Regular update of the Acceptable Means of Compliance and Guidance Material to Annex I (Part 21) to Regulation (EU) No 748/2012

EXECUTIVE SUMMARY

The European Union Aviation Safety Agency (EASA) issues, as necessary, acceptable means of compliance (AMC) and guidance material (GM) to Annex I (Part 21) to Regulation (EU) No 748/2012 to illustrate the means for stakeholders to establish compliance with the Regulation or to illustrate the meaning of a requirement. These AMC or GM require regular amendments to take specific safety issues into consideration and introduce new or amend the existing acceptable means of compliance or procedures.

The objective of this Decision is to:
— address a safety recommendation following an accident that occurred in Norway on 29 April 2016;
— resolve certain recurrent implementation issues by improving the text of the AMC and GM to Annex I (Part 21);
— leave no room for misinterpretation of the Regulation, as noticed during design organisation approval (DOA) holder initial investigations and surveillance activities, by including clarifications;
— align the means of compliance with the current industry practices; and
— remove unnecessary guidance material and correct typographical errors.

Decision 2021/001/R amends the AMC and GM to Annex I (Part 21) to Regulation (EU) No 748/2012.

The amendments are expected to increase the efficiency of implementing Annex I (Part 21) and ensure alignment with the current industry practices.

Action area: Design and production
Related rules: AMC and GM to Annex I (Part 21) to Regulation (EU) No 748/2012
Affected stakeholders: Design and production organisations; EASA; national aviation authorities (NAAs)
Driver: Efficiency/proportionality
Rulemaking group: No
Rulemaking Procedure: Standard
Table of contents

1. About this Decision ........................................................................................................................................ 3

2. In summary — why and what .......................................................................................................................... 4
   2.1. Why we need to amend the AMC and GM to Part 21 — issue/rationale .................................................. 4
       2.1.1. Related safety recommendations .................................................................................................... 4
       2.1.2. Certain recurrent Part 21 implementation issues .............................................................................. 4
       2.1.3. Clarifications on the way to implement certain Part 21 requirements ............................................. 4
       2.1.4. Alignment with the current industry practice .................................................................................... 5
       2.1.5. Simplification/reduction of the GM text and correction of typographical errors ............................. 5
   2.2. What we want to achieve — objectives ...................................................................................................... 5
   2.3. How we want to achieve it — overview of the amendments .................................................................... 5
       2.3.1. Related safety recommendations .................................................................................................... 5
       2.3.2. Certain recurrent Part 21 implementation issues .............................................................................. 6
       2.3.3. Clarifications on the ways to implement certain Part 21 requirements ............................................. 6
       2.3.4. Alignment with the current industry practice .................................................................................... 9
       2.3.5. Simplification/reduction of the GM text and correction of typographical errors ............................. 9
   2.4. What are the stakeholders’ views ............................................................................................................... 10
   2.5. What are the benefits and drawbacks ...................................................................................................... 11

3. How do we monitor and evaluate the rules ....................................................................................................... 12

4. References .................................................................................................................................................... 13
   4.1. Related regulations ..................................................................................................................................... 13
   4.2. Related decisions ....................................................................................................................................... 13
   4.3. Other reference documents ..................................................................................................................... 13

5. Related documents ......................................................................................................................................... 14
1. **About this Decision**

The European Union Aviation Safety Agency (EASA) developed Decision 2021/001/R in line with Regulation (EU) 2018/1139 (the ‘Basic Regulation’) and the Rulemaking Procedure. This rulemaking activity is included in the European Plan for Aviation Safety (EPAS) for 2020–2024 under Rulemaking Task (RMT).0031. The scope and timescales of the task were defined in the related Terms of Reference. The draft text of the Decision has been developed by EASA. All the interested parties were consulted through Notice of Proposed Amendment (NPA) 2020-04 ‘Regular update of the Acceptable Means of Compliance and Guidance Material to Annex I (Part 21) to Regulation (EU) No 748/2012’. 110 comments were received from all interested parties, including industry and national aviation authorities (NAAs).

