision of the design, and of design changes, of products, parts and appliances covered by the application. This design assurance system shall be such as to enable the organisation:

1. to ensure that the design of the products, parts and appliances or the design change thereof, comply with the applicable type-certification basis, the applicable operational suitability data certification basis and environmental protection requirements; and

2. to ensure that its responsibilities are properly discharged in accordance with:

   (i) the appropriate provisions of this Annex I (Part 21); and

   (ii) the terms of approval issued under point 21.A.251;

3. to independently monitor the compliance with, and adequacy of, the documented procedures of the system. This monitoring shall include a feed-back system to a person or a group of persons having the responsibility to ensure corrective actions.

(b) The design assurance system shall include an independent checking function of the showings of compliance on the basis of which the organisation submits compliance statements and associated documentation to the Agency.

(c) The design organisation shall specify the manner in which the design assurance system accounts for the acceptability of the parts or appliances designed or the tasks performed by partners or subcontractors according to methods which are the subject of written procedures.

[applicable until 6 March 2023]

(a) The design organisation shall establish, implement and maintain a design management system that includes a safety management element and a design assurance element with clearly defined accountability and lines of responsibility throughout the organisation.

(b) The design management system shall:

1. correspond to the size of the organisation and to the nature and complexity of its activities, taking into account the hazards and associated risks inherent in those activities;

2. be established, implemented and maintained under the accountability of a single manager appointed pursuant to point 21.A.245(a).

(c) As part of the safety management element of the design management system, the design organisation shall:

1. establish, implement and maintain a safety policy and the corresponding related safety objectives;

2. appoint key safety personnel in accordance with point 21.A.245(b);

3. establish, implement and maintain a safety risk management process that includes the identification of aviation safety hazards entailed by its activities, their evaluation and the management of the associated risks, including taking actions to mitigate the risks and verify their effectiveness;

4. establish, implement and maintain a safety assurance process that includes:

(i) the measurement and monitoring of the organisation's safety performance;

(ii) the management of changes in accordance with points 21.A.243(c) and 21.A.247;

(iii) the principles for the continuous improvement of the safety management element;

5. promote safety in the organisation through:

(i) training and education;

(ii) communication;

6. establish an occurrence reporting system in accordance with point 21.A.3A in order to contribute to continuous improvement of safety.

(d) As part of the design assurance element of the design management system, the design organisation shall:

1. establish, implement and maintain a system for the control and supervision of the design, and of design changes and repairs, of products, parts and appliances covered by the terms of approval; that system shall:

(i) include an airworthiness function responsible for ensuring that the design of products, parts and appliances, or the design changes and repairs, comply with the applicable type-certification basis, the applicable operational suitability data certification basis and the environmental protection requirements;

(ii) ensure that the design organisation properly discharges its responsibilities in accordance with this Annex and with the terms of approval issued under point 21.A.251;

2. establish, implement and maintain an independent verification function on the basis of which the design organisation demonstrates compliance with the applicable airworthiness, operational suitability data and environmental protection requirements;

3. specify the manner in which the design management system accounts for the acceptability of the parts or appliances that are designed or the tasks that are performed by its partners or subcontractors according to the methods which are the subject of written procedures.

(e) The design organisation shall establish, as part of the design management system, an independent monitoring function to verify compliance of the organisation with the relevant requirements of this Annex as well as the compliance with and adequacy of the design management system. Monitoring shall include feedback to the person or the group of persons referred to in point 21.A.245(b) and to the manager referred to in point 21.A.245(a) to ensure, where necessary, the implementation of corrective action.

(f) If the design organisation holds one or more additional organisation certificates within the scope of Regulation (EU) 2018/1139, the design management system may be integrated with that required under the additional certificate(s).

[applicable from 7 March 2023 - Regulation (EU) 2022/201]

AMC-ELA No 1 to 21.A.239(a) Design assurance system – Definition

ED Decision 2019/003/R

The term ‘design assurance system (DAS)’, in the context of the AMC-ELA to Subpart J, refers to those elements of product development and certification that ensure the control and supervision of the initial design, of changes or repairs to the design, and its continued airworthiness with respect to the applicable type certification basis, the operational suitability data certification basis and the environmental protection requirements. Therefore, elements to be considered as part of the DAS are:

— the generation, iteration, EASA acceptance and maintenance of the certification programme;

— the demonstration of compliance and its verification within the design organisation;

— the declaration of compliance provided by the design organisation to EASA;

— monitoring functions to ensure the continued airworthiness of the certified product, including the resulting activities;

— independent system monitoring of the compliance with, and the adequacy of, the documented procedures of this system.

A typical development process will include a number of additional activities, such as preliminary design, project management elements (a PDR, CDR, etc.), or development activities (test platforms, demonstrators, feasibility studies), etc., that are not part of the DAS, even when elements of the DAS form specific milestones in the development path. In the context of this Subpart, those other activities are consequently excluded from the assessment of the DAS, even when elements of the DAS are also applied to those activities.

AMC-ELA No 2 to 21.A.239(a) Design assurance system – Ensuring compliance

ED Decision 2019/018/R

An acceptable design assurance system (DAS) contains the elements of the DAS that are described in AMC-ELA No 1 to 21.A.239(a), and which are further broken down below into the following activities:

- The generation, iteration, EASA acceptance and maintenance of the certification programme:
    - ensure that adequate product, change or repair specifications have been generated and are available to support a meaningful certification programme;
    - generate a certification programme that is tailored to the product, or change, or repair specified, and that identifies:
        - the product and the kinds of operations envisaged, or the changes to them;
        - the proposed certification basis;
        - a description of how compliance will be demonstrated, with the proposed means of compliance and any selected guidance material, if this is not clearly visible from the compliance/means of compliance (MOC) checklist;
        - a compliance checklist, together with the means of compliance that is intended to be used, and any guidance material;
        - the relevant CVE to be used on the project;
        - the programme milestones for interaction with EASA;
    - iteration of the certification programme, until EASA acceptance is reached;
    - monitoring of the workflow in line with the certification programme:
        - updating the certification programme and seeking a new acceptance by EASA, if necessary;
        - ensuring that the relevant staff members adhere to the certification programme when they conduct certification activities;
    - structured methods for the classification of changes, repairs or deviations by using an adequate process flow, or by following adequate decision forms (matrices) if there are major changes that directly support the change-related certification programme.
- Demonstration of compliance and its verification within the design organisation:
    - ensure that a complete set of data has been developed in order to form a complete and concise definition of the type design;
    - ensure that the selected method for defining the type design allows for adequate configuration management, for the purposes of design and design variant management, and for the later management of production;

- ensure that the handling of changes within the type investigation process and post-TC/-STC is controlled, coordinated and repeatable;
- ensure that analyses and tests have been conducted by using methods that are adequate to support the means of compliance that was defined, and that they are documented to allow their use for showing compliance;
- ensure that the formal demonstration of compliance for the intended type design, change design or repair design, including the generation of compliance statements with respect to any relevant certification requirement, is provided;
- conduct the formal verification of compliance for the intended type design, change design or repair design, including the verification of compliance statements with respect to any relevant certification requirement by an independent person nominated within the design organisation (i.e. a compliance verification engineer (CVE));
- ensure that the applicable product-relevant documentation, such as the AFM, ICA or MMEL, is established and provided;
- ensure that prototypes or test specimens, produced by a connected production organisation, or by any prototyping facilities of the design organisation itself, are used on the basis of an adequate configuration verification against the design definitions specified for the relevant test;
- ensure that coordinated flight test activities with adequate risk mitigations are performed.

— Monitoring functions to ensure the continued airworthiness of the certified product:

- conduct monitoring of any significant events;
- ensure that all reported occurrences and events are investigated and classified;
- ensure that there is occurrence reporting for events that are classified as ‘safety-critical’ and that constitute unsafe or potentially unsafe conditions;
- ensure that information and instructions are generated and published, as applicable, and that information or instructions and any related design activity are verified by following the same principles as for any type design, change design or repair design activity/documentation.

— Declaration of compliance by the design organisation to EASA:

- verification of the completeness of the compliance verification and type design documentation as defined within the certification programme by the head of airworthiness (HoA);
- issuing of the declaration of compliance by the head of the design organisation (HDO) to EASA, subsequent to the satisfactory completion of the verification of compliance against all the applicable certification requirements.

AMC-ELA No 3 to 21.A.239(a) Design assurance system – Discharge of responsibilities

ED Decision 2019/018/R

As part of the design assurance system (DAS), at least the following responsibilities have to be allocated:

— Head of the design organisation (HDO):

  — control of budget and staffing to ensure the completion of the development and certification tasks of the design organisation approval (DOA) within reasonable time frames and workload. The HDO is ultimately responsible for providing the necessary resources for the proper functioning of the design organisation;

  — issuing the declaration of compliance (see points 21.A.15(b), 21.A.15(c), 21.A.20(c) and 21.A.20(d)) with the applicable type-certification basis, the applicable operational suitability data certification basis and the environmental protection requirements after verifying the satisfactory completion of the type investigation;

  — ensuring that adequate and timely information is provided to EASA in matters that affect the DOA.

— Compliance verification engineer (CVE):

  — conducting the verification that compliance has been demonstrated with the applicable type certification basis, the applicable operational suitability data certification basis and the environmental protection requirements and its technical content within its subject matter of nomination. Verification of a compliance demonstration implicitly includes the approval of all the referenced and supporting documents. The applicant may elect to separately document the approval of the individual supporting documents, e.g. by having a cover sheet with the supporting documents in the attachment.

— Head of airworthiness (HoA):

  — ensuring the verification of compliance with the applicable type-certification basis, the applicable operational suitability data certification basis and the environmental protection requirements by adequately qualified staff and that the activities that are necessary to demonstrate compliance are complete;

  — ensuring that a design organisation handbook (DOH) is prepared and updated as required;

  — ensuring that there is adequate and timely interaction with the authorities and internally on all relevant matters with respect to type certification, changes to type certificates, the approval of repairs and the approval of the design organisation. This includes the coordination that the required documentation (type design documents, compliance documentation and service documents including manuals/ICA and the MMEL, if applicable) is adequately established;

  — ensuring that the continued airworthiness activities are properly performed;

  — accepting the certification programme and the approval of the classification of changes/repairs, minor changes/repairs, major repairs, and flight conditions and the issue of PtFs under the relevant privileges;

  — providing verification to the HDO that all the activities required for the type investigation have been properly completed.

— Independent system monitoring (ISM):

  — monitoring that the implemented DAS is adequate, and that it is complied with, by using structured experience exchanges, regular quality meetings, brainstorming or lessons-learned sessions, project reviews at appropriate phases of the development, planned and unplanned audits, or other similar means;

  — conducting independent ISM activities and directly reporting any observations to the HDO.

AMC-ELA No 4 to 21.A.239(a) Design assurance system – Independent system monitoring

ED Decision 2019/003/R

Monitoring that the implemented design assurance system (DAS) is adequate, and that it is complied with, is done by systematic means. The systematic means of monitoring may include structured experience exchanges, regular design meetings, brainstorming or lessons-learned sessions, project reviews at appropriate phases of the development, or by other similar means.

Audits may be one element of monitoring. When implemented, audits should be conducted as combined process/product (project) audits that focus on the implemented key processes or methods practised according to the DOH (or the equivalent document), and the audits should also allow the design organisation to find ways to become more efficient by continuous improvement.

Systematic means of monitoring are coordinated by the ISM, under the responsibility of the HDO, and with a direct reporting line to the HDO. If the ISM is not independent of the activity that is monitored, especially if the HDO also fulfills the role of the head of ISM, the HDO may involve auditors that have adequate knowledge of the applicable requirements and of the implemented DAS. The system monitoring function may be undertaken by the existing quality assurance organisation, provided that it has adequate reporting lines to the HDO.

GM1 21.A.139, 21.A.157, 21.A.239, 21.A.257, 21.B.120, 21.B.140, 21.B.220, 21.B.235 and 21.B.240 The use of information and communication technologies (ICT) for performing remote audits

ED Decision 2021/007/R

This GM provides technical guidance on the use of remote information and communication technologies (ICT) to support:

— competent authorities when overseeing regulated organisations;

— regulated organisations when conducting internal audits / monitoring compliance of their organisation with the relevant requirements, and when evaluating vendors, suppliers and subcontractors.

In the context of this GM:

— ‘remote audit’ means an audit that is performed with the use of any real-time video and audio communication tools in lieu of the physical presence of the auditor on-site; the specificities of each type of approval / letter of agreement (LoA) need to be considered in addition to the general overview (described below) when applying the ‘remote audit’ concept;

— ‘auditing entity’ means the competent authority or organisation that performs the remote audit;

— ‘auditee’ means the entity being audited/inspected (or the entity audited/inspected by the auditing entity via a remote audit);

It is the responsibility of the auditing entity to assess whether the use of remote ICT constitutes a suitable alternative to the physical presence of an auditor on-site in accordance with the applicable requirements.

The conduct of a remote audit

The auditing entity that decides to conduct a remote audit should describe the remote audit process in its documented procedures and should consider at least the following elements:

— The methodology for the use of remote ICT is sufficiently flexible and non-prescriptive in nature to optimise the conventional audit process.

— Adequate controls are defined and are in place to avoid abuses that could compromise the integrity of the audit process.

— Measures to ensure that the security and confidentiality are maintained throughout the audit activities (data protection and intellectual property of the organisation also need to be safeguarded).

Examples of the use of remote ICT during audits may include but are not limited to:

— meetings by means of teleconference facilities, including audio, video and data sharing;

— assessment of documents and records by means of remote access, in real time;

— recording, in real time during the process, of evidence to document the results of the audit, including non-conformities, by means of exchange of emails or documents, instant pictures, video or/and audio recordings;

— visual (livestream video) and audio access to facilities, stores, equipment, tools, processes, operations, etc.

An agreement between the auditing entity and the auditee should be established when planning a remote audit, which should include the following:

— determining the platform for hosting the audit;

— granting security and/or profile access to the auditor(s);

— testing platform compatibility between the auditing entity and the auditee prior to the audit;

— considering the use of webcams, cameras, drones, etc., when the physical evaluation of an event (product, part, process, etc.) is desired or is necessary;

— establishing an audit plan which will identify how remote ICT will be used and the extent of their use for the audit purposes to optimise their effectiveness and efficiency while maintaining the integrity of the audit process;

— if necessary, time zone acknowledgement and management to coordinate reasonable and mutually agreeable convening times;

— a documented statement of the auditee that they shall ensure full cooperation and provision of the actual and valid data as requested, including ensuring any supplier or subcontractor cooperation, if needed; and

— data protection aspects.

The following equipment and set-up elements should be considered:

— the suitability of video resolution, fidelity, and field of view for the verification being conducted;

— the need for multiple cameras, imaging systems, or microphones, and whether the person that performs the verification can switch between them, or direct them to be switched and has the possibility to stop the process, ask a question, move the equipment, etc.;

— the controllability of viewing direction, zoom, and lighting;

— the appropriateness of audio fidelity for the evaluation being conducted; and

— real-time and uninterrupted communication between the person(s) participating to the remote audit from both locations (on-site and remotely).

When using remote ICT, the auditing entity and the other persons involved (e.g. drone pilots, technical experts) should have the competence and ability to understand and utilise the remote ICT tools employed to achieve the desired results of the audit(s)/assessment(s). The auditing entity should also be aware of the risks and opportunities of the remote ICT used and the impacts they may have on the validity and objectivity of the information gathered.

Audit reports and related records should indicate the extent to which remote ICT have been used in conducting remote audits and the effectiveness of remote ICT in achieving the audit objectives, including any item that it has not been able to be completely reviewed.

GM1 21.A.239(a) Design assurance system

ED Decision 2021/007/R

1. Purpose

This GM outlines some basic principles and objectives of 21.A.239(a).

2. Definitions

2.1 The design assurance system is the organisational structure, responsibilities, procedures and resources to ensure the proper functioning of the design organisation.

2.2 The design assurance means all those planned and systematic actions necessary to provide adequate confidence that the organisation has the capability

— to design products or parts in accordance with the applicable CS and environmental protection requirements,

— to demonstrate and verify the compliance with these CS and environmental protection requirements, and

— to demonstrate to the Agency this compliance.

2.3 The 'Type Investigation' means the tasks of the organisation in support of the type-certificate, supplemental type-certificate or other design approval processes necessary to demonstrate and verify and to maintain compliance with the applicable CS and environmental protection requirements.

3. Design Assurance

The complete process, starting with the CS and environmental protection requirements and product specifications and culminating with the issuing of a type-certificate, is shown in the diagram on Figure 1. This identifies the relationship between the design, the Type Investigation and design assurance processes.

Effective design assurance demands a continuing evaluation of factors that affect the adequacy of the design for intended applications, in particular that the product, or part, complies with applicable CS and environmental protection requirements and will continue to comply after any change.

Two main aspects should therefore be considered:

— How the planned and systematic actions are defined and implemented, from the very beginning of design activities up to continued airworthiness activities;

— How these actions are regularly evaluated and corrective actions implemented as necessary.

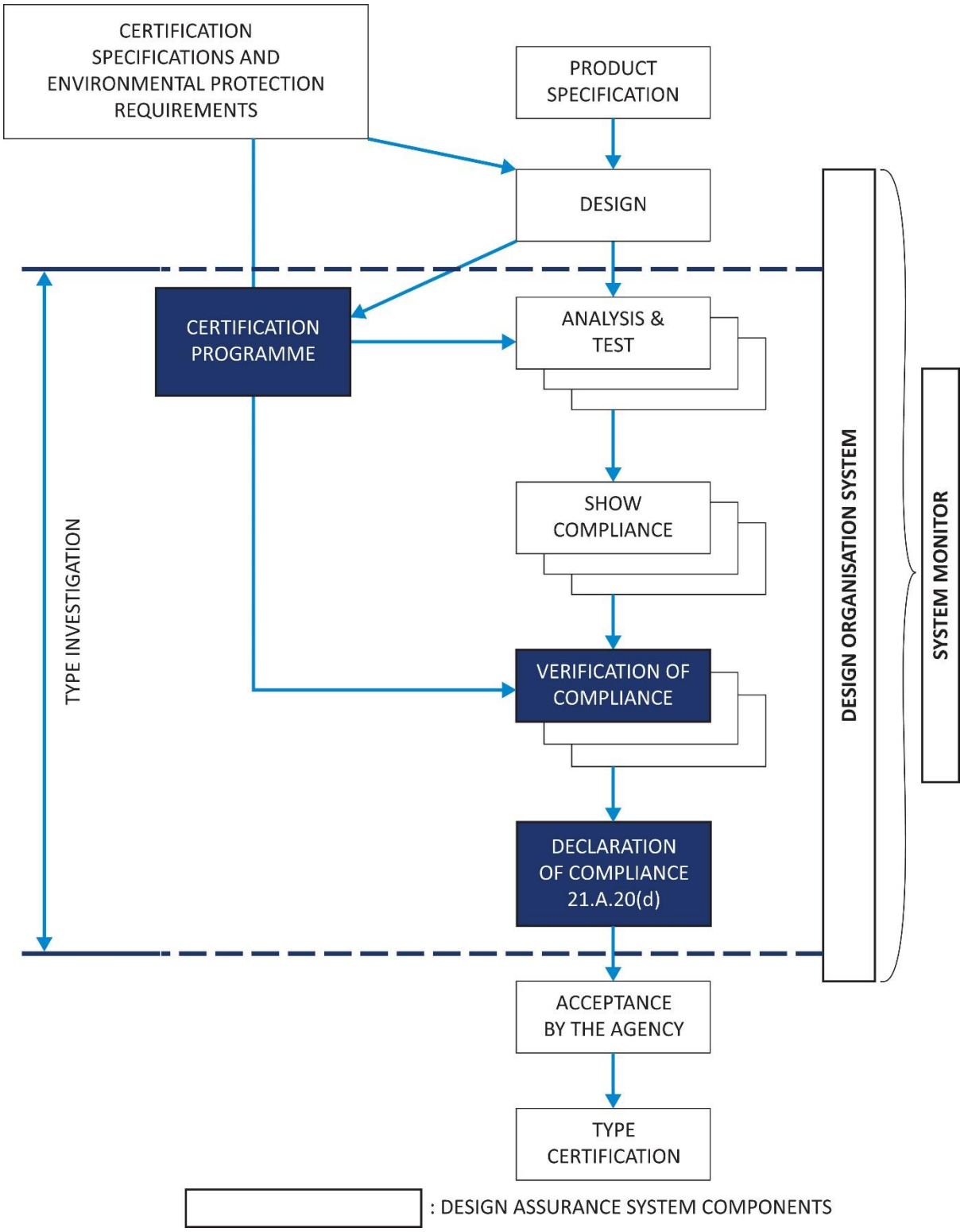


Figure 1 - RELATIONSHIPS BETWEEN DESIGN, DESIGN ASSURANCE AND TYPE INVESTIGATION

3.1 Planned and Systematic Actions

For design organisations carrying out Type Investigation of products, the planned and systematic actions should cover the following tasks and procedures should be defined accordingly:

3.1.1 General

a. To issue or, where applicable, supplement or amend the handbook in accordance with 21.A.243, in particular to indicate the initiation of design activities on a product.

b. To assure that all instructions of the Handbook are adhered to.

c. To conduct Type Investigation.

d. To nominate staff as 'compliance verification engineers' responsible to approve compliance documents as defined in paragraph 3.1.3.

e. To nominate personnel belonging to the Office of Airworthiness responsible as defined in paragraph 3.1.4.

f. In the case of an applicant for a supplemental type-certificate, to obtain the agreement of the type-certificate holder for the proposed supplemental type-certificate to the extent defined in 21.A.115.

g. To ensure full and complete liaison between the type design organisation and related organisations having responsibility for products manufactured to the type-certificate.

h. To provide the assurance to the Agency that prototype models and test specimens adequately conform to the type design (see 21.A.33(b)(1)).

3.1.2 Chief Executive and Head of design organisation (or his or her Deputy)

a. The Chief Executive should provide the necessary resources for the proper functioning of the design organisation.

b. The Head of the design organisation, or an authorised representative, should sign a declaration of compliance (see 21.A.20(d) and 21.A.97(a)(3)) with the applicable CS and environmental protection requirements after verification of satisfactory completion of the Type Investigation. In accordance with 21.A.20(e) and 21.A.97(a)(4), his or her signature on the declaration of compliance confirms that the procedures as specified in the handbook have been followed (see also GM 21.A.265(b)).

c. The functions of Chief Executive and Head of the design organisation may be performed by the same person.

3.1.3 Compliance Verification

a. Approval by signing of all compliance documents, including test programmes and data, necessary for the verification of compliance with the applicable CS and environmental protection requirements as defined in the certification programme.

b. Approval of the technical content (completeness, technical accuracy...), including any subsequent revisions, of the manuals approved by the Agency (Aircraft Flight Manual, the Airworthiness Limitations section of the Instructions for Continued Airworthiness and the Certification Maintenance Requirements (CMR) document, where applicable).

3.1.4 Office of Airworthiness

a. Liaison between the design organisation and the Agency with respect to all aspects of the certification programme.

b. Ensuring that a handbook is prepared and updated as required in 21.A.243.

c. Co-operation with the Agency in developing procedures to be used for the type certification process.

d. Issuing of guidelines for documenting compliance.

e. Co-operation in issuing guidelines for the preparation of the manuals required by the applicable implementing rules, Service Bulletins, drawings, specifications, and standards.

f. Ensuring procurement and distribution of applicable CS and environmental protection requirements and other specifications.

g. Co-operating with the Agency in proposing the type-certification basis

h. Interpretation of CS and environmental protection requirements and requesting decisions of the Agency in case of doubt.

i. Advising of all departments of the design organisation in all questions regarding airworthiness, operational suitability, environmental protection approvals and certification.

j. Preparation of the certification programme and co-ordination of all tasks related to Type Investigation in concurrence with the Agency.

k. Regular reporting to the Agency about Type Investigation progress and announcement of scheduled tests in due time.

l. Ensuring co-operation in preparing inspection and test programmes needed for demonstration of compliance.

m. Establishing the compliance checklist and updating for changes.

n. Checking that all compliance documents are prepared as necessary to demonstrate compliance with all CS and environmental protection requirements, as well as for completeness, and signing for release of the documents.

o. Checking the required type design definition documents described in 21.A.31 and ensuring that they are provided to the Agency for approval when required.

p. Preparation, if necessary, of a draft for a type-certificate data sheet and/or type-certificate data sheet modification.

q. Providing verification to the head of the design organisation that all activities required for Type Investigation have been properly completed.

r. Approving the classification of changes in accordance with 21.A.91 and granting the approval for minor changes in accordance with 21.A.95(b).

s. Monitoring of significant events on other aeronautical products as far as relevant to determine their effect on airworthiness or operational suitability of products being designed by the design organisation.

t. Ensuring co-operation in preparing Service Bulletins and the Structural Repair Manual, and subsequent revisions, with special attention being given to the manner in which the contents affect airworthiness and environmental protection and granting the approval on behalf of the Agency.

u. Ensuring the initiation of activities as a response to a failure (accident/incident/in-service occurrence) evaluation and complaints from the operation and providing of information to the Agency in case of airworthiness or operational suitability impairment (continuing airworthiness and continued operational suitability).

v. Advising the Agency with regard to the issue of airworthiness directives in general based on Service Bulletins.

w. Ensuring that the manuals approved by the Agency, including any subsequent revisions (the Aircraft Flight Manual, MMEL, the Airworthiness Limitations section of the Instructions for Continued Airworthiness and the Certification Maintenance Requirements (CMR) document, where applicable) are checked to determine that they meet the respective requirements, and that they are provided to the Agency for approval.

3.1.5 Maintenance and Operating Instructions

(a) Ensuring the preparation and update of all maintenance and operating/installation instructions (including instructions for continued airworthiness and service bulletins) needed to maintain airworthiness (continuing airworthiness) in accordance with the relevant CSs. For that purpose, the applicant should:

— establish the list of all documents it produces to comply with CS 2X.1581 and with the Appendix referred to in CS 2X.1529, CS-E 20/25 or CS-P 30/40;

— establish a system to collect in-service experience to be used for the improvement of the instructions;

— define its procedures and the organisation to produce and issue these documents, under the obligation of point 21.A.265(h); the procedures should cover:

  — preparation, including the format and language (available industrial standards can be referred to and used);

  — proofreading (checking for clarity, readability, typos, etc.);

  — verification of technical consistency with the corresponding approved change(s), repair(s) or approved data, including the effectivity, description, effects on airworthiness and environmental protection, especially when limitations are changed;

— verification of feasibility in practical applications when relevant and feasible; and

— responsibilities and authorised signatories.

Note: The compliance verification, as described in 3.1.3(b) of this GM, applies to the manuals approved by EASA (aircraft flight manual, the Airworthiness Limitations section of the Instructions for Continued Airworthiness (ICA) and the Certification Maintenance Requirements (CMR) document, where applicable). For the other ICA or other maintenance instructions, the procedure required by 3.1.5(a) provides a sufficient level of verification and does not require specific compliance verification unless, in line with 21.A.90C, additional work to demonstrate compliance is required. In this case, where additional showing of compliance is required, points 21.A.91 to 21.A.109 apply and then the independent checking function of the showings of compliance as per 21.239(b) applies.

(b) In accordance with points 21.A.6, 21.A.7 and, where applicable, 21.A.609, ensuring that these documents are made available in accordance with point 21.A.7(b).

3.1.6 Operational Suitability Data (OSD)

(a) Ensuring the preparation and update of all OSD in accordance with the relevant CSs. For that purpose, the applicant should:

— establish the list of all the documents it produces to comply with CS-MMEL or CS-GEN-MMEL, CS-FCD, CS-CCD, CS-SIMD and CS-MCSD, as applicable;

— define its procedures and the organisation to produce and issue these documents under the obligation of point 21.A.265(h); these procedures should cover the aspects described in 3.1.5(a) above.

(b) In accordance with points 21.A.6 and 21.A.7, ensuring that these documents are provided to all affected operators and training organisations and all involved authorities.

3.2 Continued effectiveness of the design assurance system. The organisation should establish the means by which the continuing evaluation (system monitoring) of the design assurance system will be performed in order to ensure that it remains effective.

GM No. 2 to 21.A.239(a) Design assurance system for minor changes to type design or minor repairs to products

ED Decision 2012/020/R

1. Purpose

This GM outlines some basic principles and objectives in order to comply with 21.A.239(a) for organisations designing only minor changes to type design or minor repairs to products.

2. Design assurance system

The design assurance system should include the following:

— an organisational structure to:

— control the design

— demonstrate compliance with applicable CS and environmental protection requirements

— independently check demonstrations of compliance

— liaise with the Agency

— continuously evaluate the design organisation

— control sub-contractors

— procedures and responsibilities associated with the functions listed above, taking due account of Part 21 requirements applicable to design and approval of minor changes to type design or minor repairs to products.

AMC 21.A.239(a)(3) Design assurance system – Independent system monitoring

ED Decision 2012/020/R

The system monitoring function required by 21.A.239(a)(3) may be undertaken by the existing quality assurance organisation when the design organisation is part of a larger organisation.

AMC 21.A.239(b) Design assurance system – Independent checking function of the demonstration of compliance

ED Decision 2012/020/R

1. The independent checking function of the demonstration of compliance should consist of the verification by a person not creating the compliance data. Such person may work in conjunction with the individuals who prepare compliance data.

2. The verification should be shown by signing compliance documents, including test programmes and data.

3. For a product, there is normally only one compliance verification engineer nominated for each relevant subject. A procedure should cover the non-availability of nominated persons and their replacement when necessary.

4. For STC cases, when compliance statement and associated documentation are produced by the TC holder, and when these data are approved under the system of the authority of TC holder, then the STC applicant does not need to provide, within its own DOA, the independent checking function required in 21.A.239(b) for these data.

AMC-ELA No 1 to 21.A.239(b) Design assurance system – Independent checking function

ED Decision 2019/003/R

The design assurance system (DAS) defines methods to ensure there is an independent verification of the compliance demonstration on the basis of which the organisation submits compliance statements and associated documentation to EASA.

Compliance verification therefore means the approval of all those compliance documents that are necessary for the verification of compliance with the applicable type-certification basis, the applicable operational suitability data certification basis and the environmental protection requirements, as defined in the certification programme. This shall include all the relevant aspects that ultimately lead to the showing of compliance, and therefore, for example, it may need to be extended to test programmes or data analysis reports if the higher-level compliance report itself does not adequately cover all the necessary levels of detail.

Compliance verification is provided by the approval of documented information by a person who did not create the approved data, and who acts as a compliance verification engineer (CVE). Approval is given after the completeness and technical accuracy of the report and the correctness of the derived statement of compliance have been verified. The approval must be documented in such a way that the date and the person who gives approval can be identified.

CVEs are nominated for specific scopes of responsibility. The structure of these scopes is defined by the applicant, and it should follow a logical structure, commensurate with the type of product, such as, for example, by disciplines (e.g. structures, flight, electrical system, etc.), by a set of CS requirements (Subpart B, Subpart C, etc.), by a (set of) ATA chapters (ATA 27 Flight Controls, ATA 32 Landing Gear, ATA 51 Structures, etc.), or by any other appropriate logic. For the kind of product addressed by this AMC, it is explicitly acceptable for the scope of the CVE to be broken down into only a few different disciplines, commensurate with the kind of product.

Compliance verification as part of the DAS is the only task within the DOA in which the creation and the CVE check of documents is mandatorily performed by different persons. It is acceptable for one person to hold multiple CVE nominations. For small companies, it is acceptable for persons who hold other functions, such as the CE, HDO and HOA, to also be nominated as design engineers and CVEs, provided they have the proper competence.

AMC-ELA No 1 to 21.A.239(c) Design assurance system – Acceptability of tasks performed by external parties

ED Decision 2019/003/R

The organisation is responsible for ensuring that the type design of the product complies with the applicable type-certification basis, the applicable operational suitability data certification basis and the environmental protection requirements. This includes the determination that components designed by, or tasks performed by, external parties are acceptable. To discharge this responsibility, the DO has to implement documented methods that ensure the compliance of the final product, and that make use of these components or task results, prior to making the final declaration of compliance.

One acceptable means to ensure this is whether the CVE(s) of the applicant conducts (conduct) the verification of compliance, in line with the definitions of the DAS of the applicant. As the verification of compliance remains with the applicant, no specific qualification measures are required other than to pragmatically verify the capabilities of the external party, and to ensure that the required level of detail is supplied to enable the work results to be adequately verified. The capability of an external party should be verified if more complex activities are subcontracted.

If a DOA subcontracts the CVE function to an external party that conducts the task, but does not hold its own DOA, then the same requirements for the qualification, nomination and documentation of qualification and nomination apply to the person who is nominated as a CVE as are defined in the design organisation handbook (DOH) of the contracting DOA. The availability of all the relevant information for the subcontracted CVE to perform their duties is ensured by the applicant. The relevant contract defines that when acting as a CVE, the external person acts on behalf of, and with direct reporting to, the applicant's head of airworthiness (HoA). The person who acts as a CVE is named in this contract, or in an attachment to it.

Alternatively, if an organisation with a DOA obtains design substantiation data from a subcontractor that also holds a DOA, and the work that is conducted is within the approved scope of this subcontractor DOA, the subcontractor's design data becomes acceptable when the contracting DOA has verified that the results adequately meet the needs of the product under development. Additional formal compliance verification by the contracting DOA is not required if the CVE of the contracted DOA signs and approves the document under its DOA.

GM 21.A.239(c) Design assurance system

ED Decision 2012/020/R

In meeting the requirements of 21.A.239(c) the applicant for a design organisation approval under Subpart J may adopt the following policy:

1. The satisfactory integration of the Partner/Sub-contractor and applicant's design assurance systems should be demonstrated for the activities covered under the applicant's terms of approval.

2. In the event that a Partner/Sub-contractor holds a design organisation approval (DOA), then in accordance with 21.A.239(c), the applicant may take this into account in demonstrating the effectiveness of this integrated system.

3. When any Partner/Sub-contractor does not hold a DOA then the applicant will need to establish to its own satisfaction and the satisfaction of the Agency, the adequacy of that partner's/sub-contractor's design assurance system in accordance with 21.A.243(b).

21.A.243 Data [applicable until 6 March 2023] / 21.A.243 Handbook [applicable from 7 March 2023 - Regulation (EU) 2022/201]

Regulation (EU) 2015/10399

(a) The design organisation shall furnish a handbook to the Agency describing, directly or by cross-reference, the organisation, the relevant procedures and the products or changes to products to be designed. If flight tests are to be conducted, a flight test operations manual defining the organisation's policies and procedures in relation to flight test shall be furnished. The flight test operations manual shall include:

(i) a description of the organisation's processes for flight test, including the flight test organisation involvement into the permit to fly issuance process;

(ii) crewing policy, including composition, competency, currency and flight time limitations, in accordance with Appendix XII to this Annex I (Part 21), where applicable;

(iii) procedures for the carriage of persons other than crew members and for flight test training, when applicable;

(iv) a policy for risk and safety management and associated methodologies;

(v) procedures to identify the instruments and equipment to be carried;

(vi) a list of documents that need to be produced for flight test.

(b) Where any parts or appliances or any changes to the products are designed by partner organisations or subcontractors, the handbook shall include a statement of how the design organisation is able to give, for all parts and appliances, the assurance of compliance required by point 21.A.239(b), and shall contain, directly or by cross-reference, descriptions and information on the design activities and organisation of those partners or subcontractors, as necessary to establish this statement.

(c) The handbook shall be amended as necessary to remain an up-to-date description of the organisation, and copies of amendments shall be supplied to the Agency.

(d) The design organisation shall furnish a statement of the qualifications and experience of the management staff and other persons responsible for making decisions affecting airworthiness and environmental protection in the organisation.

[applicable until 6 March 2023]

(a) As part of the design management system, the design organisation shall create and furnish to the Agency a handbook that describes, directly or by cross reference, the organisation, its relevant policies, processes and procedures, the type of design work, and the categories of products, parts and appliances for which the design organisation holds a design organisation approval, as identified in the terms of approval issued in accordance with point 21.A.251 and, where relevant, the interfaces with and the control of its partners or subcontractors.

If flight tests are to be conducted, a flight test operations manual that defines the organisation's policies and procedures in relation to flight tests shall also be created and furnished to the Agency. The flight test operations manual shall include:

1. a description of the organisation's processes for flight tests, including its involvement in the process for issuing a permit to fly;

2. crewing policy, including composition, competency, currency and flight time limitations, in accordance with Appendix XII, where applicable;

3. procedures for the carriage of persons other than the crew members and for flight test training, where applicable;

4. a policy for the risk and safety management and associated methodologies;

5. procedures to identify the instruments and equipment to be carried on board;

6. a list of documents that need to be produced for the flight test.

(b) Where any parts or appliances or any changes to the products are designed by partner organisations or subcontractors, the handbook shall include a statement of how the design organisation is able to demonstrate, for all parts and appliances, the compliance in accordance with point 21.A.239(d)(2), and shall contain, directly or by cross reference, descriptions of and information on the design activities and the organisation of those partner organisations or subcontractors, as necessary to establish the statement.

(c) The handbook shall be amended as necessary to remain an up-to-date description of the organisation, and copies of the amendments shall be provided to the Agency.

(d) The design organisation shall establish and maintain a statement of the qualifications and experience of the management staff and of other persons in the organisation that are responsible for making decisions that affect airworthiness, operational suitability data and environmental protection matters. It shall submit that statement to the competent authority.

[applicable from 7 March 2023 - Regulation (EU) 2022/201]

AMC to 21.A.143, 21.A.243, 21.A.14(b), 21.A.112B(b) and 21.A.432B(b) Flight Test Operations Manual (FTOM)

ED Decision 2017/024/R

1. General

   a. Scope: The FTOM covers flight test operations.

      The FTOM complexity should be proportionate to the aircraft and the organisation complexity.

   b. Format

      The FTOM may:

      — be included in the Design Organisation Approval (DOA)/Production Organisation Approval (POA)/Alternative Procedure to DOA (APDOA) documents, or

      — be a separate manual.

      The FTOM may make reference to other documents to cover the contents listed below, e.g. for record-keeping.

   c. Use by contractors or sub-contractors:

      When flight tests are performed by contractors or sub-contractors, they should comply with the FTOM of the primary organisations, unless they have established an FTOM in compliance with Part-21, the use of which has been agreed between the two organisations.

2. The FTOM should contain the following elements:

   a. Exposition (not applicable in the case of APDOA):

      If the FTOM is presented as a separate document, it should include a chart indicating the structure of the organisation and, more specifically, the functional links of the people in charge of flight test activities. It should also mention the coordination between all departments affecting flight test, e.g. Design Office, Production and Maintenance, in particular coordination for the establishment and update of a Flight Test Programme.

b. Risk and safety management:

The FTOM should describe the organisation's policy in relation to risk and safety assessment, mitigation and associated methodologies.

c. Crew members:

According to the flight test category, the FTOM should describe the organisation's policy on the composition of the crew (including the need to use a Lead Flight Test Engineer (LFTE)) and the competence and currency of its flight test crew members, including procedures for appointing crew members for each specific flight.

All crew members should be listed in the FTOM.

A flight time limitation policy should be established.

d. Carriage of persons other than crew members:

According to the flight test category, the FTOM should describe the organisation's policy in relation to the presence and safety on-board, of people other than crew members (i.e. with no flying duties).

People other than crew members should not be allowed on board for Category 1 flight tests.

e. Instruments and equipment:

The FTOM should list, depending on the nature of the flight, the specific safety-related instruments and equipment that should be available on the aircraft or carried by people on board.

The FTOM should contain provisions to allow flights to take place in case of defective or missing instruments or equipment.

f. Documents:

The FTOM should list the documents to be produced for flight test, and include (or refer to) the procedures for their issue, update and follow-up to ensure the documents' configuration control:

(i) documents associated with a Flight Test Programme:

— Flight Order for a given flight, which should include:

— a list of the tests to be performed and associated conditions;

— safety considerations relevant to the flight;

— category of the flight (e.g. Category 1);

— composition of the crew;

— names of persons other than crew members;

— aircraft configuration items relevant to the test to be highlighted to the crew;

— loading of the aircraft;

— reference to approved flight conditions; and

— restrictions relevant to the flight to be highlighted to the crew.

— Flight crew report.

(ii) documentation and information to be carried on the aircraft during flight test;

(iii) record-keeping: the FTOM should describe the policy relative to record-keeping.

g. Permit to fly:

The FTOM should describe the involvement of the flight test organisation or flight test team (as appropriate) in the process for the approval of flight conditions and the issue of permits to fly in accordance with Subpart P.

h. Currency and training:

The FTOM should describe how training for flight test is organised.

Currency of the flight test crew may be ensured either through recent experience or refresher training.

For aircraft for which Appendix XII is applicable, minimum flight experience by year should be:

— for pilots: 50 hours. In addition:

  — for pilots with a flight test rating, the 50 hours should include 20 flight test hours in any flight test category.

  — for pilots performing a Category 3 flight test, the flight test experience should be expressed in terms of a number of flights leading to the issue of a Certificate of Airworthiness (CofA) (e.g. first flights).

  — for pilots performing a Category 4 flight test, the minimum flight test experience should be proportionate to the activity envisaged.

— for LFTEs: 10 flight test hours in any flight test category.

The FTOM should specify the requirements for a refresher training in order to ensure that crew members are sufficiently current to perform the required flight test activity.

A system should be established to record the currency of the flight test crew's training.

A valid national document (i.e. licence), issued by an EASA Member State under its national regulations and ensuring compliance with the agreed currency requirements, is an acceptable means of compliance to demonstrate currency for a pilot that holds a flight test rating and for an LFTE.

AMC1 21.A.243(a) Data requirements

ED Decision 2021/007/R

HANDBOOK CONTENT

The handbook should provide the following information for each product covered by the design organisation approval.

1. A description of the tasks which can be performed under the approval, according to the following classification:

   a. General areas, like subsonic turbojet aeroplanes, turbopropeller aeroplanes, small aeroplanes, rotorcraft.

   b. Technologies handled by the organisation (composite, wood or metallic construction, electronic systems, etc.)

c. A list of types and models for which the design approval has been granted and for which privileges may be exercised, supported by a brief description for each product.

d. For repair design, classification and (if appropriate) approval activities it is necessary to specify the scope of activity in terms of structures, systems, engines, etc.

2. A general description of the organisation, its main departments, their functions and the names of those in charge; a description of the line management and of functional relationships between the various departments.

3. A description of assigned responsibilities and delegated authority of all parts of the organisation which, taken together, constitute the organisation's design assurance system together with a chart indicating the functional and hierarchical relationship of the design assurance system to Management and to other parts of the organisation; also the chains of responsibilities within the design assurance system, and the control of the work of all partners and sub-contractors.

4. A general description of the way in which the organisation performs all the design functions in relation to airworthiness, operational suitability and environmental protection approvals including:

a. The procedures followed and forms used in the Type Investigation process to ensure that the design of, or the change to the design of, the product as applicable is identified and documented, and complies with the applicable CS and environmental protection requirements, including specific requirements for import by importing authorities

b. The procedures for classifying design changes as 'major' or 'minor' and for the approval of minor changes.

c. The procedures for classifying and approving unintentional deviations from the approved design data occurring in production (concessions or non-conformance's).

d. The procedure for classifying and obtaining approval for repairs.

5. A general description of the way in which the organisation performs its functions in relation to the continuing airworthiness and continued operational suitability of the product it designs, including co-operation with the production organisation when dealing with any continuing airworthiness actions that are related to production of the product, part or appliance, as applicable.

6. A description of the human resources, facilities and equipment, which constitutes the means for design, and where appropriate, for ground and flight testing.

7. An outline of a system for controlling and informing the Staff of the organisation of current changes in engineering drawings, specifications and design assurance procedures.

8. A description of the recording system for:

a. The type design, including relevant design information, drawings and test reports, including inspection records of test specimens.

b. The means of compliance.

c. The compliance documentation (compliance check list, reports...).

9. A description of the record-keeping system to comply with 21.A.5.

10. A description of the means by which the organisation collects, monitors, analyses and responds to reports of problems which cause or might cause an adverse effect on the airworthiness or operational suitability of its product, part or appliance during design, production and in service,

in particular to comply with point 21.A.3A (see also AMC3 21.A.3A(a) and GM No 1 to 21.A.239(a), points 3.1.4(s) and (u)). These collected reports should include both mandatory and voluntary occurrence reports from organisations and natural persons involved in the operation and maintenance of the product, part or appliance.

11. The names of the design organisation authorised signatories. Nominated persons with specific responsibilities such as mentioned in 21.A.33 and 21.A.35 should be listed.

12. (Reserved).

13. A clear definition of the tasks, competence and areas of responsibility of the Office of Airworthiness.

14. A description of the procedures for the establishment and control of the maintenance and operating instructions (see points 21.A.6, 21.A.7 and, where applicable, 21.A.609).

15. A description of the means by which the continuing evaluation (system monitoring) of the design assurance system will be performed in order to ensure that it remains effective.

16. A description of the procedures for the establishment and control of the operational suitability data (see 21.A.5, 21.A.62, 21.A.108, and 21.A.120B).

AMC No 2 to 21.A.243(a) Data requirements – Model content of handbook for organisations designing minor changes to type design or minor repairs to products

ED Decision 2012/020/R

Part 1. Organisation

1.1 Objective of handbook and binding statement

1.2 Responsible person for administration of handbook

1.3 Amendment procedure

1.4 List of effective pages

1.5 Distribution list

1.6 Presentation of design organisation (including locations)

1.7 Scope of work (with identification of type and models of products)

1.8 Organisation charts

1.9 Human resources

1.10 Management staff

1.11 Certifying personnel (see GM No 2 to 21.A.243(d), paragraph 2)

1.12 Independent system monitoring

Part 2. Procedures

2.1 Management of changes to type design and design of repairs

- configuration control
- classification
- approval of minor changes to type design and minor repairs

2.2 Control of design sub-contractors

2.3 Collecting/Investigating of failures, malfunctions and defects

2.4 Co-ordination with production

2.5 Documentation control

— in relations with the changes and repairs

— in relation with failures/malfunctions and defects (i.e. Services Bulletins)

2.6 Record keeping

AMC-ELA No 1 to 21.A.243 Data – Design organisation handbook

ED Decision 2019/003/R

The organisation is responsible for ensuring that the type design complies with the applicable type-certification basis, the applicable operational suitability data certification basis and the environmental protection requirements. This includes components that are part of the product, but are designed by external parties, and that are not covered by the applicable and individual parts-related (ETSO) approvals or (type) certificates.

To discharge this responsibility, the DOA implements practised methods to ensure that there are adequate means to positively establish and verify the compliance of the design and the associated documentation that is generated. The completeness of those methods is documented within the design organisation handbook (DOH), together with the required supporting and company-specific definitions.

The extent of the documentation, and the associated training, is mandated only to the extent that is required to be able to demonstrate that the generated type designs, design changes or repair designs comply with the applicable type-certification basis, the applicable operational suitability data certification basis and the environmental protection requirements, and that the continued airworthiness activities are properly conducted. If evidence is found that the system described is not effective, then enhanced documentation may be one of the means, but not the only possible means, to rectify that situation.

The documentation of the elements within the DOH may be limited to workflow definitions (e.g. flow charts, process cards, or similar items) or to forms that are sufficiently process-oriented. If ERP systems or other IT systems that manage workflows are used, separate workflow documentation is not necessary, as long as the workflow can be demonstrated during surveillance activities on the basis of the IT system that is applied.

The ‘practising of methods’ is confirmed by observing that the methods are practised in an organised and repeatable manner on several examples. Those methods do not automatically require detailed documentation if they are otherwise defined. Nevertheless, ‘practised methods’ should be at least identified with a declarative statement.

The documentation at least covers the relevant items in the list below:

1. A unique identifier for the DOH, and a means to identify and record its revision status.

2. The name of the organisation and the address of its major place of activity, including any side offices where DAS functions as per AMC-ELA No 2 to 21.A.239(a) are performed under the DOA. If this location differs from the legal place of business, both addresses should be provided. Floor plans, or similar data, are not required.

3. A statement signed by the head of the design organisation (HDO) confirming that the DOH will be complied with at all times, and that it is used as a basic working document (i.e. a binding declaration).

4. A statement of the scope of the DOA (refer to GM-ELA No 1 to 21.A.251), which lists the key technologies used for airframe design and propulsion concepts on the projects in that scope.

5. The title and the name of the HDO, HoA and ISM, with statements of their accountability per AMC-ELA No 1 to 21.A.239(a). The delegation of tasks without responsibility does not affect accountability, and it is not required to be mentioned within the DOH.

6. The identification of the formal position and the reporting lines of the HDO, HoA and ISM within the company, possibly, but not necessarily, by means of an organisational chart.

7. A statement that the HDO assumes all the duties and responsibilities associated with the DOA, unless delegation of responsibility, beyond the delegation of tasks, is applied. In such a case, the allocation of responsibilities should be shown along with this statement.

8. A statement that the HoA is the formal point of contact for EASA.

9. Definitions of the required competences and qualifications that are necessary for the HDO and the HoA (which may be consolidated if both functions are provided by one person), and for design engineers, CVEs and ISMs.

10. A listing of the CVEs, either directly in the DOH or in a separate source (a document, listing, the intranet, etc.) that is linked to the DOH, and this data should be easily accessible to everyone concerned within the company. This list should be made available to EASA in its current version.

11. The approximate size of the company in full-time equivalent staff members, accurate enough to determine the related fees and charges that are laid down in Commission Regulation (EU) No 319/2014 (the Fees and Charges Regulation). This should include a declaration that the company ensures that the numbers and the qualifications of the staff involved in the design activities are adequate, that the company monitors these aspects, and that it takes action if necessary.

12. A confirmation that any significant changes to the DO, and any changes to the organisation that affect the contents of the DOH, will be notified to EASA in a timely manner by the responsible person defined in the DOH.

13. A confirmation that, when changes to the organisation occur that affect the documentation required here, the DOH is kept up to date by the responsible person defined in the DOH, but under the responsibility of the HDO, or their delegate. Amendments to the DOH should be released by the HDO, or by their delegate, and distributed according to the implemented method for the control of documented information, to locations that are identified in a generic or document-specific distribution list, including the responsible design organisation approval team leader (DOATL).

14. A definition of the methods that are practised to verify the effectiveness of the elements of the DAS that are stated in this listing. The main targets of Subpart J are to ensure that the type design of the product complies with the applicable type-certification basis, the applicable operational suitability data certification basis and the environmental protection requirements, and that the continued airworthiness activities are properly conducted. The surveillance mechanisms that are used may include structured experience exchanges, regular quality meetings, brainstorming or lessons learned sessions, project reviews at appropriate phases of the development, planned and unplanned audits, or other similar means. Corrective actions

that are identified should be followed up, and the means of resolution should be recorded. The DOH should define how this is accomplished.

15. A declaration that control methods are practised, and that the general principles of the applied document revision and access management processes ensure the use of current information.

16. A general identification of the documentation that is the result of all the design functions in relation to the airworthiness, operational suitability and environmental protection approvals, and continued airworthiness, each one of which should be commensurate with the complexity of the product and the risk level in terms of its content, style and format, including:

    a. a listing of the document types that form the type design, such as, for example, specifications, drawings, bills of materials, instructions, and other documents;

    b. a listing of the document types that form the compliance documentation, such as, for example, compliance reports, compliance summary documents, compliance checklists, means of compliance checklists, manuals, instructions for continued airworthiness (ICAs), master minimum equipment lists (MMELs) (if required), and others;

    c. a listing of the document types that form the change and repair design-specific documentation, such as classification matrices and approvals of minor changes, repairs, or production deviations;

    d. a listing of the documents related to continued airworthiness activities (information and instructions such as, for example, service bulletins/service instructions), if not already listed to address point a.

17. A declaration and a definition of the principles that are applied, and the accepted related duties, of the key elements of the DAS, as defined in AMC-ELA No 2 to 21.A.239(a). The definition of the elements can be provided by various means, such as precise forms that guide the user through the process, workflow modelling in IT-based design or document management systems, process charts, flow diagrams, classical process definition documents, or other comparable means that are commensurate with the complexity and the criticality of the products. If references are made to other documents that are outside the DOH, the DOH should contain a listing of those documents.

18. A confirmation that methods are practised that enable adequate airworthiness coordination with the applicant for, or the holder of, the production approval. Dedicated procedures and/or DO–PO agreements for the purpose of airworthiness coordination with the production approval holder are not required if the design and the production entities work within one consolidated team, or if the control of airworthiness-related information is conducted by the same group of persons for both design and production. However, it should be described how any occurrences, and any unintentional deviations from the approved design data that occur in production (i.e. concessions or non-conformances) are handled within the design organisation, and when a concession process or a direct approval of such non conformities under the DOA is sought, for example by using the change process. In addition, the methods/processes that are required by other AMC-ELA and GM-ELA should be defined, either directly in the DOH or in a document that is linked to it.

19. A declaration and a definition of the method applied to accept design work that is conducted by external parties, in line with AMC-ELA No 1 to 21.A.239(c).

20. The identification of the design subcontractors and satellite locations that operate under the DAS of the design organisation, and that fulfil functions required by the DAS, or are directly involved in critical aspects of compliance demonstration, such as, for example, flutter investigations and analyses. This identification may be an integral part of the DOH, or it may be provided in a separate listing that is only identified from within the DOH.

21. A reference to a flight test operations manual (FTOM) that is adequate for the flight test activities of the design organisation. If both the design and the manufacturing entities work within one consolidated team, it is sufficient to have FTOM procedures defined for only one of the entities. The FTOM shall then identify the workflow that defines how to issue flight conditions and PtFs for the purpose of conducting factory acceptance test flights.

AMC-ELA No 2 to 21.A.243 Data – Policies and procedures in relation to flight tests

ED Decision 2019/003/R

In order to conduct flight test activities, the DOA is required to implement policies and procedures for conducting these activities that include a proportionate and efficient risk and safety management system. This approach is documented either within a separate flight test operations manual (FTOM) or as an integral part of any other valid manual of the organisation, such as the DOH, or any other relevant quality manual. The FTOM, or its equivalent, should be proportionate to the risk of the product and the complexity of the organisation.

The risk and safety management system, documented within the FTOM, or its equivalent, covers the following aspects:

— The definition of the key qualifications, responsibilities and accountabilities of the staff involved in conducting the flight tests, which covers at least:

  — the head of flight test (HoFT), who coordinates all the activities related to flight test and assumes responsibility for flight testing (this can be shared with other management positions within the DO);

  — the flight test engineer, who manages individual flight tests (or test campaigns);

  — the test pilot, who conducts any flight tests;

  — the flight test mechanic, who conducts all maintenance tasks and configuration changes to the test aircraft.

  One person who has adequate qualifications may act in more than one role. The HoFT should have a direct reporting line to the HDO.

— A method that provides practical guidance on conducting a hazard assessment to classify flight tests according to the risk involved. At least two categories should be identified: Category 1 for high-risk flight tests, and Category 2 for medium- and low-risk flight tests.

— Definitions of generic risk mitigation strategies such as the use of minimum and maximum altitudes or airspeed safety margins, and safety rules to be obeyed for the typical major test phases and missions.

— Identification of the aircraft-related safety equipment that needs to be available, including references to the maintenance requirements of this equipment.

— A policy on how to alert and involve rescue services, such as the fire brigade or emergency physicians, in order to allow sufficiently short reaction times.

— Crew qualifications, including requirements for the qualifications to be current and for crew (refresher) training, as adequate.

— For aircraft with MTOMs of 2 000 kg or more:

  — the provisions of EASA Part-21 Appendix XII apply.

  — the minimum flight experience per year should be:

    — for pilots: 50 hours. In addition:

      — for pilots who have flight test ratings, the 50 hours should include 20 flight test hours in any flight test category;

      — for pilots to perform Category 3 flight tests, their flight test experience should be expressed in terms of the number of flights that led to the issuing of a certificate of airworthiness (CofA) (e.g. first flights);

      — for pilots to perform Category 4 flight tests, their minimum flight test experience should be proportionate to the activity envisaged.

— Crew composition and duty time limitations that are adequate for the kind of testing and the risk category of the flight tests conducted by the DOA.

The procedural aspects, documented within the FTOM, or its equivalent, should cover the following aspects:

— The initiation and planning of a flight test activity, including, for example, but not limited to:

  — hazard analysis;

  — detailed flight test planning;

  — the generation and approval of flight conditions;

  — the definition and verification of the test-aircraft configuration;

  — preparation of the aircraft;

  — the integration, calibration and verification of any flight test equipment;

  — verification of the fitness of the aircraft for flight;

  — issuing or obtaining a PtF;

  — the preflight briefing, and conducting the flight test; and

  — debriefing and data reporting.

The FTOM, or its equivalent, identifies all the documents and records that are required to be generated or maintained in relation to the flight test, including the definitions for the authority to sign.

The FTOM, or its equivalent, identifies how training for flight tests is organised.

The definition of the methods required may be provided in different ways, including but not limited to flow charts, process descriptions, forms that are detailed enough to enforce adherence to the required workflow, workflow implementation in IT-based ERP systems, or similar means.

The implementation of the standard FTOM, including its associated process definitions and forms, ensures adherence to this AMC, and hence that there will be compliance with the relevant requirements of Part-21.

Any flight tests that are subcontracted to a third party should comply with the FTOM of the DOA, unless the third party has established an FTOM that is in compliance with Part-21, and its use has been agreed between the two organisations.

AMC-ELA No 1 to 21.A.243(d) Data – Statement of qualifications and experience

ED Decision 2019/003/R

Evidence of their qualifications and experience is documented for the persons who accept the duties defined for the following roles:

— head of the design organisation (HDO);

— head of airworthiness (HoA);

— independent system monitoring (ISM);

— compliance verification engineer (CVE).

The credentials of the HDO, HoA and ISM are provided to EASA using EASA Form 4-DOA. The form is published on the EASA webpage.

For the CVE, no individual statement is needed. CVEs are selected by the applicant/approval holder on the basis of their knowledge, background and experience as defined in the DOH. When necessary, complementary training should be established to ensure that CVEs have sufficient background and knowledge in the scope of their authorisation.

The organisation maintains a record of the CVE personnel, which includes details of the scopes of their authorisations. The CVE personnel are given reasonable access on request to their own records. As part of its investigations, EASA has the right to access the data held in such a system.

The following minimum information on each of the CVEs should be kept on record:

a) name,

b) date of birth,

c) experience and training,

d) position in the organisation,

e) scope of the authorisation,

f) date of the first issue of the authorisation,

g) if applicable, the date of expiry of the authorisation,

h) identification number of the authorisation,

i) documented acceptance of the nomination by the CVE.

Evidence of the authorisation is provided in a reasonably accessible way within the company, so that a staff member who needs to be aware of the authorisation can verify their status whenever needed. This can be achieved by the provision of accessible listings of the nominated staff members, or by other means. The issuing of individual badges or passes is not required.

The organisation should keep the records of a CVE for at least 2 years after the CVE has ceased to be employed by the organisation, or 2 years after the withdrawal of the CVE's authorisation, whichever occurs first.

GM No 1 to 21.A.243(d) Statement of qualifications and experience

ED Decision 2014/007/R

1. Purpose

This GM provides guidelines on the following points:

— Who are the persons covered by 21.A.243(d)?

— What is requested from the applicant for these persons?

2. Who are the persons?

Three different types of functions are named or implicitly identified in the requirements of Part 21 Subpart J or in associated AMC and GM, using qualified and experienced personnel:

— the Chief Executive [see GM No 1 to 21.A.239(a), para. 3.1.2, GM 21.A.249, GM 21.A.265(b)]

— the other management staff:

— the Head of the design organisation [see GM No 1 to 21.A.239(a), para.3.1.2, GM No 1 21.A.245, para.4.1, GM 21.A.265(b)]

— the Chief of the Office of Airworthiness, or [see GM No 1 to 21.A.245, para. 4.2]

— the Chief of the independent monitoring function of the design assurance system [see 21.A.239(a)(3) and AMC No 1 to 21.A.243(a), para.2]

— the personnel making decisions affecting airworthiness, operational suitability and environmental protection:

— compliance verification engineers [see GM No 1 to 21.A.239(a), para.3.1.3; AMC 21.A.239(b)]

— personnel of the Office of Airworthiness making decisions affecting airworthiness, operational suitability and environmental protection, especially those linked with the 21.A.263 privileges (signing documents for release, approving classification of changes and repairs, and granting the approval of minor changes and minor repairs, granting the approval of SBs, and minor revisions to the aircraft flight manual) [see GM No 1 to 21.A.239(a), para. 3.1.4]

3. Kind of statement

3.1 Chief Executive

The Chief Executive should provide the necessary resources for the proper functioning of the design organisation.

A statement of the qualification and experience of the Chief Executive is normally not required.

3.2 Other management staff

The person or persons nominated should represent the management structure of the organisation and be responsible through the Head of design organisation to the Chief Executive for the execution of all functions as specified in Part 21, Subpart J. Depending on the size of the organisation, the functions may be subdivided under individual managers.

The nominated managers should be identified and their credentials furnished to the Agency on EASA Form 4-DOA (see EASA website:

http://easa.europa.eu/certification/application-forms.php) in order that they may be seen to be appropriate in terms of relevant knowledge and satisfactory experience related to the nature of the design activities as performed by the organisation.

The responsibilities and the tasks of each individual manager should be clearly defined, in order to prevent uncertainties about the relations, within the organisation. Responsibilities of the managers should be defined in a way that all responsibilities are covered.

3.3 Personnel making decisions affecting airworthiness, operational suitability and environmental protection

For these personnel, no individual statement is required. The applicant should show to the Agency that there is a system to select, train, maintain and identify them for all tasks where they are necessary.

The following guidelines for such a system are proposed:

— These personnel should be identified in the handbook, or in a document linked to the handbook. This, and the corresponding procedures, should enable them to carry out the assigned tasks and to properly discharge associated responsibilities.

— The needs, in terms of quantity of these personnel to sustain the design activities, should be identified by the organisation.

— These personnel should be chosen on the basis of their knowledge, background and experience.

— When necessary, complementary training should be established, to ensure sufficient background and knowledge in the scope of their authorization. The minimum standards for new personnel to qualify in the functions should be established. The training should lead to a satisfactory level of knowledge of the procedures relevant for the particular role.

— Training policy forms part of the design assurance system and its appropriateness forms part of investigation by the Agency within the organisation approval process and subsequent surveillance of persons proposed by the organisation.

— This training should be adapted in response to experience gained within the organisation

— The organisation should maintain a record of these personnel which includes details of the scope of their authorisation. The personnel concerned should be provided with evidence of the scope of their authorisation.

— The following minimum information should be kept on record:

a) Name

b) Date of birth

c) Experience and training

d) Position in organisation

e) Scope of the authorisation

f) Date of first issue of the authorisation

g) If appropriate, date of expiry of the authorisation

h) Identification number of the authorisation.

The record may be kept in any format and should be controlled.

— Persons authorised to access the system should be maintained at a minimum to ensure that records cannot be altered in an unauthorised manner or that such confidential records do not become accessible to unauthorised persons.

— Personnel should be given access to their own record.

— Under the provision of 21.A.257 the Agency has a right of access to the data held in such a system.

— The organisation should keep the record for at least two years after a person has ceased employment with the organisation or withdrawal of the authorisation, whichever is the sooner.

GM No 2 to 21.A.243(d) Data requirements – Statement of the qualification and experience – Organisations that design minor changes to type designs or minor repairs to products

ED Decision 2019/018/R

For organisations that design minor changes to type design or minor repairs to products, the statement of the qualifications and experience required by 21.A.243(d) should be addressed as follows:

1. The nominated managers should be identified and their credentials submitted to EASA on EASA Form 4 - DOA (see EASA website: http://easa.europa.eu/certification/application-forms.php) in order that they may be seen to be appropriate in terms of relevant knowledge and satisfactory experience related to the nature of the design activities as performed by the organisation.

2. The persons responsible for:

— classifying changes to type designs or repairs;

— verifying compliance (21.A.239(b));

— approving minor changes to type design and minor repairs (21.A.263(c)(2));

— issuing information or instructions (21.A.265(h)),

should be selected by the organisation in accordance with a procedure and criteria agreed with EASA.

21.A.245 Approval requirements [applicable until 6 March 2023] / 21.A.245 Resources [applicable from 7 March 2023 - Regulation (EU) 2022/201]

Regulation (EU) No 69/2014

The design organisation shall demonstrate, on the basis of the information submitted in accordance with point 21.A.243 that, in addition to complying with point 21.A.239:

(a) the staff in all technical departments are of sufficient numbers and experience and have been given appropriate authority to be able to discharge their allocated responsibilities and these, together with the accommodation, facilities and equipment, are adequate to enable the staff to achieve the airworthiness, operational suitability and environmental protection objectives for the product;

(b) there is full and efficient coordination between departments and within departments in respect of airworthiness, operational suitability and environmental protection matters.

[applicable until 6 March 2023]

(a) The organisation shall appoint a head of the design organisation with the authority to ensure that, within the organisation, all design activities are performed to the required standards and that the design organisation is continuously in compliance with the requirements of the design management system referred to in point 21.A.239 and the procedures specified in the handbook referred to in point 21.A.243.

(b) The head of the design organisation shall nominate and specify the extent of authority of:

1. a chief of the airworthiness function;
2. a chief of the independent monitoring function;
3. depending on the size of the organisation and the nature and complexity of its activities, any other person or group of persons that are required to ensure that the organisation complies with the requirements of this Annex.

(c) By way of derogation from point 21.A.245(b)(1), the airworthiness function referred to in point 21.A.239(d)(1)(i) may be performed under the direct supervision of the head of the design organisation in either of the following cases:

1. where the scope of activities of/of work of the design organisation, as identified in the terms of approval issued under point 21.A.251, is limited to minor changes and/or minor repairs;
2. for a limited period of time when the design organisation does not have a nominated chief of the airworthiness function and the exercise of that function under the direct supervision of the head of the design organisation is commensurate with the scope and level of the organisation's activities.

(d) The person or group of persons nominated pursuant to point (b) shall:

1. be answerable to the head of the design organisation and have direct access to them;
2. have the appropriate knowledge, background and experience to discharge their responsibilities.

(e) The design organisation shall ensure that:

1. the staff in all technical departments are of sufficient numbers and experience and have been given the appropriate authority to be able to discharge their allocated responsibilities and the facilities, equipment and accommodation that are adequate to enable the staff to fulfil the airworthiness, operational suitability data and environmental protection requirements as regards the product;

2. there is full and efficient coordination between the departments and within the departments in respect of airworthiness, operational suitability data and environmental protection matters.

[applicable from 7 March 2023 - Regulation (EU) 2022/201]

AMC-ELA No 1 to 21.A.245 Approval requirements

ED Decision 2019/003/R

The organisation demonstrates adequate staffing, infrastructure, access to facilities and discharge of responsibilities by means of the continued ability to certify type designs after it has ensured that there is positive compliance with the applicable type-certification basis, the operational suitability data certification basis and the environmental protection requirements. Adequate staffing is observed on the basis of reasonable workload, working time and project completion times.

The applicant should have access to:

— workshops and production facilities that are suitable for manufacturing prototype models and test specimens; and

— accommodation and test facilities that are suitable for carrying out the tests and measurements needed to demonstrate compliance with the certification specifications and the environmental protection requirements. The test facilities may be subject to additional technical conditions related to the nature of the tests performed.

The HDO for which an application for approval has been made has the direct or functional responsibility for all the departments of the organisation that are responsible for the design of the product. If the departments responsible for the design are functionally linked, the HDO still has the ultimate responsibility for the compliance of the organisation with Subpart J.

The function of the head of airworthiness (HoA) should be established with a direct reporting line to the HDO, and the person who fulfils this function is required to have a direct contract with the DO.

Responsibilities for all the tasks related to type investigations should be assigned in such a way that there are no gaps in authority.

Combinations of responsibilities are acceptable where:

— the role of the HDO may be fulfilled by the chief executive (CE) of the legal entity, who may also fill the role of the AM within a parallel POA;

— the HDO and the HoA are the same person, provided that the person has the competence to fulfil both functions;

— the HoA and the ISM are the same person, provided that the ISM assessment of working activities that directly affect the person in their second role is conducted by another independent person, on behalf of the ISM;

— the HDO and the ISM are the same person, provided that the auditing activity is conducted by another independent person, under the responsibility of the ISM;

— external persons are acceptable for all or for parts of the role of the ISM;

— a part-time HoA is acceptable, provided that the person is directly involved in the DOA, and not by an agreement between two DOAs, and provided that the availability of the person ensures that response times will be adequate;

— a CVE may also hold any of the other nominations, as long as there is an independent check of compliance per AMC-ELA No 1 to 21.A.239(b).

Due to the typically small size of the design organisations and the low complexity and criticality of the products within the scope of AMC-ELA, no specific provisions are required to ensure that there is full and efficient coordination between departments and within departments in respect of airworthiness, operational suitability and environmental protection matters, provided that evidence of this coordination can be observed during the surveillance activities.

GM No 1 to 21.A.245 Requirements for approval

ED Decision 2014/007/R

See 21.A.245

1. *General.* The data submitted in accordance with 21.A.243 should show that sufficient skilled personnel are available and suitable technical and organisational provisions have been made for carrying out the Type Investigation defined by GM No 1 to 21.A.239(a), paragraph 2.3.

2. *Personnel.* The applicant should show that the personnel available to comply with 21.A.245(a) are, due to their special qualifications and number, able to provide assurance of the design or modification of a product, as well as the compilation and verification of all data needed to meet the applicable CS and environmental protection requirements while taking into account the present state of the art and new experience.

3. *Technical.* The applicant should have access to:

   a. Workshops and production facilities which are suitable for manufacturing prototype models and test specimens.

   b. Accommodation and test facilities which are suitable for carrying out tests and measurements needed to demonstrate compliance with the CS and environmental protection requirements. The test facilities may be subjected to additional technical conditions related to the nature of tests performed.

4. *Organisation.* The data submitted in accordance with 21.A.243 should show that:

   4.1 The Head of the design organisation for which an application for approval has been made, has the direct or functional responsibility for all departments of the organisation which are responsible for the design of the product. If the departments responsible for design are functionally linked, the Head of the design organisation still carries the ultimate responsibility for compliance of the organisation with Part 21 Subpart J.

   4.2 An Office of Airworthiness, or equivalent function, has been established and staffed on a permanent basis to act as the focal point for co-ordinating airworthiness, operational suitability and environmental protection matters (see GM No 1 to 21.A.239(a) paragraph 3.1.4); it reports directly to the Head of the design organisation or is integrated into an independent quality assurance organisation reporting to the Head of the design organisation.

   4.3 [Reserved]

4.4 Responsibilities for all tasks related to Type Investigations are assigned in such a way that gaps in authority are excluded.

4.5 The responsibility for a number of tasks as in paragraph 4.4 may be assigned to one person especially in the case of simple projects.

