



Comment-Response Document 2013-15

Update of Part-MED (Annex IV to Commission Regulation (EU) No 1178/2011) and Acceptable Means of Compliance and Guidance Material to Part-MED (ED Decision 2011/015/R)

CRD to NPA 2013-15 — RMT.0287 and RMT.0288 (MED.001(a) and (b)) — 25.9.2014

EXECUTIVE SUMMARY

The primary objective of rulemaking tasks RMT.0287 and RMT.0288 was to review Part-MED (Annex IV to the Aircrew Regulation) and the associated Acceptable Means of Compliance (AMC) and Guidance Material (GM), to correct any editorial errors, consistency issues or gaps identified through implementation experience. Part-MED establishes the requirements for the issue of the medical certificate required for exercising the privileges of a pilot licence; medical fitness of cabin crew; certification of aero-medical examiners; and qualification of general medical practitioners and occupational health medical practitioners.

The associated Notice of Proposed Amendment NPA 2013-15 'Update of Part-MED', published on 26 July 2013, received 392 comments from 30 commentators. This Comment-Response Document includes individual comments and responses thereto, as well as a summary thereof. Proposed amendments to Part-MED, reflecting the Agency's responses to comments received are also included. A selection of some key changes to NPA 2013-15 follows:

- The structure, wording and expressions used in Part-MED and in the upcoming EU Regulation for licensing and medical certification of air traffic controllers have been harmonised, where appropriate.
- The text on anticoagulation has been amended to take account of the novel oral anticoagulants (NOACs).
- Multiple comments were received in support of the proposal to require an electrocardiogram (ECG) to be performed at the initial examination for class 2 applicants, provided that an ECG at the first examination after age 40 is also required, in line with ICAO Annex 1 and the existing rules. The text now supports this.
- A new limitation, encoded 'ORL' (Operating pilot Restriction Limitation), has been introduced to ensure that holders of a class 2 or LAPL medical certificate either operate an aircraft with a safety pilot or without passengers.
- The Colour Assessment and Diagnosis (CAD) test has been included as an acceptable means of testing colour vision for applicants who fail the Ishihara test.

Stakeholders are invited to verify if their comments have been addressed appropriately, and to submit any reactions via the Comment-Response Tool.

Any reactions to this CRD should be submitted via the CRT by clicking the 'add a general reaction' button.

The applicable CRD page and paragraph/rule reference should be clearly indicated in all reactions submitted.

Applicability		Process map	
Affected regulations and decisions:	Part MED (Annex IV to Commission Regulation (EU) No 1178/2011) ED Decision 2011/015/R on AMC/GM to Part MED	Concept Paper:	No
Affected stakeholders:	Flight Crew, Cabin Crew, Aero-medical examiners, Aero-medical Centres, General Medical Practitioners, Occupational Health Medical Practitioners, Competent Authorities	Rulemaking group:	Yes
Driver/origin:	Legal obligation, level playing field, ICAO alignment, Basic Regulation	RIA type:	None
Reference:	Not applicable	Technical consultation during NPA drafting:	Yes
		Publication date of the NPA:	26.7.2013
		Duration of NPA consultation:	3 months
		Review group:	Yes
		Focussed consultation:	No
		Publication date of the Opinion (RMT.0287):	2015/Q2
		Publication date of the Decision (RMT.0288):	2016/Q2



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1. Procedural information

1.1. The rule development procedure

The European Aviation Safety Agency (hereinafter referred to as the 'Agency') has developed this Comment-Response Document (CRD) in line with Regulation (EC) No 216/2008¹ (hereinafter referred to as the 'Basic Regulation') and the Rulemaking Procedure².

This rulemaking activity is included in the Agency's [4-year Rulemaking Programme](#), under rulemaking task number RMT.0287. Originally, two numbers were attributed to the task; one for the Opinion (RMT.0287) and one for the ED Decision (RMT.0288). Both deliverables are now included in RMT.0287. The scope and timescales for the task are defined in the related Terms of Reference (ToR) which were published on 9 November 2011 on the Agency's website, as last amended by Issue 2 which was published on 22 October 2012³. Issue 2 widened the scope to include a review of the medical aspects contained in Annexes VI (Part-ARA) and VII (Part-ORA) to Commission Regulation (EU) No 1178/2011⁴ (hereinafter referred to as the 'Aircrew Regulation'). The results of the Part-ARA and Part-ORA review will be published separately in a future NPA.

The main objective of the task is to review and update Part-MED (Annex IV to the Aircrew Regulation), as last amended, and the Acceptable Means of Compliance and Guidance Material to Part-MED (ED Decision 2011/015/R⁵, as last amended). No major changes to Part-MED were expected to be introduced through the task. Such issues will be handled under future rulemaking tasks RMT.0424 and RMT.0603 where individual organ systems will be reviewed in smaller packages to propose improvements and to take account of medical advancements.

The Agency published the NPA related to RMT.0287 and RMT.0288 (NPA 2013-15)⁶ on 26 July 2013 for public consultation until it closed 3 months later on 28 October 2013.

It should be noted that, since the NPA was published, a change to the AMC for LAPL has been introduced through ED Decision 2013/016/R. This is reflected in the resulting text to this CRD.

The responses to the comments received, as well as the resulting text have been developed by the Agency with input from the review group which was established for RMT.0287 and RMT.0288. The

1 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).

2 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.

3 <http://easa.europa.eu/system/files/dfu/EASA-ToR-RMT.0287-RMT.0288-MED.001-Issue2.pdf>

4 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); as last amended by Commission Regulation (EU) No 245/2014 of 13 March 2014 (OJ L 74, 14.3.2014, p.33).

5 ED Decision 2011/015/R of 15 December 2011 on Acceptable Means of Compliance and Guidance Material to Commission Regulation (EU) No 1178/2011 laying down technical requirements and administrative procedures related to civil aviation aircrew pursuant to Regulation (EC) No 216/2008, as last amended by ED Decision 2013/016/R of 8 August 2013.

6 <http://easa.europa.eu/system/files/dfu/EASA-NPA-2013-15.pdf>



review group comprised the same members as the initial Rulemaking group, augmented by two extra members from competent authorities (CAA UK and Austrocontrol). The review group met twice between November 2013 and January 2014 to finalise the CRD. During these meetings, the review group discussed the comments received on the NPA and changes to the amendments proposed in the NPA. These changes were subject to consideration by the Agency with guidance from the Agency's legal and standardisation departments.

