European Aviation Safety Agency — Rulemaking Directorate

Comment-Response Document 2012-20

Amendment of the AMC for pilot medical certification (LAPL)

CRD TO NPA 2012-20 — RMT.0584 — 08/08/2013
Related Decision 2013/016/R

EXECUTIVE SUMMARY

This Comment-Response Document (CRD) contains the comments received during the public consultation on NPA 2012-20 (published on 28 November 2012) and the responses provided thereto by the Agency.

The objective of the NPA was to amend ED Decision 2011/015/R[1] by adding two new paragraphs for the aero-medical assessment of applicants for a LAPL[2] medical certificate who present with a medical history of cancer or with a serious dermatological disease. The amendment is needed because acceptable means of compliance on the assessment of these conditions were unintentionally excluded from the published ED Decision.

Based on the comments and responses, the Agency has developed ED Decision 2013/016/R, containing the resulting text, which has been published at the same time as this CRD, as permitted by the rulemaking procedure adopted by the Agency's management board on 13 March 2012[3]. There are no major differences to the NPA in the resulting text, which is also published in this CRD for information.

The two new paragraphs provide the General Medical Practitioner (GMP) and Aero-Medical Examiner (AME) with some 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.

[1] 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)'.

[2] LAPL: Light Aircraft Pilot Licence.

[3] 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.

Applicability	
Affected regulations and decisions:	ED Decision 2011/015/R
Affected stakeholders:	LAPL holders; applicants for a LAPL medical certificate; aero-medical examiners; aero-medical centres; GMPs; competent authorities
Driver/origin:	Safety; level playing field; legal obligation (clarity of rules)
Reference:	ED Decision 2011/015/R

Process map	
Concept Paper:	No
Rulemaking group:	No
RIA type:	None
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

Table of contents

1. Procedural information

This CRD follows the rulemaking procedure adopted by the Agency's management board on 13 March 2012. Please refer to the related Decision 2013/016/R for the procedural information.

2. Summary of comments and responses

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. The answers to all comments are provided in this CRD. 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.

3. Draft AMC

The text of the amendment is new and therefore it appears below in grey shading, except for changes since the published NPA, which are highlighted in dark grey.

AMC17 MED.B.095 Dermatology

In cases where a dermatological condition is associated with a systemic ~~illness~~disease, full consideration should be given to the underlying illness before a fit assessment may be considered.

AMC18 MED.B.095 Oncology

(a) In the case of malignant disease, applicants may be considered for a fit assessment if:

(1) there is no evidence of residual malignant disease likely to jeopardise flight safety;

(2) time appropriate to the type of tumour has elapsed since the end of primary treatment;

(3) the risk of in-flight incapacitation from a recurrence or metastasis is sufficiently low;

(4) there is no evidence of short or long-term sequelae from treatment that may adversely affect flight safety.

(b) Arrangements for an oncological follow-up should be made for an appropriate period of time.

4. Individual comments (and responses)

In responding to comments, a standard terminology has been applied to attest the Agency's position. This terminology is as follows:

(a) **Accepted** — The Agency agrees with the comment and any proposed amendment is wholly transferred to the revised text.

(b) **Partially accepted** — The Agency either agrees partially with the comment, or agrees with it but the proposed amendment is only partially transferred to the revised text.

(c) **Noted** — The Agency acknowledges the comment but no change to the existing text is considered necessary.

(d) **Not accepted** — The comment or proposed amendment is not shared by the Agency.

(General Comments)	-

comment	*1* comment by: *Luftfahrt-Bundesamt* The LBA has no comments on NPA 2012-20.
response	*Noted* Thank you for considering this NPA.

comment	*3* comment by: *European Sailplane Manufacturers* The European sailplane manufacturer have a general comment to this NPA and the topic of medical minimum requirements for pilots flying under the LAPL regulations. Sadly within the EASA rulemaking process it has been widely forgotten what the LAPL should be all about. Our observation (which is based on service experience over more than 80 years and tens oth thousands of pilots and sailplanes) is: Gliding is possible for anyone if he/she considers himself/herself fit for other activities like driving a car, bicycling, hiking or other outside recreational activities. If a glider pilot does not feel fit, then typically he/she does not want to fly and this is the best prevention against accidents caused by medical reasons. Admittedly in a commercial context this pilot might try still to climb into the cockpit and make such a flight, but such a commercial background is totally missing when flying with a LAPL. The simple fact that even after loosing a medical, those pilots still drive their car and live a normal life only proves that the huge amount of money and time spent on these medical checks has mostly been spent for the benefit of the medical centers.

	We - together with a majority of the air sport communities - all have hoped that with the LAPL a niche could be created where flying is possible avoiding these efforts and costs. It is sad to observe that this has not become reality. Therefore we use this NPA to ask again for a more adequate regulation, which would simply require the pilot to check if he/she feels fit enough for a flight - nothing more.
response	*Noted* The objective of this NPA was to cover a gap in the acceptable means of compliance for the LAPL medical certificate. The general comment from the European Sailplane Manufacturers is noted but cannot have an effect on the specific text, as it is outside the scope of this NPA.

comment	*8* comment by: *Swiss International Airlines / Bruno Pfister* SWISS Intl Air Lines take note of the NPA without further comments.
response	*Noted* Thank you for considering this NPA

EXECUTIVE SUMMARY p. 1

comment	*5* comment by: *CAA-NL* Please be advised that the Netherlands has no commnets for this NPA
response	*Noted* Thank you for considering this NPA.