4.6 Co-ordination between technical departments and the persons in charge of the system monitoring required by 21.A.239(a)(3) has been established:

a. to ensure quick and efficient reporting and resolution of difficulties encountered using the handbook and associated procedures

b. to maintain the design assurance system

c. to optimise auditing activities.

GM No 2 to 21.A.245 Requirements for approval – Organisations designing minor changes to type design or minor repairs to products

ED Decision 2014/007/R

The data submitted in accordance with 21.A.243 should show that:

1. The manager responsible for design has the direct or functional responsibility for all departments of the organisation which are involved in the design of minor changes to type design or minor repairs to products.
2. Person(s) have been nominated to liaise with the Agency and to co-ordinate airworthiness, operational suitability and environmental protection matters. Their position in the organisation should allow direct report to the manager responsible for design.
3. Responsibilities for all tasks related to the design and approval of minor changes to type design or minor repairs to products are assigned to ensure that all areas are covered
4. The responsibility for a number of tasks as in paragraph 3 may be assigned to one person especially in the case of simple projects.

21.A.247 Changes in design assurance system [applicable until 6 March 2023] / 21.A.247 Changes in the design management system [applicable from 7 March 2023 - Regulation (EU) 2022/201]

Regulation (EU) No 69/2014

After the issue of a design organisation approval, each change to the design assurance system that is significant to the showing of compliance or to the airworthiness, operational suitability and environmental protection of the product, shall be approved by the Agency. An application for approval shall be submitted in writing to the Agency and the design organisation shall demonstrate to the Agency, on the basis of submission of proposed changes to the handbook, and before implementation of the change, that it will continue to comply with this Subpart after implementation.

[applicable until 6 March 2023]

After the issue of a design organisation approval, each change to the design management system that is significant to the demonstration of compliance or to the airworthiness, operational suitability and environmental protection of the product, part or appliance shall be approved by the Agency before being implemented. The design organisation shall submit to the Agency an application for approval demonstrating, on the basis of the proposed changes to the handbook, that it will continue to comply with this Annex.

[applicable from 7 March 2023 - Regulation (EU) 2022/201]

GM 21.A.247 Significant changes in the design assurance system

ED Decision 2019/018/R

In addition to a change in ownership (see 21.A.249), the following changes to the design assurance system should be considered to be 'significant' to the demonstration of compliance or to the airworthiness, operational suitability or environmental protection of the products:

1. Organisation

— Relocation to new premises (see also GM 21.A.249);

— Change in the industrial organisation (partnership, suppliers, design work sharing), unless it can be shown that the independent checking function of the demonstration of compliance is not affected;

— Change in the parts of the organisation that contribute directly to the airworthiness, operational suitability or environmental protection (independent checking function, office of airworthiness (or equivalent));

— Change to the independent monitoring principles (see 21.A.239(a)(3)).

2. Responsibilities

— Change of the management staff;

— the Head of the design organisation (GM No 1 to 21.A.239(a), para.3.1.2; GM No 1 to 21.A.245, para.4.1; GM 21.A.265(b));

— the Chief of the Office of Airworthiness (GM No 1 to 21.A.245, para. 4.2);

— the Chief of the independent monitoring function of the design assurance system (21.A.239(a)(3) and AMC No 1 to 21.A.243(a), para.2).

— New distribution of responsibilities affecting airworthiness, operational suitability or environmental protection;

— For organisations that design minor changes to type design or minor repairs to products, change of the persons identified in GM No 2 to 21.A.243(d).

3. Procedures

Change to the principles of procedures related to:

— the type certification;

— the classification of changes and repairs as 'major' or 'minor' (21.A.263(c)(1));

— the treatment of major changes and major repairs;

— the approval of the design of minor changes and minor repairs (21.A.263(c)(2));

— the approval of the design of certain major repairs (21.A.435(b) or 21.A.263(c)(5));

— the approval of the conditions under which a permit to fly can be issued (21.A.263(c)(6));

— the issue of a permit to fly (21.A.263(c)(7));

— the approval of certain major changes to a type certificate (21.A.263(c)(8));

— the approval of certain supplemental type certificates (21.A.263(c)(9));

— the approval of certain major changes to certain supplemental type certificates; (21.A.263(c)(9));

— continued airworthiness or continued operational suitability (see 21.A.3);

— the configuration control, when airworthiness, operational suitability or environmental protection is affected;

— the acceptability of design tasks undertaken by partners or subcontractors (21.A.239(c));

— the issue of data and information under the obligation of 21.A.265(h).

4. Resources

— A substantial reduction in the number and/or experience of staff (see 21.A.245(a)).

GM-ELA No 1 to 21.A.247 Changes in design assurance system

ED Decision 2019/003/R

The following changes are considered to be significant:

— Changes in ownership:

— relocation of the major place of activity to a different geographic location, city, airfield or similar. Relocation within one building, or to a neighbouring building on the same premises, or a similar move, does not require prior approval, as long as there is no negative effect on the interface with or the access to the related production organisation;

— Changes in the scope of approval;

— Changes in the nomination of, or the allocation of responsibilities to, the HDO, the HoA, or the ISM; or

— Changes in the parts of the organisation that contribute directly to the airworthiness, operational suitability or environmental protection functions, such as changes to the principles or to the procedures related to:

— type certification;

— the classification of changes and repairs as ‘major’ or ‘minor’;

— the handling of major changes and major repairs;

— the approval of the design of minor changes and minor repairs;

— the issue of information and instructions under the DOA privileges;

— the approval of minor revisions to the aircraft flight manual;

— the approval of the designs of major repairs;

— continued airworthiness or continued operational suitability; or

— configuration control if airworthiness, operational suitability or environmental protection is affected.

Significant changes require EASA approval prior to their implementation. The organisation should submit the application for approval of a significant change to the DOA, using EASA Form 82, to EASA sufficiently ahead of time, stating the nature of any significant change, and supported by a draft of the updated version of the DOH, so that the required extent of the investigation can be agreed upon and conducted in a reasonable way. The focus of the assessment is the continued ability to comply with the provisions of Subpart J.

Any other changes to the approved organisation do not require prior EASA approval, and will be addressed as part of the regular DOA surveillance.

To ensure that changes do not result in non-compliance with the applicable requirements of Subpart J, it is in the interest of both EASA and the approval holder to establish a relationship and to exchange data during the implementation of a change. As part of this relationship, the company should consider informing EASA sufficiently ahead of the next regular surveillance activity of any non significant changes.

21.A.249 Transferability

Regulation (EU) No 748/2012

Except as a result of a change in ownership, which is deemed significant for the purposes of point 21.A.247, a design organisation approval is not transferable.

GM 21.A.249 Transferability

ED Decision 2012/020/R

1. Transfer of the approval would normally only be agreed in cases where the organisation itself remains substantially unchanged.

2. An acceptable transfer situation could be for example a change of company name (supported by the appropriate certificate from the National Companies Registration Office or equivalent) but with no changes to site address or Chief Executive. However, if the same legal entity were to relocate to new premises with a new Chief Executive and/or new departmental heads, then a substantial investigation by the Agency would be necessary such that the change would be classified as a re-approval.

3. In the event of receivership there may be good technical justification for continuation of the approval provided that the company continues to function in a satisfactory manner. It is likely that at a later stage the approval might be surrendered by the receiver or transferred to another legal entity in which case the former paragraphs apply.

GM 21.A.149 and 21.A.249 Transferability

ED Decision 2021/001/R

GENERAL

A transfer of approval to another production or design organisation is, by default, excluded by points 21.A.149 or 21.A.249 respectively. These points only allow it exceptionally if it is a direct consequence of a transfer of ownership in an approved production or design organisation, which is then considered a significant change to the existing approval (to which point 21.A.147 or 21.A.247 applies).

As a consequence, and in order to apply this exception, the production or design organisation has to demonstrate to the competent authority the existence of a change in ownership which resulted in the fact that a different legal entity is now conducting the approved production or design functions while remaining effectively unchanged.

An example of such an exception is a change of ownership that leads to a re-registration of the organisation (supported by the appropriate certificate from the National Companies Registration Office or equivalent). In order to demonstrate that the organisation remains effectively unchanged, the organisation needs to demonstrate that there are no changes affecting the initial demonstration of compliance of the organisation with Subpart G or Subpart J. If, for instance, the change of ownership would, in addition, lead to a change of address, facilities, type of work, staff, accountable manager or persons nominated under points 21.A.145 or 21.B.245, then it is not an acceptable transfer situation; the exception does not apply in this case. A new investigation by the competent authority would be necessary. The new organisation would have to apply for its own approval. In such a case where the organisation applies for a new approval, the demonstration of compliance in accordance with points 21.A.135 or 21.A.235 may be limited to the demonstration that the changes in the organisation comply with the Subpart G or Subpart J requirements, while referring for the rest to the compliance demonstration of the previous approval holder.

A pure name change, where the ownership does not change, does not require a transfer of the approval. In this case, the natural or legal person that holds the approval remains the same. However, as a consequence of the name change, the approval document needs to be amended to reflect the new company name. This is a significant change, to which point 21.A.147 or 21.A.247 applies.

Another example of a transfer of ownership, which may be exceptionally accepted under points 21.A.149 or 21.A.249, may be the event of receivership (bankruptcy, insolvency or another equivalent legal process). In this case, there is no change to the production or design organisation, except that the custodial responsibility for its property, including its tangible and intangible assets and rights, is transferred to a receiver or insolvency administrator. The receivership aims to continue the business of the same organisation.

21.A.251 Terms of approval

Regulation (EU) 2019/897

The terms of approval shall identify the types of design work, the categories of products, parts and appliances for which the design organisation holds a design organisation approval, and the functions and duties that the organisation is approved to perform with regard to the airworthiness, operational suitability and environmental characteristics of the products. For design organisation approvals covering type-certification or European Technical Standard Order (ETSO) authorisation for auxiliary power units (APUs), the terms of approval shall contain in addition the list of products or APUs. Those terms shall be issued as part of a design organisation approval.

GM No 1 to 21.A.251 Terms of approval

ED Decision 2012/020/R

1. The terms of approval are stated on the certificate of approval issued by the Agency. The certificate states the scope of work and the products, changes or repairs thereof, with the appropriate limitations for which the approval has been granted. For design organisation approval covering type certification or ETSO authorisation for APU, the list of product types covered by the design assurance system should be included.

2. Approval of a change in the terms of approval in accordance with 21.A.253 will be confirmed by an appropriate amendment of the certificate of approval.

3. The certificate references the handbook of the approved design organisation, provided in accordance with 21.A.243. This handbook defines the tasks which may be performed under the approval.

4. Scopes of work are, for example, 'subsonic turbojet aeroplanes', 'turbopropeller aeroplanes', 'small aeroplanes', 'rotorcraft'... Technologies are quoted in the scope of work when it is considered by the Agency as a limitation for the design organisation approval.

5. For repair design activities, the certificate states the scope of work with the appropriate limitations for which the approval has been granted.

GM No 2 to 21.A.251 Terms of approval – Organisations that design minor changes to type design or minor repairs to products

ED Decision 2019/018/R

Terms of approval issued for organisations designing minor changes to type design or minor repairs to products should contain:

1. Scope of work

   This design organisation approval has been granted for:

   — designing minor changes to type design or minor repairs to [aircraft, engine, propeller] in accordance with the applicable CS and environmental protection requirements,

   — demonstrating and verifying the compliance with these CS and environmental protection requirements.

2. Category of products

   Any other indication if the Agency has found a limitation related to aircraft systems or technologies and reducing the scope as defined in paragraph 1.

3. Privileges

   The holder of this approval is entitled to list the privileges granted with the approval, pursuant to 21.A.263(c)(1) and (2).

GM-ELA No 1 to 21.A.251 Terms of approval

ED Decision 2019/003/R

1. The terms of approval are stated on the certificate issued by EASA. The certificate states the scope of work and the products, changes or repairs to them, with the appropriate limitations for which the approval has been granted. For a design organisation approval (DOA) that covers a type certification, the list of product types covered by the design assurance system (DAS) is included.
2. A change to the terms of approval in accordance with point 21.A.253 will lead to an amendment of the certificate of approval.
3. The certificate of approval references the design organisation handbook (DOH), which has been provided in accordance with point 21.A.243. This handbook defines the tasks that may be performed under the approval.
4. Scopes of work are defined, for example, by 'small aeroplanes', 'VLA', 'LSA', 'Balloons', 'Airships', etc. If the product within the framework defined in AMC-ELA No 1 to 21.A.231 is a subset of that term (for example, not for all small aeroplanes), corresponding limitations are incorporated into the terms of approval for the product category. Technologies are quoted in the scope of work when they are considered by EASA to be limitations for the DOA.
5. For repair design activities, the certificate of approval states the scope of work, along with the appropriate limitations for which the approval has been granted.

21.A.253 Changes to the terms of approval

Regulation (EU) No 748/2012

Each change to the terms of approval shall be approved by the Agency. An application for a change to the terms of approval shall be made in a form and manner established by the Agency. The design organisation shall comply with the applicable requirements of this Subpart.

AMC-ELA No 1 to 21.A.253 Changes to the terms of approval

ED Decision 2019/003/R

An application for an approval of changes to the terms of approval should be filed by the applicant using EASA Form 82.

21.A.257 Investigations

Regulation (EU) No 748/2012

(a) The design organisation shall make arrangements that allow the Agency to make any investigations, including investigations of partners and subcontractors, necessary to determine compliance and continued compliance with the applicable requirements of this Subpart.

(b) The design organisation shall allow the Agency to review any report and make any inspection and perform or witness any flight and ground test necessary to check the validity of the compliance statements submitted by the applicant under point 21.A.239(b).

[applicable until 6 March 2023 – Regulation (EU) 2022/201]

GM1 21.A.139, 21.A.157, 21.A.239, 21.A.257, 21.B.120, 21.B.140, 21.B.220, 21.B.235 and 21.B.240 The use of information and communication technologies (ICT) for performing remote audits

ED Decision 2021/007/R

This GM provides technical guidance on the use of remote information and communication technologies (ICT) to support:

— competent authorities when overseeing regulated organisations;

— regulated organisations when conducting internal audits / monitoring compliance of their organisation with the relevant requirements, and when evaluating vendors, suppliers and subcontractors.

In the context of this GM:

— 'remote audit' means an audit that is performed with the use of any real-time video and audio communication tools in lieu of the physical presence of the auditor on-site; the specificities of each type of approval / letter of agreement (LoA) need to be considered in addition to the general overview (described below) when applying the 'remote audit' concept;

— 'auditing entity' means the competent authority or organisation that performs the remote audit;

— 'auditee' means the entity being audited/inspected (or the entity audited/inspected by the auditing entity via a remote audit);

It is the responsibility of the auditing entity to assess whether the use of remote ICT constitutes a suitable alternative to the physical presence of an auditor on-site in accordance with the applicable requirements.

The conduct of a remote audit

The auditing entity that decides to conduct a remote audit should describe the remote audit process in its documented procedures and should consider at least the following elements:

— The methodology for the use of remote ICT is sufficiently flexible and non-prescriptive in nature to optimise the conventional audit process.

— Adequate controls are defined and are in place to avoid abuses that could compromise the integrity of the audit process.

— Measures to ensure that the security and confidentiality are maintained throughout the audit activities (data protection and intellectual property of the organisation also need to be safeguarded).

Examples of the use of remote ICT during audits may include but are not limited to:

— meetings by means of teleconference facilities, including audio, video and data sharing;

— assessment of documents and records by means of remote access, in real time;

— recording, in real time during the process, of evidence to document the results of the audit, including non-conformities, by means of exchange of emails or documents, instant pictures, video or/and audio recordings;

— visual (livestream video) and audio access to facilities, stores, equipment, tools, processes, operations, etc.

An agreement between the auditing entity and the auditee should be established when planning a remote audit, which should include the following:

— determining the platform for hosting the audit;

— granting security and/or profile access to the auditor(s);

— testing platform compatibility between the auditing entity and the auditee prior to the audit;

— considering the use of webcams, cameras, drones, etc., when the physical evaluation of an event (product, part, process, etc.) is desired or is necessary;

— establishing an audit plan which will identify how remote ICT will be used and the extent of their use for the audit purposes to optimise their effectiveness and efficiency while maintaining the integrity of the audit process;

— if necessary, time zone acknowledgement and management to coordinate reasonable and mutually agreeable convening times;

— a documented statement of the auditee that they shall ensure full cooperation and provision of the actual and valid data as requested, including ensuring any supplier or subcontractor cooperation, if needed; and

— data protection aspects.

The following equipment and set-up elements should be considered:

— the suitability of video resolution, fidelity, and field of view for the verification being conducted;

— the need for multiple cameras, imaging systems, or microphones, and whether the person that performs the verification can switch between them, or direct them to be switched and has the possibility to stop the process, ask a question, move the equipment, etc.;

— the controllability of viewing direction, zoom, and lighting;

— the appropriateness of audio fidelity for the evaluation being conducted; and

— real-time and uninterrupted communication between the person(s) participating to the remote audit from both locations (on-site and remotely).

When using remote ICT, the auditing entity and the other persons involved (e.g. drone pilots, technical experts) should have the competence and ability to understand and utilise the remote ICT tools employed to achieve the desired results of the audit(s)/assessment(s). The auditing entity should also be aware of the risks and opportunities of the remote ICT used and the impacts they may have on the validity and objectivity of the information gathered.

Audit reports and related records should indicate the extent to which remote ICT have been used in conducting remote audits and the effectiveness of remote ICT in achieving the audit objectives, including any item that it has not been able to be completely reviewed.

GM-ELA No 1 to 21.A.257 Investigations – Arrangements

ED Decision 2019/003/R

Investigations by EASA may include enquiries, questions, discussions, explanations and inspections of products that are developed under the scope of approval of the DOA.

The design organisation should assist EASA in its investigations by providing appropriate means to allow EASA to perform these inspections and audits, such as meeting rooms and office support.

If design partners or subcontractors fulfil nominated functions within the DO, for example as CVEs, the organisation should coordinate access to the subcontractor, when it is explicitly requested by EASA on a specific subject.

Any failure to allow EASA access to facilities to conduct investigations will be classified as a level 1 finding.

GM 21.A.257(a) Investigations

ED Decision 2012/020/R

Arrangements that allow the Agency to make investigations include the complete design organisation including partners, sub-contractors and suppliers, whether they are in the State of the applicant or not, assisting and co-operating with the Agency in performing inspections and audits conducted during initial assessment and subsequent surveillance.

Assistance to the Agency includes all appropriate means associated with the facilities of the design organisation to allow the Agency to perform these inspections and audits, such as a meeting room and office support.

21.A.258 Findings [applicable until 6 March 2023] / 21.A.258 Findings and observations [applicable from 7 March 2023 - Regulation (EU) 2022/201]

Regulation (EU) 2019/897

(a) When, during the investigations referred to in points 21.A.257 and 21.B.100, objective evidence is found demonstrating non-compliance of the holder of a design organisation approval with the applicable requirements of this Annex, the finding shall be classified as follows:

1. a “level 1” finding is any non-compliance with the requirements of this Annex that may lead to uncontrolled non-compliances with applicable requirements and affect the safety of the aircraft;

2. a “level 2” finding is any non-compliance with the requirements of this Annex that is not classified as a “level 1” finding.

(b) A level three finding is any item where it has been identified, by objective evidence, to contain potential problems that could lead to a non-compliance under point (a).

(c) After receipt of notification of findings under the applicable administrative procedures established by the Agency:

1. in the case of a “level 1” finding, the holder of a design organisation approval shall demonstrate to the satisfaction of the Agency that it has taken adequate corrective action within a period of no more than 21 working days after written confirmation of the finding;

2. in the case of a “level 2” findings, the holder of a design organisation approval shall demonstrate to the satisfaction of the Agency that it has taken adequate corrective action within a time period set by the Agency which is appropriate to the nature of the finding and is initially no longer than three months. The Agency may extend that initial time period where it considers that the nature of the finding allows such extension and where the applicant has submitted a corrective action plan which the Agency finds satisfactory; and

3. a “level 3” finding shall not require immediate action by the holder of a design organisation approval.

(d) In cases of “level 1” or “level 2” findings, the design organisation approval may be subject to a partial or full suspension or revocation under the applicable administrative procedures established by the Agency. In that case, the holder of a design organisation approval shall provide confirmation of receipt of the notice of suspension or revocation of the design organisation approval in a timely manner.

[applicable until 6 March 2023]

(a) After the receipt of the notification of findings in accordance with point 21.B.433, the holder of the design organisation approval shall:

1. identify the root cause(s) of, and contributing factor(s) to, the non-compliance;

2. establish a corrective action plan;

3. demonstrate the implementation of the corrective action to the satisfaction of the Agency.

(b) The actions referred to in point (a) shall be performed within the period agreed by the Agency in accordance with point 21.B.433.

(c) The observations received in accordance with point 21.B.433(e) shall be given due consideration by the holder of the design organisation approval. The organisation shall record the decisions taken in respect of those observations.

[applicable from 7 March 2023 - Regulation (EU) 2022/201]

21.A.259 Duration and continued validity

Regulation (EU) No 748/2012

(a) A design organisation approval shall be issued for an unlimited duration. It shall remain valid unless:

1. the design organisation fails to demonstrate compliance with the applicable requirements of this Subpart; or

2. the Agency is prevented by the holder or any of its partners or subcontractors to perform the investigations in accordance with point 21.A.257; or

3. there is evidence that the design assurance system cannot maintain satisfactory control and supervision of the design of products or changes thereof under the approval; or

4. the certificate has been surrendered or revoked under the applicable administrative procedures established by the Agency.

(b) Upon surrender or revocation, the certificate shall be returned to the Agency.

[applicable until 6 March 2023]

(a) A design organisation approval shall be issued for an unlimited period of time. It shall remain valid subject to the design organisation’s compliance with all the following conditions:

1. the design organisation continues to comply with Regulation (EU) 2018/1139 and its delegated and implementing acts; taking into account the provisions of point 21.B.433 of this Annex related to the handling of findings;

2. the holder of the design organisation approval or any of its partners or subcontractors acknowledge that the competent authority may carry out investigations in accordance with point 21.A.9;

3. the design organisation is able to provide the Agency with evidence showing that the design management system of the organisation maintains satisfactory control and supervision of the design of products, repairs and changes thereto under the approval;

4. the certificate has not been revoked by the Agency under point 21.B.65, or surrendered by the design organisation.

(b) Upon surrender or revocation, the certificate shall be returned to the Agency.

[applicable from 7 March 2023 - Regulation (EU) 2022/201]

21.A.263 Privileges

Regulation (EU) 2019/897

(a) (Reserved)

(b) (Reserved)

(c) A holder of a design organisation approval shall be entitled, within the scope of its terms of approval, as established by the Agency, and under the relevant procedures of the design assurance system:

[applicable until 6 March 2023]

(c) The holder of a design organisation approval shall be entitled, within the scope of its terms of approval issued under point 21.A.251 and under the relevant procedures of the design management system:

[applicable from 7 March 2023 - Regulation (EU) 2022/201]

1. to classify changes to a type-certificate or to a supplemental type-certificate and repair designs as “major” or “minor”;

2. to approve minor changes to a type-certificate or to a supplemental type-certificate and minor repair designs;

3. (Reserved);

4. (Reserved);

5. to approve certain major repair designs under Subpart M to products or auxiliary power units (APUs);

6. to approve for certain aircraft the flight conditions under which a permit to fly can be issued in accordance with point 21.A.710(a)(2), except for permits to fly to be issued for the purpose of point 21.A.701(a)(15);

7. to issue a permit to fly in accordance with point 21.A.711(b) for an aircraft it has designed or modified, or for which it has approved, in accordance with point 21.A.263(c)(6), the flight conditions under which the permit to fly can be issued, and where the holder of a design organisation approval itself:

   (i) controls the configuration of the aircraft, and

   (ii) attests conformity with the design conditions approved for the flight;

8. to approve certain major changes to a type-certificate under Subpart D; and

9. to issue certain supplemental type-certificates under Subpart E and approve certain major changes to those certificates.

AMC-ELA1 to 21.A.263 Privileges and AMC-ELA1 to 21.A.265(h) Obligations of the holder

ED Decision 2021/001/R

(a) The privilege to classify minor/major changes and repairs is granted in accordance with 21.A.263(c)(1) on the basis of the application of the method defined in response to AMC-ELA No 2 to 21.A.239(a).

The defined method should cover the following points:

— the identification of changes to a type design or repairs, including the applicable requirements as per the type certification data sheet (TCDS);

— the classification of changes as major if additional work is required to demonstrate compliance with the applicable requirements;

— the classification of changes as minor if no additional work is required to demonstrate compliance with the applicable requirements;

— the recording of the classification, and documented justification of the classification, for those cases that are not straightforward;

— approval of the classification by the authorised signatories.

It is acceptable to use the same classification process for repairs as for changes. Nevertheless, GM 21.A.435(a) should be taken into consideration when classifying repairs.

(b) The privilege to approve minor changes and minor repairs is granted together with the privilege of classification, on the basis of the application of the method defined in response to AMC-ELA No 2 to 21.A.239(a).

The defined method should cover the following points:

— the identification of whether additional work is required to demonstrate compliance with the applicable requirements;

— determination of the required compliance documentation and the verification by following the same workflow as the one applied for the initial design and certification;

— approving the repair under the DOA privileges by using a formalised approach. This may be, for example, defined by an adequately structured form that provides:

  — adequate identification of the change;

  — the identification of the applicable requirements;

  — reference to compliance documents;

  — the identification of the effects on limitations and approved documentation (if any);

  — evidence that independent checking has been conducted;

  — the date and evidence of the approval given by the relevant nominated staff.

— identification of the authorised signatories for the approval of minor changes and minor repairs;

— a statement that the design of minor changes/repairs is conducted using the same provisions as those defined for the design work during the initial design and certification.

It is acceptable to use the same approval process for minor repairs as the one used for minor changes.

(c) Instructions required by the certification specifications, such as the maintenance manual, the MMEL, etc., are usually prepared within the type investigation process to comply with the certification requirements. These documents are covered by the type investigation process. The generation and publication of information or instructions related to continued airworthiness, including updates to the above-mentioned ICA and MMEL and to any related design activity, are handled according to the same principles as any type design, change design or repair design activity/documentation if no separate method/process as per GM 21.A.265(h) is defined. The DOH should state how documents under this obligation are issued and distributed to the aircraft owner and to other interested parties. Using the change/repair process would be the simplest way for small companies to do this.

(d) The approval of minor revisions to the AFM and its supplements should contain the following statement: 'The technical content of this document is approved under the authority of the DOA, ref.: EASA.21J.[XXXX]. Such a change is treated as a change to the type certificate, as the AFM is formally a part of the type certificate, and it is consequently classified on the basis of the application of the method defined in response to AMC-ELA No 2 to 21.A.239(a), and identified as being related to a 'minor' design change. Administrative revisions to the AFM are also expected to be classified as 'minor'. The following revisions to the AFM are defined as 'minor' revisions:

1. editorial revisions or corrections to the AFM;
2. changes to parts of the AFM that are not required to be approved by EASA;
3. changes to limitations or procedures that are achieved without altering or exceeding the certification data;
4. conversions of units of measurement that were previously approved by the FAA or by EASA, and that are added to the AFM in a previously approved manner;
5. the addition of aircraft serial numbers to an existing AFM if the aircraft configuration, as related to the AFM, is identical to the configuration of the aircraft already in that AFM;
6. the removal of references to aircraft serial numbers that are no longer applicable to that AFM;
7. the translation of an EASA-approved AFM into the language of the State of Design or the State of Registration;
8. AFM revisions as part of minor changes to a type design.

(e) In order to be granted a privilege to approve flight conditions (FC) and to issue PtFs, the design organisation should have in place an adequate FTOM in accordance with AMC-ELA No 2 to 21.A.243 that is limited to the products designed and produced by the company, and over which the company has full configuration control. Authorised signatories shall be defined within the FTOM, or its equivalent.

In such a case, the FTOM (or another document) should contain a defined method that addresses the following points if the (FC) are approved under the DOA privileges:

— FC that must be complied with to safely perform a flight must be determined in accordance with point 21.A.708;

— management of the aircraft configuration, including the handling of changes to the aircraft configuration operated under a PtF;

— the documentation of substantiations of flight conditions;

— approval under the privilege using EASA Form 18A defined in AMC 21.A.263(c)(6), and the definition of the authorised signatories.

For a PtF that is issued under the privilege, a method should be defined that addresses the following points:

— how conformity with the approved conditions is established, documented and attested;

— the issue of the PtF under the DOA privilege (form), and the authorised signatories;

— the interface with the local authority for the flight.

Further guidance is provided in AMC 21.A.263(c)(6) and (c)(7), as well as in the GM and AMC related to Subpart P.

AMC1 21.A.263(c)(1) Privileges

ED Decision 2021/001/R

PROCEDURE FOR THE CLASSIFICATION OF CHANGES TO A TYPE CERTIFICATE (TC) OR TO A SUPPLEMENTAL TYPE CERTIFICATE (STC), AND OF REPAIR DESIGNS AS 'MINOR' OR 'MAJOR'

1. INTENT

This AMC provides the means to develop a procedure for the classification of changes to a TC, APU ETSO or to that part of the product covered by an STC, and repair designs.

Each design organisation approval (DOA) applicant should develop its own internal classification procedure following this AMC in order to obtain the associated privilege under 21.A.263(c)(1).

2. PROCEDURE FOR THE CLASSIFICATION OF CHANGES TO A TC, APU ETSO, OR TO THAT PART OF THE PRODUCT COVERED BY AN STC, AND REPAIR DESIGNS

2.1 Content

The procedure should address the following points:

— the identification of changes to a TC, APU ETSO or to that part of the product covered by an STC, and repair designs;

— classification;

— justification of the classification;

— acceptance of the classification by authorised signatories; and

— supervision of changes to a TC, APU ETSO or to that part of the product covered by an STC, and repair designs initiated by subcontractors.

2.2 Identification of changes to a TC, APU ETSO or to that part of the product covered by an STC, and repair designs

The procedure should indicate how the following are identified:

— items (consisting of areas, systems, parts, or appliances) to be affected by the change or repair following the definitions provided in paragraph 3.9 of GM 21.A.101;

— airworthiness directives which have, or might have, an impact on any of the identified items affected by the change or repair;

— other constituents of the TC and of the pre-existing change(s) to the TC as applicable to the affected items (for instance, operating limitations, OSD constituents, manuals — see also point 21.A.90A and the associated GM) to be affected by the change or repair;

— the existing type-certification basis of the affected items containing, as applicable, the certification specifications, special conditions, deviations from the applicable certification specifications and the equivalent level of safety findings incorporated by reference in the TC of the product to be changed;

— the existing OSD certification basis;

— the definition of the change or repair to the affected items and to the other affected constituents of the TC and of the pre-existing change(s) to the TC, if applicable, in accordance with the provisions of points 21.A.31 and 21.A.91;

— the certification basis of the change or repair determined in accordance with point 21.A.101 with the support of GM 21.A.101 (point 21.A.433 for repairs); this might lead to preclassification of the change as 'major significant' as per the associated definitions
(see point 2.3 below).

The procedure should request the applicant to record a justification that the information, on which those identifications are based, is adequate. This may be done either by using the DOA holder's own resources, or through an arrangement with the TC holder, or any other design approval holder as relevant.

The procedure should address cases where the pre-existing configuration of the type design is the result of multiple changes or repairs applied to the same areas, systems, parts, equipment or appliances.

2.3 Classification

The procedure should show how the effects on airworthiness, operational suitability and environmental protection are analysed, from the very beginning, by reference to the specific applicable requirements of the affected items.

If no specific CSs or environmental protection requirements are applicable to the affected items, the above review should be carried out at the level of the part or system where the affected items are integrated and where specific CSs or environmental protection requirements are applicable.

For changes to a TC, the criteria used for the classification should be in compliance with point 21.A.91 and follow the guidelines provided in GM 21.A.91.

For repairs, the criteria used for the classification should be in compliance with point 21.A.435 and follow the guidelines provided in GM 21.A.435(a).

The procedure should define provisions to contact EASA in case of doubts regarding the classification.

The procedure should take into consideration that a change to a TC may have been found to be significant according to point 21.A.101 and following the definitions provided in GM 21.A.101. Therefore, it is already preclassified at the stage of the determination of the certification basis (see point 2.2 above).

2.4 Justification of the classification

All decisions on the classification of changes to a TC, APU ETSO or to that part of the product covered by an STC, and repair designs classified as 'major' or 'minor' should be recorded, and, for those which are not straightforward, also justified according to the procedure and criteria in point 2.3 above. These records should be easily accessible to EASA for sample checking.

2.5 Acceptance of the classification by the authorised signatories

All classifications of changes to a TC, APU ETSO or to that part of the product covered by an STC, and repair designs should be accepted by an appropriately authorised signatory, belonging to or tasked by the office of airworthiness, as explained in GM No 1 to 21.A.239(a)(3.1.4)(r).

The procedure should indicate the authorised signatories for the various products listed in the terms of approval.

For those changes or repairs that are handled by subcontractors, as described under point 2.6, a description should be provided of how the DOA holder manages its classification responsibility.

The final classification may be:

— major changes significant to a TC;

— major changes not significant to a TC or major repairs;

— minor changes to a TC or minor repairs where additional work is necessary to demonstrate compliance with the certification basis, the operational suitability data certification basis, where applicable, and the environmental protection requirements; or

— minor changes to a TC or minor repairs requiring no further demonstration of compliance.

The procedure should indicate how the above four classes of changes/repairs are identified, taking into consideration the requirements laid down in point 21.A.31.

2.6 Supervision of changes to a TC, APU ETSO or to that part of the product covered by an STC, and repair designs initiated by subcontractors

The procedure should indicate, directly or by cross reference to written procedures, how changes to a TC, or to that part of the product covered by an STC, and repair designs may be initiated and classified by subcontractors, and are controlled and supervised by the DOA holder, taking into consideration the requirements laid down in point 21.A.239(c) and the associated GM 21.A.239(c).

AMC2 21.A.263(c)(1) Privileges

ED Decision 2021/001/R

ORGANISATIONS THAT DESIGN MINOR CHANGES TO A TYPE CERTIFICATE (TC) OR A SUPPLEMENTAL TYPE CERTIFICATE (STC), AND MINOR REPAIRS TO PRODUCTS: CLASSIFICATION PROCEDURE

1. Content

The procedure should address the following points:

— the configuration control rules, especially the identification of changes to a TC, APU ETSO or to that part of the product covered by an STC, and repair designs;

— the classification in compliance with point 21.A.91 and considering GM 21.A.91 for changes and GM 21.A.435(a) for repairs;

— the justification of the decisions for the classification; and

— the acceptance of the classification by authorised signatories.

2. Identification of changes to a TC, APU ETSO or to that part of the product covered by an STC, and repair designs

The procedure should indicate how the following are identified:

— the items (consisting of areas, systems, parts, or appliances) to be affected by the change or repair as per the definitions provided in paragraph 3.9 of GM 21.A.101; these include the parts, appliances, systems or areas affected, and also the other TC constituents (see definitions in GM to 21.A.90A; for instance, operating limitations, OSD constituents, manuals, etc.);

— airworthiness directives which have, or might have, an impact on any of the identified items affected by the change or repair;

— the existing type-certification basis of the affected items containing, as applicable, the certification specifications, special conditions, deviations from the applicable certification specifications and the equivalent level of safety findings incorporated by reference in the TC of the product to be changed;

— the existing OSD certification basis;

— the definition of the change or repair to the affected items in accordance with the provisions of point 21.A.31;

— the certification basis of the change or repair determined in accordance with point 21.A.101 with the support of GM 21.A.101 (point 21.A.433 for repairs); this might lead to preclassification of the change as ‘major significant’ as per the associated definitions (see paragraph 3 below).

3. Classification

The procedure should show how the effects on airworthiness, operational suitability and environmental protection are analysed, from the very beginning, by reference to the specific applicable requirements of the affected items.

If no specific CSs or environmental protection requirements are applicable to the affected items, the above review should be carried out at the level of the part or system where the affected items are integrated and where specific CSs or environmental protection requirements are applicable.

For repairs, the criteria used for the classification should be in compliance with point 21.A.435 and follow the guidelines provided in GM 21.A.435(a).

The procedure should define provisions to contact EASA in case of doubts regarding the classification.

4. Justification of the classification

All decisions on the classification of changes to a TC, APU ETSO or to that part of the product covered by an STC, and repair designs classified as 'minor', should be recorded, and, for those which are not straightforward, also justified according to the procedure and the criteria defined in paragraph 3 above.

These records should be easily accessible to EASA for sample checking.

The justification may be in the format of meeting notes or a register.

5. Acceptance of the classification by the authorised signatories

All classifications of changes to a TC, APU ETSO or to that part of the product covered by an STC, and repair designs should be accepted by an appropriately authorised signatory.

The procedure should indicate the authorised signatories for the various products listed in the terms of approval.

The final classification may be:

— minor changes to a TC or minor repairs where additional work is necessary for the demonstration of compliance with the certification basis, the operational suitability data certification basis (where applicable), and the environmental protection requirements; or

— minor changes to a TC or minor repairs that require no further demonstration of compliance.

AMC1 21.A.263(c)(2) Privileges

ED Decision 2021/001/R

PROCEDURE FOR THE APPROVAL OF MINOR CHANGES AND MINOR REPAIRS TO A TYPE CERTIFICATE (TC), AN AUXILIARY POWER UNIT EUROPEAN TECHNICAL STANDARD ORDER (APU ETSO) OR A SUPPLEMENTAL TYPE CERTIFICATE (STC)

1. INTENT

This AMC provides the means to develop a procedure for the approval of minor changes to a TC, APU ETSO or to that part of the product covered by an STC, and minor repairs.

Each design organisation approval (DOA) applicant should develop its own internal procedures following this AMC in order to obtain the associated privilege under 21.A.263(c)(2).

2. PROCEDURE FOR THE APPROVAL OF MINOR CHANGES TO A TC, AN APU ETSO OR TO THAT PART OF THE PRODUCT COVERED BY AN STC, AND MINOR REPAIRS

2.1 Content

The procedure should address the following points:

— compliance documentation;

— approval under the DOA privilege;

— authorised signatories; and

— supervision of minor changes to a TC, an APU ETSO or to that part of the product covered by an STC or minor repairs handled by subcontractors.

2.2 Compliance documentation

For those minor changes to a TC, an APU ETSO or to that part of the product covered by an STC, and minor repairs where additional work to demonstrate compliance with the applicable CSs and environmental protection requirements is necessary, compliance documentation should be established and independently checked as required by point 21.A.239(b).

The procedure should describe how the compliance documentation is produced and checked. For compliance documentation, see also AMC 21.A.20(c).

2.3 Approval under the DOA privilege

2.3.1 For those minor changes to a TC, an APU ETSO or to that part of the product covered by an STC, and minor repairs where additional work to demonstrate compliance with the applicable CSs and environmental protection requirements is necessary, the procedure should define a document to formalise the approval under the DOA privilege.

This document should include at least:

— a brief description of the change or repair and the reasons for the change or repair;

— identification of the initial configuration of the affected area and other items (which determines the eligibility for installation of the change or repair into an aircraft);

— identification of the final configuration of the affected area, and of supplements to manuals and to OSD constituents;

— the applicable CSs or environmental protection requirements and methods of compliance;

— references to the compliance documents;

— the effects, if any, on the limitations and on the approved documentation;

— evidence of the independent checking function of the demonstration of compliance;

— evidence of the approval under the privilege of point 21.A.263(c)(2) by an authorised signatory; and

— the date of the approval.

For repairs, see AMC 21.A.433(b) and 21.A.447.

2.3.2 For the other minor changes to a TC, APU ETSO or to that part of the product covered by an STC, and minor repairs, the procedure should define a means to identify the change or repair and the reasons for the change or repair, and to formalise its approval by the appropriate engineering authority under an authorised signatory. This function may be delegated by the Office of Airworthiness but should be controlled by the Office of Airworthiness, either

directly or through appropriate procedures of the DOA holder's design assurance system.

2.4 Authorised signatories

The persons authorised to sign for the approval under the privilege of point 21.A.263(c)(2) should be identified (name, signature and scope of authority) in appropriate documents that may be linked to the handbook.

2.5 Supervision of minor changes to a TC, APU ETSO or to that part of the product covered by an STC, and minor repairs handled by subcontractors

For the minor changes to a TC, APU ETSO or to that part of the product covered by an STC, and minor repairs described in 2.3.2 which are handled by subcontractors, the procedure should indicate, directly or by cross reference to written procedures, how these minor changes to a TC, APU ETSO or to that part of the product covered by an STC, and minor repairs are approved at the subcontractor level and the arrangements made for the control and supervision by the DOA holder.

AMC2 21.A.263(c)(2) Privileges

ED Decision 2021/001/R

ORGANISATIONS THAT DESIGN MINOR CHANGES TO A TYPE CERTIFICATE (TC), AN AUXILIARY POWER UNIT EUROPEAN TECHNICAL STANDARD ODER (APU ETSO) OR A SUPPLEMENTAL TYPE CERTIFICATE (STC) AND MINOR REPAIRS TO PRODUCTS: PROCEDURE FOR THE APPROVAL OF MINOR CHANGES TO A TC, AN APU ETSO OR MINOR REPAIRS

1. Content

The procedure should address the following points:

— compliance documentation;

— approval under the DOA privilege; and

— authorised signatories.

2. Compliance documentation

For those minor changes to a TC, an APU ETSO or to that part of the product covered by an STC, and minor repairs where additional work to demonstrate compliance with the applicable CSs and environmental protection requirements is necessary, compliance documentation should be established and independently checked as required by point 21.A.239(b).

The procedure should describe how the compliance documentation is produced and checked. For compliance documentation, see also AMC 21.A.20(c).

3. Approval under the DOA privilege

3.1. For those minor changes to a TC, an APU ETSO or to that part of the product covered by an STC, and minor repairs where additional work to demonstrate compliance with the applicable CSs or environmental protection requirements is necessary, the procedure should define a document to formalise the approval under the DOA privilege.

This document should include at least:

(a) a brief description of the change or the repair and the reason for change or repair;

(b) identification of the initial configuration of the affected area and other items (which determines the eligibility for installation of the change or repair into an aircraft);

(c) identification of the final configuration of the affected area, and of supplements to manuals and to OSD constituents;

(d) the applicable CSs or environmental protection requirements and methods of compliance;

(e) references to the compliance documents;

(f) the effects, if any, on the limitations and on the approved documentation;

(g) evidence of the independent checking function of the demonstration of compliance;

(h) evidence of the approval under the privilege of point 21.A.263(c)(2) by an authorised signatory; and

(i) the date of the approval.

For repairs, see also AMC 21.A.433(b) and 21.A.447.

3.2. For the other minor changes to a TC, APU ETSO or to that part of the product covered by an STC, and minor repairs, the procedure should define a means to identify the change or repair and the reasons for the change or repair, and to formalise its approval by the appropriate engineering authority under an authorised signatory. This function should be controlled through appropriate procedures of the DOA holder's design assurance system.

4. Authorised signatories

The persons authorised to sign for the approval under the privilege of 21.A.263(c)(2) should be identified (name, signature and scope of authority) in appropriate documents that may be linked to the handbook.

AMC No 3 to 21.A.263(c)(2) Procedure for the approval of minor changes to a type certificate (TC) which affect the aircraft flight manual (AFM)

ED Decision 2019/018/R

1. Intent

This AMC provides additional guidance for developing a procedure for the approval of minor changes to a TC which affect the aircraft flight manual (AFM).

Each design organisation approval (DOA) applicant/holder should develop its own internal procedure, based on these guidelines. For guidance on the classification of changes to a TC which affect the AFM, see GM 21.A.91.

2. Procedure for the approval of minor changes to a TC which affect the AFM

2.1 Content

The procedure should address the following points:

— assessment of any change to a TC for the impact of the change on the AFM;

— preparation of revisions or supplements to the AFM;

— classification of the change to a TC, taking into account the impact on the AFM;

— classification of stand-alone revisions or supplements to the AFM;

— control of the configuration of the AFM;

— approval of the revisions or supplements to the AFM; and

— the approval statement.

2.2 Assessment of a change for its impact on the AFM The procedure should include an assessment of whether or not the AFM is impacted by the change.

2.3 Preparation

The procedure should indicate how revisions or supplements to the AFM are prepared and how the coordination among the persons in charge of design changes is performed.

2.4 Classification

The procedure should indicate how changes to a TC which affect the AFM are classified, in accordance with the criteria of GM 21.A.91 Section 3.4.

The procedure should indicate how classification decisions are recorded, documented and signed.

Easy accessibility of these records to EASA for sample checking should be ensured. All classifications should be accepted by an appropriately authorised signatory. The procedure should indicate the authorised signatories for the various products listed in the terms of approval.

2.5 Configuration control of the AFM

The procedure should explain the traceability of changes in order to understand who has approved what. Especially if a given page or data module has been revised several times, it should be traceable which part(s) of the page or data module has (have) been approved directly by EASA under which approval, and which part(s) has (have) been approved under the privilege of a DOA holder.

2.6 Approval

The procedure should indicate how the approval under the privilege of point 21.A.263(c)(2) is formalised.

The authorised signatories should be identified (name, signature), together with the scope of the authorisation, in a document that is linked to the DOA handbook.

2.7 Approval statement

The amended AFM, or the supplement to the AFM, approved under the privilege of point 21.A.263(c)(2) should be issued under the obligation of point 21.A.265(h) (see point 21.A.265(h) and the related GM) with a respective statement in the log of revisions.

AMC1 21.A.263(c)(6) Privileges

ED Decision 2021/001/R

PROCEDURE FOR THE APPROVAL OF THE CONDITIONS FOR THE ISSUE OF A PERMIT TO FLY (PtF)

1. INTENT

— This AMC provides the means to develop a procedure to determine that an aircraft can fly, under the appropriate restrictions compensating for non-compliance with the certification specifications applicable to the specific aircraft category.

— Each DOA applicant or DOA holder should develop its own internal procedure following this AMC, in order to obtain the privilege to make this determination and approve the associated conditions without EASA's involvement, under point 21.A.263(c)(6). When the privilege does not apply, the DOA applicant or the DOA holder will prepare all the necessary data required for the determination in accordance with the same procedure required for the privilege, and will apply for EASA's approval.

— The establishment of flight conditions may include conditions related to engines/propellers without a type certificate or with unapproved changes that are fitted to the aircraft, for which a permit to fly (PtF) is requested. These conditions (i.e. the installation, operating limitations, maintenance conditions or limitations) should be defined by the organisation responsible for the design of the engine/propeller and provided to the organisation responsible for the design of the aircraft.

— These conditions should be established and substantiated under an arrangement between the organisation responsible for the design of the aircraft and the organisation responsible for the design of the engine/propeller. However, the establishment and substantiation of the flight conditions for the aircraft, including its engine(s), is ultimately the responsibility of the organisation responsible for the design of the aircraft.

2. PROCEDURE FOR THE APPROVAL OF THE CONDITIONS FOR THE ISSUE OF A PERMIT TO FLY (PtF)

2.1 Content

The procedure should address the following points:

— the decision to exercise the privilege;

— management of the aircraft configuration;

— determination of the conditions that should be complied with to safely perform a flight;

— documentation of substantiations of flight conditions;

— approval under the DOA privilege, when applicable; and

— the authorised signatories.

2.2 Decision to exercise the privilege of point 21.A.263(c)(6)

The procedure should include a decision to determine the flights for which the privilege of point 21.A.263(c)(6) will be exercised.

2.3 Management of the aircraft configuration

The procedure should indicate:

— how the aircraft, for which an application for a permit to fly is made, is identified; and

— how changes to the aircraft will be managed.

2.4 Determination of the conditions that should be complied with to safely perform a flight

The procedure should describe the process used by the DOA holder to justify that the aircraft can perform the intended flight(s) safely. This process should include:

— with reference to point 21.A.701(a), identification of the applicable airworthiness requirements which the aircraft does not meet, or has not been shown to meet, if applicable, and of the purpose of the flight(s); for flight conditions raised to cover unapproved changes, the identification of the applicable airworthiness requirements which the aircraft does not meet, or has not been shown to meet, can be fulfilled by referring to the certification programme of the unapproved changes;

— the analysis, calculations, tests or other means used to determine under which conditions or restrictions the aircraft can safely perform a flight (the flights);

— the establishment of specific maintenance instructions and conditions to perform these instructions;

— an independent technical verification of the analysis, calculations, tests or other means used to determine under which conditions or restrictions the aircraft can perform the intended flight(s) safely;

— a statement by the office of airworthiness (or equivalent), that the determination has been made in accordance with the related procedure and that the aircraft has no features and characteristics that render it unsafe for the intended operation(s) under the identified conditions and restrictions; and

— approval by an authorised signatory.

2.5 Documentation of flight conditions substantiations

1. The analysis, calculations, tests~~,~~ or other means used to determine under which conditions or restrictions the aircraft can safely perform a flight (or the flights) should be compiled in compliance documents. These documents should be signed by the author and by the person performing the independent technical verification.

2. Each compliance document should have a number and an issue date. The various issues of a document should be controlled.

3. The data submitted and approved by the TC holder can be used as substantiations. In that case, the independent technical verification referred to in 2.4 is not required.

2.6 Approval under the DOA privilege

2.6.1 Initial approval

The procedure should include the following EASA Form 18A (as an alternative, the DOA holder should provide an equivalent template containing the same level of information) to support the approval under the DOA privilege:

FLIGHT CONDITIONS FOR A PERMIT TO FLY — APPROVAL FORM	
1. Applicant: **Approval No:** *[Name and organisation approval number of the organisation providing the flight conditions and associated substantiations]*	**2. Approval form No:** **Issue:** *[Number and issue, for traceability purposes]*
3. Aircraft manufacturer/type	**4. Serial number(s)**
5. Purpose [Purpose in accordance with point 21.A.701(a)]	
6. Aircraft configuration The above aircraft, for which a permit to fly is requested, is defined in *[add reference to the document(s) identifying the detailed configuration of the aircraft]* *[For change(s) affecting the initial approval form: a description of the change(s). This form must be reissued]*	
7. Substantiations *[References to the document(s) justifying that the aircraft (as described in block 6) can perform the intended flight(s) safely under the defined conditions or restrictions.]* *[For change(s) affecting the initial approval form: reference(s) to additional substantiation(s). This form must be reissued]*	
8. Conditions/Restrictions The above aircraft must be used with the following conditions or restrictions: *[Details of these conditions/restrictions, or a reference to the relevant document, including specific maintenance instructions and conditions to perform these instructions.]*	
9. Statement The determination of the flight conditions has been made in accordance with the relevant DOA procedure agreed by EASA. The aircraft, as defined in block 6 above, has no features or characteristics that render it unsafe for the intended operation(s) under the identified conditions and restrictions.	
[strike through what is not applicable] **10a. Approved under the authority of DOA EASA.21J.xyz** [when the privilege of point 21.A.263(c)(6) applies] **10b. Submitted under the authority of DOA EASA.21J.xyz** [when the privilege of point 21.A.263(c)(6) does not apply]	
11. Date of issue	**12. Name and signature** *[Authorised signatory]*
13. EASA approval and date [when the privilege of point 21.A.263(c)(6) does not apply]	

EASA Form 18A — Issue 4

When the privilege of point 21.A.263(c)(6) is not applicable, the signed form should be presented by the office of airworthiness (or equivalent) to EASA.

2.6.2 Approval of changes

Except for changes that do not affect the conditions approved for the issue of the permit to fly, the procedure should specify how changes will be approved by the DOA holder. The EASA Form 18A should be updated.

2.7 Authorised signatories

The person(s) authorised to sign the approval form should be identified (name, signature and scope of authority) in the procedure, or in an appropriate document linked to the DOA handbook.

AMC 21.A.263(c)(7) Procedure for the issue of a permit to fly

ED Decision 2012/020/R

1. INTENT

This acceptable means of compliance provides means to develop a procedure for the issue of a permit to fly.

Each DOA applicant or holder must develop its own internal procedure following this AMC, in order to obtain the privilege of 21.A.263(c)(7) to issue permits to fly for aircraft it has designed or modified, or for which it has approved under 21.A.263(c)(6) the conditions under which the permit to fly can be issued, and when the design organisation itself is controlling under its DOA the configuration of the aircraft and is attesting conformity with the design conditions approved for the flight.

2. PROCEDURE FOR THE ISSUE OF A PERMIT TO FLY

2.1 Content

The procedure must address the following points:

— conformity with approved conditions;

— issue of the permit to fly under the DOA privilege;

— authorised signatories;

— interface with the local authority for the flight.

2.2 Conformity with approved conditions

The procedure must indicate how conformity with approved conditions is made, documented and attested by an authorised person.

2.3 Issue of the permit to fly under the DOA privilege

The procedure must describe the process to prepare the EASA Form 20b and how compliance with 21.A.711(b) and (e) is established before signature of the permit to fly.

2.4 Authorised signatories

The person(s) authorised to sign the permit to fly under the privilege of 21.A.263(c)(7) must be identified (name, signature and scope of authority) in the procedure, or in an appropriate document linked to the DOA handbook.

2.5 Interface with the local authority for the flight

The procedure must include provisions describing the communication with the local authority for compliance with the local requirements which are outside the scope of the conditions of 21.A.708(b) (see 21.A.711(e)).

AMC No 1 to 21.A.263(c)(5), (8) and (9) Scope and criteria

ED Decision 2019/018/R

1. Definition of 'certain major repairs'

'Certain major repairs' for which privileges may be granted as per point 21.A.263(c)(5) are:

(a) major repairs to products or auxiliary power units (APUs) for which the design organisation approval (DOA) holder holds the type certificate (TC) or the supplemental type certificate (STC) or the European technical standard order authorisation (ETSOA); or

(b) major repairs to products or APUs for which the DOA holder does not hold the TC or the STC or ETSOA and that meet the criteria of 3(a), (b) and (c) below.

1.1 Criteria for limitations on eligibility

An EASA approval may be required in cases of major repairs proposed by DOA holders who are the TC, STC or APU ETSOA holders if the major repair is:

(a) related to a new interpretation of any item of the certification basis as used for the type certification (such as the certification specifications (CSs), certification review items (CRIs) for special conditions, equivalent safety findings, deviations or 'elect to comply'); and

(b) related to the application of a CS that is different from the one used for type certification. Note: This should be established at the time of granting the privilege to the DOA holder, or later through an EASA-agreed procedure.

2. Definition of 'certain major changes' and 'certain supplemental type certificates'

'Certain major changes' and 'certain supplemental type certificates' for which privileges may be granted as per point 21.A.263(c)(8) and (9) are changes similar to those that have been previously approved by EASA for the same DOA holder.

The similarity of the changes is to be seen in terms of the design, the installation, and the operational characteristics, whereas their repetitiveness is seen in terms of the applicable requirements and the compliance demonstration.

In this context, a 'requirement' means any element of the type-certification basis as specified in point 21.B.80, or the operational suitability data (OSD) certification basis as specified in point 21.B.82, or the environmental protection requirements as specified in point 21.B.85.

2.1 Criteria for limitations on eligibility

The following types of changes are not eligible:

(a) changes that require a revision to a type certificate data sheet (TCDS) (e.g. the introduction of a derivative model or variant) or a type certificate data sheet for noise (TCDSN);

(b) changes that require an amendment to the existing certification basis by a special condition, equivalent safety finding, deviation or 'elect to comply';

(c) changes that revise airworthiness limitations or operating limitations, unless otherwise agreed with EASA;

(d) changes that are intended to be used as alternative method of compliance (AMOC) to an airworthiness directive (AD);

(e) changes that are made mandatory by an AD or that are the terminating action of an AD;

(f) changes that are classified as 'significant' in accordance with point 21.A.101;

(g) changes for which, in the affected area and for the operations for which the design is to be certified, more conservative certification requirements are applicable which were not used in the description of the EASA-approved procedure of the DOA holder, e.g. in the case of a type, model or modification with a later, more stringent certification basis;

(h) changes that affect the noise and/or emissions characteristics of the changed product, unless otherwise agreed with EASA;

(i) changes that affect a part or system, a single failure of which may have a catastrophic effect upon the product, and for which critical characteristics have been identified, which should be controlled to ensure the required level of integrity;

(j) changes to engines or propellers, a single failure of which may have a hazardous effect upon the product, and for which critical characteristics have been identified, which should be controlled to ensure the required level of integrity; and

(k) changes for which a non-compliance has been found in the referenced change during the continued-airworthiness process.

3 Criteria for major repairs, major changes and STCs for which the privileges of point 21.A.263(c)(5), (8) and (9) may be granted

The following criteria need to be met:

(a) Similarity

The installation on the product, the design, the operation, and the equipment qualification are basically the same as in projects for which EASA has already been involved and issued an approval for the same DOA holder.

(b) Repetitiveness of the certification process

The whole certification process is repetitive, i.e. identical to, or part of, an already approved referenced process. For a change or repair that is a part of the referenced 'certain major repairs', 'certain major changes' or 'certain supplemental type certificates', the certification process is still identical to the one for the affected change. This is the case when each compliance demonstration is performed to the same extent in accordance with the same requirements, GM, and content of the interpretative material, as well as with the same means and method of compliance (not only the same means-of-compliance (MoC) code).

Note: In this AMC, a 'requirement' means any element of the type-certification basis as specified in point 21.B.80, or OSD certification basis as specified in point 21.B.82, or an environmental protection requirement as specified in point 21.B.85.

(c) Performance and experience in previous projects

EASA should have classified as 'medium' or 'high' the level of performance of the organisation during at least the latest project referenced, to demonstrate 'similarity' and 'repetitiveness'.

In addition, EASA should have classified as 'low' or 'very low' the likelihood of an unidentified non-compliance for all the included compliance demonstration items (CDIs) identified in at least the latest project referenced, to demonstrate 'similarity' and 'repetitiveness' (applying the criteria for the determination of EASA's level of involvement (LoI) in product certification, see AMC 21.B.100(a) and 21.A.15(b)(6)).

The process to obtain and to use the privileges of point 21.A.263(c)(5), (8) and (9) is described in AMC No 2 to 21.A.263(c)(5), (8) and (9).

AMC No 2 to 21.A.263(c)(5), (8) and (9) Procedure for the approval of a major repair, a major change to a type certificate (TC), or a supplemental type certificate (STC) by a design organisation approval (DOA) holder under their privileges

ED Decision 2019/018/R

This AMC describes the process to be followed in order to obtain and use the privilege to approve 'certain major repairs' and 'certain major changes' to a TC, and 'certain supplemental type certificates' as defined in points 1(b) and 2 of AMC No 1 to 21.A.263(c)(5), (8) and (9).

1. PROCESS FOR OBTAINING A PRIVILEGE

A DOA holder that applies for the privileges referred to in point 21.A.263(c)(5), (8) or (9) should do the following:

(a) Submit to EASA an application for a significant change in the design assurance system (see points 21.A.247 and 21.A.253).

(b) Establish internal procedures for the application of the privilege covering the following elements, and add them to the application:

(1) The definition of the 'list associated with the privilege' of certain major repairs/changes/STCs. The 'list associated with the privilege' is a list of all 'certain major changes', 'certain STCs' and 'certain major repairs' (or families thereof) plus the associated 'justification document' references for which the privileges as per point 21.A.263(c)(5), (8) and (9) have been granted.

(2) A 'justification document' for a 'certain major repair', 'certain major change' or a 'certain STC', as applicable. The 'justification document' should contain:

(i) The reference(s) to the EASA-approved major change(s), STC(s) and major repair(s), which is (are) used to demonstrate the DOA holder's experience and performance.

Note: The number of already EASA-approved major change(s), STC(s) or major repair(s) used to demonstrate the DOA holder's experience and performance is based on an assessment of the scope of the 'certain major repairs', 'certain major changes' or 'certain supplemental type certificates' which is requested to be added to the 'list associated with the privilege', as well as on the performance of the DOA holder during previous projects.

(ii) The certification programme(s) of the major change(s), STC(s), or major repair(s), accepted by EASA, used to demonstrate the applicant's experience and performance.

(iii) The applicable product configuration(s).

The applicant should list the type(s) and model(s) to which the major change(s)/STC(s)/repair(s) applies (apply) or may apply. Exceptionally, this may be done for a dedicated product, system or equipment if the type or model has no technical influence on the major change(s)/STC(s)/repair(s), i.e. when the installation issues are negligible (e.g. the TCAS 7.1 software change for a certain equipment), such a listing is not mandatory, but it needs to be justified.

(iv) The list of 'requirements' for the demonstration of compliance, if not identical to the ones referenced in the certification programme.

(v) The certification process, if not identical to the one referenced in the certification programme.

(vi) A detailed description with all the technical data relevant to the installation of the product, the design, the operation and the qualification which ensures the proper use of the privilege for future major changes, major repairs or STCs. This description should include the criteria defining the conditions that should be met in order to apply the privileges.

(vii) Any other limits on the use of the privilege.

(3) The assessment of the acceptability of using the privilege for major repairs, major changes or STCs against the 'list associated with the privilege' and the 'justification document' of 'certain major repairs', 'certain major changes' or 'certain STCs'.

(4) The approval process, including the templates to be used, the authorised signatories, records management and the provision of a 'summary list' of major changes, major repairs and STCs approved under the privilege of point 21.A.263(c)(5), (8) and (9). This process should clarify that the approval is issued under the DOA holder's privilege.

The persons authorised under the privilege of point 21.A.263(c)(5), (8) and (9) should be identified by their names, signatures and scopes of authority in the appropriate documents and referenced in the procedure.

A 'summary list' of all the major changes, STCs and major repairs approved under a privilege should be provided to EASA on a regular basis, as agreed with EASA.

(5) Extension of the 'list associated with the privilege' after the privilege is granted.

After the granting of the privilege, the initial list of 'certain major repairs', 'certain major changes' and 'certain STCs' under the privilege may be further extended by an EASA agreement, as shown in Section 2 as well as in Figures 2 and 3 below.

(c) Identify in the 'list associated with the privilege' the eligible major changes, major repairs or STCs proposed for inclusion in the scope of the privilege (see also AMC No 1 to 21.A.263(c)(5), (8) and (9)).

(d) Provide a 'justification document' for each proposed certain major change, certain major repair or certain STC identified under (c) above.

Note: The 'list associated to the privilege' identifying all certain major repairs, certain major changes and certain STCs and the associated 'justification document(s)' are to be referenced in the DOA holder procedure mentioned under (b) above.

The process for obtaining the privilege, referred to in 21.A.263(c)(5), (8) and (9), is summarised in Figure 1 below:

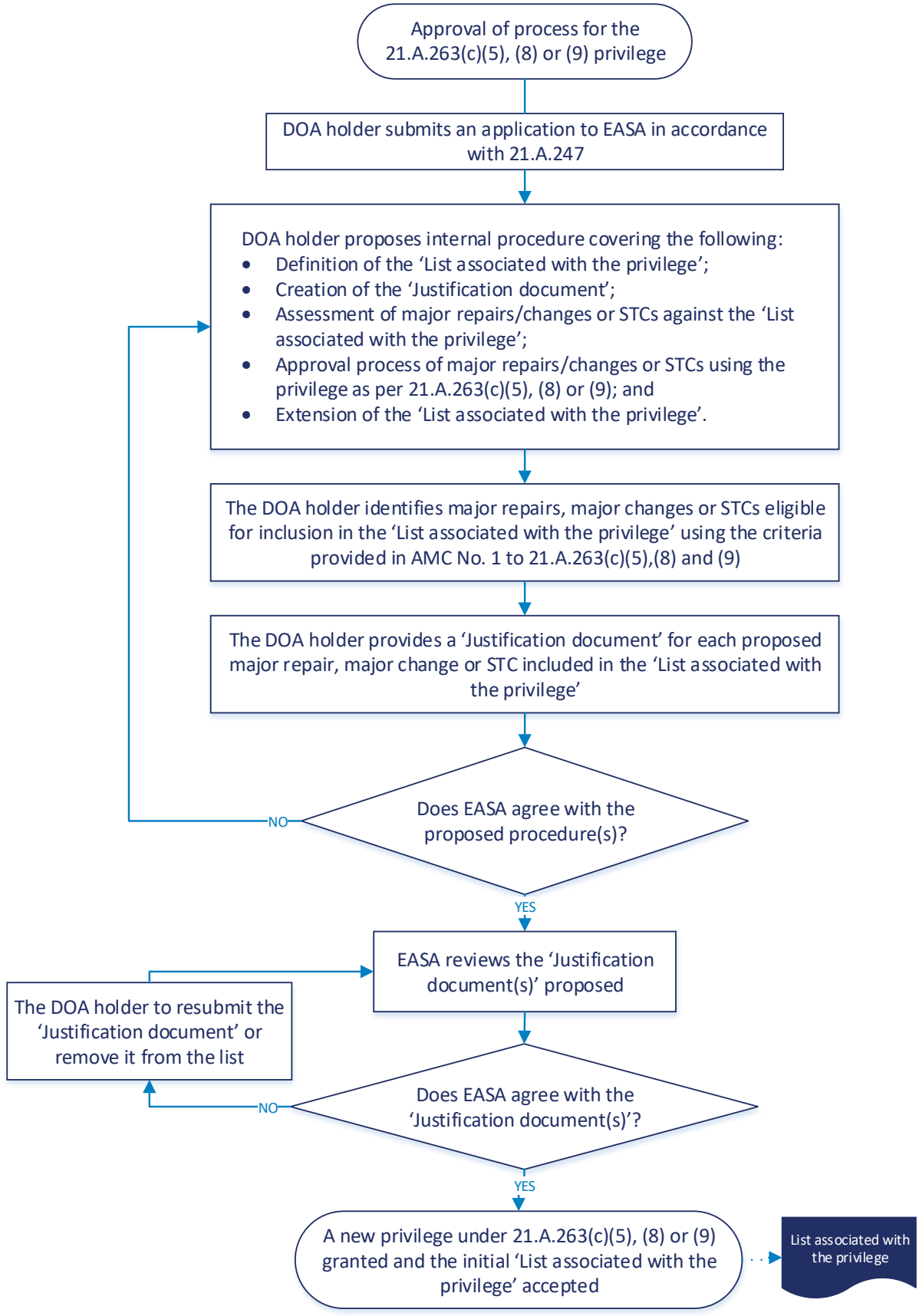

Approval of process for the 21.A.263(c)(5), (8) or (9) privilege
DOA holder submits an application to EASA in accordance with 21.A.247
DOA holder proposes internal procedure covering the following:
Definition of the 'List associated with the privilege';
Creation of the 'Justification document';
Assessment of major repairs/changes or STCs against the 'List associated with the privilege';
Approval process of major repairs/changes or STCs using the privilege as per 21.A.263(c)(5), (8) or (9); and
Extension of the 'List associated with the privilege'.
The DOA holder identifies major repairs, major changes or STCs eligible for inclusion in the 'List associated with the privilege' using the criteria provided in AMC No. 1 to 21.A.263(c)(5),(8) and (9)
The DOA holder provides a 'Justification document' for each proposed major repair, major change or STC included in the 'List associated with the privilege'
Does EASA agree with the proposed procedure(s)?
NO
YES
EASA reviews the 'Justification document(s)' proposed
The DOA holder to resubmit the 'Justification document' or remove it from the list
Does EASA agree with the 'Justification document(s)'?
NO
YES
A new privilege under 21.A.263(c)(5), (8) or (9) granted and the initial 'List associated with the privilege' accepted
List associated with the privilege

Figure 1

The privilege referred to in point 21.A.263(c)(5), (8) and (9) may be used by a DOA holder for the approval of major repairs, major changes or STCs, as applicable, under the following conditions:

(a) the privilege has already been granted by EASA;

(b) the major repair/change/STC to be approved falls under the 'List associated with the privilege' agreed by EASA; and

(c) the criteria established in the relevant 'Justification document' are met and the relevant assessment is recorded.

If all the above conditions are met, the privilege may be used and the approval of major repairs, major changes or STCs, as applicable, can be obtained by the DOA holder without EASA's involvement.

Note: If a DOA holder applies for a third-country validation after having approved a modification under its DOA holder privilege, EASA may review some of the compliance demonstration data in order to support the validation activity.

2. EXTENSION OF THE 'PRIVILEGE LIST' OF 'CERTAIN MAJOR REPAIRS', 'CERTAIN MAJOR CHANGES' OR 'CERTAIN STCs' AFTER THE PRIVILEGE IS GRANTED

When the DOA holder intends to update the 'List associated with the privilege', a 'Justification document' needs to be provided to EASA, as described in Section 1(b)(2) above. After EASA agrees with the updated 'privilege list' as part of the DOA holder's procedure, the DOA holder may proceed as per Section 4 below.

