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COVER NOTE

From:	Secretary-General of the European Commission, signed by Ms Martine DEPREZ, Director
date of receipt:	10 December 2021
To:	Mr Jeppe TRANHOLM-MIKKELSEN, Secretary-General of the Council of the European Union

No. Cion doc.:	C(2021) 8886 final
Subject:	COMMISSION DELEGATED REGULATION (EU) .../... of 10.12.2021 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

Delegations will find attached document C(2021) 8886 final.

Encl.: C(2021) 8886 final



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COMMISSION DELEGATED REGULATION (EU) .../...

of 10.12.2021

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EXPLANATORY MEMORANDUM

1. CONTEXT OF THE DELEGATED ACT

At the end of 2013, ICAO published the first edition of Annex 19 ‘Safety Management’ (referred to as ‘ICAO Annex 19’). Later, in 2016, ICAO published the second edition of Annex 19. According to Annex 19, the use of a safety management system (SMS) is foreseen for design, production and maintenance organisations.

In addition, Annex II ‘Essential requirements for airworthiness’ to Regulation (EU) 2018/1139 explicitly calls for design, production and maintenance organisations to implement and maintain a management system (MS), including the management of safety risks, and aim for the continuous improvement of that system supported by the establishment of an occurrence-reporting system.

For design and production organisations, Commission Regulation (EU) No 748/2012 already includes organisational requirements that cover some safety management aspects, but the Standards and Recommended Practices (SARPs) from ICAO Annex 19 are regards safety management are not consistently implemented and fully transposed for these organisations into the EU regulatory framework.

Furthermore, Commission Regulation (EU) No 748/2012 needs to be aligned in some points with the recent amendment of Regulation (EU) No 2015/640 by Commission Implementing Regulation (EU) 2020/1159 and amended to correct some mistakes.

2. CONSULTATIONS PRIOR TO THE ADOPTION OF THE ACT

In accordance with Article 128(4) of Regulation (EU) 2018/1139, before adopting a delegated act, the Commission shall consult experts designated by each Member State in accordance with the principles laid down in the Interinstitutional Agreement of 13 April 2016 on Better Law-Making. The draft delegated act was presented to the Air Safety experts group, which includes representatives from the Member States, at its meeting on 28 October 2021. This delegated act is based on EASA Opinion No 04/2020 whose contents had been publicly consulted through Notice of Proposed Amendment (NPA) 2019-05 ‘Embodiment of safety management system (SMS) requirements into Part-145 and Part 21’ (RMT.0251 — Phase II), published by EASA on 17 April 2019.

3. LEGAL ELEMENTS OF THE DELEGATED ACT

Articles 19 and 62(13) of Regulation (EU) 2018/1139 empower the Commission to adopt delegated acts, in accordance with Article 128 of that Regulation, laying down detailed rules with regard to the necessary features and functionalities related to the airworthiness of aircraft.

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THE EUROPEAN COMMISSION,

Having regard to the Treaty on the Functioning of the European Union,

Having regard to 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⁽¹⁾, and in particular Article 19(1) and Article 62(13) thereof,

Whereas:

- (1) Commission Regulation (EU) No 748/2012⁽²⁾ lays down the requirements for the design and production of civil aircraft as well as engines, propellers and parts to be installed therein.
- (2) In accordance with point 3.1(b) of Annex II to Regulation (EU) 2018/1139, approved design and production organisations must, as appropriate for the type of activity undertaken and the size of the organisation, implement and maintain a management system, to ensure compliance with the essential requirements set out in that Annex, manage safety risks and aim for the continuous improvement of that system.
- (3) Pursuant to Annex 19 ‘Safety Management’ to the Convention on International Civil Aviation, signed in Chicago on 7 December 1944 (the ‘Chicago Convention’), competent authorities are to require approved organisations that design and produce civil aircraft, as well as engines, propellers and parts to be installed therein, to implement a safety management system.
- (4) Regulation (EU) No 748/2012 already requires approved design and production organisations to comply with some elements of the management system; however, this management system does not completely cover the Standards and Recommended Practices (SRPs) for such a safety management system established in Annex 19 to

⁽¹⁾ OJ L 212, 22.8.2018, p. 1.

