

# **OPINION NO 07/2010**

# OF THE EUROPEAN AVIATION SAFETY AGENCY

of 13 December 2010

for a Commission Regulation XXX/2010 laying down Implementing Rules for the medical certification of pilots and medical fitness of cabin crew

#### General

- 1. The purpose of this Opinion is to assist the Commission in laying down Implementing Rules for medical certification of pilots and medical fitness of cabin crew. The scope of the related rulemaking tasks was outlined in the Terms of Reference FCL.001 and OPS.001 and was described in detail in the Explanatory Notes to NPA 2008-17(a) and to NPA 2009-02(a).
- The objective of the proposed rules is to create different medical requirements for pilots'
  medical certificates that are proportionate to the privileges of the licence concerned, and
  rules for the assessment of medical fitness of cabin crew to safely exercise their assigned
  safety duties.
- 3. The proposed rules have been developed by the European Aviation Safety Agency (the Agency) on the basis of Regulation (EC) No 216/2008 of the European Parliament and of the Council as amended by Regulation (EC) No 1108/2009 (the Basic Regulation). Further on, in the case of medical certification of pilots, the rules have been based on ICAO Standards and Recommended Practices, adopted Joint Aviation Requirements (JAR-FCL 3) and national requirements developed in Member States for medical provisions not covered by JAR-FCL 3. The proposed rules include provisions deriving from NPAs to JAR-FCL 3 that were in an advanced phase of adoption in the JAA system but did not undergo the full regulatory process due to the closure of the JAA.

In the case of cabin crew medical fitness, the relevant ICAO recommendation<sup>1</sup> and the various national practices or requirements were also considered in addition to the applicable Essential Requirement of Annex IV to the Basic Regulation, EU-OPS<sup>2</sup> and Section 2 of JAR-OPS 1<sup>3</sup>.

#### II. Consultation

- 4. The Notice of Proposed Amendment (NPA) NPA 2008-17 "Implementing Rules for Pilot Licensing" was published on the Agency's website on 5 June 2008 for consultation of all interested parties in accordance with Article 52 of the Basic Regulation and Articles 5(3) and 6 of the Rulemaking Procedure. NPA 2008-17c thereof contained draft proposals for IR and related AMC and GM for the medical certification of pilots (Part-MED).
- 5. NPA 2009-02 "Implementing Rules for Air Operations of Community Operator" was published on the Agency's website on 30 January 2009 and NPA 2009-02(e) thereof contained the draft proposals for medical fitness of cabin crew.
- 6. The Agency amended the medical provisions for pilots and cabin crew taking into account the comments received and, on 23 June 2010, published the Comment-Response Document (CRD) to NPA 2008-17c and NPA 2009-02e. The proposed rules for medical fitness of cabin crew were included as a separate Subpart in this CRD.
- 7. The CRD to NPA 2008-17c and NPA 2009-02e was open for reaction from stakeholders for a period of two months, as established in the Rulemaking Procedure. By the closing date of 23 August 2010, the Agency had received a considerable amount of reactions to medical certification of pilots from more than 200 individual commentators, including National Aviation Authorities, professional organisations, individual operators, non-profit general aviation organisations, private companies and individual persons. The reactions

<sup>&</sup>lt;sup>1</sup> ICAO Doc 7192-AN/857 Part E-1 Cabin Attendants' Safety Training Manual, Second Edition 1996 – Paragraph 1.2.23 on Minimum qualifications.

<sup>&</sup>lt;sup>2</sup> EU-OPS – Annex III to Council Regulation (EEC) No 3922/91 as amended by Commission Regulation (EC) No 8/2008 of 11 December 2007 and Commission Regulation (EC) No 859/2008 of 20 August 2008.

<sup>&</sup>lt;sup>3</sup> TGL 44.

relating to medical fitness of cabin crew were placed by 18 commentators including National Aviation Authorities, operators and cabin crew organisations.

All reactions received to the CRD to NPA 2008-17c and NPA 2009-02e were considered for the final drafting of the Opinion for the "Implementing Rules for the medical certification of pilots and medical fitness of cabin crew" (Part-MED).

