European Union Aviation Safety Agency

Explanatory Note to Decision 2019/003/R

Acceptable Means of Compliance and Guidance Material to Annex I (Part-21)
Issue 2, Amendment 8

RMT.0689

Executive Summary

This Decision introduces new Acceptable Means of Compliance (AMC) for Part-21 production and design organisation approvals, which complement the existing AMC. The objective is to provide a more proportionate approach for small, non-complex organisations that produce lower-risk products and the parts installed on these products.

The new AMC shifts the focus of both the applicant and the competent authority onto the effects on the output of the process, instead of the focus being on the detailed step-by-step documentation of the process. This is a more product-oriented approach.

The AMC provides for more proportionality for the affected organisations, without having any impact on the level of safety. It is avoiding an over-burdensome and disproportionate administrative application of regulations for these small and simple organisations.

The AMC can also serve as the baseline when a means of compliance with the Subpart G and J requirements needs to be developed outside the applicability of the AMC. In that case, coordination is needed between the applicant and the competent authority to review and, when necessary, to complement the baseline with more stringent or detailed processes or procedures so as to provide a consistent and acceptable result.

The AMC can be used by small companies that design and produce low-risk general aviation (GA) aircraft within the current Part-21. The AMC also allows experience to be gained for a possible future combined (design and production) company approval. It is anticipated that it will be used until amendments to Part-21, based on the changes brought about by the new Basic Regulation (Regulation (EU) 2018/1139), allow for new concepts for a more proportionate regulatory system. At that point, the current AMC may need to be revisited.

Action area:	General aviation		
Affected rules:	AMC/GM to Part-21		
Affected stakeholders:	Design, production and maintenance approval holders; owners of simple aircraft		
Driver:	Efficiency/proportionality	**Rulemaking group:**	N/A
Impact assessment:	None	**Rulemaking Procedure:**	Accelerated

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1. About this Decision

The European Union Aviation Safety Agency (EASA) developed ED Decision 2019/003/R in line with Regulation (EC) No 216/2008[1] and the Rulemaking Procedure[2].

This rulemaking activity is included in the European Plan for Aviation Safety (EPAS)[3] under rulemaking task (RMT).0689. The scope and timescales of the task were defined in the related Terms of Reference[4].

The text of this Decision has been developed by EASA supported by a task force, and a focused consultation with affected stakeholders. The Advisory Bodies were consulted in accordance with Article 16 'Special rulemaking procedure: accelerated procedure' of MB Decision No 18-2015. EASA has taken the decision to follow the procedure laid down in that Article, as this regulatory proposal affects a limited group of stakeholders.

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

1 Regulation (EC) No 216/2008 of the European Parliament and of the Council of 20 February 2008 on common rules in the field of civil aviation and establishing a European Aviation Safety Agency, and repealing Council Directive 91/670/EEC, Regulation (EC) No 1592/2002 and Directive 2004/36/EC (OJ L 79, 19.3.2008, p. 1) (http://eur-lex.europa.eu/legal-content/EN/TXT/?qid=1467719701894&uri=CELEX:32008R0216).

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).

3 https://www.easa.europa.eu/document-library/general-publications?publication_type%5B%5D=2467

4 http://www.easa.europa.eu/document-library/terms-of-reference-and-group-composition/tor-rmt0689

2. In summary — why and what

2.1. Why we need to change the acceptable means of compliance (AMC)

Companies that have simple organisations and produce low-risk aircraft for GA sometimes have difficulty in showing their compliance to the requirements of Part-21, especially in respect of the production organisation requirements. The existing AMC to Part-21 Subparts G and J were developed for the use by organisations that may have complex business structures, and that produce complex aircraft, whose design and production require a rigorous process for establishing procedures, control, and oversight to mitigate the risks associated with these complex processes and higher risk levels.

Why is the existing AMC not appropriate for simple organisations?

Processes are direct and relatively simple in a small company. Detailed documentation and the recording of objective evidence for each step, as embedded in the existing AMC, do not help mitigating process risks and do not increase the consistency or the quality of these processes.

Less complex designs also inherently have less complicated risks, which can be mitigated by simpler methods and personal skills instead of procedural controls.

The design and production organisations are often combined or integrated in a simple company. The existing AMC does not take into account the advantages of such consolidated teams.

What is the consequence of applying the current AMC to small companies?

Applying the existing AMC methods and the associated level of rigor for control and oversight to small companies by focusing on procedures creates additional (mostly administrative) burden for both the organisation and competent authorities.