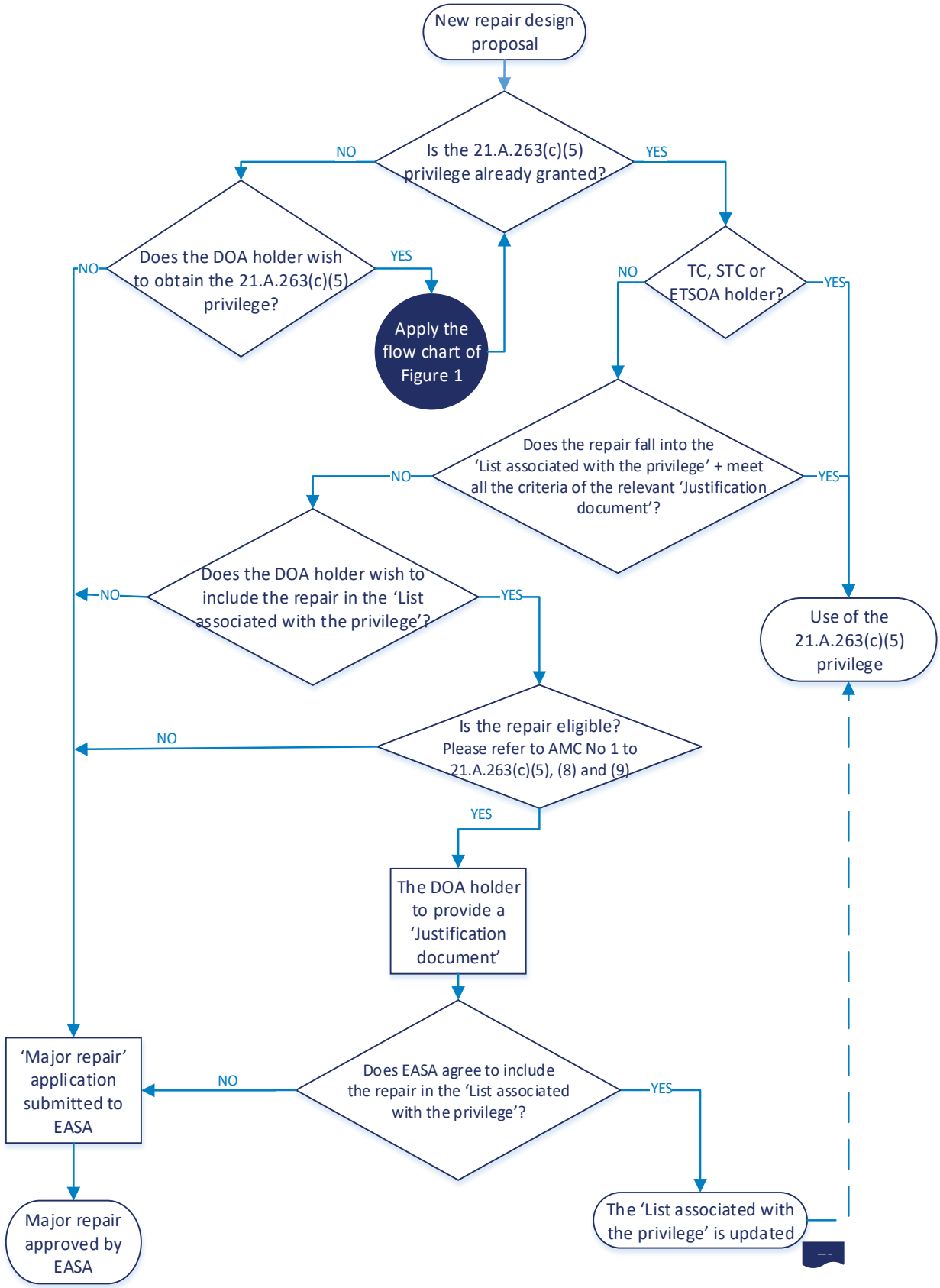

New repair design proposal
Is the 21.A.263(c)(5) privilege already granted?
NO
YES
Does the DOA holder wish to obtain the 21.A.263(c)(5) privilege?
NO
YES
Apply the flow chart of Figure 1
TC, STC or ETSOA holder?
NO
YES
Does the repair fall into the 'List associated with the privilege' + meet all the criteria of the relevant 'Justification document'?
NO
YES
Does the DOA holder wish to include the repair in the 'List associated with the privilege'?
NO
YES
Use of the 21.A.263(c)(5) privilege
Is the repair eligible? Please refer to AMC No 1 to 21.A.263(c)(5), (8) and (9)
NO
YES
The DOA holder to provide a 'Justification document'
'Major repair' application submitted to EASA
NO
Does EASA agree to include the repair in the 'List associated with the privilege'?
YES
Major repair approved by EASA
The 'List associated with the privilege' is updated

Figure 2

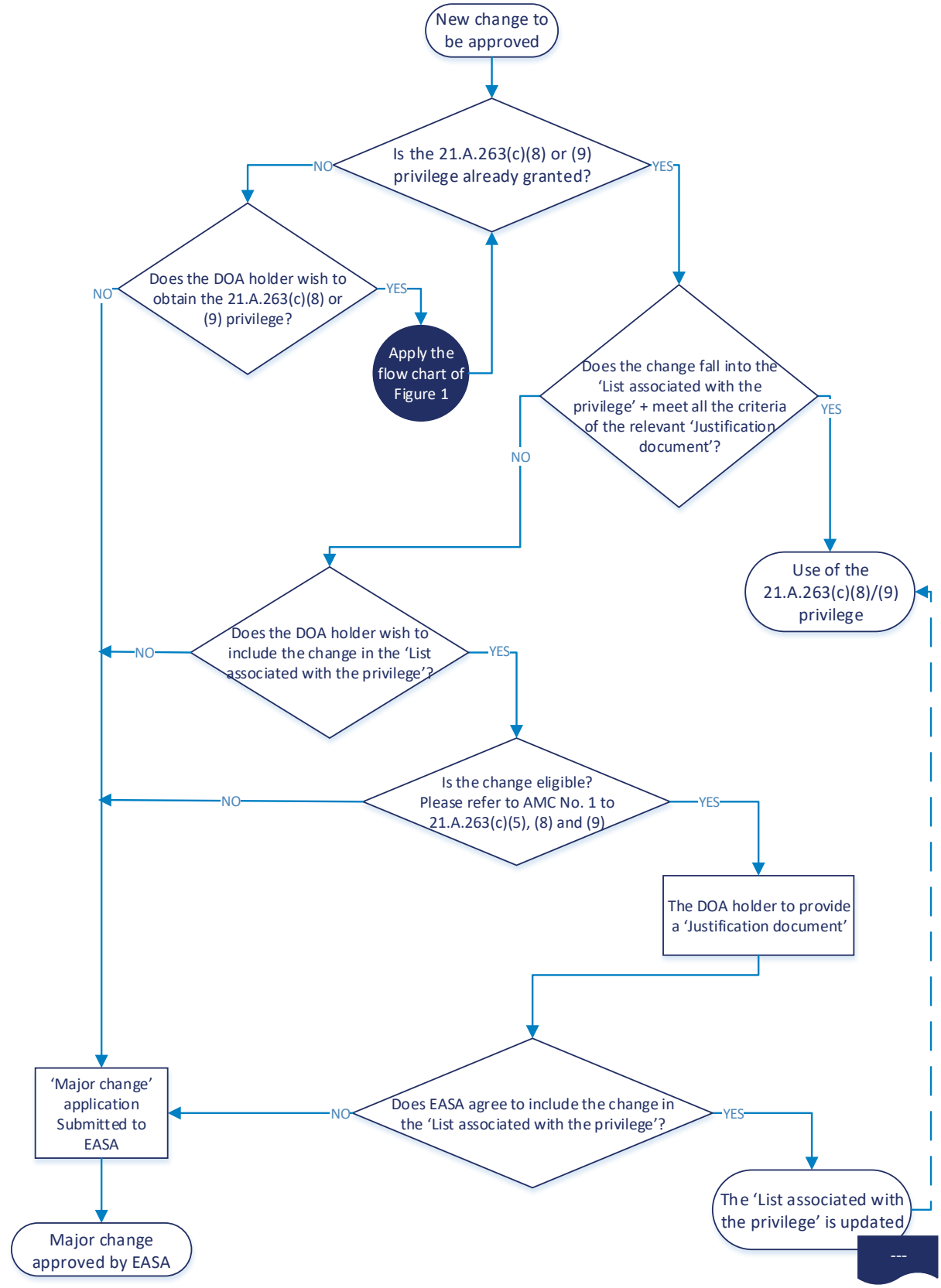

New change to be approved
Is the 21.A.263(c)(8) or (9) privilege already granted?
NO
YES
Does the DOA holder wish to obtain the 21.A.263(c)(8) or (9) privilege?
NO
YES
Apply the flow chart of Figure 1
Does the change fall into the 'List associated with the privilege' + meet all the criteria of the relevant 'Justification document'?
NO
YES
Use of the 21.A.263(c)(8)/(9) privilege
Does the DOA holder wish to include the change in the 'List associated with the privilege'?
NO
YES
Is the change eligible? Please refer to AMC No. 1 to 21.A.263(c)(5), (8) and (9)
NO
YES
The DOA holder to provide a 'Justification document'
'Major change' application Submitted to EASA
Does EASA agree to include the change in the 'List associated with the privilege'?
NO
YES
Major change approved by EASA
The 'List associated with the privilege' is updated

Figure 3

3. TC, STC OR APU ETSOA HOLDER APPROVAL OF A MAJOR REPAIR UNDER A MAJOR REPAIR PRIVILEGE — SPECIFIC CONSIDERATIONS

TC, STC or APU ETSOA DOA holders that intend to approve a major repair design under the privilege of point 21.A.263(c)(5) should ensure that:

(a) the type-certification basis for the product, part or appliance to be repaired is identified, together with all the other relevant requirements;

(b) all the records and substantiation data, including the documents that demonstrate compliance with all the relevant requirements, are provided to EASA for review; and

(c) for repair designs created for a specific product serial number, an assessment is made as to whether or not the repair design is affected by the presence of any embodied STC, change or repair.

4. DOA HOLDER'S APPROVAL BASED ON THE PRIVILEGE FOR A MAJOR REPAIR, MAJOR CHANGE OR STC — SPECIFIC CONSIDERATIONS

For the approval of:

— major repairs by DOA holders that are not the TC, STC or APU ETSO authorisation holders;

— major changes; and

— STCs

by a DOA holder under the privilege of point 21.A.263(c)(5), (8) and (9), the following should be considered.

4.1 Eligibility of the proposed major repair, major change or STC

The DOA holder should assess the proposed major repair, major change or STC against the 'list associated with the privilege' and the 'justification document' of 'certain major repairs', 'certain major changes' or 'certain supplemental type certificates' in order to determine whether the criteria of AMC No 1 to 21.A.263(c)(5), (8) and (9), Section 2.2, are met.

4.2 Forms for approval certificates

The DOA holder should use the following forms for the issuance of an approval under their privilege:

— EASA Form 991[1] for an STC;

— EASA Form 993[1] for a major change; and

— EASA Form 994[1] for a major repair.

If the DOA holder chooses to use their own forms, it must be ensured that at least the same information as requested on the EASA forms is presented.

For the numbering of major changes to TCs, STCs, as well as of major repairs approved under the privilege of point 21.A.263(c)(5), (8) or (9), please refer to GM 21.A.263(c)(5), (8) and (9).

[1] https://www.easa.europa.eu/easa-and-you/aircraft-products/design-organisations#group-easa-downloads

4.3 Approval under the DOA holder's privilege

When the DOA holder makes use of the privilege of point 21.A.263(c)(5), (8) or (9), they should include the following in the certification data package:

— a record of the assessment as described in 4.1 above;

— the reference to the 'justification document';

— the applicable product configuration;

— the applicable CSs or environmental protection requirements and methods of compliance;

— the compliance documents;

— the effects, if any, on limitations and on the approved documentation;

— the evidence of the independent checking of the compliance demonstration;

— the approval document containing the statement of the approval under the privilege of point 21.A.263(c)(5), (8) and (9) by an authorised signatory; and

— the date of approval.

In any case, before the major change, STC or major repair is approved under the DOA privilege, the DOA holder should ensure that the Part 21 requirements, in particular points 21.A.97, 21.A.115 and 21.A.433, are met.

4.4 Authorised signatories

An authorised person that is identified and authorised as described in Section 1(b)(4) above should sign the approval under the privilege of point 21.A.263(c)(5), (8) and (9).

4.5 Summary list

The DOA holder should add to the 'summary list' as described in Section 1(b)(4) above the major change, STC or major repair approved under the privilege of point 21.A.263(c)(5), (8) and (9).

GM 21.A.263(c)(5), (8) and (9) Numbering system for supplemental type certificates (STCs), major changes and major repairs issued by design organisation approval (DOA) holders, and information to EASA

ED Decision 2019/018/R

STCs, major changes and major repairs issued by a DOA holder under their privilege of point 21.A.263(c)(5), (8) and (9) should each be given a unique and consecutive reference number.

The following numbering system may be considered:

DOA holder reference	Type of certificate	Year of approval	Dash	Sequential number	Issue reference
21Jxxx	STC or MCH or MRE	17	—	001	A

Example: 21J999STC17—001A

Note: 'MCH' refers to 'major changes', 'MRE' to 'major repairs'.

With reference to STCs only, after the STC approval, the DOA holder should send a copy of the STC to EASA in a timely manner (as agreed with EASA).

21.A.265 Obligations of the holder

Regulation (EU) 2019/897

The holder of a design organisation approval shall, within the scope of its terms of approval, as established by the Agency:

(a) maintain the handbook required under point 21.A.243 in conformity with the design assurance system;

(b) ensure that this handbook or the relevant procedures included by cross-reference are used as a basic working document within the organisation;

(c) determine that the design of products, or changes or repairs thereto comply with the applicable specifications and requirements and have no unsafe features;

[applicable until 6 March 2023]

(c) determine that the design of the products, or of the changes or repairs thereto, complies with the applicable type-certification basis, operational suitability data certification basis, and the environmental protection requirements, and have no unsafe features;

[applicable from 7 March 2023 - Regulation (EU) 2022/201]

(d) provide the Agency with statements and associated documentation confirming compliance with point (c), except for approval processes carried out in accordance with point 21.A.263(c);

(e) provide to the Agency data and information related to the actions required under point 21.A.3B;

(f) determine, in accordance with point 21.A.263(c)(6), the flight conditions under which a permit to fly can be issued;

(g) establish, in accordance with point 21.A.263(c)(7), compliance with points (b) and (e) of point 21.A.711 before issuing a permit to fly to an aircraft;

(h) designate data and information issued under the authority of the approved design organisation within the scope of its terms of approval as established by the Agency with the following statement: “The technical content of this document is approved under the authority of the DOA ref. EASA. 21J.[XXXX]”.

[point (h) applicable until 6 March 2023]

(h) designate data and information issued under the authority of the approved design organisation within the scope of its terms of approval as established by the Agency with the following statement: “The technical content of this document is approved under the authority of the DOA ref. EASA. 21J [XXXX]”;’

(i) comply with Subpart A of this Section.

[points (h) and (i) applicable from 7 March 2023 - Regulation (EU) 2022/201]

AMC1 21.A.265(a) Obligations of the holder

ED Decision 2021/001/R

ADMINISTRATION OF THE HANDBOOK

1. The handbook of the applicant must be in the language which will permit the best use of it by all personnel charged with the tasks performed for the purpose of the design organisation. The applicant may be requested to provide an English translation of the handbook and other supporting documents as necessary for the investigation.

2. The handbook must be produced in a concise form with sufficient information to meet 21.A.243 relevant to the scope of approval sought by the applicant. The handbook must include the following:

   a. Organisation name, address, telephone, telex and facsimile numbers.

   b. Document title, and company document reference No (if any).

   c. Amendment or revision standard identification for the document.

   d. Amendment or revision record sheet.

   e. List of effective pages with revision/date/amendment identification for each page.

   f. Contents list or index.

   g. A distribution list for the Handbook.

   h. An introduction, or foreword, explaining the purpose of the document for the guidance of the organisation’s own personnel. Brief general information concerning the history and development of the organisation and, if appropriate, relationships with other organisations which may form part of a group or consortium, must be included to provide background information for the Agency.

   i. The certificate of approval must be reproduced in the document.

   j. Identification of the department responsible for administration of the Handbook.

   Note: In the case of an initial or revised approval it is recognised that certificate will be issued after EASA agreement to the handbook content in draft form. Arrangements for formal publication in a timely manner must be agreed before the certificate of approval is issued.

3. An updating system must be clearly laid down for carrying out required amendments and modifications to the handbook.

4. The handbook may be completely or partially integrated into the company organisation manual. In this case, identification of the information required by 21.A.243 must be provided by giving appropriate cross-references, and these documents must be made available, on request, to the Agency.

AMC2 21.A.265(a) Obligations of the holder

ED Decision 2021/001/R

HANDBOOK FORMAT AND PUBLICATION MEANS

The term 'handbook' is meant to describe a means to document the design organisation's processes and procedures. This may be in an electronic or paper format, as a stand-alone document or integrated in a management system. It may consist of:

— an online integrated management system with flowcharts and descriptions embedded in it;

— an online system referring to single documents;

— a classic handbook with references to online procedures;

— or any other combination of the above.

In any case, as required by point (c) of point 21.A.243, independently of the system chosen by the design organisation, the relevant content and the means to update the system should be clearly identified.

AMC-ELA No 1 to 21.A.265(a) Obligations of the holder – Administration of the design organisation handbook

ED Decision 2019/003/R

The design organisation handbook (DOH) of the applicant should be in a language that will permit the best use of it by all the personnel who perform tasks for the design organisation. The DOH may be completely or partially integrated into the company's organisation manual. Refer also to AMC-ELA No 1 to 21.A.243 for the required content.

AMC-ELA No 1 to 21.A.265(b) Obligations of the holder – Use of the design organisation handbook as a basic working document

ED Decision 2019/003/R

It is the responsibility of the HDO to ensure that the design organisation handbook (DOH) is used as a basic working document within the design organisation. In this sense, the HDO should include a statement to the DOH that the information provided within the DOH is binding.

The organisation should ensure that personnel have access to, and are familiar with, that part of the content of the DOH that covers their activities. This may be done, for example, by distributing the information that updates of the documentation are available, and by making the documentation available at a location where the information is accessible to all affected persons.

Staff at the design organisation who are involved in the demonstration of compliance of products under the DOA approval should be able to demonstrate their awareness of the definitions provided within the DOH. This can be achieved by any suitable means, and it does not necessarily require

training sessions to be provided. Regular internal monitoring should be conducted to verify that the relevant staff members are aware of the relevant definitions.

Monitoring of compliance with this documentation should be done by systematic means. These means do not need to be limited to, or to even include auditing, but they can be accomplished by structured experience exchanges, regular quality meetings, brainstorming or lessons-learned sessions, project reviews at appropriate phases of the product development, or other similar means accepted by EASA.

GM 21.A.265(b) Obligations of the holder

ED Decision 2021/001/R

USE OF THE HANDBOOK

1. The handbook should be signed by the chief executive and the head of the design organisation and declared as a binding instruction for all personnel charged with the development and type investigation of products. This binding statement should be provided independently of the means chosen by the design organisation to document its processes and procedures.
2. All procedures referenced in the handbook are considered as parts of the handbook and therefore as basic working documents.

AMC-ELA No 1 to 21.A.265(c) Obligations of the holder – Determination of compliance

ED Decision 2019/003/R

The organisation should apply the methods detailed in AMC-ELA No 2 to 21.A.239(a) to determine whether the design of the product, or changes or repairs to them, comply with the applicable requirements, and to ensure that the design of the product contains no unsafe features.

AMC-ELA No 1 to 21.A.265(e) Obligations of the holder – Providing information in response to airworthiness directives

ED Decision 2019/003/R

The design organisation handbook (DOH) should contain a declaration to ensure that the proposal of appropriate corrective actions/required inspections is submitted to EASA in cases where EASA has issued airworthiness directives in response to potentially unsafe conditions of a product under the responsibility of the approved DO. In addition, the provisions in the DOH should ensure that following the approval by EASA of any proposals referred to under this point, the DO makes appropriate descriptions and procedures for the corrective actions/required inspections available to all known operators or owners of the product and, upon request, to any person that is required to comply with the airworthiness directive.

GM 21.A.265(h) Designation of data and information issued under the authority of a design organisation approval (DOA) holder

ED Decision 2021/007/R

1. INTENT

This GM provides guidance for complying with the obligation of 21.A.265(h), and addresses the various aspects that the DOA holder should cover in order to have a comprehensive procedure for the designation of data and information.

2. SCOPE

The term 'data and information' as used in point 21.A.265(h) also includes instructions.

Data and information referred to in point 21.A.265(h) are issued by a DOA holder and cover the following:

— embodiment instructions for design changes or repairs (usually in the form of a service bulletin, a modification bulletin, repair instructions or engineering order, etc.);

— manuals required by Part 21 or the applicable CSs (such as the aircraft flight manual (AFM), rotorcraft flight manual, instructions for continuing airworthiness (ICAs), etc.);

— operation suitability data (OSD);

— continued-airworthiness instructions (usually in the form of service bulletins) which may be covered by airworthiness directives (ADs);

— additional data to be defined by the DOA holder (e.g. alternative maintenance instructions that are not, per se, ICAs).

Note: This data and information may be issued in a digital or paper format.

The obligation does not apply to, and the statement provided with the data and information should not be used on, the following documents:

— certification documents (e.g. the certification programme, compliance checklist, etc.);

— compliance documents;

— design data transferred to production organisations; and

— production deviations (also referred to as 'unintended deviations' or 'concessions').

3. RATIONALE

The purpose of this obligation is to give certainty to the end users about the approval status of the data and information issued by the DOA holder.

4. PROCEDURE

For the information and instructions issued under point 21.A.265(h), the DOA holder should establish a procedure that addresses the following aspects:

— their preparation;

— verification of their technical consistency with the corresponding approved change(s), repair(s) or approved data, including their effectivity, description, effects on airworthiness and environmental protection, especially when limitations are changed;

— verification of their feasibility in practical applications, when relevant and feasible;

— the authorised signatories.

The procedure should include the information or the instructions prepared by suppliers, and declared applicable to its products by the DOA holder.

5. STATEMENT

The statement provided with the data and information should also cover those items prepared by subcontractors or vendors that the DOA holder has declared as applicable to their products. The technical content of the statement is related to the type certificate data and information.

The approval included in the statement means that:

— the type certificate data has been appropriately approved; and

— the information contains practical and well-defined installation or inspection methods, and, when those methods are implemented, the product is in conformity with the approved type certificate data.

Note: Data and information related to the measures required by point 21.A.3B(b) (airworthiness directives (ADs)) are submitted to EASA to ensure their compatibility with the content of an AD (see point 21.A.265(e)), and contain a statement that they are, or will be, subject to an AD issued by EASA.

AMC-ELA1 to 21.A.263 Privileges and AMC-ELA1 to 21.A.265(h) Obligations of the holder

ED Decision 2021/001/R

(a) The privilege to classify minor/major changes and repairs is granted in accordance with 21.A.263(c)(1) on the basis of the application of the method defined in response to AMC-ELA No 2 to 21.A.239(a).

The defined method should cover the following points:

— the identification of changes to a type design or repairs, including the applicable requirements as per the type certification data sheet (TCDS);

— the classification of changes as major if additional work is required to demonstrate compliance with the applicable requirements;

— the classification of changes as minor if no additional work is required to demonstrate compliance with the applicable requirements;

— the recording of the classification, and documented justification of the classification, for those cases that are not straightforward;

— approval of the classification by the authorised signatories.

It is acceptable to use the same classification process for repairs as for changes. Nevertheless, GM 21.A.435(a) should be taken into consideration when classifying repairs.

(b) The privilege to approve minor changes and minor repairs is granted together with the privilege of classification, on the basis of the application of the method defined in response to AMC-ELA No 2 to 21.A.239(a).

The defined method should cover the following points:

— the identification of whether additional work is required to demonstrate compliance with the applicable requirements;

— determination of the required compliance documentation and the verification by following the same workflow as the one applied for the initial design and certification;

— approving the repair under the DOA privileges by using a formalised approach. This may be, for example, defined by an adequately structured form that provides:

— adequate identification of the change;

— the identification of the applicable requirements;

— reference to compliance documents;

— the identification of the effects on limitations and approved documentation (if any);

— evidence that independent checking has been conducted;

— the date and evidence of the approval given by the relevant nominated staff.

— identification of the authorised signatories for the approval of minor changes and minor repairs;

— a statement that the design of minor changes/repairs is conducted using the same provisions as those defined for the design work during the initial design and certification.

It is acceptable to use the same approval process for minor repairs as the one used for minor changes.

(c) Instructions required by the certification specifications, such as the maintenance manual, the MMEL, etc., are usually prepared within the type investigation process to comply with the certification requirements. These documents are covered by the type investigation process. The generation and publication of information or instructions related to continued airworthiness, including updates to the above-mentioned ICA and MMEL and to any related design activity, are handled according to the same principles as any type design, change design or repair design activity/documentation if no separate method/process as per GM 21.A.265(h) is defined. The DOH should state how documents under this obligation are issued and distributed to the aircraft owner and to other interested parties. Using the change/repair process would be the simplest way for small companies to do this.

(d) The approval of minor revisions to the AFM and its supplements should contain the following statement: 'The technical content of this document is approved under the authority of the DOA, ref.: EASA.21J.[XXXX]. Such a change is treated as a change to the type certificate, as the AFM is formally a part of the type certificate, and it is consequently classified on the basis of the application of the method defined in response to AMC-ELA No 2 to 21.A.239(a), and identified as being related to a 'minor' design change. Administrative revisions to the AFM are also expected to be classified as 'minor'. The following revisions to the AFM are defined as 'minor' revisions:

1. editorial revisions or corrections to the AFM;

2. changes to parts of the AFM that are not required to be approved by EASA;

3. changes to limitations or procedures that are achieved without altering or exceeding the certification data;

4. conversions of units of measurement that were previously approved by the FAA or by EASA, and that are added to the AFM in a previously approved manner;

5. the addition of aircraft serial numbers to an existing AFM if the aircraft configuration, as related to the AFM, is identical to the configuration of the aircraft already in that AFM;

6. the removal of references to aircraft serial numbers that are no longer applicable to that AFM;

7. the translation of an EASA-approved AFM into the language of the State of Design or the State of Registration;

8. AFM revisions as part of minor changes to a type design.

(e) In order to be granted a privilege to approve flight conditions (FC) and to issue PtFs, the design organisation should have in place an adequate FTOM in accordance with AMC-ELA No 2 to 21.A.243 that is limited to the products designed and produced by the company, and over which the company has full configuration control. Authorised signatories shall be defined within the FTOM, or its equivalent.

In such a case, the FTOM (or another document) should contain a defined method that addresses the following points if the (FC) are approved under the DOA privileges:

— FC that must be complied with to safely perform a flight must be determined in accordance with point 21.A.708;

— management of the aircraft configuration, including the handling of changes to the aircraft configuration operated under a PtF;

— the documentation of substantiations of flight conditions;

— approval under the privilege using EASA Form 18A defined in AMC 21.A.263(c)(6), and the definition of the authorised signatories.

For a PtF that is issued under the privilege, a method should be defined that addresses the following points:

— how conformity with the approved conditions is established, documented and attested;

— the issue of the PtF under the DOA privilege (form), and the authorised signatories;

— the interface with the local authority for the flight.

Further guidance is provided in AMC 21.A.263(c)(6) and (c)(7), as well as in the GM and AMC related to Subpart P.

SUBPART K — PARTS AND APPLIANCES

21.A.301 Scope

Regulation (EU) No 748/2012

This Subpart establishes the procedure relating to the approval of parts and appliances.

21.A.303 Compliance with applicable requirements

Regulation (EU) No 748/2012

The showing of compliance of parts and appliances to be installed in a type-certificated product shall be made:

(a) in conjunction with the type-certification procedures of Subpart B, D or E for the product in which it is to be installed; or

(b) where applicable, under the ETSO authorisation procedures of Subpart O; or

(c) in the case of standard parts, in accordance with officially recognised Standards.

AMC 21.A.303(c) Standard Parts

ED Decision 2012/020/R

1. In this context a part is considered as a 'standard part' where it is designated as such by the design approval holder responsible for the product, part or appliance, in which the part is intended to be used. In order to be considered a 'standard part', all design, manufacturing, inspection data and marking requirements necessary to demonstrate conformity of that part should be in the public domain and published or established as part of officially recognised Standards, or

2. For sailplanes and powered sailplanes, where it is a non-required instrument and/or equipment certified under the provision of CS 22.1301(b), if that instrument or equipment, when installed, functioning, functioning improperly or not functioning at all, does not in itself, or by its effect upon the sailplane and its operation, constitute a safety hazard.

'Required' in the term 'non-required' as used above means required by the applicable certification specifications (CS 22.1303, 22.1305 and 22.1307) or required by the relevant operating regulations and the applicable Rules of the Air or as required by Air Traffic Management (e.g. a transponder in certain controlled airspace).

Examples of equipment which can be considered standard parts are electrical variometers, bank/slip indicators ball type, total energy probes, capacity bottles (for variometers), final glide calculators, navigation computers, data logger / barograph / turnpoint camera, bug-wipers and anti-collision systems.

Equipment which must be approved in accordance to the certification specifications shall comply with the applicable ETSO or equivalent and is not considered a standard part (e.g. oxygen equipment).

GM No 2 to 21.A.303(c) Officially recognised Standards

ED Decision 2012/020/R

In this context 'officially recognised Standards' means:

1. Those standards established or published by an official body whether having legal personality or not, which are widely recognised by the air transport sector as constituting good practice.

2. The standard used by the manufacturer of the equipment as mentioned in paragraph 2 of AMC 21.A.303(c).

21.A.305 Approval of parts and appliances

Regulation (EU) No 748/2012

In all cases where the approval of a part or appliance is explicitly required by Union law or Agency measures, the part or appliance shall comply with the applicable ETSO or with the specifications recognised as equivalent by the Agency in the particular case.

21.A.307 The eligibility of parts and appliances for installation

Regulation (EU) 2021/699

(a) A part or appliance is eligible for installation in a type-certified product when it is in a condition for safe operation, marked in accordance with Subpart Q and accompanied by an authorised release certificate (EASA Form 1), certifying that the item was manufactured in conformity with approved design data.

(b) By way of derogation from point (a) and provided that the conditions in point (c) are met, the following parts or appliances do not require an EASA Form 1 in order to be eligible for installation in a type-certified product:

(1) a standard part;

(2) in the case of ELA1 or ELA2, a part or appliance that is:

(i) not life limited, nor part of the primary structure, nor part of the flight controls;

(ii) identified for installation in the specific aircraft;

(iii) to be installed in an aircraft whose owner has verified compliance with the applicable conditions in (i) and (ii), and has accepted responsibility for this compliance;

(3) a part or appliance for which the consequences of a non-conformity with its approved design data has a negligible safety effect on the product and which is identified as such by the holder of the design approval in the instructions for continued airworthiness. In order to determine the safety effects of a non-conforming part or appliance, the design approval holder may establish in the instructions for continued airworthiness specific verification activities to be conducted by the installer of the part or appliance on the product;

(4) in the case of the embodiment of a standard change in accordance with point 21.A.90B or a standard repair in accordance with point 21.A.431B, a part or appliance, for which the consequences of a non-conformity with its design data have a negligible safety effect on the product, and which is identified as such in the certification specifications for standard changes and standard repairs issued in accordance with point (a)(2) of point 21.A.90B and point (a)(2) of point 21.A.431B. In order to determine the safety effects of

a non-conforming part or appliance, specific verification activities to be conducted by the person that installs the part or appliance on the product may be established in the certification specifications referred to above;

(5) a part or appliance that is exempted from an airworthiness approval in accordance with Commission Regulation (EU) No 965/2012 ([1]); and

(6) a part or appliance that is an item of a higher assembly identified in points (b)(1) to (b)(5).

(c) Parts and appliances listed in point (b) are eligible for installation in a type-certified product without being accompanied by an EASA Form 1, provided that the installer holds a document issued by the person or organisation that manufactured the part or appliance, which declares the name of the part or appliance, the part number, and the conformity of the part or appliance with its design data, and which contains the issuance date.

AMC1 21.A.307(b)(3) and (b)(4) Verification activities to be conducted on the part or appliance or release documentation prior to installation

ED Decision 2021/007/R

To prevent a non-negligible safety effect on the product, due to the installation of a part or appliance referred to in point 21.A.307(b)(3) and (b)(4) that could potentially not conform to its design, the design approval holder (DAH) or EASA may identify in the ICA (in the case of 21.A.307(b)(3)) or in CS-STAN (in the case of 21.A.307(b)(4)) any specific verification activities to be conducted by the installer on the part or appliance before installing it on the product in accordance with Regulation (EU) No 1321/2014.

When assessing the safety effect of a part or appliance identified in point 21.A.307(b)(3) or (b)(4), the DAH or EASA should assume that the installer would conduct, in accordance with Regulation (EU) No 1321/2014, any specific verification activities on the part or appliance or release documentation, as identified in the ICA or in CS-STAN.

Example: Information from the DAH contained in the ICA: 'Part XXX-YY must comply with flammability requirement JJJ-KKK'.

GM1 21.A.307(b)(3) and (b)(4) Meaning of 'negligible safety effect'

ED Decision 2021/007/R

For the purpose of 21.A.307(b)(3) and (b)(4), when 'a part or appliance for which the consequences of non-conformity to its design has a negligible safety effect when installed on the product' is mentioned, it means that any non-conformity of the part or appliance not identified by the installer that conducted the specific verification activities mentioned in 21.A.307(c):

(a) for ELA1 and ELA2 aircraft, at worst:

(1) slightly reduces the operational or functional certified capabilities of the aircraft or its safety margins;

(2) causes some physical discomfort to its occupants; and

[1] Commission Regulation (EU) No 379/2014 of 7 April 2014 amending Commission Regulation (EU) No 965/2012 laying down technical requirements and administrative procedures related to air operations pursuant to Regulation (EC) No 216/2008 of the European Parliament and of the Council (OJ L 123, 24.4.2014, p. 1).

(3) slightly increases the workload of the flight crew; and

(b) for any other aircraft:

(1) has no effect on the operational or functional certified capabilities of the aircraft, or on its safety margins;

(2) causes no physical discomfort to the occupants; and

(3) has no effect on the flight crew.

GM1 21.A.307(b)(4) Certification specifications referred to in point 21.A.307(b)(4)

ED Decision 2021/007/R

The corresponding certification specifications issued by EASA and mentioned in point 21.A.307(b)(4) are the Certification Specifications for Standard Changes and Standard Repairs (CS-STAN).

GM1 21.A.307(b)(5) Equipment exempted from an airworthiness approval in accordance with Commission Regulation (EU) No 965/2012

ED Decision 2021/007/R

The equipment exempted from an airworthiness approval in accordance with Commission Regulation (EU) No 965/2012 that can be installed during maintenance as new equipment on an aircraft under point 21.A.307(b)(5) is the equipment identified in the following points:

— CAT.IDE.A.100(a),

— CAT.IDE.H.100(a),

— NCC.IDE.A.100(b) and (c),

— NCC.IDE.H.100(b) and (c),

— NCO.IDE.A.100(b) and (c),

— NCO.IDE.H.100(b) and (c),

— NCO.IDE.S.100(b) and (c),

— NCO.IDE.B.100(b) and (c),

— SPO.IDE.A.100(b) and (c),

— SPO.IDE.H.100(b) and (c),

— SPO.IDE.S.100(b) and (c), and

— SPO.IDE.B.100(b) and (c)

of Commission Regulation (EU) No 965/2012.

GM1 21.A.307(b)(6) Part or appliance that is part of a higher-level assembly

ED Decision 2021/007/R

An EASA Form 1 is not required for a part or appliance when that part or appliance is an element of a higher-level assembly for which an EASA Form 1 is not required.

(SUBPART L — NOT APPLICABLE)

SUBPART M — REPAIRS

21.A.431A Scope

Regulation (EU) 2019/897

(a) This Subpart establishes the procedure for the approval of a repair design of a product, part or appliance and establishes the rights and obligations of the applicants for, and holders of, those approvals.

(b) This Subpart defines standard repairs that are not subject to an approval process under this Subpart.

(c) A “repair” means the elimination of damage and/or restoration to an airworthy condition following the initial release to service by the manufacturer of any product, part or appliance.

(d) The elimination of damage by replacement of parts or appliances without the necessity for design activity shall be considered as a maintenance task and shall therefore require no approval under this Annex.

(e) A repair to an ETSO article other than an Auxiliary Power Unit (APU) shall be treated as a change to the ETSO design and shall be processed in accordance with point 21.A.611.

(f) In this Subpart, the references to type-certificates include type-certificates and restricted type-certificates.

GM 21.A.431A Scope

ED Decision 2019/018/R

Manuals and other instructions for continued airworthiness (such as the Manufacturers Structural Repair Manual, Maintenance Manuals and Engine Manuals provided by the holder of the type-certificate, supplemental type-certificate, or APU ETSO authorisation as applicable) for operators, contain useful information for the development and approval of repairs.

When these data are explicitly identified as approved, they may be used by operators without further approval to cope with anticipated in-service problems arising from normal usage provided that they are used strictly for the purpose for which they have been developed.

Approved data is data which is approved either by the Agency, or by an appropriately approved design organisation.

When specific repair data is approved outside of the Community, conditions for acceptance may be defined in the bilateral arrangements between the Community and the competent authority of a third country. In the absence of such arrangement, the repair data shall follow the approval route as if it was designed and approved within the Community.

GM 21.A.431A(e) Repairs to European technical standard order (ETSO) articles other than auxiliary power units (APUs)

ED Decision 2012/020/R

A repair to an ETSO article other than an APU can be either be seen:

1. Under 21.A.611 in the context of an ETSO authorisation, i.e., when an article as such is specifically approved under Subpart O, with dedicated rules that give specific rights and obligations to the designer of the article, irrespective of any product type design or change to the type design. For a repair to such an article, irrespective of installation on any aircraft, Subpart O, and 21.A.611 in particular, should be followed; or
2. When an airline or a maintenance organisation is designing a new repair (based on data not published in the TC holder or Original Equipment Manufacturer documentation) on an article installed on an aircraft, such a repair can be considered as a repair to the product in which the article is installed, not to the article taken in isolation. Therefore Subpart M can be used for the approval of this repair, that will be identified as 'repair to product x affecting article y', but not 'repair to article y'.

21.A.431B Standard repairs

Regulation (EU) 2021/699

(a) Standard repairs are repairs:

(1) in relation to:

(i) aeroplanes of 5 700 kg Maximum Take-Off Mass (MTOM) or less;

(ii) rotorcraft of 3 175 kg MTOM or less;

(iii) sailplanes and powered sailplanes, balloons and airships as defined in ELA1 or ELA2.

(2) that follow design data included in certification specifications issued by the Agency, containing acceptable methods, techniques and practices for carrying out and identifying standard repairs, including the associated instructions for continued airworthiness; and

(3) that are not in conflict with TC holders data.

(b) Points 21.A.432A to 21.A.451 are not applicable to standard repairs.

GM 21.A.431B Standard repairs – Certification Specifications

ED Decision 2015/016/R

CS-STAN contains the certification specifications referred to in 21.A.431B(a)2. Guidance on the implementation of Standard Changes and Standard Repairs can be found in AMC M.A.801 of the AMC to Part-M.

21.A.432A Eligibility

Regulation (EU) No 748/2012

(a) Any natural or legal person that has demonstrated, or is in the process of demonstrating, its capability under point 21.A.432B shall be eligible as an applicant for a major repair design approval under the conditions laid down in this Subpart.

(b) Any natural or legal person shall be eligible to apply for approval of a minor repair design.

21.A.432B Demonstration of capability

Regulation (EU) 2019/897

(a) An applicant for approval of a major repair design shall demonstrate its capability by holding a design organisation approval, issued by the Agency in accordance with Subpart J.

(b) By way of derogation from point (a), as an alternative procedure to demonstrate its capability, an applicant may seek Agency agreement for the use of procedures setting out the specific design practices, resources and sequence of activities necessary to comply with this Subpart.

(c) By way of derogation from point (a), in the case of products referred to in point 21.A.14(c), an applicant may demonstrate its capability by obtaining the Agency's acceptance of its certification programme established in accordance with point 21.A.432C(b).

GM 21.A.432B(b) Alternative procedures

ED Decision 2019/018/R

See AMC 21.A.14(b) for the details of the alternative procedures.

AMC to 21.A.143, 21.A.243, 21.A.14(b), 21.A.112B(b) and 21.A.432B(b) Flight Test Operations Manual (FTOM)

ED Decision 2017/024/R

1. General

   a. Scope: The FTOM covers flight test operations.

      The FTOM complexity should be proportionate to the aircraft and the organisation complexity.

   b. Format

      The FTOM may:

      — be included in the Design Organisation Approval (DOA)/Production Organisation Approval (POA)/Alternative Procedure to DOA (APDOA) documents, or

      — be a separate manual.

      The FTOM may make reference to other documents to cover the contents listed below, e.g. for record-keeping.

   c. Use by contractors or sub-contractors:

      When flight tests are performed by contractors or sub-contractors, they should comply with the FTOM of the primary organisations, unless they have established an FTOM in compliance with Part-21, the use of which has been agreed between the two organisations.

2. The FTOM should contain the following elements:

   a. Exposition (not applicable in the case of APDOA):

      If the FTOM is presented as a separate document, it should include a chart indicating the structure of the organisation and, more specifically, the functional links of the people in charge of flight test activities. It should also mention the coordination between all departments affecting flight test, e.g. Design Office, Production and Maintenance, in particular coordination for the establishment and update of a Flight Test Programme.

b. Risk and safety management:

The FTOM should describe the organisation's policy in relation to risk and safety assessment, mitigation and associated methodologies.

c. Crew members:

According to the flight test category, the FTOM should describe the organisation's policy on the composition of the crew (including the need to use a Lead Flight Test Engineer (LFTE)) and the competence and currency of its flight test crew members, including procedures for appointing crew members for each specific flight.

All crew members should be listed in the FTOM.

A flight time limitation policy should be established.

d. Carriage of persons other than crew members:

According to the flight test category, the FTOM should describe the organisation's policy in relation to the presence and safety on-board, of people other than crew members (i.e. with no flying duties).

People other than crew members should not be allowed on board for Category 1 flight tests.

e. Instruments and equipment:

The FTOM should list, depending on the nature of the flight, the specific safety-related instruments and equipment that should be available on the aircraft or carried by people on board.

The FTOM should contain provisions to allow flights to take place in case of defective or missing instruments or equipment.

f. Documents:

The FTOM should list the documents to be produced for flight test, and include (or refer to) the procedures for their issue, update and follow-up to ensure the documents' configuration control:

(i) documents associated with a Flight Test Programme:

— Flight Order for a given flight, which should include:

— a list of the tests to be performed and associated conditions;

— safety considerations relevant to the flight;

— category of the flight (e.g. Category 1);

— composition of the crew;

— names of persons other than crew members;

— aircraft configuration items relevant to the test to be highlighted to the crew;

— loading of the aircraft;

— reference to approved flight conditions; and

— restrictions relevant to the flight to be highlighted to the crew.

— Flight crew report.

(ii) documentation and information to be carried on the aircraft during flight test;

(iii) record-keeping: the FTOM should describe the policy relative to record-keeping.

g. Permit to fly:

The FTOM should describe the involvement of the flight test organisation or flight test team (as appropriate) in the process for the approval of flight conditions and the issue of permits to fly in accordance with Subpart P.

h. Currency and training:

The FTOM should describe how training for flight test is organised.

Currency of the flight test crew may be ensured either through recent experience or refresher training.

For aircraft for which Appendix XII is applicable, minimum flight experience by year should be:

— for pilots: 50 hours. In addition:

— for pilots with a flight test rating, the 50 hours should include 20 flight test hours in any flight test category.

— for pilots performing a Category 3 flight test, the flight test experience should be expressed in terms of a number of flights leading to the issue of a Certificate of Airworthiness (CofA) (e.g. first flights).

— for pilots performing a Category 4 flight test, the minimum flight test experience should be proportionate to the activity envisaged.

— for LFTEs: 10 flight test hours in any flight test category.

The FTOM should specify the requirements for a refresher training in order to ensure that crew members are sufficiently current to perform the required flight test activity.

A system should be established to record the currency of the flight test crew's training.

A valid national document (i.e. licence), issued by an EASA Member State under its national regulations and ensuring compliance with the agreed currency requirements, is an acceptable means of compliance to demonstrate currency for a pilot that holds a flight test rating and for an LFTE.

21.A.432C Application for a repair design approval

Regulation (EU) 2021/699

(a) An application for a repair design approval shall be made in a form and manner established by the Agency.

(b) An application for a major repair design approval shall include, or be supplemented after the initial application by, a certification programme containing:

1. a description of the damage and repair design identifying the configuration of the type design upon which the repair is made;

2. an identification of all areas of the type design and the approved manuals that are changed or affected by the repair design;

3. an identification of any reinvestigations necessary to demonstrate compliance of the repair design and areas affected by the repair design with the type-certification basis incorporated by reference in, as applicable, either the type-certificate, the supplemental type-certificate or the APU ETSO authorisation;

4. any proposed amendments to the type-certification basis incorporated by reference in, as applicable, either the type-certificate, the supplemental type-certificate or the APU ETSO authorisation;

5. a proposal for a breakdown of the certification programme into meaningful groups of compliance demonstration activities and data, including the means and process proposed to be followed to demonstrate compliance with point 21.A.433(a)(1) and references to related compliance documents;

6. a proposal for the assessment of the meaningful groups of compliance demonstration activities and data, addressing the likelihood of an unidentified non-compliance with the type-certification basis and the potential impact of that non-compliance on product safety. The proposed assessment shall take into account at least the elements set out in subpoints (1)-(4) of point 21.B.100(a). Based on this assessment, the application shall include a proposal for the Agency's involvement in the verification of the compliance demonstration activities and data; and

7. the specification whether the certification data is prepared completely by the applicant or on the basis of an arrangement with the owner of the type-certification data.

AMC 21.A.432C(a) Form and manner

ED Decision 2019/018/R

The applicant should file an application using the web-based 'EASA Applicant Portal'[1] or the application forms for the approval of major changes/major repair designs (FO.CERT.00031)[2] or for the approval of minor changes/minor repair designs (FO.CERT.00032)[3], which may be downloaded from the EASA website.

The forms should be completed in accordance with the instructions embedded at the bottom of the application forms, and sent to EASA by fax, email or regular mail following the information provided on the EASA website[4].

[1] https://ap.easa.europa.eu (changes to the link provided may not be reflected in this document).

[2] https://www.easa.europa.eu/document-library/application-forms/focert00031 (changes to the link provided may not be reflected in this document).

[3] https://www.easa.europa.eu/document-library/application-forms/focert00032 (changes to the link provided may not be reflected in this document).

[4] https://www.easa.europa.eu/document-library/application-forms/certificates-and-approvals (changes to the link provided may not be reflected in this document).

AMC 21.A.432C(b) Certification programme for a repair design approval

ED Decision 2019/018/R

Clarification of 21.A.432C(b)(1): the description of the repair should consist of:

— the pre- and post-repair configuration;

— a drawing or outline of the repair;

— a list of the detailed features;

— a description of the type and extent of the inspection; and

— an outline of the damage.

Clarification of 21.A.432C(b)(3): the identification of reinvestigations does not refer to the demonstration of compliance itself, but to the list of the affected certification specifications (CSs), together with the means of compliance.

21.A.433 Requirements for approval of a repair design

Regulation (EU) 2021/699

(a) A repair design shall only be approved:

1. when it has been demonstrated, following the certification programme referred to in point 21.A.432C(b), that the repair design complies with the type-certification basis incorporated by reference in, as applicable, either the type-certificate, the supplemental type-certificate or the APU ETSO authorisation, as well as with any amendments established and notified by the Agency in accordance with point 21.B.450;

2. when compliance with the type-certification basis that applies in accordance with point (a)(1) has been declared and the justifications of compliance have been recorded in the compliance documents;

3. when no feature or characteristic has been identified that may make the product unsafe for the uses for which certification is requested;

4. where the applicant has specified that it provided certification data on the basis of an arrangement with the owner of the type-certification data in accordance with point 21.A.432C(b)(7):

   (i) when the holder has indicated that it has no technical objection to the information submitted under point (a)(2); and

   (ii) when the holder has agreed to collaborate with the repair design approval holder to ensure discharge of all obligations for continued airworthiness of the changed product through compliance with point 21.A.451.

5. when, for a repair to an aeroplane subject to point 26.302 of Annex I to Regulation (EU) 2015/640, it has been demonstrated that the structural integrity of the repair and affected structure is at least equivalent to the level of structural integrity established for the baseline structure by point 26.302 of Annex I to Regulation (EU) 2015/640.

(b) The applicant shall submit to the Agency the declaration referred to in point (a)(2) and, on request by the Agency, all necessary substantiation data.

AMC1 21.A.433(a)(5) Requirements for the approval of repairs to large aeroplanes subject to point 26.302 of Part-26

ED Decision 2021/007/R

For repairs that affect fatigue-critical structures of turbine-powered large aeroplanes certified to carry 30 passengers or more, or with a payload capacity of 3 402 kg (7 500 lbs) or more, damage-tolerance evaluations demonstrate compliance with point 21.A.433(a)(5) when the certification basis used for the repair is:

(a) Amdt 19 to CS 25.571, or subsequent amendments; or

(b) the certification basis of the aeroplane, unless it precedes JAR 25.571 Change 7 or 14 CFR §25.571 Amendment 45, in which case the certification basis for the repair should be:

(1) JAR 25.571 Change 7 or 14 CFR §25.571 Amendment 45, or later amendments; or

(2) the specifications used for compliance with the applicable points of Part-26 for the fatigue-critical structures affected by the repair.

AMC 21.A.433(a) and 21.A.5 Repair design and record-keeping

ED Decision 2021/007/R

1. Relevant substantiation data associated with a new major repair design and record keeping should include:

   a. the identification of the damage and the reporting source;

   b. the major repair design approval sheet identifying the applicable specifications and references of justifications;

   c. the repair drawing and/or instructions and scheme identifier;

   d. the correspondence with the holder of the type certificate (TC), supplemental type certificate (STC), or auxiliary power unit European technical standard order (APU ETSO) authorisation, if its advice on the design has been sought;

   e. the structural justification (static strength, fatigue, damage tolerance, flutter, etc.) or references to this data;

   f. the effect on the aircraft, engines and/or systems (performance, flight handling, etc., as appropriate);

   g. the effect on the maintenance programme;

   h. the effect on airworthiness limitations, the flight manual and the operating manual;

   i. any weight and moment changes; and

   j. special test requirements.

2. Relevant minor repair documentation includes paragraphs 1(a) and (c). Other points of paragraph 1 may be included where necessary. If the repair is outside the approved data, a justification for the classification is required.

3. Special consideration should be given to repairs that impose subsequent limitations on the part, product or appliance (e.g. engine turbine segments that may only be repaired a finite number of times, the number of repaired turbine blades per set, oversizing of fastener holes, etc.).

4. Special consideration should also be given to life-limited parts and critical parts, notably with the involvement of the TC or STC holder, when deemed necessary under 21.A.433(a)(4).

5. Repairs to engine or APU critical parts would normally only be accepted with the involvement of the TC holder.

21.A.435 Classification and approval of repair designs

Regulation (EU) 2019/897

(a) A repair design shall be classified as either “major” or “minor” in accordance with the criteria set out in point 21.A.91 for a change to the type-certificate.

(b) A repair design shall be classified and approved by:

1. the Agency; or

2. an approved design organisation within the scope of its privileges provided for in points (1), (2) and (5) of point 21.A.263(c), as recorded in the terms of approval.

GM 21.A.435(a) Classification of repairs

ED Decision 2012/020/R

1. Clarification of the terms Major/Minor

In line with the definitions given in 21.A.91, a new repair is classified as 'major' if the result on the approved type design has an appreciable effect on structural performance, weight, balance, systems, operational characteristics or other characteristics affecting the airworthiness of the product, part or appliance. In particular, a repair is classified as major if it needs extensive static, fatigue and damage tolerance strength justification and/or testing in its own right, or if it needs methods, techniques or practices that are unusual (i.e., unusual material selection, heat treatment, material processes, jigging diagrams, etc.)

Repairs that require a re-assessment and re-evaluation of the original certification substantiation data to ensure that the aircraft still complies with all the relevant requirements, are to be considered as major repairs.

Repairs whose effects are considered minor and require minimal or no assessment of the original certification substantiation data to ensure that the aircraft still complies with all the relevant requirements, are to be considered ‘minor’.

It is understood that not all the certification substantiation data will be available to those persons/organisations classifying repairs. A qualitative judgement of the effects of the repair will therefore be acceptable for the initial classification. The subsequent review of the design of the repair may lead to it being re-classified, owing to early judgements being no longer valid.

2. Airworthiness concerns for Major/Minor classification

The following should be considered for the significance of their effect when classifying repairs. Should the effect be considered to be significant then the repair should be classified 'Major'. The repair may be classified as 'Minor' where the effect is known to be without appreciable consequence.

i) Structural performance

Structural performance of the product includes static strength, fatigue, damage tolerance, flutter and stiffness characteristics. Repairs to any element of the structure should be assessed for their effect upon the structural performance.

ii) Weight and balance

The weight of the repair may have a greater effect upon smaller aircraft as opposed to larger aircraft. The effects to be considered are related to overall aircraft centre of gravity and aircraft load distribution. Control surfaces are particularly sensitive to the changes due to the effect upon the stiffness, mass distribution and surface profile which may have an effect upon flutter characteristics and controllability.

iii) Systems

Repairs to any elements of a system should be assessed for the effect intended on the operation of the complete system and for the effect on system redundancy. The consequence of a structural repair on an adjacent or remote system should also be considered as above, (for example: airframe repair in area of a static port).

iv) Operational characteristics

Changes may include:

— stall characteristics

— handling

— performance and drag

— vibration

v) Other characteristics

— changes to load path and load sharing

— change to noise and emissions

— fire protection / resistance

Note: Considerations for classifying repairs 'Major/Minor' should not be limited to those listed above.

3. Examples of 'Major' repairs

i) A repair that requires a permanent additional inspection to the approved maintenance programme, necessary to ensure the continued airworthiness of the product. Temporary repairs for which specific inspections are required prior to installation of a permanent repair do not necessarily need to be classified as 'Major'. Also, inspections and changes to inspection frequencies not required as part of the approval to ensure continued airworthiness do not cause classification as 'Major' of the associated repair.

ii) A repair to life limited or critical parts.

iii) A repair that introduces a change to the Aircraft Flight Manual.

GM 21.A.435(b) Repair design approval

ED Decision 2019/018/R

(a) REPAIR DESIGN APPROVAL BY EASA

(1) Products first type-certified by EASA or first type-certified by a Member State (covering those type-certified through Joint Aviation Authorities (JAA) procedures or under national regulations and those nationally certified without a type certificate (TC))

EASA approval is required in cases of major repair designs proposed by design organisation approval (DOA) holders that do not hold the necessary privilege as per point 21.A.263(c)(5) to approve certain major repair designs, as well as in cases of minor repair designs proposed by persons or organisations that do not hold a DOA.

(2) Products first type-certified by the competent authority (CA) of a third country

EASA approval is always required for major repairs on products first type-certified by the CA of a third country. Approval privileges granted to DOA holders (see point 21.A.435(b)) are not available to TC holders of products first type-certified by the CA of a third country unless this third country has since become an EASA Member State. TC holders of products first type-certified by the CA of a third country may need to be involved in a repair design when an arrangement with the TC holder has been determined to be necessary under point 21.A.433(a)(4).

For repairs approved by the CA of a third country, the conditions for acceptance may be defined in the bilateral arrangement between EASA and the third country. In the absence of such an arrangement, the repair data should follow the approval route of Part 21.

(b) REPAIR DESIGN APPROVAL BY THE DOA HOLDER

(1) Approval by the DOA holder

Approval of repairs through the use of procedures agreed with EASA implies that the DOA holder issues the approval without EASA's involvement. EASA will monitor the application of this procedure within the surveillance plan for the relevant organisation. When the organisation exercises this privilege, the repair release documentation should clearly show that the approval is issued on the basis of its privilege.

(2) Previously approved data for other applications

When it is intended to use previously approved data for other applications, it is expected that an appropriately approved design organisation has checked the applicability and effectiveness of this data. After damage identification, if a repair solution exists in the available approved data, and if the application of this solution to the identified damage remains justified by the previously approved repair design (structural justifications still valid, possible airworthiness limitations unchanged), the solution may be considered to be approved and may be used again.

(3) Temporary repairs

These are life-limited repairs to be removed and replaced by permanent repairs after a limited service period. These repairs should be classified under point 21.A.435, and the service period should be defined when the temporary repair is approved.

(4) Fatigue and damage tolerance

An approved design issued before the fatigue- and damage-tolerance evaluation has been completed should specify the limited service period.

21.A.439 Production of repair parts

Regulation (EU) No 748/2012

Parts and appliances to be used for the repair shall be manufactured in accordance with production data based upon all the necessary design data as provided by the repair design approval holder:

(a) under Subpart F; or

(b) by an organisation appropriately approved in accordance with Subpart G; or

(c) by an appropriately approved maintenance organisation.

21.A.441 Repair embodiment

Regulation (EU) 2020/570

(a) the embodiment of a repair shall be made in accordance with Annex I (Part-M), Annex II (Part-145), Annex Vb (Part-ML) or Annex Vd (Part-CAO) of Regulation (EU) No 1321/2014, or by a production organisation approved in accordance with Subpart G of this Annex, in accordance with the privilege provided for in point 21.A.163(d);

(b) The design organisation shall transmit to the organisation performing the repair all the necessary installation instructions.

21.A.443 Limitations

Regulation (EU) No 748/2012

A repair design may be approved subject to limitations, in which case the repair design approval shall include all necessary instructions and limitations. These instructions and limitations shall be transmitted by the repair design approval holder to the operator in accordance with a procedure agreed with the Agency.

21.A.445 Unrepaired damage

Regulation (EU) No 748/2012

(a) When a damaged product, part or appliance, is left unrepaired, and is not covered by previously approved data, the evaluation of the damage for its airworthiness consequences may only be made;

1. by the Agency; or
2. by an appropriately approved design organisation under a procedure agreed with the Agency.

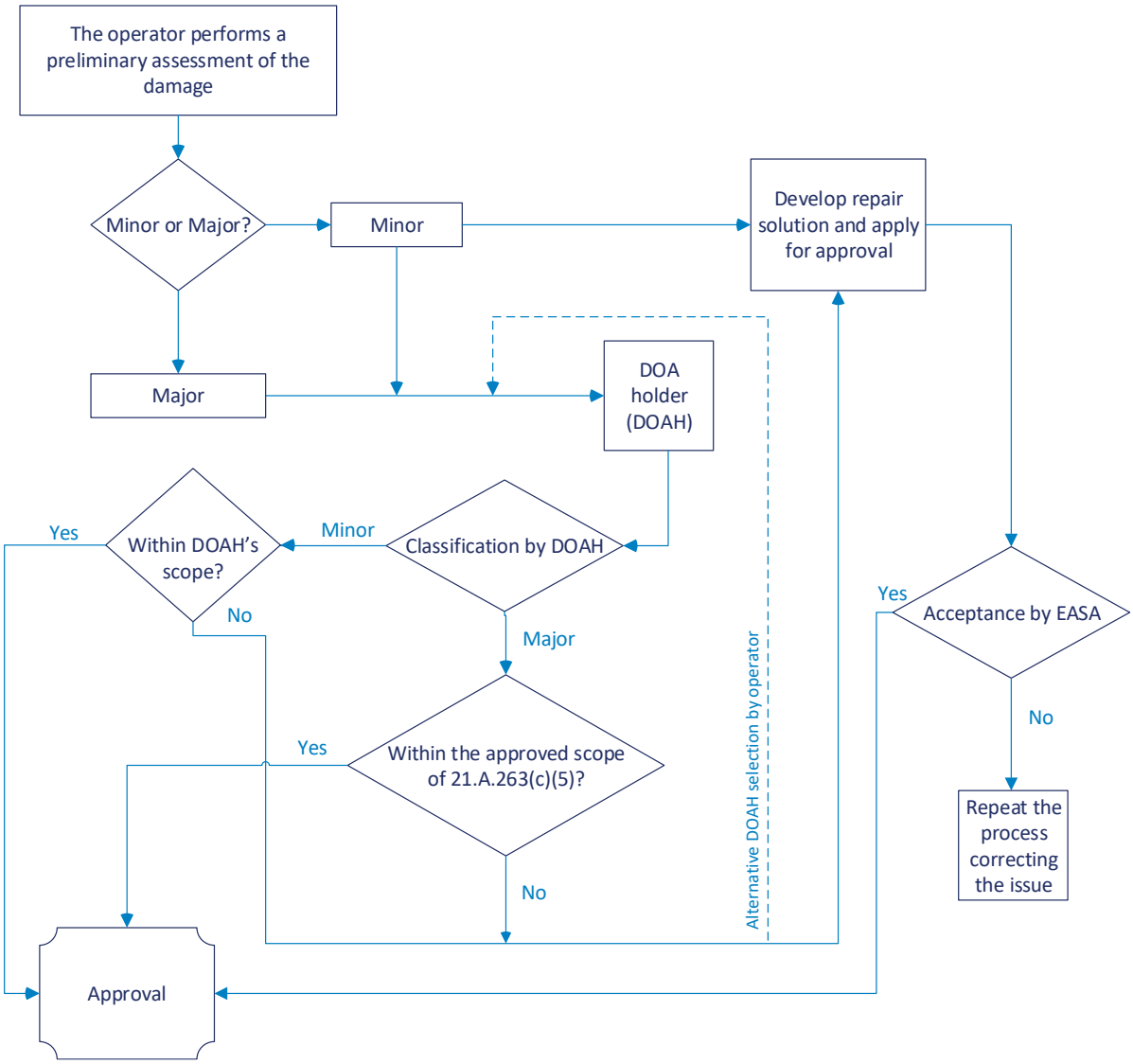
Any necessary limitations shall be processed in accordance with the procedures of point 21.A.443.

(b) Where the organisation evaluating the damage under point (a) is neither the Agency nor the type-certificate, supplemental type-certificate or APU ETSO authorisation holder, this organisation shall justify that the information on which the evaluation is based is adequate either from its organisation's own resources or through an arrangement with the type-certificate, supplemental type-certificate or APU ETSO authorisation holder, or manufacturer, as applicable.

GM 21.A.445 Unrepaired damage

ED Decision 2019/018/R

This is not intended to supersede the normal maintenance practices defined by the type-certificate holder, (e.g., blending out corrosion and re-protection, stop drilling cracks, etc.), but addresses specific cases not covered in the manufacturer's documentation.



21.A.451 Obligations and EPA marking

Regulation (EU) 2021/699

(a) Each holder of a major repair design approval shall:

1. undertake the obligations:

(i) laid down in points 21.A.3A, 21.A.3B, 21.A.4, 21.A.5, 21.A.7, 21.A.439, 21.A.441, and 21.A.443;

[applicable until 6 March 2023]

(i) laid down in points 21.A.3A, 21.A.3B, 21.A.4, 21.A.5, 21.A.6, 21.A.7, 21.A.9, 21.A.439, 21.A.441 and 21.A.443;

[applicable from 7 March 2023 - Regulation (EU) 2022/201]

(ii) implicit in the collaboration with the type-certificate, supplemental type-certificate and with the APU ETSO authorisation holder under point 21.A.433(b), as appropriate.

2. specify the marking, including EPA letters, in accordance with point 21.A.804(a).

(b) Except for type-certificate holders or APU authorisation holders for which point 21.A.44 applies, the holder of a minor repair design approval shall:

1. undertake the obligations laid down in points 21.A.4, 21.A.5 and 21.A.7; and

[applicable until 6 March 2023]

1. undertake the obligations laid down in points 21.A.4, 21.A.5 and 21.A.7;

[applicable from 7 March 2023 - Regulation (EU) 2022/201]

2. specify the marking, including EPA letters, in accordance with point 21.A.804(a).

(SUBPART N — NOT APPLICABLE)

SUBPART O — EUROPEAN TECHNICAL STANDARD ORDER AUTHORISATIONS

21.A.601 Scope

Regulation (EU) No 748/2012

This Subpart establishes the procedure for issuing ETSO authorisations and the rules governing the rights and obligations of applicants for, or holders of, such authorisations.

21.A.602A Eligibility

Regulation (EU) No 748/2012

Any natural or legal person that produces or is preparing to produce an ETSO article, and that has demonstrated, or is in the process of demonstrating, its capability under point 21.A.602B shall be eligible as an applicant for an ETSO authorisation.

21.A.602B Demonstration of capability

Regulation (EU) No 748/2012

Any applicant for an ETSO authorisation shall demonstrate its capability as follows:

(a) for production, by holding a production organisation approval, issued in accordance with Subpart G, or through compliance with Subpart F procedures; and

(b) for design:

1. for an Auxiliary Power Unit, by holding a design organisation approval, issued by the Agency in accordance with Subpart J;

2. for all other articles, by using procedures setting out the specific design practices, resources and sequence of activities necessary to comply with this Annex I (Part 21).

AMC 21.A.602B(b)(2) Procedures for ETSO authorisations

ED Decision 2012/020/R

1. Scope

1.1 A manual of procedures must set out specific design practices, resources and sequence of activities relevant for the specific projects, taking account of Part 21 requirements.

1.2 These procedures must be concise and limited to the information needed for quality and proper control of activities by the applicant/holder, and by the Agency.

2. Management of the ETSO authorisation process

A procedure explaining how the application to the Agency and certification process to obtain an ETSOA will be made, must be established.

3. Management of design changes

3.1 A procedure taking into account 21.A.611, must be established for the classification and approval of design changes on articles under ETSO authorisation

3.2 Procedure for the classification and approval of repairs and unintentional deviations from the approved design data occurring in production (concessions or non-conformance's) must be established.

4. Obligations addressed in 21.A.609

The applicant should establish the necessary procedures to show to the Agency how it will fulfil the obligations under 21.A.609.

For issue of information and instructions, a procedure following the principles of AMC 21.A.14(b), paragraph 4 must be established.

5. Control of design sub-contractors

The applicant must establish the necessary procedures to show to the Agency how it will control design sub-contractors.

21.A.603 Application

Regulation (EU) No 748/2012

(a) An application for an ETSO authorisation shall be made in a form and manner established by the Agency and shall include an outline of the information required by point 21.A.605.

(b) When a series of minor changes in accordance with point 21.A.611 is anticipated, the applicant shall set forth in its application the basic model number of the article and the associated part numbers with open brackets after it to denote that suffix change letters or numbers (or combinations of them) will be added from time to time.

21.A.604 ETSO authorisation for an auxiliary power unit (APU)

Regulation (EU) 2020/570

With regard to an ETSO authorisation for an APU:

(a) by way of derogation from points 21.A.603, 21.A.610 and 21.A.615, the following points shall apply: points 21.A.15, 21.A.20, 21.A.21, 21.A.31, 21.A.33, 21.A.44, 21.B.75 and 21.B.80. However, an ETSO authorisation shall be issued in accordance with point 21.A.606 instead of a type-certificate;

[applicable until 6 March 2023]

(a) by way of derogation from points 21.A.9, 21.A.603, 21.A.610 and 21.A.621, the following points shall apply: points 21.A.15, 21.A.20, 21.A.21, 21.A.31, 21.A.33, 21.A.44, 21.A.47, 21.B.75 and 21.B.80. However, an ETSO authorisation shall be issued in accordance with point 21.A.606 instead of the type-certificate;

[applicable from 7 March 2023 - Regulation (EU) 2022/201]

(b) by way of derogation from point 21.A.611, the requirements of Subpart D shall apply to the approval of design changes by the APU ETSO authorisation holder and design changes from other applicants classified as a minor change, and the requirements of Subpart E shall apply to the approval of design changes by other applicants classified as a major change. Where the requirements of Subpart E apply, a separate ETSO authorisation shall be issued instead of a supplemental type certificate; and

(c) the requirements of Subpart M shall apply to the approval of repair designs.

21.A.605 Data requirements

Regulation (EU) 2019/897

(a) The applicant shall submit to the Agency the following documents:

1. a certification programme for the ETSO authorisation, setting out the means to demonstrate compliance with point 21.A.606(b);
2. a statement of compliance certifying that the applicant has met the requirements of this Subpart;
3. a declaration of design and performance (DDP), stating that the applicant has demonstrated that the article complies with the applicable ETSO in accordance with the certification programme;
4. a copy of the technical data required in the applicable ETSO;
5. the exposition, or a reference to the exposition, referred to in point 21.A.143 for the purpose of obtaining an appropriate production organisation approval under Subpart G or the manual, or a reference to the manual, referred to in point 21.A.125A(b) for the purpose of manufacturing under Subpart F without production organisation approval;
6. for an APU, the handbook, or a reference to the handbook, referred to in point 21.A.243 for the purpose of obtaining an appropriate design organisation approval under Subpart J;
7. for all other articles, the procedures, or a reference to the procedures, referred to in point 21.A.602B(b)(2);

(b) The applicant shall report to the Agency any difficulty or event encountered during the approval process that may significantly impact the ETSO authorisation.

AMC 21.A.605(a)(1) Certification programme

ED Decision 2019/018/R

(a) For the purpose of the compliance demonstration in accordance with point 21.A.606(b), the applicant should:

(1) establish a certification programme;

(2) submit the certification programme to EASA; and

(3) keep the certification programme updated during the authorisation process.

(b) The certification programme should contain the following information:

(1) a detailed description of the relevant European technical standard order (ETSO) article, including all of its configurations to be certified, and the identification of ETSO and non-ETSO functions, if any;

(2) the applicable CS-ETSO, in case of different minimum performance standard (MPS) available, the selected MPS, the other requirements and any optional aspects (applicable standards, applicable requirements, choice of classes (if applicable)) as well as the expected deviations;

(3) the operating characteristics and the expected limitations;

(4) the intended use of the article and the kind of operations for which the approval is requested;

(5) the proposed means of compliance, including the list of documents and deliverables for EASA;

(6) an overview of the safety assessment for the functions supported by the article, including the main failure conditions, their classification, the associated assumptions, and architectural features supporting the safety aspects;

(7) the way in which the applicant will record the justifications of compliance; and

(8) a project schedule, including major milestones.

GM 21.A.605(b) Reporting from the compliance demonstration process and updates to the certification programme

ED Decision 2019/018/R

The applicant should report to EASA any unexpected difficulty or event encountered during the compliance demonstration which invalidates or appreciably affects the assumptions previously made, e.g.:

— an increase in the severity of the consequences of a certain condition (e.g. a failure mode) of the article;

— one or more significantly reduced margins on the 'pass–fail' criteria of the compliance demonstration;

— an unusual interpretation of the results of the compliance demonstration;

— a deviation from the agreed means as defined in the certification programme;

— a change to the conditions set out in the AMC No 2 to 21.B.100(b); and

— any potential deviations discovered by the applicant.

The applicant should also evaluate whether the unexpected difficulty or event encountered will impact on the certification programme and, if necessary, they should amend the certification programme as per point 21.A.603.

21.A.606 Requirements for the issuance of an ETSO authorisation

Regulation (EU) 2019/897

In order to be issued an ETSO authorisation, the applicant shall:

(a) demonstrate its capability in accordance with point 21.A.602B;

(b) demonstrate that the article complies with the technical conditions of the applicable ETSO or with deviations therefrom approved in accordance with point 21.A.610, if any;

(c) comply with the requirements of this Subpart; and

(d) declare that no feature or characteristic has been identified that may make the article unsafe for the uses for which certification is requested.

AMC 21.A.606(d) Declaration

ED Decision 2019/018/R

The related declaration should confirm that compliance with the applicable ETSO is successfully demonstrated and that all the assumptions, constraints, deviations, limitations, and open problem reports that are relevant for the approval of the installation are defined for both the ETSO and the non-ETSO functions.

Additionally, the applicant should demonstrate and declare that the non-ETSO functions do not interfere with the ETSO functions.

21.A.607 ETSO authorisation privileges

Regulation (EU) No 748/2012

The holder of an ETSO authorisation is entitled to produce and to mark the article with the appropriate ETSO marking.

21.A.608 Declaration of Design and Performance (DDP)

Regulation (EU) No 748/2012

(a) The DDP shall contain at least the following information:

1. information corresponding to point 21.A.31(a) and (b), identifying the article and its design and testing standard;
2. the rated performance of the article, where appropriate, either directly or by reference to other supplementary documents;
3. a statement of compliance certifying that the article has met the appropriate ETSO;
4. reference to relevant test reports;
5. reference to the appropriate Maintenance, Overhaul and Repair Manuals;
6. the levels of compliance, where various levels of compliance are allowed by the ETSO;
7. list of deviations accepted in accordance with point 21.A.610.

(b) The DDP shall be endorsed with the date and signature of the holder of the ETSO authorisation, or its authorised representative.

AMC 21.A.608 Declaration of Design and Performance

ED Decision 2012/020/R

STANDARD FORM

DDP No. ……

ISSUE No. …….