The process map on the title page contains the major milestones for this rulemaking activity.

1.2. The structure of this CRD and related documents

This CRD provides a summary of comments and responses as well as the full set of individual comments and responses thereto received to NPA 2013-15. The resulting text is provided in chapter 3 of this CRD.

1.3. The next steps in the procedure

Stakeholders are invited to submit reactions to this CRD regarding possible misunderstandings of the comments received and the responses provided.

Such reactions should be received by the Agency not later than **25 November 2014** and should be submitted using the automated **Comment-Response Tool (CRT)** available at <http://hub.easa.europa.eu/crt>⁷.

The Agency Opinion, addressed to the European Commission, containing the proposed changes to the Aircrew Regulation, will be published no less than two months after the publication of this CRD.

The associated ED Decision containing AMC and GM will be published by the Agency when the related Implementing Rules are adopted.

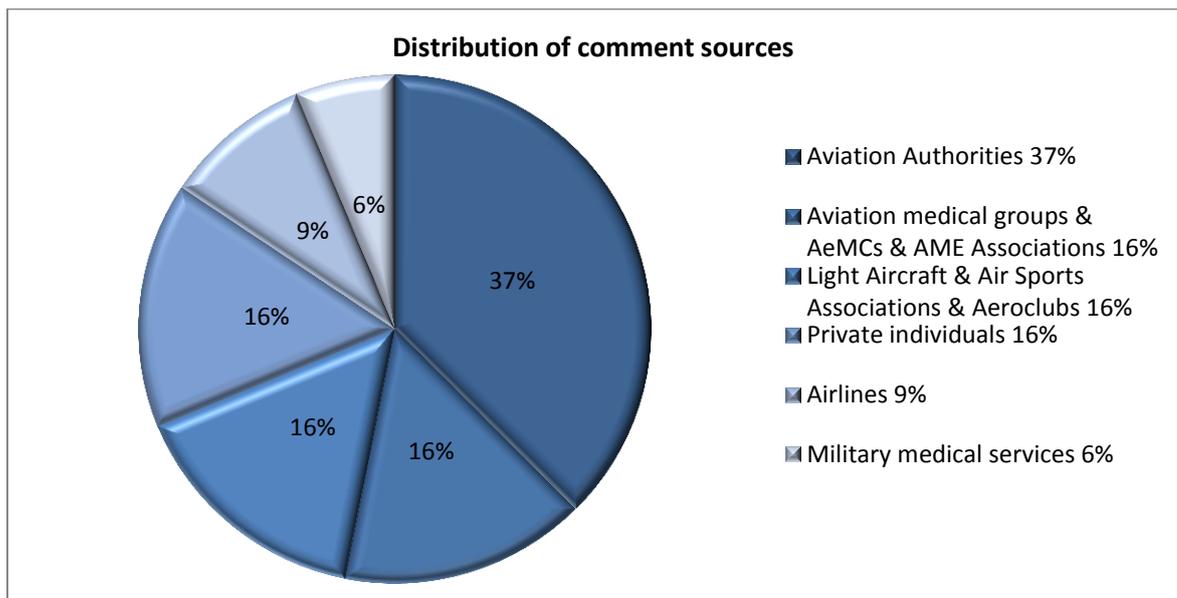
⁷ In case of technical problems, please contact the CRT webmaster (crt@easa.europa.eu).



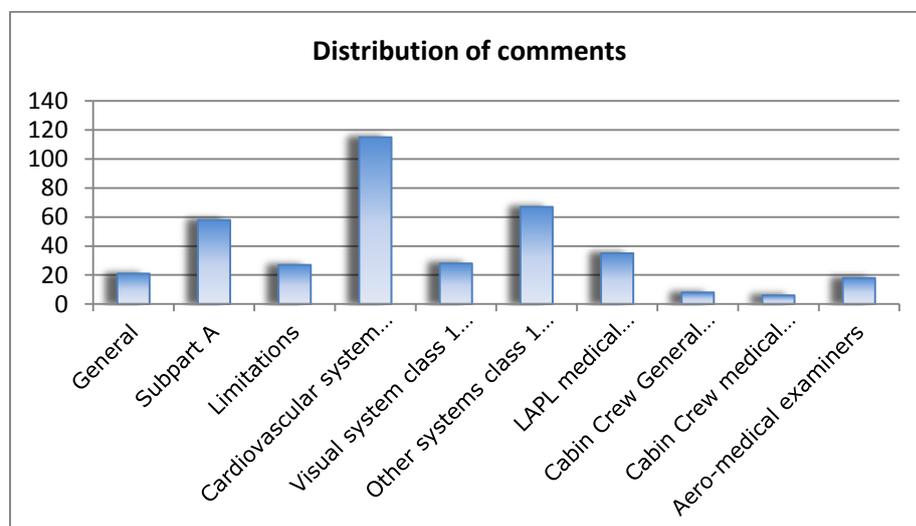
2. Summary of comments and responses

2.1. Distribution of comments received

The Agency received a total of 392 comments during the public consultation period for NPA 2013-15, from 12 aviation authorities, 5 aviation medical groups including military establishments, 5 light aircraft/air sports associations, 5 private individuals and 3 airlines. The distribution of the comment sources is illustrated in the chart below.



21 comments were submitted under 'general', 58 under subpart A and 27 under subpart B 'general' (including limitations). On the medical requirements for class 1 and class 2 medical certification, 115 comments were related to the cardiovascular system (MED.B.010) and 28 were on the visual system (MED.B.070), while the remainder were on the other organ systems. 35 comments were received on the LAPL medical certification provisions and 14 on the cabin crew AMC and GM. 18 comments were submitted on the AME certification proposals. The distribution of comments is illustrated in the following graph.



2.2. Summary of responses to comments

2.2.1 Editorial corrections and changes for clarification and consistency

- (a) Editorial changes have been made to improve the text of Part-MED, to ensure consistency of wording and, where necessary, to clarify the meaning of an Implementing Rule (IR) or Acceptable Means of Compliance (AMC) or Guidance Material (GM). In some cases, paragraphs have been rearranged to better align the IRs and AMCs. These amendments are purely editorial and do not imply a technical change to the IR, AMC or GM.
- (b) The structure, wording and expressions used in Part-MED and in the upcoming EU Regulation for licensing and medical certification of air traffic controllers have been harmonised, where appropriate.

