DOARI 2024-01 Consultation Paper

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1 Introductory Note

The hereby presented deviation requests shall be subject to public consultation, in accordance with EASA Management Board Decision No 7-2004 as amended by EASA Management Board Decision No 12-2007 products certification procedure dated 11th September 2007, Article 3 (2.) of which states:

"2. Deviations from the applicable airworthiness codes, environmental protection certification specifications and/or acceptable means of compliance with Part 21, as well as important special conditions and equivalent safety findings, shall be submitted to the panel of experts and be subject to a public consultation of at least 3 weeks, except if they have been previously agreed and published in the Official Publication of the Agency. The final decision shall be published in the Official Publication of the Agency."

2 Original PART 21 requirement and/or AMC

AMC1 21.A.239(d), AMC1 21.A.263(c)(1), AMC1 21.A.263(c)(2), AMC1 21.A.243(a) AMC3 21.B.430, AMC4 21.B.431, AMC2 21.B.435.

3 Problem Description

The coordination between Design Organisation and Production Organisation in the matter of unintentional production deviations is addressed by various PART 21 requirements and corresponding AMC/GM.

Below is an overview of PART 21 references which set the background for this DOARI.

Part 21.A.4 (a) expresses the need for coordination between production and design organisations and states:

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

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

AMC No.1 to 21A.133 (b) and (c) clarifies that the arrangement between the DOA and POA must define, among others, the following aspect:

"The responsibilities of a POA holder/applicant to assist the design organisation in dealing with continuing airworthiness matters and for required actions (e.g., traceability of parts in case of direct delivery to users, retrofitting of modifications, traceability of processes' outputs and approved deviations for individual parts as applicable, technical information and assistance, etc.)".

AMC No.1 to 21A.133(b) and (c) also states that the arrangement must also define:

The procedures to deal adequately with production deviations and non-conforming parts.

Part 21.A.165 (c) requires a POA holder to:

"1. determine that each completed aircraft conforms to the type design and is in condition for safe operation prior to submitting statements of conformity to the competent authority; or

2. determine that other products, parts or appliances are complete and conform to the approved design data or declared design data and are in a condition for safe operation before issuing an EASA Form 1 to certify conformity to approved or declared design data and condition for safe operation;

3. additionally, in the case of environmental requirements determine that:

(i) the completed engine is in compliance with the applicable engine exhaust emissions requirements on the date of manufacture of the engine; and

(ii) the completed aeroplane is in compliance with the applicable CO2 emissions requirements on the date its first certificate of airworthiness is issued.

4. determine that other products, parts or appliances conform to the applicable data before issuing an EASA Form 1 as a conformity certificate;" .

GM No. 2 to 21.A.165(c) stipulates:

"Individual configurations are often based on the needs of the customer and improvements or changes which may be introduced by the type-certificate holder. There are also likely to be unintentional divergences (concessions or non-conformances) during the manufacturing process. All these changes are required to have been approved by the design approval applicant/holder, or when necessary, by the Agency".

AMC1 21.A.239(d) point (c)(1)(i)(G) addresses the liaison between the DOA holder with production organisations:

"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".

which should be subject to a documented DOA procedure iaw AMC1 21.A.243(a), point (b)(4)(iii)):

"The procedures for classifying and approving unintentional deviations from the applicable design data occurring in production (concessions or non-conformity)"

This DOARI proposes a deviation from the acceptable means of compliance to Part 21.A.263(c)(1) and (2) for a procedure for the classification and approval of unintentional production deviation by a DOA holder within its terms of approval, which is based on the principles of AMC1 21.A.263(c)(1) & AMC1 21.A.263(c)(2), for the exercise of the corresponding privileges.

Similarly to changes and repair, minor deviations shall be approved under the DOA privilege, where applicable, while major deviations shall be applied for approval to the Agency following the same process as for major changes or STCs.

Note:
For the purpose of this DOARI the word "Deviation" is used to describe either "manufacturing deviations", "unintentional production deviations", "non-conforming parts", "non-conformities", or other words describing a condition where a product, part, or appliance has been unintentionally produced with certain differences to the approved or applicable design. Voluntary deviations such as “production permits” are not addressed by the current DOARI and should be classified and approved with the dedicated procedure as changes to TC, embodied in a specific batch or serial number of the series production.
"Deviation disposition" or “concession” is used for the approval by the design organisation of the deviations, by assessing the airworthiness impact, approving (i.e., “use as is”) or rejecting (i.e., “scrap”) the deviation directly or by defining further instructions for the treatment of the deviation and the affected part(s) (i.e., “restore airworthiness condition with our without remaining deviations”).