1. Name and address of manufacturer.
2. Description and identification of article including:

   Type No

   Modification Standard

   Master drawing record

   Weight and overall dimensions
3. Specification reference, i.e., ETSO No. and Manufacturer's design specification.
4. The rated performance of the article directly or by reference to other documents.
5. Particulars of approvals held for the equipment.
6. Reference to qualification test report.
7. Service and Instruction Manual reference number.
8. Statement of compliance with the appropriate ETSO and any deviations therefrom.
9. A statement of the level of compliance with the ETSO in respect of the ability of the article to withstand various ambient conditions or to exhibit various properties.

The following are examples of information to be given under this heading depending on the nature of the article and the specifications of the ETSO.

(a) Environmental Qualification

   i. Temperature and Altitude

   ii. Temperature Variation

   iii. Humidity

   iv. Operational Shocks and Crash Safety

   v. Vibration

   vi. Explosion Proofness

   vii. Waterproofness

   viii. Fluids Susceptibility

   ix. Sand and Dust

   x. Fungus Resistance

xi. Salt Spray

xii. Magnetic Effect

xiii. Power Input

xiv. Voltage Spike

xv. Audio Frequency Conducted Susceptibility - Power Inputs

xvi. Induced Signal Susceptibility

xvii. Radio Frequency Susceptibility (Radiated and Conducted)

xviii. Emission of Radio Frequency Energy

xix. Lightning Induced Transient Susceptibility

xx. Lightning Direct Effects

xxi. Icing

xxii. Electrostatic Discharge

xxiii. Fire, Flammability

(Note: The manufacturer should list environmental categories for each of the sections of the issue of EUROCAE ED-14/RTCA DO-160 that was used to qualify the article.)

(b) For radio transmitters the transmitting frequency band, maximum transmitting power, and emission designator.

(c) Working and ultimate pressure or loads.

(d) Time rating (e.g., continuous, intermittent) or duty cycle.

(e) Limits of accuracy of measuring instruments.

(f) Any other known limitations which may limit the application in the aircraft e.g., restrictions in mounting attitude.

10. A statement of the software level(s) used or 'None' if not applicable.

(Note: Software levels (software development assurance levels (DAL)) are those defined in the industry document referred in the latest edition of AMC 20-115)

11. A statement of design assurance level for complex hardware or a statement indicating whether complex hardware is embedded or not in the product.

(Note: Complex hardware design assurance levels are those defined in the applicable issue of EUROCAE ED–80/RTCA DO-254.)

12. The declaration in this document is made under the authority of

……..(name of manufacturer)

(Manufacturer's name) cannot accept responsibility for equipment used outside the limiting conditions stated above without their agreement.

Date: ……Signed……..(Manufacturer's authorised representative)

21.A.609 Obligations of holders of ETSO authorisations

Regulation (EU) 2021/699

The holder of an ETSO authorisation under this Subpart shall:

(a) manufacture each article in accordance with Subpart G or Subpart F that ensures that each completed article conforms to its design data and is safe for installation;

(b) prepare and maintain, for each model of each article for which an ETSO authorisation has been issued, a current file of complete technical data and records in accordance with point 21.A.5;

[applicable until 6 March 2023]

(b) prepare and maintain, for each model of each article for which an ETSO authorisation has been issued, an updated set of complete technical data and records in accordance with point 21.A.5;

[applicable from 7 March 2023 - Regulation (EU) 2022/201]

(c) prepare, maintain and update master copies of all manuals required by the applicable airworthiness specifications for the article;

(d) make available to users of the article and to the Agency on request those maintenance, overhaul and repair manuals necessary for the usage and maintenance of the article, and changes to those manuals;

(e) mark each article in accordance with point 21.A.807;

(f) comply with points 21.A.3A, 21.A.3B and 21.A.4;

[applicable until 6 March 2023]

(f) comply with points 21.A.3A, 21.A.3B, 21.A.4 and 21.A.9;

[applicable from 7 March 2023 - Regulation (EU) 2022/201]

(g) continue to meet the qualification requirements of point 21.A.602B.

AMC1 21.A.609(c) and (d) Obligations of holders of ETSO authorisations

ED Decision 2021/007/R

In CS-ETSO, there is no specification related to ICA, neither in Subpart A, nor in each specific ETSO.

Although an ETSO article itself typically does not require ICA, the applicable airworthiness standards may require the design approval holder (DAH) or the design approval applicant (DAA) who install an ETSO article into their product to develop ICA that describe an ETSO article's installation requirements, within the context of the product, to the extent necessary to ensure the product's continued airworthiness.

In addition, if the DAH or the DAA who install an ETSO article into their product explicitly uses ETSO provisions to demonstrate compliance with an installation requirement, they should review all the maintenance and inspection instructions for the particular ETSO article when defining the ICA of the product.

It may be necessary for the DAH or the DAA to incorporate these instructions into the ICA of the product to ensure that the ETSO article continues to satisfy the terms of its ETSO authorisation after installation.

Any DAH or DAA who wishes to install an ETSO article should comply with point 21.A.303.

For this, the applicant for an ETSO authorisation may provide by the time of the application and before the authorisation is issued (in accordance with point 21.A.605) the following:

— instructions that cover periodic maintenance, calibration, and repair for the continued airworthiness of the article, including specific guidance on the limits of wear and damage that would warrant replacement;

— the recommended inspection intervals, which may be affected by storage and operating conditions (i.e. temperature, humidity, etc.).

21.A.610 Approval for deviation

Regulation (EU) No 748/2012

(a) Each manufacturer who requests approval to deviate from any performance standard of an ETSO shall demonstrate that the standards from which a deviation is requested are compensated for by factors or design features providing an equivalent level of safety.

(b) The request for approval to deviate, together with all pertinent data, shall be submitted to the Agency.

21.A.611 Design changes

Regulation (EU) No 748/2012

(a) The holder of the ETSO authorisation may make minor design changes (any change other than a major change) without further authorisation by the Agency. In this case, the changed article keeps the original model number (part number changes or amendments shall be used to identify minor changes) and the holder shall forward to the Agency any revised data that are necessary for compliance with point 21.A.603(b).

(b) Any design change by the holder of the ETSO authorisation that is extensive enough to require a substantially complete investigation to determine compliance with an ETSO is a major change. Before making such a change, the holder shall assign a new type or model designation to the article and apply for a new authorisation under point 21.A.603.

(c) No design change by any natural or legal person other than the holder of the ETSO authorisation who submitted the statement of compliance for the article is eligible for approval under this Subpart O unless the person seeking the approval applies under point 21.A.603 for a separate ETSO authorisation.

GM to 21.A.611 Design changes

ED Decision 2012/020/R

A change to an ETSO article can either be seen:

— under this 21.A.611 in the context of an ETSO authorisation, i.e., when an article as such is specifically approved under Subpart O, with dedicated rules that give specific rights and obligations to the designer of the article, irrespective of any product type design or change to the type design. For a change to such an article, irrespective of installation on any aircraft, Subpart O, and this 21.A.611 in particular, should be followed; or

— when an airline or a maintenance organisation is designing a change (based on data not published in the TC holder or Original Equipment Manufacturer documentation) on an article installed on an aircraft, such a change can be considered as a change to the product in which the article is installed, not to the article taken in isolation. Therefore Subpart D can be used for the approval of

this change that will be identified as ‘change to product x affecting article y’, but not ‘change to article y’.

21.A.615 Inspection by the Agency

Regulation (EU) No 748/2012

Upon a request of the Agency, each applicant for, or holder of an ETSO authorisation for an article shall allow the Agency to:

(a) witness any tests;

(b) inspect the technical data files on that article.

[applicable until 6 March 2023 – Regulation (EU) 2022/201]

21.A.619 Duration and continued validity

Regulation (EU) No 748/2012

(a) An ETSO authorisation shall be issued for an unlimited duration. It shall remain valid unless:

1. the conditions required when ETSO authorisation was granted are no longer being observed; or
2. the obligations of the holder specified in point 21.A.609 are no longer being discharged; or
3. the article has proved to give rise to unacceptable hazards in service; or
4. the authorisation has been surrendered or revoked under the applicable administrative procedures established by the Agency.

(b) Upon surrender or revocation, the certificate shall be returned to the Agency.

[applicable until 6 March 2023]

(a) An ETSO authorisation shall be issued for an unlimited period of time. It shall remain valid subject to compliance with all the following conditions:

1. the conditions set when the ETSO authorisation was granted continue to be observed by the applicant;
2. the obligations specified in point 21.A.609 continue to be discharged by the ETSO authorisation holder;
3. the holder of the ETSO authorisation or any of its partners, suppliers or subcontractors acknowledge that the competent authority may carry out investigations in accordance with point 21.A.9;
4. it has been proved that the ETSO article does not give rise to unacceptable hazards in service;
5. the ETSO authorisation has not been revoked by the Agency under point 21.B.65, or surrendered by its holder.

(b) Upon surrender or revocation, the ETSO authorisation shall be returned to the Agency.

[applicable from 7 March 2023 - Regulation (EU) 2022/201]

21.A.621 Transferability

Regulation (EU) No 748/2012

Except for a change in ownership of the holder, which shall be regarded as a change of significance, and shall therefore comply with points 21.A.147 and 21.A.247 as applicable, an ETSO authorisation issued under this Annex I (Part 21) is not transferable.

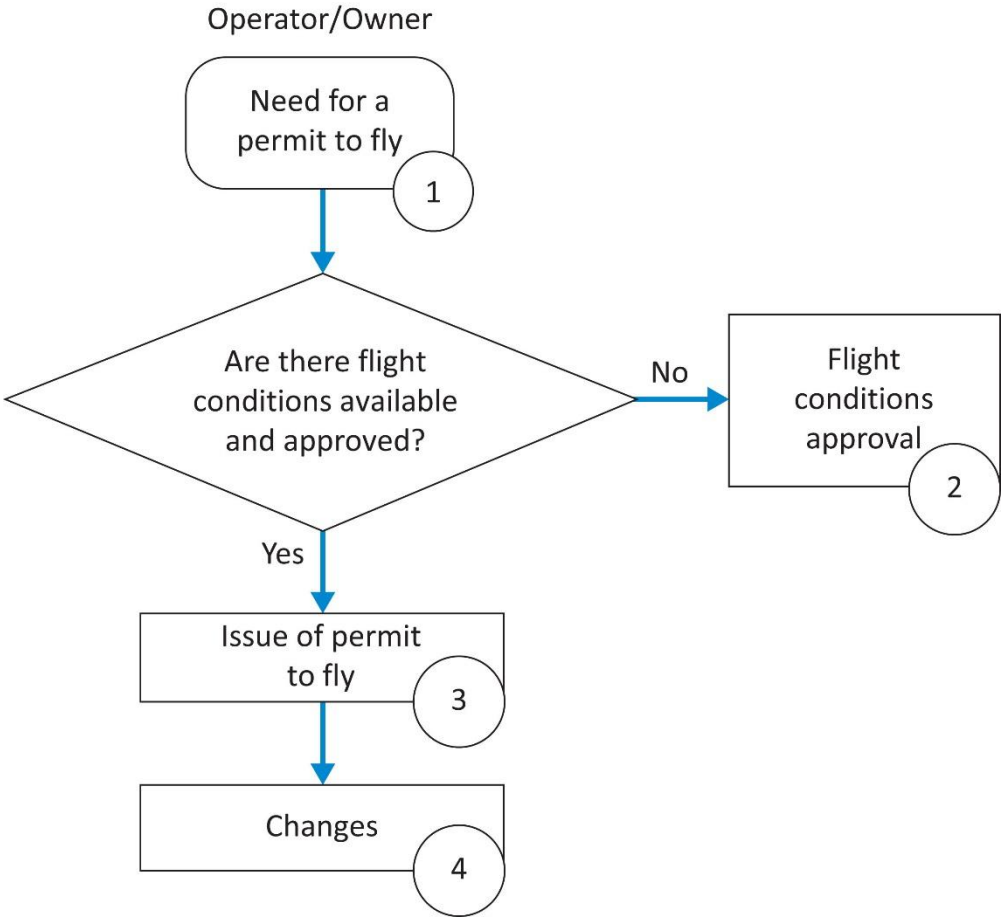
SUBPART P — PERMIT TO FLY

GM to Subpart P

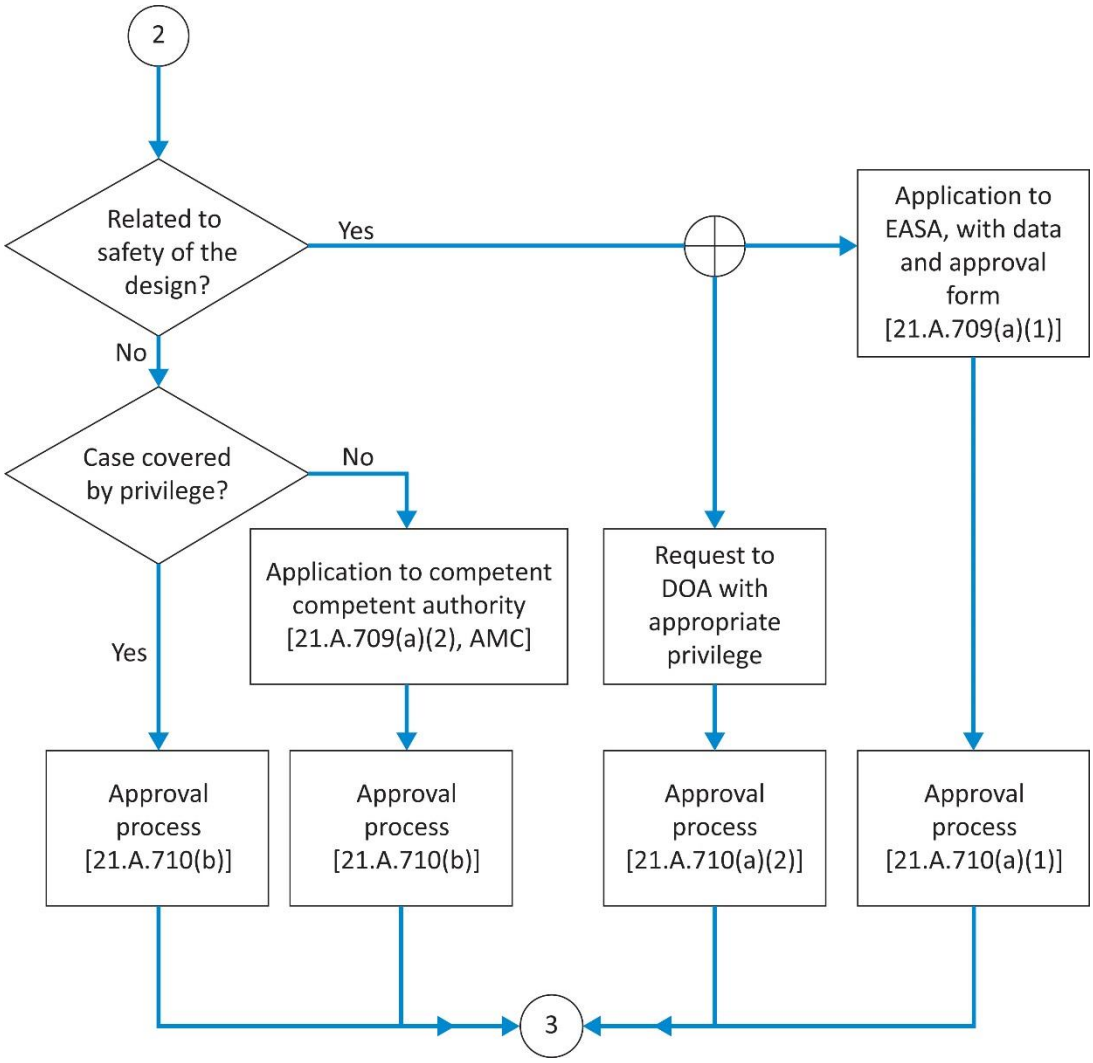
ED Decision 2012/020/R

The process allowing a flight under a permit to fly can be described as follows:

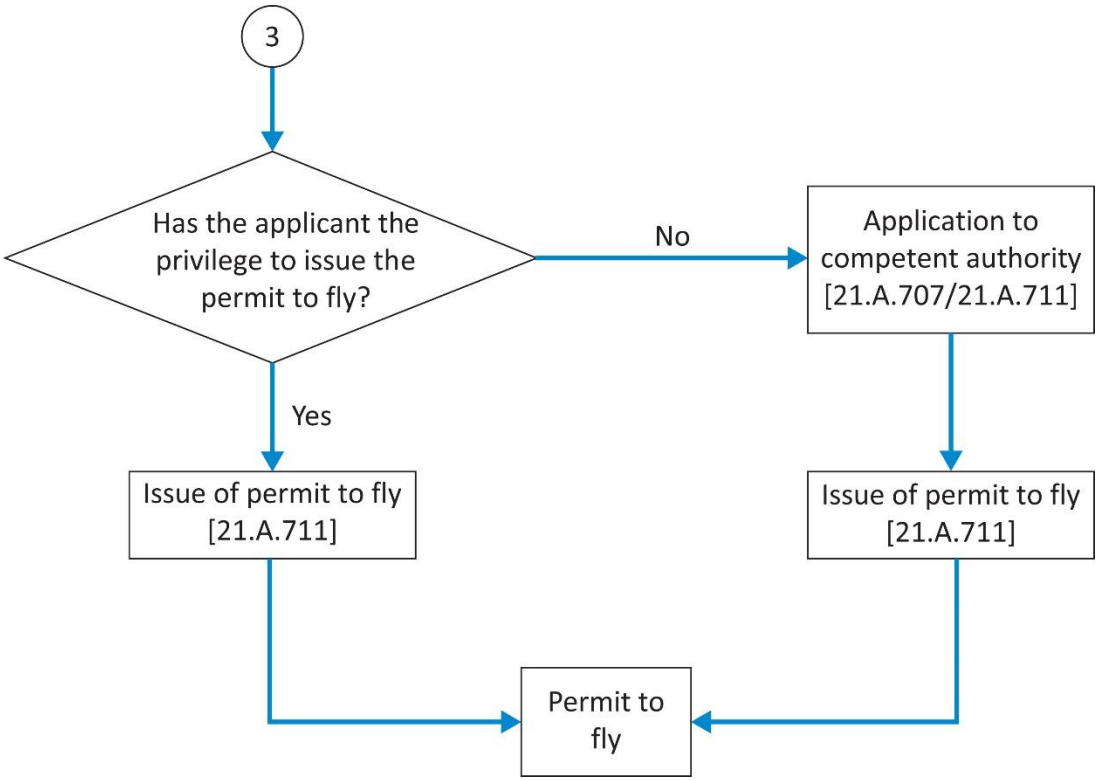
1. Flow-chart 1: overview
2. Flow-chart 2: approval of flight conditions
3. Flow-chart 3: issue of permit to fly
4. Flow-chart 4: changes after first issue of permit to fly



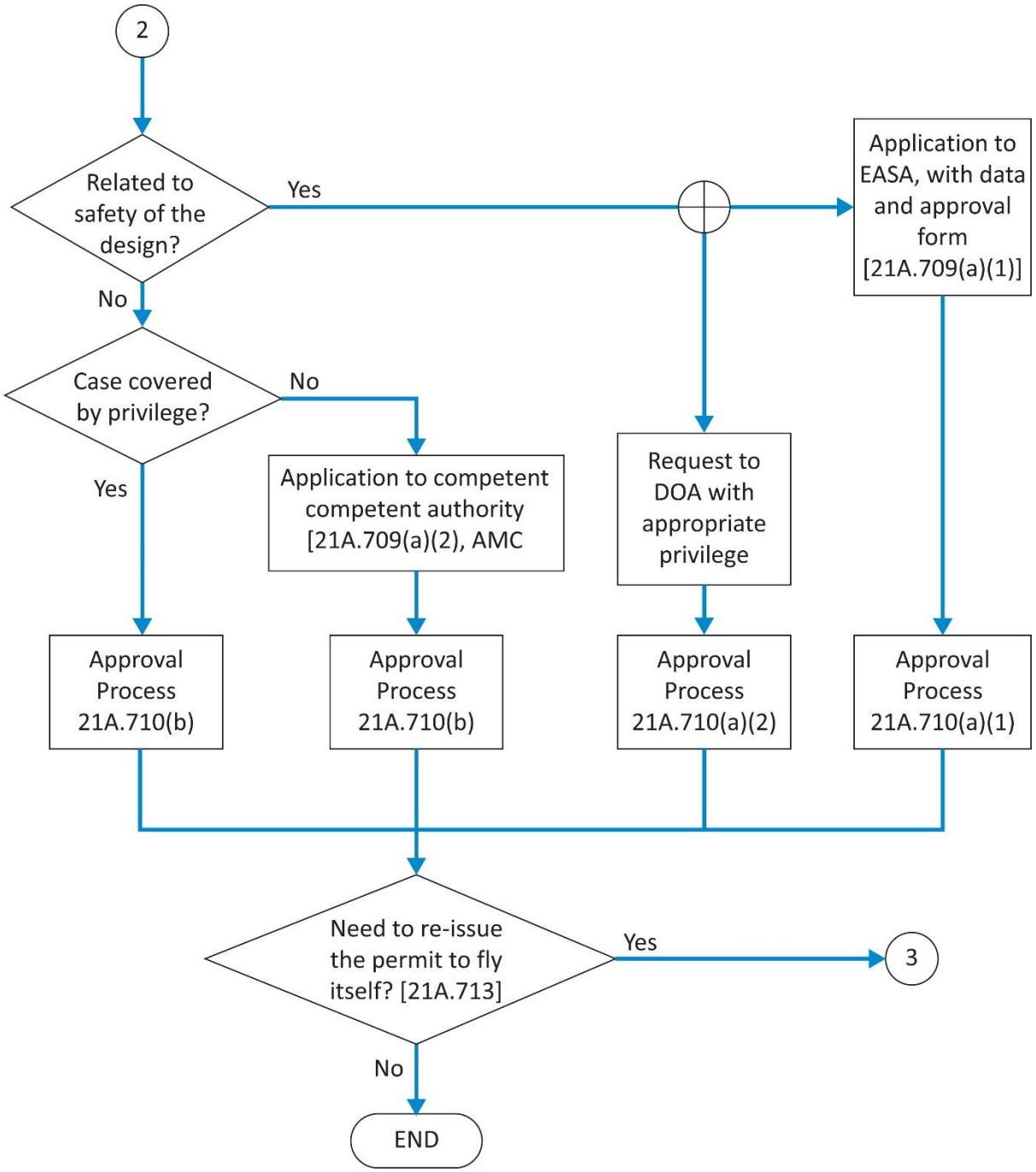
Flow-chart 1: overview



Flow-chart 2: approval of flight conditions



Flow-chart 3: issue of permit to fly



Flow-chart 4: changes after first issue of permit to fly

21.A.701 Scope

Regulation (EU) 2019/897

(a) Permits to fly shall be issued in accordance with this Subpart to aircraft that do not meet, or have not been shown to meet, applicable airworthiness requirements but are capable of safe flight under defined conditions and for the following purposes:

1. development;
2. showing compliance with regulations or certification specifications;
3. design organisations or production organisations crew training;
4. production flight testing of new production aircraft;
5. flying aircraft under production between production facilities;
6. flying the aircraft for customer acceptance;
7. delivering or exporting the aircraft;
8. flying the aircraft for Authority acceptance;
9. market survey, including customer's crew training;
10. exhibition and air show;
11. flying the aircraft to a location where maintenance or airworthiness review are to be performed, or to a place of storage;
12. flying an aircraft at a weight in excess of its maximum certificated takeoff weight for flight beyond the normal range over water, or over land areas where adequate landing facilities or appropriate fuel is not available;
13. record breaking, air racing or similar competition;
14. flying aircraft meeting the applicable airworthiness requirements before conformity to the environmental requirements has been found;
15. for non-commercial flying activity on individual non-complex aircraft or types for which a certificate of airworthiness or restricted certificate of airworthiness is not appropriate.
16. flying an aircraft for troubleshooting purposes or to check the functioning of one or more systems, parts or appliances after maintenance.

(b) This Subpart establishes the procedure for issuing permits to fly and approving associated flight conditions, and establishes the rights and obligations of the applicants for, and holders of, those permits and approvals of flight conditions.

GM 21.A.701 Scope

ED Decision 2012/020/R

An aircraft registered outside the Member States and used for flight testing by an organisation which has its principle place of business in a Member State, remains under the authority of its state of registry. The Agency or an appropriately approved design organisation can provide, on request, technical assistance to the state of registry for the issue of a permit to fly, or equivalent authorisation, under the state of registry applicable regulations.

GM 21.A.701(a) Permit to fly when a certificate of airworthiness or a restricted certificate of airworthiness is not appropriate

ED Decision 2019/018/R

A certificate of airworthiness or restricted category certificate of airworthiness may not be appropriate for an individual aircraft or aircraft type when it is not practicable to comply with the normal continued airworthiness requirements and the aircraft is to a design standard that is demonstrated to be capable of safe flight under defined conditions. Point 21.A.701 identifies cases where the issuance of a (restricted) certificate of airworthiness may not be possible or appropriate and this GM provides further information and typical examples for clarification where appropriate: -

Note: This list of examples is not exhaustive

(1) Development:

— testing of new aircraft or modifications

— testing of new concepts of airframe, engine, propeller and equipment;

— testing of new operating techniques;

(2) Demonstration of compliance with regulations or certification specifications:

— certification flight testing for type certification, supplemental type certificates, changes to type certificates or ETSO authorisation;

(3) Design organisations or production organisations crew training:

— Flights for training of crew that will perform design or production flight testing before the design approval or Certificate of Airworthiness (C of A) can be issued.

(4) Production flight testing of new production aircraft:

— For establishing conformity with the approved design, typically this would be the same program for a number of similar aircraft;

(5) Flying aircraft under production between production facilities:

— green aircraft ferry for follow on final production.

(6) Flying the aircraft for customer acceptance:

— Before the aircraft is sold and/or registered.

(7) Delivering or exporting the aircraft:

— Before the aircraft is registered in the State where the C of A will be issued.

(8) Flying the aircraft for Authority acceptance:

— In the case of inspection flight test by the authority before the C of A is issued.

(9) Market survey, including customer's crew training:

— Flights for the purpose of conducting market survey, sales demonstrations and customer crew training with non type-certificated aircraft or aircraft for which conformity has not yet been established or for non-registered a/c and before the Certificate of Airworthiness is issued.

(10) Exhibition and air show:

— Flying the aircraft to an exhibition or show and participating to the exhibition or show before the design approval is issued or before conformity with the approved design has been shown.

(11) Flying the aircraft to a location where maintenance or airworthiness review are to be performed, or to a place of storage:

— Ferry flights in cases where maintenance is not performed in accordance with approved programmes, where an AD has not been complied with where certain equipment outside the Master Minimum Equipment List (MMEL) is unserviceable or when the aircraft has sustained damage beyond the applicable limits.

(12) Flying an aircraft at a weight in excess of its maximum certificated take-off weight for flight beyond the normal range over water, or over land areas where adequate landing facilities or appropriate fuel is not available:

— Oversees ferry flights with additional fuel capacity.

(13) Record breaking, air racing or similar competition:

— Training flight and positioning flight for this purpose are included

(14) Flying aircraft meeting the applicable certification specifications before conformity to the environmental requirements has been found:

— Flying an aircraft which has been demonstrated to comply with all applicable certification specifications but not with environmental requirements.

(15) For non-commercial flying activity on individual non-complex aircraft or types for which a certificate of airworthiness or restricted certificate of airworthiness is not appropriate.

— For aircraft which cannot practically meet all applicable certification specifications, such as certain aircraft without TC-holder (‘generically termed orphan aircraft’) or aircraft which have been under national systems of Permit to Fly and have not been demonstrated to meet all applicable requirements. The option of a permit to fly for such an aircraft should only be used if a certificate of airworthiness or restricted certificate of airworthiness cannot be issued due to conditions which our outside the direct control of the aircraft owner, such as the absence of properly certified spare parts.

(16) Flying an aircraft for troubleshooting purposes or to check the functioning of one or more systems, parts or appliances after maintenance.

— After maintenance, when the diagnosis of the functioning of an aircraft system needs to be made in flight and the design approval holder has not issued instructions to perform this diagnosis within the approved aircraft limitations, the flight should be conducted under a permit to fly. Further guidance is available in subparagraph (b) of GM M.A.301(i) of the AMC and GM to Part-M.

Note: The above listing is of cases when a permit to fly MAY be issued; it does not mean that in the described cases a permit to fly MUST be issued. If other legal means are available to allow the intended flight(s), they can also be used.

21.A.703 Eligibility

Regulation (EU) No 748/2012

(a) Any natural or legal person shall be eligible as an applicant for a permit to fly except for a permit to fly requested for the purpose of point 21.A.701(a)(15) where the applicant shall be the owner.

(b) Any natural or legal person shall be eligible for application for the approval of the flight conditions.

GM 21.A.703 Applicant for a permit to fly

ED Decision 2019/018/R

The applicant for a permit to fly may be a person other than the registered owner of the aircraft. As the holder of this permit will be responsible for ensuring that all the conditions and limitations associated with the permit to fly are continuously satisfied, the applicant for the permit should be a person or organisation suitable for assuming these responsibilities. In particular, the organisations designing, modifying or maintaining the aircraft should normally be the holder of the associated permits to fly.

21.A.705 Competent authority

Regulation (EU) No 748/2012

Notwithstanding point 21.1 of this Annex I (Part 21) for the purpose of this Subpart, the 'competent authority' shall be:

(a) the authority designated by the Member State of registry; or

(b) for unregistered aircraft, the authority designated by the Member State which prescribed the identification marks.

[applicable until 6 March 2023 – Regulation (EU) 2022/201]

GM 21.A.705 Competent authority

ED Decision 2012/020/R

An aircraft registered in a Member State is under the responsibility of this Member State for continuing airworthiness aspects. Consequently, any permit to fly under Part 21 should be issued by that Member State including cases where the aircraft will fly in another State. The permit to fly contains all the conditions and restrictions to ensure safe flight but other airspace and operational rules remain the competence of the authority of the State where the flight will take place. The applicant should therefore also ensure compliance with the relevant regulations of that State.

21.A.707 Application for permit to fly

Regulation (EU) No 748/2012

(a) Pursuant to point 21.A.703 and when the applicant has not been granted the privilege to issue a permit to fly, an application for a permit to fly shall be made to the competent authority in a form and manner established by that authority.

(b) Each application for a permit to fly shall include:

1. the purpose(s) of the flight(s), in accordance with point 21.A.701;

2. the ways in which the aircraft does not comply with the applicable airworthiness requirements;

3. the flight conditions approved in accordance with point 21.A.710.

(c) Where the flight conditions are not approved at the time of application for a permit to fly, an application for approval of the flight conditions shall be made in accordance with point 21.A.709.

GM 21.A.707(b) Application

ED Decision 2012/020/R

EASA Form 21 (see AMC 21.B.520(b)) should be obtained from the competent authority.

21.A.708 Flight conditions

Regulation (EU) 2015/1039

Flight conditions include:

(a) the configuration(s) for which the permit to fly is requested;

(b) any condition or restriction necessary for safe operation of the aircraft, including:

1. the conditions or restrictions put on itineraries or airspace, or both, required for the flight(s);

2. any conditions or restrictions put on the flight crew to fly the aircraft, in addition to those defined in Appendix XII to this Annex I (Part 21);

3. the restrictions regarding carriage of persons other than flight crew;

4. the operating limitations, specific procedures or technical conditions to be met;

5. the specific flight test programme (if applicable);

6. the specific continuing airworthiness arrangements including maintenance instructions and regime under which they will be performed;

(c) the substantiation that the aircraft is capable of safe flight under the conditions or restrictions of point (b);

(d) the method used for the control of the aircraft configuration, in order to remain within the established conditions.

GM 21.A.708(b)(6) Continuing airworthiness

ED Decision 2012/020/R

In most cases a simple reference to existing maintenance requirements will suffice for aircraft that have a temporarily invalid C of A.

For other aircraft it will have to be proposed by the applicant as part of the flight conditions. For approved organisations they can be included in their procedures.

GM No 1 to 21.A.708(c) Safe flight

ED Decision 2012/020/R

Safe flight normally means continued safe flight and landing but in some limited cases (e.g. higher risk flight testing) it can mean that the aircraft is able to fly in a manner that will primarily ensure the safety of overflown third parties, the flight crew and, if applicable other occupants.

This definition of 'safe flight' should not be interpreted as allowing a test pilot, equipped with a parachute and operating over a sparsely populated area, to set out on a test flight in the full knowledge that there is a high probability of losing the aircraft. The applicant should take reasonable care to minimise safety risks and to be satisfied that there is a reasonable probability that the aircraft will carry out the flight without damage or injury to the aircraft and its occupants or to other property or persons whether in the air or on the ground.

GM No 2 to 21.A.708(c) Substantiations

ED Decision 2012/020/R

The substantiations should include analysis, calculations, tests or other means used to determine under which conditions or restrictions the aircraft can perform safely a flight.

GM No 3 to 21.A.708(c) Operation of Overweight Aircraft

ED Decision 2012/020/R

This GM provides information and guidance with respect to permit to fly for operating an aircraft in excess of its maximum certificated take-off weight, for flight beyond the normal range over water, or over land areas where adequate landing facilities or appropriate fuel is not available.

1. GENERAL.

   The excess weight that may be authorized for overweight operations should be limited to additional fuel, fuel carrying facilities, and navigational equipment necessary for the flight.

   It is recommended that the applicant discuss the proposed flight with the TC holder of the aircraft to determine the availability of technical data on the installation of additional fuel carrying facilities and/or navigational equipment.

2. CRITERIA USED TO DETERMINE THE SAFETY OF ADDITIONAL FACILITIES.

   In evaluating the installation of additional facilities, the Agency or the design organisation must find that the changed aircraft is safe for operation. To assist in arriving at such a determination, the following questions are normally considered:

   a. Does the technical data include installation drawings, structural substantiating reports, weight, balance, new centre of gravity limits computations, and aircraft performance limitations in sufficient detail to allow a conformity inspection of the aircraft to be made?

   b. In what ways does the aircraft not comply with the applicable certification specifications?

   c. Are the fuel tanks vented to the outside? Are all areas in which tanks are located ventilated to reduce fire, explosion, and toxicity hazards?

   d. Are the tanks even when empty strong enough to withstand the differential pressure at maximum operating altitude for a pressurized aircraft?

   e. Have means been provided for determining the fuel quantity in each tank prior to flight?

f. Are shutoff valves, accessible to the pilot, provided for each additional tank to disconnect these tanks from the main fuel system?

g. Are the additional fuel tank filler connections designed to prevent spillage within the aircraft during servicing?

h. Is the engine oil supply and cooling adequate for the extended weight and range?

3. LIMITATIONS.

The following types of limitations may be necessary for safe operation of the aircraft:

a. Revised operational airspeeds for use in the overweight condition.

b. Increased pilot skill requirements.

c. A prescribed sequence for using fuel from various tanks as necessary to keep the aircraft within its centre of gravity range.

d. Notification to the control tower of the overweight take-off condition to permit use of a runway to minimize flight over congested areas.

e. Avoidance of severe turbulence. If encountered, the aircraft should be inspected for damage as soon as possible.

EXAMPLE of operating limitations which may be prescribed as part of the permit to fly:

Aircraft type: xxxxxx Model: yyyy

Limitations:

1. Maximum weight must not exceed 8 150 pounds.
2. Maximum quantity of fuel carried in auxiliary tanks must not exceed 106 gallons in fwd tank, 164 gallons in centre tank, and 45 gallons in aft tank.
3. Centre of gravity limits must not exceed (fwd) +116.8 and (aft) +124.6.
4. Aerobatics are prohibited.
5. Use of autopilot while in overweight condition is prohibited.
6. Weather conditions with moderate to severe turbulence should be avoided.
7. When an overweight landing is made or the aircraft has been flown through moderate or severe turbulence while in an overweight condition, the aircraft must be inspected for damage after landing. The inspections performed and the findings must be entered in the aircraft log. The pilot must determine, before the next take-off, that the aircraft is airworthy.
8. When operated in the overweight condition, the cruising speed (Vc) shall not exceed 185 m.p.h. and the maximum speed (Vne) shall not exceed 205 m.p.h.
9. Operation in the overweight condition must be conducted to avoid areas having heavy air traffic, to avoid cities, towns, villages, and congested areas, or any other areas where such flights might create hazardous exposure to person or property on the ground.

GM 21.A.708(d) Control of aircraft configuration

ED Decision 2012/020/R

The applicant should establish a method for the control of any change or repair made to the aircraft, for changes and repairs that do not invalidate the conditions established for the permit to fly.

All other changes should be approved in accordance with 21.A.713 and when necessary a new permit to fly should be issued in accordance with 21.A.711.

21.A.709 Application for approval of flight conditions

Regulation (EU) No 748/2012

(a) Pursuant to point 21.A.707(c) and when the applicant has not been granted the privilege to approve the flight conditions, an application for approval of the flight conditions shall be made:

1. when approval of the flight conditions is related to the safety of the design, to the Agency in a form and manner established by the Agency; or
2. when approval of the flight conditions is not related to the safety of the design, to the competent authority in a form and manner established by that authority.

(b) Each application for approval of the flight conditions shall include:

1. the proposed flight conditions;
2. the documentation supporting these conditions; and
3. a declaration that the aircraft is capable of safe flight under the conditions or restrictions of point 21.A.708(b).

AMC1 21.A.709(b) Application for the approval of flight conditions

ED Decision 2021/001/R

SUBMISSION OF DOCUMENTATION SUPPORTING THE ESTABLISHMENT OF FLIGHT CONDITIONS

The applicant should submit, together with the application, the documentation required by point 21.A.709(b) with the approval form (EASA Form 18B) defined below, completed with all the relevant information. The same approval form (EASA Form 18B) should be used when the application is submitted by a DOA holder that does not have the privilege to approve flight conditions or when it has such a privilege, but the respective flight conditions are outside the approved scope of work. If the complete set of data is not available at the time of application, the missing elements can be provided later. In such cases, the approval form should be provided only when all the data is available, to allow the applicant to make the statement required in block of the form.

FLIGHT CONDITIONS FOR A PERMIT TO FLY – APPROVAL FORM	
1. Applicant *[Name of organisation providing the flight conditions and associated substantiations]*	**2. Approval form No:** **Issue:** *[Number and issue, for traceability purpose]*
3. Aircraft manufacturer/type	**4. Serial number(s)**
5. Purpose [Purpose in accordance with 21.A.701(a)]	

6. Aircraft configuration The above aircraft for which a permit to fly is requested is defined in *[add reference to the document(s) identifying the configuration of the aircraft]* *[For change(s) affecting the initial approval form: description of change(s). This form must be re-issued]*	
7. Substantiations *[References to the document(s) justifying that the aircraft (as described in 6.) can perform the intended flight(s) safely under the defined conditions or restrictions.]* *[For change(s) affecting the initial approval form: reference(s) to additional substantiation(s). This form must be re-issued]*	
8. Conditions/Restrictions The above aircraft must be used with the following conditions or restrictions: *[Details of these conditions/restrictions, or reference to relevant document, including specific maintenance instructions and conditions to perform these instructions]*	
9. Statement The flight conditions have been established and justified in accordance with 21.A.708. The aircraft as defined in block 6 above has no features and characteristics making it unsafe for the intended operation under the identified conditions and restrictions.	
[when approved under a privilege of an approved organisation] **10.** Approved under *[ORGANISATION APPROVAL NUMBER]*'	
11. Date of issue	**12. Name and signature** *[Authorised signatory]*
[when not approved under a privilege of an approved organisation] **13. Approval and date** *[the appropriate approval: EASA, competent authority]*	

EASA Form 18B Issue 3

When the flight conditions are approved under a privilege, this form should be used by the approved organisation to document the approval.

21.A.710 Approval of flight conditions

Regulation (EU) No 748/2012

(a) When approval of the flight conditions is related to the safety of the design, the flight conditions shall be approved by:

1. the Agency; or

2. an appropriately approved design organisation, under the privilege of point 21.A.263(c)(6).

(b) When approval of the flight conditions is not related to the safety of the design, the flight conditions shall be approved by the competent authority, or the appropriately approved organisation that will also issue the permit to fly.

(c) Before approving the flight conditions, the Agency, the competent authority or the approved organisation must be satisfied that the aircraft is capable of safe flight under the specified conditions and restrictions. The Agency or the competent authority may make or require the applicant to make any necessary inspections or tests for that purpose.

GM 21.A.710 Approval of flight conditions

ED Decision 2012/020/R

1. The approval of flight conditions is related to the safety of the design, when:
   a. the aircraft does not conform to an approved design; or
   b. an Airworthiness Limitation, a Certification Maintenance Requirement or an Airworthiness Directive has not been complied with; or
   c. the intended flight(s) are outside the approved envelope;
   d. the permit to fly is issued for the purpose of 21.A.701(a)(15).
2. Examples when the approval of flight conditions is not related to the safety of the design are:
   a. production flight testing for the purpose of conformity establishment;
   b. delivery / export flight of a new aircraft the design of which is approved;
   c. demonstrating continuing conformity with the standard previously accepted by the Agency for the aircraft or type of aircraft to qualify or re-qualify for a (restricted) certificate of airworthiness.

21.A.711 Issue of a permit to fly [applicable until 6 March 2023] / 21.A.711 Issuance of a permit to fly [applicable from 7 March 2023 - Regulation (EU) 2022/201]

Regulation (EU) 2021/699

(a) A permit to fly (EASA Form 20a, see Appendix III) may be issued by the competent authority under the conditions specified in point 21.B.525.

(b) An appropriately approved design organisation may issue a permit to fly (EASA Form 20b, see Appendix IV) under the privilege granted under point 21.A.263(c)(7), when the flight conditions referred to in point 21.A.708 have been approved in accordance with point 21.A.710.

(c) An appropriately approved production organisation may issue a permit to fly (EASA Form 20b, see Appendix IV) under the privilege granted under point 21.A.163(e), when the flight conditions referred to in point 21.A.708 have been approved in accordance with point 21.A.710.

(d) An approved organisation may issue a permit to fly (EASA Form 20b, see Appendix IV) under the privilege granted in accordance with point M.A.711 of Annex I (Part-M) of Regulation (EU) No 1321/2014 or point CAMO.A.125 of Annex Vc (Part-CAMO) of Regulation (EU) No 1321/2014 or point CAO.A.095 of Annex Vd (Part-CAO) of Regulation (EU) No 1321/2014, when the flight conditions referred to in point 21.A.708 of this Annex have been approved in accordance with point 21.A.710 of this Annex.

(e) The permit to fly shall specify the purpose(s) and any conditions and restrictions which have been approved in accordance with point 21.A.710.

(f) For permits issued under points (b), (c) or (d), a copy of the permit to fly and associated flight conditions shall be submitted to the competent authority at the earliest opportunity but not later than 3 days.

(g) Upon evidence that any of the conditions specified in point 21.A.723(a) are not met for a permit to fly that an organisation has issued pursuant to points (b), (c) or (d), that organisation shall immediately revoke that permit to fly and inform without delay the competent authority.

GM 21.A.711(e) Additional conditions and restrictions

ED Decision 2012/020/R

The conditions and restrictions prescribed by the competent authority may include airspace restrictions to make the conditions approved under 21.A.710 more concrete, or conditions outside the scope of the ones mentioned in 21.A.708(b) such as a radio station license.

21.A.713 Changes

Regulation (EU) No 748/2012

(a) Any change that invalidates the flight conditions or associated substantiation established for the permit to fly shall be approved in accordance with point 21.A.710. When relevant an application shall be made in accordance with point 21.A.709.

(b) A change affecting the content of the permit to fly requires the issuance of a new permit to fly in accordance with point 21.A.711.

GM 21.A.713 Changes

ED Decision 2012/020/R

Changes to the conditions or associated substantiations that are approved but do not affect the text on the permit to fly do not require issuance of a new permit to fly.

In case a new application is necessary, the substantiation for approval of the flight conditions only needs to address the change.

21.A.715 Language

Regulation (EU) No 748/2012

The manuals, placards, listings, and instrument markings and other necessary information required by applicable certification specifications shall be presented in one or more of the official language(s) of the European Union acceptable to the competent authority.

21.A.719 Transferability

Regulation (EU) No 748/2012

(a) A permit to fly is not transferable.

(b) Notwithstanding, point (a) for a permit to fly issued for the purpose of point 21.A.701(a)(15), where ownership of an aircraft has changed, the permit to fly shall be transferred together with the aircraft provided the aircraft remains on the same register, or issued only with the agreement of the competent authority of the Member State of registry to which it is transferred.

GM 21.A.719 Transfer of a permit to fly

ED Decision 2012/020/R

Except for permits to fly issued under 21.A.701(a)(15), like aircraft without TC holder, a permit to fly is issued based upon the applicant's declaration of many aspects of the proposed flight or flights, some of which are specific to the applicant. Accordingly, the basis upon which a permit to fly has been issued necessarily is no longer fully in place when the holder of a permit to fly changes, ownership changes, and/or there is a change of register. Such changes necessitate a new application under 21.A.707.

21.A.721 Inspections

Regulation (EU) No 748/2012

The holder of, or the applicant for, a permit to fly shall provide access to the aircraft concerned at the request of the competent authority.

[applicable until 6 March 2023 – Regulation (EU) 2022/201]

21.A.723 Duration and continued validity

Regulation (EU) No 748/2012

(a) A permit to fly shall be issued for a maximum of 12 months and shall remain valid subject to:

1. compliance with the conditions and restrictions of point 21.A.711(e) associated with the permit to fly;
2. the permit to fly not being surrendered or revoked;
3. the aircraft remaining on the same register.

[applicable until 6 March 2023]

(a) A permit to fly shall be issued for a maximum period of 12 months and shall remain valid subject to compliance with all the following conditions:

1. the organisation continues to comply with the conditions and restrictions associated with the permit to fly as set out in point 21.A.711(e);
2. the holder or any of its partners, suppliers or subcontractors acknowledge that the competent authority may carry out investigations in accordance with point 21.A.9;
3. the permit to fly has not been revoked by the competent authority under point 21.B.65, or surrendered by its holder;
4. the aircraft remains on the same register.

[applicable from 7 March 2023 - Regulation (EU) 2022/201]

(b) Notwithstanding point (a), a permit to fly issued for the purpose of point 21.A.701(a)(15) may be issued for unlimited duration.

(c) Upon surrender or revocation, the permit to fly shall be returned to the competent authority.

21.A.725 Renewal of permit to fly

Regulation (EU) No 748/2012

Renewal of the permit to fly shall be processed as a change in accordance with point 21.A.713.

21.A.727 Obligations of the holder of a permit to fly

Regulation (EU) No 748/2012

The holder of a permit to fly shall ensure that all the conditions and restrictions associated with the permit to fly are satisfied and maintained.

21.A.729 Record-keeping

Regulation (EU) No 748/2012

(a) All documents produced to establish and justify the flight conditions shall be held by the holder of the approval of the flight conditions at the disposal of the Agency and competent authority and shall be retained in order to provide the information necessary to ensure the continued airworthiness of the aircraft.

(b) All documents associated with the issue of permits to fly under the privilege of approved organisations, including inspection records, documents supporting the approval of flight conditions and the permit to fly itself, shall be held by the related approved organisation at the disposal of the Agency or the competent authority and shall be retained in order to provide the information necessary to ensure the continued airworthiness of the aircraft.

[applicable until 6 March 2023 – Regulation (EU) 2022/201]

SUBPART Q — IDENTIFICATION OF PRODUCTS, PARTS AND APPLIANCES

21.A.801 Identification of products

Regulation (EU) 2021/1088

(a) The identification of products shall include the following information:

1. the manufacturer's name;
2. the product designation;
3. the manufacturer's serial number;
4. the 'EXEMPT' mark in case of an engine, when the competent authority has granted an exemption from the environmental protection requirements;
5. any other information the Agency finds appropriate.

(b) Any natural or legal person that manufactures an aircraft or engine under Subpart G or Subpart F shall identify that aircraft or engine by means of a fireproof plate that has the information specified in point (a) marked on it by etching, stamping, engraving, or other approved method of fireproof marking. The identification plate shall be secured in such a manner that it is accessible and legible, and will not likely be defaced or removed during normal service, or lost or destroyed in an accident.

(c) Any natural or legal person that manufactures a propeller, propeller blade, or propeller hub under Subpart G or Subpart F shall identify it by means of a plate, stamping, engraving, etching or other approved method of fireproof identification that is placed on it on a non-critical surface, contains the information specified in point (a), and will not likely be defaced or removed during normal service or lost or destroyed in an accident.

(d) For manned balloons, the identification plate prescribed in point (b) shall be secured to the balloon envelope and shall be located, if practicable, where it is legible to the operator when the balloon is inflated. In addition, the basket, load frame assembly and any heater assembly shall be permanently and legibly marked with the manufacturer's name, part number, or equivalent, and serial number, or equivalent.

21.A.803 Handling of identification data

Regulation (EU) No 748/2012

(a) No person shall remove, change, or place identification information referred to in point 21.A.801(a) on any aircraft, engine, propeller, propeller blade, or propeller hub, or in point 21.A.807(a) on an APU, without the approval of the Agency.

(b) No person shall remove or install any identification plate referred to in point 21.A.801, or in point 21.A.807 for an APU, without the approval of the Agency.

(c) By way of derogation from points (a) and (b), any natural or legal person performing maintenance work under the applicable associated implementing rules may, in accordance with methods, techniques and practices established by the Agency:

1. remove, change, or place the identification information referred to in point 21.A.801(a) on any aircraft, engine, propeller, propeller blade, or propeller hub, or in point 21.A.807(a) on an APU; or

2. remove an identification plate referred to in point 21.A.801, or point 21.A.807 for an APU, when necessary during maintenance operations.

(d) No person shall install an identification plate removed in accordance with point (c)(2) on any aircraft, engine, propeller, propeller blade, or propeller hub other than the one from which it was removed.

21.A.804 Identification of parts and appliances

Regulation (EU) No 2021/699

(a) Each part or appliance which is eligible for installation in a type-certified product shall be marked permanently and legibly with:

1. a name, trademark, or symbol identifying the manufacturer in a manner identified by the applicable design data;

2. the part number, as defined in the applicable design data; and

3. the letters EPA for parts or appliances produced in accordance with approved design data not belonging to the type-certificate holder of the related product, except for ETSO articles and for parts and appliances covered under point (b) of point 21.A.307.

(b) By way of derogation from point (a), if the Agency agrees that a part or appliance is too small or that it is otherwise impractical to mark a part or appliance with any of the information required by point (a), the authorised release document accompanying the part or appliance or its container shall include the information that could not be marked on the part or appliance.

GM 21.A.804(a)(1) Identification of parts and appliances

ED Decision 2012/020/R

It is not the intent of 21.A.804(a)(1) to introduce an obligation for a production organisation (manufacturer) to mark new parts or appliances with information which is not identified by the design approval holder. Therefore, the physical marking of parts and appliances is only required when established by the design approval (TC, STC, ETSO, repair, change) holder.

For designs (TC, STC, ETSO, repair, change) approved after 28 December 2009 (the date of entry into force of Commission Regulation (EC) No 1194/2009), the design approval holder is required to identify to the manufacturer how the marking in accordance with 21.A.804(a)(1) should be done. This can be limited to identifying a marking field, possible depth and/or means etc., without prescribing the actual text or symbols to be used

GM1 21.A.804(a)(3) Identification of parts and appliances

ED Decision 2021/001/R

EUROPEAN PARTS APPROVAL (EPA) MARKING FOR REPAIR PARTS

The EPA marking only applies to the parts, specifically designed or modified for the repair, to be incorporated as part of the repair design. If the repair scheme does not require the addition of any new parts or the use of modified parts, there is no need to mark the repaired part with the letters 'EPA'.

AMC1 21.A.804(b) Identification of parts and appliances

ED Decision 2021/001/R

EASA AGREEMENT FOR THE DESIGN APPROVAL HOLDER TO DEROGATE FROM POINT 21.A.804(a)

A design approval holder may apply point 21.A.804(a) or make use of the derogation defined in point 21.A.804(b) by clarifying, in the relevant procedures, the conditions (e.g. the minimum dimensions of a (flat) area on a part suitable for marking) in which the marking on the part may be completely or partially omitted. This can also be supported by examples of parts or cases when certain parts do not have to be marked.

In such cases, the relevant design data (e.g. drawings) should specify the contents and location of the information that could not be marked on the part (i.e. the information to be provided in the authorised release document or on the container).

21.A.805 Identification of critical parts

Regulation (EU) No 748/2012

In addition to the requirement of point 21.A.804, each manufacturer of a part to be fitted on a type-certificated product which has been identified as a critical part shall permanently and legibly mark that part with a part number and a serial number.

GM1 21.A.805 Identification of critical parts

ED Decision 2021/001/R

PARTS TO BE MARKED

For the purposes of point 21.A.805, a part that requires individual traceability for the management of its continued airworthiness, as identified by the design approval holder, shall be permanently marked with a part number and a serial number.

The need for the design approval holder to identify and mark parts may be related to specific requirements for critical parts included in a certification specification. For instance, according to point (c) of CS-E 110 Drawings and Marking of Parts — Assembly of Parts: 'Certain parts (including Engine Critical Parts; see CS-E 515) as may be required by the Agency must be marked and the constructor must maintain records related to this marking such that it is possible to establish the relevant manufacturing history of the parts.' Another example is in point AC 29.602 of FAA AC 29-2C, as referenced in Book 2 of CS-29: '(7) – Critical parts are identified as required, and relevant records relating to the identification are maintained such that it is possible to establish the manufacturing history of the individual parts or batches of parts.'

Another typical case is for any part subject to an individually specified life limit or inspection requirement when it is also possible for that part to be removed from one serial number of the associated product during maintenance and installed on another serial number of the same product. In this case, the traceability of the part, which is necessary for continued airworthiness management purposes, is not assured through the serial number of the product alone, and it is necessary to maintain records for the part through its serial number.

21.A.807 Identification of ETSO articles

Regulation (EU) No 748/2012

(a) Each holder of an ETSO authorisation under Subpart O shall permanently and legibly mark each article with the following information:

1. the name and address of the manufacturer;
2. the name, type, part number or model designation of the article;
3. the serial number or the date of manufacture of the article or both; and
4. the applicable ETSO number.

(b) By way of derogation from point (a), if the Agency agrees that a part is too small or that it is otherwise impractical to mark a part with any of the information required by point (a), the authorised release document accompanying the part or its container shall include the information that could not be marked on the part.

(c) Each person who manufactures an APU under Subpart G or Subpart F shall identify that APU by means of a fireproof plate that has the information specified in point (a) marked on it by etching, stamping, engraving, or other approved method of fireproof marking. The identification plate shall be secured in such a manner that it is accessible and legible, and will not likely be defaced or removed during normal service, or lost or destroyed in an accident.

SECTION B — PROCEDURES FOR COMPETENT AUTHORITIES

SUBPART A — GENERAL PROVISIONS

21.B.5 Scope

Regulation (EU) 2019/897

(a) This Section establishes the procedure for the competent authority, when exercising its tasks and responsibilities concerned with the issuance, maintenance, amendment, suspension and revocation of certificates, approvals and authorisations referred to in this Annex I.

(b) The Agency shall develop in accordance with Article 19 of Regulation (EC) No 216/2008 certification specifications and guidance material to assist Member States in the implementation of this Section.

[applicable until 6 March 2023 – Regulation (EU) 2022/203]

21.B.10 Oversight documentation

Regulation (EU) 2022/203

The competent authority shall provide all the legislative acts, standards, rules, technical publications and related documents to the relevant personnel in order to allow them to perform their tasks and to discharge their responsibilities.

[applicable from 7 March 2023 - Regulation (EU) 2022/203]

21.B.15 Information to the Agency

Regulation (EU) 2022/203

(a) The competent authority of the Member State shall notify the Agency in case of any significant problems with the implementation of Regulation (EU) 2018/1139 and its delegated and implementing acts within 30 days from the time the competent authority became aware of the problem.

(b) Without prejudice to Regulation (EU) No 376/2014 of the European Parliament and of the Council and its delegated and implementing acts, the competent authority of the Member State shall provide the Agency as soon as possible with any safety-significant information stemming from the occurrence reports stored in the national database pursuant to Article 6(6) of Regulation (EU) No 376/2014.

[applicable from 7 March 2023 - Regulation (EU) 2022/203]

21.B.20 Obligations of the competent authority [applicable until 6 March 2023] / 21.B.20 Immediate reaction to a safety problem [applicable from 7 March 2023 - Regulation (EU) 2022/203]

Regulation (EU) No 748/2012

Each competent authority of the Member State is responsible for the implementation of Section A, Subparts F, G, H, I and P only for applicants, or holders, whose principal place of business is in its territory.

[applicable until 6 March 2023]

(a) Without prejudice to Regulation (EU) No 376/2014 of the European Parliament and of the Council and its delegated and implementing acts, the competent authority shall implement a system to appropriately collect, analyse and disseminate safety information.

(b) The Agency shall implement a system to appropriately analyse any relevant safety information received and, without undue delay, provide the relevant authority of the Member States and the Commission with any information, including recommendations or corrective actions to be taken, that is necessary for them to react in a timely manner to a safety problem involving products, parts, appliances, persons or organisations that are subject to Regulation (EU) 2018/1139 and its delegated and implementing acts.

(c) Upon receiving the information referred to in points (a) and (b), the competent authority shall take adequate measures to address the safety problem.

(d) The competent authority shall immediately notify measures taken under point (c) to all persons or organisations which need to comply with them under Regulation (EU) 2018/1139 and its delegated and implementing acts. The competent authority of the Member State shall also notify those measures to the Agency and, when combined action is required, to the other Member States concerned.

[applicable from 7 March 2023 - Regulation (EU) 2022/203]

GM 21.B.20 Responsibility for implementation

ED Decision 2012/020/R

Each certificate or approval in accordance with Part 21 Section A Subparts F, G, H, I and P will normally be issued and controlled by the competent authority of the Member State in whose country the applicant or holder is located. Therefore, to ensure consistency between the competent authorities of the Member States in issuing certificates and approvals, implementation of Part 21 should be based on the following three principles:

a) The establishment and maintenance of an effective organisation and corresponding processes by all competent authorities.

b) The operation of all competent authorities in accordance with Part 21 and its Acceptable Means of Compliance (AMC) and guidance material (GM).

c) A standardisation process established and operated by the Agency to access the standard achieved, and to provide timely advice and guidance to the competent authorities of the Member States.

As a result the responsibility for implementation comprises of the two main objectives:

a) To ensure that certificates and approvals are only granted to applicants that comply with the requirements of Part 21; and

b) To ensure sufficient visibility of the processes to give the Agency and the other Member States the necessary confidence in the certificates or approvals granted.

21.B.25 Requirements for the organisation of the competent authority [applicable until 6 March 2023] / 21.B.25 Management system [applicable from 7 March 2023 - Regulation (EU) 2022/203]

Regulation (EU) No 748/2012

(a) General:

The Member State shall designate a competent authority with allocated responsibilities for the implementation of Section A, Subparts F, G, H, I and P with documented procedures, organisation structure and staff.

(b) Resources:

1. the number of staff shall be sufficient to perform the allocated tasks;

2. the competent authority of the Member State shall appoint a manager, or managers, who are responsible for the execution of the related task(s) within the authority, including the communication with the Agency and the other national authorities as appropriate.

(c) Qualification and training:

All staff shall be appropriately qualified and have sufficient knowledge, experience and training to perform their allocated task.

[applicable until 6 March 2023]

(a) The competent authority shall establish and maintain a management system, including as a minimum:

1. documented policies and procedures to describe its organisation, the means and methods for establishing compliance with Regulation (EU) 2018/1139 and its delegated and implementing acts. The procedures shall be kept up to date, and serve as the basic working documents within that competent authority for all its related tasks;

2. a sufficient number of personnel to perform its tasks and discharge its responsibilities. A system shall be in place to plan the availability of personnel in order to ensure the proper completion of all tasks;

3. personnel that are qualified to perform their allocated tasks and that have the necessary knowledge and experience, and receive initial and recurrent training to ensure continuing competency;

4. adequate facilities and office accommodation for personnel to perform their allocated tasks;

5. a function to monitor the compliance of the management system with the relevant requirements, and the adequacy of the procedures, including the establishment of an internal audit process and a safety risk management process. Compliance monitoring

shall include a feedback system of audit findings to the senior management of the competent authority to ensure the implementation of corrective actions as necessary;

6. a person or group of persons having a responsibility to the senior management of the competent authority for the compliance monitoring function.

(b) The competent authority shall, for each field of activity, including the management system, appoint one or more persons with the overall responsibility for the management of the relevant task(s).

(c) The competent authority shall establish procedures for the participation in a mutual exchange of all necessary information and assistance with any other competent authorities concerned, whether from the same Member State or from other Member States, including on:

1. all findings raised and any follow-up actions taken as a result of the oversight of persons and organisations that carry out activities in the territory of a Member State, but certified by the competent authority of another Member State or by the Agency;

2. information stemming from mandatory and voluntary occurrence reporting as required by 21.A.3A.

(d) A copy of the procedures related to the management system of the competent authority of the Member State and their amendments shall be made available to the Agency for the purpose of standardisation.

[applicable from 7 March 2023 - Regulation (EU) 2022/203]

GM 21.B.25(a) Organisation

ED Decision 2012/020/R

The competent authority designated by each Member State should have an organisation in such a way that -

a) there is specific and effective management authority in the conduct of all relevant activities,

b) the functions and processes described in Part 21 and its AMC and GM may be properly implemented,

c) the competent authority of the Member State policy, organisation and operating procedures for the implementation of Part 21 are properly documented and applied,

d) all competent authority of the Member State personnel involved in the related activities are provided with training where necessary,

e) specific and effective provision is made for the communication and interface as necessary with the Agency and the competent authorities of the Member States,

f) all functions related to the implementation of Part 21 are adequately described and shown (Standardisation).

A general policy in respect of Part 21 activities should be developed, sponsored and implemented by the manager at the highest appropriate level, for example the top of the functional area of the competent authority of the Member State that is responsible for the related matters.

Appropriate steps should be taken to ensure that the policy is known and understood by all staff involved, and all necessary steps should be taken to implement and maintain the policy.

Whilst satisfying also additional national regulatory responsibilities, the general policy should in particular take into account:

a) the provisions of the Regulation (EC) No 216/2008

b) the provisions of Part 21 and its AMC and GM

c) the needs of industry

d) the needs of the Agency and of the competent authorities of the Member States.

The policy should define specific objectives for key elements of the organisation and processes for implementation of related Part 21 activities, including the corresponding control procedures and the measurement of the achieved standard.

GM 21.B.25(b) Resources

ED Decision 2012/020/R

The organisation for related Part 21 activities should be clearly defined within the general organisation of the competent authority of the Member State, with the hierarchical and functional links, and the names of the senior staff. Although final responsibility should be placed at the top of the functional area that is responsible for the related Part 21 activities as a whole, all subordinate levels of management should be suitably resourced and empowered to fulfil their delegated tasks.

The definition of an organisation for the implementation of related Part 21 activities should include the specification of

a) a manager responsible for the specific Part 21 activity acting as internal and external focal point. The responsibility is best placed with the manager who is in control of the day-to-day functions concerning the specific Part 21 activity, although he may delegate specific tasks to other individuals;

b) individual or group responsibilities, duties and associated reporting lines;

c) the resources, human and material;

d) the documented procedures to be operated in respect of the relevant Part 21 activities.

The various tasks and responsibilities of the personnel involved in the related Part 21 activities should be clearly identified. The authority attached to the responsibilities should be enough to ensure that the activities will be performed correctly.

These responsibilities include among others:

a) the management of the organisation

b) the management of investigation teams

c) the team leadership/membership

d) the investigation and surveillance activities

e) the administrative management of certificates and approvals including record keeping

f) the external and internal interface activities including feedback to the Agency

g) the control and distribution of documentation

The definition of the organisation should include means to ensure continued effectivity of the organisation. The means should provide for a regular assessment of the organisation and its related activities as well as a feedback system for the follow up of necessary corrective actions (e.g., through the implementation of a quality system, internal audit system, etc.).

GM 21.B.25(c) Qualification and training

ED Decision 2012/020/R

The competent authority of the Member State should ensure appropriate and adequate training of its personnel to meet the standard that is considered by the Agency necessary to perform the work. Arrangements should be made for initial and continuation training as required.

It is understood that the basic competence of the competent authority of the Member State staff is a matter of recruitment and normal management functions in selection of staff for particular duties. Moreover, it is understood that the competent authority of the Member State provides training in the basic skills as required for those duties.

However, to avoid differences in understanding and interpretation, it is considered important that all personnel involved in Part 21 activities should be provided with further training specifically related to the relevant Part 21 activity up to the common Agency standard.

The competent authority of the Member State should provide training through its own training organisation with qualified trainers or through another qualified training source (e.g., training provided by other competent authorities, the Agency or qualified entities).

21.B.30 Documented procedures [applicable until 6 March 2023] / 21.B.30 Allocation of tasks to qualified entities [applicable from 7 March 2023 - Regulation (EU) 2022/203]

Regulation (EU) No 748/2012

(a) The competent authority of the Member State shall establish documented procedures to describe its organisation, means and methods to fulfil the requirements of this Annex I (Part 21). The procedures shall be kept up to date and serve as the basic working documents within that authority for all related activities.

(b) A copy of the procedures and their amendments shall be available to the Agency.

[applicable until 6 March 2023]

(a) The competent authority may allocate tasks related to the initial certification or to the continuing oversight of products and parts, as well as of natural or legal persons subject to Regulation (EU) 2018/1139 and its delegated and implementing acts to qualified entities. When allocating tasks, the competent authority shall ensure that it has:

1. put a system in place to initially and continuously assess whether the qualified entity complies with Annex VI to Regulation (EU) 2018/1139. That system and the results of the assessments shall be documented;

2. established a written agreement with the qualified entity, approved by both parties at the appropriate management level, which stipulates:

(i) the tasks to be performed;

(ii) the declarations, reports and records to be provided;

(iii) the technical conditions to be met when performing such tasks;

(iv) the related liability coverage;

(v) the protection given to the information acquired when carrying out such tasks.

(b) The competent authority shall ensure that the internal audit process and safety risk management process established pursuant to point 21.B.25(a)(5) cover all the certification and continuing oversight tasks performed by the qualified entity on its behalf.

[applicable from 7 March 2023 - Regulation (EU) 2022/203]

AMC 21.B.30(a) Documented procedures

ED Decision 2012/020/R

The various elements of the organisation for the related Part 21 activities must be documented in order to establish a reference source for the establishment and maintenance of this organisation. The documented procedures must be established in a way that it will facilitate its use. They must be clearly identified, kept up-to-date and made readily available to all the personnel involved in the relevant activities.

The documented procedures must cover, as a minimum, the following aspects:

a) policy and objectives,

b) organisation structure,

c) responsibilities and attached authority,

d) procedures and processes,

e) internal and external interfaces,

f) internal control procedures,

g) training of personnel,

h) cross-references to associated documents,

i) assistance from other competent authorities or the Agency (where required).

Except for smaller competent authorities, it is likely that the information is held in more than one document or series of documents, and suitable cross-reference information must be provided. For example, organisational structure and job descriptions are not usually in the same documentation as the detailed working procedures. In such cases it is recommended that the documented procedures include an index of cross-references to all such other related information, and the related documentation must be readily available when required.

21.B.35 Changes in organisation and procedures [applicable until 6 March 2023] / 21.B.35 Changes in the management system [applicable from 7 March 2023 - Regulation (EU) 2022/203]

Regulation (EU) No 748/2012

(a) The competent authority of the Member State shall notify any significant change in its organisation and documented procedures to the Agency.

(b) The competent authority of the Member State shall update its documented procedures relating to any change to regulations in a timely manner to ensure effective implementation.

[applicable until 6 March 2023]

(a) The competent authority shall have a system in place to identify the changes that affect its capability to perform its tasks and discharge its responsibilities as defined in Regulation (EU) 2018/1139 and its delegated and implementing acts. That system shall enable the competent authority to take action necessary to ensure that its management system remains adequate and effective.

(b) The competent authority shall update in a timely manner its management system to reflect any changes to Regulation (EU) 2018/1139 and its delegated and implementing acts so as to ensure its effective implementation.

(c) The competent authority of the Member State shall notify the Agency of any changes affecting its capability to perform its tasks and discharge its responsibilities as provided for in Regulation (EU) 2018/1139 and its delegated and implementing acts.

[applicable from 7 March 2023 - Regulation (EU) 2022/203]

AMC 21.B.35(a) Changes

ED Decision 2012/020/R

Standardisation is based on the assessment of the organisation and procedures of the competent authorities of the Member States and their implementation and suitability by the Agency. Consequently, a significant change in the competent authority of the Member State organisation and documented procedures validated by the Agency needs a reassessment to maintain the confidence in the standardisation process.

Examples of significant changes include changes in the organisation hierarchy, decision making levels, number and qualification of personnel, etc.

The competent authority of the Member State must notify any of these changes to the Agency and must be prepared to provide any further explanation/information requested by the Agency. The Agency may decide to review the documented organisation and procedures of the competent authority of the Member State and request any clarification or changes. This might also apply when a change in the regulations takes place and the Agency decides that a specific assessment/monitoring of the competent authorities related to that change is necessary.

21.B.40 Resolution of disputes

Regulation (EU) No 748/2012

(a) The competent authority of the Member State shall establish a process for the resolution of disputes within its organisation documented procedures.

(b) Where a dispute, which cannot be resolved, exists between the competent authorities of the Member States it is the responsibility of the managers as defined in point 21.B.25(b)(2) to raise the issue with the Agency for mediation.

[applicable until 6 March 2023 – Regulation (EU) 2022/203]

GM 21.B.40 Principles for the resolution of disputes

ED Decision 2012/020/R

It is essential for the efficient accomplishment of the competent authority of the Member State activities related to Part 21 that all decisions regarding the resolution of disputes are taken at as low a level as possible. In addition the documented procedures for the resolution of disputes should clearly identify the chain of escalation.

21.B.45 Reporting/coordination

Regulation (EU) No 748/2012

(a) The competent authority of the Member State shall ensure coordination as applicable with other related certification, investigation, approval or authorisation teams of that authority, other Member States and the Agency to ensure efficient exchange of information relevant for safety of the products, parts and appliances.

(b) The competent authority of the Member State shall notify any difficulty in the implementation of this Annex I (Part 21) to the Agency.

[applicable until 6 March 2023 – Regulation (EU) 2022/203]

GM No 1 to 21.B.45 Co-ordination with other related activities

ED Decision 2012/020/R

The purpose of co-ordination with other related activities is to

a) harmonise the effects of various approval and certification teams especially when dealing with one organisation / applicant to prevent conflicts of conclusions,

b) ensure efficient flow of information between the various approval and certification teams to facilitate the execution of their duties

c) optimise the use of the Agency and the competent authorities resources to minimise disruption and cost.