EASA reviewed the comments received during the public consultation. The comments received and EASA’s responses to them are presented in Comment-Response Document (CRD) 2020-04. The final text of the Decision with the acceptable means of compliance (AMC) and guidance material (GM) to Part 21 has been developed by EASA.

The major milestones of this rulemaking activity are presented on the title page.

---


2. EASA is bound to follow a structured rulemaking process as required by Article 115(1) of Regulation (EU) 2018/1139. Such a process has been adopted by the EASA Management Board (MB) and is referred to as the ‘Rulemaking Procedure’. See MB Decision No 18-2015 of 15 December 2015 replacing Decision 01/2012 concerning the procedure to be applied by EASA for the issuing of opinions, certification specifications and guidance material ([http://www.easa.europa.eu/the-agency/management-board/decisions/easa-mb-decision-18-2015-rulemaking-procedure](http://www.easa.europa.eu/the-agency/management-board/decisions/easa-mb-decision-18-2015-rulemaking-procedure)).


6. In accordance with Article 115 of Regulation (EU) 2018/1139, and Articles 6(3) and 7 of the Rulemaking Procedure.

2. In summary — why and what

2.1. Why we need to amend the AMC and GM to Part 21 — issue/rationale

This Decision issues amendments to the AMC and GM to Part 21 as the outcome of a regular update process to take specific safety issues into consideration and to introduce new methods of compliance considered non-controversial and mature enough to be implemented. The amendments selected for this Decision are presented in the sections below.

2.1.1. Related safety recommendations

Following the accident involving an EC 225 LP helicopter on 29 April 2016 in Norway, the Norwegian safety investigation authority issued the following safety recommendation and addressed it to EASA.

SR NORW-2018-007:
‘The Accident Investigation Board Norway recommends that EASA make sure that helicopter manufacturers review their Continuing Airworthiness Programme to ensure that critical components, which are found to be beyond serviceable limits, are examined so that the full nature of any damage and its effect on continued airworthiness is understood, either resulting in changes to the maintenance programme, or design as necessary, or driving a mitigation plan to prevent or minimise such damage in the future.’

To accommodate this recommendation, AMC3 21.A.3A(a) is introduced with additional guidance through GM1 21.A.3B(b) and GM 21.A.3A(a), together with the update of the content of AMC1 21.A.243(a). In addition, a link to unsafe condition determination in accordance with point 21.A.3B(b), with a considered extension of point 21.A.3A(b)(1), and the reporting, is included in GM 21.A.3A(b).

2.1.2. Certain recurrent Part 21 implementation issues

During the audits conducted for the surveillance of DOA holders, EASA identified recurrent issues concerning the proper definitions of changes and repair designs. These issues pertain to the proper identification of the product configuration affected by the change or the repair (e.g. pre-mod and post-mod configurations). Clarifications in AMC1 21.A.263(c)(1), AMC2 21.A.263(c)(1), AMC1 21.A.263(c)(2) and AMC2 to 21.A.263(c)(2) are included to resolve such issues.

2.1.3. Clarifications on the way to implement certain Part 21 requirements

During the activities for the initial investigation and surveillance of DOA holders, EASA has collected a number of issues related to the implementation of Part 21. These may lead to misunderstandings, difficulties and uneven application of the Part 21 requirements.

In addition, industry, through associations⁸, proposed to EASA some improvements, clarifications and simplifications of the content of the AMC and GM to Part 21. Following a review of these industry proposals, where EASA agreed to the need for improvement, clarification or simplification, EASA included them in the regular update cycle of this RMT. The amendments associated with the industry proposals are listed below:

---

⁸ In particular, ASD proposed to EASA through its DOA WG a list of improvements to Part 21 and its AMC and GM. NPA 2020-04 addressed only some of the recommendations related to the AMC and GM. The remaining recommendations will be considered for inclusion in future NPAs.
(1) clarifications related to point 21.A.3A;
(2) clarification of the statement related to the data and information required in point 21.A.14 by
design organisations that use procedures alternative to those used by DOA holders;
(3) amendment of an AMC to delete language which may be of a prescriptive nature;
(4) clarifications related to the marking of parts and critical parts; and
(5) a clarification regarding the conditions when a POA holder or a DOA holder may be transferred.

