



# Explanatory Note to Decision 2022/021/R

## Embodiment of safety management system and occurrence-reporting requirements into Part 21

### Amendment to the Acceptable Means of Compliance and Guidance Material to Part 21

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

#### EXECUTIVE SUMMARY

The objective of this Decision is to facilitate the implementation of the safety management system (SMS) and occurrence-reporting (OR) requirements that were introduced into Annex I (Part 21) to Regulation (EU) No 748/2012 by Commission Implementing Regulation (EU) 2022/203 and Commission Delegated Regulation (EU) 2022/201, based on the International Civil Aviation Organization (ICAO) Annex 19 Standards and recommended Practices (SARPs) in the initial airworthiness domain (design and production).

This Decision amends the Acceptable Means of Compliance (AMC) and Guidance Material (GM) to Part 21 in respect of the following topics:

- production management systems and design management systems, including text correction and improvement as well as update of references;
- changes to the production management system or design management system;
- resources;
- production organisation exposition (POE)/handbook;
- findings, corrective action, and observations;
- alternative means of compliance (AltMoC);
- record-keeping; and
- reporting systems.

**Note:** This Decision does not issue all the AMC and GM that have been prepared under this Rulemaking Task (RMT).0251 to facilitate the implementation of the new Part 21 SMS and OR requirements. The European Union Aviation Safety Agency (EASA) decided to issue the AMC and GM that are related to the topics listed above, to support stakeholders, as the applicability date of Delegated Regulation (EU) 2022/201 and Implementing Regulation (EU) 2022/203 is approaching. The remaining AMC and GM will be issued by another decision in 2023/Q2.

<b>Domain:</b>	Safety management
<b>Related rules:</b>	AMC & GM to Part 21
<b>Affected stakeholders:</b>	Design and production organisations, national competent authorities (NCAs), EASA
<b>Driver:</b>	Safety
<b>Rulemaking group:</b>	Focused-consultation group
<b>Impact assessment:</b>	No

#### EASA rulemaking procedure milestones

<b>Start</b> Terms of Reference ToR RMT.0251(b) Issue 1	<b>Public Consultation</b> NPA 2019-05(B)	<b>Proposal to the Commission</b> Opinion No 04/2020	<b>Adoption by Commission</b> Regulation (EU) 2022/201 Regulation (EU) 2022/203	<b>Decision</b> Acceptable Means of Compliance and Guidance Material
12.7.2017	17.4.2019	21.12.2020	10.12.2021 14.2.2022	19.12.2022



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## 1. About this Decision

The European Union Aviation Safety Agency (EASA) developed Decision 2022/021/R in line with Regulation (EU) 2018/1139<sup>1</sup> (the ‘Basic Regulation’) and the Rulemaking Procedure<sup>2</sup>.

This Rulemaking Task (RMT).0251, Phase II (SMS in Part 21) is included in Volume II of the [European Plan for Aviation Safety \(EPAS\) 2022-2026](#). The scope and timescales of the task were defined in the related Terms of Reference (ToR)<sup>3</sup>.

EASA developed the *draft* text of this Decision considering the input of a focused-consultation group (FCG) (refer to ToR RMT.0251 (MDM.055)). All the interested parties were consulted through [Notice of Proposed Amendment \(NPA\) 2019-05\(B\)](#)<sup>4</sup>. Comments were received from affected parties, including industry and national competent authorities (NCAs).

EASA reviewed the comments received during the public consultation with the support of the FCG. The comments received and EASA’s responses to them were presented in Comment-Response Document (CRD) 2019-05<sup>5</sup>. Considering the input from the consultation, EASA published Opinion No 04/2020 on 21 December 2020. The Opinion was addressed to the European Commission, which adopted Delegated Regulation (EU) 2022/201<sup>6</sup> on 10 December 2022 and Implementing Regulation (EU) 2022/203<sup>7</sup> on 14 February 2022, amending Regulation (EU) No 748/2012<sup>8</sup> (the ‘Initial Airworthiness (IAW) Regulation’), based on the Opinion.

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<sup>1</sup> 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>).

<sup>2</sup> 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>).

<sup>3</sup> <https://www.easa.europa.eu/en/document-library/terms-of-reference-and-group-compositions/tor-rmt0251b-mdm055-mdm060>

<sup>4</sup> In accordance with Article 115 of Regulation (EU) 2018/1139 and Article 6 of the Rulemaking Procedure.

<sup>5</sup> <https://www.easa.europa.eu/document-library/comment-response-documents>

<sup>6</sup> 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>).

<sup>7</sup> 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>).

<sup>8</sup> 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>).



EASA developed the *final* text of this Decision with the acceptable means of compliance (AMC) and guidance material (GM) considering the input from the public consultation and the FCG, and published the Decision on the Official Publication<sup>9</sup> of EASA.

