

ANNEX TO ED DECISION 2022/021/R

Acceptable Means of Compliance (AMC) and Guidance Material (GM) to Annex I (Part 21) to Commission Regulation (EU) No 748/2012

Issue 2, Amendment 14

Annex I to ED Decision 2012/020/R is amended as laid down in this Annex.

The text of the amendment is arranged to show deleted text, new or amended text as shown below:

- deleted text is ~~struck through~~;
- new or amended text is highlighted in **blue**;
- an ellipsis '[...]' indicates that the rest of the text is unchanged.

Note to the reader

In amended, and in particular in existing (that is, unchanged) text, 'Agency' is used interchangeably with 'EASA'. The interchangeable use of these two terms is more apparent in the consolidated versions. Therefore, please note that both terms refer to the 'European Union Aviation Safety Agency (EASA)'.

ANNEX I (PART 21)

GM1 Annex I Definitions

For the purpose of the Acceptable Means of Compliance (AMC) and Guidance Material (GM) to Annex I (Part 21) to Regulation (EU) No 748/2012, the following definitions apply:

Audit	<p>It refers to a systematic, independent, and documented process for obtaining evidence and objectively evaluating it to determine the extent to which the requirements are complied with.</p> <p><i>Note: audits may include inspections.</i></p>
Assessment	<p>In the context of management system performance monitoring, continuous improvement, and oversight, it refers to a planned and documented activity that is performed by competent personnel to evaluate and analyse the achieved level of performance and maturity in relation to the organisation's policy and objectives.</p> <p><i>Note: an assessment focuses on desirable outcomes and the overall performance, looking at the organisation as a whole. The main objective of the assessment is to identify the strengths and weaknesses to drive continual improvement.</i></p> <p><i>Remark: for 'risk assessment', please refer to the definition below.</i></p>
Certificate	<p>It is any certificate, approval, licence, authorisation, attestation or other document that is issued as the outcome of the certification process, which attests compliance with the applicable requirements.</p>
Competency	<p>It is a combination of individual skills, practical and theoretical knowledge, attitude, training, and experience.</p>
Correction	<p>It is the action to eliminate detected non-compliance.</p>
Corrective action	<p>It is the action to eliminate or mitigate the root cause(s) and prevent the recurrence of existing detected non-compliance, or of any other undesirable condition or situation. Proper determination of the root cause(s) is crucial for defining effective corrective action to prevent reoccurrence.</p>
Error	<p>It is a person's action or inaction that may lead to deviations from the accepted procedures or regulations.</p> <p><i>Note: errors are often associated with occasions when a planned sequence of mental or physical activities either fails to achieve its</i></p>

	<i>intended outcome, or is not appropriate with regard to the intended outcome, and when results cannot be attributed purely to chance.</i>
Fatigue	It is a physiological state of reduced mental or physical performance capability, resulting from sleep loss or extended wakefulness, circadian phase, or workload (mental and/or physical activity), which can impair a person's alertness and ability to safely perform their tasks.
Hazard	It is a condition or an object with the potential to cause, or contribute to, an aircraft incident or accident.
Human factors (HF)	It is anything that affects human performance, which means principles that apply to aeronautical activities, and which seek safe interface between the human and other system components by proper consideration of human performance (ref. ICAO Doc 10151 — Human Performance (HP) Manual for Regulators ¹).
Human performance (HP)	It refers to human capabilities and limitations that have an impact on the safety and efficiency of aeronautical activities (ref. ICAO Doc 10151 — Human Performance (HP) Manual for Regulators ²).
Inspection	<p>In the context of compliance monitoring and oversight, it refers to an independent and documented conformity evaluation by observation and judgement, which is accompanied, as appropriate, by measurements, testing or gauging, in order to verify compliance with the applicable requirements.</p> <p><i>Note: inspection may be part of an audit (e.g. product audit), but may also be conducted outside the normal audit plan; for example, to verify the closure of a particular finding.</i></p>
'Just culture'	Ref. Article 2 of Regulation (EU) No 376/2014 ³ .
Near miss	It is an event in which an occurrence to be mandatorily reported according to Regulation (EU) No 376/2014 was narrowly averted or avoided.

¹ ICAO Document 10151 'Manual on Human Performance (HP) for Regulators', First Edition, 2021.

² Ibid.

³ 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) (<https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX%3A32014R0376&qid=1669377456448>).

	<p><i>Example: a staff member, on rechecking their work at the end of a task, realises that one work card step was not properly carried out.</i></p>
Organisational factor	<p>It is a condition that affects the effectiveness of safety risk controls, and is related to the culture, policies, processes, resources, and the workplace of an organisation.</p>
Oversight planning cycle	<p>It refers to the time frame within which the areas of the approval and the processes that are identified through a risk assessment should be reviewed by the competent authority by means of audits and inspections.</p>
Oversight programme	<p>It refers to the detailed oversight schedule that defines the number of audits and other activities, including the scope and duration of each activity, as well as the details of product audits and locations, as appropriate, to be performed by the competent authority, and to the tentative time frame for performing each activity.</p>
Preventive action	<p>It is the action to eliminate the cause of potential non-compliance, or any other undesirable potential situation.</p>
Risk assessment	<p>It is an evaluation that is based on engineering and operational judgement and/or analysis methods in order to establish whether the achieved or perceived risk is acceptable or tolerable.</p>
Safety culture	<p>It is an enduring set of values, norms, attitudes, and practices within an organisation, which is concerned with minimising the exposure of the workforce and the general public to dangerous or hazardous conditions. In a positive safety culture, a shared concern for, commitment to, and accountability for, safety is promoted.</p>
Safety risk	<p>It refers to the predicted probability and severity of the consequences or outcomes of a hazard.</p>
Safety training	<p>It refers to dedicated training to support safety management policies and processes, including HF training.</p> <p><i>Note 1: the main objective of the safety training programme is to ensure that personnel at all levels of the organisation maintain their competency to fulfil their roles safely. Safety training should, in particular, consider the safety knowledge that is derived from hazard identification and risk management processes, and foster a positive safety culture.</i></p>

	<i>Note 2: safety management training refers to specific training for the staff that are involved in safety management functions in accordance with points 21.A.139(c) and 21.A.239(c) of Part 21.</i>
Working days	It refers to days between, and including, Monday and Friday, except public holidays.

GM2 Annex I Abbreviations

For the purpose of the AMC and GM to Part 21, the following abbreviations apply:

AFM	Aircraft flight manual
AMC	Acceptable means of compliance
APU	Auxiliary power unit
CEO	Chief executive officer
CMR	Certification maintenance requirement
CofA	Certificate of airworthiness
CRI	Certification review item
CS	Certification specification
CS-CCD	Certification Specifications for Cabin Crew Data
CS-FCD	Certification Specifications for Operational Suitability Data (OSD) Flight Crew Data
CS-GEN-MMEL	Certification Specifications for Generic Master Minimum Equipment List
CS-MMEL	Certification Specifications for Master Minimum Equipment List
CS-MCSD	Certification Specifications for Maintenance Certifying Staff Data
CS-SIMD	Certification Specifications for Simulator Data
DAH	Design approval holder
DO	Design organisation
DOA	Design organisation approval
EDTO	Extended diversion time operation
ELOS	Equivalent level of safety

ESF	Equivalent safety finding
ETSO	European technical standard order
FOD	Foreign object damage
HDO	Head of the design organisation
ICAO	International Civil Aviation Organization
ICA	Instructions for continued airworthiness
OP	Other party
OSD	Operational suitability data
PAH	Production approval holder
PO	Production organisation
POA	Production organisation approval
POATL	Production organisation approval team leader
POE	Production organisation exposition
GM	Guidance material
MoC	Means of compliance
RCofA	Restricted certificate of airworthiness
RTC	Restricted type certificate
SC	Special condition
SMS	Safety management system
STC	Supplemental type certificate
TC	Type certificate
TCDS	Type certificate data sheet

GM1 21.1 Competent authority

RESPONSIBILITY FOR THE IMPLEMENTATION OF PART 21

Each certificate or approval in accordance with Part 21, Section A, Subparts F, G, H, I, and P is normally issued and overseen by the competent authority of the Member State in which the applicant or holder is located. Therefore, to ensure consistency between the competent authorities of the Member States in issuing certificates and approvals, the implementation of Part 21 should be based on the following three principles:

- (a) the establishment and maintenance of an effective organisation and of the corresponding processes by the competent authorities;
- (b) the operation of the competent authorities in accordance with Part 21 and the AMC and GM thereto; and
- (c) a standardisation process that is established and applied by EASA to assess the standard(s) achieved, and to provide timely advice and guidance to the competent authorities.

As a result, the responsibility for implementation of Part 21 has 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 that there is sufficient visibility of the processes, to give EASA and the Member States the necessary confidence in the certificates or approvals granted.

GM1 21.1(e) Competent authority

PERMIT TO FLY

An aircraft that is registered in a Member State is under the responsibility of that Member State regarding continuing-airworthiness aspects. Consequently, permits to fly under Part 21 may be issued by that Member State, including for cases in which the aircraft flies in another State. The permit to fly contains all the conditions and restrictions to ensure safe flight, but other airspace and operational rules remain within the competence of the authority of the State where the flight takes place, and may apply. Therefore, the applicant is also required to ensure compliance with the applicable rules of that State.

SECTION A — TECHNICAL REQUIREMENTS

SUBPART A — GENERAL PROVISIONS

GM1 21.A.3A Reporting system

LINK BETWEEN POINT 21.A.3A AND REGULATION (EU) No 376/2014

Regulation (EU) No 376/2014 of the European Parliament and of the Council lays down requirements on the reporting, analysis and follow-up of occurrences in civil aviation. Compliance with point 21.A.3A of Part 21 does not exempt organisations from compliance with Regulation (EU) No 376/2014. For each category of reporter, Regulation (EU) 2015/1018⁴ defines the nature of items to be mandatorily reported. Regulation (EU) No 376/2014 also considers voluntary reporting of other items that are perceived by the reporter as a threat to aviation safety.

Point 21.A.3A lays down requirements for the mandatory reporting of events to the competent authority, in view of performing the necessary activities linked to the continued airworthiness of aircraft, parts, and appliances.

For Part 21 design organisations (DOs) and production organisations (POs), the reportability criteria (i.e. a potential unsafe condition) are the same as the ones laid down by Regulation (EU) No 376/2014.

Furthermore, compliance with Regulation (EU) No 376/2014 does not exempt organisations from compliance with point 21.A.3A. However, this should not give rise to two parallel reporting systems, and point 21.A.3A and Regulation (EU) No 376/2014 should be seen as complementary in that respect.

In practice, this means that reporting obligations under point 21.A.3A on one hand and reporting obligations under Regulation (EU) No 376/2014 on the other hand are compatible. These reporting obligations may be discharged using one reporting channel.

In addition, any natural or legal person that has more than one role subject to the obligation to report may discharge all those obligations through a single report. Organisations are encouraged to properly describe this in their organisation manual, to address cases in which the responsibilities are discharged on behalf of the organisation.

AMC1 21.A.3A(a) Reporting system

COLLECTION, INVESTIGATION, AND ANALYSIS OF EVENTS

In the context of the following AMC and GM to point 21.A.3A, the term ‘event’ refers to any failure, malfunction, defect, error, near miss, hazard identification, incident, accident, or other occurrence that is subject to a reporting system.

The ‘collection’, ‘investigation’, and ‘analysis’ functions of the system should include means:

⁴ Commission Implementing Regulation (EU) 2015/1018 of 29 June 2015 laying down a list classifying occurrences in civil aviation to be mandatorily reported according to Regulation (EU) No 376/2014 of the European Parliament and of the Council (OJ L 163, 30.6.2015, p. 1) (<https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX%3A32015R1018&qid=1669631925416>).

- to analyse events and related available information;
- to identify adverse trends;
- to investigate the associated root cause(s); and
- to determine any necessary corrective action.

It should also allow the determination of reportable occurrences as required by point 21.A.3A(a)(3) or 21.3A(b)(3), as applicable.

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 (DAH) are fully investigated so that the exact nature of any event and its effect on continuing airworthiness is understood. This may then result in changes to the design and/or to the instructions for continued airworthiness (ICA), and/or in establishing a mitigation plan to prevent or minimise the possibility of such occurrences in the future, as necessary. The 'analysis' is not limited to those occurrences that require the involvement of EASA under point 21.A.3A(e).

GM1 21.A.3A(a) and 21.A.3A(b) Reporting system

GENERAL — COLLECTING SYSTEM

The term 'collection' means the setting up of systems and procedures that will enable relevant failures, malfunctions, and defects, or other occurrences, to be properly collected when they occur.

As the collection system needs to accept reports that originate outside the organisation (from operators, maintenance organisations, suppliers, etc.), it is necessary to inform possible reporters of the existence of the system and of the appropriate means to introduce reports into it. This does not presume that direct access to the system is to be granted if other mechanisms are more appropriate.

The collection system should also ensure the collection, through an internal reporting scheme, of internal errors, near misses, and hazards that are perceived by the reporter as an actual or potential aviation safety risk.

Considerations for the collection of information related to events should include the following:

- the analysis of failure rates;
- the early rejection of parts from service; and
- comparison with the certification assumptions.

AMC2 21.A.3A(a) Reporting system

COLLECTION, INVESTIGATION, AND ANALYSIS OF DATA RELATED TO FLAMMABILITY REDUCTION MEANS (FRM) RELIABILITY

Holders of a TC, an RTC, an STC, or any other relevant approval that is deemed to have been issued under Part 21, which have included an FRM in their design, should continuously assess the effects of aeroplane component failures on FRM reliability. This should be part of the system for the collection, investigation, and analysis of data, which is required by point 21.A.3A(a). The applicant/holder should therefore:

- (a) demonstrate effective means to collect FRM reliability data; those means should provide data that affect FRM reliability, such as component failures;
- (b) unless alternative reporting procedures are approved by EASA, submit a report to EASA every 6 months for the first 5 years after service introduction; after that period, continued reporting every 6 months may be:
 - replaced with other FRM reliability tracking methods that are deemed acceptable by EASA; or
 - eliminated if it is established that the FRM reliability meets, and will continue to meet, the exposure specifications in paragraph M25.1 of Appendix M to the Certification Specifications for Large Aeroplanes (CS-25); and
- (c) develop service instructions or revise the applicable aeroplane manual, according to a schedule that is approved by EASA, to correct any failures of the FRM that occur in service, which could increase any fuel tank's fleet average flammability exposure to more than what is specified in paragraph M25.1 of Appendix M to CS-25.

AMC3 21.A.3A(a) Reporting system

COLLECTION, INVESTIGATION, AND ANALYSIS OF DATA RELATED TO EDTO-SIGNIFICANT OCCURRENCES

- (a) Holders of a TC, an RTC, an STC, or any other relevant approval that is deemed to have been issued under Part 21 and includes extended diversion time operation (EDTO) capability should implement a specific tracking, reporting, and resolution system for EDTO-significant occurrences. That system should be suitable to ensure the initial and continued fleet compliance with the applicable EDTO reliability objectives, and be part of the system for the collection, investigation, and analysis of data, which is required by point 21.A.3A(a).

Appropriate coordination should exist between the engine TC holder, the propeller TC holder, the auxiliary power unit (APU) ETSO authorisation holder, and the aircraft TC holder, to ensure compliance with the EDTO reliability objectives.

- (b) For the tracking, reporting, and resolution of EDTO-significant occurrences, refer to the latest edition of AMC 20-6 of the 'General Acceptable Means of Compliance for Airworthiness of Products, Parts and Appliances' (AMC-20).

GM1 21.A.3A(a), 21.A.3A(e), and 21.A.3A(f) Reporting system

GENERAL

In the context of points 21.A.3A(a), 21.A.3A(e), and 21.A.3A(f), 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.

Design approval holders (DAHs) of minor changes and minor repairs do not have to comply with the requirements in point 21.A.3A(a), as 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 that affect the airworthiness of the product. However, it should be noted that the obligations under Regulation (EU) No 376/2014 and its implementing acts still apply.

GM1 21.A.3A(a)(1) and (b)(1) Reporting system

EVENTS REPORTED VOLUNTARILY TO THE ORGANISATION

A natural or a legal person (including organisations that are not approved by a Member State) may voluntarily report to an organisation any event that is perceived by that person as posing an actual or potential hazard to aviation safety.

Voluntary reports may be originated by:

- (a) persons that are not listed in Article 4(6) of Regulation (EU) No 376/2014; or
- (b) persons that are listed in Article 4(6) of Regulation (EU) No 376/2014, even though such events are not included in Regulation (EU) 2015/1018; or
- (c) an organisation, if such organisation cannot determine whether the event should be mandatorily reported.

Example

A maintenance staff member in a maintenance organisation is reporting to their maintenance organisation a perceived design issue that is not covered by Regulation (EU) 2015/1018. The maintenance organisation should make a final assessment of the voluntary report and if it assesses that the reported event 'may involve an actual or potential aviation safety risk', then it should mandatorily report it to the TC holder, the competent authority, etc., as per point 145.A.60 'Occurrence reporting' of Annex II (Part-145) to Regulation (EU) No 1321/2014⁵. If the maintenance organisation cannot determine whether a safety risk exists (due to lack of competence, lack of data, etc.), it could voluntarily report the event to the TC holder for further assessment.

GM2 21.A.3A(a)(1) and (b)(1) Reporting system

INTERNAL SAFETY REPORTING SCHEME

The internal safety reporting scheme is part of the overall collection system. The objective of this GM is to provide specific guidance on the internal safety reporting scheme only.

- (a) The overall objectives of the internal safety reporting scheme are:
 - to collect information that is reported by the organisation staff; and
 - to use that reported information to improve the safety of operations,in conjunction with the safety management elements that are defined in points 21.A.139 and 21.A.239. Each internal safety reporting scheme should include provisions for confidentiality

⁵ 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) (<https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX%3A32014R1321&qid=1669641196734>).

and enable and encourage free and frank reporting of events, as those listed in points 21.A.3A(a)(1)(i) and (ii). This is facilitated by establishing a 'just culture'.

(b) The specific objectives of the scheme are to:

- (1) enable an assessment of the safety implications of each relevant event that is reported, including previous similar events, so that any necessary action can be initiated; and
- (2) ensure that lessons from relevant events are shared so that other persons and parts of the organisation may learn from them.

(c) The scheme is an essential part of the overall management system and should be complementary to routine procedures and 'control' systems; it is not intended to duplicate or supersede any of them. The scheme is a tool to identify those instances in which routine procedures have failed or may fail.

(d) All safety-related reports should be retained as the significance of such reports may only become obvious later.

(e) The collection and analysis of timely, appropriate, and accurate data will allow the organisation to react to the information that it receives and to take necessary action.

AMC1 21.A.3A(a)(3), 21.A.3A(b)(3), 21.A.3A(d) Reporting system

REPORTING TO THE COMPETENT AUTHORITY

Within the overall limit of 72 hours, the degree of urgency for submitting a report should be determined by the level of risk that is judged to have resulted from the occurrence.

If an occurrence is judged by the organisation that identified the possible unsafe condition to have resulted in an immediate and particularly significant hazard, EASA (or the competent authority of the Member State, as required) should 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 with a full written report within 72 hours. An example would be an uncontained engine failure that results in damage to the aircraft primary structure.

In all other cases, the submission of the report may be delayed up to a maximum of 72 hours after determining the possible unsafe condition, in order to provide more details.

GM1 21.A.3A(a)(3), 21.A.3A(b)(3) and 21.A.3A(d) Reporting system

REPORTING TO THE COMPETENT AUTHORITY — GENERAL

(a) The reference to 'is aware of an occurrence' implies that the organisation identifies the event as one that falls into the category of occurrences to be reported — usually when the organisation determines that the event is reportable. The 72-hour period starts when the possible unsafe condition is identified.

(b) For organisations that have their principal place of business in a Member State, Regulation (EU) 2015/1018 lays down a generic 'list classifying occurrence in civil aviation to be mandatorily reported'. This list should not be understood as being an exhaustive collection of all the issues

that may pose a significant risk to aviation safety and, therefore, reporting should not be limited to the items that are listed in that Regulation.

- (c) AMC-20 provides further details on occurrence reporting (AMC 20-8) and also applies to organisations that are approved under Part 21 and do not have their principal place of business in a Member State.
- (d) Point 21.A.3A(a)(3) requires the reporting of occurrences that may result in an unsafe condition. GM1 21.A.3B(b) 'Failures, malfunctions and defects — Determination of an unsafe condition' could be used to assist in that determination.

AMC1 21.A.3A(e) Reporting system

FOLLOW-UP TO, AND CLOSURE OF, REPORTED OCCURRENCES

- (a) The organisation should transmit the following information to the competent authority within 30 days from the date of notification of the occurrence to the competent authority:
 - (1) the latest position of the design organisation (DO) as to whether an unsafe condition is confirmed;
 - (2) the results of the analysis and of the first investigation — including the cause(s) of the occurrence, if known; and
 - (3) the measures it has taken, intends to take, or proposes to be taken, including:
 - (i) containment measures that have already been defined by the reporting organisation and put in place (if any); and
 - (ii) in the case of reports made by the DO, for unsafe conditions, a risk assessment supporting that the product can be operated safely (see GM 21.A.3B(d)(4)) until the corrective action is defined and implemented, or that immediate mitigation measures need to be implemented until a more refined risk assessment can be provided.

Organisations are encouraged to provide a complete analysis and follow-up as soon as available and, in principle, no later than 3 months after the occurrence notification. It is recognised that analysing an occurrence may take longer than 3 months, especially if the investigation is complex or where the services of a special investigator are required.