2.1.4. Alignment with the current industry practice
Technical evolution has provided new and more efficient practices and working methods using
digital data or platforms based on intranet. AMC 21.A.265(a) is introduced to recognise the
acceptability of these new methods, together with additional information provided in GM 21.A.265(b).

2.1.5. Simplification/reduction of the GM text and correction of typographical errors
It is considered that some GM is redundant, since it repeats the related requirements without offering
any additional information. In addition, the opportunity was taken to remove a typographical error in
AMC 21.A.163(d).

2.2. What we want to achieve — objectives
The overall objectives of the EASA system are defined in Article 1 of the Basic Regulation. This Decision
will contribute to the achievement of the overall objectives by addressing the issues outlined in
Section 2.1.

The specific objective of this Decision is to amend the AMC and GM to Part 21 in order to reflect the
state of the art and the best industry practices. The amendments are based on a selection of
non-controversial and mature subjects. The ultimate goal is to increase safety, efficiency and
proportionality.

2.3. How we want to achieve it — overview of the amendments

2.3.1. Related safety recommendations
Following the issue of safety recommendation SR NORW-2018-007, AMC 21.A.3A(a) is introduced to
provide a methodology for the design approval holder to perform ‘investigation’ and ‘analysis’ of the
information related to failures, malfunctions, defects or other occurrences. Guidance on this
methodology is provided through GM1 21.A.3B(b), including the examination of worn parts to support
the determination of an unsafe condition, and also through GM 21.A.3A(a), including analysis of the
early rejection of parts from service and related to the collection of information. According to this
methodology, when during the overhaul inspection of a part, especially one whose failure could lead
to an unsafe condition, or could impact on the continued airworthiness, or which is considered critical,
or if it is found to be beyond the serviceable limit, an investigation and analysis should be performed
to understand the reason why the condition of the part is not consistent with the expected level of
wear. In addition, the design approval holder should assess whether a change to the design (e.g. to
improve the durability of the part) or to the instructions for continuing airworthiness (ICAs) (e.g. to
change the inspection or replacement frequency) is necessary, in order to maintain an acceptable level
of safety.
Moreover, a link to unsafe condition determination in accordance with point 21.A.38(b), with a considered extension of point 21.A.3A(b)(1) and the reporting, is included in GM 21.A.3A(b).

Finally, an amendment to point 10 of AMC1 21.A.243(a) is introduced to clarify that the DOA handbook should include a description of the means to collect, monitor, analyse and respond to reports of problems which cause or might cause an adverse effect on the airworthiness or operational suitability of the product, part or appliance. A link with point 21.A.3A(a) is introduced, as well as a clarification of the types of reports which should be included regarding in-service issues.

2.3.2. Certain recurrent Part 21 implementation issues

In order to address the implementation issues regarding the design definition of changes and repairs, AMC1 21.A.263(c)(1) is amended to highlight the need to identify the pre-mod (pre-repair) configuration to be affected by the change (repair), including parts, appliances, and systems, but also other type certificate (TC) constituents (operational suitability data (OSD) constituents, manuals, etc.) that might be affected. Together with this affected configuration, the DOA holder is also expected to identify the affected type certification and OSD certification basis. The same level of detail should be applied for the definition of the post-mod (post-repair) configuration.

Regarding the development of the justification of the change, when the classification is not straightforward, it is clarified that this should be done with reference to the specific applicable airworthiness requirements of the affected items and, consequently, against the criteria provided in point 21.A.91 as supported by the guidance provided in GM 21.A.91. The applicant should justify whether or not any additional demonstration of compliance is required.

In a similar manner, the Decision amends AMC1 21.A.263(c)(2) on the DOA procedure to approve minor changes or minor repairs. In particular, it specifically includes the identification of the pre-mod and post-mod configurations in the document defined by the DOA holder for the approval of the minor change or minor repair.

In a similar way, an amendment to AMC2 21.A.263(c)(1) and AMC2 21.A.263(c)(2), defining the classification procedure for a DOA holder that designs only minor changes or minor repairs, is also introduced.