2.2.2 Subpart A

- (a) MED.A.010 Definitions: The introduction of a definition for 'applicant' proposed in the NPA has been deleted, as it did not provide for a better understanding of the applicable provisions, which also refer to applicants for a Part-FCL licence and applicants for a cabin crew attestation.
- (b) MED.A.020 Decrease in medical fitness: The GM has been revised taking into account comments received, e.g. New 'no fly' times have been added for erectile dysfunction medication; strong analgesics have been addressed; advice on the use of stimulants has been added.
- (c) MED.A.025 Obligations of the AeMC, AME, GMP and OHMP: The NPA contained a proposal to delete subparagraph (b)(3) on the applicant's right to a review if assessed as unfit, for reasons explained in the NPA. In response to comments received, this subparagraph has been reinstated, however, with more generic wording and including reference to the procedures of the competent authority.
- (d) MED.A.030 Medical certificates: Changes have been made because the medical certificate is only needed for the issue of the licence (to comply with ICAO Annex 1 point 2.1.1.3) and for using the privileges of the licence exercised (to comply with ICAO Annex 1 point 1.2.4.4).
- (e) MED.A.040 Issue, revalidation and renewal of medical certificates: Subparagraph (f)(2) has been amended to allow the licensing authority to ask for a medical certificate to be returned or destroyed, as appropriate, when corrections are necessary. This will be less burdensome than that proposed in the NPA text, but equally prudent.
- (f) AMC1 MED.A.045 has been deleted as it was a duplication of the text which is already in the Implementing Rule (MED.A.045(a)(5)).
- (g) MED.A.046 Suspension or revocation of medical certificates: The text has been amended to be less burdensome than that proposed in the NPA, as the licensing authority can choose, as appropriate, to ask the pilot to return a suspended medical certificate or not.

2.2.3 Subpart B, Section 1, General

- (a) MED.B.001 Limitations to medical certificates (a)(1) and (b)(1): The text has been amended to clarify the intent, which is to provide the possibility for a fit assessment with appropriate limitations only where the Subpart indicates that a fit assessment may be considered. For cases where the Subpart does not indicate that a fit assessment may be considered, the following



solution has been proposed in a recent package of amendments for Part-ARA (Annex VI to the Aircrew Regulation). The proposal is to reintroduce the former paragraph JAR.FCL 3.046 'special medical circumstances' to Part-ARA. The aim is to allow competent authorities to consider medical advancements and to establish whether a fit assessment may be possible for certain medical conditions for which the existing provisions inevitably lead to an unfit assessment. Under new medical assessment protocols via research, it will be possible to collect specific data in a controlled aviation environment, and to develop specific risk assessments for certain medical conditions.

- (b) MED.B.001 Limitations to medical certificates new (d)(4): In response to comments received, a new limitation encoded 'ORL' (Operating pilot Restriction Limitation) has been introduced (new (d)(4)) to ensure that holders of a class 2 or LAPL medical certificate either operate an aircraft with a safety pilot or without passengers.

2.2.4 Subpart B, Medical requirements for class 1, class 2, and LAPL medical certificates

2.2.4.1 General

- (a) The aim of the rulemaking task was not to substantially change the specific medical requirements, but to apply editorial improvements, to address gaps identified, to ensure consistency of the wording, and to update the rules where feasible. More detailed amendments and technical improvements will be considered in RMT.0424 and RMT.0603 'Regular update of Part-MED', where organ systems will be addressed in individual packages, e.g. 'update cardiovascular system' or 'update respiratory system', etc.
- (b) Many paragraphs on the specific organ systems started with a general subparagraph which stated, for example, 'An applicant shall not suffer from any disorder of the [...] system which is likely to interfere with the safe exercise of the applicable licence(s)'. This subparagraph has been deleted, where appropriate, because it was considered to be a repetition of MED.B.005(a). In some cases, it has been retained as it provides the necessary legal hook for the AMC.

2.2.4.2 LAPL Urine Test

- (a) In response to multiple comments received, the urine test will not be deleted from the IR (MED.B.095(c)). Commentators explained that the test was simple, inexpensive and beneficial for identifying safety relevant conditions or for early detection of metabolic or kidney conditions.

2.2.4.3 Cardiovascular system

- (a) Anticoagulants: In light of the conclusions of the dedicated workshop with specialists in Berlin on 15th November 2013 on 'new' oral anticoagulants (also known as Novel Oral Anticoagulants (NOACs)), the text throughout Part-MED on anticoagulation has been amended to take account of direct-acting oral anticoagulants used as a prophylaxis (medication not needing INR monitoring). GM has been added for Class 1 certificate holders about 'near patient' testing of the INR, and if Class 2 certificate holders also perform 'near patient' testing prior to flight, a fit assessment may be considered without the specified limitation.
- (b) Class 1 and class 2