# III. Content of the Opinion of the Agency

- 8. This Opinion contains the Agency's proposals for Implementing Rules for:
  - the medical certification of pilots referred to in Article 4(2) of the Basic Regulation;
  - the medical certification of pilots holding light aircraft pilot licences (LAPL) referred to in Article 7 of the Basic Regulation;
  - the certification of aero-medical examiners;
  - general medical practitioners (GMP) that may act as AMEs for pilots who apply for or hold a LAPL; and
  - the medical fitness of cabin crew referred to in Article 4(2) of the Basic Regulation, as well as for occupational health medical practitioners (OHMP) that may be involved in their medical assessment.

# Structure of the Opinion

9. The structure of the Opinion has been slightly adapted. This was done for two reasons. One reason was to have a clear separation between technical rules and rules for the competent authorities, and the second one was to facilitate possible future changes to the Implementing Rules. The latter may be necessary to introduce medical requirement for air traffic controllers. The main structural changes and the order of Subparts and Sections are indicated below, a comparison table between the CRD to NPA 2008-17c and NPA 2009-02e and this Opinion is in Annex 1.

#### Subpart A General Requirements

- Section 1, General, contains all rules that are applicable to pilots and to cabin crew. Implementing Rules for air traffic controllers may be added in the future.
- Section 2, Requirements for medical certificates, is applicable to pilots only. Requirements for air traffic controllers may be added in a second step.
- Section 3, Suspension and revocation, has been deleted. The paragraph on suspension of exercise of privileges has been added to MED.A.020 on decrease of medical fitness and the paragraph on suspension and revocation of medical certificates has been deleted from Part-MED and will be added to Part-AR.

# **Subpart B** Requirements for Pilot Medical Certificates

- The paragraph on limitation to medical certificates has been moved from Subpart A to this Subpart as it will only be applicable to pilots.
- Subpart C Reserved for Air Traffic Controller Medical Certificates
- Subpart D Requirements for Medical Fitness of Cabin Crew
- Subpart E Aero-medical Examiners, General Medical Practitioners, Occupational Health Medical Practitioners
- This Subpart contains the Implementing Rules for all medical specialists involved in the assessment of medical fitness.

10. All reactions received were evaluated and some text was changed as a result. The main issues to be reviewed were related to the medical certificate for the LAPL and the medical fitness of cabin crew.

# Reactions relating to medical certificates for the LAPL

- 11. The medical requirements for LAPL holders were the most contentious topic in NPA 2008-17c and again in the CRD. Around 50% of the reactions were made to paragraph B.090 of the CRD (B.095 in this Opinion) dealing with the medical requirements for applicants for a LAPL medical certificate, and to the requirements on general medical practitioners acting as AMEs. These reactions were very diverse and made by individual pilots (114 reactions, 113 of which from UK glider pilots), Pilot Associations (17 reactions, 9 x UK, 3 x DE, 2 x SE and 1 each from CH, DK and IR), AMEs (2 x DE), AME Associations (1 x European Association, 1 X AU, 1 X DE), National Aviation Authorities (8), Ministry of Transport of 2 Member States.
- 12. British pilots and their associations strongly request that no change occurs to their present national regulations for glider pilots and holders of national private pilot licences (NPPL). The information on the CAA UK website for general practitioners (GP) is: "The first thing to emphasise is that you, the general practitioner, are not being asked to assess an applicant's "Fitness to Fly". Your countersignature confirms only that there is nothing in the applicant's medical history which would prevent him/her meeting the DVLA Group 1 or Group 2 driving standards. ...".
- 13. However, the Basic Regulation states in Article 7 that, in the case of a leisure pilot licence (LAPL), a general medical practitioner (GMP) may act as AME if permitted under national law. This may lead to the conclusion that the GMP, just as the AME, assesses a pilot's fitness to fly.
- 14. A UK general practitioner holds the medical history of the patients that are registered with him/her. According to the CAA UK website information, a UK glider pilot or NPPL holder has to see the general practitioner (GP) with whom he/she is registered for the countersignature mentioned in paragraph 12. Pilots can therefore not attend any GP. If an applicant does not have a GP, he/she has to go to an AME for a medical certificate.
- 15. The medical systems in the Member States are very different and there are MS where a person can visit any GP without being registered and also a different GP each time he/she needs one. These GPs may not have sufficient knowledge of the medical history of a patient/pilot.
- 16. Member States reacted against medical certificates that are below ICAO standards and AMEs said that driving standards are not sufficient for assessing the fitness to fly because the influence of the 3<sup>rd</sup> dimension is missing and the impact of specific stress of flying is not taken into account.
- 17. As for the requirements on the GMP, pilots said that he/she does not need any knowledge in aviation medicine or to hold or has held a pilot licence. Their main concern is that cost for the G(M)P's signature will explode or the G(M)P may not bother to sign the paper. AMEs reacted by saying that only a person who has full knowledge in the field can assess fitness to fly. The majority of Member States that placed reactions said that a GMP should not issue medical certificates.
- 18. Considering all reactions received, the following changes were made in the Opinion:
  - The requirements on the GMP concerning knowledge in aviation medicine or the rule to hold or have held a pilot licence were deleted. A requirement that additional national rules shall apply has been added.
  - The medical requirements did not change in substance but they are more flexible due to re-wording and remain well below ICAO standards. The AMCs will be redrafted to take into account the different knowledge of the applicant's medical