The requirements for follow-up are not intended to jeopardise the quality and thoroughness of an occurrence analysis. It may be detrimental to safety if the analysis is completed in a rush within the encouraged 3-month period without properly establishing the root cause(s), making a risk assessment, and determining whether remedial action is required.

The design approval holder (DAH) and the production approval holder (PAH) should cooperate, as necessary, to ensure that any corrective action can be implemented. In addition, affected organisations are expected to cooperate under their respective regulatory framework from the reporting of an occurrence until its closure, to ensure complete results.

The final (close-out) report should include:

- the final DAH position as to whether an unsafe condition exists;

- the results of the occurrence analysis and of the final investigation, including the cause(s) of the occurrence;
- any corrective and preventive action by the reporting organisation; and
- in the case of reports made by the DO, a risk assessment supporting that those corrective and preventive measures allow the product to be operated safely (see GM 21.A.3B(d)(4)).

(b) Notwithstanding point (a), when the organisation identifies that no unsafe condition exists as a result of its analysis of a voluntarily reported occurrence, it can delay further communication to the competent authority up to the issuance of the final report and report the occurrence as closed upon issue (data exchange). In such cases, no follow-up report should be submitted. The final report to EASA should include confirmation and justification that no unsafe condition exists. The organisation is requested to provide information on the cause(s) of the occurrence and on any corrective or preventive action that was taken by the organisation.

This way of reporting should not be understood as an accepted deviation from the requirements of Part 21. If at any stage during the investigation, the organisation identifies that a possible unsafe condition exists, this should be communicated to EASA via a mandatory report within 72 hours.

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

~~Holders 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 of a type certificate, restricted type certificate, supplemental type certificate or any other 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~~

~~(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~~

~~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~~

~~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

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

~~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~~

AMC1 21.A.5 Record-keeping

- (a) The record-keeping system should ensure that all the records that are required by point 21.A.5 are accessible within a reasonable time. Those records should be organised in a manner that ensures their traceability and retrievability throughout the required retention period.**
- (b) The records should remain legible throughout the required retention period and be protected against damage, alteration, and tampering.**
- (c) The format of the records should be specified in the organisation's procedures.**
- (d) The organisation should ensure that copies of all the documents and supporting information that are developed:**
 - (1) under the privileges that are defined under points 21.A.163 and 21.A.263; or**

(2) for type certificates (TCs), restricted type certificates (RTCs), supplemental type certificates (STCs), major changes, and major repairs that are not issued under the privileges that are defined under point 21.A.263,

are retained throughout the operational life of the product or part.

(e) The retention period starts when the record is created or when it is last amended.

If the organisation transfers a certificate or a letter of agreement to another natural or legal person, the records related to the certificate or to the letter of agreement should be transferred to the new holder.

GM1 21.A.5 Record-keeping

For organisations that hold or have applied for a type certificate (TC), restricted type certificate (RTC), supplemental type certificate (STC), a European technical standard order (ETSO) authorisation, a change to the TC approval, a repair design approval, a permit to fly, a production organisation approval (POA), or a letter of agreement under Part 21, the relevant design information/data includes at least the following, as applicable:

- design data such as type design data, as defined in point 21.A.31, and changes to that data, ETSO design data, and repair design data;
- drawings and test reports, including inspection records for the product tested;
- the certification programme, including related certification basis data (certification review items (CRIs), special conditions (SCs), equivalent safety findings (ESFs)); and
- compliance demonstration data.

For production organisations (POs), the relevant records include at least:

- conformity justification data; and
- conformity attestation data (e.g. EASA Form 1 or EASA Form 52).

AMC1 21.A.5(a) and 21.A.433(b) Repair design and record-keeping

(a) The relevant substantiation data related to a new major repair design and record-keeping should include:

- (1) identification of the damage and of the source of the report;
- (2) the major repair design approval sheet that identifies the applicable specifications and the references of the justifications;
- (3) the repair drawing and/or instructions, and the scheme identifier;
- (4) any correspondence with the holder of the type certificate (TC), supplemental type certificate (STC), or auxiliary power unit (APU) European technical standard order (ETSO) authorisation, if their advice on the design was sought;
- (5) the structural justification (static strength, fatigue, damage tolerance, flutter, etc.) or references to that data;

- (6) the effect on the aircraft, engines and/or systems (performance, flight handling, etc., as appropriate);
 - (7) the effect on the maintenance programme;
 - (8) the effect on the airworthiness limitations, the flight manual, and the operating manual;
 - (9) any change in the weight and moment; and
 - (10) any special test requirements.
- (b) The relevant minor repair documentation includes points (a)(1) and (a)(3). Other elements of point (a) may be included, where necessary. If the repair is outside the approved data, a justification for the classification is required.
- (c) 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, the oversizing of fastener holes, etc.).
- (d) 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 point 21.A.433(a)(4).
- (e) Repairs to engines or to APU-critical parts would normally be accepted only with the involvement of the TC holder.

GM1 21.A.5(a) and (b) Record-keeping

RECORDING AND ARCHIVING SYSTEM

The main objective of record-keeping in design organisations (DOs) and production organisations (POs) is to ensure the retrievability of data that is required for the continued airworthiness of in-service products.

In addition, records within the design environment are essential to ensure proper control of the configuration of the type design and of its compliance with the certification basis.

In the production environment, records are also required, to ensure that products or parts are in conformity with the applicable data throughout the manufacturing cycle. In addition, certain records of milestones are needed, to subsequently provide objective evidence that all the prescribed stages of the production process have been satisfactorily completed.

Therefore, the approved DO or PO (or a natural or legal person that is demonstrating their design capability through an agreement on alternative procedures or through the acceptance of the organisation's certification programme, or a natural or legal person that produces products and parts under Part 21, Subpart F) are required to implement a system for the compilation and retention of records during all stages of design or production, which covers short-term and long-term records as appropriate to the nature of the product and its processes.

The management of such information is subject to the appropriately documented procedures in the management system that is required by points 21.A.139 and 21.A.239 or to the manual/procedures that are required by points 21.A.14(b), 21.A.125A(b), or 21.A.602B(b)(2), as appropriate. This also applies in case of demonstrating the design capability through the acceptance of the certification programme under point 21.A.14(c).

All forms of recording media are acceptable (paper, film, magnetic, etc.), including the use of electronic records*, provided that they can meet the required duration for archiving under the given conditions and that the continued readability of the records is ensured.

The related procedures are required to:

- identify the records to be kept;
- describe the organisation of, and responsibility for, the archiving system (its location, compilation, format) and the conditions for access to the information (e.g. by product, subject, etc.);
- control access to the data and provide effective protection from deterioration or accidental damage, alteration, and tampering;
- ensure the continued readability of the records;
- demonstrate to the competent authority the proper functioning of the record system; and
- define an archiving period for each type of data as follows:
 - production data that supports the conformity of a product, part, or appliance is kept for not less than 3 years from the issue date of the related statement of conformity or authorised release certificate; and
 - design data, including data that supports the compliance of a product, part, or appliance with the certification basis (see GM1 21.A.5), as well as data that is considered essential for continuing airworthiness, is kept throughout the operational life of the product, part, or appliance; such continued airworthiness data may include, but are not limited to, in-service occurrence reports and mandatory continuing-airworthiness information;
- for organisations that are approved according to Part 21, Subparts G and J and organisations that demonstrate their design capability through an agreement on alternative procedures or acceptance of their certification programme by EASA, ensure that the recording and record-keeping systems that are used by the partners, suppliers, and subcontractors meet the record-keeping objectives with the same level of confidence as they do for their own system; in each case, it should be defined who should retain the data record (organisation, partner, supplier, or subcontractor), as well as the method of surveillance of the recording/record-keeping system of the partners, suppliers, or subcontractors; and
- for natural or legal persons that produce items under Part 21, Section A, Subpart F, the data on supplied parts may be retained by the supplier if the supplier has a system that is agreed by the competent authority under Part 21, Section A, Subpart F; in each case, the PO is required to define the archiving period and satisfy itself and the competent authority that the recording media are acceptable.

*Related to electronic records, the following definitions apply:

- electronic record: electronic or digital data that is created, generated, sent, communicated, received, or stored by electronic means;
- electronic data: it is typically in the form of documentation that is statically stored in a computer file that is not modifiable (e.g. pdf of a scanned document with wet ink signatures); and

- digital data: it is typically in the form of computer-generated bytes of information that is stored in a computer workable file (e.g. MS Word file, MS Excel file, 3D CAD file).

AMC1 21.A.5 (d) & (e) Record-keeping

RECORD OF STAFF INVOLVED IN DESIGN OR PRODUCTION

- (a) The following should be the minimum information to be recorded for each person that exercises the privileges of an organisation that is approved according to Part 21, Subparts G and J, or according to points 21.A.163 or 21.A.263, or that carries out the independent monitoring of compliance and adequacy according to points 21.A.139(e) and 21.A.239(e), or that carries out the independent verification function of demonstration of compliance pursuant to point 21.A.239(d)(2):
- (a) name;
 - (b) date of birth;
 - (c) basic training received and standard attained;
 - (d) specific training received and standard attained;
 - (e) continuation training received (if appropriate);
 - (f) experience gained;
 - (g) scope of the authorisation;
 - (h) date of first issue of the authorisation;
 - (i) expiry date of the authorisation (if appropriate);
 - (j) identification number of the authorisation (or equivalent means to identify the link between the authorisation and the staff member that holds the authorisation); and
 - (k) changes to the data.
- (b) The record may be kept in any format and should be controlled through an internal procedure of the organisation. That procedure is part of the management system.
- (c) The staff member should be given reasonable access, on request, to their own records as per Regulation (EU) 2016/679.
- (d) A design organisation (DO) or production organisation (PO) should keep the record for at least 3 years after the staff member is no longer employed by the organisation or has changed their position in the organisation, or after the withdrawal of the authorisation, whichever occurs sooner.
- (e) Records of authorisation of the production staff are to be archived for at least 3 years after the staff member is no longer employed by the organisation or as soon as the authorisation is withdrawn. This staff member is any person that has an activity that is essential for ensuring:
- the conformity to applicable design data, or
 - a condition for the safe operation of a product, part, or appliance.

GM1 21.A.9 Access and investigations

ARRANGEMENTS

The arrangements made by the applicant for, or holder of, a type certificate (TC), restricted type certificate (RTC), supplemental type certificate (STC), a European technical standard order (ETSO) authorisation, a major repair design approval, a permit to fly, a design organisation approval (DOA), a production organisation approval (POA), or a letter of agreement under Part 21 are required to allow the competent authority to make investigations that include the complete organisation, including its partners, subcontractors, and suppliers, whether they are in the State of the applicant or not.

The investigations may include audits, enquiries, questions, discussions, and explanations, monitoring, witnessing, inspections, checks, as well as flight and ground tests and inspections of completed products, parts, or appliances that are either designed or produced.

In order to maintain its confidence in the standards that are achieved by the organisation, the competent authority may make an investigation into a sample product, part, or appliance and of its associated records, reports, and certifications.

The arrangements are required to enable the organisation to assist the competent authority and cooperate with it in conducting the investigation during the initial assessment and the subsequent surveillance.

'Cooperation in conducting the investigation' means that the competent authority has been granted full and free access to the facilities and to any information relevant to demonstrating compliance with the Part 21 requirements, and has been provided assistance, as necessary.

'Assistance to the competent authority' includes all the appropriate means regarding the facilities of the organisation, to allow the competent authority to conduct the investigation, such as meeting rooms, offices, personnel support, records, documentation, computer data, and communication facilities, all properly and promptly made available, as necessary.

The competent authority seeks to have an open relationship with the organisation, and suitable liaison staff are required to be nominated to facilitate this, including one or more suitable representatives to accompany competent authority staff during visits, not only at the organisation's own facilities, but also at subcontractors, partners, or suppliers.

SUBPART F — PRODUCTION WITHOUT PRODUCTION ORGANISATION APPROVAL

AMC1 ~~No 1 to~~ 21.A.122 Eligibility — Link between design and production

LINK BETWEEN DESIGN AND PRODUCTION

An 'arrangement' is considered suitable if it is documented and satisfies the competent authority that ~~co-ordination~~ coordination is satisfactory.

To achieve satisfactory coordination ~~co-ordination~~, the documented arrangements must at least define the following aspects, irrespective of whether the design organisation (DO) and the organisation ~~person~~ producing or intending to produce under Part 21, Subpart F are separate legal entities or not:

- (a) ~~1.~~ The responsibilities of a ~~DO 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.);
- (b) ~~2.~~ The responsibilities and procedures of the ~~production organisation (PO) manufacturer~~ for receiving, managing, and using the applicable design data provided by the ~~DO design organisation~~;
- (c) ~~3.~~ The responsibilities and procedures of the ~~PO manufacturer~~ for developing, where applicable, its own manufacturing data in compliance with the applicable design data package;
- (d) ~~4.~~ The responsibilities of the ~~PO manufacturer~~ to assist the ~~DO 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.);
- (e) ~~5.~~ The scope of the arrangements covering Subpart F requirements, in particular, ~~points~~ 21.A.126(a)(4), 21.A.129(d), and ~~(f) 21.A.3A~~, and any associated GM or AMC;
- (f) ~~6.~~ The responsibilities of the ~~PO manufacturer~~, in the case of products prior to type certification, to assist a ~~DO design organisation~~ in demonstrating compliance with the CS (access and suitability of production and test facilities for manufacturing and testing of prototype models and test specimen);
- (g) ~~7.~~ The procedures to deal adequately with production deviations and non-conforming parts;
- (h) ~~8.~~ The means to achieve adequate configuration control of manufactured parts, to enable the ~~PO manufacturer~~ to make the final determination and identification for conformity or airworthiness release and eligibility status;
- (i) ~~9.~~ The identification of responsible persons ~~/offices who that controls control~~ the above; and

(j) ~~10.~~ The acknowledgment by the holder of the TC/STC/repair or change approval/ETSO authorisation that the approved design data **that is** provided, controlled and modified in accordance with the arrangement ~~are~~ **is** 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 ~~PO production organisation~~. This is acceptable, provided **that** an effective link between the design approval holder (DAH) and the ~~PO production organisation~~ can be maintained to satisfy the intent of **point** 21.A.122.

When the ~~DO design organisation~~ and the ~~PO manufacturer~~ are two separate legal entities, a ~~D direct D delivery A~~ 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 a ~~D direct D delivery A~~ authorisation, specific permissions may be granted (see AMC 21.A.4).

AMC1 21.A.124 Application

An applicant should submit to the competent authority a fully completed EASA Form 60 (see below):

EASA Form 60	
Application for an agreement of production under Part 21, Subpart F	
<i>Competent authority of an EU Member State or EASA</i>	
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 point 21.A.124(b):	

6. Links/arrangements with design approval holder(s) (DAHs)/ design organisation(s) (DO(s)), where different from Block 1:	
7. Human resources:	
8. Name of the person signing the application:	
<div style="border-bottom: 1px solid black; width: 80%; margin: 0 auto; margin-bottom: 5px;"></div> <p style="text-align: center;">Date</p>	<div style="border-bottom: 1px solid black; width: 80%; margin: 0 auto; margin-bottom: 5px;"></div> <p style="text-align: center;">Signature</p>

EASA Form 60 Issue 3

Block 1: The name of the applicant should be entered. For legal entities, the name should 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 should be provided to the competent authority.

Block 2: State the trade name by which the applicant is known to the public if it is different from the information given in Block 1. The use of a logo may be indicated in this block.

Block 3: State all the locations of the manufacturing activities that are covered by the application. Only those locations should be stated that are directly under the control of the applicant that is stated in Block 1.

Block 4: This block should include further details of the manufacturing activities under approval for the addresses that are indicated in Block 3. The 'Identification' block should indicate the products, parts, or appliances that are intended to be produced, while the 'Termination' block should 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 should state the evidence that supports the determination of applicability as stated in point 21.A.121. In addition, an outline of the manual that is required by point 21.A.125A(b) should be provided with the application.

Block 6: The information entered here is essential for the evaluation of the eligibility of the application. Therefore, special attention should be given concerning the completion of this block, either directly, or by reference to supporting documentation in relation to the requirements of point 21.A.122 and to AMC1 21.A.122.

Block 7: The information to be entered here should reflect the number of staff or in the case of an initial approval, the intended number of staff for the manufacturing activities under this application, and therefore, it should also include any associated administrative staff.

Block 8: State the name of the person that is authorised to sign the application.

~~GM 21.A.124(a) Application – Application form~~

~~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.~~

AMC1 21.A.124A(b) and 21.A.134A(b) Means of compliance

DESCRIPTION SUPPORTING THE ALTERNATIVE MEANS OF COMPLIANCE

(a) The description of the alternative means of compliance (AltMoC) should include:

- (1) a summary of the AltMoC;
- (2) the content of the AltMoC;
- (3) a statement that compliance with the regulation is achieved; and
- (4) in support of that statement, an assessment that demonstrates that the AltMoC reaches an acceptable level of safety, taking into account the level of safety that is achieved by the corresponding EASA AMC.

(b) All these elements that describe the AltMoC are an integral part of the management system records, in accordance with point 21.A.5.

GM1 21.A.124A and 21.A.134A Means of compliance

GENERAL

(a) Acceptable means of compliance (AMC), as referred to in Article 76(3) of Regulation (EU) 2018/1139⁶, are a tool to standardise the demonstration of compliance with, and facilitate the

⁶ Regulation (EU) 2018/1139 of the European Parliament and of the Council of 4 July 2018 on common rules in the field of civil aviation and establishing a European Union Aviation Safety Agency, and amending Regulations (EC) No 2111/2005, (EC) No 1008/2008, (EU) No 996/2010, (EU) No 376/2014 and Directives 2014/30/EU and 2014/53/EU of the European Parliament and of the Council, and repealing Regulations (EC) No 552/2004 and (EC) No 216/2008 of the European Parliament and of the Council and Council Regulation (EEC) No 3922/91 (OJ L 212, 22.8.2018, p. 1) (<https://eur-lex.europa.eu/legal-content/EN/TXT/?qid=1535612134845&uri=CELEX:32018R1139>).

verification activities of the competent authorities in relation to, that Regulation and its delegated and implementing acts. AMC are published by EASA to achieve those objectives. While competent authorities and regulated entities are not legally bound to use the AMC, applying them is recommended.

(b) If an organisation wishes to use other means to comply with Regulation (EU) 2018/1139 and its delegated and implementing acts, which are different from the AMC that are published by EASA, that organisation may need to demonstrate compliance by using alternative means of compliance (AltMoC) that are established:

- (1) by its competent authority (see GM1 21.B.115 and GM1 21.B.215); or
- (2) by that organisation and approved by its competent authority (see point (c)).

An AltMoC does not allow deviation from Regulation (EU) 2018/1139 and its delegated or implementing acts.

(c) AltMoC that are established by an organisation and approved by its competent authority

An organisation that wishes to use a different MoC than the one published by EASA can propose an AltMoC to the competent authority and use it only once the competent authority approves it. In that case, the organisation is responsible for demonstrating how that AltMoC establishes compliance with the regulation.

The approval of an AltMoC is granted to the organisation by its competent authority on an individual basis and is restricted to that specific organisation. Other organisations that wish to use the same AltMoC should go through the AltMoC process (i.e. demonstrate how that AltMoC establishes compliance with the regulation) and obtain individual approval from their competent authority.

GM2 21.A.124A and 21.A.134A Means of compliance

WHEN AN ALTERNATIVE MEANS OF COMPLIANCE IS NEEDED

When there is no EASA AMC to a certain point of a regulation, the means of compliance (MoC) that are proposed by the organisation to that point do not need to go through the AltMoC process. It is the responsibility of the competent authority to verify that compliance with the regulation is achieved. However, in certain cases, the organisation may propose, and the competent authority may agree, to have such MoC go through the AltMoC process.

When there is an EASA AMC, the AltMoC process is needed in the following cases (non-exhaustive list):

- an AltMoC to the regulation is technically different to the AMC that is published by EASA; and
- a Form is significantly different from the one that is included in the EASA AMC.

Note: a Form that is required by a delegated or implementing act cannot be modified.

Examples of issues that are not considered to require the AltMoC process include, but are not limited to:

- editorial changes to an EASA AMC, as long as they do not change the intent of the AMC; and

- incorporating an EASA AMC into the organisational structure, organisational processes, or standard operating procedures of an organisation with different wording and terminology that are customised to the organisation's environment if it does not change the intent of the AMC and its associated level of safety.

GM1 21.A.125B(a), 21.A.158(a) and 21.A.258(a) Findings and observations

ROOT CAUSE ANALYSIS

- (a) It is important that the analysis does not primarily focus on establishing who or what caused the non-compliance, but on why it was caused. Establishing the root cause(s) of non-compliance often requires an overarching view of the events and circumstances that led to it, to identify all the possible systemic and contributing factors (human factors (HF), regulatory, organisational, technical factors, etc.) in addition to the direct factors.
- (b) A narrow focus on single events or failures, or the use of a simple, linear model, such as a fault tree, to identify the chain of events that led to the non-compliance, may not properly reflect the complexity of the issue, and therefore, there is a risk that important factors that must be considered to prevent reoccurrence will be ignored.

Such an inappropriate or partial root cause analysis often leads to applying 'quick fixes' that only address the symptoms of the non-compliance. A peer review of the results of the root cause analysis may increase its reliability and objectivity.