- (1) Blood pressure: The text for applicants taking medication to control blood pressure has been amended to avoid the expression 'temporary suspension', which, according to comments received, creates an unnecessary administrative burden.
 - (2) Vasovagal syncope: Concerns were expressed by commentators that deletion of 'recurrent' from vasovagal syncope could lead to an unfit assessment for a 'one-off' (insignificant) event. The Agency agrees that a 'one-off' event should not systematically lead to an unfit assessment. The text has been amended to 'vasovagal syncope of uncertain cause', which also reflects 'a single episode of disturbance of consciousness of uncertain cause' in MED.B.065. The AMC has also been further clarified to support the above intent.
 - (3) In the current provisions for LAPL, applicants with symptomatic hypertrophic cardiomyopathy should be assessed as unfit. This has been added for class 1 and 2, as it was missing from the existing rules. In addition, a new subparagraph (b)(4) for other cardiac disorders has been added to the Implementing Rule for class 1 and 2, to support cardiac disorders which are currently addressed in the AMC for class 1 and 2, but which are not included in the current Implementing Rules.
 - (4) Rhythm and conduction disturbances; ventricular pre-excitation: According to AMC1 MED.B.010(I)(9)(i), a fit assessment may be considered without limitation(s) for initial class 1 applicants whose electrophysiological study results are satisfactory. Therefore, AMC1 MED.B.010(I)(9)(ii) has been amended to also allow this for revalidation assessments. In the amended text, if the revalidation assessment does not include an electrophysiological study, a fit assessment may be considered with appropriate limitation(s). For class 2, new GM on ventricular pre-excitation was introduced in the NPA. The associated AMC has been amended, so that if the GM is applied and the electrophysiological study results are satisfactory, limitations may not be necessary. If not, appropriate limitation(s) should be applied.
 - (5) QT prolongation: The AMC text on QT prolongation for class 1 has been clarified and copied for class 2.
 - (6) Brugada pattern: New AMC, based on a proposal from a European military medical service, has been added for the Brugada pattern on electrocardiography.
- (c) Class 2
- (1) Examination: Multiple comments were received in support of the introduction of an ECG at the initial examination for class 2 applicants. Many commentators asked for the ECG to also be performed at the first examination after age 40, in line with the existing rules. Subparagraph (a)(1)(ii) of MED.B.010 has, therefore, been amended to require a standard 12-lead electrocardiogram at the initial examination, then at the first examination after age 40 and then at the first examination after age 50, and every 2 years thereafter. This is in line with the ICAO Annex 1 standard requiring an ECG at the first examination after age 40.
 - (2) Aortic Aneurysm: Comments were received about the proposal to require an OSL for Class 2 certification in all cases regardless of size and position of the aneurysm and whether it



has been treated or not. This was thought to be too restrictive and, therefore, the AMC has been refined so that a fit assessment for a class 2 applicant with an infra-renal abdominal aortic aneurysm of less than 5 cm in diameter, or having had surgery for it, may be considered, without a limitation. This reflects the lower risk of incapacitation associated with an infra-renal abdominal aortic aneurysm compared to a supra-renal or thoracic aortic aneurysm.

- (3) Mitral valve disease: Criteria, based on the AMC for class 1 applicants, for assessing applicants with mitral valve disease has been added to support a harmonised approach for assessments for class 2 applicants.
 - (4) Rhythm and conduction disturbances; anticoagulation: Means to assess applicants for whom anticoagulation is needed after valvular surgery are mentioned in AMC2 MED.B.010(f)(2) and for thromboembolic disorders in AMC2 MED.B.010(g). However, anticoagulation is also frequently used for cardiac rhythm disturbances but is not mentioned in AMC2 MED.B.010(l) in the existing text. The criteria in AMC1 MED.B.010(f)(2) have, therefore, been added as a new subparagraph to AMC2 MED.B.010(l).
 - (5) Heart or heart/lung transplantation: AMC2 MED.B.010(m) has been aligned with the Implementing Rule, which states that applicants for a class 2 medical certificate who have undergone heart or heart/lung transplantation shall be evaluated by a cardiologist and a fit assessment may be considered in consultation with the licensing authority. The text in the NPA was in conflict with this, as it indicated that applicants for a class 2 medical certificate who had undergone heart/lung transplantation should be assessed as unfit.
- (d) LAPL
- (1) Blood pressure: The text for applicants taking medication to control blood pressure has been amended to avoid using the expression 'temporary suspension', which, according to comments received, creates an unnecessary administrative burden.
 - (2) Coronary artery disease; angina pectoris: In the NPA, a significant change was proposed under subparagraph (d)(2) of AMC2 MED.B.095 for LAPL applicants with angina pectoris requiring medication. In response to requests from some members of the Rulemaking group, the NPA contained the possibility to consider a fit assessment for LAPL applicants with angina pectoris after cardiological evaluation. However, the risk of a sudden incapacitation during flight with this condition was seen as unacceptable according to comments received from specialists. The Agency has, therefore, decided not to permit applicants with angina pectoris requiring medication to hold any class of certificate, including the LAPL.
 - (3) Rhythm and conduction disturbances: In the current provisions, class 1 and 2 applicants and cabin crew members who have an implantable defibrillating system are considered to be unfit. This has been added for LAPL applicants, as it is a critical safety issue, as explained by the medical experts in the review group for this rulemaking task.

2.2.4.4 Respiratory system

- (a) Class 1



As the AMC indicates, only applicants with minor impairment of pulmonary function may be considered for a fit assessment. If lung function testing demonstrates only minor impairment and the ECG is normal, there is no need for additional cardiological evaluation. The NPA text in MED.B.015(d) has, therefore, been amended accordingly.

(b) Class 1 and class 2 and LAPL

An amendment to AMC3 MED.C.025(b) related to cabin crew members was proposed in the NPA to allow morphological testing as well as functional testing, when required, on clinical indication, as morphological tests such as MRI scans are known to be an effective investigative tool for assessing respiratory conditions. This change has also been reflected in the provisions for class 1 and 2 and LAPL.

2.2.4.5 Metabolic and endocrine systems

(a) Class 1 and class 2

The AMC for class 1 and 2 has been amended to include a check for sleep apnoea for applicants with a Body Mass Index equal to or more than 35.

2.2.4.6 Haematology

(a) Class 1

Anaemia: It was not the intention to routinely assess applicants with a reduced haemoglobin level as unfit, but further investigation is required. The AMC text has been amended to reflect this, in response to a comment received to this effect.

(b) Class 1 and class 2

Leukaemia: The Implementing Rule has been changed from 'chronic leukaemia' to 'leukaemia', as the AMCs provide fit and unfit criteria for both acute and chronic leukaemia. In addition, this will ensure licensing authority involvement for acute as well as chronic leukaemia.

2.2.4.7 Obstetrics and gynaecology

(a) Class 1 and class 2

Pregnancy: Multiple comments were received regarding the burden of formally suspending the validity of the medical certificate after the 26th week of gestation and subsequently requiring a certificate renewal examination after the pregnancy before the pilot can exercise the privileges of her licence. Therefore, the text in MED.B.045 has been changed to retain the same standards, such as 'recovery' but without mandating physical suspension of the medical certificate during the pregnancy or examination after the end of the pregnancy.

2.2.4.8 Psychiatry

(a) Class 1 and class 2

(1) Terminology: As the expression 'psychoactive' includes medication such as sedatives and opioids, it was decided to use this throughout Part-MED, instead of 'psychotropic'.



