



Terms of Reference

for rulemaking task RMT.0424

Regular update of Regulation (EU) No 1178/2011 regarding medical certification of aircrew and the related oversight

ISSUE 1 — 9.10.2017

Issue/rationale

The European Aviation Safety Agency (EASA) needs to address a number of medical-certification issues identified on a regular basis by competent authorities (CAs) and industry, by amending Annex IV (Part-MED) to Regulation (EU) No 1178/2011 (the 'Aircrew Regulation') and the related acceptable means of compliance (AMC)/guidance material (GM). Furthermore, certification of aeromedical examiners (AMEs) is subject to oversight exercised by the CAs and, therefore, the corresponding IRs of Annex VI (Part ARA) to the Aircrew Regulation and the related AMC/GM might also need to be amended. This systematic rulemaking task (RMT) addresses various non-controversial issues: some may be directly driven by safety, while others may be primarily driven by other factors, such as ensuring that the regulatory framework promotes a competitive environment or reduces complexity.

In order to increase the efficiency of the rulemaking process, EASA decided to reduce the administrative burden of certain individual RMTs on stakeholders, by grouping the non-controversial issues into packages. This concept was reintroduced in the EASA Management Board (MB) Decision No 18-2015 (see Article 3.5. on systematic rulemaking projects) and applies to all the deliverables of this RMT.

EASA intends to review on a yearly or, whenever deemed necessary, more frequent basis whether such non-controversial issues are eligible for this RMT, and may propose amendments to the affected rules within the scope of this ToR.

Action area:	Regular updates		
Affected rules:	Regulation (EU) No 1178/2011 and related AMC/GM		
Affected stakeholders:	Pilots, aeromedical centres (AeMCs), AMEs, and CAs		
Driver:	Efficiency/proportionality	Rulemaking Group:	No, but task force
Impact assessment:	Light	Rulemaking Procedure:	Standard



1. Why we need to change the rules — issue/rationale

Part-MED contains the implementing rules (IRs) for the medical certification of aircrew, certification of AMEs, as well as the approval of general medical practitioners (GMPs) and occupational-health medical practitioners (OHMPs).

Additionally, Subpart AeMC and Subpart MED of Part ARA contain IRs for CAs, regarding the medical certification of aircrew as well as the oversight over organisations and persons performing the aforementioned medical certification.

Opinion 09/2016¹ proposes to update Part-MED and contains the related draft AMC/GM. However, the vast majority of the proposed changes are the outcome of RMT.0287 initiated back in 2012 — the related NPA 2013-15 public consultation was concluded in 2013.

In the meantime, several diagnostic and treatment protocols and techniques for various pathologies have been updated and improved, and new guidelines have been issued. This calls for an update of the relevant medical-certification IRs and AMC/GM.

During the planning stage of RMT.0287, it was considered that the medical requirements for cabin crew developed at the time should not be amended as they were not yet implemented. From April 2013, when all Member States (MSs) started implementing Part-MED, to the present, some gaps and inconsistencies in the cabin crew medical requirements have been reported during the medical-experts group (MEG) meetings and the standardisation inspections of the MSs by EASA.

EASA intends to review on a yearly or, whenever deemed necessary, more frequent basis whether such non-controversial issues are eligible for this RMT, and may propose amendments to the affected rules within the scope of this ToR.

2. What we want to achieve — objective

The overall objectives of the European Union in the field of civil aviation are defined in Article 2 of Regulation (EC) No 216/2008². This RMT will contribute to the achievement of the overall objectives by addressing the issues outlined in Chapter 1.

In addition to these general objectives, the specific objective of this proposal is to:

- ensure that emerging non-controversial issues (such as internal and external rulemaking proposals and editorial issues), where there is sufficient consensus among stakeholders and EASA about the medical certification of aircrew and the certification of AMEs, are addressed;
- align the medical-certification IRs and AMC/GM with the latest diagnostic and treatment protocols/techniques to ensure the highest possible level of safety; and
- continuously improve the regulatory framework by reducing complexity and promoting a competitive environment.

¹ <https://www.easa.europa.eu/document-library/opinions/opinion-092016>

² Regulation (EC) No 216/2008 of the European Parliament and of the Council of 20 February 2008 on common rules in the field of civil aviation and establishing a European Aviation Safety Agency, and repealing Council Directive 91/670/EEC, Regulation (EC) No 1592/2002 and Directive 2004/36/EC (OJ L 79, 19.3.2008, p. 1) (<http://eur-lex.europa.eu/legal-content/EN/TXT/?qid=1467719701894&uri=CELEX:32008R0216>).