⁽²⁾ 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).

the Chicago Convention. Therefore, the missing elements of the management system should be added to the existing requirements.

- (5) In order to ensure a proportionate implementation and consistency with the approach used for continuing airworthiness organisations operating in the general aviation domain, design and production organisations, for which an approval is not mandatory under Regulation (EU) No 748/2012, should not be required to comply with all the elements of the management system.
- (6) All organisations, including those that have their principal place of business outside the Union, when they design and produce products and parts in accordance with Regulation (EU) No 748/2012, are already required to establish a mandatory and voluntary occurrence-reporting system. However, Regulation (EU) No 748/2012 should be amended to ensure that that occurrence-reporting system is aligned with the principles of Regulation (EU) No 376/2014 of the European Parliament and of the Council³.
- (7) In addition, the requirements for the Agency with regard to the tasks related to design certification, oversight and enforcement should be amended.
- (8) A sufficient transition period should be provided for approved design organisations to ensure their compliance with the new rules and procedures introduced by this Regulation.
- (9) The measures provided for in this Regulation are based on Opinion No 04/2020⁽⁴⁾, issued by the Agency in accordance with Article 76(1) of Regulation (EU) 2018/1139.
- (10) Regulation (EU) No 748/2012 should therefore be amended accordingly.
- (11) Commission Delegated Regulation (EU) 2021/699⁵ introduced a requirement that any future holder of the type-certificate or restricted type-certificate for a large aeroplane is to ensure that the continuing structural integrity programme remains valid throughout the operational life of the aeroplane. In particular, point 21.A.101(h) was added in Annex I to Regulation (EU) No 748/2012 to the effect that certain future holder are to comply with certification specifications that provide at least an equivalent level of safety to points 26.300, 26.320 and 26.330 of Annex I to Commission Regulation (EU) 2015/640⁶. An error occurred by referring to point 26.320, which does not exist. Regulation (EU) No 748/2012 should therefore be corrected accordingly,

⁽³⁾ 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).

⁽⁴⁾ <https://www.easa.europa.eu/document-library/opinions>

⁽⁵⁾ Commission Delegated Regulation (EU) 2021/699 amending and correcting Regulation (EU) No 748/2012 as regards the instructions for continued airworthiness, the production of parts to be used during maintenance and the consideration of ageing aircraft aspects during certification (OJ L 145, 28.4.2021, p. 1).

⁽⁶⁾ Commission Regulation (EU) 2015/640 of 23 April 2015 on additional airworthiness specifications for a given type of operations and amending Regulation (EU) No 965/2012 (OJ L 106, 24.4.2015, p. 18).

HAS ADOPTED THIS REGULATION:

Article 1

Regulation (EU) No 748/2012 is amended as follows:

(1) in Article 8, the following paragraph 4 is added:

- ‘4. By way of derogation from points 21.B.433(d)(1) and (2) of Annex I (Part 21), a design organisation that holds a valid approval certificate issued in accordance with Annex I (Part 21) may correct, until [*OP please insert date: 2 years after the applicability date*], any findings of non-compliance related to the Annex I requirements introduced by Commission Delegated Regulation (EU) 2021/XXXX [*OP please insert reference of this amending Regulation*]*.

Where after [*OP please insert date: 2 years after the applicability date*] the organisation has not closed such findings, the approval certificate shall be revoked, limited or suspended in whole or in part.

* [*OP: Please insert the footnote with the full title and OJ reference*];

(2) Annex I (Part 21) is amended in accordance with Annex I to this Regulation.

Article 2

Annex I (Part 21) to Regulation (EU) No 748/2012 is corrected in accordance with Annex II to this Regulation.

Article 3

This Regulation shall enter into force on the twentieth day following that of its publication in the *Official Journal of the European Union*.

It shall apply from [*OP please insert date: 1 year after the date of entry into force*], with the exception of Article 2 which shall apply from [*OP please insert date: date of entry into force*].

This Regulation shall be binding in its entirety and directly applicable in all Member States.

Done at Brussels, 10.12.2021

For the Commission
The President
Ursula VON DER LEYEN