- history that a GP has of person registered with him/her as described for the UK, and an AME who may see a pilot only once.
- The periods of validity of LAPL medical certificates have been aligned with ICAO standards.

## Reactions relating to medical fitness of cabin crew

- 19. The reactions received show that most of the concerns originated from two main reasons:
  - the significant diversity of practices in the Member States, including the existence, or not, of a national medical certification for cabin crew; and
  - the different understandings of the intention of the legislator as foreseen in the Basic Regulation with regard to cabin crew qualifications and medical fitness.
- 20. Reactions placed by the 18 commentators were of three types. Two Member States, one airline organisation and two individual operators opposed any change beyond EU-OPS. Two other Member States agreed to some (stepped) harmonisation beyond EU-OPS, and proposed amendments accordingly. The other commentators, including three Member States and cabin crew organisations, supported in principle the CRD proposals, even though the latter considered that the rules should be more stringent.

Concretely, the main issues raised reflected the main differences between the national practices, as follows:

- whether aero-medical assessments should include, or not, a clinical examination;
- the validity periods of aero-medical assessments;
- the added value, or not, of a medical certification system;
- the need for class 2 medical requirements;
- the need for a medical 'paper' indicating the outcome of the aero-medical assessments.
- 21. The proposals published in the NPA 2009-02e and the related CRD had been initially developed on the basis of a coordinated analysis of the Basic Regulation conducted with the European Commission in May 2008, and the identification of medical conditions that would prevent a cabin crew member from performing his/her safety duties properly. The Agency's aim was that the final proposals would reflect the outcome of the consultation process, with a careful balance, taking into account the justification provided and the very different views expressed by stakeholders, including Member States, Airlines Associations, Cabin Crew Associations, and Medical Practitioners. Namely, on one hand the new flexibility proposed in the CRD for assessments to be conducted under the National Occupational Health System, as is currently the case in several Member States, seemed to address many of the concerns expressed to the NPA and would therefore be confirmed. On the other hand, aero-medical assessments would include a clinical examination, as is currently the case in the vast majority of the Member States, either by an AME or under the relevant National Occupational Health System.
- 22. During the review process of the CRD reactions, the Agency was informed by the European Commission that the proposed Implementing Rules should be carefully reconsidered and revised taking into particular account that the level of harmonisation to be achieved for medical fitness of cabin crew was not specified by the Basic Regulation.
- 23. The proposals presented in this Opinion, and further detailed in paragraphs 36 to 40 below, are the result of this revision, primarily aiming at a smoother transition, as supported by some of the reactions placed to the CRD and referred to in paragraph 20 above.
- 24. Subpart D, containing the requirements for medical fitness of cabin crew, includes for clarity purposes a new Section 3 with the additional requirements only applicable to holders of a cabin crew attestation in commercial air transport operations.

