



# Terms of Reference

for rulemaking task RMT.0287 (MED.001)

## Regular update of Part-MED, Subparts ARA.AeMC and ARA.MED of Part-ARA, and Subpart ORA.AeMC of Part-ORA, as well as of the related AMC and GM

ISSUE 3 — 31.5.2021

### Issue/rationale

The objectives of Rulemaking Task (RMT).0287 (MED.001) are:

- to allow the update of the medical requirements in line with the evolution of the medical science;
- to address the concerns and difficulties identified during the implementation process of the medical requirements; and
- to remove any editorial inconsistencies,

to ensure that the rules are fit for purpose and can be implemented in practice. To facilitate the rulemaking process and collect implementation feedback on the authority requirements and related acceptable means of compliance (AMC) and guidance material (GM), RMT.0287 was split in the following two subtasks:

- Subtask 1<sup>1</sup> (completed) aimed to update the medical requirements of Annex IV (Part-MED) to Regulation (EU) No 1178/2011 ('Aircrew Regulation') and the related AMC and GM.
- Subtask 2 (renamed 'Subtask 2a') aims to update the medically relevant subparts of Annex VI (Part-ARA) and Annex VII (Part-ORA) to the Aircrew Regulation and the related AMC and GM. Under this subtask, Notice of Proposed Amendment ([NPA 2017-22](#)) was published on 21 December 2017 and publicly consulted for 3 months.

Due to the increasing number of exemptions from the Aircrew rules regarding the age limits for pilots conducting single-pilot helicopter emergency medical service (HEMS) operations, a new subtask (Subtask 2b) is added to revisit the pilot age limit for single-pilot commercial air transport (CAT) operations. The task will explore the possibility of gradually raising that pilot age limit from 60 to 65 years, starting with pilots conducting HEMS operations. Subtask 2b takes into account the European Union Aviation Safety Agency (EASA) report [Age Limitations for Commercial Air Transport Pilots](#).

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|-------------------------------|---|------------------------------|-------------|
| <b>Domain:</b>                | Human factors and human performance — Medical   |                              |             |
| <b>Related rules:</b>         | — Part-FCL and Part-MED of the Aircrew Regulation<br>— Regulation (EU) No 965/2012 ('Air OPS Regulation')   |                              |             |
| <b>Affected stakeholders:</b> | Pilots, holders of an air operator's certificate (AOC) for aeroplanes and helicopters, aeromedical centres (AeMCs), aeromedical examiners (AMEs), and competent authorities (CAs) |                              |             |
| <b>Driver:</b>                | Level playing field   | <b>Rulemaking group:</b>     | Yes         |
| <b>Impact assessment:</b>     | Yes   | <b>Rulemaking Procedure:</b> | Accelerated |

<sup>1</sup> More information on Subtask 1 is available in [ToR RMT.0287 Issue 2](#), [NPA 2013-15](#), and the related [Opinion No 09/2016](#) and [ED Decision 2019/002/R](#).

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

Rulemaking task (RMT).0287 (MED.001) was initiated immediately after Regulation (EU) No 1178/2011<sup>2</sup> (the ‘Aircrew Regulation’) was adopted:

- to allow the update of the medical requirements in line with the evolution of the medical science;
- to address the concerns and difficulties identified during the implementation process of the medical requirements; and
- to remove any editorial inconsistencies.

Subtask 1 was completed with the update of Annex IV (Part-MED) to the Aircrew Regulation. The update included changes that were triggered by the safety concerns following the Germanwings Flight 9525 accident. The related [Opinion No 14/2016](#) was published on 9 December 2016. Following adoption of the related Regulation (EU) 2019/27<sup>3</sup>, amending the Aircrew Regulation, the European Union Aviation Safety Agency (EASA) published Executive Director (ED) [Decision 2019/002/R](#) that contains the related acceptable means of compliance (AMC) and guidance material (GM) on 28 January 2019.

Subtask 2 focuses on the update of Subparts ARA.AeMC and ARA.MED of Part-ARA, and Subpart ORA.AeMC of Part-ORA, as well as of the related AMC and GM, and was initiated in 2016. Its first deliverable, Notice of Proposed Amendment ([NPA 2017-22](#)), was published for consultation on 21 December 2017. Reprioritisation of the EASA rulemaking activities led to deprioritisation of this subtask: the publication of the related opinion was postponed to 2021 (see the [European Plan for Aviation Safety \(EPAS\) 2019-2023](#) and [EPAS 2020-2024](#)).