AMC1 21.A.125B(a)(3), 21.A.158(a)(3) and 21.A.258(a)(3) Findings and observations

FINDING-RELATED CORRECTIVE-ACTION PLAN AND IMPLEMENTATION

After receipt of notification of findings, the organisation should identify and define the action for all findings, to address the effects of the non-compliance, as well as its root cause(s) and contributing factor(s).

Depending on the issues identified, the organisation may need to take immediate corrective action.

The corrective action plan should:

- include the correction of the issue, corrective and preventive action, as well as the planning to implement them; and
- be timely submitted to the competent authority for acceptance before it is effectively implemented.

After receiving the competent authority's acceptance of the corrective action plan, the organisation should implement the associated action.

Within the agreed period, the organisation should inform the competent authority that the corrective action plan has been implemented and should send the associated pieces of evidence, on request from the competent authority.

AMC1 21.A.125B(c), 21.A.158(c), 21.A.258(c) Findings and observations

DUE CONSIDERATION TO OBSERVATIONS

For each observation that is notified by the competent authority, the organisation should analyse the related issues and determine when action is needed.

The handling of the observations may follow a process similar to the handling of the findings by the organisation.

The organisation should record the analysis and the related outputs, such as action taken, or the reasons why no action was taken.

GM1 21.A.126(b)(5) Production inspection system — Engineering and manufacturing review procedure

1. (a) The procedure should permit to record the deviation, to present it to the design approval holder (DAH) ~~Design holder~~ under the provisions of point 21.A.122, and to record the results of the review and actions taken consequently as regards the part/product.
2. (b) 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~~

- ~~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.~~

SUBPART G — PRODUCTION ORGANISATION APPROVAL

~~GM No 1 to 21.A.158(a) Uncontrolled non-compliance with applicable design data~~

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~~

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.~~

AMC1 21.A.139(c) Production management system

SAFETY MANAGEMENT ELEMENT

Demonstration of compliance with the international industry standard SM-0001 'Implementing a Safety Management System in Design, Manufacturing and Maintenance Organisations', Issue B, 31 March 2022, is an acceptable means to demonstrate compliance with the safety management element of the production management system.

GM1 21.A.139(c) Production management system

SAFETY MANAGEMENT ELEMENT

Safety management seeks to proactively identify hazards and mitigate the related safety risks before they result in aviation accidents and incidents. Safety management enables an organisation to manage its activities in a more systematic and focused manner. When an organisation has a clear understanding of its role in, and contribution to, aviation safety, this enables the organisation to prioritise safety risks and more effectively manage its resources for optimal results.

Safety should not be considered the responsibility of a single person or a limited group of people in the organisation. A safety culture should be developed throughout the organisation, which involves all the personnel as active contributors to the safety of the final product, part, or appliance (see AMC1 21.A.139(c)(1)).

The principles of the requirements in points 21.A.3A, 21.A.5, 21.A.139, 21.A.145, and 21.A.147, and the related AMC constitute the EU production management system framework for aviation safety management. This framework addresses the core elements of the International Civil Aviation Organization (ICAO) safety management system (SMS) framework that is defined in ICAO Annex 19, Appendix 2, and facilitates the introduction of the additional safety management element.

This approach is intended to encourage organisations to embed safety management and risk-based decision-making into all their activities, instead of superimposing another system onto their existing management system and governance structure. In addition, if the organisation holds multiple organisation certificates that are issued under Regulation (EU) 2018/1139, it may choose to implement a single management system to cover all of its activities. An integrated management system may be used not only to capture multiple management system requirements resulting from Regulation (EU) 2018/1139, but also to cover for other regulatory provisions requiring compliance with ICAO Annex 19 or for other business management systems, such as security, occupational health, and environmental management systems. Integration will remove duplication and exploit synergies by managing safety risks across multiple activities. Organisations may determine the best means to structure their management systems to suit their business and organisational needs.

It is important to recognise that safety management will be a continuous activity, as hazards, risks, as well as the effectiveness of safety risk mitigations, will change over time.

The safety management capability of an organisation should be commensurate with the safety risks to be managed, which can be at the product, part, and appliance level or at the organisational level.

The risks that are inherent in a complex structure require a robust safety risk management process (e.g. a complex supply chain may induce hazards that are complex to mitigate, or the rate of production, when stretched to the limit, may require more efficient safety barriers).

As a consequence, scalability and suitability of the safety management element should be a function of the inherent safety risk capability of the organisation. For instance, for organisations with a lower risk level:

- (a) the risk assessment model that is used may be very simple in cases in which the identified hazards are easy to mitigate;
- (b) expert judgement might be sufficient to measure the efficiency of safety barriers;
- (c) the collection of data, safety information, and occurrences might be very limited;
- (d) there might be no need for software or tools to manage the SMS; and
- (e) the communication policy might be limited.

AMC1 21.A.139(c)(1) Production management system

SAFETY POLICY & OBJECTIVES

- (a) The safety policy should:
 - (1) reflect organisational commitments regarding safety, and its proactive and systematic management, including the promotion of a positive safety culture;

- (2) include internal reporting principles by fostering the reporting of organisational threats as well as events, as defined in AMC3 21.A.3A(a);
 - (3) be endorsed by the accountable manager (AM);
 - (4) be communicated, with visible endorsement, throughout the organisation; and
 - (5) be periodically reviewed to ensure that it remains relevant and appropriate to the organisation.
- (b) The safety policy should include the commitment:
- (1) to comply with all the applicable legislation, meet all the applicable requirements, and adopt practices to improve safety standards;
 - (2) to provide the necessary resources for the implementation of the safety policy;
 - (3) to apply human factors (HF) principles;
 - (4) to enforce safety as a primary responsibility of all managers; and
 - (5) to apply 'just culture' principles and, in particular, not to make available or use the information on occurrences:
 - (i) to attribute blame or liability to personnel for action, omissions, or decisions that are commensurate with their experience and training; or
 - (ii) for any purpose other than the improvement of aviation safety.
- (c) Senior management should continuously promote the safety policy to all personnel, demonstrate their commitment to it, and provide the necessary human and financial resources for its implementation.
- (d) Taking due account of its safety policy, the organisation should define safety objectives. The safety objectives should:
- (1) form the basis for safety performance monitoring and measurement;
 - (2) reflect the organisation's commitment to maintaining or continuously improving the overall effectiveness of safety management;
 - (3) be communicated throughout the organisation; and
 - (4) be periodically reviewed to ensure that they remain relevant and appropriate to the organisation.

GM1 21.A.139(c)(1) Production management system

SAFETY POLICY

The safety policy is the means for the organisation to state its intention to maintain and, where practicable, to improve the safety levels of all its activities, and to minimise its contribution to the risk of an aircraft accident or serious incident occurring, as far as reasonably practicable. The safety policy reflects the management's commitment to safety and the organisation's philosophy of safety management. It is the foundation on which the organisation's management system is built and serves

as a reminder of 'how we do business here'. The creation of a positive safety culture begins with issuing a clear, unequivocal policy statement.

The commitment to apply 'just culture' principles forms the basis for the organisation's internal rules that describe how 'just culture' principles are guaranteed and implemented.

Regulation (EU) No 376/2014 defines the 'just culture' principles to be applied (refer, in particular, to Article 16(11) of that Regulation).

AMC1 21.A.139(c)(2) Production management system

ORGANISATION AND ACCOUNTABILITY

(a) The management system should encompass safety by including a safety manager and a safety review board in the organisational structure. The functions of the safety manager are defined in AMC1 21.A.145(c)(2).

(b) Safety review board

(1) The safety review board (the 'board'), sometimes referred to as 'high-level safety committee', considers matters of strategic safety in support of the safety accountability of the accountable manager.

(2) The board should be normally chaired by the accountable manager and be generally composed of the person or group of persons nominated under point 21.A.145(c)(2). Its composition can be adapted to its needs, considering point 21.A.245(c)(2).

(3) The board should monitor:

(i) the organisation's safety performance against its safety policy and objectives;

(ii) whether any safety action is taken in a timely manner; and

(iii) the effectiveness of the organisation's management system processes.

(4) The board may also be tasked with:

(i) reviewing the results of compliance monitoring; and

(ii) monitoring the implementation of any related corrective and preventive action.

(c) The board should ensure that appropriate resources are allocated to achieve the established safety objectives.

(d) Notwithstanding point (a), if justified by the size of the organisation and the nature and complexity of its activities, and subject to a risk assessment and/or mitigation measures, as well as the competent authority's agreement, the organisation may not need to establish a board. In that case, the tasks that are normally allocated to the board should be allocated to the safety manager.

GM1 21.A.139(c)(2) Production management system**SAFETY ACTION GROUP**

- (a) Depending on the size of the organisation and the nature and complexity of its activities, a safety action group may be established as a standing group or as an ad hoc group to assist, or act on behalf of, the safety manager or the safety review board.
- (b) More than one safety action group may be established, depending on the scope of the task and the specific expertise that is required.
- (c) The safety action group usually reports to, and takes strategic direction from, the safety review board, and may be composed of managers, supervisors, and personnel from operational areas.
- (d) The safety action group may be tasked with or assist in the following:
 - (1) monitoring safety performance;
 - (2) defining action to control risks to an acceptable level;
 - (3) assessing the impact of organisational changes on safety;
 - (4) ensuring that safety action is implemented within the agreed timescales; and
 - (5) reviewing the effectiveness of previous safety action and safety promotion.

AMC1 21.A.139(c)(3) and (4) Production management system**SAFETY MANAGEMENT KEY PROCESSES**

- (a) Hazard identification processes
 - (1) Hazard identification should be based on a combination of reactive and proactive methods.
 - (2) The organisation should focus in particular on hazards that may generate nonconformity of a product, part, or appliance that is produced.
- (b) Safety risk management processes
 - (1) The organisation should develop and maintain a safety risk management process that ensures a reactive, proactive, and predictive approach composed of the following elements:
 - (i) analysis (e.g. in terms of the probability or likelihood as well as severity of the consequences of hazards and occurrences);
 - (ii) assessment (in terms of tolerability); and
 - (iii) control (in terms of mitigation) of risks to an acceptable level.
 - (2) The organisation should specify, within the risk management process, who has the authority to make decisions, considering point (b)(1) of this AMC.
- (c) Regardless of the approval status of the subcontracted organisations, the production organisation (PO) is responsible for ensuring that hazard identification and risk management

activities are performed on subcontracted activities, as required by point 21.A.139(d)(2)(ii), as well as for the monitoring of their compliance and adequacy, as required by point 21.A.139(e).

(d) Internal investigation

(1) In line with 'just culture' as part of the safety policy, the organisation should define how to investigate events such as errors or near misses, in order to understand not only what happened, but also how it happened, as well as to prevent or reduce the probability and/or the consequences of any future recurrence.

(2) The scope of internal investigations should extend beyond the scope of the occurrences that are required to be reported to the competent authority in accordance with point 21.A.3A.

(e) Safety performance monitoring and measurement

(1) Safety performance monitoring and measurement should be the processes through which the safety performance of the organisation is verified against the safety policy and the safety objectives.

(2) This process may include, as appropriate to the size, nature, and complexity of the organisation, the following elements:

(i) safety reporting that also addresses the status of compliance with the applicable requirements;

(ii) safety reviews, including trend reviews, which should be conducted during the introduction and deployment of new products, parts, or new equipment/technologies, the implementation of new or changed procedures, or in cases of organisational changes that may have an impact on safety;

(iii) safety audits that focus on the integrity of the organisation's management system, and that periodically assess the status of safety risk controls;

(iv) safety surveys that examine particular elements or procedures of a specific area, such as the following:

(A) the problem areas identified;

(B) bottlenecks in the daily production management activities;

(C) the perceptions and opinions of the production management personnel; and

(D) any areas of dissent or confusion; and

(v) other indicators relevant to safety performance.

(f) Management of change

Changes to the production management system may pose new hazards or decrease the effectiveness of existing safety risk controls. The organisation should manage any safety risks that are related to change in that organisation. The management of change should be a documented process to identify external or internal change that may have an adverse effect on safety. The management of change should use the organisation's existing processes for hazard identification, risk assessment, and risk mitigation.

(g) Continuous improvement

The organisation should continuously seek to improve its safety performance and the effectiveness of its production management system. Continuous improvement may be achieved through review of the following elements:

- (1) compliance monitoring and audits;
- (2) assessments, including assessments of the effectiveness of the safety culture and of the management system, to assess in particular the effectiveness of the safety risk management processes;
- (3) staff surveys, including safety culture surveys, that can provide useful feedback on how engaged the staff are in the production management system;
- (4) the monitoring of events and their recurrence;
- (5) the evaluation of the safety performance indicators as well as reviews of all the available safety performance information; and
- (6) the identification of lessons learned.

AMC1 21.A.139(c)(4)(ii) Production management system**MANAGEMENT OF CHANGE**

This AMC provides a means to consider organisational changes for their potential impact on safety. Organisational changes should also be evaluated for their significance, as required by point 21.A.147. In addition, necessary changes should be introduced into the production organisation exposition (POE), as per point 21.A.143(c). The production management system should be designed such that all the above points are taken into account.

- (a) Organisational changes should be proactively considered for their safety implications. The magnitude of a change, its safety criticality, and its potential impact on human performance (HP) should be assessed in any process for the management of change. Certain non-complex organisational changes may not require additional assessment.
- (b) Special consideration, including human factors (HF) issues, should be given to the transition period during which the change becomes effective.
- (c) During the process for the management of change, relevant previous risk assessments and existing hazards should be reviewed for their possible effects.

GM1 21.A.139(c)(4)(ii) Production management system**MANAGEMENT OF CHANGE**

Unless properly managed, changes in the organisational structure, facilities, scope of work, personnel, documentation, policies and procedures, etc. may result in inadvertently creating new hazards, which may expose the organisation to new or greater risks. Effective organisations seek to improve their processes, while being conscious of the fact that changes may expose the organisation to potential hazards and risks if they are not properly and effectively managed.

The process for the management of change typically provides principles and a structured framework for managing all aspects of change. The disciplined implementation of management of change may maximise the effectiveness of change, engage staff, and minimise the risks that are inherent in change.

Change may have the potential to raise new HF issues, or to exacerbate existing ones. For example, changes in computer systems, equipment, technology, personnel changes (including changes in management personnel), procedures, the organisation of work, or work processes are likely to affect performance.

Effective management of change is supported by the following elements:

- (a) the implementation of a process for hazard identification/risk analysis and assessment for major operational changes, major organisational changes, changes in key personnel, and changes that may affect the way in which production management is carried out;
- (b) the identification of changes that may have a considerable impact on:
 - (1) resources (material and human);
 - (2) management direction (policies, processes, procedures, training); and
 - (3) management control;
- (c) safety cases/risk assessments that are aviation-safety-focused; and
- (d) the involvement of key stakeholders in the process for the management of change, as appropriate.

AMC1 21.A.139(c)(5) Production management system

SAFETY COMMUNICATION

- (a) The organisation should establish communication to the staff, as appropriate to their safety responsibilities, regarding safety matters, which:
 - (1) ensures awareness of safety management activities;
 - (2) conveys safety-critical information, especially related to assessed risks and analysed hazards;
 - (3) explains why particular action is taken; and
 - (4) explains why safety procedures are established or changed.
- (b) Regular meetings with staff, during which information, action, and procedures are discussed, may be used to communicate safety matters.

GM1 21.A.139(c)(5) Production management system

SAFETY PROMOTION

- (a) Safety training, combined with safety communication and information sharing, is part of safety promotion.

- (b) Safety promotion activities support the following:
- (1) the organisation's policies, encouraging a positive safety culture, thus creating an environment that is favourable to the achievement of the organisation's safety objectives;
 - (2) organisational lessons learned; and
 - (3) the implementation of an effective safety reporting scheme and the development of a 'just culture'.
- (c) Depending on the particular safety issue, safety promotion may also constitute or complement risk mitigation action.

AMC1 21.A.139(c)(5)(i) Production management system

SAFETY TRAINING

- (a) The production management staff, as described in points 21.A.145(c)(1) and (2), should receive initial and recurring safety training, as appropriate to their responsibilities, including in safety management principles and the associated safety objectives, to ensure their continued competency.
- (b) The organisation should identify the category of other staff to which safety training should be provided, and define the initial and recurrent training programmes, including appropriate timelines.
- (c) Adequate records of the safety training that is provided should be kept in accordance with point 21.A.5.

GM1 21.A.139(c)(5)(i) Production management system

SAFETY TRAINING

- (a) The main purpose of the safety training programme is:
- (1) to support safety management policies and processes; and
 - (2) to ensure that personnel at all levels of the organisation develop and maintain their competency to fulfil their safety roles.
- (b) Each organisation may adapt its syllabus to its own needs. Typically, depending on the targeted staff, to contribute to a positive safety culture, the following items may be included:
- (1) the organisational roles and responsibilities related to safety, including the hazard identification and risk management processes;
 - (2) the safety objectives and the associated safety performance indicators;
 - (3) human factors (HF) principles, including human performance (HP) and limitations;
 - (4) legislation, where applicable;
 - (5) safety reporting systems and investigations; and

(6) safety issues.

(c) The purpose of the recurrent safety training is:

(1) primarily to ensure that staff are kept abreast notably of changes to safety management system (SMS) principles, processes, and procedures; and

(2) also to share feedback on safety issues that are relevant to the organisation or lessons learned.

(d) The training staff should have sufficient knowledge and experience to teach the topics at the required level, as well as the skills to influence attitudes and behaviours.

GM-ELA No 1 to 21.A.139(a) Quality system

~~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

~~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~~ AMC1 21.A.139(d)(a) ~~Quality System~~ Production management system

QUALITY SYSTEM ELEMENT

The quality system element is an organisational structure, included in the production management system, with responsibilities, procedures, processes, and resources which that 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 point 21.A.139(d)(2)(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; and
- 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 (PO) has established and can maintain their documented quality system.

GM1 ~~No 2 to~~ 21.A.139(d)(1)(a) ~~Quality System — Conformity of supplied parts of appliances~~ Production management system

CONFORMITY OF SUPPLIED PARTS OR APPLIANCES

The production organisation approval (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~~ 21.A.139(d)(2)(ii) or ~~AMC No 2~~ 21.A.139(d)(2)(ii)(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 the supplier's quality system;
- evaluation of the supplier's capability in performing all the manufacturing activities, inspections and tests necessary to establish the conformity of parts or appliances to the type design;
- first article inspection inspections, including destruction, if necessary, to verify that the article conforms to the applicable data for a new production line or a 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; and
- 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 the results of inspections/inspection/tests performed by the supplier if it can establish that:

- the personnel responsible in charge of these tasks satisfy the competency standards of the POA quality system;
- quality measurements are clearly identified; and
- the records or reports showing evidence of conformity are available for review and audit.

The POA holder retains direct responsibility for inspections/tests that are performed either at its own facilities or at the supplier's facilities.

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, which is released under a supplier's in accordance with the supplier's privileges that are defined in point 21.A.163-privileges.

A supplier who does not hold a POA is considered as to be a sub-contractor subcontractor 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.~~

GM2 21.A.139(d)(1) Production management system

QUALITY SYSTEM ELEMENT — PARTNER AND SUBCONTRACTOR ARRANGEMENTS

When defining the arrangements between the production organisation (PO) and its partners and subcontractors, both elements of the production management system should be taken into account, i.e. the safety management element and the quality system element. The following guidance should therefore be considered applicable to both elements.

- When the PO subcontracts activities, the arrangements should consider the safety risk management process that is part of the PO's safety management element (see point 21.A.139(c)(3)). When the subcontractor does not have a safety management element, the subcontractor should be integrated into the safety management element of the PO; when the subcontractor has implemented a safety management system (such as for design

organisation approval (DOA) or production organisation approval (POA)), the two safety management systems, i.e. of the PO and of the subcontractor, should be harmonised.

(b) Depending on the complexity and criticality of those arrangements, the following elements within the arrangements should be addressed:

- (1) coordination and interfaces between all the parties involved;
- (2) applicable procedures;
- (3) safety culture, including internal safety reporting schemes (see point 21.A.3A);
- (4) communication between all the parties involved, including reporting, regular meetings, and feedback channels;
- (5) allocation of tasks, of clear accountability, and of responsibilities; and
- (6) the qualifications and competency of key personnel with reference to point 21.A.145.

(c) The safety risk management should focus on the need to exchange safety data and safety information that are deemed significant for the determination of relevant risks in terms of likelihood, severity, impact, and acceptability, such as, wherever appropriate, but not limited to the following:

- (1) (at product level) failure, malfunction, defect, or other occurrences, non-conformity or outcome of the compliance monitoring function, quality escape, process failure, foreign object damage (FOD), deviation (e.g. calibration of tools), component failure analysis, in-service event, etc.;
- (2) (at documentation level) key processes (e.g. airworthiness directives, production documentation, production processes); and
- (3) (at organisational level) organisational changes, disruptive events, resources' issues, human performance (HP) issues.

(d) Regular communication should be ensured between all the parties involved, to discuss work progress, risk mitigation measures, changes to the arrangements, as well as any other significant issues.

AMC-ELA No 1 to 21.A.139(b)(1) Quality system – Control procedures

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~~

~~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~~

~~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.