## Further reactions and their impact on this Opinion

## Subpart A - General Requirements

- 25. MED.A.001: A new point (d) has been added to define the 'Competent authority' for the occupational health medical practitioner who may be involved in the medical assessment of cabin crew.
- 26. MED.A.10: A new definition was added for "assessment" and the document was reviewed to ensure consistency when using the expression. As a result, some changes were made that are considered editorial as they were introduced to ensure consistency of text.
- 27. MED.A.020: A new paragraph (d) has been added on suspension of the exercise of cabin crew duties (former MED.E.010).
- 28. MED.A.025 (b)(4): Two reactions from Member States indicated that AeMCs, AMEs and GMPs shall keep records of aero-medical examinations, tests, investigations and assessments but that they should not send them to the licensing authority on a routine basis. The main reason for this comment to the NPA and reaction to the CRD was national data protection law.

The text was not changed for the following reasons:

- ICAO Annex 1, 1.2.4.6<sup>4</sup> requires the AME to send the examination results to the licensing authority.
- ICAO Annex 1<sup>5</sup>, 6.3.1.3 (class 1, commercial pilots) and 6.4.1.3 (class 2, private pilots) also require the licensing authority to be satisfied with the result of the aero-medical examination and assessment. The licensing authority therefore needs the corresponding examination results.
- It is commonly recognised that the complete medical history of a pilot is highly important for the assessment of fitness to fly. Pilots have a free choice to visit any AeMC or AME in Europe and the medical certificate will be accepted in all Member States. The AME may not have the full medical history of an applicant or, for language reasons, may not be able to understand evidence a pilot may offer for clarification. In such a case, the AME can turn to the licensing authority of the pilot for advice on the medical history. Also, the licensing authority is in a position to evaluate the outcome of a medical assessment if it holds the results of all aeromedical assessments the pilot underwent.
- Data protection has to be ensured by the licensing authority so that national data protection law should be satisfied.

The requirement has been transferred from JAR-FCL 3.29.

MED.A.040: A LAPL medical certificate may be issued by a GMP and this is reflected in the Implementing Rules by stating "if permitted under the national law of the licensing authority". Several reactions to the CRD proposed to simply say "if permitted under national law". The text was not changed because in this case a pilot of country A, where GMPs are not allowed to issue medical certificates could have his/her certificate issued in country B where the GMP may do so. The text in the CRD and Opinion clarifies that the law of the country where the pilots holds his/her licence applies as well.

ICAO Annex 1, 1.2.4.6 Having completed the medical examination of the applicant in accordance with chapter 6, the medical examiner shall coordinate the results of the examination and submit a signed report, or equivalent, to the Licensing Authority, in accordance with its requirements, detailing the results of the examination and evaluating the findings with regard to medical fitness.

<sup>&</sup>lt;sup>5</sup> ICAO Annex 1, 6.3.1.3 When the licensing authority is satisfied that the requirements of this section and the general provisions of 6.1 and 6.2 have been met, a Class 1 Medical Assessment shall be issued to the pilot. (Equivalent rule for Class 2 in 6.4.1.3).

30. MED.A.045: The validity periods of a LAPL medical certificate were aligned with ICAO Annex 1 SARPs. This change was discussed with all stakeholder groups and finally agreed. The shorter validity periods are balanced by allowing the AME or GMP not to perform aero-medical examinations or tests after the initial medical certificate until age 50 giving due regard to the medical history.

## Subpart B - Requirements for pilot medical certificates

31. MED.B.001 (a) The paragraph on limitations of medical fitness has been transferred from Subpart A to Subpart B as mentioned in paragraph 9. Two reactions from Member States indicated that the decision on medical fitness in cases where the pilot does not fully meet the requirements should be taken by the AeMC or AME and not by, or in consultation with, the licensing authority.