2.2. What we want to achieve — objectives

The overall objectives of the EASA system are defined in Article 1 of Regulation (EU) 2018/1139. 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 proposal is to provide a more proportionate approach for small, non-complex organisations that produce lower-risk products and the parts that are installed on those products in order to:

(a) promote cost-efficiency in the regulatory and certification processes;

(b) provide a level playing field for all the actors in the internal aviation market.

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

A new dedicated AMC for European Light Aircraft (ELA), i.e. AMC-ELA, is implemented for small companies that produce low-risk aircraft. The principles applied in this AMC are the following:

Focus on the output of the process instead of on the process and the procedural details

Because processes in small companies are relatively direct and simple, the mitigation of the procedural risks can be limited. The new approach is, therefore, to start with a focus on controlling the outputs of the process. Therefore, for production, it starts with a focus on the product. In order to investigate deficits, the processes still require the identification of responsibilities for documentation and recording, but in a way that is adjusted to a simple process. The new AMC should not lead to the creation and implementation of

administrative processes that do not provide obvious support for a safe product. Because small companies rely more on people taking responsibility and being competent, the process descriptions should take that into account. Often, a declaration of responsibilities could be sufficient.

Providing a common baseline for small companies to show compliance

The AMC for ELA provides a means of compliance for a limited scope of aircraft. Its principles can, however, also serve as the baseline when a means of compliance is being developed for small and simple companies that design/produce outside the applicability of the AMC-ELA. This assumes that the process can primarily be controlled via the outcome (the product).

AMC: a presumption of compliance

In the initial proposed draft AMC, which was provided for the focused consultation workshop, flexibility and tailoring was built into the AMC. However, when following an AMC, it is presumed that the related requirement is complied with. This was no longer true in the initial draft, in which the AMC allowed choices that did not, in all cases, result in an acceptable showing of compliance, depending on the complexity of the organisation and the design.

The re-drafted AMC is, therefore, limited in applicability, and is more specific, so the presumption of compliance with the related Part-21 requirements is justified. The reflections on the tailoring of procedures to reach a proportionate approach for different sizes and complexities of organisations has been moved to the GM.

2.4. What are the stakeholders' views

During the consultation of the draft AMC, fundamental questions of principle arose, as well as detailed comments on the proposed text. This paragraph reflects the feedback and the review of the main topics that were brought to EASA's attention during the workshop, via the survey and via EASA internal consultation. Subsequent consultation with the GA advisory bodies on the AMC and GM that was amended for the points addressed in the following paragraphs did not raise any concerns.

General issues

Scope

Discussions on the scope of the AMC identified that this proportionality would also be beneficial for companies that produce parts with a low risk, for aircraft that are beyond the proposed 'GA' scope. This AMC is intended to be used in the transition period before Part-21 is being revisited, based on the changes made to the new Basic Regulation (Regulation (EU) No 2018/1139). Widening the scope to parts that are outside the aircraft scope would complicate the definition of the scope for these parts. It was believed to be better to apply a limited scope for now.

AMC-ELA: the starting point and the process for proportionality

Reactions, primarily received from authorities, showed a general concern that the first draft of the AMC-ELA would lead to applicants only using the starting point (which is sufficient only for the lowest risk level), without the possibility for the competent authority to challenge such an approach. The first draft of the AMC-ELA described methods that often reduced the involvement of the authority to a minimum. If that approach had been strictly applied by an applicant without any further discussion with the competent authority, it might not have achieved the appropriate level of rigor or coordination that is needed.

These comments are in line with the discussion regarding the presumption of compliance with AMC (see 'AMC: a presumption of compliance' in Section 2.3). The applicability of the AMC-ELA has been reduced and the text of the AMC-ELA has been changed (sometimes also from AMC to GM) in order to provide a presumption of compliance when the AMC-ELA is applied.

Some comments were made that the existing methods have been proven to work, and that the new AMC is not required. Suggestions to apply the existing AMC methods, however, often conflict with the proposed new approach for these simple organisations that produce low-risk aircraft. Reverting this AMC-ELA to focus on procedural and process-oriented oversight would not be expected to provide the best results, and would bring a substantial administrative burden. This proposal, therefore, follows its initial direction in which the controls and oversight primarily start with a focus on their impact on the output of the process. From there, processes, procedures, and records are available to find the root cause of any problems identified in the output. It was agreed that not all aspects of a company approval could be accessed via control of the output. The initial draft AMC-ELA was, in that respect, too black and white, and it has been amended.

In various parts of the AMC, emphasis was put on the design data in order to establish what is important for the surveillance of primarily the product. This is in line with the more product-oriented approach, which requires a good understanding of the design. This was, however, too strongly expressed in the draft AMC-ELA, which was therefore considered to be too one-sided. In addition to the importance of the design data that was identified, there are also other elements which are not reflected in design data and that play an important role in the assurance of the production process. This has been amended in various parts of the AMC-ELA.

