



European Union Aviation Safety Agency

# Comment-Response Document (CRD) 2019-05(B)

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RELATED NPA: 2019-05(B), OPINION No 04/2020 & ED DECISION: 2022/021/R — RMT.0251 (MDM.055)  
PHASE II

20 OCTOBER 2023

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## 1. Background

In relation to RMT.0251 (MDM.055) Phase II (Embodiment of the safety management system (SMS) requirements into Part 21 and Part-145), the NPA was arranged in 3 sub-NPAs as follows:

- Sub-NPA 2019-05(A) for general consideration;
- Sub-NPA 2019-05(B) for Part 21 (amendments to Regulation (EU) No 748/2012 and its associated AMC & GM); and
- Sub-NPA 2019-05(C) for Part-145 (amendments to Regulation (EU) No 1321/2014 and its associated AMC & GM).

This NPA was published on 17 April 2019 and was subject to a public consultation until 6 September 2019.

On 19 December 2021 the Agency issued Opinion No 04/2020<sup>1</sup> together with CRD 2019-05 that addresses the comments related to the amendments to the Regulation as proposed in NPA 2019-05.

This CRD 2019-05(B) now intends to address the NPA comments related to the amendments to the AMC & GM as proposed in Sub-NPA 2019-05(B), i.e. the amendments to the Part 21 AMC & GM.

Another CRD, i.e. CRD 2019-05(C), was also published for the NPA comments related to the amendments to the AMC & GM amendments proposed in Sub-NPA 2019-05(C), i.e. the amendments to the Part-145 AMC & GM.

Note: Opinion No 04/2020 resulted in the adoption of Commission Delegated Regulation (EU) 2022/201 and Commission Implementing Regulation (EU) 2022/203 amending the Initial Airworthiness Regulation (Regulation (EU) No 748/2012).

On the Continuing Airworthiness side (Regulation (EU) No 1321/2014)), the Opinion resulted in the adoption of Regulation (EU) 2021/1963.

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<sup>1</sup> <https://www.easa.europa.eu/en/document-library/opinions/opinion-042020>

## 2. Summary of the outcome of the consultation and approach taken as regards the disposition of the comments on Part 21

As regards Sub-NPA 2019-05(B), 864 comments were received on the proposed text of the AMC and GM to Part 21, 50 % of which were duplicated comments. The comments were diverse, ranging from comments on the understanding of SMS, to comments related to the adaptation and application of the SMS principles in the Part 21 environment. These comments can be consulted in Appendix 6.2 to CRD 2019-05.

Similarly to the approach taken with CRD 2019-05, due to this high number of comments, the decision has been made to summarise and group the comments and their responses for CRD 2019-05(B).

Therefore, this CRD will provide a summary of the comments received on Sub-NPA 2019-05(B), limited to the AMC & GM. This CRD text has been developed by EASA, based on the review of these comments and the input of the RMT.0251 Phase II Focused Consultation Group (FCG) — the same group which was consulted on the development of the NPA. The FCG was composed of experts from industry and national competent authorities.

To review the comments on the Part 21 AMC & GM proposed in Sub-NPA 2019-05(B), these comments were clustered by topics, and various groups composed of selected members of the FCG and EASA were created to review the relevant comments. Two of these groups (AltMoC and Findings/observations) also considered the comments on the Part-145 AMC & GM proposed in Sub-NPA 2019-05(C) because the topics were affecting equally both domains (Part 21 and Part-145).

The groups created were the followings:

- Reporting system;
- Design management system and Personnel requirements;
- Production management system and Personnel requirements;
- Findings and observations;
- Alternative means of compliance (AltMoC).

Those groups met several times and there were several email exchanges over the period from 29 March 2021 till 24 October 2022. Those meetings and exchanges helped to prepare the two EASA ED Decisions (ED Decision 2022/021/R and ED Decision 2023/014/R) amending the Part 21 AMC & GM. EASA reviewed all the comments, in part with the support of the FCG, and where deemed necessary, amended the text that was proposed in NPA 2019-05(B).

Note: ED Decision 2022/021/R did not contain all the AMC and GM that had been prepared under this Rulemaking Task RMT.0251 to facilitate the implementation of the new Part 21 SMS and occurrence-reporting requirements. It was decided to issue a first set of AMC & GM related to the following topics, to support stakeholders, as the applicability date of Delegated Regulation (EU) 2022/201 and Implementing Regulation (EU) 2022/203 was approaching:

- production management systems and design management systems;
- changes to the production management system or design management system;
- resources;

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- production organisation exposition (POE)/handbook;
- findings, corrective actions, and observations;
- alternative means of compliance (AltMoC);
- record-keeping; and
- reporting systems.

