



**EXPLANATORY NOTE**

**Acceptable Means of Compliance and Guidance Material to Part-MED**

**1. General**

**Background**

Commission Regulation (EU) No 1178/2011 laying down technical requirements and administrative procedures related to civil aviation aircrew<sup>1</sup> pursuant to Regulation (EC) No 216/2008 of the European Parliament and the Council was published in the Official Journal of the European Union on 25 November 2011 and will be applicable as from 8 April 2012. Part-MED, Annex IV to this Regulation, contains the requirements for medical certification of pilots and the provisions for medical fitness of cabin crew.

Pursuant to Article 18 of Regulation (EC) No 216/2008<sup>2</sup> (the 'Basic Regulation') the European Aviation Safety Agency (the 'Agency') shall, where appropriate, issue Acceptable Means of Compliance (AMC), as well as Guidance Material (GM) for the application of the Basic Regulation and its Implementing Rules.

**Agency measures**

AMC illustrate a means, but not the only means, by which a requirement of an implementing rule can be met. Satisfactory demonstration of compliance using an AMC published by the Agency shall provide for presumption of compliance with the related requirement; it is a way to facilitate certification tasks for the applicant and the competent authority.

GM is issued by the Agency to assist the understanding of the Basic Regulation, its Implementing Rules and Certification Specifications (CSs).

**General structure and format**

This document is related to Part-MED and contains four subparts, thus following the structure of the Implementing Rules (Subparts A-D).

**Publication**

The full text of these AMC as well as GM is available on the [website](#) of the Agency.

For more information, contact the Agency at: [RPS@easa.europa.eu](mailto:RPS@easa.europa.eu).

---

<sup>1</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).

<sup>2</sup> 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, 19.03.2008, p. 1).

## 2. Consultation on draft proposals

The AMC and GM for Part-MED have been developed by the Agency, following a structured process as required by Article 52.1 of the Basic Regulation. This process has been adopted by the EASA Management Board and is referred to as the 'Rulemaking Procedure'<sup>3</sup>.

The Executive Director Decision 2011/015/R adopts the initial issue of AMC and GM to Part-MED, which is the result of two rulemaking tasks of the Agency. These are:

1. FCL.001 'Acceptable Means of Compliance and Guidance Material on the licensing of pilots', NPA number 2008-17(c); and
2. OPS.001 'Acceptable Means of Compliance and Guidance Material for Air Operations', NPA number 2009-02(e).

Both rulemaking tasks, and in consequence the respective NPAs, contained medical provisions: FCL.001 on medical certification of pilots and OPS.001 on medical fitness of cabin crew. During the NPA process both NPAs were consulted separately and in accordance with Article 52 of the Basic Regulation and Article 15 of the Rulemaking Procedure established by the Management Board. The requirements were then combined to form Part-MED during the CRD phase of the rulemaking process.

The Agency addressed and responded to the comments received on both NPAs and produced the combined Comment Response Document (CRD) with two separate Explanatory Notes. In response, the Agency received a total number of 321 reactions, 282 on the medical requirements for pilots and 32 for cabin crew. With regards to the AMCs these numbers are 131 for pilots and 9 for cabin crew. These latter comments were taken into account when amending the AMC to Part-MED.

The individual steps in the rulemaking process mentioned above are available on the Agency's website:

- NPA 2008-17(c);
- NPA 2008-02(e);
- CRD 2008-17(c) and 2009-02(e) (CRD b.3).

## 3. Publication of the AMC and GM to Part-MED

- (a) The medical requirements for professional and private pilots holding ICAO compliant licences are in the AMC to Part-MED. They are based on JAR-FCL 3 requirements but were transferred from hard law to soft law. Additional AMC material below ICAO standards was developed to cover the new Light Aircraft Pilot Licence (LAPL). Cabin crew medical fitness provisions are also outlined in AMC and based on the medical status needed to comply with cabin crew duties as listed in GM.
- (b) The reactions received in response to CRD 2008-17(c) and CRD 2009-02(e) that turned out to be a new comment to Part-MED were considered to have arrived after the end of the deadline for commenting on the corresponding NPAs and therefore as not applicable for changes to the document. Nevertheless, also these comments were carefully evaluated to decide whether an immediate safety concern exists. In any such case a new comment would have been taken on board.
- (c) Some reactions pointed out that text changes envisaged to be contained in the CRD to address comments to the NPA had been omitted for the publication of the AMC text with the CRD. Those errors were corrected.