AMC1 GM 21.A.139(d)(2)(b)(1) Quality system – Elements of the quality system Production management system

QUALITY SYSTEM — ELEMENTS OF THE QUALITY SYSTEM

- (1)- The control procedures covering the elements of point 21.A.139(d)(2)(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 and voluntary Occurrence Reporting, as required by points 21.A.3A and 21.A.139(c), and continued airworthiness as required by point 21.A.165(e);
 - Control of work occasionally performed (outside the POA facility by POA personnel);
 - Co-ordination/coordination with the applicant for, or holder of, an approved design, as required by points 21.A.133(b) and (c) and 21.A.165(g);
 - Issue of certifications within the scope of approval for the privileges of point 21.A.163;
 - Incorporation of airworthiness data in production and inspection data, as required in points 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; and
 - Personnel training and qualification procedures especially for certifying staff, as required in point 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.

AMC1 No 1 to 21.A.139(d)(2)(ii)(b)(1)(ii) Production management system ~~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.~~

VENDOR AND SUBCONTRACTOR ASSESSMENT, AUDIT AND CONTROL — PRODUCTION ORGANISATION APPROVAL HOLDER THAT USES DOCUMENTED ARRANGEMENTS WITH OTHER PARTIES FOR THE ASSESSMENT AND SURVEILLANCE OF A SUPPLIER

(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~~ point 21.A.139(d) 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 (OpOPs)~~, such as a consulting firm or quality assurance company, for supplier assessment and surveillance does not exempt the **production organisation approval (POA)** holder from its obligations under **point 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 ~~OpOPs~~.

The purpose of using an OP cannot be to replace the assessment, audit and control of the POA ~~Holder~~ 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 ~~OpOPs~~ 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 **an OP** for the purpose of assessing and/or surveying a **POA’s** supplier.

(2) ~~Approval by the competent authority~~ **Reserved**

~~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 ~~OpOPs~~ to perform supplier assessment and surveillance

- (a) The POA holder should include the use of ~~OpOPs~~ for supplier assessment and surveillance in the POA holders’ quality system to demonstrate compliance with the applicable requirements of Part 21.

- (b) The procedures that are required for using OPs for supplier assessment and surveillance should be consistent with other procedures of the POA holders' quality system
- (c) The procedures of the POA holder that uses OPs to perform supplier assessment and surveillance should include the following:
- (1) Identification of the OP that will conduct the 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 has sufficient knowledge, experience, and training to perform their allocated tasks;
 - (iii) Verification that the frequency with which the OP carry out 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 assessment and surveillance of the suppliers suppliers' assessment and surveillance is including on-site surveillance activities that are conducted on-site by the OP; and
 - (v) Verification that the OP has access to the 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 works in accordance with an aviation standard (e.g. EN 9104 series of requirements) that describes requirements for the other party assessment and surveillance by the other party, the items (ii) and (iv) shall be deemed to be complied with.
- (4) A definition that states to what scope extent the OP will conduct surveillance of the suppliers surveillance on behalf of the POA holder. If the OP partly replaces surveillance by the POA holder 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 any non-conformities that is discovered at the supplier's facility, and of the corrective action and follow-up.
- (d) The POA should make arrangements that allow the competent authority to make investigation investigations in accordance with point 21.A.921.A.157, to include OP activities.

AMC2-~~No 2~~ to 21.A.139(d)(2)(ii) ~~(b)(1)(ii)~~ Production management system ~~Vendor and sub-contractor assessment, audit and control – Production Organisation Approval (POA) holder using other party supplier certification~~

VENDOR AND SUBCONTRACTOR ASSESSMENT, AUDIT, AND CONTROL — PRODUCTION ORGANISATION APPROVAL HOLDER THAT USES OTHER PARTIES SUPPLIER CERTIFICATION

(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 (OP) supplier certification is a method whereby a supplier contracts ~~with~~ an appropriately recognised or accredited party ~~Other Party (OP)~~ for the purpose of obtaining a certification from that OP. Certification indicates that the supplier has satisfactorily demonstrated ~~to meet~~ **that it meets** 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~~ **point 21.A.139(d)** 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 **point 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 **production organisation approval (POA)** holder from its obligations under **point 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 ~~H~~ 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~~ **Reserved**

~~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) ~~The procedures that are~~ Procedures required for use of supplier certification for the supplier assessment and surveillance should be consistent with ~~the~~ other procedures of the POA holders' quality system.
 - (c) ~~The procedures~~ Procedures of the POA holder that uses supplier certification for the supplier assessment and surveillance should include the following:
 - (1) ~~A listing~~ Listing of the ~~OPs~~ OP that ~~has~~ have 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 ~~that are~~ under surveillance by the OP and ~~that are~~ 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 ~~frequency with which the~~ OP carries out 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 ~~surveillance of the~~ suppliers' ~~surveillance~~ is including ~~on-site surveillance activities that are~~ 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; ~~and~~
 - (vii) ~~Verification~~ that the OP has access to ~~the~~ applicable proprietary data to the level of detail necessary to survey ~~the suppliers'~~ suppliers functions.

Where the POA holder uses an OP accredited by a signatory to the European cooperation for Accreditation (EA) Multilateral Agreement and ~~working~~ works in

accordance with an aviation standard (e.g. EN 9104 series of requirements) that describes the requirements for the OP certification, the items (ii), (iv), and (v) shall be deemed to be complied with.

- (4) A definition that states to what scope extent the OP will conduct suppliers supplier surveillance on behalf of the POA holder. If the OP partly replaces surveillance by the POA holder in part, the POA holder should identify the functions that will continue to be surveyed by the POA holder.
 - (5) The procedures that ensure that the POA is aware of the loss of an existing certification.
 - (6) The procedures that ensure that the POA holder is aware of any non-conformities and has access to detailed information of these any non-conformities.
 - (7) The 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 investigations in accordance with point 21.A.9, 21.A.157 to include OP activities.

GM1 21.A.139(d)(2)(ii) Production management system

ASSESSMENT, AUDIT, AND CONTROL OF VENDOR AND SUBCONTRACTOR

For the purposes of AMC1 21.A.139(d)(2)(ii) and AMC2 21.A.139(d)(2)(ii), vendors and subcontractors are referred to as 'suppliers', whether they hold production organisation approvals (POAs) or not; audit and control are hereinafter referred to as 'surveillance'. Implementing or significantly changing procedures to use an OP for supplier assessment and surveillance is a significant change to the quality system, and it requires approval in accordance with point 21.A.147.

AMC1 21.A.139(e) and 21.A.139(d)(2)(xiv) Production management system

INDEPENDENT MONITORING FUNCTION

(a) The independent monitoring function should ensure that:

- (1) the activities of the production organisation (PO) are monitored for their compliance with the applicable requirements and with any additional requirements as established by the organisation, and that those activities are properly performed under the supervision of the nominated persons that are referred to in point 21.A.145(c)(2); furthermore, compliance with, and the adequacy of, the production management system should be monitored;
- (2) all subcontracted production activities are monitored for compliance and adequacy with the applicable arrangements;

- (3) an objective review of the complete set of production-management-related activities is provided through independent monitoring activities, such as audits, inspections, reviews;
 - (4) the independence of the monitoring activities is established by always ensuring that those activities and inspections are performed by staff that are not involved in the function, procedure, or products that they monitor, and that are independent from the operating managers of the function(s) being monitored; however, this should not exclude support by domain experts during monitoring;
 - (5) a monitoring plan is established to show when and how often the activities that are required by Part 21 will be audited;
 - (6) the monitoring cycle should not exceed the applicable oversight planning cycle that is established according to point 21.B.222; the determination of the monitoring plan should consider at least the following aspects:
 - (i) the criticality of the items checked; and
 - (ii) the safety performance of the organisation, including any previous findings and root causes;
 - (7) when non-compliance is found, the root cause(s) and contributing factor(s) are identified, and corrective action is defined and followed up;
 - (8) feedback is provided to the management of the PO; and
 - (9) the above elements perform the planned continuing and systematic evaluations or audits of the factors that affect the conformity (and, where required, the safe operation) of the products, parts, or appliances to the applicable design; this evaluation should include all the elements of the production management system to demonstrate compliance with Part 21.
- (b) The staff performing an independent monitoring function should have access to all the parts of the PO and, as necessary, to any subcontracted organisations.

~~AMC-ELA No 1 to 21.A.139(b)(2) Quality system – Independent quality assurance function~~

~~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~~

~~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

~~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.~~

GM1 No 2 to 21.A.139(f)(b)(2) Production management system Quality System – Adequacy of procedures and monitoring function

ADEQUACY OF PROCEDURES AND OF THE MONITORING FUNCTION

~~'Adequacy of procedures' means that the production management system, through the use of the procedures as set forth defined, is capable of meeting the conformity objectives that are identified in point 21.A.139(d)(1)(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.~~

AMC-ELA No 1 to 21.A.139(b)(2) Quality system – Independent quality assurance function

~~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~~

~~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.~~

~~AMC-ELA No 1 to 21.A.143 Exposition~~

~~*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/ 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 lined 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

~~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.~~

GM1 21.A.143 ~~Exposition~~ — Production organisation ~~Exposition~~ (POE)

GENERAL

(a) The purpose of the **production organisation exposition (POE)** is to ~~set forth~~ **state** in a concise ~~document~~ **documented** format the organisational relationships, responsibilities, terms of reference, and ~~the~~ **associated authority, procedures, means and methods of the organisation.**

The information to be provided is specified in **point 21.A.143(a)**. Where this information is documented and integrated in manuals, procedures and ~~instruction~~ **instructions**, the POE should provide a summary of the information and an appropriate cross-reference.

(b) **Point 21.A.143(b) requires that the initial issued of the POE is approved by the competent authority. Revisions of the POE are subject to the process that is described in point (c) below.** ~~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.~~

(c) When changes to the organisation occur, **according to point 21.A.143(c)**, the POE is required to be kept up to date. **This should be done as per a procedure, that is laid down in the POE. If the changes are significant, the organisation should not amend the POE before the competent authority approves the change in accordance with point 21.A.147.** ~~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.~~

AMC1 21.A.143(a)(1) Production organisation exposition

CONTENT OF THE PRODUCTION ORGANISATION EXPOSITION

- (a) All staff should be familiar with those production organisation exposition (POE) parts that are relevant to their tasks.
- (b) A paragraph in the POE should provide a description of the organisation, as well as the safety policy and the corresponding objectives, as required by point 21.A.139(c)(1).
- (c) The POE should include a statement, signed by the accountable manager (and countersigned by the senior company manager, if different), which confirms that the POE and any associated manuals are complied with at all times.

This statement should read as follows, or embrace the intent of the following text:

'This exposition defines the organisation and the procedures upon which the competent authority's production organisation approval (POA) is based.*

These procedures are approved by the undersigned, and must be complied with, as applicable, to ensure that all production activities are performed on time and to an approved standard.

It is understood that the approval of the production organisation (PO) is based on the organisation's continuous compliance with the applicable requirements of Part 21, and with the organisation's procedures that are described in this exposition. The competent authority is entitled to limit, suspend, or revoke the approval if the organisation fails to fulfil the obligations that are imposed by Part 21, or any conditions according to which the approval was issued.*

Signed

Dated

Accountable manager and (quote the position of the signatory)

Senior company manager

For and on behalf of (quote the organisation's name)'

**Where 'competent authority' is stated, please insert the actual name of the approving competent-authority organisation or administration that grants the POA.*

The statement should be reissued at the earliest opportunity when the accountable manager changes.

- (d) The POE should include the description of the internal safety reporting scheme that is required by point 21.A.3A(a)(1)(ii).
- (e) The POE should include the safety management procedures (including identification of safety hazards, evaluation, and associated risks management), safety assurance procedures, and safety promotion processes.

- (f) If the organisation holds one or more additional organisation certificates within the scope of Regulation (EU) 2018/1139 and the delegated and implementing acts that are adopted on the basis thereof, so that the organisation is required to establish another exposition, the organisation may combine the documents by producing a separate manual or supplement that covers the differences between the POE and the other exposition. In that case, the manual or supplement should identify where in the other exposition the remaining information on the production organisation (PO) is covered. That remaining information then formally becomes part of the exposition.
- (g) The organisation may document its safety policy, safety objectives, and all the safety management system key processes (as required by point 21.A.139(c)) in a separate manual (e.g. a safety management manual or management system manual) or in its POE. Organisations that hold multiple organisation approvals, which are issued under Regulation (EU) 2018/1139 and the delegated and implementing acts that are adopted on the basis thereof, may prefer to have a separate manual to avoid duplication.

~~AMC-ELA No 1 to 21.A.143(a)(13) Exposition – Policies and procedures related to flight test~~

~~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~~

~~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.

AMC1 21.A.145(a) Resources

EQUIPMENT AND TOOLS

The organisation's equipment and tools should enable all the specified tasks to be accomplished in a repeatable manner without any detrimental effects. The calibration control of the equipment and tools that affect the dimensions and values of products should demonstrate compliance with, and be traceable to, national or international standards.

AMC2 21.A.145(a) Resources

STAFF NUMBER AND COMPETENCY

- (a) Sufficient personnel means that, for each function, according to the nature of the work and the production rate, the organisation has a sufficient number of qualified staff to accomplish all the specified manufacturing tasks and to attest the conformity of such task. The number of staff should be such that the relevant airworthiness considerations may be applied in all areas without any undue pressure.
- (b) The organisation should have a system in place to plan the availability of staff to ensure that the organisation has sufficient appropriately qualified staff to plan, perform, supervise, inspect, and monitor the organisation's activities in accordance with the organisation's terms of approval.
- (c) The organisation should establish and control the competency of the staff that is involved in activities of the organisation, as detailed in the organisation's terms of approval, in accordance with documented procedures. In addition to the necessary expertise that is related to the job function, the competency of the staff should include an understanding of safety management and human factors (HF) principles, which is appropriate to the staff member's function and responsibilities in the organisation.
- (d) The competency evaluation should include verification, where appropriate, that specific qualification standards have been applied, for example, welding for non-destructive testing (NDT), etc.
- (e) To assist in the assessment of competency and to perform the analysis of the training needs, job (job family) descriptions are recommended, which should contain sufficient criteria to enable the required competency assessment throughout the duration of the employment/contract.
- (f) The organisation should develop a procedure that describes the process for assessing the competency of the staff. The procedure should specify:
 - (1) the staff that are responsible for that process;
 - (2) the means and methods for the initial assessment;
 - (3) the means and methods for the continuous control of the competency of the personnel, including feedback on their performance;
 - (4) the action to be taken if the assessment is not satisfactory; and

(5) how to record assessment results.

(g) Adequate initial and recurrent training should be provided in relation to the job function to ensure that staff remain competent. That training should be adapted based on experience that is gained within the organisation (for safety training, refer also to AMC1 21.A.139(c)(5)(i)).

(h) The organisation should record the training that is provided as described in point (g).

AMC-ELA No 1 to 21.A.145(a) Approval requirements – General

~~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.~~

GM1 21.A.145(a) Resources Approval Requirements

FACILITIES

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, and 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

~~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.~~

GM1 21.A.145(b)(2) Resources ~~Approval Requirements – Airworthiness, noise, fuel venting and exhaust emissions /production data procedures~~

PRODUCTION DATA

- 1—When a **production organisation approval (POA)** holder ~~or an~~ applicant **for a POA** is developing its own manufacturing data, such as computer-based data, from the design data package **that is** delivered by a design organisation, procedures are required to demonstrate the ~~right~~ **correct** transcription of the original design data.
- 2—Procedures are required to define the manner in which airworthiness, noise, fuel venting, and exhaust emissions data is used to issue and update the production/quality data, which determines the conformity of products, parts, and appliances. The procedure ~~should~~ **must** also define the traceability of such data to each individual product, part, or appliance for the purpose of certifying ~~at their~~ condition for safe operation and ~~of~~ issuing a ~~S~~ statement of ~~C~~ conformity or EASA Form 1.

~~AMC-ELA No 1 to 21.A.145(c) Approval requirements – Management and staff~~

~~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 competent authority.~~

AMC1 21.A.145(c)(1) Resources

ACCOUNTABLE MANAGER

(a) The accountable manager (AM) should:

- (1) have sufficient knowledge and authority to be able to respond to the competent authority regarding major issues concerning the production organisation approval (POA), and to carry out any necessary improvements;
- (2) promote the safety policies and objectives that are specified in AMC1 21.A.139(c)(1); and

(3) demonstrate a Part 21 understanding that is sufficient to discharge the relevant responsibilities.

(b) The production organisation exposition (POE) that is submitted in accordance with point 21.A.143 should show that the AM has the direct or functional responsibility for all the departments of the organisation which are involved in the POA. If any of those departments are functionally linked, the AM still has the ultimate responsibility for compliance of the PO with Part 21.

GM1 21.A.145(c)(1) Resources ~~Approval Requirements~~ – Accountable manager

ACCOUNTABLE MANAGER

‘Accountable manager’ refers to ~~means~~ the manager ~~that~~ ~~who~~ is responsible, and has corporate authority for ensuring that all production work is carried out to the required standard. This function may be ~~performed~~ ~~carried out~~ by the ~~Chief Executive~~ chief executive officer (CEO) or by another person in the organisation, nominated by ~~him or her~~ the CEO to fulfil the function, provided that the ~~his or her~~ position and authority of that person in the organisation ~~permits~~ ~~allows~~ that person to discharge the ~~associated~~ ~~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 li with the quality manager.~~

AMC1 GM 21.A.145(c)(2) Resources ~~Approval Requirements~~ – Responsible managers

NOMINATED MANAGERS

(a) The person or ~~group of~~ persons nominated in accordance with point 21.A.145(c)(2) should represent the management structure of the organisation and be responsible for all the functions as specified in Part 21, ~~Subpart G~~ ~~Section A Subpart G~~. ~~It therefore follows that,~~ ~~depending~~ ~~Depending~~ on the size of the ~~Part 21 Section A Subpart G~~ ~~approved~~ production organisation (PO), the functions may be subdivided under individual managers (and in fact may be further subdivided) or combined in a variety of ways.

(b) The organisation should nominate a person or a group of persons that are responsible for:

(1) the independent monitoring function as defined in point 21.A.139(e); and

(2) ensuring the development, administration, and maintenance of effective safety risk management processes as defined in point 21.A.139(c)(3).

- (c) If more than one person is designated for the management of the independent monitoring function, the AM should identify a unique focal point, typically known as the 'quality manager'.
- (d) If more than one person is designated for the development, administration, and maintenance of effective safety risk management processes as defined in point 21.A.139(c)(3), the AM should identify a 'safety manager' as the unique focal point.
- (e) ~~The competent authority requires the~~ Each nominated ~~managers~~ manager ~~to~~ should 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 ~~as a significant change in order~~ so that they may be seen to be appropriate in terms of ~~their~~ relevant knowledge and satisfactory experience related to the nature of the production activities as performed by the ~~Part 21 Section A Subpart G approved PO~~ organisation.
- (f) The responsibilities and the ~~duties~~ tasks of each individual manager ~~are required to~~ should 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 ~~the~~ responsibilities are covered.
- (g) Where ~~a Part 21 Section A Subpart G~~ an approved PO organisation chooses to appoint managers for all or ~~for~~ any combination of the ~~functions that are~~ identified in Part 21 ~~functions~~ because of the size of the undertaking, ~~it is necessary that the~~ those managers ~~should ultimately~~ report ~~ultimately~~ to the accountable manager. ~~When~~ ~~In cases where~~ a manager does not directly report to the accountable manager, ~~he or she~~ that manager should have ~~a formally established~~ direct access to the accountable manager ~~formally established~~.
- (h) The independent monitoring function should be independent from other functions. As such, the quality manager should not be at the same time one of the other persons that are referred to in point 21.A.145(c)(2), except for the safety manager. If the same person is designated to manage both the independent monitoring function and safety-management-related processes and tasks, the accountable manager, in order to discharge their safety accountability, should ensure that sufficient resources are allocated to both functions, taking into account the size of the organisation, and the nature and complexity of its activities.
- (i) Quality manager
- The role of the quality manager should be to ensure that:
- (1) the activities of the organisation are monitored for compliance with the applicable requirements and any additional requirements as established by the organisation, and that those activities are performed properly under the supervision of the nominated persons that are referred to in point 21.A.145(c)(2);
 - (2) an audit plan is properly implemented, maintained, and continually reviewed and improved; and
 - (3) corrections and corrective action are requested, as necessary.

(j) Safety manager

The role of the safety manager should be:

- (1) to facilitate hazard identification, as well as risk assessment and management;
- (2) to monitor the implementation of action taken to mitigate risks, as listed in the safety action plan, unless action follow-up is addressed by the independent monitoring function;
- (3) to provide periodic reports on safety performance to the safety review board (the functions of the safety review board are defined in AMC1 21.A.139(c)(2));
- (4) to ensure the maintenance of safety management documentation;
- (5) to ensure that there is safety training available, and that it meets acceptable standards;
- (6) to provide advice on safety matters; and
- (7) to ensure the initiation and follow-up of internal investigations of occurrences.

(k) Subject to a risk assessment and the competent authority's agreement, with due regard to the size of the organisation, and the nature and complexity of its activities, the functions of the compliance monitoring manager and the safety manager may be performed by the accountable manager, provided that the accountable manager has demonstrated the related level of competency.

~~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.~~

AMC2 21.A.145(c)(2) Resources

MANAGEMENT STAFF COMPETENCIES

- (a) The organisation should provide initial and recurrent training to the persons or group of persons that are nominated in accordance with point 21.A.145(c)(2), which is adequate to their job function and ensures that their continued competency is maintained throughout the duration of their employment/contract.
- (b) All prospective members of the production management staff and staff that is nominated in accordance with point 21.A.145(c)(2) should:
 - (1) be assessed for their competency, qualifications, and capabilities that are related to their intended duties;
 - (2) be able to demonstrate their knowledge of, and compliance with, the production management organisation procedures that are applicable to their job function; and
 - (3) be able to demonstrate an understanding of the safety management principles, as well as human factors (HF) issues and human performance (HP) issues that are related to their tasks.