A. Explanatory Note - VI. Regulatory Impact Assessment p. 4

comment	*9* comment by: *AOPA Sweden* AOPA Sweden does not support the conclusion that no RIA is necessary due to the classification of the rulemaking task. In fact, we consider it very important that all rulemaking activities are subject to a RIA, even if the RIA itself is not of a big size. With a proper assessment,

	conclusions can be made if the suggested regulation is motivated in terms of cost and benefit.
response	*Noted* The paragraphs subject to this NPA were unintentionally excluded in the final drafting phase of the initial issue of Part-MED as explained in the Explanatory Note to the NPA and this gap in the AMC had to be filled to complete Part-MED. Therefore, a RIA was not applicable for this NPA.

comment	*11* comment by: *AOPA Sweden* There are no facts presented in terms of quantified flight safety related figures, for instance number of saved lifes or reduced number of accidents or incidents, due to this new regulation. We strongly recommend EASA to make the normal quantified RIA both in terms of cost and benefit, also for this rulemaking task. A non-regulative case should also be considered and evaluated. The benefits as stated in the RIA should be quantified in terms of both flight safety related figures as well as lowered costs. We are aware that this rulemaking task only has a small effect on the whole regulatory package in terms of Crew Licencing. However, the small size of this RMT should make the RIA easy and simple to perform. With a RIA for this NPA, EASA would have the necessary documentation to see if the cost benefit analysis ends up on the benefit side or not.
response	*Noted* See response to comment number 9 in this segment

comment	*12* comment by: *AOPA Sweden* If the intention of EASA is to not perform any RIA, we suggest that the Agency also removes the paragraph VI from the text, since no RIA was included in the report.
response	*Not accepted* A RIA is drafted in most cases, but in this one it was not considered to be applicable, as explained in the response to comment number 9 in this segment. Paragraph VI was included in the NPA to explain this for completeness.

B. Draft Decision - AMC 17 MED.B.095 Dermatology p. 5

comment	*2* comment by: *Finnish Transport Safety Agency* Finland fully supports the amendments to **AMC 17 MED.B.095**. and **AMC18**

	MED.B.095 as presented in NPA 2012-20.
response	*Noted* Thank you for considering this NPA.

comment	*6* comment by: *UK CAA* **Page No:** 5 **Paragraph No:** AMC 17 MED.B.095 Dermatology **Comment:** The UK agrees with the proposed text.
response	*Noted* Thank you for considering this NPA.

comment	*13* comment by: *AOPA Sweden* It should be evaluated if the wording "full consideration" should be replaced with "consideration". In case Part-MED or other Union legislation specifies a difference between the two types of considereations, this comment can be omitted. What is the difference between a consideration and a "full consideration"? We do not see the regulatory effect of adding the word "full". We recommend the Agency to remove the word "full" and use only "consideration" which is sufficient.
response	*Not accepted* It is intended to be equivalent to the terms 'careful consideration' and 'due consideration' which are used in ICAO Doc 8984. 'full consideration' is also used in the AMCs on dermatology for class 1 and class 2 aero-medical certification.

B. Draft Decision - AMC 18 MED.B.095 Oncology p. 5

comment	*4* comment by: *K Franzen* t is good that there is less force on the medical conditions that do not directly involve the risk of acute incapacitation in flight. This proposal, however, contains too large element of subjective judgments which may result in very different applications of this AMC in practice. Remove expressions as "time appropriate to" and "sufficidently low" and "an appropriate period" as far as possible or replace these expressions with more objective data.

response	*Not accepted* There is no objective data that would be correct for all tumours, stages of tumours and possible effects of treatment. Therefore a rather general wording was chosen to provide the AME and GMP with enough flexibility to ensure that, as far as possible, a LAPL certificate holder can continue his/her flying activity.

comment	*7* comment by: *UK CAA* **Page No:** 5 **Paragraph No:** AMC 18 MED.B.095 Oncology **Comment:** The UK agrees with the proposed text.
response	*Noted* Thank you for considering this NPA.

comment	*10* comment by: *AOPA Sweden* When defining levels of risk and flight safety according to (a) (3) and (4): Considerations and comparisons should also be made to other parts of the transportation system, to assure no over-regulation of the LAPL holders. For instance, a holder of a drivers licence for a normal car is equivalent to the LAPL. Thus, in general, a LAPL holder should not have stricter conditions than a holder of a driver's licence. One reason is the high risk of a driver of a car, to hit other persons and vehicles operated meters from the vehicle of the driver.
response	*Noted* The objective of this NPA was to cover a gap in the acceptable means of compliance for the LAPL medical certificate. The general comment from AOPA Sweden is noted but cannot have an effect on the specific text, as it is outside the scope of this NPA.