A new Subtask 2b on pilot age limit was added to the original Subtask 2, which was renamed ‘Subtask 2a’. In the context of this new Subtask 2b and the COVID-19 pandemic, the timelines of the deliverables of Subtask 2a and 2b were reconsidered: an NPA in accordance with Article 16 ‘Accelerated procedure’ of MB Decision No 18-2015<sup>4</sup> is planned under Subtask 2b for 2022/Q1 and a merged Opinion stemming from both Subtasks 2a and 2b is scheduled for 2023/Q1.

Subtask 2b addresses the issue that flight crew conducting in single-pilot commercial air transport (CAT) operations cannot exercise the privileges of their licence beyond the age of 60, as provided for in point FCL.065 (a) of the Aircrew Regulation. This requirement raises a social issue due to the

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<sup>2</sup> 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)

(<https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX%3A32011R1178&qid=1616419451079>).

<sup>3</sup> 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) 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/?uri=CELEX%3A32019R0027>).

<sup>4</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 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>).

increasing retirement age in the European Union (on average, 65 years in most Member States (MSs)) and due to the longer life expectancy.

In operational terms, point FCL.065(a) triggered several exemptions<sup>5</sup> in accordance with Article 71 of Regulation (EU) 2018/1139<sup>6</sup> ('Basic Regulation'), mainly on helicopter emergency medical services (HEMS) operations. Since 2012, EASA has given positive recommendations on exemptions from point FCL.065 (a) in the context of HEMS, which were granted by nine MSs. Those exemptions were extended several times and issued by Germany, Austria, Switzerland, Poland, Hungary, France, the Slovak Republic, Finland, and the Netherlands.

The number of exemptions granted and the increasing retirement age in the MSs led EASA to launch a research study ([Age Limitations for Commercial Air Transport Pilots](#)) in 2017 on the appropriateness of the existing pilot age limits for CAT pilots. The study results allowed for extending the age limit for CAT pilots conducting single-pilot operations from 60 to 65 years, subject to operational and medical mitigating measures. The results were presented to and welcomed by stakeholders during a dedicated workshop that took place on 18-19 March 2019.

### **Alternative means of compliance relevant to the content of this RMT**

There are no alternative means of compliance (AltMoC) having an impact on the development of the content of this RMT.

### **ICAO and third-country references relevant to the content of this RMT**

Subtask 2b of this RMT should be addressed taking into consideration International Civil Aviation Organization (ICAO) Annex 1, point 2.1.10: *'A Contracting State, having issued pilot licences, shall not permit the holders thereof to act as pilot of an aircraft engaged in international commercial air transport operations if the licence holders have attained their 60th birthday or, in the case of operations with more than one pilot, their 65th birthday.'*

However, as HEMS operations, in most cases, are conducted at national level, their international dimension and, consequently, their impact on the aforementioned ICAO standard are minimal.

## **2. What we want to achieve — objective**

The overall objectives of the EASA system are defined in Article 1 of the Basic Regulation. This RMT will contribute to the achievement of the overall objectives by addressing the issues outlined in Chapter 1.

The specific objective of this RMT is to maintain the applicable medical, authority, and organisation requirements, as well as the related AMC and GM, in line with the evolution of the medical science

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<sup>5</sup> Exemptions having an impact on the development of this RMT content and referring to Article 71(1): 'Limited in scope and duration exemptions from substantive requirements laid down in Regulation (EU) 2018/1139 and its implementing rules in the event of urgent unforeseeable affecting persons or urgent operational needs of those persons'.

<sup>6</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=1536149403076&uri=CELEX:32018R1139>).

and the implementation feedback that is received during the Medical Experts' Group (MEG) meetings and the standardisation inspections.

By adding the new Subtask 2b, the specific objectives of this RMT were complemented with the following one: facilitate and ensure the safe continuation of all essential HEMS operations, while considering social aspects, such as the increasing retirement age, longer life expectancy, and higher health care standards in the European Union.

Subtask 2a is also expected to limit the increasing number of exemptions from point FCL.065 (a), which are granted by several MSs, by revisiting the pilot age limit for single-pilot CAT operations.

### 3. How we want to achieve it

Subtask 1 of this RMT was completed in January 2019. The final deliverables were:

- [Opinion No 14/2016](#), which was published on 9 December 2016 and adopted through Commission Implementing Regulation (EU) 2019/27 on 19 December 2018; and
- [ED Decision 2019/002/R](#) with the related AMC and GM, which was issued on 28 January 2019.

Under Subtask 2a, the proposed changes to the authority and organisation requirements and the related AMC and GM were published in [NPA 2017-22](#) on 21 December 2017 for stakeholder consultation. More than 400 comments were received during the consultation and will be reviewed and reflected, if applicable, in the related Opinion.