- (c) The quality manager should be able to demonstrate relevant knowledge, background, and appropriate experience that are related to the activities of the organisation, including knowledge of, and experience in, independent system monitoring.
- (d) The competency of the person that assumes (or the persons that assume) the function of the safety manager should include, but not be limited to, the following:
- (1) knowledge of the International Civil Aviation Organization (ICAO) standards and EU requirements for safety management;
 - (2) an understanding of management systems, including compliance monitoring systems;
 - (3) an understanding of risk management;
 - (4) an understanding of safety investigation techniques;
 - (5) an understanding of HF, including HP and limitations;
 - (6) an understanding of a positive safety culture and of its promotion; and
 - (7) operational experience related to the activities of the organisation.

AMC1 21.A.145(d)(1) Resources Approval Requirements – Certifying staff

CERTIFYING STAFF

1. (a) Certifying staff should be nominated by the production organisation to ensure that each of their products, parts, and/or appliances qualify for a statement of conformity or a release certificate. The position and number of certifying staff should be appropriate to the complexity of the product and the production rate.
2. (b) The qualifications of certifying staff should be based on their knowledge, background and experience and on a specific training (or testing) that is established by the organisation to ensure that it is appropriate to the product, part, or appliance to be released.
3. (c) Training must be given to certifying staff to develop a satisfactory level of knowledge of product/part specifications, the organisation's procedures, production management systems (including compliance monitoring), aviation legislation, and the associated regulations implementing rules, CSAMC and GM that are relevant to their particular role. Training should include on-the-job training, as relevant.
4. (d) For that purpose, in addition to the general training policy, the organisation should 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.(e) A feedback system to ascertain that the required standards are being maintained **must** should be put in place to ensure the continuing compliance of personnel **to**with authorisation requirements.~~
- ~~8.(f) For **the** release of products, parts, or appliances, the responsibilities to issue statements of conformity **or** /release certificates (EASA Form 1) or **permit**permits to fly, including **the** approval of flight conditions, are allocated to the certifying staff **that is** identified in **point** 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

~~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

- ~~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

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.

AMC1 21.A.145(d)(2)(3) Resources Approval requirements – Evidence of authorisation

EVIDENCE OF AUTHORISATION

- (1.a) The certifying staff should be provided with evidence of their authorisation. This should be done through an internal authorisation document. That document ~~must~~ should be in a style that makes its scope clear to the certifying staff and any entitled authorised person that who may require to examine the authorisation. It should include the privileges that are granted to the certifying staff and the category of products upon which they may exercise those privileges. Where codes are used to define the scope, an interpretation document should be readily available.
- (2.b) Certifying staff are not required to carry the authorisation document at all times, but they should be able to make it available within a reasonable time following of a request from an entitled authorised person. ~~Authorised persons, which~~ includes the competent authority.

AMC-ELA No 1 to 21.A.145(d)(3) Approval requirements – Evidence of authorisation

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.

AMC1 21.A.147 Changes to the production management system

APPLICATION FOR APPROVAL OF SIGNIFICANT CHANGES OR VARIATIONS IN THE SCOPE OR TERMS OF A PRODUCTION ORGANISATION APPROVAL

- (a) An application for approval of significant changes or variations in the scope or terms of a production organisation approval (POA) should be submitted in writing to the competent authority. The production organisation (PO) should demonstrate to the competent authority, on the basis of the submission of any proposed changes to the production organisation exposition (POE), and before the implementation of the changes, that it will continue to comply with Part 21 after the implementation.
- (b) The approved PO should submit to the competent authority an application for any significant change(s), or for a variation in the scope or terms of its POA, using an EASA Form 51 (see below).

EASA Form 51 Application for significant changes or variation of the scope or terms of a 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. Location(s) for which changes in the terms of approval are requested:	
4. Brief summary of the 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:	
<hr style="width: 100%;"/> Date	<hr style="width: 100%;"/> Signature of the accountable manager (or nominee)

EASA Form 51

Block 1: The name should be entered as written on the current approval certificate. If 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 should 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 location(s) for which changes in the terms of approval are requested, or state 'not applicable' if no change is anticipated.

Block 4: This block should include further details for the variation of the scope of approval for the addresses indicated in Block 3. The 'General' block should include overall information for the change (including changes e.g. in workforce, facilities, etc.), while the 'Scope of approval' block should address the change in the scope of work and products/categories, following the principles laid down in GM 21.A.151. The 'nature of privileges' block should indicate a change in the privileges as defined in points 21.A.163(b)-(d). State 'not applicable' if no change is anticipated.

Block 5: This block should state the changes to the organisation as it is defined in the current POE, including changes to the organisational structure, functions, and responsibilities. This block should therefore also be used to indicate a change in the accountable manager in accordance with point 21.A.145(c)(1) or a change in the nomination of the responsible managers in accordance with point 21.A.145(c)(2). State 'not applicable' if no change is anticipated.

Block 6: State the position and name of the accountable manager. Where there is a change in the nomination of the accountable manager, the information should refer to the nominee for that position. State 'not applicable' if no change is anticipated.

In case of an application for a change of the accountable manager, EASA Form 51 should be signed by the new nominee for that position. In all other cases, EASA Form 51 should be signed by the accountable manager.

~~GM-ELA No 1 to 21.A.147 Changes to the approved production organisation~~

~~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.~~

GM1 21.A.147(a) Changes to the ~~approved~~ production management system ~~organisation~~ — Significant changes

SIGNIFICANT CHANGES

1. Changes to be approved by the competent authority include:

- ~~S~~ignificant changes to ~~the~~ production capacity or methods;
- ~~C~~hanges in the organisation's structure, especially those parts of the organisation in charge of quality and safety;
- a change of the accountable manager or of any other person that is nominated under ~~point 21.A.145(c)(2)~~;
- ~~C~~hanges in the production ~~or quality management~~ systems that may have an important impact on the conformity ~~or~~ airworthiness of ~~any each~~ product, part, or appliance, including in the reporting lines between the personnel that is nominated in accordance with ~~point 21.A.145(c)(2)~~ and the accountable manager; and
- ~~C~~hanges in the placement or control of significant ~~sub-contracted~~ subcontracted 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 (refer to ~~point 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 ~~point 21.A.148~~, and changes of ownership in ~~point 21.A.149~~, and the change of scope of ~~the~~ approval in ~~point 21.A.153~~.

GM1 21.A.149 and 21.A.249 Transferability

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.A.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.

AMC 21.A.153 Changes to the terms of approval — Application for a change to the terms of approval

EASA Form 51 (see AMC ~~21.A.147 No 1 to 21.B.240~~) must be obtained from the competent authority and completed in accordance with the procedures of the **production organisation exposition (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~~ **should** 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

EASA Form 51 (see AMC ~~1 21.A.147~~ ~~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 (POA) 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.

~~GM 21.A.157 Investigations – Arrangements~~

~~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

[...]

~~GM-ELA No 1 to 21.A.157 Investigations – Arrangements~~

~~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.~~

~~GM-ELA No 1 to 21.A.158 Findings~~

~~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~~

~~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~~

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.~~

~~GM 21.A.165(d) and (h) Obligations of the holder – Recording and archiving system~~

~~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 Safety System required by 21.A.139.~~

~~All forms of recording media 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~~

~~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 coctive actions.~~

~~AMC-ELA No 1 to 21.A.165(e);(f) Obligations of the holder – Reporting to the design holder~~

~~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~~

~~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~~

~~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 recordkeeping to that partner, supplier or subcontractor.~~

SUBPART J — DESIGN ORGANISATION APPROVAL

AMC1 21.A.239(c) Design management system

SAFETY MANAGEMENT ELEMENT

Demonstration of compliance with the international industry standard SM-0001 'Implementing a Safety Management System in Design, Manufacturing and Maintenance Organisations', Issue B, 31 March 2022, is an acceptable means to demonstrate compliance with the safety management element of the design management system.

GM1 21.A.239(c) Design management system

SAFETY MANAGEMENT ELEMENT

Safety management seeks to proactively identify hazards and mitigate the related safety risks before they result in aviation accidents and incidents. Safety management enables an organisation to manage its activities in a more systematic and focused manner. When an organisation has a clear understanding of its role in, and contribution to, aviation safety, this enables the organisation to prioritise safety risks and more effectively manage its resources for optimal results.

Safety should not be considered the responsibility of a single person or a limited group of people in the organisation. A safety culture should be developed throughout the organisation, which involves all the personnel as active contributors to the safety of the final product, part, or appliance, (see AMC1 21.A.239(c)(1)).

The principles of the requirements in points 21.A.3A, 21.A.5, 21.A.239, 21.A.245, and 21.A.247, and the related AMC constitute the EU design management system framework for aviation safety management. This framework addresses the core elements of the International Civil Aviation Organization (ICAO) safety management system (SMS) framework that is defined in ICAO Annex 19, Appendix 2, and facilitates the introduction of the additional safety management element.

This approach is intended to encourage organisations to embed safety management and risk-based decision-making into all their activities, instead of superimposing another system onto their existing management system and governance structure. In addition, if the organisation holds multiple organisation certificates that are issued under Regulation (EU) 2018/1139, it may choose to implement a single management system to cover all of its activities. An integrated management system may be used not only to capture multiple management system requirements resulting from Regulation (EU) 2018/1139, but also to cover for other regulatory provisions requiring compliance with ICAO Annex 19 or for other business management systems, such as security, occupational health, and environmental management systems. Integration will remove duplication and exploit synergies by managing safety risks across multiple activities. Organisations may determine the best means to structure their management systems to suit their business and organisational needs.

It is important to recognise that safety management will be a continuous activity, as hazards, risks, as well as the effectiveness of safety risk mitigations, will change over time.

The safety management capability of an organisation should be commensurate with the safety risks to be managed, which can be at the product, part, and appliance level or at the organisational level.

The risks that are inherent in a complex structure require a robust safety risk management process (e.g. complex interfaces with different partners that participate in the design of a product may pose hazards that are complex to mitigate).

As a consequence, scalability and suitability of the safety management element should be a function of the inherent safety risk capability of the organisation. For instance, for organisations with a lower risk level:

- (a) the risk assessment model that is used may be very simple in cases in which the identified hazards are easy to mitigate;
- (b) expert judgement might be sufficient to measure the efficiency of safety barriers;
- (c) the collection of data, safety information, and occurrences might be very limited;
- (d) there might be no need for software or tools to manage the SMS; and
- (e) the communication policy might be limited.

AMC1 21.A.239(c)(1) Design management system

SAFETY POLICY & OBJECTIVES

- (a) The safety policy should:
 - (1) reflect organisational commitments regarding safety, and its proactive and systematic management, including the promotion of a positive safety culture;
 - (2) include internal reporting principles by fostering the reporting of organisational threats as well as events, as defined in AMC3 21.A.3A(a);
 - (3) be endorsed by the head of the design organisation (HDO);
 - (4) be communicated, with visible endorsement, throughout the organisation; and
 - (5) be periodically reviewed to ensure that it remains relevant and appropriate to the organisation.
- (b) The safety policy should include the commitment:
 - (1) to comply with all the applicable legislation, meet all the applicable requirements, and adopt practices to improve safety standards;
 - (2) to provide the necessary resources for the implementation of the safety policy;
 - (3) to apply human factors (HF) principles;
 - (4) to enforce safety as a primary responsibility of all managers; and
 - (5) to apply 'just culture' principles and, in particular, not to make available or use the information on occurrences:
 - (i) to attribute blame or liability to personnel for actions, omissions, or decisions that are commensurate with their experience and training; or
 - (ii) for any purpose other than the improvement of aviation safety.

- (c) Senior management should continuously promote the safety policy to all personnel, demonstrate their commitment to it, and provide the necessary human and financial resources for its implementation.
- (d) Taking due account of its safety policy, the organisation should define safety objectives. The safety objectives should:
- (1) form the basis for safety performance monitoring and measurement;
 - (2) reflect the organisation's commitment to maintaining and continuously improving the overall effectiveness of safety management;
 - (3) be communicated throughout the organisation; and
 - (4) be periodically reviewed to ensure that they remain relevant and appropriate to the organisation.

GM1 21.A.239(c)(1) Design management system

SAFETY POLICY

The safety policy is the means for the organisation to state its intention to maintain and, where practicable, to improve the safety levels of all its activities, and to minimise its contribution to the risk of an aircraft accident or serious incident occurring, as far as reasonably practicable. The safety policy reflects the management's commitment to safety and the organisation's philosophy of safety management. It is the foundation on which the organisation's management system is built and serves as a reminder of 'how we do business here'. The creation of a positive safety culture begins with issuing a clear, unequivocal policy statement.

The commitment to apply 'just culture' principles forms the basis for the organisation's internal rules that describe how 'just culture' principles are guaranteed and implemented.

Regulation (EU) No 376/2014 defines the 'just culture' principles to be applied (refer, in particular, to Article 16(11) of that Regulation).

AMC1 21.A.239(c)(2) Design management system

ORGANISATION AND ACCOUNTABILITY

- (a) The management system should encompass safety by including a safety manager and a safety review board in the organisational structure. The functions of the safety manager are defined in AMC1 21.A.245(b).
- (b) Safety review board
- (1) The safety review board (the 'board'), sometimes referred to as 'high-level safety committee', considers matters of strategic safety in support of the safety accountability of the head of the design organisation (HDO).
 - (2) The board should be normally chaired by the HDO and be generally composed of the person or group of persons nominated under point 21.A.245(b). Its composition can be adapted to its needs, considering point 21.A.245(b).

- (3) The board should monitor:
 - (i) the organisation's safety performance against its safety policy and objectives;
 - (ii) whether any safety action is taken in a timely manner; and
 - (iii) the effectiveness of the organisation's management system processes.
- (4) The board may also be tasked with:
 - (i) reviewing the results of compliance monitoring; and
 - (ii) monitoring the implementation of related corrective and preventive action.
- (c) The board should ensure that appropriate resources are allocated to achieve the established safety objectives.
- (d) Notwithstanding point (a), if justified by the size of the organisation and the nature and complexity of its activities, and subject to a risk assessment and/or mitigation measures, as well as the competent authority's agreement, the organisation may not need to establish a board. In that case, the tasks that are normally allocated to the board should be allocated to the safety manager.

GM1 21.A.239(c)(2) Design management system

SAFETY ACTION GROUP

- (a) Depending on the size of the organisation and the nature and complexity of its activities, a safety action group may be established as a standing group or as an ad hoc group to assist, or act on behalf of, the safety manager or the safety review board.
- (b) More than one safety action group may be established, depending on the scope of the task and the specific expertise that is required.
- (c) The safety action group usually reports to, and takes strategic direction from, the safety review board, and may be composed of managers, supervisors, and personnel from operational areas.
- (d) The safety action group may be tasked with or assist in the following:
 - (1) monitoring safety performance;
 - (2) defining action to control risks to an acceptable level;
 - (3) assessing the impact of organisational changes on safety;
 - (4) ensuring that safety action is implemented within the agreed timescales; and
 - (5) reviewing the effectiveness of previous safety action and safety promotion.

AMC1 21.A.239(c)(3) and (4) Design management system**SAFETY MANAGEMENT KEY PROCESSES****(a) Hazard identification processes**

- (1) Hazard identification should be based on a combination of reactive and proactive methods.
- (2) The organisation should focus in particular on hazards that may result from non-compliance or errors in the design of a product, part, or appliance.

(b) Safety risk management processes

- (1) The organisation should develop and maintain a safety risk management process that ensures a reactive, proactive, and predictive approach composed of the following elements:
 - (i) analysis (e.g. in terms of the probability or likelihood as well as severity of the consequences of hazards and occurrences);
 - (ii) assessment (in terms of tolerability); and
 - (iii) control (in terms of mitigation) of risks to an acceptable level.
- (2) The organisation should specify, within the risk management process, who has the authority to make decisions, considering point (b)(1) of this AMC.

(c) Regardless of the approval status of the subcontracted organisations, the design organisation (DO) is responsible for ensuring that hazard identification and risk management activities are performed on subcontracted activities, as required by point 21.A.239(d)(3), as well as for the monitoring of their compliance and adequacy, as required by point 21.A.239(e).

(d) Internal investigation

- (1) In line with 'just culture' as part of the safety policy, the organisation should define how to investigate events such as errors or near misses, in order to understand not only what happened, but also how it happened, as well as to prevent or reduce the probability and/or the consequences of any future recurrence.
- (2) The scope of internal investigations should extend beyond the scope of the occurrences that are required to be investigated in accordance with point 21.A.3A.

(e) Safety performance monitoring and measurement

- (1) Safety performance monitoring and measurement should be the processes through which the safety performance of the organisation is verified against the safety policy and the safety objectives.
- (2) This process may include, as appropriate to the size, nature, and complexity of the organisation, the following elements:
 - (i) safety reporting that also addresses the status of compliance with the applicable requirements;

- (ii) safety reviews, including trend reviews, which should be conducted during the introduction of new technologies, the implementation of new or changed procedures, or in cases of organisational changes that may have an impact on safety;
- (iii) safety audits that focus on the integrity of the organisation's management system, and that periodically assess the status of safety risk controls;
- (iv) safety surveys that examine particular elements or procedures of a specific area, such as the following:
 - (A) the problem areas identified;
 - (B) bottlenecks in the daily design management activities,
 - (C) the perceptions and opinions of the design management personnel; and
 - (D) any areas of dissent or confusion; and
- (v) other indicators relevant to safety performance.

(f) Management of change

Changes to the design management system may pose new hazards or decrease the effectiveness of existing safety risk controls. The organisation should manage any safety risks that are related to change in that organisation. The management of change should be a documented process to identify external or internal change that may have an adverse effect on safety. The management of change should use of the organisation's existing processes for hazard identification, risk assessment, and risk mitigation.

(g) Continuous improvement

The organisation should continuously seek to improve its safety performance and the effectiveness of its design management system. Continuous improvement may be achieved through review of the following elements:

- (1) compliance monitoring and audits;
- (2) assessments, including assessments of the effectiveness of the safety culture and of the management system, to assess in particular the effectiveness of the safety risk management processes;
- (3) staff surveys, including safety culture surveys, that can provide useful feedback on how engaged the staff are in the design management system;
- (4) the monitoring of events and their recurrence;
- (5) the evaluation of the safety performance indicators as well as reviews of all the available safety performance information; and
- (6) the identification of lessons learned.

AMC1 21.A.239(c)(4)(ii) Design management system**MANAGEMENT OF CHANGE**

This AMC provides a means to consider organisational changes for their potential impact on safety. Organisational changes should also be evaluated for their significance, as required by point 21.A.247. In addition, necessary changes should be introduced into the handbook, as per point 21.A.243(c). The design management system should be designed such that all the above points are taken into account.

- (a) Organisational changes should be proactively considered for their safety implications. The magnitude of a change, its safety criticality, and its potential impact on human performance (HP) should be assessed in any process for the management of change. Certain non-complex organisational changes may not require additional assessment.
- (b) Special consideration, including human factors (HF) issues, should be given to the transition period during which the change becomes effective.
- (c) During the process for the management of change, relevant previous risk assessments and existing hazards should be reviewed for their possible effects.

GM1 21.A.239(c)(4)(ii) Design management system**MANAGEMENT OF CHANGE**

Unless properly managed, changes in the organisational structure, facilities, scope of work, personnel, documentation, policies and procedures, etc. may result in inadvertently creating new hazards, which may expose the organisation to new or greater risks. Effective organisations seek to improve their processes, while being conscious of the fact that changes may expose the organisation to potential hazards and risks if they are not properly and effectively managed.

The process for the management of change typically provides principles and a structured framework for managing all aspects of changes. The disciplined implementation of management of change may maximise the effectiveness of change, engage staff, and minimise the risks that are inherent in change.

Change may have the potential to raise new HF issues, or to exacerbate existing ones. For example, changes in computer systems, equipment, technology, personnel changes (including changes in management personnel), procedures, the organisation of work, or work processes are likely to affect performance.

Effective management of change is supported by the following elements:

- (a) the implementation of a process for hazard identification/risk analysis and assessment for major operational changes, major organisational changes, changes in key personnel, and changes that may affect the way in which design management is carried out;
- (b) the identification of changes that may have a considerable impact on:
 - (1) resources (material and human);
 - (2) management direction (policies, processes, procedures, training); and
 - (3) management control;
- (c) safety cases/risk assessments that are aviation-safety focused; and

- (d) the involvement of key stakeholders in the process for the management of change, as appropriate.

AMC1 21.A.239(c)(5) Design management system

SAFETY COMMUNICATION

- (a) The organisation should establish communication to the staff, as appropriate to their safety responsibilities, regarding safety matters, which:
- (1) ensures awareness of safety management activities;
 - (2) conveys safety-critical information, especially related to assessed risks and analysed hazards;
 - (3) explains why particular action is taken; and
 - (4) explains why safety procedures are established or changed.
- (b) Regular meetings with staff, during which information, action, and procedures are discussed, may be used to communicate safety matters.

GM1 21.A.239(c)(5) Design management system

SAFETY PROMOTION

- (a) Safety training, combined with safety communication and information sharing, is part of safety promotion.
- (b) Safety promotion activities support the following:
- (1) the organisation's policies, encouraging a positive safety culture, thus creating an environment that is favourable to the achievement of the organisation's safety objectives;
 - (2) organisational lessons learned; and
 - (3) the implementation of an effective safety reporting scheme and the development of a 'just culture'.
- (c) Depending on the particular safety issue, safety promotion may also constitute or complement risk mitigation action.