The text of the Opinion has not been changed as compared to the CRD for the following reasons:

- ICAO Annex 1, 6.1.36 where the AME is obliged to identify to the licensing authority any individual case where an applicant does not fully meet the requirements.
- The present regulations of JAR-FCL 3 require the aero-medical section (AMS) of the authority to evaluate cases where fitness according to the rules cannot be demonstrated and decide whether or not a fit assessment, with or without limitation(s), can be made. In Amendment 7, JAR-FCL 3.125 provides a possibility of delegation of this AMS task to an Aero-medical Centre (AMC) or AME, however, the decision is still taken in consultation with the AMS and the Authority has to be informed of the details of the case.
- The vast majority of Member States has a system in place that is reflected in the Implementing Rules of Part-MED.
- 32. MED.B.001 (d) Following reactions received, a new operational limitation has been added to this subparagraph to have the highest possible flexibility for fit assessments for LAPL and class 2 medical certificates. In cases where these pilots cannot meet the applicable requirements but could still be able to continue flying, they can be restricted to flying without passengers only (OPL Operational Passenger Limitation).
- 33. All other (medical) limitations are in Acceptable Means of Compliance in order to provide a certain degree of flexibility.
- 34. Stakeholders also proposed changes to medical technical requirements in Subpart B. The main issues were insulin dependant diabetes, hyperopia in applicants for initial class 1 medical certificates, colour vision testing, and the assessment of pilots with asthma. These comments and reactions were not accepted as these amendments would result in significant changes to JAR-FCL 3 which was the basis of this Opinion and, in the case of diabetes be in conflict with ICAO Annex 1. All proposals that were not included in this Opinion will be re-considered during rulemaking task MED.001 and will undergo the consultation that is foreseen in the rulemaking process.
- 35. MED.B.095 The LAPL medical requirements were already well below ICAO standards in the CRD. They have been slightly reworded but remain basically unchanged.

## Subpart D - Requirements for medical fitness of cabin crew

- 36. MED.D.001 General, only includes editorial changes for clarity.
- 37. MED.D.005 Aero-medical assessments. This rule includes three changes. The first one, which applies to the whole subpart, results from the addition of a definition of

<sup>&</sup>lt;sup>6</sup> ICAO Annex 1, 6.1.3 The medical examiner shall report to the Licensing Authority any individual case where, to the examiner's judgement, an applicant's failure to meet any requirement, whether numerical or otherwise, is such that exercise of the privileges of the licence being applied for, or held, is not likely to jeopardise flight safety.

'assessment' in MED.A.010. Reference is now proposed to be limited to 'aero-medical assessment', meaning that, as further specified in section 2, an aero-medical assessment may include, or not, a clinical examination. Another change has been made to the intervals for aero-medical assessments. Instead of three different validity periods depending on the age, a maximum validity is now proposed, whilst shorter periods or intervals are still possible if needed. The last change to be noted also results from changes made to the structure of Part-MED. The qualifications required for an occupational health medical practitioner to conduct aero-medical assessments of cabin crew have been moved under MED.E.040 in the specific Subpart E covering all medical doctors assessing medical fitness.

- 38. MED.D.025 Content of aero-medical assessments, this rule has also been significantly changed as a result of the addition of the definition of 'assessment'. Point (a)(1) has been amended for clarity, which has allowed deleting the former point (a)(3). Point (b) has been amended to provide the flexibility requested in accordance with current practices with regard to the conduct of a clinical examination in case of re-assessment.
- 39. MED.D.030 Cabin crew medical report. As recommended by many comments to the NPA, a requirement for some 'medical paper' was proposed under former MED.E.015(a) and (b) in the CRD. It has been moved for clarity to this new section. Also, the wording 'attestation' has been replaced by 'report' as suggested by a reaction to the CRD. The elements to be specified on this cabin crew medical report have been clarified and are differentiated from those that fall under the requirement for medical confidentiality.
- 40. MED.D.035 Limitations. This provision had been added in the CRD as a mitigating measure to the flexibility provided in the CRD, as requested by comments to the NPA, for some particular medical conditions that are usually considered as potentially not compatible with cabin crew duties and responsibilities. It has not been amended, only moved to the new section 3 for clarity.