The first draft of the AMC was originally written for each requirement of Part-21 Subparts J and G in order to create a 'stand-alone' AMC document for small companies that covers all requirements. This, however, created AMC for certain requirements for which there is no need for AMC (e.g. for instance, definitions of levels of findings). These AMC that were close to, or identical to, the Part-21 requirements, have been removed or replaced by guidance material (GM-ELA).

Specific AMC for ELA embedded in Part-21 AMC and templates (for the company handbook, production organisation exposition (POE))

The suggestion was made to separate this AMC-ELA from the other AMC to Part-21, for instance in a separate appendix. For the time being, this suggestion has not been considered. At a later stage, when implementation of the new basic regulation to Part-21 will be proposed, this AMC and GM-ELA may need to be revisited.

The initial proposal involved the inclusion of templates in the AMC, to create a stronger tool for a standardised application of the AMC and GM-ELA. It was, however, concluded that, because of the need to tailor these documents to the specificities of each organisation, they should not be included in the AMC-ELA. EASA is therefore developing templates that are intended to be provided as additional informative material.

GM-ELA to 21.A.131 Scope — General considerations

The AMC&GM-ELA to 21.A.131 has been amended to better explain the generic principles of this new AMC. In addition, the use of 'methods practised' is put in perspective by having documented procedures and records that are sufficient, but non-excessive.

The intention of the POE in the AMC-ELA, which is different from its use in the existing AMC, is also explained in more detail. In the existing AMC, the POE serves as the entry point into the documented structure of the organisation. For AMC-ELA, the organisation is controlled via the control of products, practices and documented procedures, (and very importantly, in that order,) to reflect the day-to-day operation of a small company. Several comments requested EASA to re-establish the solid link to, or to include in the POE, certain data items that were based on the existing AMC. This has not been accepted, since the POE in AMC-ELA is not the entry point for organisational controls. The POE in the AMC-ELA serves as the document that gives the high-level description of the company, and explains where to find the system that is applied to control the company. Details are not captured in the POE. An important reason for this difference in the role of the POE in AMC-ELA is to reduce the administrative burden when changes that affect the POE require approval. The lower level of detail will reduce the need for amendments to the POE, and therefore for approval by the competent authority.

AMC-ELA to 21.A.133(b);(c) Eligibility — The link between design and production

The initial draft AMC-ELA did not foresee a documented arrangement, while the Part-21 rule does foresee it. The initial driver was the fact that in simple companies, there may be only a legal differentiation between the design holder and the producer, rather than a practical separation.

The AMC-ELA has been changed, and it now includes an arrangement template in order to capture the fact that the legal responsibilities are clearly identified. In order to avoid falling back to a process-oriented approach, the arrangement does not include specific references to procedures.

AMC&GM-ELA to 21.A.139(a) Quality system

The initial draft AMC-ELA indicated that holding or applying an existing quality standard system (e.g. ISO 9001, EN 9100 and ASTM F2972) would be sufficient to show the compliance of the quality system. The approach of 'blindly' accepting the application of these standards was questioned, and indeed it would not help to encourage coordination between the organisation and the competent authority. The intent was to avoid any duplication of effort if a company used such quality systems. It is, therefore, important to establish whether and how those existing quality systems, if applied, can be relied upon. This means that if these systems are used, their integration or use as part of the quality system of the company needs to be reviewed.

The way in which the conformity of supplied parts or appliances is controlled has a great impact on work and costs for small companies, and this is an area in which proportionality could bring benefits. It is also the area where the draft AMC-ELA generated many concerns. The discussions show a wide variety of examples, ranging from a supplier who builds wings to a supplier of automotive engine oil filters. Prescribing in the AMC-ELA what does or does not work is impossible. Where the draft AMC-ELA initially specifically focused on the disadvantages of supplier audits, that text has been removed. Instead, the AMC-ELA lists all the available methods to check for conformity to the design. The emphasis remains that, primarily, the design data should identify what is needed or what is important to be verified. This is, however, not always the only data that drives this process. As in the general considerations, this needs to be tailored to the situation in coordination between the organisation and the competent authority.