2.3.3. Clarifications on the ways to implement certain Part 21 requirements

2.3.3.1. Clarifications related to point 21.A.3A ‘Failures, malfunctions and defects’

According to the criteria for the classification of design changes (defined in point 21.A.91), and of repairs (defined in point 21.A.435), minor changes and minor repairs have no appreciable effect on the characteristics affecting the airworthiness of the product. Consequently, the design approval holder of a minor change or of a minor repair has no obligations related to the continued airworthiness of the part affected by the change or repair. In order to make this concept clearer, GM 21.A.33(a) is amended to clarify that organisations that only design minor changes and minor repairs do not have to comply with the requirements defined in point 21.A.33(a).

Moreover, EASA received several questions regarding the interpretation of the text included in point 21.A.33(a): ‘[...] or any other relevant approval deemed to have been issued under this Regulation.’ This opportunity was taken to clarify that the above-mentioned text was introduced with the first
issue of Regulation (EU) No 748/2012 in order to grant ‘grandfathered’ approvals to projects, which at that time were in use in the EU Member States, following an approval based on national regulations.

2.3.3.2. Clarification of the statement related to the data and information required in point 21.A.14 ‘Demonstration of capability’

AMC 21.A.14(b) defines the acceptable means of compliance for design organisations that use procedures alternative to those used by DOA holders. Point 4 of this AMC describes that design organisations should issue information and instructions (e.g. instructions for continued airworthiness (ICAs), instructions for the embodiment of design changes, repair instructions) to owners, operators or others that are required to use the design data they produce. As part of this information, point 4.4 of the AMC introduces a statement showing EASA’s approval.

An amendment to AMC 21.A.14(b) is introduced to clarify that the data and information are initially approved by EASA as part of the respective design approval (i.e. TC, supplemental type certificate (STC), major change/repair approval, minor change/repair approval). Changes to this data and information defined at a later stage are carried out by the design organisation according to the EASA-agreed procedures. The statement to be included in the data and information should reflect the fact that the documentation has been produced in accordance with a procedure alternative to that used by a DOA holder, and make reference to the EASA approvals (TC, STC, major change/repair approval, minor change/repair approval), when applicable.

2.3.3.3. Amendment of an AMC to delete language which may be of prescriptive nature

In the current AMC 21.A.263(c)(6), ‘must’ is used in several instances, which is not appropriate for an AMC. An AMC cannot prescribe a requirement; it only provides one way to show compliance with the regulation. This term is used also in regard to the applicability of EASA Form 18A, as the template for the approval of flight conditions. As a confirmation of the non-prescriptive nature of the AMC, in several cases, forms developed by DOA holders, equivalent to EASA Form 18A, have been accepted. Consequently, an amendment to this AMC is introduced to replace all instances of ‘must’ with ‘should’ and to better clarify that a DOA holder may develop its own template for the approval of flight conditions under the privilege of point 21.A.263(c)(6). In any case, the templates developed by the DOA holders should be such that it is evident that the requirements defined in the Regulation are met.

Moreover, in several instances, EASA noticed the incorrect use of EASA Form 18A and EASA Form 18B by applicants holding a DOA, with or without the privilege to approve the flight conditions, as defined in point 21.A.263(c)(6). An amendment to AMC 21.A.709(b) is introduced to make clear when an EASA Form 18B should be used for the approval of flight conditions; that is, when the DOA holder does not have the privilege to approve flight conditions or when it has such a privilege but the respective flight conditions are outside the approved scope of work.

2.3.3.4. Clarifications related to the marking of parts and critical parts

AMC and GM (GM1 21.A.804(a)(3), AMC1 21.A.804(b) and GM1 21.A.805) are introduced to clarify the respective part-marking requirements, as follows:

— Point (a)(3) of point 21.A.804 mandates manufacturers to apply a European part approval (EPA) marking to parts or appliances produced in accordance with approved design data that does not belong to the TC holder of the related product, except for European technical standard order (ETSO) articles. EASA has received several questions on the applicability of this
requirement in cases of repairs. In such cases, if the repair design does not need to incorporate new parts, the EPA marking is not required. The EPA marking only applies to the new parts to be incorporated as defined in the repair scheme. GM 21.A.804(a)(3) is introduced to include this clarification.

