



Explanatory Note to ED Decision 2023/014/R

in accordance with Article 4(2) of MB Decision 01-2022

Amendment to the Acceptable Means of Compliance and Guidance Material to Commission Regulation (EU) No 748/2012

‘Embodiment of safety management system and occurrence-reporting requirements into Annex I (Part 21) to Regulation (EU) No 748/2012’

RMT.0251 (MDM.055) PHASE II

EXECUTIVE SUMMARY

This ED Decision 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/introduced competent authority requirements in Part 21 on the following topics: initial certification procedures; oversight principles; oversight programme; management systems; changes to the management system; record-keeping; finding, corrective actions, observations; suspension, limitation and revocation. In addition, this ED Decision corrects editorial errors. This Decision also removes the remaining ‘AMC-ELA’ and ‘GM-ELA’ to Part 21 introduced with ED Decision 2019/003/R since they are not up to date.

The objectives of this ED Decision are to further support the implementation of the safety management system and occurrence-reporting requirements that were introduced by Commission Delegated Regulation (EU) 2022/201 and Commission Implementing Regulation (EU) 2022/203.

REGULATION(S) TO BE AMENDED/ISSUED

Not applicable

ED DECISION TO BE AMENDED

— ED Decision 2012/020/R — AMC & GM to Part 21

AFFECTED STAKEHOLDERS

National competent authorities (NCAs), EASA, DOA/POA holders and applicants, ETSOA holders and applicants

WORKING METHOD(S)

Development	Impact assessment(s):	Consultation
— By EASA with external support	Detailed	NPA — Public

Related documents / information

- ICAO Annex 19
- ToR RMT.0251; NPA 2019-05(B); Opinion No 04/2020; CRD 2019-05(A), 2019-05(B), 2029-05(C)

PLANNING MILESTONES: Refer to the latest edition of the EPAS Volume II.



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1. About this Decision

1.1. How this regulatory material was developed

This rulemaking activity is included in the 2023 edition of Volume II of the European Plan for Aviation Safety (EPAS)¹ under Rulemaking Task RMT.0251.

EASA developed the regulatory material in question in line with Regulation (EU) 2018/1139² (the Basic Regulation) and the Rulemaking Procedure³, as well as in accordance with the objectives and working methods described in the Terms of Reference (ToR) for this RMT⁴.

This was done with the support of a focused consultation group (FCG) (refer to ToR RMT.0251 (MDM.055)

The draft regulatory material was consulted in accordance with the ToR for this RMT with all stakeholders (public consultation) through [Notice of Proposed Amendment \(NPA\) 2019-05\(B\)](#)⁵. Comments were received from interested parties, including industry and national competent authorities (NCAs).

EASA reviewed the comments received with the support of the FCG and duly considered them.

EASA published Opinion No 04/2020 on 21 December 2020, proposing amendments to Regulation (EU) No 748/2012⁶, based on which the European Commission adopted Delegated Regulation (EU) 2022/201⁷ on 10 December 2021 and Implementing Regulation (EU) 2022/203⁸ on 14 February 2022, amending that Regulation (the 'Initial Airworthiness (IAW) Regulation').

¹ <https://www.easa.europa.eu/en/document-library/general-publications/european-plan-aviation-safety-epas-2023-2025>

² 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>).

³ 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 01-2022 of 2 May 2022 on the procedure to be applied by EASA for the issuing of opinions, certification specifications and other detailed specifications, acceptable means of compliance and guidance material ('Rulemaking Procedure'), and repealing Management Board Decision No 18-2015 (<https://www.easa.europa.eu/the-agency/management-board/decisions/easa-mb-decision-01-2022-rulemaking-procedure-repealing-mb>).

⁴ <https://www.easa.europa.eu/en/document-library/terms-of-reference-and-rulemaking-group-compositions/tor-rmt0251b-mdm055-mdm060>

⁵ In accordance with Article 115 of Regulation (EU) 2018/1139 and Article 6 of the Rulemaking Procedure.

⁶ 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 (recast) (OJ L 224, 21.8.2012, p. 1) (<https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX%3A32012R0748&qid=1693475023741>).

⁷ Commission Delegated Regulation (EU) 2022/201 of 10 December 2021 amending Regulation (EU) No 748/2012 as regards management systems and occurrence-reporting systems to be established by design and production organisations, as well as procedures applied by the Agency, and correcting that Regulation (OJ L 33, 15.2.2022, p. 7) (<https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX%3A32022R0201>).

⁸ Commission Implementing Regulation (EU) 2022/203 of 14 February 2022 amending Regulation (EU) No 748/2012 as regards management systems and occurrence-reporting systems to be established by competent authorities, and correcting Regulation (EU) No 748/2012 as regards the issuance of airworthiness review certificates (OJ L 33, 15.2.2022, p. 46) (<https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX%3A32022R0203>).