Therefore, for a given organisation / applicant the responsible person(s) of the Agency or competent authorities of the Member State should arrange for exchange of information with, and provide necessary assistance, as appropriate, to the relevant competent authority of the Member State or Agency teams or staff - e.g.:

a) the appropriate certification teams;

b) the design organisation approval team;

c) the production organisation approval team;

d) the maintenance organisation approval team; or

e) other approval or certification teams as appropriate.

GM No 2 to 21.B.45 Co-ordination

ED Decision 2012/020/R

An exchange of information should especially take place in accordance with Article 15 of the Regulation (EC) No 216/2008:

(a) an immediate reaction of a competent authority of the Member State to a safety problem

(b) granting of exemptions by the competent authority of the Member State from the substantive requirements of the Regulation (EC) No 216/2008 and its implementing rules (for a period of more than two months or when the exemptions become repetitive)

(c) granting of approvals on an equivalent level of protection by the competent authority of the Member State by derogation from the Part 21 requirements

GM No 3 to 21.B.45 Reporting – Information relevant to registers established by the Agency

ED Decision 2012/020/R

When so requested by the Agency, the competent authority of the Member State should notify any certificate or approval issued, changed or revoked including details of the scope of that certificate or approval to the Agency for inclusion in a central register managed by the Agency.

21.B.55 Record-keeping

Regulation (EU) No 748/2012

The competent authority of the Member State shall keep, or maintain access to, the appropriate records related to the certificates, approvals and authorisations it has granted in accordance with the respective national regulations, and for which responsibility is transferred to the Agency, as long as these records have not been transferred to the Agency.

[applicable until 6 March 2023]

(a) The competent authority shall establish a record-keeping system that allows the adequate storage, accessibility and reliable traceability of:

1. the management system's documented policies and procedures;
2. the training, qualifications and authorisation of its personnel;
3. the allocation of tasks, covering the elements required by point 21.B.30, as well as the details of tasks allocated;
4. certification processes and continuing oversight of certified organisations, including:
   (i) the application for a certificate, approval, authorisation and letter of agreement;
   (ii) the competent authority's continuing oversight programme, including all the assessments, audits and inspection records;
   (iii) the certificates, approvals, authorisations and letters of agreement issued, including any changes to them;

(iv) a copy of the oversight programme, listing the dates when audits are due and when audits were carried out;

(v) copies of all formal correspondence;

(vi) recommendations for the issue or continuation of a certificate, an approval authorisation or a letter of agreement, detail of findings and actions taken by the organisations to close those findings, including the date of closure, enforcement actions and observations;

(vii) any assessment, audit and inspection report issued by another competent authority pursuant to points 21.B.120(d), 21.B.221(c) or 21.B.431(c);

(viii) copies of all the organisation expositions, handbooks or manuals, and of any amendments to them;

(ix) copies of any other documents approved by the competent authority;

5. Statements of Conformity (EASA Form 52, see Appendix VIII) and Authorised Release Certificates (EASA Form 1, see Appendix I) that it has validated for organisations that produce products, parts or appliances without a production organisation approval certificate according to Subpart F of Section A of this Annex.

(b) The competent authority shall include in the record-keeping:

1. documents supporting the use of alternative means of compliance

2. safety information in accordance with point 21.B.15 and follow-up measures;

3. the use of safeguard and flexibility provisions in accordance with Articles 70, 71(1) and 76(4) of Regulation (EU) 2018/1139.

(c) The competent authority shall maintain a list of all the certificates, approvals, authorisations and letters of agreement it has issued.

(d) All the records referred to in points (a), (b) and (c) shall be kept for a minimum period of 5 years, subject to applicable data protection law.

(e) All the records referred to in points (a), (b) and (c) shall be made available, upon request, to a competent authorities of another Member State or to the Agency.

[applicable from 7 March 2023 - Regulation (EU) 2022/203]

GM 21.B.55 Record-keeping for design approvals transferred to the Agency

ED Decision 2021/007/R

Record-keeping related to design approvals, for which the responsibility is transferred to the Agency, will remain initially with the competent authority of the Member State that has granted the design approvals, but will be at the disposal of the Agency. This GM specifies the administrative documents to be kept for the various kinds of design approvals. It does not repeat the requirements for design approvals holders to keep records (ref.: 21.A.55, 21.A.605).

1. Type-certificate

a) Copy of the type-certificate

b) Copy of the type-certificate data sheet

c) Environmental protection approval data

d) Documents defining the type-certification basis including information to justify special conditions, equivalent safety findings and exemptions (Certification Review Items or equivalent)

e) List of approved modifications,

f) List of the competent authority's approved publications (Flight Manual, Repair Manual, Airworthiness Limitations, Certification Maintenance Requirements)

g) Airworthiness directives

h) Master Minimum Equipment List

i) Maintenance Review Board Report

2. Supplemental type certificate

— Copy of supplemental type certificate

— Environmental protection approval data

— Documents defining the certification basis including information to justify special conditions, equivalent safety findings and exemptions (Certification Review Items or equivalent)

— List of the competent authority's approved documents

— Airworthiness directives

3. JTSO Authorisation

— Copy of JTSO authorisation letter

— Copy of Declaration of Design and Performance

— Statement of compliance with applicable standards

— Airworthiness directives

4. Other part or appliance approvals

a) Copy of approval letter,

b) Copy of Declaration of Design and Performance or equivalent

c) Statement of compliance with applicable standards

d) Airworthiness Directives

5. Changes from non TC or STC holders

a) Modification approval sheet, or equivalent document

b) Documents required by 21.A.105, or equivalent national requirement

Note: Not applicable to minor design changes approved under a DOA privilege, for which record keeping is under the DOA holder responsibility.

6. Repair design approvals

a) Repair approval sheet

b) Documents listed in 21.A.447, or equivalent national requirement

Note: Not applicable to repair design approved under a DOA privilege, for which record keeping is under the DOA holder responsibility.

21.B.60 Airworthiness directives

Regulation (EU) No 748/2012

When the competent authority of a Member State receives an airworthiness directive from the competent authority of a non-member State, that airworthiness directive shall be transferred to the Agency for dissemination in accordance with Article 20 of Regulation (EC) No 216/2008.

[applicable until 6 March 2023 – Regulation (EU) 2022/203]

21.B.65 Suspension, limitation and revocation

Regulation (EU) 2022/203

The competent authority shall:

(a) suspend a certificate, approval, permit to fly, authorisation or letter of agreement when it considers that there are reasonable grounds that such action is necessary to prevent a credible threat to aircraft safety;

(b) suspend, revoke or limit a certificate, approval, permit to fly, authorisation or letter of agreement if such action is required pursuant to points 21.B.125, 21.B.225 or 21.B.433;

(c) suspend or revoke a certificate of airworthiness or a noise certificate upon evidence that some of the conditions specified in points 21.A.181(a) or 21.A.211(a) are not met;

(d) suspend or limit in whole or in part a certificate, approval, permit to fly, authorisation or letter of agreement if unforeseeable circumstances outside the control of the competent authority prevent its inspectors from discharging their oversight responsibilities over the oversight planning cycle.

[applicable from 7 March 2023 - Regulation (EU) 2022/203]

SUBPART B — TYPE-CERTIFICATES AND RESTRICTED TYPE-CERTIFICATES

21.B.70 Certification specifications

Regulation (EU) 2019/897

The Agency, in accordance with Article 76(3) of Regulation (EU) 2018/1139, shall issue certification specifications and other detailed specifications, including certification specifications for airworthiness, operational suitability data and environmental protection, that competent authorities, organisations and personnel may use to demonstrate compliance of products, parts and appliances with the relevant essential requirements set out in Annexes II, IV and V to that Regulation, as well as with those for environmental protection set out in Article 9(2) and Annex III of that Regulation. Such specifications shall be sufficiently detailed and specific to indicate to applicants the conditions under which certificates are to be issued, amended or supplemented.

21.B.75 Special conditions

Regulation (EU) 2019/897

(a) The Agency shall prescribe special detailed technical specifications, named 'special conditions, for a product if the related certification specifications do not contain adequate or appropriate safety standards for the product because:

1. the product has novel or unusual design features relative to the design practices on which the applicable certification specifications are based;
2. the intended use of the product is unconventional; or
3. experience from other similar products in service or products having similar design features or newly identified hazards have shown that unsafe conditions may develop.

(b) Special conditions contain such safety standards as the Agency finds necessary in order to establish a level of safety equivalent to that of the applicable certification specifications.

GM1 21.B.75 Special conditions

ED Decision 2021/001/R

GENERAL

The term 'novel or unusual design features' should be judged in view of the applicable certification basis for the product. A design feature, in particular, should be judged to be a 'novel or unusual design feature' when the certification basis does not sufficiently cover this design.

The term 'unsafe condition' is used with the same meaning as described in GM1 21.A.3B(b).

The term 'newly identified hazards' is intended to address new risks that may be recognised in the design (e.g. questionable features) or its operational characteristics (e.g. volcanic ash) for which there is not yet enough in-service experience.

21.B.80 Type-certification basis for a type-certificate or restricted type-certificate

Regulation (EU) 2019/897

The Agency shall establish the type certification basis and notify it to the applicant for a type-certificate or restricted type-certificate. The type certification basis shall consist of:

(a) the certification specifications for airworthiness designated by the Agency from those applicable to the product at the date of application for that certificate, unless:

1. the applicant chooses to comply, or is required to comply in accordance with point 21.A.15(f), with certification specifications which became applicable after the date of the application; If an applicant chooses to comply with a certification specification which became applicable after the date of the application, the Agency shall include in the type-certification basis any other certification specification that is directly related; or

2. the Agency accepts any alternative to a designated certification specification that cannot be complied with, for which compensating factors have been found that provide an equivalent level of safety; or

3. the Agency accepts or prescribes other means that:

(i) in the case of a type-certificate, demonstrate compliance with the essential requirements of Annex II to Regulation (EU) 2018/1139; or

(ii) in the case of a restricted type-certificate, provide a level of safety adequate with regard to the intended use; and

(b) any special condition prescribed by the Agency in accordance with point 21.B.75(a).

GM 21.B.80 Type-certification basis for a type certificate (TC) or restricted type certificate (RTC)

ED Decision 2019/018/R

1. INTRODUCTION

This GM addresses the type-certification basis for a TC or an RTC.

2. APPLICABLE CERTIFICATION SPECIFICATIONS (CSs) (see point 21.B.80(a))

The type-certification basis for a TC or an RTC consists of the airworthiness CSs that were effective on the date of application and were applicable for that certificate.

The effectivity date of the initial application may be changed, as per point 21.A.15(f)(2), when the period of validity of an application for a type certificate is exceeded, or it is evident that it will be exceeded, and the applicant requests an extension; see GM 21.A.15(e) and (f).

The certification basis is then revised accordingly.

3. ELECT TO COMPLY (see point 21.B.80(a)(1))

It is also possible for an applicant to elect to comply with a CS that entered into force after the date on which the applicant has submitted the application.

EASA should assess whether the proposed certification basis is appropriate to ensure that the 'elect to comply' proposal includes any other CSs that are 'directly related' to one or several of the CSs in it. Directly related CSs are those that are deemed to contribute to the same safety objective by building on each other's requirements, addressing complementary aspects of the

same safety concern, etc. Typically, they are adopted simultaneously with, or prior to, the CSs with which the applicant has elected to comply.

4. EQUIVALENT LEVEL OF SAFETY (see point 21.B.80(a)(2))

In cases in which the applicable CSs cannot be literally complied with, either fully or in part, EASA may accept a suitable alternative which provides an equivalent level of safety through the use of appropriate compensating factors.

In cases in which the requirements contain not only objectives but also prescriptive parts, an equivalent level of safety may be accepted if:

— the objectives are met by designs or features other than those required in the CSs; or

— suitable compensating factors are proposed.

5. ALTERNATIVE MEANS OF COMPLIANCE (see point 21.B.80(a)(3))

If the intent of the CSs defined in point 21.B.80(a) cannot be met, EASA may accept mitigating factors to the CSs, provided that the safety objective is met.

In the case of a TC, the alternative means should provide a demonstration of compliance with the essential requirements for airworthiness laid down in Annex II to Regulation (EU) 2018/1139.

In the case of an RTC, the alternative means should provide a sufficient level of safety for the intended use.

Note: 'Alternative means of compliance' should not be confused with 'AMC'.

6. SPECIAL CONDITIONS (see point 21.B.75)

EASA may also prescribe special conditions in accordance with point 21.B.75. Guidance on special conditions is provided in GM 21.B.75.

21.B.82 Operational suitability data certification basis for an aircraft type-certificate or restricted type-certificate

Regulation (EU) 2019/897

The Agency shall establish the operational suitability data certification basis and notify it to the applicant for an aircraft type-certificate or restricted type-certificate. The operational suitability data certification basis shall consist of:

(a) the certification specifications for operational suitability data designated by the Agency out of those applicable to the aircraft at the date of the application or at the date of the application supplement for operational suitability data, whichever date is later, unless:

1. the applicant chooses to comply, or in accordance with point 21.A.15(f) is required to comply with certification specifications which became applicable after the date of the application; If an applicant chooses to comply with a certification specification which became applicable after the date of the application, the Agency shall include in the type-certification basis any other certification specification that is directly related; or

2. the Agency accepts or prescribes alternative means to demonstrate compliance with the relevant essential requirements of Annexes II, IV and V to Regulation (EU) 2018/1139.

(b) any special condition prescribed by the Agency in accordance with point 21.B.75(a).

GM 21.B.82 Operational suitability data (OSD) certification basis for an aircraft type certificate (TC) or restricted type certificate (RTC)

ED Decision 2019/018/R

1. INTRODUCTION

This GM addresses the OSD certification basis for a TC or an RTC.

2. APPLICABLE CERTIFICATION SPECIFICATIONS (CSs) (see point 21.B.80(a))

The OSD certification basis for a TC or an RTC consists of the OSD CSs that were applicable for that certificate and that were effective on the date of application for the TC or RTC or, if applicable, on the date of the application supplement.

The effectivity date of the initial application for the TC or RTC may be changed, as per point 21.A.15(f)(2), when the period of validity for an application for a type certificate is exceeded, or it is evident that it will be exceeded, and the applicant requests an extension; see GM 21.A.15(e) and (f). As a consequence, the OSD certification basis will be revised accordingly.

3. ELECT TO COMPLY (see point 21.B.82(a)(1))

It is also possible for an applicant to elect to comply with a CS that entered into force after the date on which the applicant has submitted the application.

EASA should assess whether the proposed certification basis is appropriate to ensure that the 'elect to comply' proposal includes any other CSs that are 'directly related' to one or several of the CSs in it.

Directly related CSs are those that are deemed to contribute to the same safety objective by building on each other's requirements, addressing complementary aspects of the same safety concern, etc. Typically, they are adopted simultaneously with, or prior to, the CSs with which the applicant has elected to comply.

4. EQUIVALENT LEVEL OF SAFETY (see point 21.B.82(a)(2))

In cases in which the applicable CS(s) cannot be literally complied with, either fully or in part, EASA may accept a suitable alternative which provides an equivalent level of safety through the use of appropriate compensating factors.

In cases in which the requirements contain not only objectives but also prescriptive parts, an equivalent level of safety may be accepted if:

— the objectives are met by designs or features other than those required in the CSs; or

— appropriate compensating factors are proposed.

5. ALTERNATIVE MEANS OF COMPLIANCE (see point 21.B.82(a)(2))

If the intent of the CSs defined in point 21.B.82(a) cannot be met, EASA may accept mitigating factors to the CSs, provided that the safety objective is met.

In the case of a TC, the alternative means should provide a demonstration of compliance with the essential requirements for airworthiness laid down in Annex II to Regulation (EU) 2018/1139.

In the case of an RTC, the alternative means should provide a sufficient level of safety for the intended use.

Note: 'Alternative means of compliance' should not be confused with 'AMC'.

6. SPECIAL CONDITIONS (see point 21.B.75)

EASA may also prescribe special conditions in accordance with point 21.B.75. Guidance on special conditions is provided in GM 21.B.75.

21.B.85 Designation of applicable environmental protection requirements for a type-certificate or restricted type-certificate

Regulation (EU) 2021/1088

(a) The Agency shall designate and notify to the applicant the applicable environmental protection requirements for a type-certificate or restricted type-certificate for an aircraft or for a type certificate for an engine. The designation and notification shall contain:

1. the applicable noise requirements established in:

(i) Annex 16 to the Chicago Convention, Volume I, Part II, Chapter 1 and:

(A) for subsonic jet aeroplanes, in Chapters 2, 3, 4 and 14;

(B) for propeller-driven aeroplanes, in Chapters 3, 4, 5, 6, 10, and 14;

(C) for helicopters, in Chapters 8 and 11;

(D) for supersonic aeroplanes, in Chapter 12; and

(E) for tilt rotors, in Chapter 13.

(ii) Annex 16 to the Chicago Convention, Volume I:

(A) Appendix 1 for aeroplanes for which Chapters 2 and 12 of Annex 16 to the Chicago Convention, Volume I, Part II are applicable;

(B) Appendix 2 for aeroplanes for which Chapters 3, 4, 5, 8, 13 and 14 of Annex 16 to the Chicago Convention, Volume I, Part II are applicable;

(C) Appendix 3 for aeroplanes for which Chapter 6 of Annex 16 to the Chicago Convention, Volume I, Part II is applicable;

(D) Appendix 4 for aeroplanes for which Chapter 11 of Annex 16 to the Chicago Convention, Volume I, Part II is applicable; and

(E) Appendix 6 for aeroplanes for which Chapter 10 of Annex 16 to the Chicago Convention, Volume I, Part II is applicable;

2. the applicable emissions requirements for preventions of intentional fuel venting for aircraft established in Annex 16 to the Chicago Convention, Volume II, Part II, Chapters 1 and 2;

3. the applicable smoke, gaseous and particulate matter engine emissions requirements established in:

(i) Annex 16 to the Chicago Convention, Volume II, Part III, Chapter 1 and:

(A) for smoke and gaseous emissions of turbojet and turbofan engines intended for propulsion only at subsonic speeds, in Chapter 2;

(B) for smoke and gaseous emissions of turbojet and turbofan engines intended for propulsion at supersonic speeds, in Chapter 3; and

(C) for particulate matter emissions of turbojet and turbofan engines intended for propulsion only at subsonic speeds, in Chapter 4;

(ii) Annex 16 to the Chicago Convention, Volume II:

(A) Appendix 1 for the measurement of reference pressure ratio;

(B) Appendix 2 for smoke emissions evaluation;

(C) Appendix 3 for instrumentation and measurement techniques for gaseous emissions;

(D) Appendix 4 for specifications for fuel to be used in aircraft turbine engine emissions testing;

(E) Appendix 5 for instrumentation and measurement techniques for gaseous emissions from afterburning gas turbine engines;

(F) Appendix 6 for compliance procedure for gaseous, smoke and particulate matter emissions; and

(G) Appendix 7 for instrumentation and measurement techniques for non-volatile particulate matter;

4. the applicable aeroplane CO_2 emissions requirements established in:

(i) Annex 16 to the Chicago Convention, Volume III, Part II, Chapter 1, and:

(A) for subsonic jet aeroplanes, in Chapter 2; and

(B) for subsonic propeller-driven aeroplanes, in Chapter 2;.

(ii) Annex 16 to the Chicago Convention, Volume III, Appendices 1 and 2, for aeroplanes for which Chapter 2 of Annex 16 to the Chicago Convention, Volume III, Part II is applicable;

5. for engines, the applicable requirements in Annex 16 to the Chicago Convention, Volume II, Part IV and Appendix 8 concerning non-volatile particulate matter assessment for inventory and modelling purposes.

(b) (reserved).

GM1 21.B.85(a) Applicable environmental protection requirements

ED Decision 2021/011/R

1. APPLICABLE ENVIRONMENTAL PROTECTION REQUIREMENTS

The applicable environmental protection requirements are the Standards and Recommended Practices in Volume I, Volume II and Volume III of Annex 16 to the Chicago Convention for aircraft and engines for which the first subparagraph of Article 9(2) of Regulation (EU) 2018/1139 applies. The applicable levels of amendment to Annex 16 to the Chicago Convention are those adopted in the first subparagraph of Article 9(2) of Regulation (EU) 2018/1139.

2. AIRCRAFT NOISE

Guidance material for the application of the certification procedures for aircraft noise is presented in:

(a) Volume I of Annex 16 to the Chicago Convention:

(1) in Attachment A for equations for the calculation of maximum permitted noise levels as a function of take-off mass;

(2) in Attachment D for evaluating an alternative method of measuring helicopter noise during approach;

(3) in Attachment E for applicability of noise certification standards for propeller-driven aeroplanes; and

(4) in Attachment F for guidelines for noise certification of tilt rotors; and

(b) ICAO Doc 9501 'Environmental Technical Manual', Volume I 'Procedures for the Noise Certification of Aircraft', except Chapter 8.

3. FUEL VENTING

Guidance material for the application of the certification procedures for aircraft engine emissions is presented in ICAO Doc 9501 'Environmental Technical Manual' Volume II 'Procedures for the Emissions Certification of Aircraft Engines'.

4. ENGINE EMISSIONS

4.1. Guidance material related to engine emissions requirements

Guidance material for the application of the certification procedures for aircraft engine emissions is presented in:

(a) Attachment E to Appendix 3 to Volume II of Annex 16 to the Chicago Convention for the calculation of the emissions parameters; and

(b) ICAO Doc 9501 'Environmental Technical Manual' Volume II 'Procedures for the Emissions Certification of Aircraft Engines'.

4.2. Engine emissions requirements for inventory and modelling purposes

Aircraft engine manufacturers are required to calculate the nvPM mass and nvPM number system loss correction factors as per Appendix 8 to Volume II of Annex 16 to the Chicago Convention and to report them to the competent authority. The nvPM mass and number system loss correction factors permit an estimation of the nvPM mass and number emissions at the exhaust of the aircraft engine from the nvPM mass and number concentration obtained in accordance with the procedures laid down in Appendix 7 to Volume II of Annex 16 to the Chicago Convention.

5. AEROPLANE CO_2 EMISSIONS

Guidance material for the application of the certification procedures for aeroplane CO_2 emissions is contained in ICAO Doc 9501 'Environmental Technical Manual', Volume III 'Procedures for the CO_2 Emissions Certification of Aeroplanes'.

21.B.100 Level of involvement

Regulation (EU) 2019/897

(a) The Agency shall determine its involvement in the verification of the compliance demonstration activities and data related to the application for a type-certificate, restricted type-certificate, major change approval, supplemental type certificate, major repair design approval or ETSO authorisation for APU. It shall do so on the basis of an assessment of meaningful groups of compliance demonstration activities and data of the certification programme. That assessment shall address:

— the likelihood of an unidentified non-compliance with the type-certification basis, operational suitability data certification basis or environmental protection requirements; and

— the potential impact of that non-compliance on product safety or environmental protection,

and consider at least the following elements:

1. novel or unusual features of the certification project, including operational, organisational and knowledge management aspects;
2. complexity of the design and/or demonstration of compliance;
3. criticality of the design or technology and the related safety and environmental risks, including those identified on similar designs; and
4. performance and experience of the design organisation of the applicant in the domain concerned.

(b) For the approval of a minor repair design, minor change or ETSO authorisation other than for APU, the Agency shall determine its involvement at the level of the entire certification project, taking into account any novel or unusual features, complexity of the design and/or demonstration of compliance, criticality of the design or technology, as well as the performance and experience of the applicant's design organisation.

(c) The Agency shall notify its level of involvement to the applicant and it shall update its level of involvement when this is warranted by information which has an appreciable impact on the risk previously assessed pursuant to point (a) or (b). The Agency shall notify the applicant about the change in the level of involvement.

AMC 21.B.100(a) and 21.A.15(b)(6) Level of involvement (LoI) in a certification project for a type certificate (TC), a major change to a TC, a supplemental type certificate (STC), a major repair design or European technical standard order (ETSO) authorisation for an auxiliary power unit (APU)

ED Decision 2019/018/R

1. Definitions

Risk: the combination of the likelihood and the potential impact of a non-compliance with part of the certification basis.

Likelihood: a prediction of how likely an occurrence of non-compliance with part of the certification basis is, based on a combination of the novelty and complexity of the proposed design and its related compliance demonstration activities, as well as on the performance of the design organisation.

Criticality: a measure of the potential impact of a non-compliance with part of the certification basis on product safety or on the environment.

Compliance demonstration item (CDI): a meaningful group of compliance demonstration activities and data of the certification programme, which can be considered in isolation for the purpose of performing a risk assessment.

EASA panel: an EASA panel is composed of one or more experts who are responsible for a particular technical area. Each technical area addressed during product certification is covered by an EASA panel.

EASA discipline: an EASA discipline is a technical subarea of an EASA panel.

EASA's level of involvement (LoI): the compliance demonstration activities and data that EASA retains for verification during the certification process, as well as the depth of the verification.

2. Background

The applicant has to submit a certification programme for their compliance demonstrations in accordance with point 21.A.15(b). The applicant has to break down the certification programme into meaningful groups of compliance demonstration activities and data, hereinafter referred as 'CDIs', and provide their proposal for EASA's LoI.

The applicant should also indicate the EASA panel(s) that is (are) affected by each CDI.

This AMC explains:

(a) how to propose EASA's LoI for each CDI as per points 21.A.15(b)(6), 21.A.93(b)(3)(iii), 21.A.432C(b)(6) as well as 21.A.113(b); and

(b) how EASA will determine its LoI on the basis of the criteria established in point 21.B.100.

EASA will review the proposal and determine its LoI. Both parties, in mutual trust, should ensure that the certification project is not delayed through the LoI proposal and determination.

Additionally, in accordance with point 21.A.20, the applicant has the obligation to update the certification programme, as necessary, during the certification process, and report to EASA any difficulty or event encountered during the compliance demonstration process which may require a change to the LoI that was previously notified to the applicant.

In such a case, or when EASA has other information that affects the assumptions on which the LoI was based, EASA will revisit its LoI determination.

In accordance with points 21.A.33, 21.A.447 and 21.A.615, irrespective of the LoI, EASA has the right to review any data and information related to compliance demonstration.

Note: This AMC should not be considered to be interpretative material for the classification of changes or repairs.

3. Principles and generic criteria for the LoI determination EASA determines its LoI based on the applicant's proposal in view of the risk (the combination of the likelihood of an unidentified non-compliance and its potential impact). This is performed after proper familiarisation with the certification project in three steps:

— Step 1: identification of the likelihood of an unidentified non-compliance,

— Step 2: identification of the risk class, and

— Step 3: determination of EASA's LoI.

This AMC contains criteria, common to all EASA panels, for the determination of:

— any novel or unusual features of the certification project, including operational, organisational and knowledge management aspects;

— the complexity of the design and/or compliance demonstration;

— the performance and experience of the design organisation of the applicant in the domain concerned;

— the criticality of the design or technology and the related safety and environmental risks, including those identified on similar designs; and

— the data and activities to be retained by EASA.

Note: Additional panel-specific criteria are available in further informative material published by EASA[1]. This material should not be considered to be AMC.

For CS-23 commuter (or CS-23 level 4 airplanes as defined in CS-23 Amdt 5), CS-25, CS-27 and CS-29 aircraft, all the panel-specific additional criteria should be considered. For the other products, the panel-specific criteria should only be considered for CDIs that affect noise, propulsion, development assurance and safety assessment (DASA), operational suitability data (OSD) and software and airborne electronic hardware.

The criteria used to determine the likelihood and the potential impact of an unidentified non-compliance generally allow a proportionate approach to be applied, in particular in order to differentiate between CS-25 and general aviation (GA) aircraft projects.

3.1. LoI determination at CDI level

The determination of EASA's LoI is performed at the level of the CDI (please refer to AMC 21.A.15(b)(5)).

The applicant should demonstrate that all the affected elements of the type-certification basis as specified in point 21.B.80, of the OSD certification basis as specified in point 21.B.82, and of the environmental protection requirements as specified in 21.B.85, the corresponding means and methods of compliance, as well as the corresponding certification activities and data, are fully covered by the proposed CDIs. If the provided data does not clearly show that this is the case, the applicant should clearly state to EASA that all the above-mentioned elements are fully covered.

Note: There could be different ways to 'clearly show' that all the elements of the certification basis are included in at least one CDI. For instance, this could be achieved by means of a 'CDI reference' column added in the table that lists all the elements of the certification basis.

3.2. Method for determining the likelihood of an unidentified non-compliance

3.2.1. Principle The likelihood of an unidentified non-compliance is assessed on the basis of the following criteria:

— novelty,

— complexity, and

— the performance of the design organisation.

3.2.2. Novelty

For the purpose of risk class determination, the following simplification has been made: a CDI may be either novel or non-novel.

Whether or not a CDI is novel is based on the extent to which the respective elements of the certification project, as well as the related requirement or means

[1] Such additional criteria are contained as an attachment to the EASA Certification Memorandum (CM) CM-21.A/21.B-001, available at: https://www.easa.europa.eu/document-library/product-certification-consultations/cm-21a21b-001.

of compliance, are new/novel to either the industry as a whole, or to the applicant, including their subcontractors, or from an EASA panel perspective.

The determination that a CDI is novel may be driven by the use of new technology, new operations, new kind of installations, the use of new requirements or the use of new means of compliance.

When an applicant utilises a type of technology for the first time, or when that applicant is relatively unfamiliar with the technology, this technology is considered to be 'novel', even if other applicants may be already familiar with it. This also means that a type of technology may no longer be novel for one applicant, while it may still be novel for other applicants.

The following list includes some examples:

— new materials or combinations of materials;

— a new application of materials or combinations of materials;

— new manufacturing processes;

— a new or unusual aircraft configuration and/or system architecture;

— a novel reconfiguration of systems;

— a new interface or interaction with other parts or systems;

— the unusual location of a part or a system, or an unusual construction;

— a new or unusual use;

— new functions;

— new kinds of operations;

— the potential for new failure modes;

— the introduction of a new threat (e.g. new threats regarding fire, fuel, hydrogen, energy storage devices, etc.) or a new prevention/detection/mitigation method;

— new maintenance techniques;

— novel operating conditions or limitations;

— a new human-machine interface (HMI); or

— new flight or cabin crew tasks.

Another consideration is the extent to which the requirements, means of compliance or guidance have changed or need to be adapted due to particular novel features of the design.

The following list includes some examples:

— recently issued or amended CSs with which the applicant has little or no experience;

— new or adapted special conditions;

— new or adapted equivalent safety findings;

— new or adapted deviations;

— new or adapted guidance or interpretative material;

— new or adapted means of compliance (i.e. other than those previously applied by the applicant) or unusual means of compliance (different from the existing guidance material and/or different from industry standard practices), e.g. the replacing of tests by simulation, numerical models or analytical methods;

— the use of new or adapted industry standards or in-house methods, as well as EASA's familiarity with these standards and methods;

— a change in methodology, tools or assumptions (compared with those previously applied by the applicant), including changes in software tools/programs; or

— novelty in the interpretation of the results of the compliance demonstration, e.g. due to in-service occurrences (compliance demonstration results are interpreted differently from the past).

Additional new guidance/interpretative material in the form of new certification memoranda (CM) may be considered for the determination of novelty if its incorrect application/use may lead to an unidentified non-compliance. In the context of novelty, the time between the last similar project and the current project of the applicant should also be considered.

Regardless of the extent of an organisation's previous experience in similar projects, a CDI may be classified as novel if there are specific discontinuities in the process for transferring information and know-how within the organisation.

3.2.3. Complexity For the purpose of risk class determination, the following simplification has been made: a CDI may be either complex or non-complex. For each CDI, the determination of whether it is complex or not may vary based on factors such as the design, technology, associated manufacturing process, compliance demonstration (including test set-ups or analysis), interpretation of the results of the compliance demonstration, interfaces with other technical disciplines/CDIs, and the requirements. The compliance demonstration may be considered to be 'complex' for a complex (or highly integrated) system, which typically requires more effort from the applicant. The following list includes some examples:

— Compliance demonstration in which challenging assessments are required, e.g.:

  — for requirements of a subjective nature, i.e. they require a qualitative assessment, and do not have an explicit description of the means of compliance with that requirement, or the means of compliance are not a common and accepted practice; this is typically the case where the requirement uses terms such as 'subjective', 'qualitative', 'assessment' or 'suitable'/'unsuitable'

  — in contrast, engineering judgement for a very simple compliance demonstration should not be classified as 'complex';

  — a test for which extensive interpretation of the results may be anticipated;

  — an analysis that is sensitive to assumptions and could potentially result in a small margin of safety;

— the classification of structures, depending on the conservatism of the method;

— an advanced analysis of dynamic behaviour;

— a multidisciplinary compliance demonstration in which several panels are involved and interface areas need to be managed (e.g. sustained engine imbalance, extended-range twin-engine operation performance standards (ETOPS), 2X.1309 assessment, flight in known icing conditions, full authority digital engine control (FADEC)-controlled engines, etc.);

— when the representativeness of a test specimen is questionable, e.g. due to its complexity;

— the introduction of complex work-sharing scheme with system or equipment suppliers.

For major changes, the complexity of the change should be taken into account, rather than the complexity of the original system.

Whether or not a CDI is complex should be determined in a conservative manner if this cannot be determined at an early stage of the certification project. When greater clarity has been achieved, the complexity may be re-evaluated and the LoI adapted accordingly.

3.2.4. Performance of the design organisation

The assessment of the level of performance of the design organisation takes into account the applicant's experience with the applicable certification processes, including their performance on previous projects and their degree of familiarity with the applicable certification requirements.

For approved design organisations, EASA uses relevant data to consider the design organisation's expected performance at an organisational, panel or discipline level, depending on the availability of data[1].

This data stems from design organisation audits, the applicant's measured level of performance on previous projects, and their performance during the familiarisation phase. EASA shares this data with the respective design organisations (in the form of the design organisation approval (DOA) dashboard).

For each CDI proposed by the applicant, the DOA holder's performance associated with the affected disciplines or panels is to be considered.

If one CDI affects more panels or disciplines than the others, a conservative approach should be followed in selecting the lower performance level. As an alternative, that CDI may be assessed separately for each affected EASA panel or discipline.

If, for a well-established organisation, there is no shared performance data available at the panel level, it may be acceptable to propose the overall DOA holder's performance. If the organisation or its scope are fundamentally new, the 'unknown' level of performance should be conservatively proposed by the applicant.

[1] The ultimate objective is to define the organisation's performance at the discipline level.

The determination of the performance of the design organisation may also take into consideration information that is more specific or more recent than the information on the DOA holder's dashboard, e.g. experience gained during technical familiarisation with the current certification project, the performance of compliance verification engineers and of the affected technical areas, as well as the performance of the design organisation in overseeing subcontractors and suppliers.

The performance of some applicants' organisations is not known if:

— EASA has agreed in accordance with point 21.A.14(b) that the applicants may use procedures that set out specific design practices, as an alternative means to demonstrate their capability (excluding European technical standard order (ETSO) applicants for other than APU, covered by point 21.B.100(b)); or

— the applicants demonstrate their capability by providing EASA with the certification programme in accordance with point 21.A.14(c).

In these cases, the assumed level of performance is 'unknown'.

Exceptionally, EASA may consider a higher level of performance for a specific CDI if that is proposed and properly justified by the applicant.

The following list includes some examples:

— a CDI with which EASA is fully familiar and satisfied (from previous similar projects) regarding the demonstration of compliance proposed by the applicant;

— if the applicant fully delegates the demonstration of compliance to a supplier that holds a DOA, the performance level of the supplier may be proposed.

3.2.5. Likelihood of an unidentified non-compliance

Assessing the likelihood of an unidentified non-compliance is the first step that is necessary to determine the risk class.

The likelihood of an unidentified non-compliance should not be confused with the likelihood of occurrence of an unsafe condition as per AMC 21.A.3B(b). In fact, that AMC provides EASA's confidence level that the design organisation addresses all the details of the certification basis for the CDI concerned, and that a non-compliance will not occur.

The likelihood of an unidentified non-compliance is established as being in one of four categories (very low, low, medium, high), depending on the level of performance of the design organisation as assessed by EASA, and on whether the CDI is novel or complex, as follows:

Step 1 — Likelihood of an unidentified non-compliance			
CDI Performance level of the DOAH	No novel aspects, no complex aspects	No novel aspects, but complex ones; Novel aspects, but no complex ones	Novel and complex aspects
High	Very low	Low	Medium
Medium	Low	Medium	High
Low or unknown	Medium	High	High

3.3. Criticality

The second step that is necessary to determine the risk class is the assessment of the potential impact of a non-compliance on part of the certification basis regarding the airworthiness or the environmental protection of the product. For the purpose of risk class determination, the following simplification has been made: the impact of a non-compliance can be either critical or non-critical.

Some of the guidance below has been derived from GM 21.A.91, not due to a major/minor change classification, but because the same considerations may be applied to determine the effect of a non-compliance on the airworthiness or environmental protection at the CDI level. It is therefore normal that some of the CDIs of a major change that consists of several CDIs may be critical, and others may be non-critical.

The potential impact of a non-compliance within a CDI should be classified as critical if, for example:

— a function, component or system is introduced or affected where the failure of that function, component or system may contribute to a failure condition that is classified as hazardous or catastrophic at the aircraft level, for instance for 'equipment, systems and installations', e.g. where applicable as defined in 2X.1309;

— a CDI has an appreciable effect on the human–machine interface (HMI) (displays, approved procedures, controls or alerts);

— airworthiness limitations or operating limitations are established or potentially affected;

— a CDI is affected by an existing airworthiness directive (AD), or affected by an occurrence (or occurrences) potentially subject to an AD, a known in-service issue or by a safety information bulletin (SIB); or

— a CDI affects parts that are classified as critical as per CS 27.602/29.602, CS-E 515, or that have a hazardous or catastrophic failure consequence (e.g. a principal structural element as per CS 25.571).

If the classification of the potential impact of a non-compliance within a CDI as critical is based on the criterion that the CDI is affected by an AD, then the impact of a non-compliance within that CDI may be reclassified by EASA as non-critical due to the involvement of EASA in the continued-airworthiness process.

During the early stages of a project, the criticality in terms of the potential safety consequence of a failure may not always be known, but should be conservatively estimated and the LoI should be subsequently re-evaluated, if appropriate. 3.4. Method for the determination of risk classes The risk is determined as a combination of the potential impact of an unidentified non-compliance with part of the certification basis (vertical axis) and of the likelihood of the unidentified non-compliance (horizontal axis) using the following matrix. As a consequence, four qualitative risk classes are established at the CDI level.

Step 2 — Risk classes				
Likelihood (see Section 3.2.5) Criticality (see Section 3.3)	Very low	Low	Medium	High
Non-critical	Class 1	Class 1	Class 2	Class 3
Critical	Class 1	Class 2	Class 3	Class 4

The various inputs and the resulting risk class determination are of a continuous nature, rather than consisting of discrete steps. The selected risk class provides the order of magnitude of EASA's involvement and is used as a qualitative indicator for the determination of EASA's involvement described in Section 3.5 below.

Under specific circumstances, the risk class that is determined on the basis of the above criteria may be reduced or increased on the basis of justified and recorded arguments. For a reused and well-proven item of compliance demonstration for which:

— the CDI is independent of the affected product type or model; and

— the design, operation, qualification, and installation of the product are basically the same; and

— the certification process is identical to one that was used in a modification already approved by EASA,

the CDI may be accepted as being similar, resulting in reduced LoI, as the likelihood of an unidentified non-compliance is low. Furthermore, when an identical CDI is reused for the compliance demonstration in a new project, there is no involvement in the compliance demonstration verification, as the likelihood of an unidentified non-compliance is very low.

3.5. Determination of EASA's LoI

EASA's LoI in the verification of compliance demonstration is proposed by the applicant and determined by EASA in Step 3 on the basis of the qualitative risk class identified per CDI in Step 2, as well as by applying sound engineering judgement.

EASA's LoI is reflected in a list of activities and data, in which EASA retains the verification of compliance demonstration (e.g. review and acceptance of compliance data, witnessing of tests, etc.), as well as the depth of the verification. The depth of the verification for individual compliance reports, data, test witnessing, etc., may range from spot checks to extensive reviews. EASA always responds to those retained compliance demonstration activities and data with corresponding comments or a 'statement of no objection'.

In addition, some data that is not retained for verification may be requested for information. In this case, no 'statement of no objection' will be provided.

It is recommended that an LoI should be proposed for each of the EASA disciplines involved. Depending on the risk classes determined in Section 3.4 above, EASA's LoI in:

(a) compliance demonstration verification data; and

(b) compliance demonstration activities (witnessing of tests, audits, etc.),

may be as follows:

— risk Class 1: there is no EASA involvement in verifying the compliance data/activities performed by the applicant to demonstrate compliance at the CDI level;

— risk Class 2: EASA's LoI is typically limited to the review of a small portion of the compliance data; there is either no participation in the compliance activities, or EASA participates in a small number of compliance activities (witnessing of tests, audits, etc.);

— risk Class 3: in addition to the LoI defined for Class 2, EASA's LoI typically comprises the review of a large amount of compliance data, as well as the participation in some compliance activities (witnessing of tests, audits, etc.); and

— risk Class 4: in addition to the LoI defined for Class 3, EASA's LoI typically comprises the review of a large amount of compliance data, the detailed interpretation of test results, and the participation in a large number of compliance activities (witnessing of tests, audits, etc.).

By default, the following activities require EASA's involvement in all cases:

— initial issues of, and changes to, a flight manual (for those parts that require EASA approval and that do not fall under the DOA holder's privilege);

— classification of failure cases that affect the handling qualities and performance, when:

  — performed through test (in flight or in a simulator); and

  — initial issues of, and non-editorial changes to, airworthiness limitations.

If the risk assessment (Steps 1 and 2 above) is made on the level of a compliance demonstration activity or on the level of a document, the risk class provides an indication for the depth of the involvement, i.e. the verification may take place only for certain compliance data within a compliance document.

4. Documentation of the LoI

The LoI proposal in the certification programme should include the applicant's proposal regarding the compliance demonstration verification activities and data that would be retained by EASA, as well as the data on which the LoI proposal has been based. For this purpose, the applicant should appropriately document the analysis per CDI, considering the above criteria. In cases where the rationale for the assessment is obvious, it is considered to be sufficient for the applicant to indicate whether or not a CDI is novel or complex, and whether or not the impact is critical.

EASA documents the LoI determination by accepting the certification programme or, if it deviates from the proposal, by recording its analysis regarding the deviations from the proposal, and notifies the applicant accordingly.

5. Sampling during surveillance of the DOA holder

It should be noted that all the previously defined risk classes may be complemented by the sampling of project files during surveillance of the DOA holder, independently from the ongoing certification project. This is necessary in order to maintain confidence in the DOA system and to constantly monitor its performance.

AMC No 1 to 21.B.100(b) Level of involvement (LoI) in projects for minor changes and minor repairs

ED Decision 2019/018/R

In contrast to 21.B.100(a), the assessment of the LoI for minor repair designs and minor changes is performed by EASA at the level of the certification project.

EASA reviews the information provided by the applicant in accordance with point 21.A.93(b) for novel or unusual features, the complexity of the design and/or the compliance demonstration, as well as the criticality of the design or technology.

An application for EASA's approval of a minor change implies that the applicant either does not hold a design organisation approval (DOA) or that the change is outside the DOA holder's terms of approval. However, EASA takes into account the performance and experience of the applicant with similar design changes, for which data may be already available at EASA. The applicant may be also requested to present its experience with similar design changes if insufficient information is available at EASA.

By definition (see point 21.A.91), a minor change has no appreciable effect on the airworthiness of the product. Therefore, the potential impact of a non-compliance with part of the certification basis regarding the airworthiness or environmental protection aspects of the product should, in most cases, be non-critical.

This facilitates the assessment of the likelihood of an unidentified non-compliance.

A process similar to the one described in AMC 21.B.100(a) and 21.A.15(b)(6) should be used to justify and document EASA's LoI.

Following a first assessment of the criticality of the described design or technology, EASA evaluates the existence of any novel or unusual features, as well as the complexity of the design and/or the compliance demonstration.

Depending on the results of this evaluation, and based on the table below, EASA determines its LoI as follows:

		Risk class	
Non-critical	Non-novel and non-complex	Class A	Class A
	Novel and/or complex	Class B	Class C
Critical	All cases	Class C	Class C
		Level of experience: high or medium	**Level of experience: low or unknown**

— Class A: EASA's involvement is limited to the review of the information that summarises the main results of the compliance demonstration, without any participation in compliance activities (witnessing of tests, audits, etc.).

— Class B: in addition to the LoI defined for risk Class A, EASA's involvement is limited to the review of those compliance elements that are related to the identified novel or unusual features, complexity of the design and/or compliance demonstration. EASA may exceptionally participate in the related compliance activities (by witnessing tests, audits, etc.).

— Class C: EASA's involvement is limited to the review of all the compliance documents that are related to the identified criticality of the design or technology, if applicable, or to the identified novel or unusual features. EASA may participate in the related compliance activities (by witnessing tests, audits, etc.).

AMC No 2 to 21.B.100(b) Level of involvement (LoI) in European technical standard order authorisation (ETSOA) projects

ED Decision 2019/018/R

The applicant for an ETSOA is required to demonstrate its capability by obtaining EASA's agreement for the use of procedures that incorporate its specific design practices.

The assessment by EASA that these procedures are properly applied is performed solely through the various ETSOA projects of the applicant. No regular audits of the organisation are performed by EASA outside the ETSOA projects.

A properly completed Form 34 and the certification programme, including a technical description of the proposed design of the ETSO article, are the basis for the determination of EASA's initial LoI.

EASA assesses the compliance of the proposed ETSO article with the ETSO requirements as defined in the applicable CS-ETSO standards, as well as compliance with Part 21 Subpart O (e.g. the declaration of design and performance (DDP), ETSO marking, rating of performance, etc.). The ETSOA applicant should deliver a complete data package per point 21.A.605.

EASA's LoI is further reassessed and adapted throughout the certification project until the ETSOA is issued, depending on the applicant's data, as well as on the ETSO project changes regarding the applicant's compliance demonstration (e.g. methods, design changes, deviations, limitations, problem reports, etc.).

1. Principles

EASA's LoI in ETSO projects is defined based both on the responsibility of EASA to assess the applicant's demonstration of compliance, and on the risk evaluated, according to the following criteria:

— the applicant's level of experience in the ETSO process and scope of work;

— the applicant's level of performance in the ETSO scope of work;

— the use of novelties in the technology/design or in the means of compliance; and

— the complexity of the ETSO article.

1.1. Applicant's experience in the ETSOA process and scope of work

This Section addresses the experience of the applicant's organisation in the ETSOA process, as well as in the scope of the certification basis of the ETSO article, and of the related requirements. The presence of any of the following aspects contributes to EASA's identification of the risk related to the level of experience of the applicant in the ETSOA process, or to the scope of work of the article:

— the applicant is new and has just applied for the acceptance of its procedures by EASA, or it is the first project of the applicant after EASA has accepted such procedures;

— the organisation has changed significantly the agreed procedures; and

— the scope of work of the ETSOA project (ETSO standards) is new to the applicant.

1.2. ETSOA applicant's performance within its scope of work

The ETSOA applicant's level of performance within its scope of work is evaluated using criteria that enable EASA to identify risks in the applicant's performance due to the following situations:

— the applicant has deficiencies in the procedures that it uses to demonstrate compliance with the certification requirements;

— the applicant has changed its methods or procedures to demonstrate compliance with the certification requirements;

— the assessment of the applicant's compliance on previous projects in the same ETSO scope of work has revealed significant issues in complying with the certification requirements, in the completion of data, or in the repetition of errors;

— the scope of work is new to the applicant's team at the facilities where the project is developed, or the team had significant issues on preceding projects;

— EASA has not conducted an ETSOA project assessment of the applicant in the same ETSO scope of work for a long period (i.e. 2 or 3 years); and

— the applicant did not regularly report minor changes or occurrences in a timely manner.

1.3. Novelty in the technology or in the means of compliance

A 'novelty' is understood to be the use of new technology, new sensors, new material, the use of new requirements or the use of new means of compliance. When an applicant is faced with a technology for the first time, or when that applicant is relatively unfamiliar with the technology, this is considered to be 'novel' even if other applicants may be already familiar with that technology.

Also related to novelty is the extent to which requirements, means of compliance or guidance need to be adapted due to particular novel features of the design. The following list includes some examples:

— recently issued CS-ETSO standards, with which the applicant has limited experience;

— novel deviations;

— new guidance;

— new means of compliance (i.e. other than those previously applied by the applicant) or unusual means of compliance (different from the existing guidance material and/or different from industry standard practices);

— the use of new industry standards or new in-house methods, as well as EASA's familiarity with these new standards and methods;

— changes in methodology, tools or assumptions (compared with those previously applied by the applicant), including changes in software tools/programs.

Technology or means of compliance may be new/novel either from a global industry, applicant or EASA perspective.

1.4. Complexity

Complexity may result from the design, technology, associated manufacturing process, compliance demonstration (including test set-ups or analysis), as well as from the variety of ETSOs with which the applicant intends to comply, and their possible interactions.

The demonstration of compliance may be 'complex' for complex (or highly integrated) equipment, so it typically requires more effort from the applicant.

1.5. Criticality of the design and of the technology

The criticality levels of the design and of the technology of the ETSO article are considered, but have a minor impact on the definition of EASA's LoI. The main reasons are:

— the assessment of ETSO compliance is as important for an ETSO article that hosts a critical function as it is for equipment that host less critical functions (e.g. flight data recorders); and

— the criticality of the design or technology is not always defined for an ETSO article, and it may depend on the installation of the design or technology (e.g. a multifunction display), which may only occur later.

2. Determination of EASA's LoI

EASA's LoI in the assessment of the applicant's compliance demonstration is determined by EASA on the basis of the qualitative risk class and EASA's responsibilities in assessing the ETSO project certification data package, together with the procedures for compliance with the ETSO requirements (Part 21 Subpart O, and CS-ETSO).

EASA's LoI is defined in the following paragraph 2.1 and, as per point 21.B.100(c), the EASA's LoI that is applicable to each project is notified to the applicant.

To every LoI class corresponds a list of activities that govern EASA's involvement. By means of these activities, EASA verifies the demonstration of compliance (e.g. by document review and acceptance, test witnessing, sampling on the applicant's site, desktop assessments, etc.).

The ETSO applicant is responsible for providing a complete ETSO certification data package.

2.1. Definition of the LoI classes

EASA's LoI for an ETSO certification project is classified as one of the following:

— class high,

— class high reduced,

— class medium, or

— class basic.

Class 'high reduced' is, by default, EASA's initial LoI in an ETSO project.

The following is a description of each LoI class:

— High

EASA evaluates and samples/checks in an extensive manner all the compliance data to assess the applicant's demonstration of compliance with the applicable ETSO standards. EASA assesses the applicant's DDP and general compliance with Part 21 Subpart O. EASA performs desktop reviews, as well as on-site assessments of compliance demonstrations. This occurs when design and verification evidence is available.

— High reduced

EASA assesses all the compliance data; sampling/checking is significant and adapted to the likelihood of an unidentified non-compliance. The sampling rate may be reduced if the content of the life cycle data provides confidence in compliance and is focused in the area where confidence needs to be gained. EASA assesses the DDP and general compliance with Part 21 Subpart O. EASA performs

desktop reviews, as well as an on-site assessment of the applicant's compliance demonstration. This occurs when design and verification evidence is available.

— Medium

EASA assesses all the compliance data, but for some compliance data, it performs no or limited sampling/checking. EASA adapts its sampling and focuses on the likelihood of an unidentified non-compliance, taking into account the level of complexity and novelty of the project. EASA assesses the DDP and general compliance with Part 21 Subpart O. EASA performs desktop reviews and may perform an on-site assessment of the applicant's compliance demonstration.

— Basic

EASA assesses the DDP and general compliance with Part 21 Subpart O, and verifies the completeness of the data package.

Generally, EASA performs a desktop assessment.

3. The process of determining EASA's LoI

The determination of EASA's LoI is captured as a process. This process is performed mainly in three steps and is illustrated in the following figure:

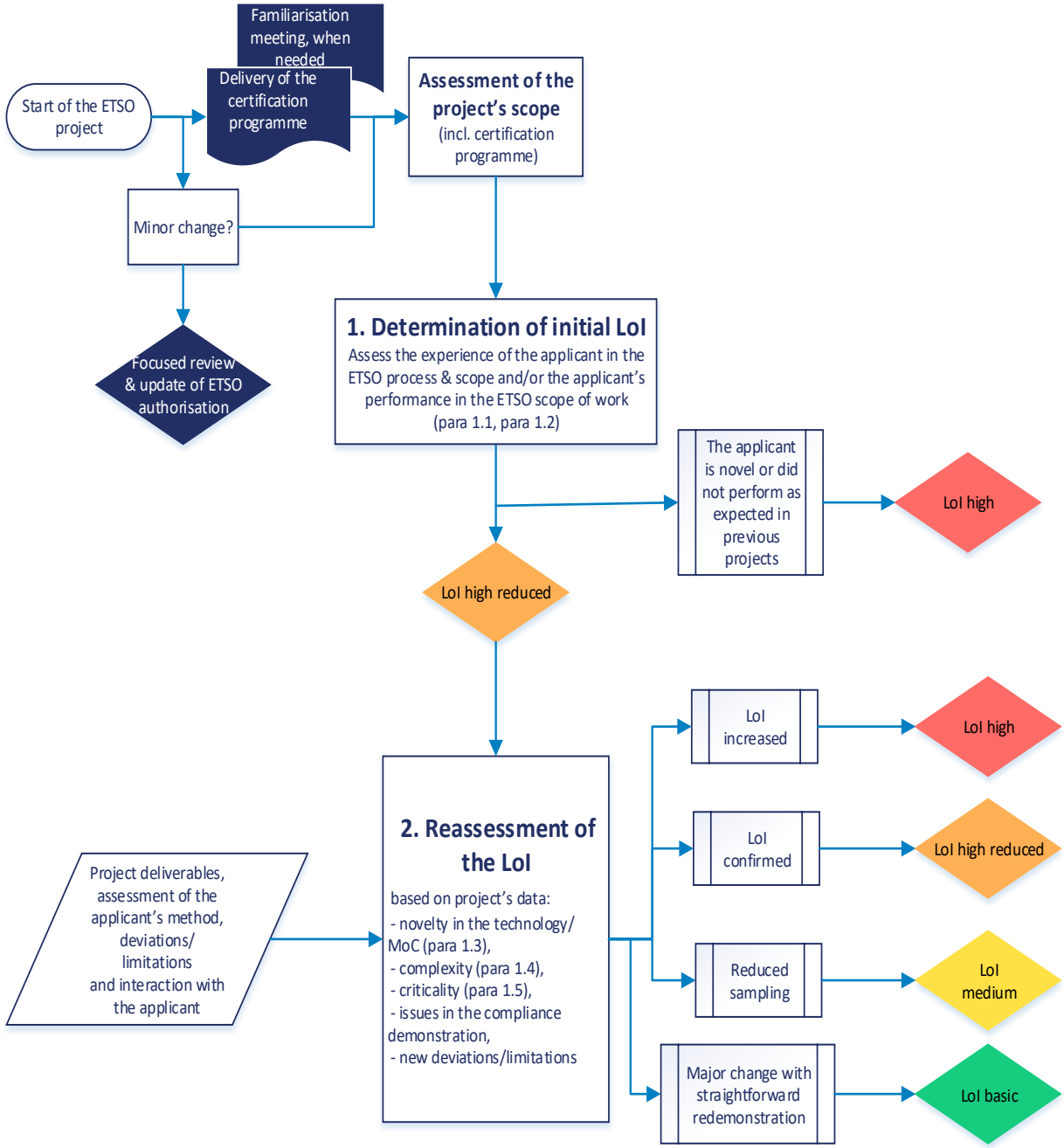


Figure 1: Process of determination of EASA's LoI in ETSO certification projects

Step 1 consists of the initial LoI determination which EASA evaluates by assessing:

- the applicant's experience in the ETSOA process and scope of work according to Section 1.1 above, and
- the ETSOA applicant's performance within its scope of work according to Section 1.2 above.

The result of this determination of EASA's initial LoI is either high or high reduced.

Step 2 consists of reassessing EASA's LoI. Throughout the ETSO project, EASA receives project deliverables (e.g. plans, reports), means of compliance, requests for deviations, limitations, etc., and interacts with the applicant.

If EASA's LoI has been initially set to high reduced, EASA re-evaluates it considering:

— the novelty in the technology or in the means of compliance according to Section 1.3 above, and

— the complexity of the ETSO project according to Section 1.4 above.

The result of this reassessment may vary from high to medium according to the following table:

Assessment results	LoI adaptation
The ETSO article is novel and complex or a significant issue is detected during the compliance demonstration.	LoI is increased to high.
The ETSO article is novel or complex or a new deviation is requested ([1]).	LoI is confirmed as high reduced.
The ETSO article is non-novel and non-complex, no issue is detected during the compliance demonstration or method, and no novel deviation or new limitation is requested.	LoI is decreased to medium.
There is a major change with straightforward redemonstration of the ETSO compliance ([2]).	LoI is reduced to basic.

1 It refers to deviations from ETSO minimum operational performance standards (MOPSs), excluding deviations for requesting compliance with a new revision of an industry MOPS standard.

2 When EASA agrees that a major change only requires a straightforward redemonstration of the ETSO compliance using previous methods, without any identified risk, then EASA's LoI is reduced to basic. Please note that this may only be defined after a minimum assessment of the applicant's compliance demonstration methods.

Note: For a minor change, this process does not apply; in that case, EASA's LoI consists of an assessment of the minor change classification, an update of the certificate, and, when needed, an assessment of the DDP.

21.B.103 Issuance of a type-certificate or restricted type-certificate [applicable until 6 March 2023] / 21.B.103 Issuance of a type-certificate or a restricted type-certificate [applicable from 7 March 2023 - Regulation (EU) 2022/201]

Regulation (EU) 2019/897

(a) The Agency shall issue an aircraft, engine or propeller type-certificate or an aircraft restricted type-certificate, provided that:

1. the applicant has complied with point 21.A.21;
2. the Agency, through verifications of the demonstration of compliance in accordance with its involvement determined pursuant to point 21.B.100, has not found any non-compliance with the type-certification basis, the operational suitability data certification basis where applicable in accordance with point 21.B.82, and the environmental protection requirements; and
3. no feature or characteristic has been identified that may make the product unsafe for the uses for which the certification is requested.

(b) By derogation from point (a), at the applicant's request included in the declaration referred to in point 21.A.20(d), the Agency may issue an aircraft type-certificate before compliance with the operational suitability data certification basis has been demonstrated, provided that the applicant demonstrates such compliance before the date at which those data are to be actually used.

GM 21.A.21(b), 21.A.95(c), 21.A.97(c), 21.A.115(c), 21.B.103(b), 21.B.107(b) and 21.B.111(b) Approval of operational suitability data (OSD)

ED Decision 2019/018/R

It is acknowledged that it may not always be possible to have the OSD available on the date of the issue of the (restricted) type certificate ((R)TC), change approval or supplemental type certificate (STC). The derogation provided by 21.A.21(b), 21.A.95(c), 21.A.97(c), 21.A.115(c), 21.B.103(b), 21.B.107(b) and 21.B.111(b) is intended for that case. The (R)TC, change approval or STC can be issued before compliance with the OSD certification basis has been demonstrated.

However, the OSD needs to be approved before the data is used by a training organisation for the purpose of obtaining a European Union (EU) licence, rating or attestation, or by an EU operator. This is normally done before the entry into service of the first aircraft by an EU operator but it could also be done later for some of the OSD constituents, such as the definition of the scope of validation source data to support the objective qualification of a simulator, which should only be available when a simulator has to be qualified.

The derogation provided in points 21.A.97(c), 21.A.115(c), 21.B.103(b), 21.B.107(b), and 21.B.111(b) is applicable to all major changes to a TC, so it is also applicable to minor design changes when triggering a major master minimum equipment list (MMEL) change, as well as to changes in which at least one of the OSD constituent changes is major.

(SUBPART C — NOT APPLICABLE)

SUBPART D — CHANGES TO TYPE-CERTIFICATES AND RESTRICTED TYPE-CERTIFICATES

21.B.105 Type-certification basis, environmental protection requirements and operational suitability data certification basis for a major change to a type-certificate

Regulation (EU) 2019/897

The Agency shall establish the applicable type-certification basis, the environmental protection requirements, and in the case of a change affecting the operational suitability data, the operational suitability data certification basis established in accordance with point 21.A.101 and notify them to the applicant for a major change to a type certificate.

21.B.107 Issuance of an approval of a change to a type-certificate

Regulation (EU) 2019/897

(a) The Agency shall issue an approval of a change to a type-certificate provided that:

1. the applicant for an approval has complied with:

   (i) point 21.A.95 for a minor change; or

   (ii) point 21.A.97 for a major change;

2. the Agency, through its verification of the demonstration of compliance in accordance with the level of its involvement determined pursuant to point (a) or (b) of point 21.B.100 has not found any non-compliance with the type-certification basis, operational suitability data certification basis where applicable in accordance with point 21.B.82, and environmental protection requirements; and

3. no feature or characteristic has been identified that may make the product unsafe for the uses for which certification is requested.

(b) In the case of a change affecting the operational suitability data, by derogation from points (1) and (2) of point (a), at the applicant's request included in the declaration referred to in point 21.A.20(d), the Agency may approve a change to an aircraft type-certificate before compliance with the operational suitability data certification basis has been demonstrated, provided that the applicant demonstrates such compliance before the date at which those data are to be actually used.

(c) The approval of the changes to the operational suitability data shall be included in the approval of the change to the type-certificate.

(d) The approval of a change to a type-certificate shall be limited to the specific configuration(s) in the type-certificate to which the change relates.

GM 21.B.107 and 21.B.111 Operational suitability data (OSD) considerations for the approval of changes to type certificates (TCs) or supplemental type certificates (STCs)

ED Decision 2019/018/R

The requirement for EASA in points 21.B.107(c) or 21.B.111(c) are applicable to necessary changes to the OSD as foreseen by 21.A.95(b) Section 2 for minor changes, 21.A.97(b) Section 2 for major changes, and 21.A.115(b) Section 3 for STCs. By analogy, these requirements should also be considered by design organisation approval (DOA) holders that approve changes or issue supplemental type certificates (STCs) under their privileges (without EASA's involvement), as stated in the GM to A.21.A.90A.

Changes to TCs can comprise several interrelated changes to the TC. For example, a change to the cockpit design may trigger a necessary change to the flight crew data, which is part of the OSD, and is, therefore, included in the TC.

Interrelated changes (e.g. type design changes and necessary changes to the MMEL and/or flight crew data) should be approved together under a single approval.

GM 21.A.21(b), 21.A.95(c), 21.A.97(c), 21.A.115(c), 21.B.103(b), 21.B.107(b) and 21.B.111(b) Approval of operational suitability data (OSD)

ED Decision 2019/018/R

It is acknowledged that it may not always be possible to have the OSD available on the date of the issue of the (restricted) type certificate ((R)TC), change approval or supplemental type certificate (STC). The derogation provided by 21.A.21(b), 21.A.95(c), 21.A.97(c), 21.A.115(c), 21.B.103(b), 21.B.107(b) and 21.B.111(b) is intended for that case. The (R)TC, change approval or STC can be issued before compliance with the OSD certification basis has been demonstrated.

However, the OSD needs to be approved before the data is used by a training organisation for the purpose of obtaining a European Union (EU) licence, rating or attestation, or by an EU operator. This is normally done before the entry into service of the first aircraft by an EU operator but it could also be done later for some of the OSD constituents, such as the definition of the scope of validation source data to support the objective qualification of a simulator, which should only be available when a simulator has to be qualified.

The derogation provided in points 21.A.97(c), 21.A.115(c), 21.B.103(b), 21.B.107(b), and 21.B.111(b) is applicable to all major changes to a TC, so it is also applicable to minor design changes when triggering a major master minimum equipment list (MMEL) change, as well as to changes in which at least one of the OSD constituent changes is major.

SUBPART E — SUPPLEMENTAL TYPE-CERTIFICATES

21.B.109 Type-certification basis, environmental protection requirements and operational suitability data certification basis for a supplemental type-certificate

Regulation (EU) 2019/897

The Agency shall establish the applicable type-certification basis, the environmental protection requirements and, in the case of a change affecting the operational suitability data, the operational suitability data certification basis established in accordance with point 21.A.101 and notify them to the applicant for a supplemental type-certificate.

21.B.111 Issuance of a supplemental type-certificate

Regulation (EU) 2019/897

(a) The Agency shall issue a supplemental type-certificate, provided that:

1. the applicant has complied with point 21.A.115(b);
2. the Agency, through its verification of the demonstration of compliance in accordance with the level of involvement established pursuant to point 21.B.100(a), has not found any non-compliance with the type-certification basis, operational suitability data certification basis where applicable in accordance with point 21.B.82, and environmental protection requirements; and
3. no feature or characteristic has been identified that may make the product unsafe for the uses for which certification is requested.

(b) In the case of a supplemental type-certificate affecting the operational suitability data, by derogation from points (1) and (2) of point (a), at the applicant's request included in the declaration referred to in point 21.A.20(d), the Agency may issue a supplemental type-certificate before compliance with the operational suitability data certification basis has been demonstrated, provided that the applicant demonstrates such compliance before the date at which those data are to be actually used.

(c) The approval of the changes to the operational suitability data shall be included in the supplemental type-certificate.

(d) The supplemental type-certificate shall be limited to the specific configuration(s) in the type-certificate to which the related major change relates.

GM 21.B.107 and 21.B.111 Operational suitability data (OSD) considerations for the approval of changes to type certificates (TCs) or supplemental type certificates (STCs)

ED Decision 2019/018/R

The requirement for EASA in points 21.B.107(c) or 21.B.111(c) are applicable to necessary changes to the OSD as foreseen by 21.A.95(b) Section 2 for minor changes, 21.A.97(b) Section 2 for major changes, and 21.A.115(b) Section 3 for STCs. By analogy, these requirements should also be considered by design organisation approval (DOA) holders that approve changes or issue supplemental type certificates (STCs) under their privileges (without EASA's involvement), as stated in the GM to A.21.A.90A.

Changes to TCs can comprise several interrelated changes to the TC. For example, a change to the cockpit design may trigger a necessary change to the flight crew data, which is part of the OSD, and is, therefore, included in the TC.

Interrelated changes (e.g. type design changes and necessary changes to the MMEL and/or flight crew data) should be approved together under a single approval.

GM 21.A.21(b), 21.A.95(c), 21.A.97(c), 21.A.115(c), 21.B.103(b), 21.B.107(b) and 21.B.111(b) Approval of operational suitability data (OSD)

ED Decision 2019/018/R

It is acknowledged that it may not always be possible to have the OSD available on the date of the issue of the (restricted) type certificate ((R)TC), change approval or supplemental type certificate (STC). The derogation provided by 21.A.21(b), 21.A.95(c), 21.A.97(c), 21.A.115(c), 21.B.103(b), 21.B.107(b) and 21.B.111(b) is intended for that case. The (R)TC, change approval or STC can be issued before compliance with the OSD certification basis has been demonstrated.

However, the OSD needs to be approved before the data is used by a training organisation for the purpose of obtaining a European Union (EU) licence, rating or attestation, or by an EU operator. This is normally done before the entry into service of the first aircraft by an EU operator but it could also be done later for some of the OSD constituents, such as the definition of the scope of validation source data to support the objective qualification of a simulator, which should only be available when a simulator has to be qualified.

The derogation provided in points 21.A.97(c), 21.A.115(c), 21.B.103(b), 21.B.107(b), and 21.B.111(b) is applicable to all major changes to a TC, so it is also applicable to minor design changes when triggering a major master minimum equipment list (MMEL) change, as well as to changes in which at least one of the OSD constituent changes is major.

SUBPART F — PRODUCTION WITHOUT PRODUCTION ORGANISATION APPROVAL

21.B.115 Means of compliance

Regulation (EU) 2022/203

(a) The Agency shall develop acceptable means of compliance ('AMC') that may be used to establish compliance with Regulation (EU) 2018/1139 and its delegated and implementing acts.

(b) Alternative means of compliance may be used to establish compliance with this Regulation.

(c) Competent authorities shall inform the Agency of any alternative means of compliance used by organisations under their oversight or by themselves for establishing compliance with this Regulation.

[applicable from 7 March 2023 - Regulation (EU) 2022/203]

21.B.120 Investigation [applicable until 6 March 2023] / 21.B.120 Initial certification procedure [applicable from 7 March 2023 - Regulation (EU) 2022/203]

Regulation (EU) No 748/2012

(a) The competent authority shall appoint an investigation team for each applicant for, or holder of, a letter of agreement to conduct all relevant tasks related to this letter of agreement, consisting of a team-leader to manage and lead the investigation team and, if required, one or more team members. The team-leader shall report to the manager responsible for the activity, as defined in point 21.B.25(b)(2).

(b) The competent authority shall perform sufficient investigation activities for an applicant for, or holder of, a letter of agreement to justify recommendations for the issuance, maintenance, amendment, suspension or revocation of the letter of agreement.

(c) The competent authority shall prepare procedures for the investigation of applicants for, or holders of, a letter of agreement as part of the documented procedures covering at least the following elements:

1. evaluation of applications received;
2. determination of investigation team;
3. investigation preparation and planning;
4. evaluation of the documentation (manual, procedures, etc.);
5. auditing and inspection;
6. follow up of corrective actions; and
7. recommendation for issuance, amendment, suspension or revocation of the letter of agreement.

[applicable until 6 March 2023]

(a) Upon receiving an application for the issue of a letter of agreement for the purpose of demonstrating conformity of the individual products, parts and appliances, the competent authority shall verify the applicant's compliance with the applicable requirements.

(b) The competent authority shall record all the findings issued, closure actions as well as recommendations for the issue of the letter of agreement.

(c) The competent authority shall confirm to the applicant in writing all the findings raised during the verification. For initial certification, all findings must be corrected to the satisfaction of the competent authority before the letter of agreement can be issued.

(d) When satisfied that the applicant complies with the applicable requirements, the competent authority shall issue the letter of agreement (EASA Form 65, see Appendix XI).

(e) The letter of agreement shall contain the scope of the agreement, a termination date and, where applicable, the appropriate limitations.

(f) The duration of the letter of agreement shall not exceed 1 year.

[applicable from 7 March 2023 - Regulation (EU) 2022/203]

AMC 21.B.120(a) Investigation team – Qualification criteria for the investigation team members

ED Decision 2012/020/R

The competent authority must ensure that the team leader and team members have received appropriate training in the relevant Subpart of Part 21 and in the related competent authority documentation before performing investigations. They must also have knowledge and experience at the appropriate level in aviation production and inspection activities relative to the particular application for a letter of agreement.