AMC1 21.A.239(c)(5)(i) Design management system

SAFETY TRAINING

- (a) The design management staff, as described in points 21.A.245(a) and (b), should receive initial and recurring safety training, as appropriate to their responsibilities, including in safety management principles and the associated safety objectives, to ensure their continued competency.

- (b) The organisation should identify the category of other staff to which safety training should be provided, and define the initial and recurrent training programmes, including appropriate timelines.
- (c) Adequate records of the safety training that is provided should be kept in accordance with point 21.A.5.

GM1 21.A.239(c)(5)(i) Design management system

SAFETY TRAINING

- (a) The main purpose of the safety training programme is:
 - (1) to support safety management policies and processes; and
 - (2) to ensure that personnel at all levels of the organisation develop and maintain their competency to fulfil their safety roles.
- (b) Each organisation may adapt its syllabus to its own needs. Typically, depending on the targeted staff, to contribute to a positive safety culture, the following items may be included:
 - (1) the organisational roles and responsibilities related to safety, including the hazard identification and risk management processes;
 - (2) the safety objectives and the associated safety performance indicators;
 - (3) human factors (HF) principles, including human performance (HP) and limitations;
 - (4) legislation, where applicable;
 - (5) safety reporting systems and investigations; and
 - (6) safety issues.
- (c) The purpose of the recurrent safety training is:
 - (1) primarily to ensure that staff are kept abreast notably of changes to safety management system (SMS) principles, processes, and procedures; and
 - (2) also to share feedback on safety issues that are relevant to the organisation or lessons learned.
- (d) The training staff should have sufficient knowledge and experience to teach the topics at the required level, as well as the skills to influence attitudes and behaviours.

AMC-ELA No 1 to 21.A.239(a) Design assurance system – Definition

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~~

~~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

~~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~~

~~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.239(d)(a) Design assurance management system

DESIGN ASSURANCE ELEMENT

(a) ~~1.~~ Purpose

This GM outlines some basic principles and objectives of ~~21.A.239(a)~~ the design assurance element.

(b) ~~2.~~ Definitions

~~2.(1)~~ The design assurance element includes system is the organisational structure, responsibilities, procedures, and resources to ensure the proper functioning of the design organisation.

~~2.(2)~~ The design 'Design assurance' refers to means all these planned and systematic actions necessary to provide adequate confidence that the organisation has the capability to:

- ~~to~~ design products or parts in accordance with the applicable type certification basis, the operational suitability data (OSD) certification basis, CS and the environmental protection requirements;
- ~~to~~ demonstrate and verify the compliance with these type certification basis, the OSD certification basis, CS and the environmental protection requirements; and
- ~~to~~ demonstrate to the Agency EASA that is compliance.

~~2.(3)~~ The 'Type Investigation' means refers to the tasks of the organisation in support of the type certificate (TC), supplemental type certificate (STC), or other design approval processes necessary to demonstrate, and verify, and ~~to~~ maintain compliance with the applicable type certification basis, OSD certification basis, 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.~~

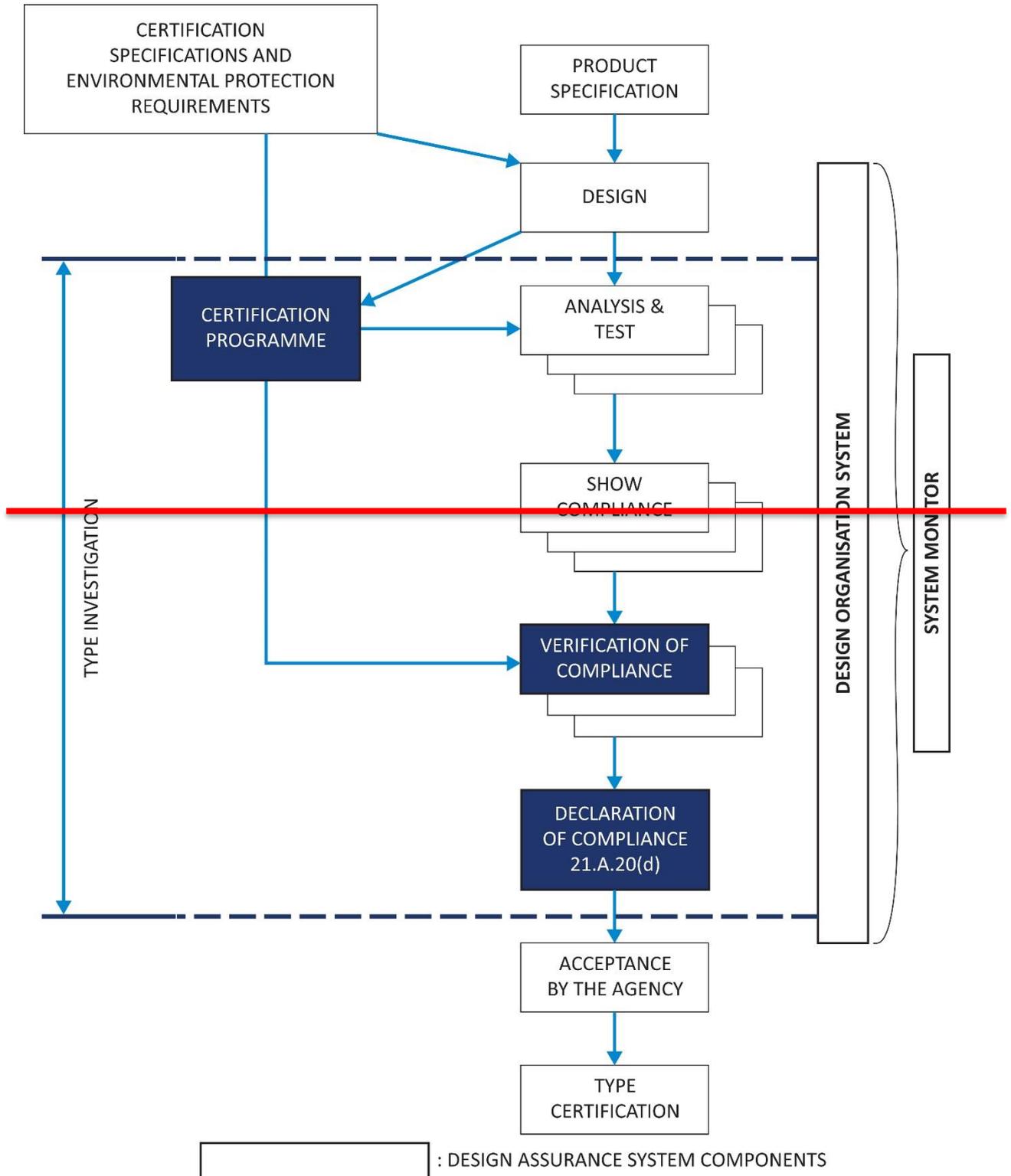


Figure 1— RELATIONSHIPS BETWEEN DESIGN, DESIGN ASSURANCE AND TYPE INVESTIGATION

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 21.A.57, 21.A.61, 21.A.107, 21.A.119, 21.A.120A and 21.A.449, ensuring that these documents are provided to all affected operators and all involved authorities.~~

~~3.1.6 Operational Suitability Data~~

- ~~(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.~~

AMC1 21.A.239(d) Design management system**DESIGN ASSURANCE ELEMENT**

(a) Reserved

(b) Reserved

(c) Design assurance system

The complete design process, starting with the type certification basis, operational suitability data (OSD) certification basis, as well as environmental protection requirements and product specifications, and culminating with the issuing of a type certificate (TC), is shown in Figure 1, which identifies the relationships between the design, the certification, and the design assurance processes.

Effective design assurance requires a continuing evaluation of all the factors that affect the adequacy of the design for the intended applications. In particular, it should be ensured that the product or part complies with the applicable type certification basis, OSD certification basis, and environmental protection requirements, and that it will continue to comply after any change to the TC or any repair.

Planned and systematic tasks should therefore be defined and performed from the very beginning of the design activities up to the continued-airworthiness activities.

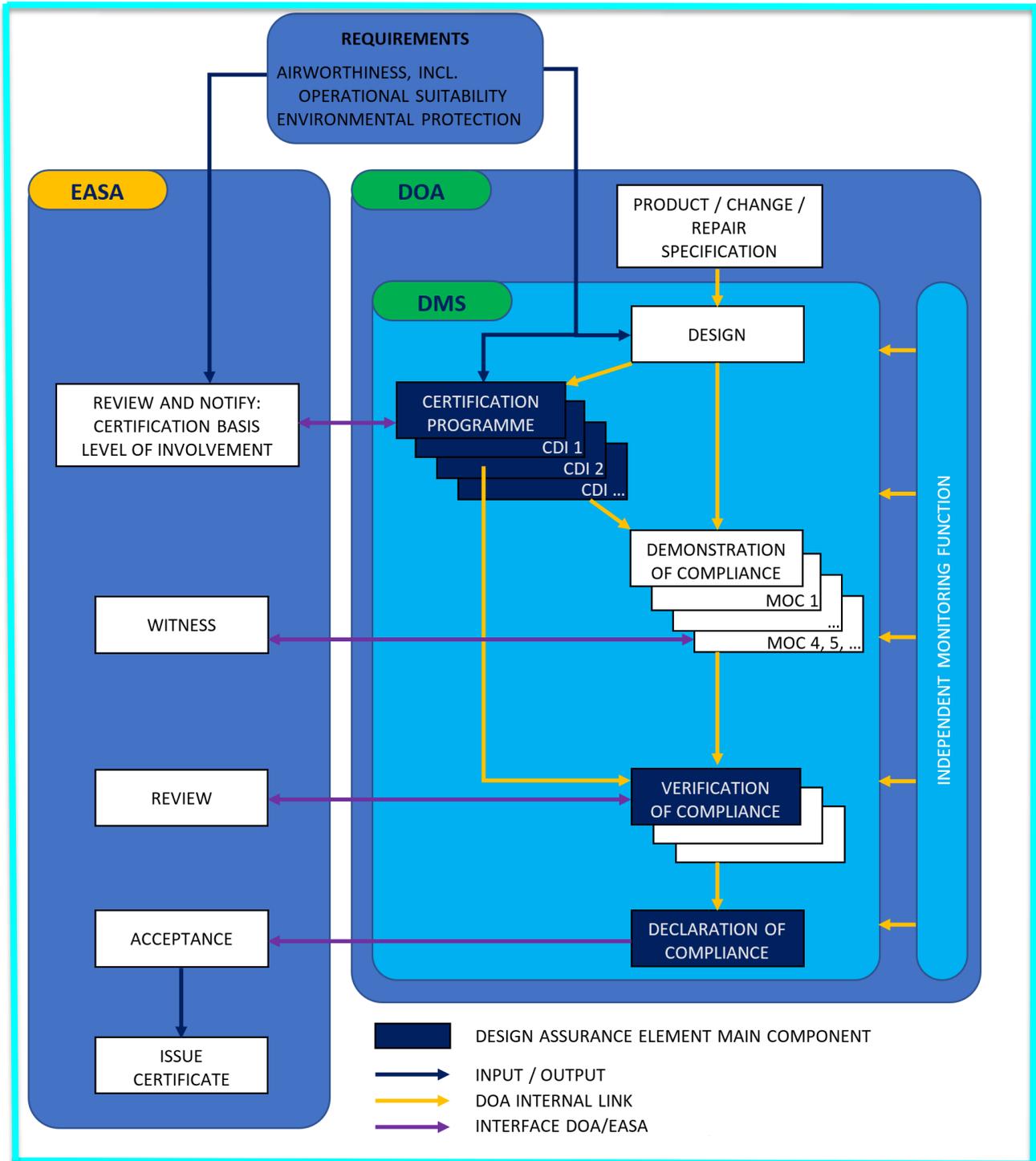


Figure 1 — RELATIONSHIPS' CONCEPT IN DESIGN AND CERTIFICATION

(1) Planned and systematic tasks

For design organisations that carry out the certification process of products, their planned and systematic tasks should cover the following, and the related procedures should be defined accordingly.

(i) General

- (A) Issue or, where applicable, supplement, or amend the handbook in accordance with point 21.A.243, in particular to indicate the initiation of design activities on a product.
- (B) Assure that all the instructions of the handbook are adhered to.
- (C) Conduct the certification process.
- (D) Nominate staff as 'compliance verification engineers' that are responsible for approving compliance documents as defined in point (c)(1)(iii).
- (E) Nominate staff that belong to the Office of Airworthiness and are responsible as defined in point (c)(1)(iv).
- (F) In the case of an applicant for an STC, obtain the agreement of the TC holder for the proposed supplemental type certificate (STC) to the extent that is defined in point 21.A.115.
- (G) Ensure that there is full and complete liaison between the design organisation and the related organisations that have responsibility for the products and parts that are manufactured according to the type design.
- (H) Provide assurance to EASA that any prototype models and test specimens adequately conform to the type design (see point 21.A.33(c)).

(ii) Head of the design organisation (or deputy)

The head of the design organisation (HDO), or an authorised representative, should sign a declaration of compliance (see points 21.A.20(d) and 21.A.97(b)(3)) with the applicable type certification basis, OSD certification basis, and environmental protection requirements after verifying the satisfactory completion of the certification process. In accordance with point 21.A.20(e), the signature of the HDO on the declaration of compliance confirms that the procedures as specified in the handbook have been followed (see also GM 21.A.265(b)).

(iii) Compliance verification

- (A) Approval through the signing of all the compliance documents, including test programmes and data that are necessary for the verification of compliance with the applicable type certification basis, OSD certification basis and environmental protection requirements, as defined in the certification programme.
- (B) Approval of the technical content (completeness, technical accuracy, etc.), including any subsequent revisions of the manuals to be approved by EASA (aircraft flight manual (AFM), airworthiness limitations section of the instructions for continued airworthiness (ICA), and certification maintenance requirements (CMRs) document, where applicable).

(iv) Airworthiness function

The airworthiness function is commonly performed by the Office of Airworthiness and should cover the following tasks as relevant*:

- (A)** liaison between the design organisation (DO) and EASA with respect to all aspects of the certification programme;
- (B)** ensuring that a handbook and the flight test operations manual, when relevant, are prepared and updated as required by point 21.A.243;
- (C)** cooperation with EASA in developing procedures to be used for the type certification process;
- (D)** issuing of guidelines for documenting compliance;
- (E)** cooperation in issuing guidelines for the preparation of the manuals that are required by the applicable requirements, service bulletins (SBs), drawings, specifications, and standards;
- (F)** ensuring procurement and distribution of the applicable type certification basis, OSD certification basis, as well as environmental protection requirements and other specifications;
- (G)** cooperating with EASA in proposing the type certification basis, OSD certification basis, and environmental protection requirements;
- (H)** the interpretation of the type certification basis, OSD certification basis, and environmental protection requirements, and requesting EASA to take decisions in case of doubt;
- (I)** advising all the departments of the DO on any question regarding airworthiness, operational suitability, environmental protection approvals, and certification;
- (J)** the preparation of the certification programme, including a proposal for EASA involvement in the verification of compliance demonstration activities and data, and coordination of all the tasks related to the certification process in agreement with EASA;
- (K)** regular reporting to EASA about the progress of the certification process, including any difficulty or event that may necessitate a change of the previously notified EASA level of involvement, and announcing scheduled activities (e.g. tests) in due time;
- (L)** ensuring cooperation in preparing the inspection and test programmes needed for demonstration of compliance;
- (M)** establishing the compliance checklist and updating it with any changes;
- (N)** checking that all the compliance documents that are necessary to demonstrate compliance with the type certification basis, OSD certification

- basis, and environmental protection requirements are prepared and complete, and signing the documents for release;
- (O) checking the required type design definition documents that are described in point 21.A.31 and ensuring that they are provided to EASA for approval when required;
 - (P) preparation, if necessary, of a draft of a type certification data sheet (TCDS) and/or a modification to a TCDS;
 - (Q) providing verification to the HDO that all the activities that are required for the certification process have been properly completed;
 - (R) managing the exercise of the DO privileges in accordance with point 21.A.263(c);
 - (S) monitoring significant events on other aeronautical products, as far as they are relevant, to determine their effect on the airworthiness or operational suitability of the products that are designed by the DO;
 - (T) ensuring that there is cooperation in preparing SBs and the structural repair manual, and any subsequent revisions, with special attention to the manner in which the contents affect airworthiness and environmental protection, and granting the approval on behalf of EASA;
 - (U) ensuring the initiation of activities in response to a failure (accident/incident/in-service occurrence) evaluation and to complaints from the operation, and providing information to EASA if airworthiness or operational suitability are impaired (continuing airworthiness and continued operational suitability);
 - (V) advising EASA on the issuing of airworthiness directives in general based on SBs; and
 - (W) ensuring that the manuals that are approved by EASA, including any subsequent revisions, (AFM, airworthiness limitations section of the ICA, and CMR document, where applicable) are checked, to determine whether they meet their respective requirements, and that they are provided to EASA for approval.
- * Some of the above tasks may be carried out through a different organisational function.
- (v) Maintenance and operating instructions
 - (A) Ensuring the preparation and updating of all the maintenance and operating instructions (including ICA and SBs) that are needed to maintain airworthiness (i.e. continuing airworthiness) in accordance with the relevant certification specifications (CSs). For that purpose, the applicant should:

- (a) establish the list of all the documents they produce to comply with CS 2X.1581 (CS 23.2620) and with the Appendix that is referred to in CS 2X.1529, CS-E 20/25, or CS-P 30/40, or CS 23.2625;
- (b) establish a system to collect in-service experience to be used for the improvement of the instructions; and
- (c) define the procedures and the organisation for producing and issuing those documents, taking into account the obligation of point 21.A.265(h); those procedures should cover the following elements:
 - (1) preparation, including format and language (available industrial standards can be referred to and used);
 - (2) proofreading (checking for clarity, readability, typos, etc.);
 - (3) verification of technical consistency with the corresponding approved change(s), repair(s), or approved data, including effectivity, description, effects on airworthiness and environmental protection, especially when limitations are changed;
 - (4) verification of feasibility in practical applications, when relevant and feasible; and
 - (5) responsibilities and authorised signatories.

Note: Compliance verification, as described in point (c)(1)(iii) of this AMC, applies to the manuals that are approved by EASA (AFM, airworthiness limitations section of the ICA, and CMR document, where applicable); for the other ICA or other maintenance instructions, the procedure that is required by (c)(1)(v) of this AMC provides a sufficient level of verification and does not require specific compliance verification unless, as per point 21.A.90C, additional work to demonstrate compliance is required; in that case, where additional compliance demonstration is required, points 21.A.91 to 21.A.109, as well as the independent checking function of compliance demonstration as per point 21.A.239(b), apply.

- (B) In accordance with points 21.A.6 and 21.A.7 and, where applicable, point 21.A.609, ensuring that those documents are made available as per point 21.A.7(b).

(vi) Operational suitability data

- (A) Ensuring the preparation and updating of all OSD in accordance with the relevant CSs. For that purpose, the applicant should:
 - (a) establish the list of all the documents that they produce to comply with CS-MMEL or CS-GEN-MMEL, CS-FCD, CS-CCD, CS-SIMD, and CS-MCSD, as applicable; and

(b) define the procedures and the organisation for producing and issuing those documents, taking into account the obligation of point 21.A.265(h); those procedures should cover the aspects that are described in (c)(1)(v)(A).

(B) In accordance with points 21.A.6, 21.A.62, 21.A.108, and 21.A.120B, ensuring that those documents are provided to all the affected operators and training organisations, as well as to all the authorities involved.

~~AMC2 GM No 2 to 21.A.239(d)(a) Design management system~~ **Design assurance system for minor changes to type design or minor repairs to products**

DESIGN ASSURANCE ELEMENT FOR MINOR CHANGES TO TYPE DESIGN OR MINOR REPAIRS TO PRODUCTS

(a) ~~1.~~ Purpose

This ~~GM~~ **AMC** outlines some basic principles and objectives in order to comply with ~~21.A.239(a)~~ **the design assurance element** for organisations designing only minor changes to type design or minor repairs to products.

(b) ~~2.~~ Design assurance system

The design assurance system should include the following:

- an organisational structure ~~to~~:
 - **to** control the design;
 - **to** demonstrate compliance with the applicable type certification basis, operational suitability data (OSD) certification basis, ~~CS~~ and environmental protection requirements;
 - **to** independently check demonstrations of compliance;
 - **to** liaise with ~~the Agency~~ **EASA**;
 - **to** continuously evaluate the design organisation; and
 - **to** control ~~sub-contractors~~ **subcontractors**; and
- 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~~

~~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.~~

AMC1 21.A.239(d)(2)(b) Design management assurance system – Independent checking function of the demonstration of compliance

INDEPENDENT VERIFICATION FUNCTION OF THE DEMONSTRATION OF COMPLIANCE

- (a) 1. The independent verification checking function of the demonstration of compliance should consist of the verification by a person that did not creating create the compliance data. Such a person may work in conjunction with the individuals that who prepare compliance data.
- (b) 2. The verification should be shown by signing compliance documents, including test programmes and data.
- (c) 3. For a product, there is normally only one compliance verification engineer that is nominated for each relevant subject. A procedure should cover the non-availability of nominated persons and their replacement, when necessary.
- (d) 4. For STC cases, when compliance statement and associated documentation are produced by the TC holder, and when this these data is 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 verification checking function that is required in point 21.A.239(d)(2)(b) for these that data.