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

As it is inherent in the intention of this AMC-ELA to put more initial focus on checking the output of the process, the elements of the quality system reflect this in their focus on the direct impact that is expected on the safe operation of the aircraft. Information from the design should be the basis to identify the level of robustness needed for the elements of the quality system. Comments were received that questioned the actual definition of such information in the design data. It is true that today, this could be insufficiently included in the design data. However, a proper understanding of the design is necessary to apply this 'product-oriented' approach. The AMC-ELA has been changed in order to also underline that it is not only the design data that drives the quality system, but that it could need to be complemented with production data. The main issue in this AMC-ELA for production organisation approval (POA) is that for small companies that combine design and production, the understanding of the importance and the effect of the elements of the quality system is important in order to find a proportionate implementation of that quality system. The depth of detail in procedures, documentation and record keeping needs to be tailored to the expected impact on safety. Finally, the quality system should ensure that each product, part and appliance supplied to the end-user conforms to the applicable design data. This also applies to spare parts.

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

The general intention of the POE is explained in GM-ELA No 1 to 21.A.143. Comments were received on specific items in the POE, such as the listing of certifying staff. This list shall be identified by the POE, as required by Part-21, however the list itself does not need to be part of the POE. This will reduce the need for changes to the POE. The determination of whether such a change is significant, and requires approval by the competent authority, has been removed from this AMC and explained by GM-ELA No 1 to 21.A.147. Other comments that concerned established methods, and requested details to be included in the POE, were not accepted if they reflected the existing procedurally oriented AMC. Some competent authorities raised comments that a training of inspectors would be necessary in order to accept the use of other systems such as EN 9100 or ASTM F2972. This was not supported, since the intent is to use the systems that are integrated within the quality system that cover POA elements. Knowledge of POA systems is considered to be sufficient, while the understanding of a product might be of more value. As mentioned before, the combination of design and production is also an important element for the oversight function for these small companies.

GM-ELA No 1 to 21.A.147 Changes to the approved PO

Comments indicated that examples of significant changes that require an approval were missing. These have been added. At the same time, the AMC-ELA has been changed into GM, since it wasn't a means of showing compliance but explained the emphasis on the coordination between the competent authority and the approval holder when the change process is determined.

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

The initial draft said that the competent authority would not examine certain details unless a non-conformity was found that endangered safe operation. This raised comments, and it was considered to be too prescriptive for the process. This has been changed into GM-ELA, underlining that the investigations should focus on issues that could result in unsafe conditions. Details and methods are left to the discretion of the competent authorities.

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

Because the first draft of the AMC was basically a repetition of the Part-21 requirements, this AMC has been re-written as guidance material. The follow-up, and in particular, the corrective action times for level 2 findings, were not correct in the AMC-ELA, and have been corrected. In order to minimise the burden, and making use of the coordination between the competent authority and the approval holder, a note has been added that it is recommended to reach an agreement on the administrative closure of level 2 findings at regular surveillance intervals.

AMC-ELA No 1 to 21.A.165(d) Obligations of the holder

The draft AMC-ELA did not sufficiently indicate that the recording of work carried out by the POA is their responsibility. However, to make sure that the recorded data will focus on the important information, coordination with the design holder is necessary. In addition, it is highlighted that the level of production data recording can have consequences for corrective actions if there are continued airworthiness issues.

2.5. What are the benefits and drawbacks

This decision introduces AMC and GM for a limited scope of design and production organisations, as alternative AMC/GM to the existing AMC and GM. The scope of the affected General Aviation stakeholders is therefore very limited. Organisations outside the specific and limited scope of this new AMC and GM are not affected.

The new AMC and GM are intended to provide more proportionality for those organisations, without having any impact on the level of safety. Indeed, the benefit of this AMC-ELA is that it provides a proportionate means of compliance with Subparts G and J for small, non-complex organisations that produce low-risk aircraft. Since there are currently no such proportionate means, the competent authorities either apply the current AMC, which is too burdensome and is disproportionate for these small and simple organisations, or they act more pragmatically, but not in a standardised manner.

3. How do we monitor and evaluate the rules

The challenge of this AMC-ELA is that it introduces a new approach that requires more cooperation and coordination between the applicants and the competent authority, and in a new and more coordinated manner. This new role for both the participants requires a culture change that cannot be achieved by the publication of this AMC-ELA alone. EASA intends to evaluate the effectiveness of the new AMC-ELA by more closely monitoring pilot cases and using standardisation feedback. This information is considered to be beneficial for the development of the fundamental changes to Part-21.

4. References

4.1. Related regulations

— Commission Regulation (EU) No 748/2012 of 3 August 2012 laying down implementing rules for the airworthiness and environmental certification of aircraft and related products, parts and appliances, as well as for the certification of design and production organisations (OJ L 224, 21.8.2012, p. 1)

4.2. Affected 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 N° 2003/01/RM of the Executive Director of the Agency of 17 October 2003