Under Subtask 2b, EASA will explore the possibility of gradually raising the pilot age limit for pilots conducting single pilot HEMS operations by amending point FCL.065 (a) and introducing sufficient mitigating measures to avoid a potential adverse impact on safety. A full impact assessment (IA) was carried out during the best intervention strategy (BIS) process. The BIS was consulted with the EASA Advisory Bodies (ABs) in 2020. The results of that consultation were considered in the development of this Terms of Reference (ToR) document. However, during the BIS consultation, some issues were raised, which will be addressed in the IA of the related NPA ('Accelerated procedure') containing the proposed draft rules.

### 4. What are the deliverables

The final deliverables of Subtask 1 are the following:

- [Opinion No 14/2016](#), which was published on 9 December 2016 and adopted through Commission Implementing Regulation (EU) 2019/27 on 19 December 2018; and
- [ED Decision 2019/002/R](#) with the related AMC and GM, which was issued on 28 January 2019.

The deliverables of Subtasks 2a and 2b are the following:

- For Subtask 2a, [NPA 2017-22](#) with draft implementing rules, AMC, and GM was published on 21 December 2017 and publicly consulted for 3 months.
- For Subtask 2b, an NPA ('Accelerated procedure') with draft implementing rules, AMC, and GM. An extensive IA as well as the justification and the description of this subtask were consulted and published via the BIS process. However, during the BIS consultation, some issues were raised that will be further clarified in the IA of the NPA.



- Opinion with draft implementing acts. The outcome of the NPA consultations for Subtasks 2a and 2b will be considered in a single opinion.
- EASA ED Decision. The outcome of the NPA consultations for Subtask 2a and 2b will be considered in a single decision that will contain the related AMC and GM.

## 5. How we consult

For Subtask 2a, [NPA 2017-22](#) was published on 21 December 2017 and publicly consulted for 3 months.

For Subtask 2b, the development of the NPA will be based on an earlier preliminary consultation of various policy options with MSs and affected stakeholders. The subject of the NPA affects a very limited group of stakeholders, namely HEMS pilots and operators, and the IA developed during the BIS process demonstrated that the impact is expected to be very low. For those reasons, EASA will consult the NPA in accordance with Article 16 ‘Accelerated procedure’ of [EASA MB Decision 18-2015](#), via a focused consultation. This focused consultation will take the form of one or more technical meetings with affected stakeholders from MSs and ABs.

## 6. Interface issues

Among the mitigating measures to reduce the cardiovascular risk factors, Rulemaking Group (RMG) RMT.0287 for Subtask 2b will discuss the prevention of fatigue. This may have an impact on the deliverables of RMT.0494<sup>7</sup> ‘FTL rules for helicopter operations’.

## 7. Profile and contribution of the rulemaking group

The composition of the initial RMG RMT.0287 was amended twice: [Group Composition \(GC\) Issue 3 of RMG RMT.0287](#) was published on 13 April 2016. In that composition, RMG RMT.0287 developed and published [NPA 2017-22](#).

EASA will develop the NPA ‘Accelerated procedure’ for Subtask 2b with the support of RMG RMT.0287 (GC Issue 4).

Due to the specificities of this subtask, special competences and expertise are required: specific knowledge of the rotary wing environment and in particular of the HEMS environment as well as of the EU regulatory framework in terms of licensing, aviation medicine, and aircraft operations.

The required profile of the RMG RMT.0287 members should include:

- expertise in the specificities of HEMS operations and in aviation medicine, as well as specific knowledge of rulemaking; and
- expertise from the MSs’ stakeholders that represent HEMS operators, flight crew, aeromedical experts and MSs’ representatives, as well as from EASA experts.

The role, responsibilities, and duties of the RMG RMT.0287 members for this subtask should be:

- to develop the NPA using an ‘Accelerated procedure’;

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<sup>7</sup> <https://www.easa.europa.eu/document-library/general-publications/european-plan-aviation-safety-2021-2025>

- to support EASA rulemaking experts in the development of the NPA, in the focused consultation as well as in producing the resulting opinion and decision;
- to contribute to EASA’s implementation support regarding the resulting requirements and related AMC and GM; and
- to support EASA in further developing the IA for the NPA.

## 8. Reference documents for Subtask 2b

### 8.1. Related EU 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).
- Commission Regulation (EU) No 965/2012 of 5 October 2012 laying down technical requirements and administrative procedures related to air operations pursuant to Regulation (EC) No 216/2008 of the European Parliament and of the Council (OJ L 296, 25.10.2012, p. 1)<sup>8</sup>.

### 8.2. Related EASA decisions

- Decision No 2011/016/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-FCL’.
- 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 1178/2011, 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’.

### 8.3. Other references

EASA report [Age Limitations for Commercial Air Transport Pilots](#), EASA\_REP\_RESEA\_2017\_1.

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<sup>8</sup> <https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX%3A32012R0965&qid=1616496035576>.