# Subpart E - Aero-medical Examiners, General Medical Practitioners, Occupational Health Medical Practitioners

- 41. MED.E.035 The requirements on GMPs to have knowledge in aviation medicine or hold or have held a pilot licence have been deleted. However, a rule that additional national rules apply to allow a GMP to assess the medical fitness of pilots has been added.
- 42. MED.E.040 The requirements on the OHMP, originally in MED.E.005 (c)(2), have been re-worded for clarity reasons.

P. GOUDOU

**Executive Director** 

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# **Annex I - Conversion Table CRD to Opinion**

Opinion / Title	Opinion	CRD	CRD / Title			
Subpart A - General Requirements						
Section 1 - General						
Competent Authority	MED.A.001	MED.A.001	Competent Authority			
Scope	MED.A.005	MED.A.005	Scope			
Definitions	MED.A.010	MED.A.010	Definitions			
Medical Confidentiality	MED.A.015	MED.A.015	Medical Confidentiality			
Decrease in medical fitness	MED.A.020	MED.A.025 MED.A.060 MED.E.010	Suspension of exercise of duties Suspension of exercise of privileges Suspension of the exercise of duties			
Obligations of AeMC, AME, GMP and OHMP	MED.A.025	MED.A.050	Obligations of AeMC, AME and GMP			
Section 2 - Requirements for medical certification						
Medical Certificates	MED.A.030	MED.A.020	Medical certification			
Application for a medical certificate	MED.A.035	MED.A.035	Application for a medical certificate			
Issue, revalidation and renewal of medical certificates	MED.A.040	MED.A.030 MED.A.040 MED.A.050	Competence for the issue, revalidation and renewal of medical certificates  Requirements for the issue, revalidation and renewal of medical certificates  Obligations of AeMC, AME and GMP			
Validity, revalidation and renewal of medical certificates	MED.A.045	MED.A.055	Validity, revalidation and renewal of medical certificates			
Referral	MED.A.050	MED.A.050	(c)			
		Section 3 - Suspension and revocation				
./.	MED.A.020	MED.A.060	Suspension of exercise of privileges			

Opinion / Title	Opinion	CRD	CRD / Title
./.	MED.A.055	MED.A.065	Suspension and revocation of medical certificates
Subpart B Red	quirements for p	l ilot medical ce	rtificates
Section 1 - General			
Limitations to medical certificates	MED.B.001	MED.A.045	Limitations to medical certificates
	renumbering thereafter		
Subpart C - Reserved			
Subpart D - Requ	uirements for me	dical fitness of	f cabin crew
Section 1 - General requirements			
General	MED.D.001	MED.E.001	General requirements
Aero-medical assessments	MED.D.005	MED.E.005	Aero-medical examinations and assessments
Section 2 - Requirements for aero-medical assessment of cabin crew			
General	MED.D.020	MED.E.020	General requirements
Content of aero-medical assessments	MED.D.025	MED.E.025	Content of aero-medical examinations and assessments
Section 3 - Additional requirements for applicants of, a cabin crew attestation	s for, or holders		
Cabin crew medical report	MED.D.030	MED.E.015(a) and (b)	Additional requirements for applicants for, and holders of, a cabin crew attestation in commercial air transport operations (Medical attestation)
Limitations	MED.D.035	MED.E.015(c)	Additional requirements for applicants for, and holders of, a cabin crew attestation in commercial air transport operations (Limitations)

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Opinion / Title	Opinion	CRD	CRD / Title
Section 1 - Aero-medical examiners			
Privileges	MED.E.001	MED.C.001	Privileges
	re-numbering thereafter		
Section 2 - General Medical Practitioners			
Requirements for general medical practitioners	MED.E.035	MED.D.001	Requirements for general medical practitioners
Section 3 - Occupational health medical practitioners			
Requirements for occupational health medical practitioners	MED.E.040	MED.E.005	(c) Aero-medical examinations and assessments