ED Decision 2023/014/R complements ED Decision 2022/021/R and further amends the Acceptable Means of Compliance (AMC) and Guidance Material (GM) to Part 21. It provides AMC & GM to amended or newly introduced competent authority requirements in Part 21 on the following topics:

- Initial certification procedure;
- Oversight principles;
- Oversight programme;
- Management system;
- Changes to the management system;
- Record-keeping;
- Finding, corrective actions, observations;
- Suspension, limitation and revocation.

Summary of comments and dispositions under the ‘21 OC#1 - Occurrence reporting’ group

Several comments requested more guidance/explanation on the link between Part 21.A.3A and Regulation (EU) No 376/2014. Further clarification on the concept of voluntary reporting to the organisation and how those reports could be captured by the collecting system. There were also several comments requesting clarification on what kind of events were to be reported to the competent authority.

Further to the review of those comments and discussion with the FCG, EASA developed additional AMC & GM or amended the ones proposed in NPA 2019-05(C), with the objective of providing information/clarification on:

- the link between point 21.A.3A and Regulation (EU) No 376/2014 on the reporting, analysis, and follow-up of occurrences in civil aviation;
- what is intended to be collected through the collecting system put in place by the organisation;
- the internal reporting scheme;
- mandatory reporting and the type of events falling under the ‘mandatory’ report;
- voluntary reporting and the type of events falling under the ‘voluntary’ report;
- follow-up and closure of reported events.



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Summary of comments and disposition under the 'DOA#2 - Design management system and DO personnel requirements' group

In general, the commentators were pointing out that the AMC & GM were too prescriptive as regards, for example, the governance of the safety management system of the organisation, the interface between organisations or the management of change.

Following the review of the comments and discussion with the FCG, EASA redrafted the AMC & GM proposed with the NPA, and provided for more flexibility where deemed necessary.

In AMC1 21.A.239(c), the industry standard SM-0001 Rev B is recognised as an acceptable means to demonstrate compliance with the safety management element of the design management system.

Further AMC & GM are issued to support the implementation of the various SMS pillars and elements appearing in 21.A.239, such as *safety policy and objectives; safety management key processes; or safety communication.*

As regards the resources requirements under 21.A.245, the AMC & GM have been restructured to consider the comments on the NPA and the additional discussion with the FCG. The AMC & GM issued now are deemed less prescriptive, in particular in terms of management of competency and training of personnel.

Summary of comments and disposition under the 'POA#1 - Production management system and PO personnel requirements' group

The comments received on the production management system and the personnel requirements were similar to the ones on the design management system and DO personnel requirements. There was therefore no need for additional discussion with the group. EASA nevertheless took benefit of the feedback by the mini group on DOA to adapt the related AMC & GM.

Summary of comments and dispositions under the 'CD#1 - Findings and Observations' group

As explained in CRD 2019-05, the amendments to the Regulation proposed in NPA 2019-05 in relation to 'findings' raised numerous comments. Following the publication of Opinion No 04/2020, the group reviewed the AMC & GM as proposed in the NPA to clarify the expected steps an organisation should take (including the corrective action plan) upon receipt of a finding. The review also led to improved GM on root cause analysis and to the development of further GM on the difference between a 'level 2 finding' and an 'observation', as well as on the handling of the newly created observations.

Summary of comments and dispositions under the 'CD#2 - AltMoC' (Alternative means of compliance)' group

As explained in CRD 2019-05, because of a high number of comments raised on the amendments to the regulation points, as proposed in NPA 2019-05, addressing AltMoC, EASA organised an ad hoc webinar on 26 October 2020 with the FCG experts to explain the background and rationale behind the AltMoC provisions being kept in Opinion No 04/2020.



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Based on these principles and based on the text adopted through Regulation (EU) 2021/1963, the 'AltMoC' group reviewed the entire set of AMC & GM proposed in the NPA, and the related comments, to clarify the intent, benefit, and scope of the AltMoC.

The new AltMoC-related AMC & GM developed by the group (in Section A and Section B) clarify what an AltMoC is, who can propose them, what the process requires and how an organisation can benefit from them. The material also indicates examples of issues not requiring AltMoC. Due consideration was given to the differences between AltMoC proposed by organisations and AltMoC issued by competent authorities.



### 3. Individual comments

The comments on NPA 2019-05(C) can be found in Appendix 6.2 to CRD 2019-05.