2. In summary – why and what

2.1. Why we need to act – issue/rationale

Implementing Regulation (EU) 2022/203 was adopted on 14 February 2022 and published in the EU Official Journal on 15 February 2022. Delegated Regulation (EU) 2022/201 was adopted on 10 December 2021 and published in the EU Official Journal on 15 February 2022. Both Regulations amend the IAW Regulation as regards Part 21 safety management systems (SMSs) for design and production organisations. In addition, Delegated Regulation (EU) 2022/201 also amends the occurrence-reporting (OR) requirements to ensure harmonisation with Regulation (EU) No 376/2014⁹ (the ‘OR Regulation’). As the applicability date of those Regulations was approaching (7 March 2023), a first Decision was published in December 2022 (EDD 2022/021/R), with the necessary AMC and GM to help design and production organisations prepare for the implementation of the requirements that were introduced by the Regulations. The changes to Part 21 also introduced or amended the requirements on competent authorities. The associated AMC and GM (revised, deleted or created) supporting the competent authorities in their initial investigation and surveillance activities of Part 21 organisations were still to be published.

Furthermore, the AMC & GM to Part 21 included, through ED Decision 2019/003/R, several specific AMC and GM associated with European Light Aircraft (ELA). The objective was to provide a more proportionate approach for small, non-complex organisations that produce lower-risk products and the parts installed on these products. These AMC and the GM related to them (indicated as ‘AMC-ELA’ and ‘GM-ELA’ respectively), provide an alternative set of AMC and GM to the other available AMC and GM. Following the amendments introduced to Part 21 through Commission Implementing Regulation (EU) 2022/203 and Commission Delegated Regulation (EU) 2022/201, there has been a disconnection between the numbering and content of these specific ‘AMC-ELA’ and ‘GM-ELA’ and the requirements applicable since 7 March 2023.

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 achieving these overall objectives by addressing the issues described in Section 2.1.

More specifically, this Decision is intended to further facilitate:

⁹ 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=1668778895018>).

- the application of the SMS and OR requirements by Part 21-approved design and production organisations, which were introduced through Regulations (EU) 2022/203 and 2022/201. Those requirements are based on the International Civil Aviation Organization (ICAO) Annex 19 Standards and Recommended Practices (SARPs) and are in line with the SMS and OR systems that are mandated by Section 3.1 of Annex II to the Basic Regulation; and
- the initial certification and the surveillance of the affected design and/or production organisations by the competent authority.

2.3. How we want to achieve it — overview of the amendments to the AMC and GM to Part 21

This ED Decision complements the set of AMC & GM published with ED Decision 2022/021/R, by providing AMC & GM to the following competent authority requirements:

- initial certification procedures;
- oversight principles;
- oversight programme;
- management systems;
- changes to the management system;
- record-keeping;
- finding, corrective actions, observations;
- suspension, limitation, and revocation.

In addition, this ED Decision corrects editorial errors introduced with EDD 2022/021/R and deletes the remaining ‘AMC-ELA’ and ‘GM-ELA’ to Part 21 introduced through ED Decision 2019/003/R.

2.4. What are the stakeholders’ views

864 comments were received on the proposed text of the AMC and GM to Part 21 in [NPA 2019-05\(B\)](#), 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.

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

EASA reviewed all the comments received, in part with the support of the FCG, and where deemed necessary, amended the text that was proposed in [NPA 2019-05\(B\)](#).

The summary of comments received and EASA’s responses to them are presented in Comment-Response Document (CRD) 2019-05(B).



3. What are the expected benefits and drawbacks of the regulatory material

The AMC and GM that are issued by this Decision do not create any impacts beyond those that were created by the related Regulations (EU) 2022/201 and 2022/203. Please refer to Chapter 4 'Impact assessment (IA)' of [NPA 2019-05\(A\)](#) for more details.

The AMC and GM introduced through this Decision and ED Decision 2022/021/R are expected to improve flexibility and proportionality, in particular regarding the management system requirements, and limit their economic impact on the affected organisations.

The recognition of the industry association 'international SMS industry standard' as an AMC to the SMS requirements for design and production organisations, should furthermore allow for a level playing field with the SMS approach followed by other major authorities such as the Federal Aviation Administration (FAA), the Transport Canada's Civil Aviation (TCCA) or the National Civil Aviation Agency of Brazil (ANAC) since that international SMS industry standard is also intended to be recognised by these major authorities.



4. Monitoring and evaluation

EASA will monitor and evaluate the effectiveness of the amendments to the AMC and GM to Part 21, once this Decision becomes applicable. Action might be triggered through the feedback collected from the implementation of Regulations (EU) 2022/201 and 2022/203, and from the oversight of design and production organisations.

A monitoring indicator will be the number of questions/issues received/raised on the understanding and implementation of the AMC and about the understanding of the GM. Such monitoring will be performed by EASA and the competent authority, on a recurrent basis.



5. Proposed actions to support implementation

Since the initiation of the activities of RMT.0251, EASA has taken different actions to raise awareness of the affected stakeholders and provide them with implementation support. The AMC and GM published with ED Decision 2022/021/R and this ED Decision are part of this strategy. In addition, several conferences and/or workshops dedicated to the topic have taken place or are planned. The next workshop is planned for 25 October 2023.

The various policies already published will be reviewed and updated to reflect the state of the art.

The Agency is also updating its published management system assessment tool to reflect Regulations (EU) 2022/201 and 2022/203. Such tool, although intended to be used by competent authorities, may also be used by organisations to assess the effectiveness of their own management system, for the purpose of continuous improvement. Finally, the Agency is also considering making available part of its training material and resources to further support stakeholders.



6. References

Not applicable.