The major milestones of this RMT are presented on the cover page.

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<sup>9</sup> <https://www.easa.europa.eu/official-publication>



## 2. In summary — why and what

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

Implementing Regulation (EU) 2022/203 was adopted on 14 February 2022 and published on 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 376/2014<sup>10</sup> (the ‘Occurrence Reporting (OR) Regulation’). As the applicability date of those regulations is approaching (7 March 2023), this Decision issues the related AMC and GM to help stakeholders prepare for the implementation of the requirements that were introduced by the regulations.

### 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 the overall objectives by addressing the issues that are described in Section 2.1.

The specific objective of this Decision is to facilitate the implementation of the SMS and OR requirements by Part 21 approved design and production organisations, which were introduced into the IAW Regulation 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 system that are mandated by Section 3.1 of Annex II to the Basic Regulation. This Decision also provides guidance on the implementation within Part 21 of reporting systems in compliance with the Basic and OR Regulations.

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

The amendments include adaptation of existing AMC and GM to Part 21 or introduction of new ones, to integrate the various aspects of SMS, so that they become part of the daily business of the Part 21 approved design and production organisations. Those SMS aspects include the following:

- new concepts and policy (e.g. ‘just culture’, safety policy, and safety objectives);
- new terminology (e.g. ‘design management system’ instead of ‘design assurance system’, ‘production management system’ instead of ‘quality system’);
- new organisational processes (e.g. internal safety reporting scheme, risk assessment); and
- new roles and functions (e.g. safety manager).

<sup>10</sup> 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>).

This Decision amends the AMC and GM to Part 21 in respect of the following topics:

- design management systems and production management systems, to introduce safety management based on the 12 elements that are defined in ICAO Annex 19;
- correction and improvement of the text on design management systems and production management systems, and update of references;
- resources, to harmonise the AMC and GM to the requirements for design organisations and for production organisations (e.g. introduction of ‘chief of the office of the airworthiness function’, ‘chief of the independent monitoring function’ (of compliance and adequacy of the design management system));
- improvement of the text on production organisation exposition (POE)/handbooks, and update of references;
- findings, corrective action, and observations, to further clarify the classification of findings, and introduce the concept of ‘observation’;
- alternative means of compliance (AltMoC), to formalise the AltMoC process;
- record-keeping, to replace the record-keeping AMC and GM that were formerly spread throughout Section A; and
- reporting system, to harmonise the AMC and GM with the OR Regulation, and introduce the concept of ‘voluntary reporting’ to the design or production organisation.

In addition, this Decision deletes those AMC and GM that will not be valid as soon as Regulations (EU) 2022/201 and 2022/203 become applicable (7 March 2023).

**Note:** This Decision issues the AMC and GM that have been prepared under this Rulemaking Task (RMT).0251 and are related to the topics listed above, to facilitate the implementation of the new Part 21 SMS and OR requirements, as the applicability date of Regulations (EU) 2022/201 and 2022/203 is approaching. The AMC and GM that are related to other topics that were introduced into Part 21 by said regulations will be issued by another decision in 2023/Q2.

#### 2.4. What are the stakeholders’ views — outcome of the consultation

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.

As explained in Chapter 1, EASA reviewed all the comments with the support of the FCG, and where deemed necessary, amended the text that was proposed in [NPA 2019-05\(B\)](#).

EASA will provide a written response to the comments received during the consultation, by issuing a dedicated Comment-Response Document (CRD) 2019-05(B).

#### 2.5. What are the benefits and drawbacks of the amendments

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.



### 3. How we monitor and evaluate the amended AMC and GM

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 oversight activities during design organisation approval (DOA).



## 4. References

### 4.1. Related EU regulations

- 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)
- 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)
- 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)
- Commission Implementing Regulation (EU) 2015/1018 of 29 June 2015 laying down a list classifying occurrences in civil aviation to be mandatorily reported according to Regulation (EU) No 376/2014 of the European Parliament and of the Council(OJ L 163, 30.6.2015, p. 1)

### 4.2. Related EASA 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

ICAO Annex 19 'Safety Management', 2nd edition, July 2016





## 5. Related documents

- [NPA 2019-05\(A\)](#) ‘Embodiment of safety management system (SMS) requirements into Part-145 and Part 21’
- [NPA 2019-05\(B\)](#) ‘Embodiment of safety management system (SMS) requirements into Part-145 and Part 21’
- [CRD 2019-05](#) ‘Embodiment of the safety management system (SMS) requirements into Part-145 and Part 21’ (published on 21 December 2020, linked to Opinion No 04/2020)
- CRD 2019-05(B) ‘Embodiment of the safety management system (SMS) requirements into Part-21’ (to be published and linked to a future decision)