AMC 21.B.120(c)(1) Evaluation of applications

ED Decision 2012/020/R

1. General

When applying Part 21 Section A Subpart F and Section B Subpart F the competent authority must consider that these Subparts are only an alternative way for production to Part 21 Section A Subpart G and Section B Subpart G. To meet the ICAO airworthiness obligations and to issue a Certificate of Airworthiness for an individual aircraft in a practical and efficient way, the competent authority must use a system of approval of production organisations (POA) under Part 21 Section A Subpart G and Section B Subpart G, providing to the competent authority the necessary confidence in technical standards. The consistent standards of these approvals will also support the standardisation efforts by the Agency. Nevertheless it is recognised that it is not always practical, economical and/or advisable to use the POA.

Considering ICAO airworthiness obligations as well, Part 21 Section A Subpart F and Section B Subpart F is provided for such a case on the basis of the following principles:

a) Subpart F must be considered as an alternative option for particular cases

b) Its adoption must be done on an individual basis, as consequence of an assessment by the competent authority (see 21.A.121, 21.A.133(a) and their associated CS and GM).

2. Application

The competent authority must receive an application for a letter of agreement on an EASA Form 60 (see below) completed by the applicant. The eligibility of the application should be verified in relation to the competent authority procedures, based on 21.A.121 and its associated CS and GM. The applicant should be advised accordingly about the acceptance or rejection of the application.

3. Location of the applicant

The location of the applicant seeking acceptance for production under Part 21 Section A Subpart F determines which competent authority is responsible for issuing the letter of agreement.

EASA Form 60 **Application for agreement of production under Part 21 Subpart F**	
Competent authority *of an EU Member State or* *EASA*	
1. Registered name and address of the applicant:	
2. Trade name (if different):	
3. Location(s) of manufacturing activities:	
4. Description of the manufacturing activities under application a) Identification (TC, P/N , … as appropriate): b) Termination (No. of units, Termination date, …):	
5. Evidence supporting the application, as per 21.A.124(b):	
6. Links/arrangements with design approval holder(s)/ design organisation(s) where different from Block 1. :	
7. Human resources:	
8. Name of the person signing the application:	
_____ Date	_____ Signature

EASA Form 60 Issue 3

Block 1: The name of the applicant must be entered. For legal entities the name must be as stated in the register of the National Companies Registration Office. In this case a copy of the entry in the register of the National Companies Registration Office must be provided to the competent authority.

Block 2: State the trade name by which the applicant is known to the public if different from the information given in Block 1. The use of a logo may be indicated in this Block.

Block 3: State all locations of manufacturing activities that are covered by the application. Only those locations must be stated that are directly under the control of the applicant stated in Block 1.

Block 4: This Block must include further details of the manufacturing activities under the approval for the addresses indicated in Block 3. The Block 'Identification' must indicate the products, parts or appliances intended to be produced, while the Block 'Termination' must address any information on the limitation of the activity, e.g., by stating the intended number of units to be manufactured or the expected date of completion of the manufacturing activities.

Block 5: This Block must state evidence supporting the determination of applicability as stated in 21.A.121. In addition an outline of the manual required by 21.A.125A(b) must be provided with the application.

Block 6: The information entered here is essential for the evaluation of eligibility of the application. Therefore special attention must be given concerning the completion of this Block either directly or by reference to supporting documentation in relation to the requirements of 21.A.122 and AMC No 1 to 21.A.122.

Block 7: The information to be entered here must reflect the number of staff, or in case of an initial approval the intended number of staff, for the manufacturing activities under this application and therefore must include also any associated administrative staff.

Block 8: State the name of the person authorised to sign the application.

GM1 21.A.139, 21.A.157, 21.A.239, 21.A.257, 21.B.120, 21.B.140, 21.B.220, 21.B.235 and 21.B.240 The use of information and communication technologies (ICT) for performing remote audits

ED Decision 2021/007/R

This GM provides technical guidance on the use of remote information and communication technologies (ICT) to support:

— competent authorities when overseeing regulated organisations;

— regulated organisations when conducting internal audits / monitoring compliance of their organisation with the relevant requirements, and when evaluating vendors, suppliers and subcontractors.

In the context of this GM:

— 'remote audit' means an audit that is performed with the use of any real-time video and audio communication tools in lieu of the physical presence of the auditor on-site; the specificities of each type of approval / letter of agreement (LoA) need to be considered in addition to the general overview (described below) when applying the 'remote audit' concept;

— 'auditing entity' means the competent authority or organisation that performs the remote audit;

— 'auditee' means the entity being audited/inspected (or the entity audited/inspected by the auditing entity via a remote audit);

It is the responsibility of the auditing entity to assess whether the use of remote ICT constitutes a suitable alternative to the physical presence of an auditor on-site in accordance with the applicable requirements.

The conduct of a remote audit

The auditing entity that decides to conduct a remote audit should describe the remote audit process in its documented procedures and should consider at least the following elements:

— The methodology for the use of remote ICT is sufficiently flexible and non-prescriptive in nature to optimise the conventional audit process.

— Adequate controls are defined and are in place to avoid abuses that could compromise the integrity of the audit process.

— Measures to ensure that the security and confidentiality are maintained throughout the audit activities (data protection and intellectual property of the organisation also need to be safeguarded).

Examples of the use of remote ICT during audits may include but are not limited to:

— meetings by means of teleconference facilities, including audio, video and data sharing;

— assessment of documents and records by means of remote access, in real time;

— recording, in real time during the process, of evidence to document the results of the audit, including non-conformities, by means of exchange of emails or documents, instant pictures, video or/and audio recordings;

— visual (livestream video) and audio access to facilities, stores, equipment, tools, processes, operations, etc.

An agreement between the auditing entity and the auditee should be established when planning a remote audit, which should include the following:

— determining the platform for hosting the audit;

— granting security and/or profile access to the auditor(s);

— testing platform compatibility between the auditing entity and the auditee prior to the audit;

— considering the use of webcams, cameras, drones, etc., when the physical evaluation of an event (product, part, process, etc.) is desired or is necessary;

— establishing an audit plan which will identify how remote ICT will be used and the extent of their use for the audit purposes to optimise their effectiveness and efficiency while maintaining the integrity of the audit process;

— if necessary, time zone acknowledgement and management to coordinate reasonable and mutually agreeable convening times;

— a documented statement of the auditee that they shall ensure full cooperation and provision of the actual and valid data as requested, including ensuring any supplier or subcontractor cooperation, if needed; and

— data protection aspects.

The following equipment and set-up elements should be considered:

— the suitability of video resolution, fidelity, and field of view for the verification being conducted;

— the need for multiple cameras, imaging systems, or microphones, and whether the person that performs the verification can switch between them, or direct them to be switched and has the possibility to stop the process, ask a question, move the equipment, etc.;

— the controllability of viewing direction, zoom, and lighting;

— the appropriateness of audio fidelity for the evaluation being conducted; and

— real-time and uninterrupted communication between the person(s) participating to the remote audit from both locations (on-site and remotely).

When using remote ICT, the auditing entity and the other persons involved (e.g. drone pilots, technical experts) should have the competence and ability to understand and utilise the remote ICT tools

employed to achieve the desired results of the audit(s)/assessment(s). The auditing entity should also be aware of the risks and opportunities of the remote ICT used and the impacts they may have on the validity and objectivity of the information gathered.

Audit reports and related records should indicate the extent to which remote ICT have been used in conducting remote audits and the effectiveness of remote ICT in achieving the audit objectives, including any item that it has not been able to be completely reviewed.

GM 21.B.120(c)(3) Investigation preparation and planning

ED Decision 2012/020/R

Following acceptance of an application and before commencing an investigation the competent authority should:

— identify the site locations needing investigation

— liaise with the competent authority of another Member State where there is seen to be a need to visit a production facility in that State for one of the following reasons:

a) where a manufacturer has contracted part of the production to another organisation holding a production organisation approval and a need arises to ensure the contract has the same meaning for all parties to the contract, and the local competent authority of the Member State agrees

b) to inspect a product (or part or appliance) under production where the sub-contractor is not holding a POA

— co-ordinate with the competent authority of a third country and/or the Agency where there is seen to be a need to visit a production facility in that country for one of the following reasons:

a) where a manufacturer has contracted part of the production to another organisation holding a production organisation approval issued by the Agency or accepted through an recognition agreement in accordance with Article 12 of the Basic Regulation and a need arises to ensure the contract has the same meaning for all parties to the contract, and the Agency and/or the competent authority agrees

b) to inspect a product (or part or appliance) under production where the sub-contractor is not holding a POA.

GM 21.B.120(c)(5) and (6) Auditing and investigation findings

ED Decision 2012/020/R

During its investigation process, the competent authority may make findings which should then be recorded. These may be non-conformities to the requirements, the manual as supplied by the manufacturer describing its inspection procedures or non-conformities related to the items under inspection. The manner in which the findings will be handled by the competent authority before and during the validity of the letter of agreement, should be detailed in its procedures.

21.B.125 Findings [applicable until 6 March 2023] / 21.B.125 Findings and corrective actions; observations [applicable from 7 March 2023 - Regulation (EU) 2022/203]

Regulation (EU) No 748/2012

(a) When during audits or by other means objective evidence is found by the competent authority, showing non-compliance of the holder of a letter of agreement with the applicable requirements of Section A of this Annex, this finding shall be classified in accordance with point 21.A.125B(a).

(b) The competent authority shall take the following actions:

1. for level 1 findings, immediate action shall be taken by the competent authority to limit, suspend or revoke the letter of agreement in whole or in part, depending upon the extent of the finding, until successful corrective action has been completed by the organisation;

2. for level 2 findings, the competent authority shall grant a corrective action period appropriate to the nature of the finding that shall not be more than 3 months. In certain circumstances, at the end of this period and subject to the nature of the finding, the competent authority can extend the 3 months period subject to a satisfactory corrective action plan provided by the organisation.

(c) Action shall be taken by the competent authority to suspend the letter of agreement in whole or in part in case of failure to comply within the timescale granted by the competent authority.

[applicable until 6 March 2023]

(a) The competent authority shall have a system in place to analyse findings for their safety significance.

(b) A level 1 finding shall be issued by the competent authority when any significant non-compliance is detected with the applicable requirements of Regulation (EU) 2018/1139 and its delegated and implementing acts, with the organisation's procedures and manuals, or with the terms of the letter of agreement which lowers safety or seriously endangers flight safety.

Level 1 findings shall also include:

1. any failure to grant the competent authority access to the organisation's facilities referred to in point 21.A.9 during normal operating hours and after two written requests;

2. obtaining the letter of agreement or maintaining its validity by falsification of the submitted documentary evidence; and

3. any evidence of malpractice or fraudulent use of the letter of agreement.

(c) A level 2 finding shall be issued by the competent authority when any non-compliance is detected with the applicable requirements of Regulation (EU) 2018/1139 and its delegated and implementing acts, with the organisation's procedures and manuals, or with the terms of the letter of agreement, which is not classified as a level 1 finding.

(d) When a finding is detected during oversight or by any other means, the competent authority shall, without prejudice to any additional action required by Regulation (EU) 2018/1139 and its delegated and implementing acts, communicate in writing the finding to the organisation and request corrective action to address the non-compliance(s) identified. Where a level 1 finding directly relates to an aircraft, the competent authority shall inform the competent authority of the Member State in which the aircraft is registered.

1. If there are any level 1 findings, the competent authority shall take immediate and appropriate action to prohibit or limit the activities of the organisation involved and, if appropriate, it shall take action to revoke the letter of agreement or to limit or suspend it in whole or in part, depending on the extent of the level 1 finding, until successful corrective action has been taken by the organisation.

2. If there are any level 2 findings, the competent authority shall:

(i) grant the organisation a corrective action implementation period that is appropriate to the nature of the finding, and that in any case shall initially not be more than 3 months. The period shall commence from the date of the written communication of the finding to the organisation, requesting corrective action to address the non-compliance identified. At the end of that period, and subject to the nature of the finding, the competent authority may extend the 3-month period provided that a corrective action plan has been agreed with the competent authority;

(ii) assess the corrective action plan and implementation plan proposed by the organisation, and if the assessment concludes that they are sufficient to address the non-compliance, accept them;

(iii) if the organisation fails to submit an acceptable corrective action plan, or fails to perform the corrective action within the time period accepted or extended by the competent authority, the finding shall be raised to level 1 and action shall be taken as laid down in point (f)(1)(i).

(e) The competent authority may issue observations for any of the following cases not requiring level 1 or level 2 findings:

1. for any item whose performance has been assessed to be ineffective;

2. when it has been identified that an item has the potential to cause a non-compliance under points (b) or (c);

3. when suggestions or improvements are of interest for the overall safety performance of the organisation.

The observations issued under this point shall be communicated in writing to the organisation and recorded by the competent authority.

[applicable from 7 March 2023 - Regulation (EU) 2022/203]

GM 21.B.125(a) Objective evidence

ED Decision 2012/020/R

Objective evidence is a fact which is, or can be documented, based on observations, measurements or tests that can be verified. Objective evidence generally comes from the following:

a) documents or manuals

b) examination of equipment/products

c) information from interview questions and observations of production activities

21.B.130 Issue of letter of agreement

Regulation (EU) No 748/2012

(a) When satisfied that the manufacturer is in compliance with the applicable requirements of Section A, Subpart F, the competent authority shall issue a letter of agreement to the showing of conformity of individual products, parts or appliances (EASA Form 65, see Appendix XI) without undue delay.

(b) The letter of agreement shall contain the scope of the agreement, a termination date and, where applicable, the appropriate limitations relating to the authorisation.

(c) The duration of the letter of agreement shall not exceed one year.

[applicable until 6 March 2023 – Regulation (EU) 2022/203]

AMC 21.B.130 Issue of the letter of agreement

ED Decision 2012/020/R

Unless otherwise agreed by the competent authority no production before the issue of the letter of agreement may be accepted under Part 21 Section A Subpart F.

GM 21.B.130(b) Issue of the letter of agreement

ED Decision 2012/020/R

The agreement should include or reference a pre-defined plan of inspection points established as part of the production inspection system and agreed with the competent authority to be used as a basis for the inspections described in 21.A.129 and 21.B.120(c)(5) and its associated CS and GM. The plan should clearly identify inspection point, places, inspection subjects (materials, process, tooling documentation, human resources, etc.), as well as the focal points and the method of communication between the manufacturer and the competent authority.

The competent authority should detail a method how it will assure itself that the manufacturer is working in accordance with the manual and the agreed inspection procedures during the validity period of the agreement. For renewal of this validity period the procedure as defined in 21.B.140 should be used.

Any conditions under which the agreement will expire (such as termination date and/or number of units to produce), should be clearly stated in the letter of agreement.

21.B.135 Maintenance of the letter of agreement

Regulation (EU) No 748/2012

The competent authority shall maintain the letter of agreement as long as:

(a) the manufacturer is properly using the EASA Form 52 (see Appendix VIII) as a statement of conformity for complete aircraft, and the EASA Form 1 (see Appendix I) for products other than complete aircraft, parts and appliances; and

(b) inspections performed by the competent authority of the Member State before validation of the EASA Form 52 (see Appendix VIII) or the EASA Form 1 (see Appendix I), as per point 21.A.130(c) did not reveal any findings of non-compliance with the requirements or the procedures as contained in the manual provided by the manufacturer, or any non-conformity of the respective products, parts or appliances. These inspections shall check at least that:

1. the agreement covers the product, part or appliance being validated, and remains valid;

2. the manual described in point 21.A.125A(b) and its change status referred in the letter of agreement is used as basic working document by the manufacturer. Otherwise, the inspection shall not continue and therefore the release certificates shall not be validated;

3. production has been carried out under the conditions prescribed in the letter of agreement and satisfactorily performed;

4. inspections and tests (including flight tests, if appropriate), as per points 21.A.130(b)(2) and/or (b)(3), have been carried out under the condition prescribed in the letter of agreement and satisfactorily performed;

5. the inspections by the competent authority described or addressed in the letter of agreement have been performed and found acceptable;

6. the statement of conformity complies with point 21.A.130, and the information provided by it does not prevent its validation; and

(c) any termination date for the letter of agreement has not been reached.

21.B.140 Amendment of a letter of agreement

Regulation (EU) No 748/2012

(a) The competent authority shall investigate, as appropriate, in accordance with point 21.B.120 any amendment of the letter of agreement.

(b) When the competent authority is satisfied that the requirements of Section A, Subpart F continue to be complied with, it shall amend the letter of agreement accordingly.

AMC 21.B.140 Amendment of a letter of agreement

ED Decision 2012/020/R

The competent authority must be satisfied that any change affecting a letter of agreement comply with the shows of Section A Subpart F before implementation can start. A plan for the change should be agreed with the applicant in accordance with AMC 21.B.130. If the change affects the content of the letter of agreement, a new application should be filed and an amended/revised letter of agreement should be obtained subsequently.

GM1 21.A.139, 21.A.157, 21.A.239, 21.A.257, 21.B.120, 21.B.140, 21.B.220, 21.B.235 and 21.B.240 The use of information and communication technologies (ICT) for performing remote audits

ED Decision 2021/007/R

This GM provides technical guidance on the use of remote information and communication technologies (ICT) to support:

— competent authorities when overseeing regulated organisations;

— regulated organisations when conducting internal audits / monitoring compliance of their organisation with the relevant requirements, and when evaluating vendors, suppliers and subcontractors.

In the context of this GM:

— ‘remote audit’ means an audit that is performed with the use of any real-time video and audio communication tools in lieu of the physical presence of the auditor on-site; the specificities of

each type of approval / letter of agreement (LoA) need to be considered in addition to the general overview (described below) when applying the 'remote audit' concept;

— 'auditing entity' means the competent authority or organisation that performs the remote audit;

— 'auditee' means the entity being audited/inspected (or the entity audited/inspected by the auditing entity via a remote audit);

It is the responsibility of the auditing entity to assess whether the use of remote ICT constitutes a suitable alternative to the physical presence of an auditor on-site in accordance with the applicable requirements.

The conduct of a remote audit

The auditing entity that decides to conduct a remote audit should describe the remote audit process in its documented procedures and should consider at least the following elements:

— The methodology for the use of remote ICT is sufficiently flexible and non-prescriptive in nature to optimise the conventional audit process.

— Adequate controls are defined and are in place to avoid abuses that could compromise the integrity of the audit process.

— Measures to ensure that the security and confidentiality are maintained throughout the audit activities (data protection and intellectual property of the organisation also need to be safeguarded).

Examples of the use of remote ICT during audits may include but are not limited to:

— meetings by means of teleconference facilities, including audio, video and data sharing;

— assessment of documents and records by means of remote access, in real time;

— recording, in real time during the process, of evidence to document the results of the audit, including non-conformities, by means of exchange of emails or documents, instant pictures, video or/and audio recordings;

— visual (livestream video) and audio access to facilities, stores, equipment, tools, processes, operations, etc.

An agreement between the auditing entity and the auditee should be established when planning a remote audit, which should include the following:

— determining the platform for hosting the audit;

— granting security and/or profile access to the auditor(s);

— testing platform compatibility between the auditing entity and the auditee prior to the audit;

— considering the use of webcams, cameras, drones, etc., when the physical evaluation of an event (product, part, process, etc.) is desired or is necessary;

— establishing an audit plan which will identify how remote ICT will be used and the extent of their use for the audit purposes to optimise their effectiveness and efficiency while maintaining the integrity of the audit process;

— if necessary, time zone acknowledgement and management to coordinate reasonable and mutually agreeable convening times;

— a documented statement of the auditee that they shall ensure full cooperation and provision of the actual and valid data as requested, including ensuring any supplier or subcontractor cooperation, if needed; and

— data protection aspects.

The following equipment and set-up elements should be considered:

— the suitability of video resolution, fidelity, and field of view for the verification being conducted;

— the need for multiple cameras, imaging systems, or microphones, and whether the person that performs the verification can switch between them, or direct them to be switched and has the possibility to stop the process, ask a question, move the equipment, etc.;

— the controllability of viewing direction, zoom, and lighting;

— the appropriateness of audio fidelity for the evaluation being conducted; and

— real-time and uninterrupted communication between the person(s) participating to the remote audit from both locations (on-site and remotely).

When using remote ICT, the auditing entity and the other persons involved (e.g. drone pilots, technical experts) should have the competence and ability to understand and utilise the remote ICT tools employed to achieve the desired results of the audit(s)/assessment(s). The auditing entity should also be aware of the risks and opportunities of the remote ICT used and the impacts they may have on the validity and objectivity of the information gathered.

Audit reports and related records should indicate the extent to which remote ICT have been used in conducting remote audits and the effectiveness of remote ICT in achieving the audit objectives, including any item that it has not been able to be completely reviewed.

21.B.145 Limitation, suspension and revocation of a letter of agreement

Regulation (EU) No 748/2012

(a) The limitation, suspension or revocation of the letter of agreement shall be communicated in writing to the holder of the letter of agreement. The competent authority shall state the reasons for the limitation, suspension or revocation and inform the holder of the letter of agreement on its right to appeal.

(b) When a letter of agreement has been suspended it shall only be reinstated after compliance with Section A Subpart F has been re-established.

[applicable until 6 March 2023 – Regulation (EU) 2022/203]

21.B.150 Record-keeping

Regulation (EU) No 748/2012

(a) The competent authority shall establish a system of record-keeping that allows adequate traceability of the process to issue, maintain, amend, suspend or revoke each individual letter of agreement.

(b) The records shall at least contain:

1. the documents provided by the applicant for, or holder of, a letter of agreement;
2. documents established during investigation and inspection, in which the activities and the final results of the elements defined in point 21.B.120 are stated;
3. the letter of agreement, including changes; and
4. minutes of the meetings with the manufacturer.

(c) The records shall be archived for a minimum retention period of six years after termination of the letter of agreement.

(d) The competent authority shall also maintain records of all Statements of Conformity (EASA Form 52, see Appendix VIII) and Authorised Release Certificates (EASA Form 1, see Appendix I) that it has validated.

[applicable until 6 March 2023 – Regulation (EU) 2022/201 and Regulation (EU) 2022/203]

GM 21.B.150(d) Record keeping – Traceability of release certificates

ED Decision 2012/020/R

The recordkeeping for those EASA Forms 52 and 1 that have been validated by the competent authority should allow verification of such validation by concerned parties including the recipients of the release certificates.

SUBPART G — PRODUCTION ORGANISATION APPROVAL

21.B.215 Means of compliance

Regulation (EU) 2022/203

(a) The Agency shall develop acceptable means of compliance ('AMC') that may be used to establish compliance with Regulation (EU) 2018/1139 and its delegated and implementing acts.

(b) Alternative means of compliance may be used to establish compliance with this Regulation.

(c) Competent authorities shall inform the Agency of any alternative means of compliance used by organisations under their oversight or by themselves for establishing compliance with this Regulation.

[applicable from 7 March 2023 - Regulation (EU) 2022/203]

21.B.220 Investigation [applicable until 6 March 2023] / 21.B.220 Initial certification procedure [applicable from 7 March 2023 - Regulation (EU) 2022/203]

Regulation (EU) No 748/2012

(a) The competent authority shall appoint a production organisation approval team for each applicant, or holder of, a production organisation approval to conduct all relevant tasks related to this production organisation approval, consisting of a team leader to manage and lead the approval team and, if required, one or more team members. The team leader shall report to the manager responsible for the activity as defined in point 21.B.25(b)(2).

(b) The competent authority shall perform sufficient investigation activities for an applicant for, or holder of, a production organisation approval to justify recommendations for the issuance, maintenance, amendment, suspension or revocation of the approval.

(c) The competent authority shall prepare procedures for the investigation of a production organisation approval as part of the documented procedures covering at least the following elements:

1. evaluation of applications received;
2. determination of production organisation approval team;
3. investigation preparation and planning;
4. evaluation of the documentation (production organisation exposition, procedures, etc.);
5. auditing;
6. follow up of corrective actions;
7. recommendation for issuance, amendment, suspension or revocation of production organisation approval;
8. continued surveillance.

[applicable until 6 March 2023]

(a) Upon receiving an application for the initial issue of a production organisation approval certificate, the competent authority shall verify the applicant's compliance with the applicable requirements.

(b) A meeting with the accountable manager of the applicant shall be convened at least once during the investigation for initial certification to ensure that this person understands his or her role and accountability.

(c) The competent authority shall record all the findings issued, closure actions as well as the recommendations for the issue of the production organisation approval certificate.

(d) The competent authority shall confirm to the applicant in writing all the findings raised during the verification. For initial certification, all findings must be corrected to the satisfaction of the competent authority before the certificate can be issued.

(e) When satisfied that the applicant complies with the applicable requirements, the competent authority shall issue the production organisation approval certificate (EASA Form 55, see Appendix X).

(f) The certificate reference number shall be included on the EASA Form 55 in a manner specified by the Agency.

(g) The certificate shall be issued for an unlimited duration. The privileges and the scope of the activities that the organisation is approved to conduct, including any limitations as applicable, shall be specified in the terms of approval attached to the certificate.

[applicable from 7 March 2023 - Regulation (EU) 2022/203]

GM1 21.A.139, 21.A.157, 21.A.239, 21.A.257, 21.B.120, 21.B.140, 21.B.220, 21.B.235 and 21.B.240 The use of information and communication technologies (ICT) for performing remote audits

ED Decision 2021/007/R

This GM provides technical guidance on the use of remote information and communication technologies (ICT) to support:

— competent authorities when overseeing regulated organisations;

— regulated organisations when conducting internal audits / monitoring compliance of their organisation with the relevant requirements, and when evaluating vendors, suppliers and subcontractors.

In the context of this GM:

— 'remote audit' means an audit that is performed with the use of any real-time video and audio communication tools in lieu of the physical presence of the auditor on-site; the specificities of each type of approval / letter of agreement (LoA) need to be considered in addition to the general overview (described below) when applying the 'remote audit' concept;

— 'auditing entity' means the competent authority or organisation that performs the remote audit;

— 'auditee' means the entity being audited/inspected (or the entity audited/inspected by the auditing entity via a remote audit);

It is the responsibility of the auditing entity to assess whether the use of remote ICT constitutes a suitable alternative to the physical presence of an auditor on-site in accordance with the applicable requirements.

The conduct of a remote audit

The auditing entity that decides to conduct a remote audit should describe the remote audit process in its documented procedures and should consider at least the following elements:

— The methodology for the use of remote ICT is sufficiently flexible and non-prescriptive in nature to optimise the conventional audit process.

— Adequate controls are defined and are in place to avoid abuses that could compromise the integrity of the audit process.

— Measures to ensure that the security and confidentiality are maintained throughout the audit activities (data protection and intellectual property of the organisation also need to be safeguarded).

Examples of the use of remote ICT during audits may include but are not limited to:

— meetings by means of teleconference facilities, including audio, video and data sharing;

— assessment of documents and records by means of remote access, in real time;

— recording, in real time during the process, of evidence to document the results of the audit, including non-conformities, by means of exchange of emails or documents, instant pictures, video or/and audio recordings;

— visual (livestream video) and audio access to facilities, stores, equipment, tools, processes, operations, etc.

An agreement between the auditing entity and the auditee should be established when planning a remote audit, which should include the following:

— determining the platform for hosting the audit;

— granting security and/or profile access to the auditor(s);

— testing platform compatibility between the auditing entity and the auditee prior to the audit;

— considering the use of webcams, cameras, drones, etc., when the physical evaluation of an event (product, part, process, etc.) is desired or is necessary;

— establishing an audit plan which will identify how remote ICT will be used and the extent of their use for the audit purposes to optimise their effectiveness and efficiency while maintaining the integrity of the audit process;

— if necessary, time zone acknowledgement and management to coordinate reasonable and mutually agreeable convening times;

— a documented statement of the auditee that they shall ensure full cooperation and provision of the actual and valid data as requested, including ensuring any supplier or subcontractor cooperation, if needed; and

— data protection aspects.

The following equipment and set-up elements should be considered:

— the suitability of video resolution, fidelity, and field of view for the verification being conducted;

— the need for multiple cameras, imaging systems, or microphones, and whether the person that performs the verification can switch between them, or direct them to be switched and has the possibility to stop the process, ask a question, move the equipment, etc.;

— the controllability of viewing direction, zoom, and lighting;

— the appropriateness of audio fidelity for the evaluation being conducted; and

— real-time and uninterrupted communication between the person(s) participating to the remote audit from both locations (on-site and remotely).

When using remote ICT, the auditing entity and the other persons involved (e.g. drone pilots, technical experts) should have the competence and ability to understand and utilise the remote ICT tools employed to achieve the desired results of the audit(s)/assessment(s). The auditing entity should also be aware of the risks and opportunities of the remote ICT used and the impacts they may have on the validity and objectivity of the information gathered.

Audit reports and related records should indicate the extent to which remote ICT have been used in conducting remote audits and the effectiveness of remote ICT in achieving the audit objectives, including any item that it has not been able to be completely reviewed.

GM-ELA No 1 to 21.B.220 Investigation

ED Decision 2019/003/R

The AMC indicated with 'AMC-ELA' and the GM related to them (as indicated with 'GM-ELA'), provide an alternative set of AMC and GM to the other available AMC and GM.

The AMC-ELA provide acceptable means to meet the requirements for small, non-complex organisations that produce aircraft as specified in AMC ELA No 1 to 21.A.131.

GM-ELA No 1 to 21.B.220(a) Investigation team

ED Decision 2019/003/R

1. Type of team

When appointing a production organisation approval team (POAT), it is important for the member(s) of that team to have a very good understanding of the organisational processes, as well as of the nature and the established manufacturing practices for products that are within the scope of work of the applicant.

The AMC-ELA of Section A of Subpart G for production organisations substantially relies on product conformity and uses, if possible, existing quality management systems. The team should, therefore, be familiar with:

(a) conducting product conformity audits;

(b) alternative quality management systems that are typically applied by companies that produce light aeroplanes, such as ISO 9001, EN 9100, ASTM F2972, or similar standards;

(c) the typical practices used for the production of light aeroplanes and the related products and parts.

If the team is not able to cover all the aspects of the product that are considered to be within the scope of work of the applicant, the production organisation approval team leader (POATL) should coordinate with both the competent authority and the production organisation on identifying suitable subject-matter expert(s) who may provide support during the investigation. The overall size of the team should be adequate for the size of the company to be investigated.

GM 21.B.220(a) Investigation team

ED Decision 2012/020/R

1. Type of Team

Where the applicant is located in a Member State, the competent authority should appoint a production organisation approval team (POAT) leader and members appropriate to the nature and scope of the applicant's organisation.

Where the facilities of the applicant are located in more than one Member State, the competent authority of the country of manufacture should liaise with the other involved competent authorities to agree and appoint a POAT leader and members appropriate to the nature and scope of the applicant's organisation.

2. Team leader selection

The team leader should satisfy all of the criteria for a team member and will be selected by considering the following additional criteria:

a) the capability to lead and manage a team

b) the capability to prepare reports and be diplomatic

c) experience in approval team investigations (not necessarily only Part 21 Section A Subpart G)

d) a knowledge of production and quality systems for aircraft and related products and parts

3. Team member selection

The team leader should agree with the competent authority on the size of the POA team and the specialisations to be covered taking into account the scope of work and the characteristics of the applicant. Team members should be selected by considering the following criteria:

— training, which is mandatory, for Part 21 Section A, Subpart G and Section B, Subpart G

— education and experience, to cover appropriate aviation knowledge, audit practices and approval procedures

— the ability to verify that an applicant's organisation conforms to its own POA procedures, and that its key personnel are competent.

AMC-ELA No 1 to 21.B.220(b) Extent of the investigation

ED Decision 2019/003/R

The initial and the continued investigations of a company should primarily be conducted by investigating the conformity of products on which work is in progress, or following their completion, and by direct product assessment, or the assessment of product-related production records.

When conducting investigations on companies that apply either a production organisation exposition (POE) and/or a company manual that is based on a template[1] provided in accordance with the GM-ELA to Subpart G of Section A, the competent authority should verify whether the documentation has been adequately adapted to the specific details of the company.

Note [1]: A POE template, published by EASA, is provided as additional informative material. This material should not be considered as an AMC.

In order to avoid any duplication of oversight, the competent authority may use systems that implement ISO 9001 or AS/EN 9100 (including audit records) as evidence for compliance investigations.

When the company is capable of manufacturing products that are within the scope of work in a repeatable way, so that they conform to the type design, the competent authority should consider this to be sufficient evidence for the issuance, maintenance or amendment of the approval.

If non-conformities are encountered that reveal a lack of consistent production control, further investigations should be conducted by the company to establish the root cause and the appropriate corrective actions.

AMC 21.B.220(c) Procedures for investigation – Evaluation of applications

ED Decision 2012/020/R

The competent authority must receive an application for POA on an EASA Form 50 (see below) completed by the applicant. The eligibility and appropriateness of the application must be evaluated in accordance with 21.A.133 at that time and the applicant must be advised about acceptance or rejection of its application in writing accordingly.

EASA Form 50 **Application for Part 21 production organisation approval**	
Competent authority *of an EU Member State or* *EASA*	
1. Registered name and address of the organisation:	
2. Trade name (if different):	
3. Locations for which the approval is applied for:	
4. Brief summary of proposed activities at the item 3 addresses a) General: b) Scope of approval: c) Nature of privileges:	
5. Description of organisation:	
6. Links/arrangements with design approval holder(s)/design organisation(s) where different from 1.:	
7. Approximate number of staff engaged or intended to be engaged in the activities:	
8. Position and name of the accountable manager:	

_____ Date	_____ Signature of the accountable manager

EASA Form 50

Block 1: The name of the organisation must be entered as stated in the register of the National Companies Registration Office. For the initial application a copy of the entry in the register of the National Companies Registration Office must be provided to the competent authority.

Block 2: State the trade name by which the organisation is known to the public if different from the information given in Block 1. The use of a logo may be indicated in this Block.

Block 3: State all locations for which the approval is applied for. Only those locations must be stated that are directly under the control of the legal entity stated in Block 1.

Block 4: This Block must include further details of the activities under the approval for the addresses indicated in Block 4. The Block 'General' must include overall information, while the Block 'Scope of approval' must address the scope of work and products/categories following the principles laid down in the GM 21.A.151. The Block 'nature of privileges' must indicate the requested privileges as defined in 21.A.163(b)-(e). For an application for renewal state 'not applicable'.

Block 5: This Block must state a summary of the organisation with reference to the outline of the production organisation exposition, including the organisational structure, functions and responsibilities. The nomination of the responsible managers in accordance with 21.A.145(c)(2) must be included as far as possible, accompanied by the corresponding EASA Forms 4.

For an application for renewal state 'not applicable'.

Block 6: The information entered here is essential for the evaluation of eligibility of the application. Therefore special attention must be given concerning the completion of this Block either directly or by reference to supporting documentation in relation to the requirements of 21.A.133(b) and (c) and the AMC to 21.A.133(b) and (c).

Block 7: The information to be entered here must reflect the number of staff, or in case of an initial approval the intended number of staff, for the complete activities to be covered by the approval and therefore must include also any associated administrative staff.

Block 8: State the position and name of the accountable manager.

AMC-ELA No 1 to 21.B.220(c) Procedures for investigation – Evaluation of applications

ED Decision 2019/003/R

EASA Form 50 from AMC 21.B.220(c) applies, with the following instructions for its completion:

Block 1: The name of the organisation must be entered as stated in the register of the National Companies Registration Office. For the initial application, a copy of the entry in the register of the National Companies Registration Office must be provided to the competent authority.

Block 2: state the trade name by which the organisation is known to the public if different from the information given in Block 1. The use of a logo may be indicated in this Block.

Block 3: State the major place of activity as per definition in GM-ELA No 2 to 21.A.131 and where the products are completed and checked out, and for which the approval is applied for.

Block 4: This Block must include further details of the activities under the approval for the addresses indicated in Block 4. 'General' shall include the relevant part of the Scope definition provided by AMC-ELA No 1 to 21.A.131. 'Scope of approval' shall name the applicable scope (refer to GM-ELA No 1 to 21.B.230). A reference to the product type(s) may be provided for further clarification, even when this information will not be part of the terms of approval of the approved production organisation. 'Nature of privileges' shall list what is applicable of '21.A.163(a), (b), (c), (d), (e)'.

Block 5: If existing at the time of application, make reference to the draft version of the POE as per AMC-ELA No 1 to 21.A.143. Otherwise state: 'Will be provided when the POE draft is available.' For an application for renewal, state: 'Not applicable.'

Block 6: Depending on the case, either of 'Production and holder of the type certificate/design approval operate within one consolidated entity and under one management'; or 'Satisfactory coordination between production and type certificate/design approval holder is ensured by implementation of adequate responsibilities for the coordination in both directions.'

Block 7: The information to be entered here must reflect the approximate number of staff, or in case of an initial approval, the intended number of staff, for the complete activities to be covered by the approval and therefore must include also any associated administrative staff.

Block 8: State the position and name of the accountable manager.

AMC-ELA No 2 to 21.B.220(c) Procedures for investigation – General

ED Decision 2019/003/R

1. General

The competent authority needs to investigate the applicant's production organisation for its ability to produce products within the scope of work and that conform to the type in a repeatable way, so that they conform to the type design. It should establish procedures that include the following aspects:

2. Preparation and planning for an investigation

2.1. The POA team leader (POATL) should initiate the investigation of a new applicant by arranging a meeting with the applicant, in which the applicant should provide a general presentation of its organisation and products, parts or appliances, and in which the POATL should describe the investigation process to the applicant.

2.2. The POA team (POAT) should study the information gathered in the initiation phase, including information from other teams of the competent authority of the Member State or EASA on the functioning of the applicant's organisation, especially when the production organisation and the design organisation form one consolidated team.

2.3. The POAT should establish an investigation plan that:

— takes account of the location of the POA applicant's facilities;

— defines the subject matter that will be covered by the team members;

— identifies any areas of expertise that the team may be lacking in, and how to seek external advice;

— includes a comprehensive plan for auditing a representative set of products while work is in progress or following its completion, and by direct product assessment, or assessment of product-related production records; and

— includes liaison with the applicant in order to plan mutually suitable dates and times for visits, to determine the necessary size of the investigation team on both sides, and to agree on the investigation plan and the approximate timescales.

3. Investigation

3.1. Evaluation of the documentation (production organisation exposition (POE), procedures, etc.)

The POAT should:

— assess the POE for compliance with point 21.A.143, e.g. by using AMC-ELA No 1 to 21.A.143;

— evaluate (as applicable) the use of ISO 9001 or AS/EN 9100 in accordance with AMC-ELA No 1 to 21.B.220(b).

3.2. Auditing

The POAT should:

— audit the product and its associated documentation for conformity with the provisions of the relevant type design. If discrepancies are found on the audited product, the POATL should assess whether the definitions of the quality system have been adhered to, and whether those definitions may have been misleading and may have contributed to the discrepancies, which may indicate a need for a modification;

— review the acceptance of the key nominated personnel, confirmed by the completed EASA Form 4 (refer to AMC-ELA No 1 to 21.A.145(c)), on the basis of a review of the skills of each nominee, used as the basis for the nomination;

— conduct sample audits at appropriate stages of production to verify that:

(i) the products, parts, appliances and material produced by the organisation are in conformity with the applicable design data;

(ii) the level of product conformity achieved indicates that the facilities, working conditions, equipment and tools are appropriate to allow the work to be performed in a repeatable way;

(iii) the achieved production rate and the number of product non-conformities indicate that the number of personnel and their competences are sufficient to allow the work to be performed in a repeatable way; and

(iv) the identified responsibilities and examples show that there is satisfactory and effective coordination between the production entity and the design entity.

The investigation team should be accompanied during the sample audits by company representatives who are knowledgeable about the applicant's organisation and procedures. This will ensure that the organisation is aware of the progress of the audit and of any problems as they arise. This will also make it easier for the investigation team to gain access to the information of the company;

— coordinate with the subject-matter experts who provide external advice for any areas of expertise that the team may be lacking in, and enable an efficient investigation to take place, which will provide consistent and effective investigations and reporting;

— meet the accountable manager at least once during the investigation process, and preferably twice. The accountable manager should be briefed on the investigation process and on the results of the investigation.

3.3. Follow-up of corrective actions

In order to draft the audit report, the POAT should hold a meeting with the applicant to review any findings and observations.

The POAT, upon completion of the investigation, should hold a meeting with the applicant to verbally present the report.

The POAT should present the findings, the corrective action plan, and the preliminary arrangements for any follow-up that may be necessary.

The POATL should transmit the final report, together with the minutes of the final meeting with the applicant, to the competent authority of the applicant. The report should include any recommendations for improvements and any significant findings, together with appropriate conclusions and a corrective action plan. In particular, it should indicate whether the POE is acceptable, or changes are required.

If the findings made during the investigation mean that a recommendation for approval will not or cannot be issued, then the related findings should be provided to the applicant in writing within 2 weeks' time from the date of the visit.

3.4. Recommendation for the issuance, amendment, suspension or revocation of a production organisation approval

The POATL should track the feedback obtained from the applicant, taking into consideration the timelines specified in point 21.A.158(c). The POATL should consider the means provided by AMC No 1 to 21.B.230. The recommendation should be documented using EASA Form 56, Part 5.

3.5. Continued surveillance

Subsequent to an initial approval, the POATL should coordinate with the applicant on a mutually agreed surveillance plan that is appropriate for the size, product range and production rate of the company, taking into consideration the means provided by AMC-ELA No 1 to 21.B.235.

GM No 1 to 21.B.220(c) Procedures for investigation – Investigation preparation and planning

ED Decision 2012/020/R

Following the acceptance of the application and before commencing an investigation, the competent authority should, for the preparation and planning of the investigation:

— identify the site locations needing investigation taking into account the scope of any other POA issued by a Member State, which are valid in the circumstances

— liaise with the Agency for the appointment of any necessary observer(s) for standardisation purposes

— establish any necessary liaison arrangement with other competent authorities

— agree the size and composition of the POAT and any specialist tasks likely to be covered and to select suitable team members from all involved competent authorities

— seek any necessary advice and guidance from the Agency

— liaise with the competent authority of the other Member State where there is seen to be a need to visit a production approval holder facility in that Member State for one of the following reasons:

1) where a manufacturer has subcontracted production to another organisation and therefore a need arises to ensure that contract has the same meaning for all parties to the contract, and the competent authority of the Member State agrees

2) to inspect a product, part, appliance, or material under production for its own, Member States or non-EU register.

GM No 2 to 21.B.220(c) Procedures for investigation – General

ED Decision 2019/018/R/R

1. Purpose of the Procedures

The purpose is to investigate the applicant production organisation for compliance with Part 21 Subpart G in relation to the requested terms of approval. When appropriate, this procedure should also be used to investigate significant changes or applications for variation of scope of approval.

The following procedure assumes that the application has been accepted and that an investigation team has been selected.

2. Initiation

The POA Team Leader initiates the procedure by:

2.1 arranging a meeting with the POAT members to review the information provided in accordance with 21.A.134 and to take account of any knowledge that the POAT members have regarding the production standards of the applicant

2.2. obtaining information from other teams of a competent authority of the Member State or the Agency on the functioning applicant organisation (see GM No 1 to 21.B.45)

2.3 arranging a meeting with the applicant in order to:

— enable the applicant to make a general presentation of its organisation and products, parts or appliances

— enable the POAT to describe the proposed investigation process

— enable the POAT to confirm to the applicant the identity of those managers nominated in accordance with Part 21 Subpart G who need to complete an EASA Form 4 (See EASA Form 4 for Production Organisations on EASA website: http://easa.europa.eu/certification/application-forms.php). The applicant should provide a completed copy of EASA Form 4 for each of the key management staff identified by Part 21 Subpart G. The EASA Form 4 is a confidential document and will be treated as such.

3. Preparation

The POAT:

3.1 studies the information gathered in the initiation phase

3.2 establishes an investigation plan which:

— takes account of the location of the POA applicants facility as identified per GM No 3 to 21.B.220(c)

— defines areas of coverage and work-sharing between POAT members taking account of their individual expertise

— defines areas where more detailed investigation is considered necessary

— establishes the need for external advice to POAT members where expertise ay be lacking within the team

— includes completion of a comprehensive plan for the investigation in order to present it to the applicant

— recognises the need to:

— review the documentation and procedures

— verify compliance and implementation

— audit a sample of products, parts, and appliances

3.3 co-ordinates with the appropriate Part 21 Section A Subpart J design organisation approval Teams sufficiently for both parties to have confidence in the applicants co-ordination links with the holder of the approval of the design (as required by 21.A.133)

3.4 establishes liaison with the applicant to plan mutually suitable dates and times for visits at each location needing investigation, and also to agree the investigation plan and approximate time scales with the applicant

4. Investigation

The POAT:

4.1 makes a check of the POE for compliance with Part 21 Subpart G

4.2 audits the organisation, its organisational structure, and its procedures for compliance with Part 21 Subpart G, using EASA Form 56 as a guide during the investigation, and as a checklist at the end of it

4.3. generates compliance checklists for investigations of working processes and procedures on site as required

4.4 accepts or rejects each EASA Form 4 completed by the key nominated personnel in accordance with 21.A.145(c)(2)

4.5 checks that the production organisation exposition (POE) standard reflects the organisation, its procedures, practices and 21.A.143. Having checked and agreed a POE issue or subsequent amendment, the competent authority should have a clear procedure to indicate its acceptance or rejection

4.6 makes sample audits at working level to verify that:-

(i) work is performed in accordance with the system described in the POE

(ii) products, parts, appliances or material produced by the organisation are in conformity with the applicable design data (see GM 21.B.235(b)(4)).

(iii) facilities, working conditions, equipment and tools are in accordance with the POE and appropriate for the work being performed

(iv) competence and numbers of personnel is appropriate for the work being performed

(v) co-ordination between production and design is satisfactory

4.7 at an advanced stage of the investigation, conducts an interim team review of audit results and matters arising, in order to determine any additional areas requiring investigation.

Each investigation team should be accompanied during the process by company representatives who are knowledgeable of the applicants organisation and procedures. This will ensure that the organisation is aware of audit progress and problems as they arise. Access to information will also be facilitated.

The POATL should co-ordinate the work of POAT members for an efficient investigation process, which will provide a consistent and effective investigation and reporting standards.

5. Conclusions

5.1 The POATL holds a team meeting to review findings and observations so as to produce a final agreed report of findings.

5.2 The POATL, on completion of the investigation, holds a meeting to verbally presents the report to the applicant.

The POATL should be the chairman of this meeting, but individual team members may present their own findings and observations.

5.3 The meeting should agree the findings, corrective action time scales, and preliminary arrangements for any follow up that may be necessary.

5.4 Some items may as a result of this meeting be withdrawn by the POATL but if the investigation has been correctly performed, at this stage there should be no disagreement over the facts presented.

5.5 Inevitably there will be occasions when the POAT member carrying out the audit may find situations in the applicant or POA holder where it is unsure about compliance. In this case, the organisation is informed about possible non-compliance at the time and advised that the situation will be reviewed within the competent authority before a decision is made. The organisation should be informed of the decision without undue delay. Only if the decision results in a confirmation of non-compliance this is recorded in Part 4 of EASA Form 56.

5.6 The POATL will transmit the final signed report on EASA Form 56 together with notes of the final meeting with the applicant to the competent authority where the applicant is located. The report will include recommendations and significant findings, together with appropriate conclusions and corrective actions. In particular, it should indicate if the POE is acceptable, or changes are required.

5.7 Completion of EASA Form 56 includes the need to record in Part 4 comments, criticisms, etc., and this must reflect any problems found during the visit and must be the same as the comments, criticisms made to the organisation during the debrief. Under no circumstances should additional comments, criticisms, etc., be included in Part 4 of the report unless the applicant or POA holder has previously been made aware of such comments.

Many applicants may need to take corrective action and amend the proposed exposition before the competent authority is able to conclude its investigation. Such corrective actions should be summarised in Part 4 of the EASA Form 56 and a copy always given to the applicant, so that there is a common understanding of the actions necessary before approval can be granted.

The intention of the EASA Form 56 Part 4 is to provide a summary report of findings and outstanding items during initial investigation and major changes. The competent authority will need to operate a supporting audit system to manage corrective action monitoring, closure etc. While the EASA Form 56 Part 4 format may be used for monitoring purposes, it is not adequate on its own to manage such system.

5.8 If the findings made during the investigation mean that approval recommendation will not or cannot be issued, then it is essential that such findings are confirmed in writing to the organisations within two weeks of the visit. The reason for confirmation in writing is that many organisations take a considerable time to establish compliance. As a result, it is too easy to establish a position of confusion where the organisation claims it was not aware of the findings that prevented issue of an approval.

6. Management Involvement

The accountable manager will be seen at least once during the investigation process and preferably twice, because he or she is ultimately responsible for ensuring compliance with the requirements for initial grant and subsequent maintenance of the production organisation approval. Twice is the preferred number of visits to the accountable manager, with one being conducted at the beginning of the audit to explain the investigation process and the second, at the end, to debrief on the results of the investigation.

Competent authority
of an EU Member State or
EASA

RECOMMENDATION REPORT IN SUPPORT OF Part 21 SUBPART G APPROVAL
ISSUE / CONTINUATION / VARIATION / SIGNIFICANT CHANGE

PART ONE OF FIVE PARTS: **BASIC DETAILS OF THE ASSESSMENT**

Name of the organisation:

Approval reference: _____

Address(es) of the facilities surveyed:

Main Part 21 Subpart G activities at facilities surveyed:

Date(s) of survey:

Names and positions of the organisation's senior management attended during survey:

Names of the competent authority staff:

Office: EASA Form 56 completion date:

Note: If it is determined that recommendation for issue/continuation/variation/significant change of approval cannot be made because of non-compliance with Part 21 Subpart G, the reasons for non-compliance need to be identified in PART 4 of the report. A copy of PART 1 and PART 4, or at least the information included in these parts, must be given to the organisation to ensure that the organisation, in failing to obtain Part 21 Subpart G approval, even if only temporarily, has the same information as is on the files of the competent authority.

Competent authority
of an EU Member State or
EASA

RECOMMENDATION REPORT IN SUPPORT OF Part 21 SUBPART G ISSUE / CONTINUATION / VARIATION/SIGNIFICANT CHANGE

PART TWO OF FIVE PARTS: **Part 21 SUBPART G COMPLIANCE**

Name of organisation:

Approval of organisation:

Approval reference: _____ Survey reference:

Note A: This form has been compiled according those points of Part 21 Subpart G which are relevant to an organisation trying to demonstrate compliance.

Note B: The right hand part of each box must be completed with one of three indicators:

1. a tick (✓) which means compliance;
2. NR which means the requirement is Not Relevant to the activity at the address surveyed; (the reason for NR should be stated in Part 4 of the report, unless the reason is obvious)
3. a number relating to a comment which must be recorded in Part 4 of the report.

The left hand part of each box is optional for use by the competent authority.

21.A.133 **Eligibility**

Any natural or legal person ('organisation') shall be eligible as an applicant for an approval under this Subpart. The applicant shall:

(a) justify that, for a defined scope of work, an approval under this Subpart is appropriate for the purpose of showing conformity with a specific design; and

(b) hold or have applied for an approval of that specific design; or

(c) have ensured, through an appropriate arrangement with the applicant for, or holder of, an approval of that specific design, satisfactory co-ordination between production and design.

21.A.134 **Application**

Each application for a production organisation approval shall be made to the competent authority in a form and manner established by that authority, and shall include an outline of the information required by point 21.A.143 and the terms of approval requested to be issued under point 21.A.151.

PART TWO OF FIVE (CONTINUED):	SURVEY REFERENCE:

21.A.139 **Quality System**

(a) The production organisation shall demonstrate that it has established and is able to maintain a quality system. The quality system shall be documented. This quality system shall be such as to enable the organisation to ensure that each product, part or appliance produced by the organisation or by its partners, or supplied from or subcontracted to outside parties, conforms to the applicable design data and is in condition for safe operation, and thus exercise the privileges set forth in point 21.A.163.

(b) The quality system shall contain:

(1) as applicable within the scope of approval, control procedures for:

(i)	☐	document issue, approval, or change;
(ii)	☐	vendor and sub-contractor assessment audit and control;
(iii)	☐	verification that incoming products, parts, materials, and equipment, including items supplied new or used by buyers of products, are as specified in the applicable design data;
(iv)	☐	identification and traceability;
(v)	☐	manufacturing processes;
(vi)	☐	inspection and testing, including production flight tests;
(vii)	☐	calibration of tools, jigs, and test equipment;
(viii)	☐	non-conforming item control;
(ix)	☐	airworthiness co-ordination with the applicant for, or holder of, a design approval;
(x)	☐	records completion and retention;
(xi)	☐	personnel competence and qualification;
(xii)	☐	issue of airworthiness release documents;
(xiii)	☐	handling, storage and packing;
(xiv)	☐	internal quality audits and resulting corrective actions;
(xv)	☐	work within the terms of approval performed at any location other than the approved facilities;
(xvi)	☐	work carried out after completion of production but prior to delivery, to maintain the aircraft in a condition for safe operation;
(xvii)	☐	issue of permit to fly and approval of associated flight conditions.
	☐	The control procedures need to include specific provisions for any critical parts.

(b) The quality system shall contain (cont'd) –

(2) An independent quality assurance function to monitor compliance with, and adequacy of, the documented procedures of the quality system. This monitoring shall include a feedback system to the person or group of persons referred to in point 21.A.145(c)(2) and ultimately to the manager referred to in point 21.A.145(c)(1) to ensure, as necessary, corrective action.

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PART TWO OF FIVE (CONTINUED):	SURVEY REFERENCE:

21.A.143 Exposition

(a) The organisation shall submit to the competent authority a production organisation exposition providing the following information: (see Part 3 of this Form)

(b) The production organisation exposition shall be amended as necessary to remain an up-to-date description of the organisation, and copies of any amendments shall be supplied to the competent authority.

21.A.145 Approval requirements

The production organisation shall demonstrate, on the basis of the information submitted in accordance with point 21.A.143 that:

(a) with regard to general approval requirements, facilities, working conditions, equipment and tools, processes and associated materials, number and competence of staff, and general organisation are adequate to discharge obligations under 21.A.165;

(b) with regard to all necessary airworthiness, noise, fuel venting and exhaust emissions data:

(1) the production organisation is in receipt of such data from the Agency, and from the holder of, or applicant for, the type-certificate, restricted type-certificate or design approval to determine conformity with the applicable design data;

(2) the production organisation has established a procedure to ensure that airworthiness, noise, fuel venting and exhaust emissions data are correctly incorporated in its production data;

(3) such data are kept up to date and made available to all personnel who need access to such data to perform their duties;

(c) with regard to management and staff:

(1) A manager has been nominated by the production organisation, and is accountable to the competent authority. His or her responsibility within the organisation shall consist of ensuring that all production is performed to the required standards and that the production organisation is continuously in compliance with the data and procedures identified in the exposition referred to in point 21.A.143.

(2) a person or a group of persons have been nominated by the production organisation to ensure that the organisation is in compliance with the requirements of this Annex I (Part 21), and are identified, together with the extent of their authority. Such person(s) shall act under the direct authority of the accountable manager referred to in point (1). The knowledge, background and experience of the persons nominated shall be appropriate to discharge their responsibilities;

(3) staff at all levels have been given appropriate authority to be able to discharge their allocated responsibilities and that there is full and effective co-ordination within the production organisation in respect of airworthiness, noise, fuel venting and exhaust emission data matters;

(d) with regard to certifying staff, authorised by the production organisation to sign the documents issued under point 21.A.163 under the scope or terms of approval:

(1) the knowledge, background (including other functions in the organisation), and experience of the certifying staff are appropriate to discharge their allocated responsibilities;

(2) the production organisation maintains a record of all certifying staff which shall include details of the scope of their authorisation;

(3) certifying staff are provided with evidence of the scope of their authorisation.

PART TWO OF FIVE (CONTINUED):	SURVEY REFERENCE:

21.A.147 **Changes to the approved production organisation**

(a) After the issue of a production organisation approval, each change to the approved production organisation that is significant to the showing of conformity or to the airworthiness and characteristics of noise, fuel venting and exhaust emissions of the product, part or appliance, particularly changes to the quality system, shall be approved by the competent authority. An application for approval shall be submitted in writing to the competent authority and the organisation shall demonstrate to the competent authority before implementation of the change, that it will continue to comply with this Subpart.

(b) The competent authority shall establish the conditions under which a production organisation approved under this Subpart may operate during such changes unless the competent authority determines that the approval should be suspended.

21.A.148 **Changes of location**

A change of the location of the manufacturing facilities of the approved production organisation shall be deemed of significance and therefore shall comply with point 21.A.147.

21.A.149 **Transferability**

Except as a result of a change in ownership, which is deemed significant for the purposes of point 21.A.147, a production organisation approval is not transferable.

21.A.151 **Terms of approval**

The terms of approval shall identify the scope of work, the products or the categories of parts and appliances, or both, for which the holder is entitled to exercise the privileges under point 21.A.163. Those terms shall be issued as part of a production organisation approval.

21.A.153 **Changes to the terms of approval**

Each change to the terms of approval shall be approved by the competent authority. An application for a change to the terms of approval shall be made in a form and manner established by the competent authority. The applicant shall comply with the applicable requirements of this Subpart.

21.A.157 **Investigations**

A production organisation shall make arrangements that allow the competent authority to make any investigations, including investigations of partners and sub-contractors, necessary to determine compliance and continued compliance with the applicable requirements of this Subpart.

21.A.163 **Privileges**

Pursuant to the terms of approval issued under point 21.A.135, the holder of a production organisation approval may:

(a) perform production activities under this Annex I (Part 21).

(b) in the case of complete aircraft and upon presentation of a statement of conformity (EASA Form 52) under point 21.A.174, obtain an aircraft certificate of airworthiness and a noise certificate without further showing;

(c) in the case of other products, parts or appliances, issue authorised release certificates (EASA Form 1) under 21.A.307 without further showing;

(d) maintain a new aircraft that it has produced and issue a certificate of release to service (EASA Form 53) in respect of that maintenance;

(e) under procedures agreed with its competent authority for production, for an aircraft it has produced, and when the production organisation itself is controlling under its POA the configuration of the aircraft and is attesting conformity with the design conditions approved for the flight, to issue a permit to fly in accordance with point 21.A.711(c) including approval of the flight conditions in accordance with point 21.A.710(b).

PART TWO OF FIVE (CONTINUED):	SURVEY REFERENCE:

21.A.165 **Obligations of the holder**

The holder of a production organisation approval shall:

(a) ensure that the production organisation exposition furnished in accordance with point 21.A.143 and the documents to which it refers, are used as basic working documents within the organisation;

(b) maintain the production organisation in conformity with the data and procedures approved for the production organisation approval;

(c) (1) determine that each completed aircraft conforms to the type design and is in condition for safe operation prior to submitting statements of conformity to the competent authority; or

(2) determine that other products, parts or appliances are complete and conform to the approved design data and are in a condition for safe operation before issuing an EASA Form 1 to certify conformity to approved design data and in a condition for safe operation, and additionally in case of engines, determine according to data provided by the engine type-certificate holder that each completed engine is in compliance with the applicable emissions requirements as defined in point 21.B.85(b), current at the date of manufacture of the engine, to certify emissions compliance; or

(3) determine that other products, parts or appliances conform to the applicable data before issuing EASA Form 1 as a conformity certificate;

(d) record all details of work carried out;

(e) establish and maintain an internal occurrence reporting system in the interest of safety, to enable the collection and assessment of occurrence reports in order to identify adverse trends or to address deficiencies, and to extract reportable occurrences. This system shall include evaluation of relevant information relating to occurrences and the promulgation of related information;

(f) (1) report to the holder of the type-certificate or design approval, all cases where products, parts or appliances have been released by the production organisation and subsequently identified to have possible deviations from the applicable design data, and investigate with the holder of the type-certificate or design approval in order to identify those deviations which could lead to an unsafe condition;

(2) report to the Agency and the competent authority of the Member State, or both, the deviations which could lead to an unsafe condition identified according to point (1). Such reports shall be made in a form and manner established by the Agency under point 21.A.3A(b)(2) or accepted by the competent authority of the Member State;

(3) where the holder of the production organisation approval is acting as a supplier to another production organisation, report also to that other organisation all cases where it has released products, parts or appliances to that organisation and subsequently identified them to have possible deviations from the applicable design data;

(g) provide assistance to the holder of the type-certificate or design approval in dealing with any continuing airworthiness actions that are related to the products parts or appliances that have been produced;

(h) establish an archiving system incorporating requirements imposed on its partners, suppliers and sub-contractors, ensuring conservation of the data used to justify conformity of the products, parts or appliances. Such data shall be held at the disposal of the competent authority and be retained in order to provide the information necessary to ensure the continuing airworthiness of the products, parts or appliances;

(i) where, under its terms of approval, the holder issues a certificate of release to service, determine that each completed aircraft has been subjected to necessary maintenance and is in condition for safe operation, prior to issuing the certificate;

(j)	where applicable, under the privilege of point 21.A.163(e), determine the conditions under which a permit to fly can be issued;
(k)	where applicable, under the privilege of point 21.A.163(e), establish compliance with point 21.A.711(c) and (e) before issuing a permit to fly to an aircraft.

Competent authority
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EASA

RECOMMENDATION REPORT IN SUPPORT OF Part 21 SUBPART G ISSUE / CONTINUATION / VARIATION/SIGNIFICANT CHANGE

PART THREE OF FIVE PARTS: Part 21 SUBPART G EXPOSITION COMPLIANCE

Name of organisation:

Approval of organisation:

Approval reference: _____ Survey reference:

Note A: Each box must be completed with one of three indicators:

1. a tick (✓) which means compliance;
2. NR which means the requirement is NOT RELEVANT to the activity at the address surveyed; (The reason for NR should be stated in Part 4 of the report unless the reason is obvious.);
3. a number relating to a comment which must be recorded in Part 4 of the report.

Note B: The exposition may be compiled in any subject order as long as all applicable subjects are covered.
Note C: If the organisation holds another Part approval requiring an exposition or handbook it is acceptable to use this index as a supplement to the existing exposition or handbook and to cross-refer each subject to the position in the existing exposition or handbook.

Production organisation exposition
Revision Status:

(Content as required by 21.A.143(a))

(1) A statement signed by the accountable manager confirming that the production organisation exposition and any associated manuals which define the approved organisation's compliance with this Subpart will be complied with at all times;

(2) the title(s) and names of the managers accepted by the competent authority in accordance with point 21.A.145(c)(2);

(3) the duties and responsibilities of the manager(s) as required by point 21.A.145(c)(2) including matters on which they may deal directly with the competent authority on behalf of the organisation.

(4) an organisational chart showing associated chains of responsibility of the managers as required by point 21.A.145(c)(1) and (c)(2);

(5) a list of certifying staff as referred to in point 21.A.145(d)

[Note : a separate document may be referenced]

(6) a general description of man-power resources;

PART THREE OF FIVE (CONTINUED):	**SURVEY REFERENCE:**

(7) a general description of the facilities located at each address specified in the production organisation's certificate of approval.

(8) a general description of the production organisation's scope of work relevant to the terms of approval;

(9) the procedure for the notification of organisational changes to the competent authority;

(10) the amendment procedure for the production organisation exposition;

(11) a description of the quality system and the procedures as required by point 21.A.139(b)(1);

(12) a list of those outside parties referred to in point 21.A.139(a).

[Note : a separate document may be referenced]

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Competent authority
of an EU Member State or
EASA

RECOMMENDATION REPORT IN SUPPORT OF Part 21 SUBPART G APPROVAL ISSUE / CONTINUATION / VARIATION/SIGNIFICANT CHANGE

PART FOUR OF FIVE PARTS: FINDINGS ON Part 21 SUBPART G COMPLIANCE STATUS

Name of organisation:

Approval reference: _____ Survey reference: _____

Note A: Each finding must be identified by number and the number must cross-refer to the same number in a box in Part 2 or 3 of the Part 21 Subpart G survey report.

Note B: As stated in Part 1 any comments recorded in this Part 4 should be copied to the organisation surveyed together with Part 1.

Note C: In case of a partial clearance of a finding with some outstanding action remaining, this action has to be identified.

NO:	FINDING	LEVEL	OUTSTANDING ACTION	CLEARANCE	
				DATE	REP.REF.

NAME & SIGNATURE OF SURVEYOR: Date:

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PART FOUR OF FIVE (CONTINUED): Sheet ___ of ___ SURVEY REFERENCE:					
NO:	FINDING	LEVEL	OUTSTANDING ACTION	CLEARANCE	
				DATE	REP.REF.
NAME & SIGNATURE OF SURVEYOR:			Date:		

EASA Form 56 Issue 3 - POAT Recommendation Report POA Audit Report - Part 4 of 5, Page 2 of 2 MONTH YEAR

Competent authority
of an EU Member State or
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RECOMMENDATION REPORT IN SUPPORT OF Part 21 SUBPART G APPROVAL ISSUE / CONTINUATION / VARIATION/SIGNIFICANT CHANGE

PART FIVE OF FIVE PARTS: Part 21 SUBPART G APPROVAL RECOMMENDATION

Name of organisation:

Approval reference: _____ Survey reference: _____

Recommendation for issue / variation of approval/significant change:

The following Part 21 Subpart G Terms of approval are recommended for the above organisation at the address(es) specified in Part 1 of this report:

or

Recommendation for continuation of existing approval:

It is recommended that the Part 21 Subpart G Terms of approval identified in EASA Form 55 referenced

_____ be continued.

☐ Reporting performed according to procedure for authority surveillance of suppliers of a POA holder located in other Member States, if applicable (Strict confidentiality to be observed)

Name of competent authority surveyor making recommendation:

Signature of the competent authority surveyor:

Competent authority office: Date:

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GM No 3 to 21.B.220(c) Procedures for investigation – POA applications received from organisations with facilities/partners/ suppliers/sub-contractors located in a third country

ED Decision 2012/020/R

The obligations of the applicant are totally independent from the surveillance exercised by the competent authority. It is not acceptable that the applicant relies on surveillance activities of the competent authority to simplify its tasks.

Facilities located in a third country

When any part of the production facilities of an applicant for POA is located outside the Member States, then the location will be treated in all aspects as part of the applicant's POA organisation.

Therefore the investigating competent authority will:

a) include the facilities outside the Member States fully in their investigation and surveillance activities for the applicant for, or holder of, the POA

b) include the facilities outside the Member States in the terms of approval of the EASA Form 55 (see Annex I Part 21 Appendix X) when issuing the POA.

Partners/suppliers/sub-contractors located in a third country

The competent authority should define on the basis of Part 21, its associated CS and GM, a clear procedure on supplier control. This procedure should include the control of partners/suppliers/sub-contractors of the applicant for, or holder of, a POA that are located outside the Member States.

In respect of the applicant for, or holder, of the POA, the competent authority should:

1) investigate, for the initial approval and consequent continued surveillance, the production organisation, and its partners/suppliers/sub-contractors at the necessary level to ensure the organisation can comply with the requirements of Part 21,

2) in accordance with the competent authority procedure, assess and accept the documented procedure for supplier control as part of the POA holder's quality system, and changes to that procedure prior to implementation,

3) in accordance with competent authority procedure, assess the necessary level of surveillance to be exercised by the production organisation on partners / suppliers / sub-contractors and check the audit plan of the production organisation against this level.

The level of co-operation between the competent authority and the competent authority of the third country where a partner/supplier/sub-contractor of the production organisation is located may influence the authorities' activities concerning this partner/supplier/sub-contractor. Co-operation with the competent authority of the third country should be based on the capability and goodwill of that authority, and a complete interchange of necessary information.

The involvement of this competent authority of the third country in the surveillance of the partner/supplier/sub-contractor will be based on the following principles:

— When a recognition agreement under Article 12 of Regulation (EC) No 216/2008 covering production subjects has been concluded:

  a) The competent authority in accordance with GM No 2 to 21.A.139(a) may decide that direct surveillance of the POA holder activities at the foreign location may not be necessary.

b) In any other case, provisions of the recognition agreement on the subject apply (technical assistance, ...).

— If a recognition agreement has not been concluded, or it does not cover production subjects, it may be necessary that the competent authority of the Member State, the Agency, and the competent authority of a third country enter into a specific working arrangement addressing the following matters:

a) acceptance by the competent authority of the third country of conducting manufacturing surveillance of the relevant production activities on behalf of the competent authority, under the respective quality standards defined by the competent authority.

b) tasks to be performed

c) practical methods

These arrangements are between authorities and do not relieve the applicant of its obligations.

— In all cases, even though surveillance tasks are delegated to the competent authority of the third country, the competent authority remains the responsible authority and may consequently exercise direct surveillance if necessary.

— In case that it is not possible to delegate surveillance tasks to the competent authority of the third country, the competent authority will have to establish a direct surveillance program in accordance with its procedure concerning supplier control as part of the overall surveillance of the POA holder.

GM No 4 to 21.B.220(c) Procedures for investigation – Competent authority surveillance of suppliers of a POA holder located in other Member States

ED Decision 2012/020/R

1. The aviation legislation identifies specific State obligations in relation to complete products:

State of manufacture, as used in ICAO Annex 8, normally identifies the country where the final assembly and the final determination of airworthiness is made. However, sub-assemblies and parts may be produced by POA holders in other countries and the EASA Form 1 - Authorised Release Certificate will identify those countries as the location for production.

Among Member States the obligations of the State of manufacture may be discharged through the use of the Part 21 POA system.

According to Part 21 Subpart G, each POA holder must have established and documented in its POE a system for its own control of suppliers/supplies. Surveillance of this system is part of the responsibility of the competent authority of the POA holder wherever the suppliers are located.

This surveillance may be exercised through the POA holder and/or at supplier level especially in the cases where the supplier would be eligible for its own POA.

The purpose of this procedure is to ensure the completeness of the responsibilities chain so that no separate technical agreement between these national authorities is necessary and when necessary to establish a means of communication between the involved competent authorities of the Member States.

2. Principle to organise competent authority supplier surveillance between Member States:

In order to avoid duplication and to take the best advantage of Regulation (EC) No 216/2008 that establishes under Article 11 mutual recognition of certificates issued by production organisations approved in accordance with Part 21 Section A Subpart G by an Member State, the principle for the competent authority surveillance of the suppliers of a POA holder located in other Member States is for the responsible competent authority to delegate surveillance activity to the other competent authority of the supplier.

This applies between Member States and for suppliers holding a Part 21 POA.

Delegation of surveillance tasks does not imply a delegation of the overall responsibility, therefore the competent authority of the contractor always retains the right of direct supervision at the supplier location especially when serious quality problems are encountered. In such a case, co-ordination will be organised between both competent authorities.

This delegation of surveillance is to be considered automatic as soon as the supplier holds a Part 21 POA provided that the intended supply is included in the approved scope of work. Evidence of that approval will normally be found through the release of the supplied parts with an EASA Form 1. In addition, the competent authority of the supplier should immediately inform the competent authority of the contractor in case of a serious quality problem.

In the cases where the competent authority of the contractor considers that it is necessary to establish closer ties with the competent authority of the supplier (i.e., critical or significant parts) exchange of information between the competent authorities should be organised as follows:

2.1 Tasks of the competent authority of the POA contractor

The competent authority of the contractor should inform in writing the competent authority of the sub-contractor with the following:

a. Identification (and location) of the contractor

b. Identification (and location) of the sub-contractor

c. Identification of the subcontracting (parts, contract N°, etc.)

d. Reference to the quality requirements attached to the contract

e. Name and address of the competent authority office/person in charge of the POA

f. Whether Direct Delivery Authorisation (DDA) applies

g. Any specific action item/requirement from the competent authority

h. Request for a bi-annual reporting (both ways).