- (2) The requirement for referral to, and consultation with, the licensing authority, was duplicated in the Implementing Rules, so the rule has been amended so that it now only remains under the subparagraph (d) on aero-medical assessment.
- (3) According to the existing rules, applicants who use or misuse psychoactive substances or psychoactive medication likely to affect flight safety should be assessed as unfit. Additional text has been added so that if stability on maintenance psychoactive medication is confirmed, a fit assessment with an OML may be considered. If the dosage or type of medication is changed, a further period of unfit assessment should be required until stability is confirmed. This reflects the provisions on disorders due to alcohol or other psychoactive substance use or misuse.
- (4) Deliberate self-harm: The inclusion of reports from the applicant's flight instructor for LAPL has been added and the whole paragraph has been copied to the AMC for class 2, as it was missing in the existing AMC. It is not required for class 1, as this will be covered during the routine proficiency checks.

2.2.4.9 Neurology

- (a) Class 1 and class 2
 - (1) Traumatic injury: The AMC on traumatic injury which was introduced in the NPA has been deleted as it was considered to be covered already under (g) on spinal or peripheral nerve injury.
 - (2) The rule text has been changed to require further evaluation and also licensing authority involvement for applicants diagnosed with migraine or inflammatory central or peripheral nerve disease, as this was missing from the existing provisions. Criteria for assessing applicants diagnosed with migraine have been added to the AMC.
 - (3) Conditions with a high propensity for cerebral dysfunction: This subparagraph has been deleted from the AMC as it is considered to be covered in the Implementing Rule.
- (b) LAPL
 - (1) The AMC has been changed to require further evaluation for applicants diagnosed with migraine, as this was missing from the existing provisions.

2.2.4.10 Visual system

- (a) Class 1
 - (1) Comprehensive eye examination: Subparagraph (b) of the AMC has been amended to 'assessment of mesopic contrast sensitivity', as this is the way it is referred to in (i)(1)(v).
 - (2) Refractive error: The AMC for class 1 applicants with refractive errors has been amended so that there is no difference in the criteria for initial and revalidation and renewal. Additional criteria and examinations have been introduced for applicants with hypermetropia exceeding +5.0 dioptres. One of the criteria is to require corrected distant visual acuity in each eye to be 6/6 or better. As this is more restrictive than the 6/9 required for initial applicants according to the Implementing Rule, it has been moved to the Implementing Rule. This does not directly conflict with ICAO Annex I which sets a



general standard of 6/9 or better. Referral to the licensing authority has been moved from the AMC to the Implementing Rule.

- (b) Class 1 and class 2 and LAPL

GM has been added to provide a comparison of the various reading charts for the visual system.

2.2.4.11 Colour Vision

- (a) Class 1

Colour vision testing: The AMC indicates that the applicant should be a normal trichromat to pass the anomaloscopy test; this would be more restrictive than the Implementing Rule, so it has been added to MED.B.075(b)(2).

- (b) Class 1 and class 2

Colour vision testing: The Colour Assessment and Diagnosis (CAD) test has been added as an acceptable means of testing colour vision for those failing the Ishihara test.

2.2.4.12 Otorhinolaryngology (ENT)

- (a) Class 1 and 2

- (1) There was a change proposed in the NPA text which was unclear. This has been amended to correctly reflect the original intention, i.e. that hearing shall be tested with pure-tone audiometry for class 1 medical certificates, and for class 2 medical certificates when an instrument rating or en route instrument rating is to be added to the licence (MED.B.080(a)(1)(i)).
- (2) 'Sequelae of surgery of the internal or middle ear' has been added to MED.B.080(b) as it was missing from the existing provisions and further examination is appropriate. Criteria for the assessment have been added to the AMC.
- (3) New GM has been introduced for testing 4 000 Hz frequency by means of the pure tone audiogram for early detection of decrease in hearing.

2.2.4.13 Oncology

- (a) LAPL

Intracerebral malignant tumour: Text based on the text in the IR for class 1 and 2 has been added to AMC18 MED.B.095, as it was missing from the existing provisions for LAPL.

2.2.5 Subpart C Requirements for medical fitness of cabin crew

2.2.5.1 General

As indicated in the Terms of Reference for this rulemaking task, the scope of this update of Subpart C is limited to the AMC and GM only.



2.2.5.2 Aero-medical assessments

- (a) Interval between CC aero-medical assessments: The text in AMC1 MED.C.005(b)(2) and (b)(3) has been amended in order to address comments received, including clarification on who can reduce the interval between aero-medical assessments.
- (b) Revalidation assessments undertaken before the expiry date of the medical report: A maximum amount of time permitted for undergoing revalidation assessments in advance of the 'due date' is now specified in AMC1 MED.C.005(b)(3), in line with that set for pilots.
- (c) The GM related to MED.C.025 on the 'content of aero-medical assessments' has been repositioned to directly follow the associated AMC1 MED.C.025, as this is more reader-friendly.

2.2.5.3 Cardiovascular system

- (a) Vasovagal syncope: Concerns were expressed by commentators that deletion of 'recurrent' from vasovagal syncope could lead to an unfit assessment for an 'one-off' (insignificant) event. The Agency agrees that an 'one-off' event should not routinely lead to an unfit assessment. AMC2 MED.C.025(b)(2)(viii) has, therefore, been amended to 'vasovagal syncope of uncertain cause', and a new subparagraph (d) has been introduced with the assessment criteria.
- (b) Blood pressure: The figures in MED.B.010 for class 1 and 2 applicants and the AMC for LAPL applicants defining normal blood pressure have been added to the assessment criteria for cabin crew members (AMC2 MED.C.025(e)(1)). In addition, the text for cabin crew members taking medication to control blood pressure has been amended to avoid using the expression 'temporary suspension', which, according to comments received creates an unnecessary administrative burden (AMC2 MED.C.025(e)(2)).
- (c) In the current provisions for LAPL, applicants with symptomatic hypertrophic cardiomyopathy should be assessed as unfit. This has been added for cabin crew members under AMC2 MED.C.025(g)(3)(ii), as the occurrence of hypertrophic cardiomyopathy is a significant cause of sudden unexpected cardiac death in any age group and a cause of incapacitating cardiac symptoms.

2.2.5.4 Neurology

The text has been changed to require further evaluation for cabin crew members diagnosed with migraine or inflammatory disease of the central or peripheral nervous system, as this was missing from the existing AMC.