AMC-ELA No 1 to 21.A.239(b) Design assurance system – Independent checking function

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~~

~~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.~~

GM1 21.A.239(d)(3)(e) Design management system ~~assurance system~~ **Design**

DESIGN ASSURANCE ELEMENT — PARTNERS AND SUBCONTRACTORS

In meeting the requirements of **point 21.A.239(d)(3)(e)**, the applicant for a design organisation approval under Subpart J may adopt the following policy:

- (a)1.** The satisfactory integration of the ~~Partner/Sub-contractor~~ **partner and subcontractor** and applicant's design assurance systems ~~should be~~ demonstrated for the activities ~~that are~~ covered under the applicant's terms of approval.
- (b)2.** In the event that a ~~Partner/Sub-contractor~~ **partner and subcontractor** holds a design organisation approval (DOA), then in accordance with **point 21.A.239(d)(3)(e)**, the applicant may take this into account in demonstrating the effectiveness of ~~that~~ **this** integrated system.
- (c)3.** When any ~~Partner/Sub-contractor~~ **partner and subcontractor** does not hold a DOA, then the applicant will need to establish to its own satisfaction and the satisfaction of ~~the Agency~~ **EASA**, the adequacy of that partner's/~~sub-contractor's~~ **subcontractor's** design assurance system in accordance with **point 21.A.243(b)**.

GM2 21.A.239(d)(3) Design management system

DESIGN ASSURANCE ELEMENT — PARTNER AND SUBCONTRACTOR ARRANGEMENTS

When defining the arrangements between the design organisation (DO) and its partners and subcontractors, both elements of the design management system should be taken into account, i.e. the safety management element and the design assurance element. The following guidance should therefore be considered applicable to both elements.

- (a)** When the DO subcontracts activities, the arrangements should consider the safety risk management process that is part of its safety management element (see point 21.A.239(c)(3)). When the subcontractor does not have a safety management element, the subcontractor should be integrated into the safety management element of the DO; when the subcontractor has implemented a safety management system (such as for design organisation approval (DOA) or production organisation approval (POA)), the two safety management systems, i.e. of the DO and of the subcontractor, should be harmonised.
- (b)** Depending on the complexity and criticality of those arrangements, the following elements within the arrangements should be addressed:
 - (1)** coordination and interfaces between all the parties involved;
 - (2)** applicable procedures;
 - (3)** safety culture, including internal safety reporting scheme (see point 21.A.3A).
 - (4)** communication between all the parties involved, including reporting, regular meetings, and feedback channels;
 - (5)** allocation of tasks, of clear accountability, and of responsibilities; and
 - (6)** the qualifications and competency of key personnel with reference to point 21.A.245.

- (c) The safety risk management should focus on the needs to exchange safety data and safety information that are deemed significant for the determination of relevant risks in terms of likelihood, severity, impact, and acceptability, such as, wherever appropriate, but not limited to the following:
- (1) (at product level) failure, malfunction, defect, or other occurrences, non-conformity or outcome of the compliance monitoring function, component failure analysis, in-service event, etc.;
 - (2) (at documentation level) key processes (e.g. airworthiness directives, design and certification documentation, design processes); and
 - (3) (at organisation level) changes, disruptive events, resources' issues, human performance (HP) issues.
- (d) Regular communication should be ensured between all the parties involved, to discuss work progress, risk mitigation measures, changes to the arrangements, as well as any other significant issues.

AMC1 21.A.239(e) Design management system

INDEPENDENT MONITORING FUNCTION

- (a) The independent monitoring function should ensure that:
- (1) the activities of the design organisation (DO) are monitored for their compliance with the applicable requirements and with any additional requirements as established by the organisation, and that those activities are properly performed under the supervision of the nominated persons that are referred to in point 21.A.245(b); furthermore, compliance with, and the adequacy of, the design management system should be monitored;
 - (2) all subcontracted design activities are monitored for adequacy and compliance with the applicable arrangements;
 - (3) an objective review of the complete set of design-management-related activities is provided through independent monitoring activities, such as audits, inspections, reviews;
 - (4) the independence of the monitoring activities is established by always ensuring that those activities and inspections are performed by staff that are not involved in the function, procedure, or products that they monitor, and that are independent from the operating managers of the function(s) being monitored; however, this should not exclude support by domain experts during monitoring;
 - (5) a monitoring plan is established to show when and how often the activities that are required by Part 21 will be audited;
 - (6) the monitoring cycle should not exceed the applicable oversight planning cycle that is established according to point 21.B.432; the determination of the monitoring plan should consider at least the following aspects:
 - the criticality of the items checked; and

- the safety performance of the organisation, including any previous findings and root causes;
 - (7) when non-compliance is found, the root cause(s) and contributing factor(s) are identified, and corrective action is defined and followed up; and
 - (8) feedback is provided to the management of the DO.
- (b) The independent monitoring function that is required by point 21.A.239(e) may be undertaken by the existing quality assurance organisation if the DO is part of a larger organisation.
- (c) The staff performing an independent monitoring function should have access to all the parts of the DO and, as necessary, to any subcontracted organisations.

AMC1 21.A.243(a) ~~Data requirements~~ Handbook

HANDBOOK CONTENT ~~GENERAL~~

- (a) All personnel should be familiar with those parts of the handbook that are relevant to their tasks.
- (b) The handbook should provide the following information for each product that is covered by the design organisation approval (DOA).
- (1) A description of the tasks that ~~which~~ can be performed under the approval, according to the following classification:
 - (i) ~~a. General areas, like subsonic turbojet aeroplanes, turbopropeller turboprop aeroplanes, small aeroplanes, rotorcraft, etc.;~~
 - (ii) ~~b. Technologies handled by the organisation (composite, wood or metallic construction, electronic systems, etc.);~~
 - (iii) ~~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; and~~
 - (iv) ~~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 the functional relationships between the various departments.
 - (3) A description of the assigned responsibilities and delegated authority of all parts of the organisation, which, taken together, constitute the organisation's design assurance management system, together with a chart indicating the functional and hierarchical relationship of the design assurance management system to the Management and to other parts of the organisation; also the chains of responsibilities within the design assurance management system, and the control of the work of all partners and ~~sub-contractors~~ subcontractors.

- (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:
- (i) a. The procedures followed and forms used in the ~~Type Investigation~~ certification 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 ~~type certification basis, operational suitability data (OSD) certification basis, CS~~ and the environmental protection requirements, including specific requirements for import by importing authorities;
 - (ii) b. The procedures for classifying design changes as 'major' or 'minor' and for the approval of minor changes;
 - (iii) c. The procedures for classifying and approving unintentional deviations from the applicable ~~approved~~ design data occurring in production (concessions or non-conformity ~~non-conformance's~~); and
 - (iv) 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~~ cooperation with the production organisation when dealing with any continuing airworthiness actions that ~~are~~ are related to the 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 ~~personnel~~ Staff of the organisation of current changes in engineering drawings, specifications, and design ~~assurance~~ management procedures.
- (8) A description of the recording system for:
- (i) a. ~~The~~ the type design, including relevant design information, drawings and test reports, including inspection records of test specimens;
 - (ii) b. ~~The~~ the means of compliance; and
 - (iii) c. ~~The~~ the compliance documentation (compliance ~~checklist~~ check list, reports, etc.).
- (9) A description of the record-keeping system to comply with ~~point~~ 21.A.5.
- (10) A description of the means by which the organisation collects, monitors, analyses and responds to problems ~~that~~ 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 AMC1 21.A.239(d) and GM No 1 to 21.A.239(a), points 3.1.4(s) and (t)).

- (11) The names of the design organisation (DO)-authorised signatories. Nominated persons with specific responsibilities such as those mentioned in points 21.A.33 and 21.A.35 should be listed as well.
- (12) (Reserved).
- (13) A clear definition of the tasks, competency, e and areas of responsibility of the Office of Airworthiness.
- (14) A description of the procedures for the establishment and the control of the manuals and instructions for continued airworthiness (ICA) ~~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 management system will be performed in order to ensure that it remains effective.
- (16) A description of the procedures for the establishment and the control of the OSD ~~operational suitability data~~ (see points 21.A.5, 21.A.62, 21.A.108, and 21.A.120B).
- (17) A description of the organisation's safety policy and objectives, as required by point 21.A.239(c)(1).
- (18) A description of the internal safety reporting scheme, as required by point 21.A.3A(a)(1).
- (19) A description of the safety management procedures (including identification of safety hazards, evaluation, and associated risks management), safety assurance procedures, and safety promotion processes.
- (20) A statement, signed by the head of the design organisation (HDO) (and countersigned by the senior company manager, if different), which confirms that the design management handbook and any associated manuals are complied with at all times.

This statement should read as follows, or embrace the intent of the following text:

This handbook defines the organisation and procedures upon which EASA's DOA is based.

These procedures are approved by the undersigned, and must be complied with, as applicable, to ensure that all design activities are performed on time and to an approved standard.

It is understood that the approval of the DO is based on the organisation's continuous compliance with the applicable requirements of Part 21, and with the organisation's procedures that are described in this handbook. EASA is entitled to limit, suspend, or revoke the approval if the organisation fails to fulfil the obligations that are imposed by Part 21, or any conditions according to which the approval was issued.

Signed

Dated

HDO and (quote the position of the signatory)

Senior company manager

For and on behalf of (quote the organisation's name)

The statement should be reissued at the earliest opportunity when the HDO changes.

- (c) The organisation may document its safety policy, safety objectives, and all the safety management system key processes (as required by point 21.A.239(c)) in a separate manual (e.g. a safety management manual or management system manual) or in its handbook. Organisations that hold multiple organisation approvals, which are issued under Regulation (EU) 2018/1139 and the delegated and implementing acts that are adopted on the basis thereof, may prefer to have a separate manual to avoid duplication.

AMC2 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 Handbook

TYPICAL CONTENT OF HANDBOOK FOR ORGANISATIONS THAT DESIGN MINOR CHANGES TO TYPE DESIGN OR MINOR REPAIRS TO PRODUCTS

The following is a typical table of contents for the handbook:

Part 1. Organisation

- 1.1 Objective of the handbook and binding statement
- 1.2 Responsible person for the administration of the handbook
- 1.3 Amendment procedure
- 1.4 List of effective pages
- 1.5 Distribution list
- 1.6 Presentation of the design organisation (DO) (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-No2 to 21.A.243(d), paragraph point 2)
- 1.12 Independent system monitoring

1.13 Safety management system

Part 2. Procedures

- 2.1 Management of changes to type design and design of repairs:
 - configuration control,
 - classification, and
 - approval of minor changes to type design and minor repairs

- 2.2 Control of design ~~sub-contractors~~ subcontractors
- 2.3 Collecting/Investigating of failures, malfunctions, and defects
- 2.4 ~~Co-ordination~~ Coordination with production
- 2.5 Documentation control
 - in ~~relations~~ relation to with the changes and repairs, and
 - in relation to with failures/malfunctions and defects (i.e. ~~S~~ services ~~B~~ bulletins)
- 2.6 Record-keeping

~~AMC-ELA No 1 to 21.A.243 Data – Design organisation handbook~~

~~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

~~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~~

~~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.~~

AMC1 21.A.243(d) Handbook

STATEMENT OF QUALIFICATIONS AND EXPERIENCE

(a) The following statements should be provided:

(1) Other management staff as defined in GM1 21.A.243(d)

For each nominated manager, the organisation should provide this data to EASA to show that the nominated managers are suitable in terms of their relevant knowledge and satisfactory experience related to the nature of the design activities that are performed by the organisation.

(2) The staff that make decisions that affect airworthiness, operational suitability, and environmental protection

For that staff, no individual statements are required. The organisation should demonstrate that there is an internal authorisation system that allows it to select, train, maintain, and identify them for all the tasks for which they are needed.

(b) The staff that is defined in point (a) should be identified in the handbook or linked to it. This, together with the corresponding procedures, should enable that staff to carry out the assigned tasks and to properly discharge the associated responsibilities.

~~GM No AMC2 to 21.A.243(d) Handbook Data requirements – Statement of the qualification and experience – Organisations that design minor changes to type designs or minor repairs to products~~

STATEMENT OF THE QUALIFICATION AND EXPERIENCE — ORGANISATIONS THAT DESIGN MINOR CHANGES TO TYPE DESIGN OR MINOR REPAIRS TO PRODUCTS

For organisations that designing minor changes to type design or minor repairs to products, the statement of the qualifications and experience that is required by point 21.A.243(d) should be addressed as follows:

(a) ~~1.~~ The nominated managers should be identified and their relevant knowledge and satisfactory experience related to the nature of the design activities that they perform should be demonstrated. For each nominated manager, the organisation should provide evidence of competency ~~credentials submitted to on EASA Form 4 - DOA (see <http://easa.europa.eu/certification/application-forms.php>) in order~~ so that they may be seen considered to be appropriate in terms of relevant knowledge and satisfactory experience related to the nature of the design activities as performed by the organisation.

(b) ~~2.~~ The persons responsible ~~to~~ for:

- ~~classify~~ classifying changes to type designs or repairs (point 21.A.263(c)(1));
- ~~verify~~ verifying compliance (point 21.A.239(b)(d)(2));
- ~~approve~~ approving minor changes to type design and minor repairs (point 21.A.263(c)(2)); and
- ~~issue~~ issuing information or instructions (point 21.A.265(h)),

should be selected by the organisation in accordance with a procedure and criteria that are agreed with by the Agency EASA.

GM ~~No 1 to 21.A.243(d) Handbook Statement of qualifications and experience~~

STATEMENT OF QUALIFICATIONS AND EXPERIENCE

~~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 the associated AMC and GM, when using qualified and experienced personnel:

- the ~~Chief Executive~~ chief executive officer (CEO) ~~{(see GM No 1 to 21.A.239(a), para. 3.1.2, AMC1 21.A.239(d), point (c)(1)(ii), GM 21.A.249, GM 21.A.265(b));}~~

- the other management staff:
 - the ~~Head~~ of the design organisation (HDO) (see points 21.A.239(b)(2) and 21.A.245(a)); ~~[see 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~~ chief of the airworthiness function, (see point 21.A.245(b)(1)); ~~or see [see GM No 1 to 21.A.245, para. 4.2]~~
 - the ~~C~~ chief of the independent monitoring function (see point 21.A.245(b)(2)); ~~of the design assurance system [see 21.A.239(a)(3) and AMC No 1 to 21.A.243(a), para.2]~~
 - the safety manager (see GM1 21.A.239(c)(2), AMC1 21.A.239(c)(2) and AMC1 21.A.245(b), point (g)); and
 - when a safety review board is established, the chairperson of that board, if different from the HDO (see AMC1 21.A.239(c)(2)); and
- the ~~staff~~ personnel making decisions affecting airworthiness, operational suitability, and environmental protection:
 - compliance verification engineers (see AMC1 21.A.239(d), point (c)(1)(iii) and AMC1 21.A.239(d)(2)); ~~and [see GM No 1 to 21.A.239(a), para.3.1.3; AMC 21.A.239(b)]~~
 - ~~staff~~ personnel of the Office of Airworthiness making decisions affecting airworthiness, operational suitability, and environmental protection, especially those that are linked with the 21.A.263 privileges (signing documents for release, approving classification of changes and repairs, and granting the approval of minor/major changes, supplemental type certificates (STCs) and minor/major repairs, granting the approval of service bulletins (SBs), and minor revisions to the aircraft flight manual) (see AMC1 21.A.239(d), point (c)(1)(iv)). ~~[see GM No 1 to 21.A.239(a), para. 3.1.4]~~

A statement of the qualifications and experience of the CEO is not required. For the other two categories that are identified above, a statement of qualifications and experience should be provided (see AMC1 21.A.243(d) and AMC2 21.A.243(d) respectively).

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~~

- ~~e) — 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.~~

AMC1 21.A.245(a) Resources

HEAD OF THE DESIGN ORGANISATION

(a) The head of the design organisation (HDO) should:

- (1) have sufficient knowledge and authority to be able to respond to the competent authority regarding major issues concerning the design organisation (DO) and the product design approval, and to carry out any necessary improvements;
- (2) promote the safety policy that is specified in AMC1 21.A.239(c)(1); and
- (3) demonstrate a Part 21 understanding that is sufficient to discharge the relevant responsibilities.

(b) The handbook that is submitted in accordance with point 21.A.243 should show that the HDO has the direct or functional responsibility for all the departments of the organisation which are responsible for the design of the product. If the departments responsible for design are functionally linked, the HDO still has the ultimate responsibility for compliance of the DO with Part 21.

AMC1 21.A.245(b) Resources

NOMINATED MANAGERS

(a) The person or group of persons nominated in accordance with point 21.A.245(b) should represent the management structure of the organisation and be responsible for all the functions as specified in Part 21, Subpart J.

- (b) The nominated managers should be identified (see GM1 21.A.243(d)).
- (c) The responsibilities and the duties of each individual manager should be defined.
- (d) The independent monitoring function should be independent from the design and airworthiness functions. As such, the chief of the independent monitoring function should not be at the same time one of the other persons that are referred to in point 21.A.245(b)(1) or (b)(3), except for the safety manager. If the same person is designated to manage both the independent monitoring function and safety-management-related processes and tasks, the head of the design organisation (HDO), in order to discharge their safety accountability, should ensure that sufficient resources are allocated to both functions, taking into account the size of the organisation, and the nature and complexity of its activities.

(e) Chief of the airworthiness function

If more than one team, including their management, are designated for the airworthiness function as defined in point 21.A.239(d)(1)(i), the HDO should identify the person that acts as the unique focal point for the entire design organisation (DO), i.e. the 'chief of the airworthiness function'.

The need to designate more than one team may be triggered by the specific scope and volume of activity of the DO. For example:

- managing several lines of products (separate airworthiness representative per line of product); and
- division between initial and continued airworthiness activities.

The tasks for which the chief of the airworthiness function should be responsible are presented in AMC1 21.A.239(d), point (c)(1)(iv).

(f) Chief of the independent monitoring function

The role of the chief of the independent monitoring function should be to ensure that:

- (1) the activities of the organisation are monitored for compliance with the applicable requirements and any additional requirements as established by the organisation, and that those activities are performed properly under the supervision of the nominated persons that are referred to in point 21.A.245(b);
- (2) an audit plan is properly implemented, maintained, and continually reviewed and improved; and
- (3) corrections and corrective action are requested, as necessary.

(g) Safety manager

If more than one person is designated for the development, administration, and maintenance of effective safety management processes as defined in point 21.A.239(c)(2), the HDO should identify the 'safety manager' as the unique focal point.

The role of the safety manager should be:

- (1) to facilitate hazard identification, as well as risk assessment and management;

- (2) to monitor the implementation of action taken to mitigate risks, as listed in the safety action plan, unless action follow-up is addressed by the independent monitoring function;
- (3) to provide periodic reports on safety performance to the safety review board (the functions of the safety review board are defined in AMC1 21.A.239(c)(2));
- (4) to ensure the maintenance of safety management documentation;
- (5) to ensure that there is safety training available, and that it meets acceptable standards;
- (6) to provide advice on safety matters; and
- (7) to ensure the initiation and follow-up of internal investigations of occurrences.

GM1 21.A.245(c)(2) Resources

DIRECT SUPERVISION OF THE AIRWORTHINESS FUNCTION BY THE HEAD OF THE DESIGN ORGANISATION

To cope with unexpected circumstances, for a period of time, it is possible for the head of the design organisation (HDO) to directly supervise the airworthiness function activities. This period of time should be limited and should typically not exceed 6 months.

Such a situation should be discussed with EASA and may be subject to certain limitations (e.g. only continued airworthiness activities may be allowed).

AMC1 21.A.245(d) Resources

MANAGEMENT REPORTING LINES AND COMPETENCIES

- (a) Managers that are nominated in accordance with point 21.A.245(b) should report directly to the HDO through either a hierarchical or a formal functional link.
- (b) All prospective members of the design management staff and staff that is nominated in accordance with point 21.A.245(b) should:
 - (1) be assessed for their competency, qualifications, and capabilities that are related to their intended duties;
 - (2) be able to demonstrate their knowledge of, and compliance with, the design management organisation procedures that are applicable to their tasks; and
 - (3) be able to demonstrate an understanding of the safety management principles, as well as human factors (HF) issues and human performance (HP) issues that are related to their tasks.
- (c) The chief of the airworthiness function should be able to demonstrate relevant knowledge, background, and appropriate experience that are related to the product certification and continued airworthiness, including knowledge of, and experience in, managing the design assurance system.

- (d) The chief of the independent monitoring function should be able to demonstrate relevant knowledge, background, and appropriate experience that are related to the activities of the organisation, including knowledge of, and experience in, independent system monitoring.
- (e) The competency of the person that assumes (or the persons that assume) the function of the safety manager should include, but not be limited to, the following:
- (1) knowledge of the International Civil Aviation Organization (ICAO) standards and EU requirements for safety management;
 - (2) an understanding of management systems, including compliance monitoring systems;
 - (3) an understanding of risk management;
 - (4) an understanding of safety investigation techniques;
 - (5) an understanding of HF, including HP and limitations;
 - (6) an understanding of a positive safety culture and of its promotion; and
 - (7) operational experience related to the activities of the organisation.

AMC1 21.A.245(e) Resources

STAFF, FACILITIES, AND COORDINATION

(a) *General*

The handbook that is submitted in accordance with point 21.A.243 should show that sufficient skilled personnel are available, and that suitable technical and organisational provisions are made for carrying out the type investigation that is defined in GM1 21.A.239(d), point (b)(3).