4 Industry Position

N/A

5 EASA position

A deviation from the approved design data introduces *evolutions* to the manufactured product, part, or appliance. They can be seen as equivalent to those evolutions which are introduced by a change. They may affect the physical or functional condition of a product, part, or appliance, and the impact on airworthiness could be appreciable or not appreciable.

Such evolutions can affect the form, fit, function, material, and performance in a similar manner to an embodied change or repair. Since the airworthiness shall be guaranteed under any circumstance, such evolutions shall be addressed following the same principles in place of changes to TC for their classification and approval.

In the frame of this DOARI, the term classification means the evaluation of the impact on airworthiness in accordance with PART 21.A.91.
The airworthiness classification should complement the assessment of a deviation which might have been already identified by a DOAH for industrial reasons.

Conclusively, a POA must ensure that each completed product, part, or appliance conforms to the applicable/approved design data before its release. As such, deviations need to be approved by the design approval holder.

Any deviation to a product, part or appliance shall be classified and approved in accordance with a defined procedure, which should be similar to the one required for the classification and approval of changes to TC and repairs. The airworthiness of the product, part or appliance shall be demonstrated regardless of the number of *units* produced.

Note: As formally the definition of a repair (21.A.431A(c)) excludes deviations, they can only formally be treated as changes to TC in accordance with Part 21 Subpart D.

Means of compliance with Part 21.A.263(c)(1) & (2)

The procedures for the classification and approval of deviations should follow AMC1 21.A.263(c)1 and AMC1 21.A.263(c)2, with differences as detailed in the following paragraphs.

Whereas, for those deviations classified as major, the DOH shall file an application to EASA in accordance with 21.A.93 or 21.A.117(c), unless they can be approved under the provisions of 21.A.263(c)8 or 21.A.263(c)9.

Classification criteria and signatories for classification

Part 21.A.435(a) & GM 21.A.435(a) (for Repair designs) may be used as reference for the classification criteria of the production deviations.
The design organization may authorise specific personnel for the approval of the classification decision.

Independent Verification of Compliance

Independent verification of compliance (21.A.239 (d)2) is only relevant when additional work to demonstrate compliance is necessary.

The Design Organisation may nominate other staff for the independent verification of compliance specifically related to the approval of deviation dispositions. Where normally this function is performed by "Compliance Verification Engineers", a specific title could be used for the verification of compliance related to the approval of the deviation dispositions.

If the deviation remains justified by previously approved data (i.e., disposition/concession), there is no requirement for the independent verification of compliance. Here, three cases may be anticipated:

Use of a previously approved deviation

In analogy with repairs (GM 21.A.435 (b)2), for a previously approved deviation (and disposition), the DOA Holder should demonstrate its applicability to the new case, within certain conditions (e.g., Aircraft/engine/propeller type, same location same configuration of the affected items, same or smaller deviation, etc.).

The above-mentioned conditions should be documented within the deviation procedure; when those conditions are fulfilled (*), the DOA holder should demonstrate that, with respect to the newly affected items and associated requirements, an existing disposition remains valid.

(*) Fulfilment of the conditions to be justified and documented, when not straightforward, as contributing to the classification process, AMC1 21.A.263(c)1 par. 2.4) ensures that a minor deviation can be further classified as minor without additional demonstration of compliance.

Substantiation by margin exploration

This is the case where a deviation remains justified by the compliance demonstration provided at the time of type certificate or subsequent changes, without changing assumptions, means of compliance, methodologies, and tools.

In this scenario, applicable requirements linked to the affected items need to be identified along with the reference compliance data, which is the basis for the margin exploration. The technical work performed to compile the existing compliance data and to justify that this still covers the new deviation, should be documented, as contributing to the classification process (AMC1 21.A.263(c)1 par. 2.4).

Predefined cases of deviations

A DOA holder may have provided the production organisation with a catalogue of deviations or engineering criteria, for which the impact on airworthiness was already assessed and which are as such approved.

Conclusions

When the means of compliance documented in this DOARI is adopted, the DOA Holders may provide to the Agency:

- a gap analysis between the existing deviation treatment process and the content of this DOARI;
- If changes are deemed necessary, the determination of the impact on the DMS (ref. 21.A.239(c)4(ii)) of those changes;
- Roadmap for the implementation as necessary, with timeline to be agreed with EASA, depending on the magnitude of the identified gaps.

6 Final disposition after consultation process

TBD.