— Point 21.A.804(b) provides the possibility for totally or partially omitting the marking of a part when EASA concurs that the part is too small or that marking it is impractical. In such cases, the missing marking information should be provided in the authorised release document or on the container.

— AMC1 21.A.804(b) is introduced to define that an acceptable means to comply with this requirement consists of the description to be added to the procedures developed by the design organisation, and of the conditions that qualify the lack of the necessity for the part to be marked. In such cases, the design data should specify the contents of the marking and the location where it will be added.

— Point 21.A.805 provides the requirements for the marking of some parts referred to as ‘critical parts’. This term is defined in some Certification Specifications (CSs) (e.g. CS-E, CS-APU, CS-27, CS-29); however, other CSs related to aeroplanes (i.e. CS-23, CS-25) do not include such a definition. GM is introduced to explain that what this point requires is to have individual traceability for continued airworthiness management purposes. The GM provides guidance to the design approval holder in order to identify when a part needs to be marked.

2.3.3.5. Clarification regarding the conditions when a POA or a DOA may be transferred

Points 21.A.149 and 21.A.249 provide a basic principle that a POA or a DOA, respectively, is not transferable, with only one exception when the transfer is the result of a change in ownership.

The requirement has been expressed in a very clear and prescriptive way, since a transfer puts in question the continuous compliance of the assessed organisation with the requirements in Subpart G or Subpart J of Part 21.

So, as a consequence, the natural or legal person needs to (re)apply for a POA or a DOA. If many aspects of the previous approval holder remain unchanged, no full substantial reinvestigation may be necessary.

If the transfer is the result of a change in ownership, then the transfer is considered a significant change requiring the POA or the DOA holder to apply for an approval according to point 21.A.147 or 21.A.247.

As the above is an exception, it has to be interpreted in a narrow way, and it shall only be applied in demonstrated cases of a change in ownership resulting in a need to transfer.

Based on the feedback received from the stakeholders, GM 21.A.149 and GM 21.A.249 are considered to be unclear, since they do not really clarify what a ‘transfer as a result of a change of ownership’ is.

For example, the following terms used in the GM should be reconsidered:

— ‘substantially unchanged’, which leaves room for interpretation, may be even better replaced by ‘unchanged’; and
2. In summary — why and what

— ‘change of company name’; this addresses the certificate (paper), as a transfer situation. A change of ownership may result in a new company name. The new company name does not affect the approval if there are no changes to the company’s premises and key personnel. If the company, as a result of the name change, also changes its registration number and therefore may be considered to be a new legal entity, then the GM may make sense, by saying that the ‘change in ownership’ is an acceptable transfer, i.e. only a significant change.

2.3.4. Alignment with the current industry practice

It is becoming common for some DOA holders to replace the traditional design organisation handbook with an integrated management system manual, often based on an intranet platform, containing procedures related to different management systems. In this case, the design organisation procedures become merely an element of the overall manual. If the system guarantees that all the required information is available, either directly or through a cross reference/link, and ensures the effective use of the handbook by the DOA holder’s staff, then this is considered acceptable. Consequently, AMC2 21.A.265(a) is introduced to clarify the format and means to publish such a handbook, and additional information is provided in GM 21.A.265(b). Note that from new AMC2 21.A.265(a), ‘AMC 21.A.265[a]’ is renamed ‘AMC1 21.A.265(a)’.

It is also clarified that it is mandatory for EASA to have access to the handbook, in whatever form it is made available.

2.3.5. Simplification/reduction of the GM text and correction of typographical errors

During the revision of the content of some GM, it was noticed that in some cases, the GM does not provide any additional clarification of the requirement it refers to, and that it is only a repetition of it. The following items are therefore deleted:

— GM 21.A.439 and GM 21.A.441, since they basically repeat the text of the Regulation; and
— GM 21.443, which refers to the procedures required by Regulation (EU) No 965/20129 on air operations, which are not applicable to design or production organisations.