---

<sup>3</sup> Management Board decision concerning the procedure to be applied by the Agency for the issuing of opinions, certification specifications and guidance material ('Rulemaking Procedure'), EASA MB 08-2007, 13.6.2007.

- (d) Reactions related to editorials were dealt with during a general text review that led to numerous (editorial) changes.
- (e) Changes to AMC and GM compared to CRD 2008-17(c) and 2009-02(e) are either based on reactions received to the CRD, or following changes to Implementing Rules during the Commitology Process:

(1) Subpart A

The paragraphs in Subpart A were renumbered following a re-arrangement of the Implementing Rules. Additional GM, based on Section 2 material of JAR-FCL 3, was inserted to explain the limitations for medical certificates for pilots that are outlined in the AMC.

(2) Subpart B

- (i) The specific medical requirements for pilots holding ICAO compliant class 1 and class 2 medical certificates did not undergo major changes. All reactions requesting an update of the medical provisions to acknowledge medical advance since 2005 when JAR-FCL 3 was last amended had to be rejected due to the instructions not to change existing rules/provisions in order to help transition. These reactions and, of course, corresponding comments previously made to the original NPA, have been recorded and will be re-considered during the recently initiated rulemaking task MED.001. This concerns mainly fitness to fly in cases of diabetes mellitus, visual requirements in general, and specifically for hyperopia, as well as provisions for colour vision testing and other medical conditions that could be considered as acceptable for a fit assessment with limitations. However, it will have to be taken into account that ICAO Annex 1 still stipulates that diabetes requiring insulin entails unfitness to fly.
- (ii) The specific requirements for pilots who will apply for the LAPL were considerably changed from NPA to CRD following comments from stakeholders. These AMCs attracted the majority of comments from individual pilots (114) as well as from Organisations (9) asking for the requirements presently in place in one Member State to continue unchanged. These reactions included, more specifically, the request to allow private pilots holding sub-ICAO national licences today to continue flying with a LAPL medical certificate in spite of certain medical conditions, the most important one being insulin dependent diabetes mellitus.

With regards to diabetes mellitus one first step has been taken in this AMC to allow, under stringent conditions, applicants with type 2 diabetes requiring insulin to hold a LAPL medical certificate. However, it was not possible to open this possibility for applicants presenting with type 1 diabetes where the use of insulin is obligatory, or for other medication that bears the potential to induce hypoglycaemias without a full consultation process. However, the issue will be taken up in the rulemaking task MED.001 with the intention to open the possibility to hold a LAPL medical certificate for more pilots with diabetes.

(3) Subpart C (previously Subpart E)

- (i) To ensure consistency with the changes made to the Implementing Rules during the comitology process, the order of sections in this Subpart was changed and all references to the term 'examination' were reviewed and replaced, or complemented, as relevant by 'assessment'. Also, the different sub-paragraphs containing the specific medical requirements for the different systems were numbered as AMC 2 to AMC 18 to the same MED.C.025 for easier reference.
- (ii) Regarding the specific medical requirements under Section 2, changes have been made only to the provisions for cabin crew with diabetes requiring insulin

and for pregnant cabin crew members, taking into account the suggestions made by reactions.

- (iii) The initial GM1-MED.E.025 has been significantly reviewed as suggested by the reactions received. To facilitate common understanding of the level of fitness required to perform cabin crew duties and to provide a support to the conduct of the aero-medical assessments of cabin crew taking also into account the changes made to the Implementing Rules, the first paragraph of the initial GM has been moved to AMC material, and the initial very detailed list of duties has been replaced by a description of the main duties and responsibilities of cabin crew.
  - (iv) Section 3: Applicants for and holders of a cabin crew attestation will receive a cabin crew medical report by the AME or OHMP providing the outcome of the aero-medical assessment. The format of this report has been simplified and some of the limitation codes have been clarified as recommended by reactions
- (4) Subpart D (previously Subpart C)

No changes apply to Subpart D with regards to Aero-medical Examiners (AME) training and certification. The Implementing Rule on General Medical Practitioners (GMP), originally published in Subpart D in the NPA and CRD 2008-17(c), has been deleted following stakeholder reactions. Therefore, no AMC material has been developed and no specific requirements exist for GMPs acting as AMEs if permitted under national law. This was important for Member States and pilots where GMPs may already today issue medical certificates for pilots who hold national licences. Any additional burden on these GMPs that may lead to a discontinuation of their service was to be avoided.