2.2.5.5 Visual system

Reference to GM1 MED.B.070 'Comparison of different reading charts' has been added to AMC14 MED.C.025(c).

2.2.5.6 Otorhinolaryngology (ENT)

New GM has been introduced for testing 4 000 Hz frequency by means of the pure tone audiogram for early detection of decrease in hearing.



2.2.5.7 Cabin crew medical report

- (a) Cabin crew medical report general comment: One commentator suggested that the cabin crew member medical report should only be issued if a fit assessment is reached. However, the medical report is intended to show the outcome of the aero-medical assessment, e.g. is fit or unfit. No text change is, therefore, applied.
- (b) Cabin crew medical report format: According to AMC1 MED.C.030(b), the cabin crew medical report should include the State where the aero-medical assessment of the Cabin Crew Attestation (CCA) applicant/holder was conducted. In the NPA, this was defined as 'competent authority name and logo' in the format under GM1 MED.C.030(b). One commentator suggested that the competent authority logo should be deleted, as the competent authority was not responsible for providing the forms. This has, therefore, been changed to 'State of issue'.

2.2.6 Subpart D Requirements for AME, GMP, OHMP

2.2.6.1 Section 1 Aero-Medical Examiners (AME)

- (a) MED.D.010 Requirements for the issue of an AME certificate: One commentator suggested that 'hold a Certificate of Completion, or have other evidence, of specialist medical training' in subparagraph (a) should be changed to 'either hold a Certificate of Completion of specialist training, or a statement from the doctor's national regulatory body that the applicant is eligible to work as a specialist in that country'. The text has been changed to make it clear that the intent was for the applicant to have evidence of completion of specialist medical training.
- (b) MED.D.015(c) Practical training: Comments received indicated that the rule on practical training at an AeMC was difficult to comply with. The Agency established, during a meeting with medical experts, including representation from competent authorities, that the duration of practical training ranged between 2 and 10 days across the EASA Member States. Therefore, a duration of 2 to 4 days has been introduced, in order to keep the minimum and maximum to a reasonable duration.
- (c) MED.D.030 Validity of AME certificates: The wording under (a) has been changed to avoid the expression 'medical practitioner' which may be referred to in different ways across the EASA Member States. The wording of MED.D.010(a) has been replicated instead (i.e. licensed to practise medicine).



3. Resulting Text

The resulting text reflects the proposed changes to the existing Regulation and associated ED Decision, taking into account the results of the review of the comments received on the NPA. Showing changes to the amendments proposed in the NPA would not be reader-friendly as it would show 2 sets of changes. However, changes between the text proposals in the NPA and the CRD are traceable through the summary of comments and responses (Chapter 2) and through the individual comments and responses (Chapter 4).

The text is arranged to show deleted, new or amended text as indicated below:

- (a) deleted text is marked with ~~strike through~~;
- (b) new or amended text is highlighted in grey;
- (c) an ellipsis (...) indicates that the remaining text is unchanged in front of or following the reflected amendment; and
- (d) where the order of a subparagraph has been changed, the affected text is marked with a strike through and the new order only shows changes to substance with strike through and highlights.



3.1. Draft Regulation (Draft Agency Opinion)

ANNEX IV

[PART-MED]

SUBPART A

GENERAL REQUIREMENTS

SECTION 1

General

MED.A.001 Competent authority

For the purpose of this Part, the competent authority shall be:

- (a) for aero-medical centres (AeMC):
 - (1) the authority designated by the Member State where the AeMC has its principal place of business;
 - (2) where the AeMC is located in a third country, the Agency;
- (b) for aero-medical examiners (AME):
 - (1) the authority designated by the Member State where the AMEs have their principal place of practice;
 - (2) if the principal place of practice of an AME is located in a third country, the authority designated by the Member State to which the AME applies for the issue of the AME certificate;
- (c) for general medical practitioners (GMP), the authority designated by the Member State to which the GMP notifies his/her activity;
- (d) for occupational health medical practitioners (OHMP) assessing the medical fitness of cabin crew, the authority designated by the Member State to which the OHMP notifies his/her activity.

MED.A.005 Scope

This Part establishes the requirements for:

- (a) the issue, validity, revalidation and renewal of the medical certificate required for exercising the privileges of a pilot licence or of a student pilot;
- (b) the medical fitness of cabin crew;
- (c) the certification of AMEs; and
- (d) the qualification of GMPs and of occupational health medical practitioners (OHMP).



MED.A.010 Definitions

For the purpose of this Part, the following definitions apply:

- ‘Accredited medical conclusion’ means the conclusion reached by one or more medical experts acceptable to the licensing authority, on the basis of objective and non-discriminatory criteria, for the purposes of the case concerned, in consultation with flight operations or other experts as necessary and including an operational risk assessment,
- ‘Assessment’ means the conclusion on the medical fitness of a person an applicant based on the evaluation of the person’s applicant’s medical history and/or aero-medical examinations as required in this Part and further examinations as necessary, and/or medical tests as necessary such as, but not limited to, ECG, blood pressure measurement, blood testing, X ray,
- ‘Colour safe’ means the ability of an applicant to readily distinguish the colours used in air navigation and to correctly identify aviation coloured lights,
- ‘Eye specialist’ means an ophthalmologist or a vision care specialist qualified in optometry and trained to recognise pathological conditions,
- ‘Examination’ means an inspection, palpation, percussion, auscultation or any other means of investigation especially for diagnosing disease determining the medical fitness to exercise the privileges of the licence, or to carry out cabin crew safety duties,
- ‘Investigation’ means the assessment of a suspected pathological condition of an applicant by means of examinations and tests in order to verify the presence or absence of a medical condition,
- ‘Licensing authority’ means the competent authority of the Member State that issued the licence, or to which a person applies for the issue of a licence, or, when a person has not yet applied for the issue of a licence, the competent authority in accordance with this Part-FCL,
- ‘Limitation’ means a condition placed on the medical certificate, licence or cabin crew medical report that shall be complied with whilst exercising the privileges of the licence, or cabin crew attestation,
- ‘Refractive error’ means the deviation from emmetropia measured in dioptres in the most ametropic meridian, measured by standard methods,
- ‘Significant’ means a degree of a medical condition, the effect of which would prevent the safe exercise of the privileges of the licence or of the cabin crew safety duties.