Following the amendments to Part 21 introduced with Regulation (EU) 2019/89710, point 21.A.15 was amended by deleting the definition of operational suitability data (OSD) as it was introduced in paragraph (k) of Article 1 of Regulation (EU) No 748/2012. Then, ED Decision 2019/018/R11 amended accordingly the relevant AMC and GM; however, GM No 4 to 21.A.15(d) was not revised to reflect the new location of the OSD definition. Moreover, GM No 1 to 21.A.15(d)(6) was not deleted, following the deletion of the subparagraphs of paragraph (d) of point 21.A.15. These two mistakes are corrected.

AMC-ELA No 1 to 21.A.263 was also revised to update the statement that DOAs are required to include in the aircraft flight manual, in cases of minor revisions, to reflect the new text that was introduced,

with the last amendment of Part 21, in paragraph (h) of point 21.A.265. In addition, AMC 21.A.163(d) was revised to correct a typographical error. It was identified that the text of this AMC refers to GM 21.A.163(c) (EASA Form 1). Actually, there is no such GM, and the AMC should refer to point 21.A.163(c) instead.

Lastly, it has been noted that GM No 1 to 21.A.112B only addresses STCs for products for which a DOA is required according to point 21.A.14. A line is therefore added in the table reported in the GM to also cover STCs for products where a DOA is not required as defined in point 21.A.14(b).

2.4. What are the stakeholders’ views

The commentators were in general supportive of the proposed amendments to the AMC and GM.

The nature of the comments received ranged from specific technical comments to observations aimed at improving the wording.

Several comments were merely statements, without providing a proposal for amendment.

Hereafter is a summary of the major comments, with a summary of the outcome of the NPA consultation.

(a) NPA 2020-04 Section 2.3.1 ‘Safety recommendation’:

Some organisations requested EASA to provide clarification on critical parts that need to be investigated because their condition is deemed to be beyond the serviceable limit, and what is the intention of a thorough investigation. Even if one of the purposes of the RMT is linked to a safety recommendation, the rule is neither exclusive to critical parts, nor to TC holders. The wording has been adapted to reflect this and to provide better and complementary information.

(b) AMC3 21.A.3A(a):

Some organisations highlighted the need to indicate that parts with defects need to be made available to the TC holders / design approval holders to allow their analysis, and to also provide clarification of the wording ‘thoroughly investigated’. The wording has been revised, and now indicates that the parts whose failure could lead to an unsafe condition are sent to the design approval holder. In addition, the word ‘thoroughly’ is replaced by additional information included in GM1 21.A.3B(b). Additionally, complementary information is provided in GM 21.A.3A(a) and in GM 21.A.3A(b). From the amended GM 21.A.3A(b), the link in the titles initially proposed in the NPA for AMC1 21.A.3A(b)(1) and point 21.A.3B(b), and for GM1 21.A.3A(b)(1) and point 21.A.3B(b) is not needed, so the references in the titles are related to AMC1 21.A.3B(b) and to GM1 21.A.3B(b).

(c) GM 21.A.3A(a):

Some organisations misinterpreted the relation of minor change organisations with the system for continued airworthiness and reporting clarified in the NPA (Section 2.3.3.1, and the associated AMC and GM to point 21.A.3.A(a)). EASA provided additional clarification in the answers to those comments (i.e. when the minor design holder is aware of a potential unsafe condition related to their design, they must report it; the minor change classification remains the responsibility of the organisation).
2.5. **What are the benefits and drawbacks**

The main benefits of this Decision are the following:

— safety concerns are addressed; and

— the efficiency of the implementation of Part 21 is increased.

There are no foreseen drawbacks.
3. How do we monitor and evaluate the rules

Additional actions might be triggered by the feedback collected during DOA audits, and the certification of products and the associated changes.
4. References

4.1. Related regulations


4.2. Related decisions

— Decision N° 2012/020/R of the Executive Director of the Agency of 30th October 2012 on acceptable means of compliance and guidance material for the airworthiness and environmental certification of aircraft and related products, parts and appliances, as well as for the certification of design and production organisations (‘AMC and GM to Part 21’) repealing Decision No 2003/01/RM of the Executive Director of the Agency of 17 October 2003

4.3. Other reference documents

n/a
5. Related documents