EASA Form 58A is provided for convenience of the competent authority for this purpose.

The competent authority of the contractor should require that the contract/order from the contractor to the sub-contractor should indicate that it is placed under the surveillance of its competent authority on behalf of the competent authority of the contractor and should address the subject to the payment of the possible surveillance fees.

2.2 Tasks of the competent authority of the supplier (sub-contractor)

On receipt of the information from the competent authority of the contractor, the competent authority of the sub-contractor should:

— Verify that the scope of work of the POA of the supplier covers the intended supply (or envisage to extend it in liaison with the supplier).

— Verify that the specific quality requirements for the parts have been introduced in the quality system of the supplier.

— Confirm to the competent authority of the contractor that the procurement is included in the POA of the supplier and that their surveillance will cover this activity.

— Indicate the name and address of the competent authorities office/person in charge of the POA.

If the supplier has no POA under Part 21, or does not want to extend it, and/or if its competent authority cannot conduct surveillance on behalf of the other competent authority, the competent authority of the supplier will inform the competent authority of the contractor in order for it to decide on appropriate actions.

2.3 Exchange of information between the competent authorities

This information should normally take two forms:

— Immediate exchange of information between both competent authorities in case of serious quality problems;

— A bi-annual exchange of information at a given date in order to guarantee proper on going control of the subcontract by both competent authorities.

This information should cover in a concise form:

a) For the competent authority of the contractor:

— A resume of the quality problems encountered by the contractor, on receipt inspection, on installation on aircraft or on in service aircraft;

— A status of the reference documents.

b) For the competent authority of the sub-contractor:

— A resume of at least the following subjects:

— Changes in organisation and qualification of the sub-contractor.(in case of impact on the procurement),

— Quality problems encountered during manufacture,

— Corrective actions following problems encountered earlier on the procurement,

— Findings from national authorities surveillance that may have an impact on the procurement,

— Quality problems related to the contractor procurement (materials, documentation, procedures, processes).

Exchange of information between national authorities according to this procedure is strictly confidential and should not be disclosed to other parties.

It is recommended to plan at least every 5 years a meeting between Industry and the two national authorities to review each major subcontract to verify proper management by the various parties involved.

3. Miscellaneous

a) Release documentation

Release of parts by the POA sub-contractor to the contractor will be accompanied by an «Authorised Release Certificate EASA Form 1» issued for «Airworthiness» or for «Conformity» as appropriate.

b) Sub-subcontracting

If the sub-contractor wants itself to subcontract, it is up to the competent authority of the sub-contractor to verify that this is done in accordance with the conditions of the contract, to organise as necessary the related authority surveillance and to inform the competent authority of the contractor.

c) Language

Except if agreed otherwise it is recommended to use the English language for exchange of information between the competent authorities.

Competent authority *of an EU Member State or* *EASA* **REQUEST FOR REPORTING ON SUB-CONTRACTOR SURVEILANCE**	
Document reference number:	*<REQUEST REF. NO.>*
As competent authority which issued a POA to:	*<CONTRACTOR COMPANY>*
With approval reference:	*<CONTRACTOR POA REF. NO..>*
The *<COMPETENT AUTHORITY>* has determined that there is a need for direct authority supplier surveillance of:	*<SUB-CONTRACTOR COMPANY>*
With approval reference:	*<SUB-CONTRACTOR POA REF.NO.>*
Which is situated in:	*<COUNTRY OF SUB-CONTRACTOR COMPANY>*
As part of the surveillance as required for the Part 21 Section A Subpart G approved production organisation, according to GM No. 4 to 21.B.220(c) the competent authority of the sub-contractor is requested to perform authority surveillance on the specific sub assemblies and parts as details and requirements are defined below.	
Identification of subcontracting (parts, contract No., …):	
Reference to the quality requirements attached to the contract between contractor and sub-contractor:	
Name and address of the requesting competent authority office/person in charge of the POA:	
Direct Delivery Authorisation (DDA) applies:	☐ Yes ☐ No
Specific action item/requirement from the competent authority of the contractor:	
Request and details required for a bi-annual reporting (both ways) according to GM No. 4 to 21.B.220(c) (Strict confidentiality to be observed):	
Name and signature of competent authority person making the request:	
Competent authority office:	**Date:**

EASA Form 58A – Request for reporting on sub-contractor surveillance, Page x of x

Competent authority *of an EU Member State or* *EASA* **REPORT ON SUB-CONTRACTOR SURVEILLANCE**	
Document reference number:	*<REPORT REF. NO.>*
Reporting request reference number:	*< REQUEST REF. NO >*
As responsible competent authority the *<COMPETENT AUTHORITY>* issued a POA to and is performing direct authority surveillance of:	*<SUB-CONTRACTOR COMPANY>*
With approval reference:	*<SUB-CONTRACTOR POA REF. NO..>*
Which is a subcontracted supplier of:	*<CONTRACTOR COMPANY>*
With approval reference :	*<CONTRACTOR POA REF.NO.>*
Which is situated in:	*<COUNTRY OF CONTRACTOR COMPANY>*
According to GM No. 4 to 21.B.220(c) and on request of the competent authority of the contractor company the <COMPETENT AUTHORITY> reports on the results of its authority surveillance on the specific parts and appliances defined below:	
Identification of subcontracting (parts, contract No., …):	
Identification of attachments to this report (if needed):	
Date and identification of previous report:	
Resume of surveillance results:	
Changes in organisation and qualification of the sub-contractor. (in case of impact on the procurement):	
Quality problems encountered during manufacture:	
Corrective actions following problems encountered earlier on the procurement:	
Findings from competent authority surveillance that may have an impact on the procurement:	
Quality problems related with the contractor procurement (materials, documentation, procedures, processes):	
Note: Exchange of information between national authorities according to this procedure is strictly confidential and should not be disclosed to other parties.	
Name and signature of competent authority person reporting:	
Competent authority office:	**Date:**

EASA Form 58B – Report on sub-contractor surveillance, Page x of x

21.B.221 Oversight principles

Regulation (EU) 2022/203

(a) The competent authority shall verify:

1. compliance with the requirements that are applicable to organisations, prior to issuing the production organisation approval certificate;
2. continued compliance with the applicable requirements of the organisations it has certified;
3. the implementation of appropriate safety measures mandated by the competent authority according to points 21.B.20(c) and (d).

(b) This verification shall:

1. be supported by documentation specifically intended to provide personnel responsible for oversight with guidance to perform their functions;
2. provide the organisations concerned with the results of oversight activities;
3. be based on assessments, audits, inspections and, if needed, unannounced inspections;
4. provide the competent authority with the evidence needed in case further action is required, including the measures provided for in point 21.B.225.

(c) The competent authority shall establish the scope of the oversight defined in points (a) and (b) taking into account the results of past oversight activities and the safety priorities.

(d) If the facilities of an organisation are located in more than one State, the competent authority, as defined in point 21.1, may agree to have the oversight tasks performed by the competent authority(ies) of the Member State(s) where the facilities are located, or by the Agency for facilities that are located outside a territory for which Member States are responsible under the Chicago Convention. Any organisation that is subject to such an agreement shall be informed of its existence and of its scope.

(e) For any oversight activities that are performed at facilities located in a Member State other than where the organisation has its principal place of business, the competent authority, as defined in point 21.1, shall inform the competent authority of that Member State before performing any on-site audit or inspection of the facilities.

(f) The competent authority shall collect and process any information deemed necessary for performing oversight activities.

[applicable from 7 March 2023 - Regulation (EU) 2022/203]

21.B.222 Oversight programme

Regulation (EU) 2022/203

(a) The competent authority shall establish and maintain an oversight programme covering the oversight activities required by point 21.B.221(a).

(b) The oversight programme shall take into account the specific nature of the organisation, the complexity of its activities, the results of past certification and/or oversight activities, and it shall be based on the assessment of the associated risks. It shall include, within each oversight planning cycle:

1. assessments, audits and inspections, including, as appropriate:
   (i) management system assessments and process audits;
   (ii) product audits of a relevant sample of the products, parts and appliances that are within the scope of the organisation;
   (iii) sampling of the work performed; and
   (iv) unannounced inspections;
2. meetings convened between the accountable manager and the competent authority to ensure that both parties remain informed of all significant issues.

(c) The oversight planning cycle shall not exceed 24 months.

(d) Notwithstanding point (c), the oversight planning cycle may be extended to 36 months if the competent authority has established that during the previous 24 months:

1. the organisation has demonstrated that it can effectively identify aviation safety hazards and manage the associated risks;
2. the organisation has continuously demonstrated compliance with points 21.A.147 and 21.A.148 and it has full control over all changes to the production management system;
3. no level 1 findings have been issued;
4. all corrective actions have been implemented within the time period that was accepted or extended by the competent authority as defined in point 21.B.225.

Notwithstanding point (c), the oversight planning cycle may be further extended to a maximum of 48 months if, in addition to the conditions provided in points (1) to (4) above, the organisation has established, and the competent authority has approved, an effective continuous system for reporting to the competent authority on the safety performance and regulatory compliance of the organisation itself.

(e) The oversight planning cycle may be reduced if there is evidence that the safety performance of the organisation has decreased.

(f) The oversight programme shall include records of the dates when assessments, audits, inspections and meetings are due, and when assessments, audits, inspections and meetings have been effectively carried out.

(g) At the completion of each oversight planning cycle, the competent authority shall issue a recommendation report on the continuation of the approval, reflecting the results of the oversight.

[applicable from 7 March 2023 - Regulation (EU) 2022/203]

21.B.225 Findings [applicable until 6 March 2023] / 21.B.225 Findings and corrective actions; observations [applicable from 7 March 2023 - Regulation (EU) 2022/203]

Regulation (EU) No 748/2012

(a) When during audits or by other means objective evidence is found by the competent authority, showing non-compliance of the holder of a production organisation approval with the applicable requirements of Section A, this finding shall be classified in accordance with point 21.A.158(a).

(b) The competent authority shall take the following actions:

1. for level 1 findings, immediate action shall be taken by the competent authority to limit, suspend or revoke the production organisation approval, in whole or in part, depending upon the extent of the finding, until successful corrective action has been completed by the organisation;

2. for level 2 findings, the competent authority shall grant a corrective action period appropriate to the nature of the finding that shall not be more than 3 months. In certain circumstances, at the end of this period and subject to the nature of the finding, the competent authority can extend the 3 months period subject to a satisfactory corrective action plan provided by the organisation.

(c) Action shall be taken by the competent authority to suspend the approval in whole or in part in case of failure to comply within the timescale granted by the competent authority.

[applicable until 6 March 2023]

(a) The competent authority shall have a system in place to analyse findings for their safety significance.

(b) A level 1 finding shall be issued by the competent authority when any significant non-compliance is detected with the applicable requirements of Regulation (EU) 2018/1139 and its delegated and implementing acts, with the organisation's procedures and manuals, or with the certificate including the terms of approval which lowers safety or seriously endangers flight safety.

The level 1 findings shall also include:

1. any failure to grant the competent authority access to the organisation's facilities referred to in point 21.A.9 during normal operating hours and after two written requests;

2. obtaining the production organisation approval certificate or maintaining its validity by falsification of the submitted documentary evidence;

3. any evidence of malpractice or fraudulent use of the production organisation approval certificate; and

4. failure to appoint an accountable manager pursuant to point 21.A.245(a)/

(c) A level 2 finding shall be issued by the competent authority when any non-compliance is detected with the applicable requirements of Regulation (EU) 2018/1139 and its delegated and implementing acts, with the organisation's procedures and manuals, or with the certificate including the terms of approval, which is not classified as a level 1 finding.

(d) When a finding is detected during oversight or by any other means, the competent authority shall, without prejudice to any additional action required by Regulation (EU) 2018/1139 and its delegated and implementing acts, communicate in writing the finding to the organisation and request corrective action to address the non-compliance(s) identified. Where a level 1 finding directly relates to an aircraft, the competent authority shall inform the competent authority of the Member State in which the aircraft is registered.

1. If there are any level 1 findings, the competent authority shall take immediate and appropriate action to prohibit or limit the activities of the organisation involved and, if appropriate, it shall take action to revoke the production organisation approval certificate or to limit or suspend it in whole or in part, depending upon the extent of the level 1 finding, until successful corrective action has been taken by the organisation.

2. If there are any level 2 findings, the competent authority shall:

(i) grant the organisation a corrective action implementation period that is appropriate to the nature of the finding, and that in any case shall initially not be more than 3 months. The period shall commence from the date of the written communication of the finding to the organisation requesting corrective action to address the non-compliance identified. At the end of this period, and subject to the nature of the finding, the competent authority may extend the 3-month period provided that a corrective action plan has been agreed by the competent authority;

(ii) assess the corrective action and implementation plan proposed by the organisation, and if the assessment concludes that they are sufficient to address the non-compliance, accept them;

(iii) if the organisation fails to submit an acceptable corrective action plan, or fails to perform the corrective action within the time period accepted or extended by the competent authority, the finding shall be raised to level 1 and action shall be taken as laid down in point (d)(1).

(e) The competent authority may issue observations for any of the following cases not requiring level 1 or level 2 findings:

1. for any item whose performance has been assessed to be ineffective; or

2. when it has been identified that an item has the potential to cause a non-compliance under points (b) or (c); or

3. when suggestions or improvements are of interest for the overall safety performance of the organisation.

The observations issued under this point shall be communicated in writing to the organisation and recorded by the competent authority.

[applicable from 7 March 2023 - Regulation (EU) 2022/203]

GM 21.B.225(a) Objective evidence

ED Decision 2012/020/R

Objective evidence is a fact which is, or can be documented, based on observations, measurements or tests that can be verified. Objective evidence generally comes from the following:

a) documents or manuals

b) examination of equipment/products

c) information from interview questions and observations of POA activities.

AMC 21.B.225(a) Notification of findings

ED Decision 2012/020/R

In case of a level one finding confirmation must be obtained in a timely manner that the accountable manager received the letter containing details of the level one finding and the approval suspension details.

A level two finding requires timely and effective handling by the competent authority to ensure completion of the corrective action. This includes intermediate communication, including reminding letters as necessary, with the POA holder to verify that the corrective action plan is followed.

21.B.230 Issue of certificate

Regulation (EU) No 748/2012

(a) When satisfied that the production organisation is in compliance with the applicable requirements of Section A, Subpart G, the competent authority shall issue a Production Organisation Approval (EASA Form 55, see Appendix X) without undue delay.

(b) The reference number shall be included on the EASA Form 55 in a manner specified by the Agency.

[applicable until 6 March 2023 – Regulation (EU) 2022/203]

AMC No 1 to 21.B.230 Issue of the certificate

ED Decision 2012/020/R

The competent authority should base its decision to issue or amend a POA on the recommendation report (EASA Form 56, see GM No 2 to 21.B.220(c)) of the POAT submitted by the POA team leader. The EASA Form 56 includes a proposal by the POAT for the scope and terms of approval defining the products, parts and appliances for which the approval is to be granted, with appropriate limitations.

When the competent authority issues the approval a final controlled copy of an acceptable exposition for the organisation should have been supplied to the competent authority.

In some cases it may be accepted that some findings are not fully closed because corrective actions are still in progress. The competent authority may decide according to the following principles:

1) Findings should be equivalent to level two, which do not need to be rectified as a matter of urgency within less than three months, and should normally not exceed three in number.

2) Corrective action plan, including timescales, should have been accepted and should not require an additional and specific follow-up audit by the competent authority.

A record should be kept by the competent authority and should be brought to the attention of the Agency on request for standardisation purposes.

GM-ELA No 1 to 21.B.230 Issue of certificate

ED Decision 2019/003/R

The terms of approval, which identify the products or the categories of parts and appliances, or both, for which the holder is entitled to exercise their privileges, will be described by the competent authority using standard terms, as follows:

Starts with selection of:	*…continues with selection from:*	*…ends with:*
Manufacturing of	aeroplanes that are within the scope of CS-LSA, CS-VLA and CS-23 level 1, not classified as complex motor-powered aircraft,	where <company> holds the type design approval, including all related spare parts.
Manufacturing of engines used on	sailplanes or powered sailplanes that are within the scope of CS-22,	
Manufacturing of propeller used on	balloons,	
	hot-air airships,	
	gas airships that comply with 3 % maximum static heaviness, non-vectored thrust (except reverse thrust), conventional and simple design of structure, control system and ballonet system, and non-power-assisted controls,	

The type and the model should not be listed within the terms of approval. They are provided within the company's manual (or the equivalent documentation).

Changes to the list of types and models are not, in themselves, considered to be changes in the scope of work, and they should be coordinated with the competent authority.

If the scope of work is related to a restricted type design in which the approval of the engine and/or the propeller is included in the aircraft type design, the work associated with these engines and/or propellers is included in the scope of work related to the aircraft. A separate scope related to the engine and/or the propeller is not required.

21.B.235 Continued surveillance

Regulation (EU) No 748/2012

(a) In order to justify the maintenance of the production organisation approval the competent authority shall perform continued surveillance:

1. to verify that the production organisation approval holder's quality system complies with Section A Subpart G;
2. to verify that the organisation of the production organisation approval holder operates in accordance with the production organisation exposition;
3. to verify the effectiveness of the production organisation exposition procedures; and
4. to monitor by sample the standards of the product, part or appliance.

(b) Continued surveillance shall be performed in accordance with point 21.B.220.

(c) The competent authority shall provide through planned continued surveillance that a production organisation approval is completely reviewed for compliance with this Annex I (Part 21) during a period of 24 months. The continued surveillance may be made up of several investigation activities during this period. The number of audits may vary depending upon the complexity of the organisation, the number of sites and the criticality of the production. As a minimum the holder of a production organisation approval shall be subject to continued surveillance activity by the competent authority at least once every year.

[applicable until 6 March 2023 – Regulation (EU) 2022/203

AMC-ELA No 1 to 21.B.235 Continued surveillance

ED Decision 2019/003/R

The competent authority should determine whether there is continued conformity to the type design by assessing:

1. the adherence of the company to the procedures laid out in the quality system that is referenced by the POE; and
2. a representative number of sample products at various stages of production.

Surveillance activities are:

1. planned activities to a schedule that are adequate for the size, product range and production rate of the company, so as to ensure that there is a complete review within 24 months. To obtain the required complete review of the production organisation within 24 months, all the relevant stages of production should be audited once within this 24-month period;
2. unplanned activities in response to unsafe situations that may be caused by a problem in the production organisation, and that are significant enough to require a detailed assessment that cannot be delayed until the next scheduled surveillance event.

GM1 21.A.139, 21.A.157, 21.A.239, 21.A.257, 21.B.120, 21.B.140, 21.B.220, 21.B.235 and 21.B.240 The use of information and communication technologies (ICT) for performing remote audits

ED Decision 2021/007/R

This GM provides technical guidance on the use of remote information and communication technologies (ICT) to support:

— competent authorities when overseeing regulated organisations;

— regulated organisations when conducting internal audits / monitoring compliance of their organisation with the relevant requirements, and when evaluating vendors, suppliers and subcontractors.

In the context of this GM:

— ‘remote audit’ means an audit that is performed with the use of any real-time video and audio communication tools in lieu of the physical presence of the auditor on-site; the specificities of each type of approval / letter of agreement (LoA) need to be considered in addition to the general overview (described below) when applying the ‘remote audit’ concept;

— ‘auditing entity’ means the competent authority or organisation that performs the remote audit;

— 'auditee' means the entity being audited/inspected (or the entity audited/inspected by the auditing entity via a remote audit);

It is the responsibility of the auditing entity to assess whether the use of remote ICT constitutes a suitable alternative to the physical presence of an auditor on-site in accordance with the applicable requirements.

The conduct of a remote audit

The auditing entity that decides to conduct a remote audit should describe the remote audit process in its documented procedures and should consider at least the following elements:

— The methodology for the use of remote ICT is sufficiently flexible and non-prescriptive in nature to optimise the conventional audit process.

— Adequate controls are defined and are in place to avoid abuses that could compromise the integrity of the audit process.

— Measures to ensure that the security and confidentiality are maintained throughout the audit activities (data protection and intellectual property of the organisation also need to be safeguarded).

Examples of the use of remote ICT during audits may include but are not limited to:

— meetings by means of teleconference facilities, including audio, video and data sharing;

— assessment of documents and records by means of remote access, in real time;

— recording, in real time during the process, of evidence to document the results of the audit, including non-conformities, by means of exchange of emails or documents, instant pictures, video or/and audio recordings;

— visual (livestream video) and audio access to facilities, stores, equipment, tools, processes, operations, etc.

An agreement between the auditing entity and the auditee should be established when planning a remote audit, which should include the following:

— determining the platform for hosting the audit;

— granting security and/or profile access to the auditor(s);

— testing platform compatibility between the auditing entity and the auditee prior to the audit;

— considering the use of webcams, cameras, drones, etc., when the physical evaluation of an event (product, part, process, etc.) is desired or is necessary;

— establishing an audit plan which will identify how remote ICT will be used and the extent of their use for the audit purposes to optimise their effectiveness and efficiency while maintaining the integrity of the audit process;

— if necessary, time zone acknowledgement and management to coordinate reasonable and mutually agreeable convening times;

— a documented statement of the auditee that they shall ensure full cooperation and provision of the actual and valid data as requested, including ensuring any supplier or subcontractor cooperation, if needed; and

— data protection aspects.

The following equipment and set-up elements should be considered:

— the suitability of video resolution, fidelity, and field of view for the verification being conducted;

— the need for multiple cameras, imaging systems, or microphones, and whether the person that performs the verification can switch between them, or direct them to be switched and has the possibility to stop the process, ask a question, move the equipment, etc.;

— the controllability of viewing direction, zoom, and lighting;

— the appropriateness of audio fidelity for the evaluation being conducted; and

— real-time and uninterrupted communication between the person(s) participating to the remote audit from both locations (on-site and remotely).

When using remote ICT, the auditing entity and the other persons involved (e.g. drone pilots, technical experts) should have the competence and ability to understand and utilise the remote ICT tools employed to achieve the desired results of the audit(s)/assessment(s). The auditing entity should also be aware of the risks and opportunities of the remote ICT used and the impacts they may have on the validity and objectivity of the information gathered.

Audit reports and related records should indicate the extent to which remote ICT have been used in conducting remote audits and the effectiveness of remote ICT in achieving the audit objectives, including any item that it has not been able to be completely reviewed.

GM-ELA No 1 to 21.B.235 Continued surveillance

ED Decision 2019/003/R

A sampling plan in support of the planned surveillance activity could, for example, include:

— a (part of the) product with the modification (or change) incorporated;

— the installation, testing, or operation of a major part or system;

— the accuracy and the generation of the flight test report data;

— the accuracy and the generation of the weighing report data;

— an engine test bed run;

— the traceability of production records as defined from the type design;

— the accuracy and the generation of the statement of conformity data, and the associated determination of safe operation;

— the accuracy and generation of the EASA Form 1 data.

It is recommended that flexibility should be allowed in the sampling plan so as to:

— accommodate changes in the rate of production;

— make use of results from other samples;

— make use of results from other POA investigations;

— provide the maximum confidence to the national authorities.

GM 21.B.235(a)(4) Guide to the conduct of monitoring production standards.

ED Decision 2012/020/R

1. 21.B.235(a)(4) identifies a need for a sample investigation of products, parts or appliances, their associated conformity determinations and certifications made by a POA holder. For this to be performed effectively and efficiently, the competent authority should integrate a sampling plan as part of the planning of the investigation and continued surveillance activities appropriate to the scope and size of the relevant applicant.

2. The sampling plan could, for example, investigate:

— a modification (or change)

— the installation, testing, or operation of a major part or system

— the accuracy and generation of the Flight Test report data

— the accuracy and generation of the Weighing report data

— an engine test bed run

— records traceability

— the accuracy and generation of the Statement of Conformity data and the associated safe operation determination

— the accuracy and generation of EASA Form 1 data.

The sampling plan should be flexible so as to:

— accommodate changes in production rate

— make use of results from other samples

— make use of results from other POA Investigations

— provide the maximum national authorities confidence

To be effective this product sample requires that the individual investigator(s):

— have a good practical knowledge of the product, part or appliance

— have a good practical knowledge of the manufacturing processes

— have an up to date knowledge of the manufacturers production programme

— use an appropriate and up to date sample plan and compliance check lists

— have a suitable recording system for the results

— have a properly operating feedback system to their national authorities organisation for POA and the manufacturer

— maintain an effective working relationship with the manufacturer and his staff

— be able to communicate effectively

GM 21.B.235(b) Maintenance of the POA - Work allocation within the competent authority

ED Decision 2012/020/R

After issue of the approval the competent authority should appoint a suitable member of its technical staff as the POATL to be in charge of the approval for the purpose of continued surveillance.

Where the POA holder facilities are located in more than one Member State the competent authority of the State of manufacture will liaise with the competent authorities of the various partners/members to ensure appropriate continued surveillance.

GM 21.B.235(b) and (c) Continued surveillance

ED Decision 2012/020/R

Continued surveillance consists of:

1. Planned continued surveillance, in which the total surveillance actions are split into several audits, which are carried out at planned intervals during the validity period of the production organisation approval. Within the continued surveillance one aspect may be audited once or several times depending upon its importance.
2. Unplanned POA reviews, which are specific additional investigation of a POA holder related to surveillance findings or external needs. The competent authority is responsible for deciding when a review is necessary taking into account changes in the scope of work, changes in personnel, reports on the organisation performance submitted by other EASA or national authorities teams, reports on the in service product.

AMC 21.B.235(c) Continuation of POA

ED Decision 2012/020/R

At the end of the 24 months continued surveillance cycle the POATL responsible for the POA should complete an EASA Form 56 (see GM No 2 to 21.B.220(c)) as a summary report for the continued surveillance including the recommendation for continuation of the POA as applicable. The EASA Form 56 should be countersigned by the person responsible within the competent authority for his acceptance. At this stage there is no limitation to the number of level two findings that may be open, provided they are within the time limits of the respective corrective action plans.

21.B.240 Amendment of a production organisation approval [applicable until 6 March 2023] / 21.B.240 Changes in production management system [applicable from 7 March 2023 - Regulation (EU) 2022/203]

Regulation (EU) No 748/2012

(a) The competent authority shall monitor any minor change through the continued surveillance activities.

(b) The competent authority shall investigate as appropriate in accordance with point 21.B.220 any significant change of a production organisation approval or application by the holder of a production organisation approval for an amendment of the scope and terms of approval.

(c) When the competent authority is satisfied that the requirements of Section A, Subpart G continue to be complied with it shall amend the production organisation approval accordingly.

[applicable until 6 March 2023]

(a) Upon receiving an application for a significant change to the production management system, the competent authority shall verify the organisation's compliance with the applicable requirements of this Annex before issuing the approval.

(b) The competent authority shall establish the conditions under which the organisation may operate during the evaluation of a change unless the competent authority determines that the production organisation approval certificate needs to be suspended.

(c) When it is satisfied that the organisation complies with the applicable requirements, the competent authority shall approve the change.

(d) Without prejudice to any additional enforcement measures, if the organisation implements a significant change to the production management system without having received the approval of the competent authority pursuant to point (c), the competent authority shall consider the need to suspend, limit or revoke the organisation's certificate.

(e) For non-significant changes to the production management system, the competent authority shall include the review of such changes in its continuing oversight in accordance with the principles set forth in point 21.B.221. If any non-compliance is found, the competent authority shall notify the organisation, request further changes and act in accordance with point 21.B.225.

[applicable from 7 March 2023 - Regulation (EU) 2022/203]

AMC No 1 to 21.B.240 Application for significant changes or variation of scope and terms of the POA

ED Decision 2012/020/R

The competent authority must receive an application for significant changes or variation of scope and terms of the POA on an EASA Form 51 (see below) completed by the applicant.

EASA Form 51 **Application for significant changes or variation of scope and terms of Part 21 POA**		
Competent authority of an EU Member State or EASA		
1.	Name and address of the POA holder:	
2.	Approval reference number:	
3.	Locations for which changes in the terms of approval are requested:	
4.	Brief summary of proposed changes to the activities at the item 3 addresses: a) General: b) Scope of approval: c) Nature of privileges:	
5.	Description of organisational changes:	
6.	Position and name of the accountable manager or nominee:	
	_____ Date	_____ Signature of the accountable manager (or nominee)

EASA Form 51

Block 1: The name must be entered as written on the current approval certificate. Where a change in the name is to be announced state the old name and address here, while using Block 5 for the information about the new name and address. The change of name and/or address must be supported by evidence, e.g. by a copy of the entry in the register of commerce.

Block 2: State the current approval reference number.

Block 3: State the locations for which changes in the terms of approval are requested or state 'not applicable' if no change is to be anticipated here.

Block 4: This Block should include further details for the variation of the scope of approval for the addresses indicated in Block 3. The Block 'General' must include overall information for the change (including changes e.g. in workforce, facilities etc.), while the Block 'Scope of approval' must address the change in the scope of work and products/categories following the principles laid down in the GM 21.A.151. The Block 'nature of privileges' must indicate a change in the privileges as defined in 21.A.163(b)-(d). State 'not applicable' if no change is anticipated here.

Block 5: This Block must state the changes to the organisation as defined in the current production organisation exposition, including changes the organisational structure, functions and responsibilities. This Block must therefore also be used to indicate a change in the accountable manager in accordance with 21.A.145(c)(1) or a change in the nomination of the responsible managers in accordance with 21.A.145(c)(2). A change in the nomination of responsible managers must be accompanied by the corresponding EASA Forms 4. State 'not applicable' if no change is anticipated here.

Block 6: State the position and name of the accountable manager here. Where there is a change in the nomination of the accountable manager, the information must refer to the nominee for this position. State 'not applicable' if no change is anticipated here.

In case of an application for a change of the accountable manager the EASA Form 51 must be signed by the new nominee for this position. In all other cases the EASA Form 51 must be signed by the accountable manager.

AMC-ELA No 1 to 21.B.240 Amendment of a production organisation approval

ED Decision 2019/003/R

The competent authority should conduct adequate investigations in accordance with AMC-ELA No 1 to 21.B.220(c) prior to an amendment of the POA that is classified as a significant change. Refer to GM-ELA No 1 to 21.A.147.

Minor changes are monitored by the competent authority in the course of the regularly scheduled surveillance activities.

GM1 21.A.139, 21.A.157, 21.A.239, 21.A.257, 21.B.120, 21.B.140, 21.B.220, 21.B.235 and 21.B.240 The use of information and communication technologies (ICT) for performing remote audits

ED Decision 2021/007/R

This GM provides technical guidance on the use of remote information and communication technologies (ICT) to support:

— competent authorities when overseeing regulated organisations;

— regulated organisations when conducting internal audits / monitoring compliance of their organisation with the relevant requirements, and when evaluating vendors, suppliers and subcontractors.

In the context of this GM:

— 'remote audit' means an audit that is performed with the use of any real-time video and audio communication tools in lieu of the physical presence of the auditor on-site; the specificities of each type of approval / letter of agreement (LoA) need to be considered in addition to the general overview (described below) when applying the 'remote audit' concept;

— ‘auditing entity’ means the competent authority or organisation that performs the remote audit;

— ‘auditee’ means the entity being audited/inspected (or the entity audited/inspected by the auditing entity via a remote audit);

It is the responsibility of the auditing entity to assess whether the use of remote ICT constitutes a suitable alternative to the physical presence of an auditor on-site in accordance with the applicable requirements.

The conduct of a remote audit

The auditing entity that decides to conduct a remote audit should describe the remote audit process in its documented procedures and should consider at least the following elements:

— The methodology for the use of remote ICT is sufficiently flexible and non-prescriptive in nature to optimise the conventional audit process.

— Adequate controls are defined and are in place to avoid abuses that could compromise the integrity of the audit process.

— Measures to ensure that the security and confidentiality are maintained throughout the audit activities (data protection and intellectual property of the organisation also need to be safeguarded).

Examples of the use of remote ICT during audits may include but are not limited to:

— meetings by means of teleconference facilities, including audio, video and data sharing;

— assessment of documents and records by means of remote access, in real time;

— recording, in real time during the process, of evidence to document the results of the audit, including non-conformities, by means of exchange of emails or documents, instant pictures, video or/and audio recordings;

— visual (livestream video) and audio access to facilities, stores, equipment, tools, processes, operations, etc.

An agreement between the auditing entity and the auditee should be established when planning a remote audit, which should include the following:

— determining the platform for hosting the audit;

— granting security and/or profile access to the auditor(s);

— testing platform compatibility between the auditing entity and the auditee prior to the audit;

— considering the use of webcams, cameras, drones, etc., when the physical evaluation of an event (product, part, process, etc.) is desired or is necessary;

— establishing an audit plan which will identify how remote ICT will be used and the extent of their use for the audit purposes to optimise their effectiveness and efficiency while maintaining the integrity of the audit process;

— if necessary, time zone acknowledgement and management to coordinate reasonable and mutually agreeable convening times;

— a documented statement of the auditee that they shall ensure full cooperation and provision of the actual and valid data as requested, including ensuring any supplier or subcontractor cooperation, if needed; and

— data protection aspects.

The following equipment and set-up elements should be considered:

— the suitability of video resolution, fidelity, and field of view for the verification being conducted;

— the need for multiple cameras, imaging systems, or microphones, and whether the person that performs the verification can switch between them, or direct them to be switched and has the possibility to stop the process, ask a question, move the equipment, etc.;

— the controllability of viewing direction, zoom, and lighting;

— the appropriateness of audio fidelity for the evaluation being conducted; and

— real-time and uninterrupted communication between the person(s) participating to the remote audit from both locations (on-site and remotely).

When using remote ICT, the auditing entity and the other persons involved (e.g. drone pilots, technical experts) should have the competence and ability to understand and utilise the remote ICT tools employed to achieve the desired results of the audit(s)/assessment(s). The auditing entity should also be aware of the risks and opportunities of the remote ICT used and the impacts they may have on the validity and objectivity of the information gathered.

Audit reports and related records should indicate the extent to which remote ICT have been used in conducting remote audits and the effectiveness of remote ICT in achieving the audit objectives, including any item that it has not been able to be completely reviewed.

21.B.245 Suspension and revocation of a production organisation approval

Regulation (EU) No 748/2012

(a) In case of a level one or level two finding, the competent authority shall partly or fully limit, suspend or revoke a production organisation approval as follows:

1. in case of a level one finding the production organisation approval shall be immediately limited or suspended. If the holder of the production organisation approval fails to comply with point 21.A.158(c)(1), the production organisation approval shall be revoked;

2. in case of a level two finding, the competent authority shall decide on any restriction to the scope of approval by temporary suspension of the production organisation approval or parts thereof. If the holder of a production organisation approval fails to comply with point 21.A.158(c)(2), the production organisation approval shall be revoked.

(b) The limitation, suspension or revocation of the production organisation approval shall be communicated in writing to the holder of the production organisation approval. The competent authority shall state the reasons for the suspension or revocation and inform the holder of the production organisation approval of its right to appeal.

(c) When a production organisation approval has been suspended it shall only be reinstated after compliance with Section A, Subpart G has been re-established.

[applicable until 6 March 2023 – Regulation (EU) 2022/203]

AMC-ELA No 1 to 21.B.245 Suspension and revocation of a production organisation approval

ED Decision 2019/003/R

If there is a level 1 finding and the competent authority intends to limit the production organisation approval (POA), the competent authority should not limit the possibility for the manufacturer to issue or release conformity certificates unless it is absolutely necessary to do so. In that case, the competent authority may apply conditions for the issue or release of conformity certificates.

GM 21.B.245 Continued validity

ED Decision 2012/020/R

1. GENERAL

   Decisions on restriction, surrender, suspension or revocation of POA will always be actioned in such a way as to comply with any applicable national laws or regulations relating to appeal rights and the conduct of appeals, unless the decision has been taken by the Agency. In such case, the Agency appeal procedures will apply.

2. RESTRICTION is temporary withdrawal of some of the privileges of a POA under 21.A.163.

3. SURRENDER is a permanent cancellation of a production organisation approval by the competent authority upon formal written request by the accountable manager of the organisation concerned. The organisation effectively relinquishes its rights and privileges granted under the approval and, after cancellation, may not make certifications invoking the approval and must remove all references to the approval from its company documentation.

4. SUSPENSION is temporary withdrawal of all the privileges of a production organisation approval under 21.A.163. The approval remains valid but no certifications invoking the approval may be made while the suspension is in force. Approval privileges may be re-instated when the circumstances causing the suspension are corrected and the organisation once again can demonstrate full compliance with the Requirements.

5. REVOCATION is a permanent and enforced cancellation of the whole of an approval by the competent authority. All rights and privileges of the organisation under the approval are withdrawn and, after revocation, the organisation may not make any certifications or other statements invoking the approval and must remove all references to the approval from its company documentation.

AMC 21.B.245 Corrective action plan

ED Decision 2012/020/R

It is expected that any established POA holder will move quickly to re-establish compliance with Part 21 and not risk the possibility of approval suspension. Therefore, the corrective action period granted by the competent authority must be appropriate to the nature of the finding but in any case initially must not be more than six months. In certain circumstances and subject to the nature of the finding the competent authority can vary the six months period subject to a satisfactory corrective action plan agreed by the competent authority.

Failure to comply within time scale agreed by the competent authority means that provisional suspension of the POA in whole or in part must proceed.

21.B.260 Record-keeping

Regulation (EU) No 748/2012

(a) The competent authority shall establish a system of record-keeping that allows adequate traceability of the process to issue, maintain, amend, suspend or revoke each individual production organisation approval.

(b) The records shall at least contain:

1. the documents provided by the applicant for, or holder of, a production organisation approval certificate;
2. documents established during the investigation, in which the activities and the final results of the elements defined in point 21.B.220 are stated, including findings established in accordance with point 21.B.225;
3. the continued surveillance programme, including records of investigations performed;
4. the production organisation approval certificate, including changes;
5. minutes of the meetings with the holder of the production organisation approval.

(c) The records shall be archived for a minimum retention period of six years.

[applicable until 6 March 2023 – Regulation (EU) 2022/201 and Regulation (EU) 2022/203]

SUBPART H — CERTIFICATES OF AIRWORTHINESS AND RESTRICTED CERTIFICATES OF AIRWORTHINESS

21.B.320 Investigation

Regulation (EU) No 748/2012

(a) The competent authority of the Member State of registry shall perform sufficient investigation activities for an applicant for, or holder of, an airworthiness certificate to justify the issuance, maintenance, amendment, suspension or revocation of the certificate or permit.

(b) The competent authority of the Member State of registry shall prepare evaluation procedures covering at least the following elements:

1. evaluation of eligibility of the applicant;
2. evaluation of the eligibility of the application;
3. classification of airworthiness certificates;
4. evaluation of the documentation received with the application;
5. inspection of aircraft;
6. determination of necessary conditions, restrictions or limitations to the airworthiness certificates.

GM 21.B.320(b)(6) Investigation

ED Decision 2012/020/R

1. Determination of necessary conditions, restrictions and/or limitations on the airworthiness certificate issued by a Member State

The competent authority of the Member State of registry may issue under its own legislation a document to list and identify all necessary conditions, restrictions and limitations that result from the investigation by the Agency and/or from the legislation of the competent authority of the Member State of registry. This document could take the form of an addendum to the approved flight manual or operating instruction or comparable document and should be referenced in Block 5 (limitations/remarks) of the appropriate certificate of airworthiness.

21.B.325 Issue of airworthiness certificate [applicable until 6 March 2023] / 21.B.325 Issuance of airworthiness certificate [applicable from 7 March 2023 - Regulation (EU) 2022/203]

Regulation (EU) 2022/203

(a) The competent authority of the Member State of registry shall issue or change a certificate of airworthiness (EASA Form 25, see Appendix VI) without undue delay when it is satisfied that the requirements of point 21.B.326 and the applicable requirements of Section A of Subpart H of this Annex I (Part 21) are met.

(b) The competent authority of the Member State of registry shall issue or change a Restricted certificate of airworthiness (EASA Form 24, see Appendix V) without undue delay when it is satisfied that requirements of point 21.B.327 and the applicable requirements of Section A of Subpart H of this Annex I (Part 21) are met.

(c) For new aircraft, and used aircraft originating from a non-member State, in addition to the appropriate airworthiness certificate referred to in point (a) or (b), the competent authority of the Member State of registry shall issue:

1. for aircraft subject to Annex I (Part-M) to Commission Regulation (EU) No 1321/2014, an initial airworthiness review certificate (EASA Form 15a, Appendix II);

2. for new aircraft subject to Annex Vb (Part-ML) to Commission Regulation (EU) No 1321/2014, an initial airworthiness review certificate (EASA Form 15c, Appendix II);

3. for used aircraft originating from a non-member State and subject to Annex Vb (Part-ML) to Commission Regulation (EU) No 1321/2014, an initial airworthiness review certificate (EASA Form 15c, Appendix II), when the competent authority has performed the airworthiness review.

GM 21.B.325(a) Airworthiness certificates

ED Decision 2012/020/R

1. Completion of the certificate of airworthiness by a Member State

Block 5: Insert restrictions developed in accordance with Part 21, including any reference to limitations as indicated in GM 21.B.320(b)(6).

2. Completion of the restricted certificate of airworthiness by a Member State

Block 5: Insert restrictions developed in accordance with Part 21, including any reference to limitations as indicated in GM 21.B.320(b)(6).

GM 21.B.325(b) Completion of the Airworthiness Review Certificate by a Member State

ED Decision 2012/020/R

1. Purpose

In accordance with the applicable continuing airworthiness requirements a certificate of airworthiness is valid only if a valid airworthiness review certificate is attached to it. For new aircraft, the competent authority will issue the airworthiness review certificate when issuing the certificate of airworthiness.

21.B.326 Certificate of airworthiness

Regulation (EU) 2020/570

The competent authority of the Member State of registry shall issue a certificate of airworthiness for:

(a) new aircraft:

1. upon presentation of the documentation required by point 21.A.174(b)(2);

2. where the competent authority of the Member State of registry is satisfied that the aircraft conforms to an approved design and is in a condition for safe operation; this may include inspections by the competent authority of the Member State of registry; and

3. where the competent authority of the Member State of registry is satisfied that the aircraft is in compliance with the applicable CO_2 emissions requirements on the date on which the certificate of airworthiness is first issued.

(b) used aircraft:

1. upon presentation of the documentation required by point 21.A.174(b)(3) demonstrating that:

(i) the aircraft conforms to a type design approved under a type-certificate and any supplemental type- certificate, change or repair approved in accordance with this Annex I (Part 21) and;

(ii) the applicable airworthiness directives have been complied with and;

(iii) the aircraft has been inspected in accordance with the provisions of Annex I (Part-M) or Annex Vb (Part-ML) of Regulation (EU) No 1321/2014, as appropriate;

(iv) the aircraft was in compliance with the applicable CO_2 emissions requirements on the date on which the certificate of airworthiness was first issued;

2. where the competent authority of the Member State of registry is satisfied that the aircraft conforms to an approved design and is in a condition for safe operation; this may include inspections by the competent authority of the Member State of registry and

3. where the competent authority of the Member State of registry is satisfied that the aircraft was in compliance with the applicable CO_2 emissions requirements on the date on which the certificate of airworthiness was first issued.

21.B.327 Restricted certificate of airworthiness

Regulation (EU) 2020/570

(a) The competent authority of the Member State of registry shall issue a restricted certificate of airworthiness for:

1. new aircraft:

(i) upon presentation of the documentation required by point 21.A.174(b)(2);

(ii) when the competent authority of the Member State of registry is satisfied that the aircraft conforms to a design approved by the Agency under a restricted type-certificate or in accordance with specific airworthiness specifications, and is in a condition for safe operation. This may include inspections by the competent authority of the Member State of registry;

2. used aircraft:

(i) upon presentation of the documentation required by point 21.A.174(b)(3) demonstrating that:

(A) the aircraft conforms to a design approved by the Agency under a restricted type-certificate or in accordance with specific airworthiness specifications and any supplemental type-certificate change or repair approved in accordance with this Annex I (Part 21); and

(B) the applicable airworthiness directives have been complied with; and

(C) the aircraft has been inspected in accordance with the provisions of Annex I (Part-M) or Annex Vb (Part-ML) of Regulation (EU) No 1321/2014, as appropriate.

(ii) when the competent authority of the Member State of registry is satisfied that the aircraft conforms to the approved design and is in a condition for safe operation. This may include inspections by the competent authority of the Member State of registry.

(b) For an aircraft that cannot comply with the essential requirements referred to in Regulation (EC) No 216/2008 and which is not eligible for a restricted type-certificate, the Agency shall, as necessary to take account of deviations from these essential requirements:

1. issue and check compliance with specific airworthiness specifications ensuring adequate safety with regard to the intended use, and

2. specify limitations for use of this aircraft.

(c) Limitations for use will be associated with restricted certificates of airworthiness, including airspace restrictions, as necessary to take account of deviations from essential requirements for airworthiness laid down in Regulation (EC) No 216/2008.

21.B.330 Suspension and revocation of certificates of airworthiness and restricted certificates of airworthiness

Regulation (EU) No 748/2012

(a) Upon evidence that any of the conditions specified in point 21.A.181(a) is not met, the competent authority of the Member State of registry shall suspend or revoke an airworthiness certificate.

(b) Upon issuance of the notice of suspension and revocation of a certificate of airworthiness or restricted certificate of airworthiness the competent authority of the Member State of registry shall state the reasons for the suspension or revocation and inform the holder of the certificate of its right to appeal.

[applicable until 6 March 2023 – Regulation (EU) 2022/203]

21.B.345 Record-keeping

Regulation (EU) No 748/2012

(a) The competent authority of the Member State of registry shall establish a system of record-keeping that allows adequate traceability of the process to issue, maintain, amend, suspend or revoke each individual airworthiness certificate.

(b) The records shall at least contain:

1. the documents provided by the applicant;

2. documents established during the investigation, in which the activities and the final results of the elements defined in point 21.B.320(b) are stated; and

3. a copy of the certificate or permit, including amendments.

(c) The records shall be archived for a minimum retention period of six years after leaving that national register.

[applicable until 6 March 2023 – Regulation (EU) 2022/203]

SUBPART I — NOISE CERTIFICATES

21.B.420 Investigation

Regulation (EU) No 748/2012

(a) The competent authority of the Member State of registry shall perform sufficient investigation activities for an applicant for, or holder of, a noise certificate to justify the issuance, maintenance, amendment, suspension or revocation of the certificate.

(b) The competent authority of the Member State of registry shall prepare evaluation procedures as part of the documented procedures covering at least the following elements:

1. evaluation of eligibility;
2. evaluation of the documentation received with the application;
3. inspection of aircraft.

21.B.425 Issue of noise certificates [applicable until 6 March 2023] / 21.B.425 Issuance of noise certificates [applicable from 7 March 2023 - Regulation (EU) 2022/201]

Regulation (EU) No 748/2012

The competent authority of the Member State of registry shall, as applicable, issue, or amend noise certificates (EASA Form 45, see Appendix VII) without undue delay when it is satisfied that the applicable requirements of Section A, Subpart I are met.

GM 21.B.425(a) Noise certificates

ED Decision 2016/003/R

1. Completion of the noise certificate by a Member State

1.1 Completion instructions

Block 1. State of registry

The name of the State issuing the noise certificate. This item should match the corresponding information on the certificate of registration and certificate of airworthiness.

Block 2. Noise certificate

The title of the EASA Form 45 is ‘Noise Certificate’

Block 3. Document No

A unique number, issued by the State of registry that identifies this particular document in their administration. Such a number will facilitate any enquiries with respect to the document.

Block 4. Registration marks

The nationality or common mark and registration marks as issued by the State of registry in accordance with Annex 7 to the Chicago Convention[1]. This item should match the corresponding information on the certificate of registration and certificate of airworthiness.

Block 5. Manufacturer and manufacturer's designation of aircraft

The type and model of the subject aircraft. This item should match the corresponding information on the certificate of registration and certificate of airworthiness.

Block 6. Aircraft serial No

The aircraft serial number as given by the manufacturer of the aircraft. This item should match the corresponding information on the certificate of registration and certificate of airworthiness.

Block 7. Engine

The designation of the installed engine(s) for identification and verification of the aircraft configuration. It should contain the type and model of the subject engine(s). The designation should be in accordance with the type certificate or supplemental type certificate for the subject engine(s).

Block 8. Propeller

The designation of the installed propeller(s) for identification and verification of the aircraft configuration. It should contain the type and model of the subject propeller(s). The designation should be in accordance with the type certificate or supplemental type certificate for the subject propeller(s). This item is included only in noise certification documentation for propeller driven aeroplanes.

Block 9. Maximum take-off mass (kg)

The maximum take-off mass associated with the certificated noise levels of the aircraft in kilograms. The unit (kg) should be specified explicitly in order to avoid misunderstanding. If the primary unit of mass for the State of manufacture of the aircraft is different from kilograms, the conversion factor used should be in accordance with Annex 5 to the Chicago Convention.

Block 10. Maximum landing mass (kg)

The maximum landing mass associated with the certificated noise levels of the aircraft in kilograms. The unit (kg) should be specified explicitly in order to avoid misunderstanding. If the primary unit of mass for the State of manufacture of the aircraft is different from kilograms, the conversion factor used should be in accordance with Annex 5 to the Chicago Convention. This item will only be included in the noise certification documentation for noise certificates issued under Chapter 2, 3, 4, 5, 12 and 14.

[1] The Convention on International Civil Aviation on 7 December 1944

Block 11. Noise certification standard

The chapter to which the subject aircraft is noise certificated. For Chapters 2, 8, 10 and 11, the section specifying the noise limits should also be included.

Block 12. Additional modifications incorporated for the purpose of compliance with the applicable noise certification standards

This item should contain as a minimum all additional modifications to the basic aircraft as defined by Blocks 5, 7 and 8 that are essential in order to meet the requirements of the chapter to which the aircraft is certificated as given under Block 11. Other modifications that are not essential to meet the stated chapter but are needed to attain the certificated noise levels as given may also be included at the discretion of the certificating authority. The additional modifications should be given using unambiguous references, such as supplemental type certificate (STC) numbers, unique part numbers or type/model designators given by the manufacturer of the modification.

Block 13. Lateral/full-power noise level

The lateral/full-power noise level as defined in the relevant chapter. It should specify the unit (e.g. EPNdB) of the noise level and the noise level should be stated to the nearest tenth of a decibel (dB). This item is included only in noise certification documentation for aircraft certificated to Chapters 2, 3, 4, 5, 12 and 14.

Block 14. Approach noise level

The approach noise level as defined in the relevant chapter. It should specify the unit (e.g. EPNdB) of the noise level and the noise level should be stated to the nearest tenth of a dB. This item is included only in noise certification documentation for aircraft certificated to Chapters 2, 3, 4, 5, 8, 12, 13 and 14.

Block 15. Flyover noise level

The flyover noise level as defined in the relevant chapter. It should specify the unit (e.g. EPNdB) of the noise level and the noise level should be stated to the nearest tenth of a dB. This item is included only in noise certification documentation for aircraft certificated to Chapters 2, 3, 4, 5, 12 and 14.

Block 16. Overflight noise level

The overflight noise level as defined in the relevant chapter. It should specify the unit (e.g. EPNdB or dB(A)) of the noise level and the noise level should be stated to the nearest tenth of a dB. This item is included only in noise certification documentation for aircraft certificated to Chapters 6, 8, 11 and 13. For tilt-rotors certificated according to Chapter 13 only the overflight noise level established in vertical take-off and landing (VTOL)/conversion mode needs to be stated.

Block 17. The take-off noise level

The take-off noise level as defined in the relevant chapter. It should specify the unit (e.g. EPNdB or dB(A)) of the noise level and the noise level should be stated to the nearest tenth of a dB. This item is included only in noise certification documentation for aircraft certificated to Chapters 8, 10 and 13.

Block 18. Statement of compliance, including reference to Annex 16 to the Chicago Convention, Volume I

The statement is provided in EASA Form 45.

Block 19. Date of issue

The date on which the document was issued.

Block 20. Signature

The signature of the officer issuing the noise certificate. Other items may be added such as seal, stamp etc.

Additional information:

1. Logo and name of the issuing authority

In order to facilitate recognition the logo or symbol and the name of the issuing authority may be added in the box 'For use by the State of registry'.

2. Language

States issuing their noise certification documentation in a language other than English should provide an English translation.

21.B.430 Suspension and revocation of a noise certificate

Regulation (EU) No 748/2012

(a) Upon evidence that some of the conditions specified in point 21.A.211(a) are not met, the competent authority of the Member State of registry shall suspend or revoke a noise certificate.

(b) Upon issuance of the notice of suspension and revocation of a noise certificate the competent authority of the Member State of registry shall state the reasons for the suspension and revocation and shall inform the holder of the certificate on its right to appeal.

[applicable until 6 March 2023 – Regulation (EU) 2022/201]

21.B.445 Record-keeping

Regulation (EU) No 748/2012

(a) The competent authority of the Member State of registry shall establish a system of record-keeping with minimum retention criteria that allows adequate traceability of the process to issue, maintain, amend, suspend or revoke each individual noise certificate.

(b) The records shall at least contain:

1. the documents provided by the applicant;
2. documents established during the investigation, in which the activities and the final results of the elements defined in point 21.B.420(b) are stated;
3. a copy of the certificate including amendments.

(c) The records shall be archived for a minimum retention period of six years after leaving that national register.

[applicable until 6 March 2023 – Regulation (EU) 2022/201]

SUBPART J — DESIGN ORGANISATION APPROVAL

Administrative procedures established by the Agency shall apply
[applicable until 6 March 2023 – Regulation (EU) 2022/201]

21.B.430 Initial certification procedure

Regulation (EU) 2022/201

(a) Upon receiving an application for the initial issue of a design organisation approval, the competent authority shall verify the applicant's compliance with the applicable requirements,

(b) A meeting with the head of the design organisation shall be convened at least once during the investigation for initial certification to ensure that this person understands their role and accountability.

(c) The competent authority shall record all the findings issued, closure actions as well as recommendations for the issue of the design organisation approval.

(d) The competent authority shall confirm to the applicant in writing all the findings raised during the verification. For initial certification, all findings must be corrected to the satisfaction of the competent authority before the design organisation approval can be issued.

(e) When satisfied that the applicant complies with the applicable requirements, the competent authority shall issue the design organisation approval.

(f) The certificate reference number shall be included in the design organisation approval in a manner specified by the Agency.

(g) The certificate shall be issued for an unlimited period of time. The privileges and the scope of the activities that the design organisation is approved to perform, including any limitations as applicable, shall be specified in the terms of approval attached to the design organisation approval.

[applicable from 7 March 2023 - Regulation (EU) 2022/201]

21.B.431 Oversight principles

Regulation (EU) 2022/201

The competent authority shall verify whether certified organisations continue to comply with the applicable requirements

(a) The verification shall:

1. be supported by documentation specifically intended to provide personnel responsible for oversight with guidance to perform their functions;
2. provide the organisations concerned with the results of oversight activities;
3. be based on assessments, audits, inspections and, if needed, unannounced inspections;
4. provide the competent authority with the evidence needed in case further action is required, including the measures provided for in point 21.B.433.

(b) The competent authority shall establish the scope of the oversight set out in point (a) taking into account the results of past oversight activities and the safety priorities.

(c) The competent authority shall collect and process any information deemed necessary for performing oversight activities.

[applicable from 7 March 2023 - Regulation (EU) 2022/201]

21.B.432 Oversight programme

Regulation (EU) 2022/201

(a) The competent authority shall establish and maintain an oversight programme covering the oversight activities required to comply with point 21.B.431(a).

(b) The oversight programme shall take into account the specific nature of the organisation, the complexity of its activities, the results of past certification or oversight activities, or both, and it shall be based on the assessment of the associated risks. It shall include, within each oversight planning cycle:

1. assessments, audits and inspections, including, where appropriate:

   (i) management system assessments and process audits;

   (ii) product audits of a relevant sample of the design and certification of the products, parts and appliances that are within the scope of work of the organisation;

   (iii) sampling of the work performed;

   (iv) unannounced inspections;

2. meetings convened between the head of the design organisation and the competent authority to ensure that both parties remain informed of all significant issues.

(c) The oversight planning cycle shall not exceed 24 months.

(d) Notwithstanding point (c), the oversight planning cycle may be extended to 36 months if the competent authority has established that during the previous 24 months:

1. the organisation has demonstrated that it can effectively identify aviation safety hazards and manage the associated risks;

2. the organisation has continuously demonstrated compliance with point 21.A.247 and has full control over all changes to the design management system;

3. no level 1 findings have been issued;

4. all corrective actions have been implemented within the time period that was accepted or extended by the competent authority as provided for in point 21.B.433(d).

   Notwithstanding point (c), the oversight planning cycle may be further extended to a maximum of 48 months if, in addition to the conditions laid down in points (d)(1) to (d)(4), the organisation has established, and the competent authority has approved, an effective continuous system for reporting to the competent authority on the safety performance and regulatory compliance of the organisation itself.

(e) The oversight planning cycle may be reduced if there is evidence that the safety performance of the organisation has decreased.

(f) The oversight programme shall include records of the dates when assessments, audits, inspections and meetings are due, and when assessments, audits, inspections and meetings have been effectively carried out.

(g) At the completion of each oversight planning cycle, the competent authority shall issue a recommendation report on the continuation of the approval, reflecting the results of the oversight.

[applicable from 7 March 2023 - Regulation (EU) 2022/201]

21.B.433 Findings and corrective actions; observations

Regulation (EU) 2022/201

(a) The competent authority shall have a system in place to analyse findings for their safety significance.

(b) A level 1 finding shall be issued by the competent authority when a non-compliance is detected with the applicable requirements of Regulation (EU) 2018/1139 and its delegated and implementing acts, with the organisation's procedures and manuals, or with the design organisation's certificate including the terms of approval, which may lead to uncontrolled non-compliances and to a potential unsafe condition.

The level 1 findings shall also include:

1. any failure to grant the competent authority access to the organisation's facilities referred to in point 21.A.9 during normal operating hours and after two written requests;
2. obtaining the design organisation approval or maintaining its validity by falsification of the submitted documentary evidence;
3. any evidence of malpractice or fraudulent use of the design organisation approval;
4. failure to appoint a head of the design organisation pursuant to point 21.A.245(a).

(c) A level 2 finding shall be issued by the competent authority when any non-compliance is detected with the applicable requirements of Regulation (EU) 2018/1139 and its delegated and implementing acts, with the organisation's procedures and manuals, or with the certificate including the terms of approval, which is not classified as a level 1 finding.

(d) When a finding is detected during oversight or by any other means, the competent authority shall, without prejudice to any additional action required by Regulation (EU) 2018/1139 and its delegated and implementing acts, communicate in writing the finding to the organisation and request corrective action to address the non- compliance(s) identified. Where a level 1 finding directly relates to a product, the competent authority shall inform the competent authority of the Member State in which the aircraft is registered.

1. If there are any level 1 findings, the competent authority shall:
   (i) grant the organisation a corrective action implementation period that is appropriate to the nature of the finding and that in any case shall not be more than 21 working days. That period shall commence from the date of the written communication of the finding to the organisation requesting corrective action to address the non-compliance(s) identified;
   (ii) assess the corrective action plan and implementation plan proposed by the organisation, and if it concludes that they are sufficient to address the non-compliance(s), accept them;
   (iii) if the organisation fails to submit an acceptable corrective action plan, or fails to perform the corrective action within the time period accepted by the competent authority, take immediate and appropriate action to prohibit or limit the activities

of the organisation involved and, if appropriate, take action to revoke the design organisation approval or to limit or suspend it in whole or in part, depending upon the extent of the level 1 finding, until successful corrective action has been taken by the organisation.

2. If there are any level 2 findings, the competent authority shall:

(i) grant the organisation a corrective action implementation period that is appropriate to the nature of the finding, and that in any case shall initially not be more than 3 months. That period shall commence from the date of the written communication of the finding requesting corrective action. At the end of this period, and subject to the nature of the finding, the competent authority may extend the 3-month period provided that a corrective action plan has been agreed by the competent authority;

(ii) assess the corrective action and the implementation plan proposed by the organisation, and if it concludes that they are sufficient to address the non-compliance(s), accept them;

(iii) if the organisation fails to submit an acceptable corrective action plan, or fails to perform the corrective action within the time period accepted or extended by the competent authority, the finding shall be raised to level 1 and action shall be taken as laid down in point (d)(1).

(e) The competent authority may issue observations for any of the following cases not requiring level 1 or level 2 findings:

1. for any item whose performance has been assessed to be ineffective;

2. when it has been identified that an item has the potential to cause a non-compliance under points (b) or (c);

3. when suggestions or improvements are of interest for the overall safety performance of the organisation.

The observations issued under this point shall be communicated in writing to the organisation and recorded by the competent authority.

[applicable from 7 March 2023 - Regulation (EU) 2022/201]

21.B.435 Changes in the design management system

Regulation (EU) 2022/201

(a) Upon receiving an application for a significant change to the design management system, the competent authority shall verify the organisation's compliance with the applicable requirements of Regulation (EU) 2018/1139 and its delegated and implementing acts, before issuing the approval.

(b) The competent authority shall establish the conditions under which the organisation may operate during the change unless the competent authority determines that the design organisation approval needs to be suspended.

(c) When it is satisfied that the organisation complies with the applicable requirements of Regulation (EU) 2018/1139 and its delegated and implementing acts, the competent authority shall approve the change.

(d) Without prejudice to any additional enforcement measures, if the organisation implements a significant change to the design management system without having received the approval of the competent authority pursuant to point (c), the competent authority shall consider the need to suspend, limit or revoke the organisation's certificate.

(e) For non-significant changes to the design management system, the competent authority shall include the review of such changes in its continuing oversight in accordance with the principles set forth in point 21.B.431. If any non-compliance is found, the competent authority shall notify the organisation, request further changes and act in accordance with point 21.B.433.

[applicable from 7 March 2023 - Regulation (EU) 2022/201]

SUBPART K — PARTS AND APPLIANCES

Administrative procedures established by the Agency shall apply

(SUBPART L — NOT APPLICABLE)

SUBPART M — REPAIRS

21.B.450 Type-certification basis and environmental protection requirements for a repair design approval

Regulation (EU) 2019/897

The Agency shall designate any amendments to the type-certification basis incorporated by reference in, as applicable, either the type-certificate, the supplemental type-certificate or the APU ETSO authorisation, which the Agency considers necessary for maintaining a level of safety equal to that previously established and notify them to the applicant for a repair design.

21.B.453 Issuance of a repair design approval

Regulation (EU) 2019/897

(a) The Agency shall issue an approval of a major repair design, provided that:

1. the applicant has demonstrated its capability in accordance with point 21.A.432B;
2. the applicant has complied with point 21.A.433;
3. the Agency, through its verification of the demonstration of compliance in accordance with the level of involvement established pursuant to point 21.B.100(a), has not found any non-compliance with the type-certification basis and environmental protection requirements; and
4. no feature or characteristic has been identified that may make the product unsafe for the uses for which certification is requested.

(b) The Agency shall issue an approval of a minor repair design, provided that the applicant has complied with points (2) and (4) of point (a) and provided that the Agency, through its verifications of the demonstration of compliance in accordance with the level of involvement pursuant to point 21.B.100(b), has not found any non-compliance with the type-certification basis and environmental protection requirements.

(SUBPART N — NOT APPLICABLE)

SUBPART O — EUROPEAN TECHNICAL STANDARD ORDER AUTHORISATIONS

21.B.480 Issuance of an ETSO authorisation

Regulation (EU) 2019/897

The Agency shall issue an ETSO authorisation, provided that:

(a) the applicant has complied with point 21.A.606;

(b) the Agency, through its verifications of the demonstration of compliance in accordance with the level of involvement pursuant to point 21.B.100(b), has not found any non-compliance with the technical conditions of the applicable ETSO or with deviations therefrom approved in accordance with point 21.A.610, if any; and

(c) no feature or characteristic has been identified that may make the article unsafe for the uses for which certification is requested.

SUBPART P — PERMIT TO FLY

21.B.520 Investigation

Regulation (EU) No 748/2012

(a) The competent authority shall perform sufficient investigation activities to justify the issuance, or revocation of the permit to fly.

(b) The competent authority shall prepare evaluation procedures covering at least the following elements:

1. evaluation of the eligibility of the applicant;
2. evaluation of the eligibility of the application;
3. evaluation of the documentation received with the application;
4. inspection of the aircraft;
5. approval of the flight conditions in accordance with point 21.A.710(b).

AMC 21.B.520(b) Application for a permit to fly

ED Decision 2012/020/R

The competent authority must receive an application for permit to fly in a form and manner established by that authority, e.g. on EASA Form 21 (see below) completed by the applicant.

Application for Part 21 Permit to Fly	
1. Applicant:	*[Name of applicant]*
2. Aircraft nationality and identification marks:	
3. Aircraft owner:	
4. Aircraft manufacturer/type	**5. Serial number**
6. Purpose of flight *[Use terminology of 21.A.701(a) and add any additional information for accurate description of the purpose, e.g. place, itinerary, duration…]* [For an application due to a change of purpose (ref. 21.A.713): reference to initial request and description of new purpose]	
7. Expected target date(s) for the flight(s) and duration	
8. Aircraft configuration as relevant for the permit to fly 8.1 The above aircraft for which a permit to fly is requested is defined in [add reference to the document(s) identifying the configuration of the aircraft. Same as required in AMC 21.A.263(c)(6) or AMC 21.A.709(b) application approval form 18A or 18B, box 6] 8.2 The aircraft is in the following situation related to its maintenance schedule: *[Describe status]*	

9. Approval of flight conditions *[if not available at the time of application, indicate reference of request for approval]* *[Reference to:* *1. EASA approval, if flight conditions are approved by EASA; or* *2.* DOA approval form (see AMC 21.A.263(c)(6)), if approved under DOA privilege; or *3. Competent authority approval.*	
10. Date:	**11. Name and signature:** *[Authorised signatory]*

EASA Form 21

21.B.525 Issue of permits to fly [applicable until 6 March 2023] / 21.B.525 Issuance of a permit to fly [applicable from 7 March 2023 - Regulation (EU) 2022/203]

Regulation (EU) No 748/2012

The competent authority shall issue a permit to fly (EASA Form 20a, see Appendix III) without undue delay:

(a) upon presentation of the data required by point 21.A.707; and

(b) when the flight conditions referred to in point 21.A.708 have been approved in accordance with point 21.A.710; and

(c) when the competent authority, through its own investigations, which may include inspections, or through procedures agreed with the applicant, is satisfied that the aircraft conforms to the design defined under point 21.A.708 before flight.

21.B.530 Revocation of permits to fly

Regulation (EU) No 748/2012

(a) Upon evidence that any of the conditions specified in point 21.A.723(a) are not met for a permit to fly it has issued, the competent authority shall revoke that permit to fly.

(b) Upon issuance of the notice of revocation of a permit to fly the competent authority shall state the reasons for the revocation and inform the holder of the permit to fly on the right to appeal.

[applicable until 6 March 2023 – Regulation (EU) 2022/203]

21.B.545 Record-keeping

Regulation (EU) No 748/2012

(a) The competent authority shall operate a system of record-keeping that provides adequate traceability of the process for the issue and revocation of each individual permit to fly.

(b) The records shall at least contain:

1. the documents provided by the applicant;
2. documents established during the investigation, in which the activities and the final results of the elements defined in point 21.B.520(b) are stated; and
3. a copy of the permit to fly.

(c) The records shall be kept for a minimum of six years after the permit ceases to be valid.

[applicable until 6 March 2023 – Regulation (EU) 2022/203]

SUBPART Q — IDENTIFICATION OF PRODUCTS, PARTS AND APPLIANCES

Administrative procedures established by the Agency shall apply

APPENDICES TO ANNEX I

EASA FORMS

Regulation (EU) 2020/570

When the Forms of this Annex are issued in a language other than English they shall include an English translation.

The EASA ('European Aviation Safety Agency') Forms referred to in the appendices to this Part shall have the following obligatory features. Member States shall ensure that the EASA Forms they issue are recognisable and shall be responsible for having those Forms printed.

Appendix I — EASA Form 1 Authorised release Certificate

Appendix II — EASA Form 15a and 15c – Airworthiness Review Certificate

Appendix III — EASA Form 20a Permit to Fly

Appendix IV — EASA Form 20b Permit to Fly (issued by approved organisations)

Appendix V — EASA Form 24 Restricted Certificate of Airworthiness

Appendix VI — EASA Form 25 Certificate of Airworthiness

Appendix VII — EASA Form 45 Noise Certificate

Appendix VIII — EASA Form 52 Aircraft Statement of Conformity

Appendix IX — EASA Form 53 Certificate of Release to Service

Appendix X — EASA Form 55 Production Organisation Approval Certificate

Appendix XI — Letter of Agreement – EASA Form 65 [applicable until 6 March 2023] / Letter of agreement for production without a production organisation approval – EASA Form 65 [applicable from 7 March 2023 - Regulation (EU) 2022/201]

Appendix XII — Categories of flight tests and associated flight test crew qualifications 85

Appendix I — Authorised Release Certificate — EASA Form 1 referred to in Annex I (Part 21)

Regulation (EU) No 69/2014

<table>
<tr><td colspan="2">1. Approving Competent Authority / Country</td><td colspan="3">2. AUTHORISED RELEASE CERTIFICATE
EASA FORM 1</td><td>3. Form Tracking Number</td></tr>
<tr><td colspan="5">4. Organisation Name and Address:</td><td>5. Work Order/Contract/Invoice</td></tr>
<tr><td>6. Item</td><td>7. Description</td><td>8. Part No.</td><td>9. Qty.</td><td>10. Serial No.</td><td>11. Status/Work</td></tr>
<tr><td></td><td></td><td></td><td></td><td></td><td></td></tr>
<tr><td colspan="6">12. Remarks</td></tr>
<tr><td colspan="2">13a. Certifies that the items identified above were manufactured in conformity to:
□ approved design data and are in a condition for safe operation
□ non-approved design data specified in block 12</td><td colspan="4">14a □ Part-145.A.50 Release to Service □ Other regulation specified in block 12
Certifies that unless otherwise specified in block 12, the work identified in block 11 and described in block 12, was accomplished in accordance with Part-145 and in respect to that work the items are considered ready for release to service.</td></tr>
<tr><td colspan="2">13b. Authorised Signature</td><td colspan="2">13c. Approval/Authorisation Number</td><td>14b. Authorised Signature</td><td>14c. Certificate/Approval Ref. No.</td></tr>
<tr><td colspan="2">13d. Name</td><td colspan="2">13e. Date (dd mmm yyyy)</td><td>14d. Name</td><td>14e. Date (dd mmm yyyy)</td></tr>
<tr><td colspan="6">USER/INSTALLER RESPONSIBILITIES
This certificate does not automatically constitute authority to install the item(s).
Where the user/installer performs work in accordance with regulations of an airworthiness authority different than the airworthiness authority specified in block 1, it is essential that the user/installer ensures that his/her airworthiness authority accepts items from the airworthiness authority specified in block 1.
Statements in blocks 13a and 14a do not constitute installation certification. In all cases aircraft maintenance records must contain an installation certification issued in accordance with the national regulations by the user/installer before the aircraft may be flown.</td></tr>
</table>

EASA Form 1-21 Issue 2.