(b) *Personnel*

The organisation should show that the personnel that is available to comply with point 21.A.245(e)(1) are able, based on their special qualifications and numbers, to provide assurance of the design or modification of a product, as well as of the compilation and verification of all the data that is needed to meet the applicable type certification basis, operational suitability data (OSD) certification basis, and environmental protection requirements, while taking into account the state of the art and new experience.

The organisation should have a system in place to plan the availability of staff to ensure that the organisation has sufficient appropriately qualified staff to plan, perform, supervise, inspect, and monitor the organisation's activities in accordance with the organisation's terms of approval.

(c) *Technical*

The organisation should have access to:

- (1) workshops and production facilities that are suitable for manufacturing prototype models and test specimens; and
- (2) accommodation and test facilities that are suitable for carrying out the tests and measurements that are needed to demonstrate compliance with the type certification

basis, OSD certification basis, and environmental protection requirements; the test facilities may be subject to additional technical conditions that are related to the nature of the tests performed.

(d) Organisation

The handbook that is submitted in accordance with point 21.A.243 should show that:

- (1) the responsibilities for all the tasks that are related to the certification process are assigned in such a way that gaps in authority are excluded;
- (2) the responsibility for a number of tasks as in point (d)(1) may be assigned to one person, especially in cases of simple projects; and
- (3) coordination between technical departments and the persons in charge of the system monitoring that is required by point 21.A.239(e) is established:
 - (i) to ensure the quick and efficient reporting and resolution of difficulties that are encountered using the handbook and associated procedures;
 - (ii) to maintain the design management system; and
 - (iii) to optimise auditing activities.

(e) Competency and training

- (1) The organisation should establish and control the competency of the staff that is involved in the activities of the organisation, as detailed in the organisation's terms of approval, in accordance with documented procedures. In addition to the necessary expertise that is related to the job function, the competency of the staff should include an understanding of safety management and human factors (HF) principles, which is appropriate to the staff member's function and responsibilities in the organisation.
- (2) To assist in the assessment of competency and to perform the analysis of the training needs, job (job family) descriptions are recommended, which should contain sufficient criteria to enable the required competency assessment throughout the duration of the employment/contract.
- (3) The organisation should develop a procedure that describes the process for assessing the competency of the staff. The procedure should specify:
 - (i) the staff that are responsible for that process;
 - (ii) the means and methods for the initial assessment;
 - (iii) the means and methods for the continuous control of the competency of the personnel, including feedback on their performance;
 - (iv) the action to be taken if the assessment is not satisfactory; and
 - (v) how to record assessment results.
- (4) Adequate initial and recurrent training should be provided in relation to the job function to ensure that staff remain competent. This training should be adapted based on

experience that is gained within the organisation (for safety training, refer also to AMC1 21.A.239(c)(5)(i)).

(5) The organisation should record the training that is provided as described in point (e)(4).

AMC-ELA No 1 to 21.A.245 Approval requirements

~~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

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~~

~~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.~~

AMC1 21.A.247 Changes to the design management system

APPLICATION FOR APPROVAL OF SIGNIFICANT CHANGES OR CHANGES IN THE TERMS OF APPROVAL OF A DESIGN ORGANISATION

An application for approval of significant changes or changes in the terms of approval of a design organisation (DO) should be submitted in writing to EASA. The design organisation (DO) should demonstrate to EASA, on the basis of the submission of any proposed changes to the handbook or the DOA, and before the implementation of the changes, that it will continue to comply with Part 21 after the implementation.

GM1 21.A.247 Significant Changes to ~~in~~ the design management ~~assurance~~ system

In addition to a change in ownership (see [point 21.A.249](#)), the following changes to the design ~~assurance~~ management system should be considered to be 'significant' ~~to~~for the demonstration of compliance, or ~~to~~for the airworthiness, operational suitability, or environmental protection of the products:

(a) ~~1.~~ Organisation

- Relocation to new premises (see also GM 21.A.249);
- A change ~~Change~~ in the industrial organisation (partnership, ~~subcontractors~~suppliers, design work sharing), unless it can be shown that the independent ~~verification~~checking function of the demonstration of compliance is not affected;
- A change ~~Change~~ in the parts of the organisation that contribute directly to the airworthiness, operational suitability, or environmental protection (independent ~~verification~~checking function, ~~airworthiness function~~office of airworthiness (or equivalent));
- A change ~~Change~~ to the independent monitoring principles of compliance and adequacy (see [point 21.A.239\(e\)](#) ~~(a)(3)~~).

(b) ~~2.~~ Responsibilities

- Change of the management ~~personnel~~staff:
 - the ~~H~~head of the design organisation (HDO) (see [point 21.A.245\(a\)](#)) ~~(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 ~~C~~chief of the ~~Office of Airworthiness~~ function (see [point 21.A.245\(b\)](#)) ~~(GM No 1 to 21.A.245, para. 4.2)~~; and
 - the ~~C~~chief of the independent monitoring function of compliance and adequacy of the design ~~management~~assurance system (see [point 21.A.245\(b\)\(2\)](#)) ~~(21.A.239(a)(3) and AMC No 1 to 21.A.243(a), para.2)~~; and
 - the safety manager (see [point 21.A.239\(c\)\(2\)](#)).
- Reporting lines between the personnel that is nominated in accordance with [point 21.A.245\(b\)](#) and the HDO.
- ~~New distribution~~Allocation of responsibilities that affecting safety, airworthiness, operational suitability, or environmental protection;
- ~~For organisations designing minor changes to type design or minor repairs to products, change of the persons identified in GM No 2 to 21.A.243(d).~~

(c) ~~3.~~ Procedures

Change to the principles of procedures related to:

- the type certification;

- the classification of changes and repairs as ‘major’ or ‘minor’ (see point 21.A.263(c)(1));
- the ~~treatment~~ **handling** of major changes and major repairs;
- the approval of the design of minor changes and minor repairs (see point 21.A.263(c)(2));
- the approval of the design of certain major repairs (see point 21.A.435(b) or 21.A.263(c)(5));
- the approval of the conditions under which a permit to fly can be issued (see point 21.A.263(c)(6));
- the issue of a permit to fly (see point 21.A.263(c)(7));
- the approval of certain major changes to a type certificate (TC) (see point 21.A.263(c)(8));
- the approval of certain supplemental type certificates (STCs) (see point 21.A.263(c)(9));
- the approval of certain major changes to certain ~~STCs~~ **supplemental type certificates**; (see point 21.A.263(c)(9));
- continued airworthiness or continued operational suitability (see point 21.A.3B);
- the configuration control, when airworthiness, operational suitability, or environmental protection is affected;
- the acceptability of design tasks **that are** undertaken by partners or subcontractors (see point 21.A.239(d)(3)(~~e~~));
- the issue of data and information under the obligation of point 21.A.265(h); and
- **the safety risk management process (see point 21.A.239(c)(3)).**

(d)4. Resources

- **A substantial** ~~Substantial~~ reduction in the number and/or experience of **personnel** ~~staff~~ (see point 21.A.245(d)(1)(~~a~~)).

GM-ELA No 1 to 21.A.247 Changes to the ~~in~~ design management ~~assurance~~ system

[...]

~~GM-ELA No 1 to 21.A.257 Investigations – Arrangements~~

~~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~~

~~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.~~

SUBPART P — PERMIT TO FLY

~~GM-21.A.705 Competent authority~~

~~An aircraft registered in a Member State is under the responsibility of this Member State regarding continuing airworthiness aspects. Consequently, any permit to fly under Part 21 is issued by that Member State, including any cases in which 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 within the competence of the authority of the State where the flight will take place. The applicant is also therefore required to ensure compliance with the relevant regulations of that State.~~

SECTION B — PROCEDURES FOR COMPETENT AUTHORITIES**SUBPART A — GENERAL PROVISIONS****AMC1 21.B.15(b) Information to the Agency****AIRWORTHINESS DIRECTIVES**

When the competent authority of a Member State receives an airworthiness directive from the competent authority of a non-Member State, that airworthiness directive should be transferred to EASA for dissemination in accordance with Article 76 of Regulation (EU) 2018/1139.

AMC2 21.B.15(b) Information to the Agency**EXCHANGE OF SAFETY-SIGNIFICANT INFORMATION WITH EASA**

Each competent authority should appoint a coordinator to act as the contact point for the exchange of safety-significant information between the competent authority and EASA.

GM1 21.B.15(b) Information to the Agency**MEANING OF SAFETY-SIGNIFICANT INFORMATION THAT STEMS FROM OCCURRENCE REPORTS**

Safety-significant information that stems from occurrence reports means:

- (a) a conclusive safety analysis that summarises individual occurrence data and provides an in-depth analysis of a safety issue, and that may be relevant for EASA's safety action planning; and
- (b) individual occurrence data for the cases in which EASA is the competent authority and which fulfils the reporting criteria of GM3 21.B.15(b).

GM2 21.B.15(b) Information to the Agency**RECOMMENDED CONTENT FOR CONCLUSIVE SAFETY ANALYSES**

A conclusive safety analysis should contain the following:

- (a) a detailed description of the safety issue, including the scenario in which the safety issue takes place; and
- (b) an indication of the stakeholders that are affected by the safety issue, including types of operations and organisations;

and, as appropriate:

- (c) a risk assessment that establishes the severity and probability of all the possible consequences of the safety issue;
- (d) information about the existing safety barriers that the aviation system has in place to prevent the likely consequences of the safety issue from occurring;

- (e) any mitigating action that is already in place or developed to deal with the safety issue;
- (f) recommendations for future action to control the risk; and
- (g) any other element that the competent authority considers essential for EASA to properly assess the safety issue.

GM 21.B.15(b) Information to the Agency

OCURRENCES IN WHICH EASA IS THE COMPETENT AUTHORITY

Occurrences that are related to organisations or products that are certified by EASA should be notified to EASA if:

- (a) the occurrence is defined as a reportable occurrence in accordance with the applicable regulation;
- (b) the organisation that is responsible for addressing the occurrence is certified by EASA; and
- (c) the competent authority of the Member State comes to the conclusion that:
 - (1) the organisation that is certified by EASA to which the occurrence relates was not informed of the occurrence; or
 - (2) the occurrence was not properly addressed or was left unattended by the organisation that is certified by EASA.

Such occurrence data should be reported in a format that is compatible with the European Coordination Centre for Accident and Incident Reporting Systems (ECCAIRS) and should provide all the relevant information for its assessment and analysis, including necessary additional files in the form of attachments.

~~GM 21.B.20 Responsibility for implementation~~

~~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 assess 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.~~

AMC 21.B.30(a) Documented procedures

~~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.~~

AMC 21.B.35(a) Changes

~~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.

GM 21.B.40 Principles for the resolution of disputes

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.

GM No 1 to 21.B.45 Co-ordination with other related activities

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

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~~

~~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.~~

AMC1 21.B.55(a) Record-keeping

GENERAL

- (a) The record-keeping system should ensure that all the records are accessible within a reasonable time whenever they are needed. Those records should be organised in a manner that ensures their traceability and retrievability throughout the required retention period.
- (b) All the records that contain sensitive data on applicants or organisations should be stored in a secure manner with controlled access, to ensure their confidentiality.
- (c) The records should be kept in paper form, or in an electronic format, or a combination of both. Records that are stored on microfilm or optical discs are also acceptable. The records should remain legible and accessible throughout the required retention period. The retention period starts when the record is created.
- (d) Paper record systems should use robust material that can withstand normal handling and filing. Computer record systems should have at least one backup system that should be updated within 24 hours of any new entry. Computer record systems should include safeguards to prevent unauthorised personnel from altering the data.
- (e) All the computer hardware that is used to ensure the backup of data should be stored in a different location from the one that contains the working data and in an environment that ensures that the data remains in a good condition. When hardware or software changes take place, special care should be taken that all the necessary data continues to be accessible throughout at least the full period that is specified in point 21.B.55(d).

AMC1 21.B.55(a)(1) and (a)(2) Record-keeping

COMPETENT AUTHORITY MANAGEMENT SYSTEM

The records that are related to the competent authority's management system should include, as a minimum, and as applicable:

- (a) the documented policies and procedures;
- (b) the personnel files of the competent authority personnel, with the supporting documents related to their training and qualifications;

- (c) the results of the competent authority's internal audits and safety risk management processes, including audit findings, as well as any corrective, preventive, and risk mitigation action; and
- (d) the contracts that are established with the qualified entities that perform certification or oversight tasks on behalf of the competent authority.

GM1 21.B.55(e) Record-keeping

TRACEABILITY OF RELEASE CERTIFICATES

The record-keeping of those EASA Forms 52 and 1 that are validated by the competent authority should allow the verification of that validation by the parties concerned, including the recipients of the release certificates.

SUBPART F — PRODUCTION WITHOUT PRODUCTION ORGANISATION APPROVAL

GM1 21.B.115 and 21.B.215 Means of compliance

ALTERNATIVE MEANS OF COMPLIANCE — GENERAL

(a) A competent authority may establish means to comply with the regulation, which are different from the AMC that are established by EASA.

In that case, the competent authority is responsible for demonstrating how those alternative means of compliance (AltMoC) establish compliance with the regulation.

(b) AltMoC that are used by a competent authority, or by an organisation under its oversight, may be used by other competent authorities, or another organisation, only if they are processed by those authorities in accordance with point 21.B.115 or 21.B.215, and by that organisation in accordance with point 21.A.124A or 21.A.134A.

(c) AltMoC that are issued by the competent authority may cover the following cases:

(1) AltMoC to be used by organisations under the oversight of the competent authority and which are made available to those organisations; and

(2) AltMoC to be used by the authority itself to discharge its responsibilities.

AMC1 21.B.115(b),(c) and 21.B.215(b),(c) Means of compliance

PROCESSING THE ALTERNATIVE MEANS OF COMPLIANCE

To meet the objective of points (b) and (c) of points 21.B.115 and 21.B.215:

(a) the competent authority should establish the means to consistently evaluate over time that all the AltMoC that are used by itself or by organisations under its oversight allow for the establishment of compliance with the regulation;

(b) if the competent authority issues AltMoC for itself or for the organisations under its oversight, it should:

(1) make them available to all relevant organisations; and

(2) notify EASA of the AltMoC as soon as it is issued, including the information that is described in point (d) of this AMC;

(c) the competent authority should evaluate the AltMoC that is proposed by an organisation by analysing the documentation provided and, if considered necessary, by inspecting the organisation; when the competent authority finds that the AltMoC is in accordance with the Regulation, it should:

(1) notify the applicant that the AltMoC is approved;

(2) indicate that this AltMoC may be implemented, and agree when the production organisation exposition (POE) is to be amended accordingly; and

- (3) notify EASA of the AltMoC approval as soon as it is approved, including the information that is described in point (d) of this AMC; and
- (d) the competent authority should provide EASA with the following information:
- (1) a summary of the AltMoC;
 - (2) the content of the AltMoC;
 - (3) a statement that compliance with the regulation is achieved; and
 - (4) in support of that statement, an assessment that demonstrates that the AltMoC reaches an acceptable level of safety, taking into account the level of safety that is achieved by the corresponding EASA AMC.
- (e) All these elements that describe the AltMoC are an integral part of the records to be kept, which are managed in accordance with point 21.B.55.

GM1 21.B.115(b) and (c) and 21.B.215(b) and (c) Means of Compliance

CASES IN WHICH THERE IS NO CORRESPONDING EASA AMC

When there is no EASA AMC to a certain requirement in the regulation, the competent authority may choose to develop national guides or other types of documents to assist the organisations under its oversight in compliance demonstration. The competent authority may inform EASA so that such guides or other documents may be later considered for incorporation into an AMC that is published by EASA using the EASA rulemaking process.

GM1 ~~21.B.125(a)~~ 21.B.125(b), 21.B.225(b) and 21.B.430(b) Findings and corrective actions; observations ~~Objective evidence~~

EVIDENCE

~~Objective evidence~~ Evidence is a fact ~~that~~ ~~which~~ is, or can be, documented, based on observations, measurements, or tests that can be verified. ~~Objective evidence~~ Evidence generally comes from the following:

- (a) documents or manuals;
- (b) examination of equipment/products; and
- (c) information from interview questions and from observations of an organisation's ~~production~~ activities, as applicable.

GM1 21.B.125(b) Findings and corrective actions

EXAMPLES OF LEVEL 1 FINDINGS

Examples of level 1 findings are non-compliance with any of the following points, which may affect the safety of the aircraft:

- point 21.A.126;

- point 21.A.127;
- point 21.A.128; and
- point 21.A.129.

It should be anticipated that non-compliance with those points is only considered a level 1 finding if there is objective evidence that that finding is uncontrolled non-compliance that could affect the safety of the aircraft.

GM1 21.B.125(b) and 21.B.225(b) Findings and corrective actions; observations

SIGNIFICANT NON-COMPLIANCE

Significant non-compliance includes uncontrolled non-compliance with applicable design data, which is non-compliance that:

- (a) cannot be discovered through systematic analysis; or
- (b) prevents the identification of the affected products, parts, appliances, or material.

AMC1 21.B.125(d) Findings and corrective actions

NOTIFICATION OF FINDINGS

In the case of a level 1 finding, confirmation should be obtained in a timely manner that the accountable manager has taken note of the finding and its details.

Level 1 and level 2 findings require timely and effective oversight by the competent authority to ensure the completion of the corrective action. That oversight may include intermediate communication, such as letters, as necessary, to remind the approval holder to verify that the corrective action plan is followed.

GM1 21.B.125(e) Findings and corrective actions; observations

DIFFERENCE BETWEEN A 'LEVEL 2 FINDING' AND AN 'OBSERVATION'

- (a) 'Findings' are issued for non-compliance with the regulation, whereas 'observations' may be issued to an organisation that remains compliant to the regulation, while additional input to the organisation may be considered for continuous improvement (see points (1), (2), and (3) of point 21.B.125(e)).

However, the competent authority may decide to issue a 'level 2' finding when the 'observations' process is not managed correctly or is overlooked.

- (b) Examples to help differentiate between a 'level 2 finding' and an 'observation' are provided below, based on the requirements for the control and calibration of tools in accordance with point 21.A.139(b)(1)(vii).

Example of a 'level 2 finding':

The organisation could not demonstrate compliance with some elements of point 21.A.145(a) regarding the control register of the tools and equipment, as evidenced by the fact that:

- (a) some sampled tools that are physically available in the tool store were missing in the tool control register that is managed by the organisation; or
- (b) one tool was not correctly identified (e.g. incorrect part number or serial number) in the tool control register.

Examples of 'observations':

- (a) Accumulation of tools in the tool store, which have not been yet sent for calibration. This situation may have some consequences regarding the availability of tools and the operational capabilities during a peak of activities (ineffectiveness of the process).
- (b) The process for managing the tool control register through the dedicated software is not detailed enough (potential to cause a 'level 2 finding').
- (d) The colour of the 'unserviceable' tag of the tools may generate some confusion. The organisation should consider changing the colour of that unserviceable tag to better alert its staff to the particular status of the unserviceable tools (potential improvement).

AMC 21.B.130 Issue of the letter of agreement

~~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

~~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.~~

GM 21.B.150(d) Record-keeping – Traceability of release certificates

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

~~AMC No 1 to 21.B.230 Issue of the certificate~~

~~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~~

~~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-vectorised 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.

AMC-ELA No 1 to 21.B.235 Continued surveillance

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.

GM-ELA No 1 to 21.B.235 Continued surveillance

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.

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~~

~~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~~

~~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~~

~~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.~~

AMC No 1 to 21.B.240 Application for significant changes or variation of scope of terms of the POA

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 a variation of the scope or terms of a Part 21 POA	
<i>Competent authority of an EU Member State or EASA</i>	
1. Name and address of the POA holder:	
2. Approval reference number:	
3. Location(s) for which changes in the terms of approval are requested:	
4. Brief summary of the 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:	
<hr style="border: none; border-top: 1px solid red; width: 100%;"/> <hr style="border: none; border-top: 1px solid red; width: 100%;"/> Date	<hr style="border: none; border-top: 1px solid red; width: 100%;"/> <hr style="border: none; border-top: 1px solid red; width: 100%;"/> Signature of the accountable manager (or nominee)

EASA Form 51

~~Block 1: the name should be entered as written on the current approval certificate. If 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 should 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 location(s) for which changes in the terms of approval are requested, or state 'not applicable' here if no change is anticipated.~~

~~Block 4: this block should include further details for the variation of the scope of approval for the addresses indicated in Block 3. The 'General' block should include overall information for the change (including changes e.g. in workforce, facilities, etc.), while the 'Scope of approval' block should address the change in the scope of work and products/categories following the principles laid down in GM 21.A.151. The 'nature of privileges' block should indicate a change in the privileges as defined in points 21.A.163(b)-(d). State 'not applicable' here if no change is anticipated.~~

~~Block 5: this block should state the changes to the organisation as it is defined in the current production organisation exposition, including changes to the organisational structure, functions and responsibilities. This block should therefore also be used to indicate a change in the accountable manager in accordance with point 21.A.145(c)(1) or a change in the nomination of the responsible managers in accordance with point 21.A.145(c)(2). A change in the nomination of the responsible managers should be accompanied by the corresponding EASA Forms 4. State 'not applicable' here if no change is anticipated.~~

~~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 should refer to the nominee for this position. State 'not applicable' here if no change is anticipated.~~

~~In case of an application for a change of the accountable manager, EASA Form 51 should be signed by the new nominee for this position. In all other cases, EASA Form 51 should be signed by the accountable manager.~~

GM-21-B.245 Continued validity

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

~~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.~~