MED.A.015 Medical confidentiality

All persons involved in aero-medical examinations, assessments and certification shall ensure that medical confidentiality is respected at all times.

MED.A.020 Decrease in medical fitness

- (a) Licence holders shall not exercise the privileges of their licence(s) and related ratings or certificates, and student pilots shall not fly solo, at any time when they:
- (1) are aware of any decrease in their medical fitness which might render them unable to safely exercise those privileges;
 - (2) take or use any prescribed or non-prescribed medication which is likely to interfere with the safe exercise of the privileges of the applicable licence(s);



- (3) receive any medical, surgical or other treatment that is likely to interfere with flight safety the safe exercise of the privileges of the applicable licence(s).
- (b) In addition, licence holders of a medical certificate shall, without undue delay and before exercising the privileges of their licence, seek aero-medical advice when they:
- (1) have undergone a surgical operation or invasive procedure;
 - (2) have commenced the regular use of any medication;
 - (3) have suffered any significant personal injury involving incapacity to function as a member of the flight crew;
 - (4) have been suffering from any significant illness involving incapacity to function as a member of the flight crew;
 - (5) are pregnant;
 - (6) have been admitted to hospital or medical clinic;
 - (7) first require correcting lenses.
- (c) In these cases referred to in (b):
- (1) holders of class 1 and class 2 medical certificates shall seek the advice of an AeMC or AME. The AeMC or AME shall assess their medical fitness of the licence holder and decide whether they are fit to resume the exercise of their privileges;
 - (2) holders of LAPL medical certificates shall seek the advice of an AeMC or AME, or the GMP who signed the medical certificate. The AeMC, AME or GMP shall assess their medical fitness of the licence holders and decide whether they are fit to resume the exercise of their privileges;
- (d) Cabin crew members shall not perform duties on an aircraft and, where applicable, shall not exercise the privileges of their cabin crew attestation when they are aware of any decrease in their medical fitness, to the extent that this condition might render them unable to discharge their safety duties and responsibilities.
- (e) In addition, if in any of the medical conditions specified in (b)(1) to (b)(5) apply, cabin crew members shall, without undue delay, seek the advice of an AME, AeMC, or OHMP as applicable. The AME, AeMC or OHMP shall assess the medical fitness of the cabin crew members and decide whether they are fit to resume their safety duties.

MED.A.025 Obligations of the AeMC, AME, GMP and OHMP

- (a) When conducting aero-medical examinations and/or assessments as required in this Part, the AeMC, AME, GMP and OHMP shall:
- (1) ensure that communication with the person applicant can be established without language barriers;
 - (2) make the person applicant aware of the consequences of providing incomplete, inaccurate or false statements on their medical history;
 - (3) notify the licensing authority, or, in the case of cabin crew attestation holders, notify the competent authority, if the applicant provides incomplete, inaccurate or false statements on their medical history;



- (4) notify the licensing authority if an applicant withdraws the application for a medical certificate at any stage of the process.
- (b) After completion of the aero-medical examinations and/or assessments, the AeMC, AME, GMP and OHMP shall:
- (1) advise the person-applicant whether fit, unfit or referred to the licensing authority, AeMC or AME as applicable;
 - (2) inform the person-applicant of any limitation that may restrict flight training or the privileges of their licence, or cabin crew attestation as applicable;
 - (3) if the person-applicant has been assessed as unfit, inform him/her them of his/her their right of a secondary review of the decision according to the procedures of the competent authority; and
 - (4) in the case of applicants for a medical certificate, submit without delay to the licensing authority a signed, or electronically authenticated, report containing the detailed results of the aero-medical examinations and assessments as required for the class of medical certificate to include the assessment result and a copy of the application form, the examination form, and the medical certificate to the licensing authority; and
 - (5) inform the applicant of their responsibilities in the case of decrease in medical fitness, as specified in MED.A.020.
- (c) Where consultation with the licensing authority is required in accordance with this Part, the AeMC and AME shall follow the procedure established by the competent authority.
- (de) AeMCs, AMEs, GMPs and OHMPs shall maintain records with details of aero-medical examinations and assessments performed in accordance with this Part and their results in accordance with national legislation for a minimum of 10 years, or for a longer period if so determined by national legislation.
- (ed) When required for medical certification and/or oversight functions, AeMCs, AMEs, GMPs and OHMPs shall submit to the medical assessor of the competent authority, upon request, all aero-medical records and reports, and any other relevant information when required for:
- (1) medical certification;
 - (2) oversight functions.

SECTION 2

Requirements for medical certificates

MED.A.030 Medical certificates

- (a) A student pilot shall not fly solo unless that student pilot holds a medical certificate, as required for the relevant licence.
- (b) An applicant for a Part-FCL licence shall hold a medical certificate issued in accordance with Part-MED and appropriate to the licence privileges applied for.
- (c) When exercising the privileges of a licence:
- (1b) Applicants for and holders of a light aircraft pilot licence (LAPL) shall hold at least an LAPL medical certificate;



- (2e) ~~Applicants for and~~ holders of a private pilot licence (PPL), a sailplane pilot licence (SPL), or a balloon pilot licence (BPL) shall hold at least a class 2 medical certificate-;
- (3d) ~~Applicants for and~~ holders of an SPL or a BPL involved in commercial sailplane or balloon flights shall hold at least a class 2 medical certificate-;
- ~~(e) If a night rating is added to a PPL or LAPL, the licence holder shall be colour safe.~~
- (4f) ~~Applicants for and~~ holders of a commercial pilot licence (CPL), a multi-crew pilot licence (MPL), or an airline transport pilot licence (ATPL) shall hold a class 1 medical certificate.
- (de) If a night rating is added to a PPL or LAPL, the licence holder shall be colour safe.
- (eg) If an instrument rating or en route instrument rating is added to a PPL, the licence holder shall undertake pure tone audiometry examinations in accordance with the periodicity and the standard required for class 1 medical certificate holders.
- (fh) A licence holder shall not at any time hold more than one medical certificate issued in accordance with this Part.

