



## Explanatory Note to Decision 2013/016/R

### Amendment of the AMC for pilot medical certification (LAPL)

RELATED NPA/CRD 2012-20 — RMT.0584 — 08/08/2013

#### EXECUTIVE SUMMARY

This Decision addresses the aero-medical assessment of applicants for a LAPL<sup>1</sup> medical certificate who present with a medical history of cancer or with a serious dermatological disease.

The specific objective is to introduce two new Acceptable Means of Compliance (AMC) paragraphs to the specific medical requirements for the LAPL to ED Decision 2011/015/R<sup>2</sup>, as they were unintentionally excluded from the initial published Decision.

The Agency has developed Comment-Response Document (CRD) 2012-20, which has been published at the same time as this Decision, as permitted by the rulemaking procedure adopted by the Agency's management board on 13 March 2012.

The proposed changes are expected to provide the General Medical Practitioner (GMP) and Aero-Medical Examiner (AME) with criteria for assessing applicants for a LAPL medical certificate who have a malignant tumour or a serious dermatological disease. The resulting provisions support the goal of the Agency to create LAPL medical requirements that are proportionate and less restrictive than for other classes of medical certificate.

<sup>1</sup> LAPL: Light Aircraft Pilot Licence.

<sup>2</sup> Decision 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)'.

Applicability		Process map	
Affected regulations and decisions:	ED Decision 2011/015/R	Concept Paper:	No
Affected stakeholders:	LAPL holders; applicants for a LAPL medical certificate; aero-medical examiners; aero-medical centres; GMPs; competent authorities	Rulemaking group:	No
Driver/origin:	Safety; level playing field; legal obligation (clarity of rules)	RIA type:	None
Reference:	ED Decision 2011/015/R	Technical consultation during NPA drafting:	Yes
		Publication date of the NPA:	28/11/2012
		Duration of NPA consultation:	1 month
		Review group:	No
		Focussed consultation:	Yes
		Publication date of the Opinion:	Not applicable
		Publication date of the Decision:	2013/Q3

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## 1. Procedural information

### 1.1. The rule development procedure

The European Aviation Safety Agency (hereinafter referred to as the 'Agency') developed ED Decision 2013/016/R in line with Regulation (EC) No 216/2008<sup>3</sup> (hereinafter referred to as the 'Basic Regulation') and the Rulemaking Procedure<sup>4</sup>.

This rulemaking activity was added to the Agency's Rulemaking Programme as RMT.0584 to cover a gap in the existing acceptable means of compliance to Annex IV (Part-MED) to Commission Regulation (EU) No 1178/2011<sup>5</sup> (hereinafter referred to as 'Regulation Aircrew'). The task was classified as urgent, systematic and non-controversial.

The scope and timescale of the task were defined in the related Terms of Reference RMT.0584<sup>6</sup>.

The draft text of this Decision has been developed by the Agency. All interested parties were consulted through NPA 2012-20<sup>7</sup>. Thirteen comments were received from interested parties, including industry and national aviation authorities.

The Agency has reviewed the comments received on the NPA. The comments received and the Agency's responses are presented in the Comment-Response Document (CRD) 2012-20<sup>8</sup>.

The final text of this Decision has been developed by the Agency in consultation with Chief Medical Officers from national aviation authorities and industry.

The process map on the title page summarises the major milestones of this rulemaking activity.

### 1.2. Structure of the related documents

Chapter 1 contains the procedural information related to this task. Chapter 2 explains the core technical content. Chapter 3 explains why a Regulatory Impact Assessment was not applicable. The text of the acceptable means of compliance is annexed to the ED Decision.

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<sup>3</sup> Regulation (EC) No 216/2008 of the European Parliament and 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), as last amended by Commission Regulation (EU) No 6/2013 of 8 January 2013 (OJ L 4, 9.1.2013, p. 34).

<sup>4</sup> The Agency is bound to follow a structured rulemaking process as required by Article 52(1) of the Basic Regulation. Such process has been adopted by the Agency's Management Board and is referred to as the 'Rulemaking Procedure'. See 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 Decision No 01-2012 of 13 March 2012.

<sup>5</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). Regulation as last amended by Commission Regulation (EU) No 290/2012 of 30 March 2012 (OJ L 100, 5.4.2012, p.1).