Instructions for the use of EASA Form 1

These instructions relate only to the use of the EASA Form 1 for production purposes. Attention is drawn to Appendix II to Annex I (Part M) of Regulation (EC) No 2042/2003 which covers the use of the EASA Form 1 for maintenance purposes.

1. PURPOSE AND USE

1.1. A primary purpose of the certificate is to declare the airworthiness of new aviation products, parts and appliances ('the item(s)').

1.2. Correlation must be established between the certificate and the item(s). The originator must retain a certificate in a form that allows verification of the original data.

1.3. The certificate is acceptable to many airworthiness authorities, but may be dependent on bilateral agreements and/or the policy of the airworthiness authority.

1.4. The certificate is not a delivery or shipping note.

1.5. Aircraft are not to be released using the certificate.

1.6. The certificate does not constitute approval to install the item on a particular aircraft, engine, or propeller but helps the end user determine its airworthiness approval status.

1.7. A mixture of production released and maintenance released items is not permitted on the same certificate.

1.8. A mixture of items certified in conformity with 'approved data' and to 'non-approved data' is not permitted on the same certificate.

2. GENERAL FORMAT

2.1. The certificate must comply with the format attached including block numbers and the location of each block. The size of each block may however be varied to suit the individual application, but not to the extent that would make the certificate unrecognisable.

2.2. The certificate must be in 'landscape' format but the overall size may be significantly increased or decreased so long as the certificate remains recognisable and legible. If in doubt consult the competent authority.

2.3. The User/Installer responsibility statement can be placed on either side of the form.

2.4. All printing must be clear and legible to permit easy reading.

2.5. The certificate may either be pre-printed or computer generated but in either case the printing of lines and characters must be clear and legible and in accordance with the defined format.

2.6. The certificate should be in English, and if appropriate, in one or more other languages.

2.7. The details to be entered on the certificate may be either machine/computer printed or hand-written using block letters and must permit easy reading.

2.8. Limit the use of abbreviations to a minimum, to aid clarity.

2.9. The space remaining on the reverse side of the certificate may be used by the originator for any additional information but must not include any certification statement. Any use of the reverse side of the certificate must be referenced in the appropriate block on the front side of the certificate.

3. COPIES

3.1. There is no restriction in the number of copies of the certificate sent to the customer or retained by the originator.

4. ERROR(S) ON A CERTIFICATE

4.1. If an end-user finds an error(s) on a certificate, he must identify it/them in writing to the originator. The originator may issue a new certificate if they can verify and correct the error(s).

4.2. The new certificate must have a new tracking number, signature and date.

4.3. The request for a new certificate may be honoured without re-verification of the item(s) condition. The new certificate is not a statement of current condition and should refer to the previous certificate in block 12 by the following statement: 'This certificate corrects the error(s) in block(s) [enter block(s) corrected] of the certificate [enter original tracking number] dated [enter original issuance date] and does not cover conformity/condition/release to service'. Both certificates should be retained according to the retention period associated with the first.

5. COMPLETION OF THE CERTIFICATE BY THE ORIGINATOR

Block 1 Approving competent authority/Country

State the name and country of the competent authority under whose jurisdiction this certificate is issued. When the competent authority is the Agency, only 'EASA' must be stated.

Block 2 EASA Form 1 header

'AUTHORISED RELEASE CERTIFICATE EASA FORM 1'

Block 3 Form Tracking Number

Enter the unique number established by the numbering system/procedure of the organisation identified in block 4; this may include alpha/numeric characters.

Block 4 Organisation Name and Address

Enter the full name and address of the production organisation (refer to EASA Form 55 Sheet A) releasing the item(s) covered by this certificate. Logos etc. of the organisation are permitted if they can be contained within the block.

Block 5 Work Order/Contract/Invoice

To facilitate customer traceability of the item(s), enter the work order number, contract number, invoice number, or similar reference number.

Block 6 Item

Enter line item numbers when there is more than one line item. This block permits easy cross-referencing to the Remarks in block 12.

Block 7 Description

Enter the name or description of the item. Preference should be given to the term used in the instructions for continued airworthiness or maintenance data (e.g. Illustrated Parts Catalogue, Aircraft Maintenance Manual, Service Bulletin, Component Maintenance Manual).

Block 8 Part Number

Enter the part number as it appears on the item or tag/packaging. In case of an engine or propeller the type designation may be used.

Block 9 Quantity

State the quantity of items.

Block 10 Serial Number

If the item is required by regulation to be identified with a serial number, enter it here. Additionally, any other serial number not required by regulation may also be entered. If there is no serial number identified on the item, enter 'N/A'.

Block 11 Status/Work

Enter either 'PROTOTYPE' or 'NEW'.

Enter 'PROTOTYPE' for:

(i) the production of a new item in conformity with non-approved design data;

(ii) re-certification by the organisation identified in block 4 of the previous certificate after alteration or rectification work on an item, prior to entry into service, (e.g. after incorporation of a design change, correction of a defect, inspection or test, or renewal of shelf-life.) Details of the original release and the alteration or rectification work are to be entered in block 12.

Enter 'NEW' for:

(i) the production of a new item in conformity with the approved design data;

(ii) re-certification by the organisation identified in block 4 of the previous certificate after alteration or rectification work on an item, prior to entry into service, (e.g. after incorporation of a design change, correction of a defect, inspection or test, or renewal of shelf-life.) Details of the original release and the alteration or rectification work are to be entered in block 12;

(iii) re-certification by the product manufacturer or the organisation identified in block 4 of the previous certificate of items from 'prototype' (conformity only to non-approved data) to 'new' (conformity to approved data and in a condition for safe operation), subsequent to approval of the applicable design data, provided that the design data has not changed. The following statement must be entered in block 12:

'RE-CERTIFICATION OF ITEMS FROM 'PROTOTYPE' TO 'NEW': THIS DOCUMENT CERTIFIES THE APPROVAL OF THE DESIGN DATA [INSERT TC/STC NUMBER, REVISION LEVEL], DATED [INSERT DATE IF NECESSARY FOR IDENTIFICATION OF REVISION STATUS], TO WHICH THIS ITEM (THESE ITEMS) WAS (WERE) MANUFACTURED.'

The box 'approved design data and are in a condition for safe operation' should be marked in block 13a;

(iv) the examination of a previously released new item prior to entry into service in accordance with a customer-specified standard or specification (details of which and of the original release are to be entered in block 12) or to establish airworthiness (an explanation of the basis of release and details of the original release are to be entered in block 12).

Block 12 Remarks

Describe the work identified in block 11, either directly or by reference to supporting documentation, necessary for the user or installer to determine the airworthiness of item(s) in relation to the work being certified. If necessary, a separate sheet may be used and referenced from the EASA Form 1. Each statement must clearly identify which item(s) in block 6 it relates to. If there is no statement, state 'None'.

Enter the justification for release to non-approved design data in block 12 (e.g. pending type-certificate, for test only, pending approved data).

If printing the data from an electronic EASA Form 1 any data not appropriate in other blocks should be entered in this block.

Block 13a Mark only one of the two boxes:

1. Mark the 'approved design data and are in a condition for safe operation' box if the item(s) was/were manufactured using approved design data and found to be in a condition for safe operation.

2. Mark the 'non-approved design data specified in block 12' box if the item(s) was/were manufactured using applicable non-approved design data. Identify the data in block 12 (e.g. pending type-certificate, for test only, pending approved data).

   Mixtures of items released against approved and non-approved design data are not permitted on the same certificate.

Block 13b Authorised Signature

This space shall be completed with the signature of the authorised person. Only persons specifically authorised under the rules and policies of the competent authority are permitted to sign this block. To aid recognition, a unique number identifying the authorised person may be added.

Block 13c Approval/Authorisation Number

Enter the approval/authorisation number/reference. This number or reference is issued by the competent authority.

Block 13d Name

Enter the name of the person signing block 13b in a legible form.

Block 13e Date

Enter the date on which block 13b is signed, the date must be in the format dd = 2 digit day, mmm = first 3 letters of the month, yyyy = 4 digit year.

Block 14a-14e General Requirements for blocks 14a-14e:

Not used for production release. Shade, darken, or otherwise mark to preclude inadvertent or unauthorised use.

User/Installer Responsibilities

Place the following statement on the certificate to notify end users that they are not relieved of their responsibilities concerning installation and use of any item accompanied by the form:

'THIS CERTIFICATE DOES NOT AUTOMATICALLY CONSTITUTE AUTHORITY TO INSTALL.

WHERE THE USER/INSTALLER PERFORMS WORK IN ACCORDANCE WITH REGULATIONS OF AN AIRWORTHINESS AUTHORITY DIFFERENT THAN THE AIRWORTHINESS AUTHORITY SPECIFIED IN BLOCK 1, IT IS ESSENTIAL THAT THE USER/INSTALLER ENSURES THAT HIS/HER AIRWORTHINESS AUTHORITY ACCEPTS ITEMS FROM THE AIRWORTHINESS AUTHORITY SPECIFIED IN BLOCK 1.

STATEMENTS IN BLOCKS 13A AND 14A DO NOT CONSTITUTE INSTALLATION CERTIFICATION. IN ALL CASES AIRCRAFT MAINTENANCE RECORDS MUST CONTAIN AN INSTALLATION CERTIFICATION ISSUED IN ACCORDANCE WITH THE NATIONAL REGULATIONS BY THE USER/INSTALLER BEFORE THE AIRCRAFT MAY BE FLOWN.'

Appendix II — EASA Form 15a and 15c — Airworthiness Review Certificate

Regulation (EU) 2021/699

[MEMBER STATE]

A Member of the European Union[1]

AIRWORTHINESS REVIEW CERTIFICATE

ARC reference: …….

Pursuant to Regulation (EU) 2018/1139 of the European Parliament and of the Council the [COMPETENT AUTHORITY OF THE MEMBER STATE] hereby certifies that the following aircraft:

Aircraft manufacturer: ……

Manufacturer's designation: ……

Aircraft registration: ……

Aircraft serial number: ……

is considered airworthy at the time of the review.

Date of issue: …… Date of expiry: ……

Airframe flight hours (FH) at date of issue[2]: ……

Signed: …… Authorisation No: ……

1st extension: The aircraft has remained in a controlled environment in accordance with point M.A.901 of Annex I (Part-M) to Commission Regulation (EU) No 1321/2014 for the last year. The aircraft is considered to be airworthy at the time of the issuance of this certificate.

Date of issue: …… Date of expiry: ……

Airframe flight hours (FH) at date of issue[1]: ……

Signed: …… Authorisation No: ……

Company Name: …… Approval reference: ……

2nd extension: The aircraft has remained in a controlled environment in accordance with point M.A.901 of Annex I (Part-M) to Commission Regulation (EU) No 1321/2014 for the last year. The aircraft is considered to be airworthy at the time of the issuance of the certificate.

Date of issue: …… Date of expiry: ……

Airframe flight hours (FH) at date of issue[1]: ……

Signed: …… Authorisation No: ……

Company Name: …… Approval reference: ……

EASA Form 15a – Issue 5

[1] Delete for non-EU Member States.

[2] Except for airships.

Airworthiness Review Certificate – EASA Form 15c

NOTE: persons and organisations performing the airworthiness review in combination with the 100-h/annual inspection may use the reverse side of this form in order to issue the CRS referred to in point ML.A.801 corresponding to the 100-h/annual inspection.

AIRWORTHINESS REVIEW CERTIFICATE (ARC) (for aircraft complying with Part-ML)

ARC reference: ……

Pursuant to Regulation (EU) 2018/1139 of the European Parliament and of the Council:

[NAME OF THE COMPETENT AUTHORITY] (**)

hereby certifies that:

☐…..it has performed an airworthiness review in accordance with Regulation (EU) No 1321/2014 on the following aircraft:

[or]

☐…..the following new aircraft:

Aircraft manufacturer:……Manufacturer's designation:……..

Aircraft registration:……Aircraft serial number:……..

(and that this aircraft) is considered airworthy at the time of the review.

Date of issue: .....Date of expiry: ……..

Airframe flight hours (FH) at date of review (*): ……..

Signed: .....Authorisation No (if applicable): ……

[OR]

[NAME OF APPROVED ORGANISATION, ADDRESS and APPROVAL REFERENCE] (**)

[or]

[FULL NAME OF THE CERTIFYING STAFF AND PART-66 LICENCE NUMBER (OR NATIONAL EQUIVALENT)] (**)

hereby certifies that it has performed an airworthiness review in accordance with Regulation (EU) No 1321/2014 on the following aircraft:

Aircraft manufacturer:……Manufacturer's designation:……..

Aircraft registration:……Aircraft serial number:……..

and that this aircraft is considered airworthy at the time of the review.

Date of issue: .....Date of expiry: ……..

Airframe flight hours (FH) at date of review (*): ……..

Signed: .....Authorisation No (if applicable): ……

==========

1st extension: The aircraft complies with the conditions of ML.A.901(c) of Annex Vb (Part-ML)

Date of issue: .....Date of expiry: ……..

Airframe flight hours (FH) at date of issue (*): ……..

Signed: .....Authorisation No: ……..

Company name: .....Approval reference: ……..

==========

2nd extension: The aircraft complies with the conditions of ML.A.901(c) of Annex Vb (Part-ML)

Date of issue: .....Date of expiry: ……

Airframe flight hours (FH) at date of issue (*): ……

Signed: .....Authorisation No: ……

Company name: .....Approval reference: ……

(*) Except for balloons and airships

(**) The issuer of the Form can tailor it to his need by deleting the name, the certifying statement, the reference to the subject aircraft and the issuance details that are not relevant for his use.

EASA Form 15c, Issue 4

Appendix III — Permit to Fly — EASA Form 20a

Regulation (EU) No 748/2012

Competent authority logo	**PERMIT TO FLY**

[1]	
This permit to fly is issued pursuant to Regulation (EC) No 216/2008, Article 5(4)(a) and certifies that the aircraft is capable of safe flight for the purpose and within the conditions listed below and is valid in all Member States This permit is also valid for flight to and within non-Member States provided separate approval is obtained from the competent authorities of such States:	1. Nationality and registration marks:
2. Aircraft manufacturer/type:	3. Serial No:
4. The permit covers: [purpose in accordance with 21.A.701(a)]	
5. Holder: [in case of a permit to fly issued for the purpose of 21.A.701(a)(15) this should state: 'the registered owner']	
6. Conditions/remarks:	
7. Validity period:	
8. Place and date of issue:	9. Signature of the competent authority representative:

EASA Form 20a

[1] For use by State of Registry.

Appendix IV — Permit to Fly (issued by approval organisations) — EASA Form 20b

Regulation (EU) No 748/2012

Member State of the Competent Authority having issued the organisation approval under which the permit to fly is issued; or 'EASA' when approval issued by EASA

PERMIT TO FLY

Name and Address of the organisation issuing the permit to fly	[1]
This permit to fly is issued pursuant to Regulation (EC) No 216/2008, Article 5(4)(a) and certifies that the aircraft is capable of safe flight for the purpose and within the conditions listed below and is valid in all Member States This permit is also valid for flight to and within non-Member States provided separate approval is obtained from the competent authorities of such States.	1. Nationality and registration marks:
2. Aircraft manufacturer/type:	3. Serial No:
4. The permit covers: [purpose in accordance with 21.A.701(a)	
5. Holder: *[Organisation issuing the permit to fly]*	
6. Conditions/remarks:	
7. Validity period:	
8. Place and date of issue:	9. Authorised signature: Name: Approval Reference No:

EASA Form 20b

[1] For use by Organisation Approval holder.

Appendix V — Restricted Certificate of Airworthiness — EASA Form 24

Regulation (EU) No 748/2012

Competent authority LOGO

RESTRICTED CERTIFICATE OF AIRWORTHINESS

[1]	[Member State of registry] [COMPETENT AUTHORITY OF THE MEMBER STATE]	[1]
1. Nationality and registration marks	2. Manufacturer and manufacturer's designation of aircraft	3. Aircraft serial number
4. Categories		
5. This Certificate of Airworthiness is issued pursuant to [2] [the Convention on International Civil Aviation dated 7 December 1944] and Regulation (EC) No 216/2008, Article 5(4)(b) in respect of the abovementioned aircraft which is considered to be airworthy when maintained and operated in accordance with the foregoing and the pertinent operating limitations. In addition to above the following restrictions apply: [1] [1] [The aircraft may be used in international navigation notwithstanding above restrictions].		
Date of issue:	Signature:	
6. This Restricted Certificate of Airworthiness is valid unless revoked by the competent authority of the Member State of registry. A current Airworthiness Review Certificate shall be attached to this certificate.		

EASA Form 24 Issue 2.

This certificate shall be carried on board during all flights

[1] For use by the State of Registry.

[2] Delete as applicable.

Appendix VI — Certificate of Airworthiness — EASA Form 25

Regulation (EU) No 748/2012

Competent authority LOGO

CERTIFICATE OF AIRWORTHINESS

[1]	[Member State of registry] [COMPETENT AUTHORITY OF THE MEMBER STATE]	[1]
1. Nationality and registration marks	2. Manufacturer and manufacturer's designation of aircraft	3. Aircraft serial number
4. Categories		
5. This Certificate of Airworthiness is issued pursuant to the Convention on International Civil Aviation dated 7 December 1944 and Regulation (EC) No 216/2008, Article 5(2)(c) in respect of the abovementioned aircraft which is considered to be airworthy when maintained and operated in accordance with the foregoing and the pertinent operating limitations. Limitations/Remark: [1] Date of issue: Signature:		
6. This Certificate of Airworthiness is valid unless revoked by the competent authority of the Member State of registry. A current Airworthiness Review Certificate shall be attached to this certificate.		

EASA Form 25 Issue 2.

This certificate shall be carried on board during all flights

[1] For use by the State of Registry.

Appendix VII — Noise Certificate — EASA Form 45

Regulation (EU) No 748/2012

For use by State of registry	1. **State of Registry**	3. Document No:
	2. NOISE CERTIFICATE	
4. Registration marks: …….	5. Manufacturer and manufacturer's designation of aircraft: ……	6. Aircraft serial No: ……
7. Engine: ……	8. Propeller:[1] ……	
9. Maximum take-off mass (kg) ……	10. Maximum landing mass (kg)[1] ……	11. Noise certification standard: ……
12. Additional modifications incorporated for the purpose of compliance with the applicable noise certification standards: ……		
13. Lateral/full-power noise level:[1] ……	14. Approach noise level[1] ……	15. Flyover noise level[1] ……
16. Overflight noise level[1] ……	17. Take-off noise level[1] ……	
Remarks		
18. This Noise Certificate is issued pursuant to Annex 16, Volume I to the Convention on International Civil Aviation dated 7 December 1944 and Regulation (EC) No 216/2008, Article 6 in respect of the abovementioned aircraft, which is considered to comply with the indicated noise standard when maintained and operated in accordance with the relevant requirements and operating limitations.		
19. Date of issue ……20. Signature ……		

EASA Form 45

[1] These boxes may be omitted depending on noise certification standard.

Appendix VIII — Aircraft statement of conformity — EASA Form 52

Regulation (EU) No 748/2012

AIRCRAFT STATEMENT OF CONFORMITY		
1. State of manufacture	2. [MEMBER STATE][1] A Member of the European Union[2]	3. Statement Ref No:
4. Organisation		
5. Aircraft Type	6. Type-certificate Refs:	
7. Aircraft Registration Or Mark	8. Manufacturers Identification No	
9. Engine/Propeller Details[3]		
10. Modifications and/or Service Bulletins[1]		
11. Airworthiness Directives		
12. Concessions		
13. Exemptions, Waivers or Derogations[1]		
14. Remarks		
15. Certificate of Airworthiness		
16. Additional Requirements		
17. Statement of Conformity It is hereby certified that this aircraft confirms fully to the type-certificated design and to the items above in boxes 9, 10, 11, 12 and 13. The aircraft is in a condition for safe operation. The aircraft has been satisfactorily tested in flight.		
18. Signed	19. Name	20. Date (d/m/y)
21. Production Organisation Approval Reference		

EASA Form 52 Issue 2.

Instructions for the use of the Aircraft Statement of Conformity EASA Form 52

1. PURPOSE AND SCOPE

1.1. Use of the aircraft Statement of Conformity issued by a manufacturer producing under Part 21 Section A Subpart F is described under point 21.A.130 and the corresponding acceptable means of compliance.

1.2. The purpose of the aircraft Statement of Conformity (EASA Form 52) issued under Part 21 Section A Subpart G is to enable the holder of an appropriate production organisation approval to exercise the privilege to obtain an individual aircraft certificate of airworthiness from the competent authority of the Member State of registry.

2. GENERAL

2.1. The Statement of Conformity must comply with the format attached including block numbers and the location of each block. The size of each block may however be varied to suit the individual application, but not to the extent that would make the Statement of Conformity unrecognisable. If in doubt consult the competent authority.

[1] Or EASA if EASA is the competent authority.

[2] Delete for non-EU Member States or EASA.

[3] Delete as applicable.

2.2. The Statement of Conformity must either be pre-printed or computer generated but in either case the printing of lines and characters must be clear and legible. Pre-printed wording is permitted in accordance with the attached model but no other certification statements are permitted.

2.3. Completion may be either machine/computer printed or hand-written using block letters to permit easy reading. English, and where relevant, one or more of the official language(s) of the issuing Member State are acceptable.

2.4. A copy of the Statement and all referenced attachments are to be retained by the approved production organisation.

3. COMPLETION OF THE STATEMENT OF CONFORMITY BY THE ORIGINATOR

3.1. There should be an entry in all blocks to make the document a valid statement.

3.2. A Statement of Conformity may not be issued to the competent authority of the Member State of registry unless the design of the aircraft and its installed products are approved.

3.3. The information required in blocks 9, 10, 11, 12, 13 and 14 may be by reference to separate identified documents held on file by the production organisation, unless the competent authority agrees otherwise.

3.4. This Statement of Conformity is not intended to include those items of equipment that may be required to be fitted in order to satisfy applicable operational rules. However, some of these individual items may be included in block 10 or in the approved type design. Operators are therefore reminded of their responsibility to ensure compliance with the applicable operational rules for their own particular operation.

Block 1 Enter name of the State of manufacture.

Block 2 The competent authority under which authority the Statement of Conformity is issued.

Block 3 A unique serial number should be pre-printed in this block for statement control and traceability purposes. Except that in the case of a computer generated document the number need not be pre-printed where the computer is programmed to produce and print a unique number.

Block 4 The full name and location address of the organisation issuing the statement. This block may be pre-printed. Logos etc. are permitted if the logo can be contained within the block.

Block 5 The aircraft type in full as defined in the type-certificate and its associated data sheet.

Block 6 The type-certificate reference numbers and issue for the subject aircraft.

Block 7 If the aircraft is registered then this mark will be the registration mark. If the aircraft is not registered then this will be such a mark that is accepted by the competent authority of the Member State and, if applicable, by the competent authority of a third country.

Block 8 The identification number assigned by the manufacturer for control and traceability and product support. This is sometimes referred to as a Manufacturers Serial No or Constructors No.

Block 9 The engine and propeller type(s) in full as defined in the relevant type-certificate and its associated data sheet. Their manufacturer identification No and associated location should also be shown.

Block 10 Approved design changes to the aircraft definition.

Block 11 A listing of all applicable airworthiness directives (or equivalent) and a declaration of compliance, together with a description of the method of compliance on the subject individual aircraft including products and installed parts, appliances and equipment. Any future compliance requirement time should be shown.

Block 12 Approved unintentional deviation to the approved type design sometimes referred to as concessions, divergences, or non-conformances.

Block 13 Only agreed exemptions, waivers or derogations may be included here.

Block 14 Remarks. Any statement, information, particular data or limitation which may affect the airworthiness of the aircraft. If there is no such information or data, state; 'NONE'.

Block 15 Enter 'Certificate of Airworthiness', or 'Restricted Certificate of Airworthiness', or for the Certificate of Airworthiness requested.

Block 16 Additional requirements such as those notified by an importing country should be noted in this block.

Block 17 Validity of the Statement of Conformity is dependent on full completion of all blocks on the form. A copy of the flight test report together with any recorded defects and rectification details should be kept on file by the POA holder. The report should be signed as satisfactory by the appropriate certifying staff and a flight crew member, e.g. test pilot or flight test engineer. The flight tests performed are those defined under the control of the quality system, as established by point 21.A.139 in particular 21.A.139(b)(1)(vi), to ensure that the aircraft conforms with the applicable design data and is in condition for safe operation.

The listing of items provided (or made available) to satisfy the safe operation aspects of this statement should be kept on file by the POA holder.

Block 18 The Statement of Conformity may be signed by the person authorised to do so by the production approval holder in accordance with point 21.A.145(d). A rubber stamp signature should not be used.

Block 19 The name of the person signing the certificate should be typed or printed in a legible form.

Block 20 The date the Statement of Conformity is signed should be given.

Block 21 The competent authority approval reference should be quoted.

[applicable until 6 March 2023]

AIRCRAFT STATEMENT OF CONFORMITY		
1. State of manufacture	2. [MEMBER STATE][1] A Member of the European Union[2]	3. Statement ref. no:
4. Organisation		
5. Aircraft type	6. Type-certificate ref. nos:	
7. Aircraft registration or mark	8. Production organisation identification no:	
9. Engine/propeller details[3]		
10. Modifications and/or service bulletins[4]		
11. Airworthiness directives		
12. Concessions		
13. Exemptions, waivers or derogations[5]		
14. Remarks		
15. Certificate of airworthiness		
16. Additional requirements		
17. Statement of conformity It is hereby certified that the aircraft conforms fully to the type-certificated design and to the items in blocks 9, 10, 11, 12 and 13. The aircraft is in a condition for safe operation. The aircraft has been satisfactorily tested in flight.		
18. Signed	19. Name	20. Date (d/m/y)
21. Production organisation approval reference		

EASA Form 52 - Issue 3

Instructions for the use of the "Aircraft statement of conformity – EASA Form 52"

1. PURPOSE AND SCOPE

1.1. The use of the aircraft statement of conformity issued by a production organisation that produces under Part 21 Section A Subpart F is described in point 21.A.130 and in the related acceptable means of compliance (AMC).

1.2. The purpose of the aircraft statement of conformity (EASA Form 52) issued under Part 21 Section A Subpart G is to enable the holder of an appropriate production organisation approval certificate to exercise the privilege to obtain an individual aircraft certificate of airworthiness and, if requested, a certificate of noise from the competent authority of the Member State of registry.

2. GENERAL

2.1. The statement of conformity must comply with the model, including the block numbers and the location of each block. The size of each block may, however, be varied to suit the individual application, but not to the extent that would render the statement of conformity unrecognisable. If in doubt, consult the competent authority.

[1] Or "EASA", if EASA is the competent authority.

[2] Delete for non-EU Member States or EASA.

[3] Delete as applicable.

[4] Delete as applicable.

[5] Delete as applicable.

2.2. The statement of conformity must be either preprinted or computer generated, but in either case, the printing of lines and characters must be clear and legible. Preprinted wording is permitted in accordance with the attached model, but no other certification statements are permitted.

2.3. The completion of the statement may be either machine/computer printed or handwritten, using block letters to allow for easy reading. English, and where relevant, one or more of the official language(s) of the issuing Member State, are acceptable.

2.4. A copy of the statement and all the referenced attachments are to be retained by the approved production organisation.

3. COMPLETION OF THE STATEMENT OF CONFORMITY BY THE ORIGINATOR

3.1. There must be an entry in all blocks to render the document a valid statement.

3.2. A statement of conformity may not be issued to the competent authority of the Member State of registry unless the design of the aircraft and its installed products are approved.

3.3. The information required in blocks 9, 10, 11, 12, 13 and 14 may be by reference to separate identified documents held on file by the production organisation, unless the competent authority agrees otherwise.

3.4. This statement of conformity is not intended to include those items of equipment that may be required to be fitted in order to satisfy the applicable operational rules. However, some of those individual items may be included in block 10 or in the approved type design. Operators are therefore reminded of their responsibility to ensure compliance with the applicable operational rules for their own particular operations.

Block 1 Enter the name of the State of manufacture.

Block 2 The competent authority that issues the statement of conformity under its authority.

Block 3 A unique serial number must be preprinted in this block for statement control and traceability purposes. An exception is in the case of a computer-generated document: the number need not be preprinted where the computer is programmed to produce and print a unique number.

Block 4 The full name and the address of the location of the organisation that issues the statement. This block may be preprinted. Logos, etc., are permitted if the logo, etc., can be contained within the block.

Block 5 The aircraft type in full as specified in the type-certificate and its associated data sheet.

Block 6 The type-certificate reference numbers and issue for the subject aircraft.

Block 7 If the aircraft is registered, then this mark will be the registration mark. If the aircraft is not registered, then this will be the mark that is accepted by the competent authority of the Member State and, if applicable, by the competent authority of a third country.

Block 8 The identification number assigned by the production organisation for control and traceability and product support purposes. This is sometimes referred to as a “production organisation serial number” or “constructor’s number”.

Block 9 The engine type and the propeller type(s) in full as specified in the relevant type-certificate and its associated data sheet. Their production organisation identification number and the associated location must also be stated.

Block 10 Approved design changes to the aircraft definition.

Block 11 A listing of all the applicable airworthiness directives (or equivalent) and a declaration of compliance, together with a description of the method of compliance of the subject individual aircraft, including products and installed parts, appliances and equipment. Any future compliance requirement time must be stated.

Block 12 Approved unintentional deviations from the approved type design, sometimes referred to as “concessions”, “divergences” or “non-conformances”.

Block 13 Only agreed exemptions, waivers or derogations may be included here.

Block 14 Remarks. Any statement, information, particular data or limitation which may affect the airworthiness of the subject aircraft. If there is no such information or data, state “NONE”.

Block 15 Enter “certificate of airworthiness”, or “restricted certificate of airworthiness”, as requested.

Block 16 Additional requirements such as those notified by an importing country must be noted in this block.

Block 17 The validity of the statement of conformity is subject to the full completion of all the blocks on the form. A copy of the flight test report, together with any recorded defects and rectification details, must be kept on file by the production organisation approval certificate holder. The report must be signed as satisfactory by the appropriate certifying staff and a flight crew member, e.g. the test pilot or the flight test engineer. The flight tests performed are those defined under the control of the quality management element of the production system, as established by point 21.A.139, in particular point 21.A.139(d)(1)(vi), to ensure that the aircraft conforms to the applicable design data, and is in condition for safe operation.

The listing of items provided (or made available) to satisfy the aspects of this statement that relate to the safe operation of the aircraft must be kept on file by the production organisation approval certificate holder.

Block 18 The statement of conformity may be signed by the person that is authorised to do so by the production approval holder in accordance with point 21.A.145(d). A rubber stamp signature must not be used.

Block 19 The name of the person that signs the statement must be typed or printed in a legible form.

Block 20 The date on which the statement of conformity is signed must be given.

Block 21 The competent authority approval reference must be quoted.

[applicable from 7 March 2023 - Regulation (EU) 2022/201]

Appendix IX — Certificate of release to service — EASA Form 53

Regulation (EU) No 748/2012

CERTIFICATE OF RELEASE TO SERVICE

[APPROVED PRODUCTION ORGANISATION NAME]

Production organisation approval Reference:

Certificate of release to service in accordance with 21.A.163(d)**.**

Aircraft: …… Type: …… Constructor No/Registration: ……

has been maintained as specified in Work Order: ……

Brief description of work performed:

Certifies that the work specified was carried out in accordance with 21.A.163(d) and in respect to that work the aircraft is considered ready for release to service and therefore is in a condition for safe operation.

Certifying Staff (name):

(signature):

Location:

Date: . . - . . - . . . . (day, month, year)

EASA Form 53

COMPLETION INSTRUCTIONS

The Block BRIEF DESCRIPTION OF WORK PERFORMED appearing in EASA FORM 53 should include reference to the approved data used to perform the work.

The Block LOCATION appearing in EASA FORM 53 refers to the location where the maintenance has been performed, not to the location of the facilities of the organisation (if different).

Appendix X — Production Organisation Approval Certificate — EASA Form 55

Regulation (EU) No 748/2012

Production Organisation Approval Certificates referred to in Subpart G of Annex I (Part 21)

[MEMBER STATE][1]

A Member of the European Union[2]

PRODUCTION ORGANISATION APPROVAL CERTIFICATE

Reference: [MEMBER STATE CODE[1]].21G.XXXX

Pursuant to Regulation (EC) No 216/2008 of the European Parliament and of the Council and to Commission Regulation [(EC) No 1702/2003] for the time being in force and subject to the condition specified below, the [COMPETENT AUTHORITY OF THE MEMBER STATE] hereby certifies:

[COMPANY NAME AND ADDRESS]

as a production organisation in compliance with Annex I (Part 21), Section A, Subpart G of Regulation [(EC) No 1702/2003], approved to produce products, parts and appliances listed in the attached approval schedule and issue related certificates using the above references.

CONDITIONS:

1. This approval is limited to that specified in the enclosed terms of approval, and
2. This approval requires compliance with the procedures specified in the approved production organisation exposition, and
3. This approval is valid whilst the approved production organisation remains in compliance with Annex I (Part 21) of Regulation [(EC) No 1702/2003].
4. Subject to compliance with the foregoing conditions, this approval shall remain valid for an unlimited duration unless the approval has previously been surrendered, superseded, suspended or revoked.

Date of original issue: ……

Date of this revision: ……..

Revision No: ……..

Signed: ……..

For the competent authority: [COMPETENTAUTHORITY IDENTIFICATION[1]]

EASA Form 55a issue 2.

[1] or EASA if EASA is the competent authority.

[2] Delete for non-EU Member States.

[MEMBER STATE][1] A Member of the European Union[2]	**Terms of Approval**	TA: [MEMBER STATE CODE[1]].21G.XXXX
This document is part of Production Organisation Approval Number [MEMBER STATE CODE[1]].21G.XXXX issued to: Company name:		
Section 1. **SCOPE OF WORK:**		
PRODUCTION OF	PRODUCTS/CATEGORIES	
For details and limitations refer to the Production Organisation Exposition, Section xxx		
Section 2. **LOCATIONS:**		
Section 3. **PRIVILEGES:**		
The Production Organisation is entitled to exercise, within its Terms of Approval and in accordance with the procedures of its Production Organisation Exposition, the privileges set forth in 21.A.163. Subject to the following:		
[keep only applicable text]		
Prior to approval of the design of the product an EASA Form 1 may be issued only for conformity purposes.		
A Statement of Conformity may not be issued for a non-approved aircraft		
Maintenance may be performed, until compliance with maintenance regulations is required, in accordance with the Production Organisation Exposition Section xxx		
Permits to fly may be issued in accordance with the Production Organisation Exposition Section yyy		
Date of original issue:	Signed:	
Date of this revision:		
Revision No.:	For [COMPETENT AUTHORITY IDENTIFICATION[1]]	

EASA Form 55b Issue 2.

[applicable until 6 March 2023]

[1] or EASA if EASA is the competent authority.

[2] Delete for non-EU Member States.

Production organisation approval certificates referred to in Subpart G of Annex I (Part 21)

[MEMBER STATE][1]

A Member of the European Union[2]

PRODUCTION ORGANISATION APPROVAL CERTIFICATE

Reference: [MEMBER STATE CODE[3]].21G.XXXX

Pursuant to Regulation (EU) 2018/1139 of the European Parliament and of the Council and to Commission Regulation (EU) No 748/2012, for the time being in force and subject to the conditions specified below, the [COMPETENT AUTHORITY OF THE MEMBER STATE] hereby certifies:

[COMPANY NAME AND ADDRESS]

as a production organisation in compliance with Annex I (Part 21) Section A of Regulation (EU) No 748/2012, is approved to produce products, parts and appliances listed in the attached approval schedule and issue the related certificates using the above references.

CONDITIONS:

1. This approval is limited to that specified in the enclosed terms of approval.
2. This approval is subject to compliance with the procedures specified in the approved production organisation exposition.
3. This approval is valid while the approved production organisation remains in compliance with Annex I (Part 21) to Regulation (EU) No 748/2012].
4. Subject to compliance with the foregoing conditions, this approval shall remain valid for an unlimited period of time unless it has previously been surrendered, superseded, suspended or revoked.

Date of original issue: .....

Date of this revision: .....

Revision No: .....

Signed: .....

For the competent authority: [COMPETENTAUTHORITY IDENTIFICATION[4]]

EASA Form 55a - Issue 3

1 Or “EASA”, if EASA is the competent authority.

2 Delete for non-EU Member States.

3 Or “EASA”, if EASA is the competent authority.

4 Or “EASA”, if EASA is the competent authority.

[MEMBER STATE][1] A Member of the European Union[2]	**Terms of Approval**	TA: [MEMBER STATE CODE[3]].21G.XXXX
This document is part of production organisation approval number [MEMBER STATE CODE[4]].21G.XXXX issued to: Company name:		
Section 1. **SCOPE OF WORK**:		
PRODUCTION OF	PRODUCTS/CATEGORIES	
For details and limitations, refer to the Production Organisation Exposition, Section xxx		
Section 2. **LOCATIONS**:		
Section 3. **PRIVILEGES**:		
The production organisation is entitled to exercise, within its terms of approval and in accordance with the procedures of its Production Organisation Exposition, the privileges laid down in point 21.A.163, subject to the following:		
[keep only applicable text]		
Prior to the approval of the design of the product, the EASA Form 1 may be issued only for conformity purposes.		
A statement of conformity may not be issued for a non-approved aircraft.		
Maintenance may be performed, until compliance with the maintenance regulations is required, in accordance with the Production Organisation Exposition Section xxx		
Permits to fly may be issued in accordance with the Production Organisation Exposition Section yyy		
Date of original issue:	Signed:	
Date of this revision:		
Revision No.:	For [COMPETENT AUTHORITY IDENTIFICATION[5]]	

EASA Form 55b - Issue 3

[applicable from 7 March 2023 - Regulation (EU) 2022/201]

1 Or "EASA", if EASA is the competent authority.

2 Delete for non-EU Member States.

3 Or "EASA", if EASA is the competent authority.

4 Or "EASA", if EASA is the competent authority.

5 Or "EASA", if EASA is the competent authority.

Appendix XI – Letter of Agreement – EASA Form 65 [applicable until 6 March 2023] / Letter of agreement for production without a production organisation approval – EASA Form 65 [applicable from 7 March 2023 - Regulation (EU) 2022/201]

Regulation (EU) No 748/2012

Letter of agreement referred to in Subpart F of Annex I (Part 21)

[MEMBER STATE][1]

A Member of the European Union[2]

LETTER OF AGREEMENT FOR PRODUCTION WITHOUT PRODUCTION ORGANISATION APPROVAL

[NAME OF THE APPLICANT]
[TRADE NAME (if different)]
[FULL ADDRESS OF THE APPLICANT]
Date (Day, Month, Year)
Reference: [MEMBER STATE CODE[1]].21F.XXXX

Dear Sirs,
Your production inspection system has been evaluated and found to be in compliance with Section A, Subpart F of Annex I (Part 21) of Regulation [(EC) No 1702/2003].

Therefore, subject to the conditions specified below, we agree that showing of conformity of products, parts and appliances mentioned below may be done under Section A, Subpart F of Annex I (Part 21) of Regulation [(EC) No 1702/2003].

No of Units	**P/N**	**S/N**

AIRCRAFT

PARTS

The following conditions are applicable to this agreement:

(1) It is valid whilst [Company Name] remains in compliance with Section A, Subpart F of Annex I (Part 21) of Regulation [(EC) No 1702/2003].

(2) It requires compliance with the procedures specified in [Company Name] Manual Ref./Issue date……

(3) It terminates on ……..

(4) The Statement of Conformity issued by [Company Name] under the provisions of point 21.A.130 of the abovementioned regulation shall be validated by the issuing authority of this letter of agreement in accordance with the procedure …… of the referenced manual.

(5) [Company Name] shall notify the issuing authority of this letter of agreement immediately of any changes to the production inspection system that may affect the inspection, conformity, or airworthiness of the products and parts listed in this letter.

For the competent authority: [COMPETENT AUTHORITY IDENTIFICATION [(1)]2]

[1] or EASA if EASA is the competent authority.

[2] Delete for non-EU Member States.

Date and Signature

EASA Form 65, Issue 2.

[applicable until 6 March 2023]

Letter of agreement referred to in Subpart F of Annex I (Part 21)

[MEMBER STATE][1]
A Member of the European Union[2]

LETTER OF AGREEMENT FOR PRODUCTION WITHOUT PRODUCTION ORGANISATION APPROVAL

[NAME OF THE APPLICANT]
[TRADE NAME (if different from the name of the applicant)]
[FULL POSTAL ADDRESS OF THE APPLICANT]
Date (Day, Month, Year)
Reference: [MEMBER STATE CODE[3]].21F.XXXX

Dear Mr/Ms [Name of the Applicant],
Your production inspection system has been evaluated and found to be in compliance with Section A, Subpart A and Subpart F of Annex I (Part 21) to Commission Regulation (EU) No 748/2012.

Therefore, subject to the conditions specified below, we agree that the showing of conformity of the products, parts and appliances mentioned below may be done under Section A, Subpart F of Annex I (Part 21) to Regulation (EU) No 748/2012.

No of Units	P/N	S/N

AIRCRAFT

PARTS

The following conditions are applicable to this letter of agreement:

(1) It is valid while [Company Name] remains in compliance with Section A, Subpart A and Subpart F of Annex I (Part 21) to Regulation (EU) No 748/2012.

(2) It requires compliance with the procedures specified in [Company Name] manual ref./issue date.....

(3) It terminates on .....

(4) The statement of conformity issued by [Company Name] under point 21.A.130 of Regulation (EU) No 748/2012 shall be validated by the issuing authority of this letter of agreement in accordance with the procedure..... of the referenced manual.

(5) [Company Name] shall notify the issuing authority of this letter of agreement immediately of any changes to the production inspection system that may affect the inspection, conformity or airworthiness of the products and parts listed in this letter.

For the competent authority: [COMPETENT AUTHORITY IDENTIFICATION[4][5]]

Date and Signature

1 Or "EASA", if EASA is the competent authority.

2 Delete for non-EU Member States.

3 Delete for non-EU Member States.

4 Or "EASA", if EASA is the competent authority.

5 Delete for non-EU Member States.

EASA Form 65 – Issue 3

[applicable from 7 March 2023 - Regulation (EU) 2022/201]

Appendix XII — Categories of flight tests and associated flight test crew qualifications

Regulation (EU) No 748/2012

A. General

This Appendix establishes the qualifications necessary for flight crew involved in the conduct of flight tests for aircraft certified or to be certified in accordance with CS-23 for aircraft with a maximum take-off mass (MTOM) of or above 2 000 kg, CS-25, CS-27, CS-29 or equivalent airworthiness codes.

B. Definitions

1. 'Flight test engineer' means any engineer involved in flight test operations either on the ground or in flight.

2. ‘Lead flight test engineer’ means a flight test engineer assigned for duties in an aircraft for the purpose of conducting flight tests or assisting the pilot in the operation of the aircraft and its systems during flight test activities.

3. ‘Flight tests’ mean:

3.1. flights for the development phase of a new design (aircraft, propulsion systems, parts and appliances);

3.2. flights to demonstrate compliance to certification basis or conformity to type design;

3.3. flights intended to experiment new design concepts, requiring unconventional manoeuvres or profiles for which it could be possible to exit the already approved envelope of the aircraft;

3.4. flight test training flights.

C. Categories of flight tests

1. General

The descriptions below address the flights performed by design and production organisations under Annex I (Part 21).

2. Scope

If more than one aircraft is involved in a test, each individual aircraft flight shall be assessed under this Appendix to determine if it is a flight test and when appropriate, its category.

The flights referred to in point (6)(B)(3) are the only flights that belong to the scope of this Appendix.

3. Categories of flight tests

Flights tests include the following four categories:

3.1. Category One (1)

(a) Initial flight(s) of a new type of aircraft or of an aircraft of which flight or handling characteristics may have been significantly modified;

(b) Flights during which it can be envisaged to potentially encounter flight characteristics significantly different from those already known;

(c) Flights to investigate novel or unusual aircraft design features or techniques;

(d) Flights to determine or expand the flight envelope;

(e) Flights to determine the regulatory performances, flight characteristics and handling qualities when flight envelope limits are approached;

(f) Flight test training for Category 1 flight tests.

3.2. Category Two (2)

(a) Flights not classified as Category 1 on an aircraft whose type is not yet certified;

(b) Flights not classified Category 1 on an aircraft of an already certified type, after embodiment of a not yet approved modification and which:

(i) require an assessment of the general behaviour of the aircraft; or

(ii) require an assessment of basic crew procedures, when a new or modified system is operating or is needed; or

(iii) are required to intentionally fly outside of the limitations of the currently approved operational envelope, but within the investigated flight envelope.

(c) Flight test training for Category 2 flight tests.

3.3. Category Three (3)

Flights performed for the issuance of statement of conformity for a new-built aircraft which do not require flying outside of the limitations of the type certificate or the aircraft flight manual.

3.4. Category Four (4)

Flights not classified as Category 1 or 2 on an aircraft of an already certified type, in case of an embodiment of a not yet approved design change.

D. Competence and experience of pilots and lead flight test engineers

1. General

Pilots and lead flight test engineers shall have the competences and experience specified in the following table.

	Categories of flight tests			
Aircraft	**1**	**2**	**3**	**4**
CS-23 commuter or aircraft having a design diving speed (Md) above 0.6 or a maximum ceiling above 7 260 m (25 000 ft), CS-25, CS-27, CS-29 or equivalent airworthiness codes	Competence level 1	Competence level 2	Competence level 3	Competence level 4
Other CS-23 with an MTOM of or above 2 000 kg	Competence level 2	Competence level 2	Competence level 3	Competence level 4

1.1 Competence level 1:

1.1.1 Pilots shall comply with the requirements of Annex I (Part-FCL) to Commission Regulation (EU) No 1178/2011 of 3 November 2011[1].

1.1.2 Lead flight test engineer shall have:

(a) satisfactorily completed a Competence level 1 training course; and

(b) a minimum of 100 hours of flight experience, including flight test training.

1.2 Competence level 2:

1.2.1 Pilots shall comply with the requirements of Annex I (Part-FCL) to Commission Regulation (EU) No 1178/2011 of 3 November 2011.

1.2.2 The lead flight test engineer shall have:

(a) satisfactorily completed a Competence level 1 or level 2 training course; and

(b) a minimum of 50 hours of flight experience, including flight test training.

The competence level 1 or level 2 training courses for Lead flight test engineer shall cover at least the following subjects:

(i) Performance;

(ii) Stability and control/handling qualities;

(iii) Systems;

(iv) Test management; and

(v) Risk/safety management.

1.3 Competence level 3:

1.3.1 Pilot(s) shall hold a valid licence appropriate to the category of aircraft under test, issued in accordance with Part-FCL and hold a Commercial Pilot Licence (CPL) as a minimum. In addition, the pilot-in-command shall:

(a) hold a flight test rating, or;

(b) have at least 1 000 hours of flight experience as pilot-in-command on aircraft having similar complexity and characteristics, and

(c) have participated, for each class or type of aircraft, in all flights that are part of the programme leading to the issuance of the individual certificate of airworthiness of at least five aircraft;

[1] Commission Regulation (EU) No 1178/2011 of 3 November 2011 laying down technical requirements and administrative procedures related to civil aviation aircrew pursuant to Regulation (EC) No 216/2008 of the European Parliament and of the Council (OJ L 311, 25.11.2011, p.1).

1.3.2 Lead flight test engineer shall:

(a) satisfy Competence level 1 or level 2, or;

(b) have gained a significant amount of flight experience relevant to the task; and

(c) have participated in all flights that are part of the programme leading to the issuance of the individual certificate of airworthiness of at least five aircraft.

1.4 Competence level 4:

1.4.1 Pilot(s) shall hold a valid licence appropriate to the category of aircraft under test, issued in accordance with Part-FCL and hold a CPL as a minimum. The pilot-in-command shall hold a flight test rating or have at least 1 000 hours as pilot-in-command on aircraft having similar complexity and characteristics.

1.4.2 Competence and experience for lead flight test engineers is defined in the flight test operations manual.

2. Lead flight test engineers

Lead flight test engineers shall receive an authorisation from the organisation that employs them detailing the scope of their functions within the organisation. The authorisation shall contain the following information:

(a) name;

(b) date of birth;

(c) experience and training;

(d) position in organisation;

(e) scope of the authorisation;

(f) date of first issue of the authorisation;

(g) date of expiry of the authorisation, if appropriate; and

(h) identification number of the authorisation.

Lead flight test engineers shall only be appointed for a specific flight if they are physically and mentally fit to safely discharge assigned duties and responsibilities.

The organisation shall make all relevant records related to authorisations available to their holders.

E. Competence and experience of other flight test engineers.

Other flight test engineers on board the aircraft shall have an amount of experience and training commensurate with the tasks assigned to them as crew members, and in accordance with the flight test operations manual, when applicable.

The organisation shall make all relevant records related to their flight activities available to the relevant flight test engineer.

AMC No 1 to Appendix XII – Training courses for Lead Flight Test Engineers (LFTEs)

ED Decision 2015/026/R

GENERAL

1. Competency-based training

1.1. LFTE training courses should be competency-based. The training programme should, as much as possible, follow the syllabus outlined below, but may be adapted taking into account the previous experience, skills and theoretical knowledge level of the students.

1.2. It should also be recognised that the syllabus below assume that suitable flight test experience will be gained subsequent to course attendance. Should the student be significantly experienced already, then consideration should be made of that experience and it is possible that the course content might be reduced in areas where that experience has been gained.

1.3. Furthermore, it should be noted that LFTE courses are specific both to a certain category of aircraft (aeroplanes or helicopters) and to a certain category of flight test (Category 1 or 2). Therefore, an LFTE wishing to extend their privileges to further categories of aircraft or to further categories of flight test (this is only relevant for someone having already undertaken a Category 2 course) should not be requested to undertake the same course as an 'ab initio applicant'. In these cases, the organisation providing the training should develop specific 'bridge courses' taking into account the same principles mentioned above.

1.4. To allow proper consideration of the student's previous experience, a pre-entry assessment of the student's skills should be undertaken on the basis of which the organisation providing the training may evaluate the level of the applicant in order to better tailor the course. Consequently, the syllabi listed below should be regarded as a list of individual demonstrable competencies and qualifications rather than a list of mandatory training objectives.

2. Continuous evaluation

2.1. Training courses should be built on a continuous evaluation model in order to ensure that successful completion of the course ensures that the student has reached the level of competence (both theoretical and practical) necessary to carry on their functions.

COURSE CONTENT

3. In addition, the content of the course should vary taking into account whether the student wants to undertake a Category 1 or Category 2 flight test, as well as the relevant category of aircraft, and their level of complexity. In order to better take these factors into account, LFTE training courses have been divided into levels similar to those for the pilot flight test rating.

3.1 Competence Level 1 courses apply to Category 1 flight tests on:

a. helicopters certified in accordance with the standards of CS-27 or CS-29 or equivalent airworthiness codes;

b. aeroplanes certified in accordance with:

(i) the standards of CS-25 or equivalent airworthiness codes; or

(ii) the standards of CS-23 or equivalent airworthiness codes within the commuter category or having a design diving speed (MD) above 0,6 or a maximum ceiling above 25 000 ft.

3.2 Competence Level 2 courses apply to:

a. Category 2 flight tests for:

(i) helicopters certified in accordance with the standards of CS-27 or CS-29 or equivalent airworthiness codes;

(ii) aeroplanes certified in accordance with:

— the standards of CS-25 or equivalent airworthiness codes; or

— the standards of CS-23 or equivalent airworthiness codes (including those mentioned in 3.1.b.(ii)), except for aeroplanes with a maximum take-off mass of less than 2 000 kg.

b. Category 1 flight tests for aeroplanes certified in accordance with the standards of CS-23, with a maximum take-off mass of 2 000 kg or above, with the exclusion of those mentioned in 3.1.b.(ii) (which are subject to competence Level 1 courses).

AEROPLANES

4. Competence Level 1 courses for aeroplanes

4.1. These courses should include approximately:

a. 350 hours of ground training; and

b. 60 hours of flight training, during which at least 10 flights should be made without an FTE tutor on board (i.e. unsupervised).

c. Principles of test management and risk and safety management should be integrated throughout the course. In addition, principles and methods applicable to the certification activity and safety assessments should be taught. A review of the principles of Crew Resource Management (CRM) tailored to the flight test environment should be included.

4.2. These courses should include instruction on at least six different aircraft types, of which at least one should be certified in accordance with CS-25 standards or equivalent airworthiness codes.

4.3. During the course, the student should be required to develop at least five substantial flight test reports.

4.4. The student should be evaluated through examinations on all of the theoretical knowledge subjects, and should undertake a final in-flight test upon completion of the syllabus.

4.5. Syllabus. The following subjects should be covered in the course:

COMPETENCE LEVEL 1 — AEROPLANES		
Theoretical knowledge	— Aerodynamics — Stability and control/handling qualities — Engines and performance — Measurements and flight test instrumentation (including telemetry) — Human factors	
Flight test techniques and flight training	Performance (at least one flight test report should be developed)	— Airspeed calibration — Climb multi-engine — Take-off and landing, including turboprop/turbofan one-engine-inoperative (OEI) — Level flight performance
	Engines	— Turboprop/turbofan limitations and relight envelope
	Handling qualities (at least two flight test reports should be developed)	— Flight controls characteristics — Longitudinal handling qualities — Longitudinal manoeuvre stability — Take-off and landing multi-turboprop/ turbofan, including Vmcg and Vmu — Lateral-directional handling qualities — Handling qualities evaluation — Variable stability demo flights including High-Order Flight Control Systems (HOFCS) — Stalls — Spins — Vmca
	Systems (at least one flight test report should be developed)	At least three different systems, for example: — Autopilot/Automatic Flight Control System (AFCS) — Glass cockpit evaluation — Radio navigation, instruments qualification and integrated avionics — Enhanced Ground Proximity Warning System (EGPWS) — ACAS
	High-speed certification test	
	Final evaluation exercise (a flight test report should be developed)	

5. Competence Level 2 courses for aeroplanes

5.1. These courses should include approximately:

a. 150 hours of ground training; and

b. 30 hours of flight training, during which at least 6 flights should be made without an FTE tutor on board (i.e. unsupervised).

c. Principles of test management and risk and safety management should be integrated throughout the course. In addition, principles and methods applicable to the certification activity and safety assessments should be taught. A review of the principles of CRM tailored to the flight test environment should be included.

5.2. These courses should include instruction on at least five different aircraft types, of which at least one should be certified in accordance with CS-25 standards or equivalent airworthiness codes.

5.3. During the course, the student should be required to develop at least three substantial flight test reports.

5.4. The student should be evaluated through examinations on all of the theoretical knowledge subjects, and should undertake a final in-flight test upon completion of the syllabus.

5.5. Syllabus. The following subjects should be covered in the course:

COMPETENCE LEVEL 2 — AEROPLANES		
Theoretical knowledge	— Aerodynamics — Stability and control/handling qualities — Engines and performance — Measurements and flight test instrumentation (including telemetry) — Human factors	
Flight test techniques and flight training	Performance (at least one flight test report should be developed)	— Airspeed calibration — Climb multi-engine — Take-off and landing multi-turboprop/ turbofan — Level flight performance
	Handling qualities	— Flight control characteristics — Longitudinal static/dynamic stability and control/handling qualities — Lateral-directional stability and control/ handling qualities — Stalls — Spins
	Systems (at least one flight test report should be developed)	At least three different systems, for example: — Autopilot/AFCS — Glass cockpit evaluation — Radio navigation, instruments qualification and integrated avionics — EGPWS — ACAS
	Final evaluation exercise (a flight test report should be developed)	

HELICOPTERS

6. Competence Level 1 courses for helicopters

6.1. These courses should include approximately:

a. 350 hours of ground training; and

b. 60 hours of flight training, during which at least 15 flights should be made without an FTE tutor on board (i.e. unsupervised).

c. Principles of test management and risk and safety management should be integrated throughout the course. In addition, principles and methods applicable to the certification activity and safety assessments should be taught. A review of the principles of CRM tailored to the flight test environment should be included.

6.2. These courses should include instruction on at least six different aircraft types, of which at least one should be certified in accordance with CS-29 standards or equivalent airworthiness codes.

6.3. During the course, the student should be required to develop at least five substantial flight test reports.

6.4. The student should be evaluated through examinations on all of the theoretical knowledge subjects, and should undertake a final in-flight test upon completion of the syllabus.

6.5. Syllabus. The following subjects should be covered in the course:

COMPETENCE LEVEL 1 — HELICOPTERS		
Theoretical knowledge	— Aerodynamics — Stability and control/handling qualities — Engines and performance — Measurements and flight test instrumentation (including telemetry) — Human factors	
Flight test techniques and flight training	Performance (at least one flight test report should be developed)	— Airspeed calibration — Level flight, climb and descent, vertical and hover performance
	Engines	— Digital engine governing — Turbine/piston engine evaluation
	Handling qualities (at least one flight test report should be developed)	— Flight control characteristics — Longitudinal static/dynamic stability and control/handling qualities — Lateral-directional stability and control/ handling qualities — ADS 33 — Rotor assessment with different control powers — Variable stability demo flights including High-Order Flight Control Systems (HOFCS)
	Systems (at least one flight test report should be developed)	At least three different systems, for example: — Navigation management systems — Auto-pilot/AFCS — Night-vision goggles/electro-optics — Glass cockpit evaluation
	Height/velocity envelope and Engine-Off Landings (EOL), including relights	
	Category A procedure	
	Vibrations and rotor adjustments	
	Autorotations	
	Final evaluation exercise (a flight test report should be developed)	

7. Competence Level 2 courses for helicopters.

7.1. These courses should include approximately:

a. 150 hours of ground training; and

b. 30 hours of flight training, during which at least 6 flights should be made without an FTE tutor on board (i.e. unsupervised);

c. Principles of test management and risk and safety management should be integrated throughout the course. In addition, principles and methods applicable to the certification activity and safety assessments should be taught. A review of the principles of CRM tailored to the flight test environment should be included.

7.2. These courses should include instruction on at least four different aircraft types, of which at least one should be certified in accordance with CS-29 standards or equivalent airworthiness codes.

7.3. During the course, the student should be required to develop at least three substantial flight test reports.

7.4. The student should be evaluated through examinations on all of the theoretical knowledge subjects, and should undertake a final in-flight test upon completion of the syllabus.

7.5. Syllabus. The following subjects should be covered in the course:

COMPETENCE LEVEL 2 — HELICOPTERS		
Theoretical knowledge	Aerodynamics Stability and control/handling qualities Engines and performance Measurements and flight test instrumentation (including telemetry) Human factors	
Flight test techniques and flight training	Performance (at least one flight test report should be developed)	— Airspeed calibration — Level flight, climb and descent, vertical and hover performance
	Engines	— Digital engines governing — Turbine/piston engine evaluation
	Handling qualities	— Flight control characteristics — Longitudinal static/dynamic stability and control/handling qualities — Lateral-directional stability and control/ handling qualities
	Systems (at least one flight test report should be developed)	At least three different systems, for example: — Navigation management systems — Auto-pilot/AFCS — Night-vision goggles/electro-optics — Glass cockpit evaluation
	Vibration and rotor adjustments	
	Final evaluation exercise (a flight test report should be developed)	

AMC No 2 to Appendix XII – Conditions for appointment of Lead Flight Test Engineers (LFTEs) – Medical fitness

ED Decision 2015/026/R

1. Before the organisation issues an authorisation for an LFTE, the LFTE should undergo an initial medical examination and assessment. Afterwards, the LFTE should be regularly (typically every 2 years) reassessed to ensure that they will remain physically and mentally fit to safely discharge their duties. These examinations and assessments should take due account of the actual flight environment of the intended flight test activity.
2. Any medical examination or assessment should be carried out according to best aero-medical practice by an aero-medical practitioner who has sufficient, detailed knowledge of the applicant's medical history.
3. The organisation should maintain a record of medical fitness for each LFTE.
4. These assessments should attest that the LFTE:
   a. is in good health;
   b. is free from any physical or mental illness which might lead to incapacitation or inability to perform crew duties;
   c. has normal cardiorespiratory function;
   d. has normal central nervous system;
   e. has adequate visual acuity 6/9 with or without glasses;
   f. has adequate hearing; and
   g. has normal function of ear, nose and throat.
5. If the LFTE holds a Class 1 or Class 2 medical certificate issued in accordance with Part-MED, the assessment or examination is not necessary.

AMC No 3 to Appendix XII – Demonstration of compliance with competence level 1 or level 2 requirements

ED Decision 2017/024/R

The design organisation could demonstrate compliance with the LFTE competence level 1 or level 2 training course Part 21 requirements using one of the following:

1. training carried out internally, established in accordance with AMC No 1 to Appendix XII under a procedure agreed with EASA;
2. a certificate of course completion for the training established in accordance with AMC No 1 to Appendix XII, issued by an approved training organisation under its privilege in accordance with ORA.ATO.355; or
3. a national document (i.e. licence) issued by an EASA Member State after 1 January 2018, under its national regulations, ensuring compliance with the competence requirements of Part 21.

GM No 1 to Appendix XII – Lead Flight Test Engineer (LFTE)

ED Decision 2015/026/R

LFTEs are Flight Test Engineers (FTEs) that have specific duties and privileges as a flight test crew member, to operate the test aircraft's systems either directly or through dedicated flight test instrumentation, that could significantly interfere with the aircraft basic systems (such as flight controls and engine controls), or that could significantly impact aircraft stability and control (e.g. through weight and balancing flight management or flight control configuration changes). As an example, an LFTE could be permitted to shut down the engines or change the engine parameters through controls which are not accessible to the pilots.

The word 'assisting' (the pilots) should be understood in the sense of the critical actions (e.g. actions described above) which could be performed by the LFTE, if requested by the flight test order and agreed by the pilot-in-command.

Flight test categories

The purpose of this GM is to help operators to:

— determine whether an operation is a flight test; and

— to classify the flight test.

Flight test categories are defined in Appendix XII to Part-21, and are described in this GM in such a manner that an operator who wishes to classify a flight, should first determine whether the flight is defined as a flight test according to the 'General' paragraph. The operator should then determine if the flight test falls within the definition of Category 1 before moving to Category 2 and so on throughout the list until the correct category is determined.

Other types of flights, such as maintenance check flights, are not included in the flights described in this GM and are, therefore, not subject to it.

a) General

The testing of aircraft performance, handling qualities and systems, including checking compliance with Certification Specifications (CSs), requires specialist techniques, skills and theoretical knowledge. Therefore, flight test training and specific experience is required to enable a test crew to:

— safely perform systematic and comprehensive flight envelope exploration;

— acquire specific skills and abilities for some particularly difficult tests;

— mitigate risks by anticipating potentially hazardous situations, and by applying methods that permit the safest flight possible in these situations;

— understand the relevant CSs; and

— learn methods to assess whether the aircraft or its systems comply with these regulations.

It should be noted that the content of the flight test determines its category, and the flight test category determines the required competence of the crew.

Nevertheless,

— flight tests of an aircraft which does not have a Type Certificate (TC) should be considered either as Category 1 or Category 2 flight test until the type has been certified; and

— flight tests for a modification of an already certified type may be Category 1, 2 or 4, depending on the purpose of the test.

The rationale for this difference is the fact that a new aircraft type is considered under continuous assessment until the TC is issued.

Cases where more than one aircraft is involved in a flight test point:

Chase flights are a typical example of flights in which more than one aircraft is involved. Every aircraft participating in the test point(s) should be evaluated through this classification. The guiding principle should be the role of the crew of the chase aircraft in the safety of the aircraft under test or of the formation.

b) Category 1 flight test

Below are examples of flight tests to be considered as Category 1:

— Fixed-wing aircraft: V_{MCG}, V_{MU}, spinning, initial stalling, or for rotary-wing aircraft: H/V diagrams and Category A engine failures.

— Where encounter of surprising or even hazardous flight characteristics can be expected.

— Upon determination, aircraft handling and performance in conditions where at least one of the following parameters is approaching the actual limits of the aircraft envelope: altitude, attitudes, weights, CG, speed/Mach, stalls, temperature, engine and aerofoil performance.

— Where the embodiment of new systems is anticipated to significantly affect the aircraft's handling or performance characteristics.

— When the crew of the chase aircraft has the duty to assist the test aircraft crew in recovering from a critical flight situation (i.e. assist the spinning aircraft crew in assessing the spin or triggering recovery actions).

c) Category 2 flight test

Below are examples of flight tests to be considered as Category 2:

— The flight test envelope has already been opened and it has been demonstrated that the general behaviour of the aircraft is adequately safe and there are no unsafe flight characteristics.

— All-engines-operating climb performance.

— Cruise performance.

— Static stability demonstration.

— Function and reliability flights.

— Systems tests of autopilot or guidance/warning systems such as Terrain Awareness and Warning System (TAWS) or Airborne Collision Avoidance System (ACAS), when the modes themselves are tested, requiring operating the aircraft by deviating from the standard operational procedures. Additionally, in the case of embodiment of such systems on an already certified aircraft, when the system integration in an existing

cockpit requires a more global crew procedure assessment — for example, when the system has been integrated in cockpit screens and a centralised warning system which requires a new cockpit procedure assessment (note that some system tests may fall under Category 4; see below).

d) Category 3 flight test

These flights are commonly referred to as production flight tests. They are performed on each new aircraft of a type that is already certified. The aim is to check that the aircraft and its systems are working properly and conform to the certified type. As the type is already certified, the behaviour of the aircraft is known.

However, experience has shown that during production flight tests of a new aircraft, unexpected failures can occur which could not be described in the Aircraft Flight Manual (AFM). For this reason, it is considered that special experience should be required.

It should be noted that a TC or a Supplemental Type Certificate (STC) should have been issued in order for a production flight test to be considered as Category 3. Until a TC or STC is issued, any flight, including production flight tests, will be Category 1, 2 or 4 according to classification criteria.

It should be noted also that if the flight of an aircraft with a TC or STC requires flying outside the AFM limitations, then this flight should be considered as Category 1 or Category 2 flight.

e) Category 4 flight test

Typical Category 4 flights are those required by a DOA to demonstrate compliance with the airworthiness requirements of 'not yet approved data':

- cabin conversion;
- zonal drying system installation;
- Emergency Locator Transmission (ELT) installation;
- new cabin installation;
- cabin aircraft location pictorial system installation;
- new entertainment system installation;
- SATCOM and telephone installation; and
- new radio equipment installation.

Category 4 includes also flights after embodiment of guidance/warning systems which are not Category 2 and for which:

- good functioning test only is required; and
- there is no need to fly the aircraft outside the AFM limitations.

The modification should not affect the behaviour of the aircraft in any way.

However, there may be modifications whose tests, despite the fact that they have no influence on the behaviour of the aircraft, require flying in conditions which deviate significantly from the standard operational use of the aircraft. These unusual flight test conditions may require classifying the flight as Category 2, as mentioned above. The typical example to consider here is the approval of the modification of an already certified TAWS system. In this situation, it is required to fly at very low altitude and/or towards high terrain. Such a flight can be classified as Category 4 flight on a light aircraft (or helicopter) because that flight test is performed in a

domain corresponding to the normal operation of the aircraft, whereas the same flight performed with a heavy CS-25 aircraft, especially if it needs to be flown in clean configuration significantly below gear and flaps warning heights, should be classified as Category 2 because such a flight does not correspond to the normal use of the aircraft and needs to adopt specific testing procedures as demonstrated in the Category 2 training.

GM No 2 to Appendix XII – Competence and experience of pilots for Category 3 and Category 4 flight tests and of Lead Flight Test Engineers (LFTEs)

ED Decision 2015/026/R

Definition of similar 'complexity and characteristics':

Similar 'complexity and characteristics' for aircraft can normally be assumed for aircraft of the same category and in the same class, and certified under the same CSs, e.g. CS-23/CS-25. However, it could be considered that aircraft certified under different CSs but having small difference in weight and operating procedure (e.g. Citation 525/Citation 550, 560) have similar complexity and characteristics.

Flight experience of LFTEs:

The flight experience includes experience as a crew member in flight tests or other flights (e.g. flights as a student pilot or with a pilot licence).

GM No 3 to Appendix XII. Demonstration of compliance with competence level 1 or level 2 requirements

ED Decision 2017/024/R

It is the organisation's responsibility to show proof of compliance with the competence requirements of Part 21 defined in AMC No 3 to Appendix XII.

ANNEX II

Repealed Regulation with list of its successive amendments

Commission Regulation (EC) No 1702/2003	(OJ L 243, 27.9.2003, p. 6)
Commission Regulation (EC) No 381/2005	(OJ L 61, 8.3.2005, p. 3)
Commission Regulation (EC) No 706/2006	(OJ L 122, 9.5.2006, p. 16)
Commission Regulation (EC) No 335/2007	(OJ L 88, 29.3.2007, p. 40)
Commission Regulation (EC) No 375/2007	(OJ L 94, 4.4.2007, p. 3)
Commission Regulation (EC) No 287/2008	(OJ L 087, 29.3.2008, p. 3)
Commission Regulation (EC) No 1057/2008	(OJ L 283, 28.10.2008, p. 30)
Commission Regulation (EC) No 1194/2009	(OJ L 321, 8.12.2009, p. 5)

ANNEX III

Regulation (EU) No 748/2012

Regulation (EC) No 1702/2003	This Regulation
Article 1(1)	Article 1(1)
Article 1(2)	Article 1(2), points (a) to (h)
-	Article 1(2), points (i) and (j)
Article 2(1) and (2)	Article 2(1) and (2)
Article 2(3)	-
Article 2a(1), introductory wording	Article 3(1), introductory wording
Article 2a(1), points (a) and (b)	Article 3(1), points (a) and (b)
Article 2a(1), points (c) and (d)	-
Article 2a (2) to (5)	Article 3(2) to (5)
Article 2b	Article 4
Article 2c(1)	Article 5
Article 2c(2) and (3)	-
Article 2d	Article 6
Article 2e, first paragraph	Article 7
Article 2e, second paragraph	-
Article 3(1), (2) and the first sentence of point 3	Article 8(1), (2) and (3)
Article 3(3) second sentence, (4) and (5)	-
Article 3(6)	-
Article 4(1), (2) and the first sentence of point 3	Article 9(1), (2) and (3)
Article 4(3) second sentence, (4), (5) and (6)	-
-	Article 10
-	Article 11
Article 5(1)	Article 12
Article 5(2) to (5)	-
Annex	Annex I
-	Annex II
-	Annex III