3. How we want to achieve it

In order to reflect the state of the art and best practices, this RMT intends to propose the following amendments to the Aircrew Regulation³, taking into account the objectives of Chapter 2 above:

- review of the structure and content of the current Part-MED IRs and of the related AMC/GM;
- review of the non-controversial issues;
- amendment to the medical-certification IRs and/or AMC/GM, as applicable; and
- amendment to the authority requirements (Part-ARA) and to the related AMC/GM which are affected by the proposed amendments to the above-mentioned medical-certification IRs and AMC/GM.

Due to its generic nature, this RMT is open-ended. Each individual proposed-amendment package should, however, provide the specific planning and intended dates for the issuing of the respective AMC/GM and/or, where needed, opinions (IRs).

Consequently, EASA may:

- select those issues for rulemaking, which contribute to the achievement of the above-mentioned objectives;
- consult the affected stakeholders, as prescribed in MB Decision No 18-2015⁴ on the ‘Rulemaking Procedure’, proposing amendments to the affected AMC/GM and/or, where needed, to the affected IRs, as mentioned above;
- publish the AMC/GM which will be annexed to decisions; and
- where the IRs need to be amended, publish the related Opinions.

4. What are the deliverables

As most of the medical content is included in the AMC/GM, it is expected that most of the proposed changes will affect those AMC/GM. However, if there is the need to amend the IRs as well, the amendments will be grouped in such way to minimise the number of opinions.

The main deliverables of this RMT are the following:

- NPAs with draft AMC/GM and/or IRs, as applicable;
- decisions with AMC/GM; and
- as appropriate, opinions with IRs.

5. How we consult

Following publication of the NPAs (with the draft AMC/GM and/or IRs), a public consultation (including stakeholders and CAs) of those documents is envisaged.

³ 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) (<http://eur-lex.europa.eu/legal-content/EN/TXT/?qid=1499944384463&uri=CELEX:02011R1178-20160408>).

⁴ MB Decision No 18-2015 of 15 December 2015 replacing Decision 01/2012 concerning the procedure to be applied by EASA for the issuing of opinions, certification specifications and guidance material (<http://www.easa.europa.eu/the-agency/management-board/decisions/easa-mb-decision-18-2015-rulemaking-procedure>).



Moreover, and depending on the needs, EASA will consider additional measures for consultation. These may include the following:

- technical meetings with affected stakeholders;
- focused consultation with the EASA Advisory Bodies (ABs); and/or
- focused consultations on key issues via surveys or via sharing documents per email with a limited group of stakeholders.

6. Interface issues

N/a

7. Profile and contribution of the rulemaking group

For this RMT, no rulemaking group (RMG) is envisaged. As an alternative, if it is decided that external aeromedical experts are needed, a task force will be created consisting of six external aeromedical experts representing CAs and industry and three EASA experts in the field of aviation medicine. The task force will provide technical expertise during the rules drafting phase as well as support for the review of comments received through the consultation.

Apart from the members of the task force, for specific medical topics (e.g. cardiology, psychiatry, ophthalmology), EASA may invite additional medical experts with relevant special knowledge.

The task force members should have at least three years of experience in aviation medicine. Additional experience in rulemaking activities is considered beneficial.

8. Reference documents

8.1. Affected regulations

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)

8.2. Affected decisions

- Decision N° 2011/015/R of the Executive Director of the European Aviation Safety Agency of 15 December 2011 on Acceptable Means of Compliance and Guidance Material to 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 'Acceptable Means of Compliance and Guidance Material to Part-MED (Annex IV)'
- Decision N° 2012/006/Directorate R of the Executive Director of the Agency of 19th April 2012 on Acceptable Means of Compliance and Guidance Material to 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 'Acceptable Means of Compliance and Guidance Material to Part-ARA'



8.3. Reference documents

Regulation (EC) No 216/2008 of the European Parliament and of the Council of 20 February 2008 on common rules in the field of civil aviation and establishing a European Aviation Safety Agency, and repealing Council Directive 91/670/EEC, Regulation (EC) No 1592/2002 and Directive 2004/36/EC (OJ L 79, 19.3.2008, p. 1)