<sup>6</sup> See: <http://easa.europa.eu/rulemaking/docs/tor/RMT/ToR%20RMT.0584.pdf>.

<sup>7</sup> In accordance with Article 52 of the Basic Regulation and Articles 5(3), 6 and 7(2) of the Rulemaking Procedure.

<sup>8</sup> See: <http://easa.europa.eu/rulemaking/r-archives.php#crd>.

## 2. Explanatory Note

This Decision provides additional acceptable means of compliance to Annex IV (Part-MED) of Regulation Aircrew. It covers the aero-medical assessment of applicants for a LAPL medical certificate in the areas oncology and dermatology. The specific medical requirements for LAPL medical certificates are laid down in ED Decision 2011/015/R to Regulation Aircrew.

### 2.1. Overview of the issue to be addressed

In the NPA 2008-17(c)<sup>9</sup>, the specific medical requirements for applicants for a LAPL medical certificate were presented as a table with embedded requirements for their assessment. The aim was to provide General Medical Practitioners, who may issue LAPL medical certificates if permitted under national law, with an easy tool for aero-medical assessments of these applicants. However, this approach led to numerous negative comments from stakeholders and the content of the table was consequently transformed into flow text in the corresponding CRD<sup>10</sup>.

While transposing the material contained in the table into flow text the assessment criteria for oncology and dermatology were unintentionally omitted. In the absence of reactions regarding this error, ED Decision 2011/015/R was published without acceptable means of compliance (AMC) on how to assess an applicant for a LAPL medical certificate if he/she presents with a condition in the area of oncology or dermatology.

When implementing Regulation Aircrew, including the provisions for the LAPL, one competent authority noticed the omission and asked the Agency to fill the gap as soon as possible.

### 2.2. Objectives

The overall objectives of the EASA system are defined in Article 2 of the Basic Regulation. This proposal will contribute to the achievement of the overall objectives by addressing the issues outlined in Chapter 2.1. The specific objective of this proposal is, therefore, to amend Decision 2011/015/R of the Executive Director of 15 December 2011 by adding two paragraphs for AMC material to paragraph MED.B.095 of Regulation Aircrew.

### 2.3. Outcome of the consultation

Out of the 13 comments received, 6 provided support and considered that no change to the proposed text was necessary. In other comments it was stated that the medical requirements for the LAPL are different from the requirements for driving, that the wording was too open and that no Regulatory Impact Assessment (RIA) was provided. No change to the text was made after consideration of the comments.

During a meeting with Chief Medical Officers from national aviation authorities and industry on 05 March 2013 the proposed requirements were presented again. The focussed discussion led to one text change by inserting the word 'primary' in subparagraph AMC18 MED.B.095 (a)(2) which now reads: '... time appropriate to the type of tumour has elapsed since the end of primary treatment;'. This caters for cases in which on-going treatment may be acceptable for a fit assessment.

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<sup>9</sup> See: <http://easa.europa.eu/rulemaking/docs/npa/2008/2008-17/NPA%202008-17c.pdf>.

<sup>10</sup> See: <http://easa.europa.eu/rulemaking/r-archives.php#crd>.

#### **2.4. Summary of the Regulatory Impact Assessment (RIA)**

A Regulatory Impact Assessment is not applicable as the rulemaking task is classified as systematic and non-controversial.

#### **2.5. Overview of the amendments**

The existing AMCs 1 through 16 in Section 4, 'Specific requirements for LAPL medical certificates', are amended by additional AMCs, namely AMC17 MED.B.095 and AMC18 MED.B.095. The AMCs for the assessment of applicants for a LAPL medical certificate are based on the same principle as currently applied to the existing AMCs for the LAPL, namely with regard to proportionality considering the privileges of the licence. The AMCs also provide for sufficient flexibility in the aero-medical assessment of the respective conditions.

### **3. References**

#### **3.1. Related regulations**

- Regulation (EC) No 216/2008 of the European Parliament and 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), as last amended by Commission Regulation (EU) No 6/2013 of 8 January 2013 (OJ L 4, 9.1.2013, p. 34).
- 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). Regulation as last amended by Commission Regulation (EU) No 290/2012 of 30 March 2012 (OJ L 100, 5.4.2012, p.1).

#### **3.2. Affected decisions**

Decision 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.

#### **3.3. Reference documents**

EASA NPA 2008-17(c)

EASA CRD 2008-17(c)