

Executive Director Decision

2019/002/R

of 28 January 2019

issuing Acceptable Means of Compliance and Guidance Material to Annex IV (Part-MED) of Commission Regulation (EU) No 1178/2011¹, repealing Decision 2011/015/R of the Executive Director of the Agency of 15 December 2011 and Decision 2013/016/R of the Executive Director of the Agency of 8 August 2013 amending Decision 2011/015/R, and amending Acceptable Means of Compliance and Guidance Material to Part-ARA of Regulation (EU) No 1178/2011

‘AMC & GM to Part-MED — Issue 2’ and ‘AMC & GM to Part-ARA — Issue 1, Amendment 7’

THE EXECUTIVE DIRECTOR OF THE EUROPEAN UNION AVIATION SAFETY AGENCY,

Having regard to Regulation (EU) 2018/1139², and in particular Article 104(3)(a) thereof,

Having regard to Commission Regulation (EU) No 1178/2011, and in particular point ARA.GEN.120 of Annex VI (Part-ARA) thereto,

Whereas:

- (1) EASA shall, pursuant to Article 76(3) of Regulation (EU) 2018/1139, issue certification specifications and acceptable means of compliance, as well as guidance material, for the

¹ Commission Regulation (EU) No 1178/2011 of 3 November 2011 laying down technical requirements and administrative procedures related to civil aviation aircrew pursuant to Regulation (EC) No 216/2008 of the European Parliament and of the Council (OJ L 311, 25.11.2011, p.1); as last amended by Commission Regulation (EU) No 245/2014 of 13 March 2014 (OJ L 74, 14.3.2014, p.33) (<https://eur-lex.europa.eu/legal-content/EN/ALL/?uri=CELEX:32011R1178>).

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>).

application of Regulation (EU) 2018/1139 and of the delegated and implementing acts adopted on the basis thereof.

- (2) Acceptable means of compliance are non-binding standards adopted by EASA which may be used by persons and organisations to demonstrate compliance with Regulation (EU) 2018/1139 and the delegated and implementing acts adopted on the basis thereof.
- (3) Guidance material is non-binding material developed by EASA which helps to illustrate the meaning of a requirement or specification and is used to support the interpretation of Regulation 2018/1139 and the delegated and implementing acts adopted on the basis thereof.
- (4) With Decision 2011/015/R³ of 15 December 2011, the Executive Director issued Acceptable Means of Compliance and Guidance Material to Part-MED of Regulation (EU) No 1178/2011.
- (5) With Decision 2013/016/R⁴ of 8 August 2013, the Executive Director amended the Acceptable Means of Compliance and Guidance Material to Part-MED of Regulation (EU) No 1178/2011.
- (6) With Decision 2012/006/R⁵ of 19 April 2012, the Executive Director issued Acceptable Means of Compliance and Guidance Material to Part-ARA of Regulation (EU) No 1178/2011.
- (7) EASA shall, pursuant to Article 19(2) of Regulation 4(1)(a) of Regulation (EU) 2018/1139, reflect the state of the art and the best practices in the fields of aviation and update its decisions taking into account worldwide aviation experience and scientific and technical progress in the respective fields.
- (8) EASA analysed the implementation issues reported by the Member States and the standardisation inspection reports and determined that an update of the requirements and AMC & GM is needed to address the identified issues and editorial errors as well to keep the requirements up to date with the developments in the field of medicine and ensure harmonisation with the provisions of Commission Regulation (EU) 2015/340⁶. Such updates have been prepared by the RMT.0287 rulemaking group comprising expertise from industry and national aviation authorities.
- (9) Following the accident of the Germanwings Flight 9525, the EASA-led Germanwings Task Force identified a number of safety risks and issued six recommendations to mitigate those risks. Four of these recommendations, namely recommendation 2 ‘Mental health assessment of flight crew’, recommendation 3 ‘Prevention of misuse of alcohol and other psychoactive substances by the flight crew’, recommendation 4 ‘Training, oversight and network of AMEs’, and recommendation 5 ‘European aero-medical data repository’ require regulatory changes in the requirements regarding aircrew medical certification. Therefore, the existing requirements as well as the AMC and GM to Part-MED and Part-ARA should be also amended in order to address the identified safety risks. In this context, Commission Implementing Regulation (EU) 2019/27⁷ was officially

³ <http://www.easa.europa.eu/document-library/agency-decisions/ed-decision-2011015r>

⁴ <https://www.easa.europa.eu/document-library/agency-decisions/ed-decision-2013016r>

⁵ <http://www.easa.europa.eu/document-library/agency-decisions/ed-decision-2012006r>

⁶ Commission Regulation (EU) 2015/340 of 20 February 2015 laying down technical requirements and administrative procedures relating to air traffic controllers’ licences and certificates pursuant to Regulation (EC) No 216/2008 of the European Parliament and of the Council, amending Commission Implementing Regulation (EU) No 923/2012 and repealing Commission Regulation (EU) No 805/2011 (OJ L 63, 6.3.2015, p. 1.) (<https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX%3A32015R0340>).

⁷ Commission Implementing Regulation (EU) 2019/27 of 19 December 2018 amending Regulation (EU) No 1178/2011 laying down technical requirements and administrative procedures related to civil aviation aircrew pursuant to Regulation (EU)



published on 10 January 2019. Following this, through this Decision, EASA amends the associated AMC & GM.

- (10) EASA, pursuant to Article 115(1)(c) of Regulation (EU) 2018/1139 and Articles 6(3), 7, 8, and 15 ‘Special rulemaking procedure: direct publication’ of MB Decision No 18-2015⁸, has consulted its Advisory Bodies on the matters which are the subject of this Decision and has provided thereafter a written response to the comments received⁹. Additionally, EASA has consulted the affected stakeholders on the matters which are the subject of this Decision at a public conference held in June 2016 and a technical meeting with members of the Advisory Bodies,

HAS DECIDED:

Article 1

The Acceptable Means of Compliance and Guidance Material to Part-MED of Commission Regulation (EU) No 1178/2011 are those laid down in Annex I to this Decision.

Article 2

The Annex to Decision 2012/006/R of the Executive Director of the Agency of 19 April 2012 ‘Acceptable Means of Compliance and Guidance Material to Part-ARA’ is amended as laid down in Annex II to this Decision.

Article 3

Decision 2011/015/R of the Executive Director of the Agency of 15 December 2011 on Acceptable Means of Compliance and Guidance Material to Part-MED (Annex IV) and Decision 2013/016/R of the Executive Director of the Agency of 8 August 2013 amending Decision 2011/015/R are hereby repealed.

Article 4

This Decision shall enter into force on the day following that of its publication in the Official Publication of EASA and shall apply as from 30 January 2019.

Cologne, 28 January 2019

*For the European Union Aviation Safety Agency
The Executive Director*

Patrick KY

2018/1139 of the European Parliament and of the Council (OJ L 8, 10.1.2019, p. 1) (<https://eur-lex.europa.eu/legal-content/EN/TXT/?qid=1547130029105&uri=CELEX:32019R0027>).

⁸ EASA Management Board (MB) Decision No 18-2015 of 15 December 2015 replacing Decision 01/2012 concerning the procedure to be applied by the Agency for the issuing of opinions, certification specifications, acceptable means of compliance and guidance material (‘Rulemaking Procedure’)

(<http://www.easa.europa.eu/system/files/dfu/EASA%20MB%20Decision%2018-2015%20on%20Rulemaking%20Procedure.pdf>)

⁹ <http://easa.europa.eu/document-library/comment-response-documents>