MED.A.035 Application for a medical certificate

- (a) Applications for a medical certificate shall be made in a ~~format~~ form and manner established by the competent authority.
- (b) Applicants for a medical certificate shall provide the AeMC, AME or GMP as applicable, with:
- (1) proof of their identity;
 - (2) a signed declaration:
 - (i) of medical facts concerning their medical history;
 - (ii) as to whether they have previously applied for a medical certificate or have undergone an examination for a medical certificate and, if so, by whom and with what result;
 - (iii) as to whether they have ever been assessed as unfit or had a medical certificate suspended or revoked.
- (c) When applying for a revalidation or renewal of the medical certificate, applicants shall present the most recent medical certificate to the AeMC, AME or GMP prior to the relevant examinations.

MED.A.040 Issue, revalidation and renewal of medical certificates

- (a) A medical certificate shall only be issued, revalidated or renewed once the required ~~aero-~~ medical examinations and/or assessments, as applicable, have been completed and the applicant has been assessed as fit ~~assessment is made~~.
- (b) ~~Initial issue:~~ *Initial issue*
- (1) Class 1 medical certificates shall be issued by an AeMC.
 - (2) Class 2 medical certificates shall be issued by an AeMC or an AME.
 - (3) LAPL medical certificates shall be issued by an AeMC, an AME or, if permitted under the national law of the Member State where the licence is issued, by a GMP.



- (c) ~~Revalidation and renewal:~~ *Revalidation and renewal*
- (1) Class 1 and ~~Class 2~~ medical certificates shall be revalidated or renewed by an AeMC or an AME.
 - (2) LAPL medical certificates shall be revalidated or renewed by an AeMC, an AME or, if permitted under the national law of the Member State where the licence is issued, by a GMP.
- (d) The AeMC, AME or GMP shall only issue, revalidate or renew a medical certificate if:
- (1) the applicant has provided them with a complete medical history and, if required by the AeMC, AME or GMP, results of medical examinations and tests conducted by the applicant's ~~doctor~~ *physician* or any medical specialists; and
 - (2) the AeMC, AME or GMP ~~have~~ *has* conducted the aero-medical assessment based on the medical examinations and tests as required for the relevant medical certificate to verify that the applicant complies with all the relevant requirements of this Part.
- (e) The AME, AeMC or, in the case of referral, the licensing authority may require the applicant to undergo additional medical examinations and investigations when clinically indicated before ~~they~~ *the medical certificate is issued, revalidated or renewed* ~~a medical certificate~~.
- (f) The licensing authority may issue or reissue a medical certificate, as applicable, if:
- (1) a case is referred;
 - (2) it has identified that corrections to the information on the certificate are necessary, *in which case the holder shall destroy the incorrect medical certificate or return it to the licensing authority, as determined by the authority.*

MED.A.045 Validity, revalidation and renewal of medical certificates

- (a) *Validity*
- (1) Class 1 medical certificates shall be valid for a period of 12 months.
 - (2) The period of validity of ~~Class 1~~ medical certificates shall be reduced to 6 months for licence holders who:
 - (i) are engaged in single-pilot commercial air transport operations carrying passengers and have reached the age of 40;
 - (ii) have reached the age of 60.
 - (3) Class 2 medical certificates shall be valid for a period of:
 - (i) 60 months until the licence holder reaches the age of 40. A medical certificate issued prior to reaching the age of 40 shall cease to be valid after the licence holder reaches the age of 42;
 - (ii) 24 months between the age of 40 and 50. A medical certificate issued prior to reaching the age of 50 shall cease to be valid after the licence holder reaches the age of 51; and
 - (iii) 12 months after the age of 50.
 - (4) LAPL medical certificates shall be valid for a period of:



- (i) 60 months until the licence holder reaches the age of 40. A medical certificate issued prior to reaching the age of 40 shall cease to be valid after the licence holder reaches the age of 42;
- (ii) 24 months after the age of 40.
- (5) The validity period of a medical certificate, including any associated examination or special investigation, shall be:
 - (i) determined by the age of the applicant ~~at~~ on the date when the ~~aero~~-medical examination takes place; and
 - (ii) calculated from the date of the ~~aero~~-medical examination in the case of initial issue and renewal, and from the expiry date of the previous medical certificate in the case of revalidation.

(b) *Revalidation*

Examinations and/or assessments, as applicable, for the revalidation of a medical certificate may be undertaken up to 45 days prior to the expiry date of the medical certificate.

(c) *Renewal*

- (1) If the holder of a medical certificate does not comply with (b), a renewal examination and/or assessment, as applicable, shall be required.
- (2) In the case of ~~€~~class 1 and ~~€~~class 2 medical certificates:
 - (i) if the medical certificate has expired for less than 2 years, a routine revalidation examination shall be performed;
 - (ii) if the medical certificate has expired for more than 2 years, the AeMC or AME shall only conduct the renewal examination after assessment of the aero-medical records of the applicant;
 - (iii) if the medical certificate has expired for more than 5 years, the examination requirements for initial issue shall apply and the assessment shall be based on the revalidation requirements.
- (3) In the case of LAPL medical certificates, the AeMC, AME or GMP shall assess the medical history of the applicant and perform the aero-medical examinations and/or assessments, as applicable, in accordance with MED.B.005 and MED.B.095.

MED.A.046 Suspension or revocation of medical certificates

- (a) Upon revocation of the medical certificate, the holder shall immediately return the medical certificate to the licensing authority.
- (b) Upon suspension of the medical certificate, the holder shall return the medical certificate to the licensing authority on request of the authority.

MED.A.050 Referral

- (a) If an applicant for a ~~€~~class 1 or ~~€~~class 2 medical certificate is referred to the licensing authority in accordance with MED.-B.001, the AeMC or AME shall transfer the relevant medical documentation to the licensing authority.



- (b) If an applicant for a LAPL medical certificate is referred to an AME or AeMC in accordance with MED.B.001, the GMP shall transfer the relevant medical documentation to the AeMC or AME.



SUBPART B

REQUIREMENTS FOR PILOT MEDICAL CERTIFICATES

SECTION 1

General

MED.B.001 Limitations to medical certificates(a) *Limitations to ~~Class 1 and Class 2~~ medical certificates*

- (1) Where a fit assessment may be considered but if the applicant does not fully comply with the requirements for the relevant class of medical certificate but is considered to be not likely to jeopardise flight the safety exercise of the privileges of the applicable licence, the AeMC or AME shall:
- (i) in the case of applicants for a ~~Class 1~~ medical certificate, refer the decision on fitness of the applicant to the licensing authority as indicated in this Subpart;
 - (ii) in cases where a referral to the licensing authority is not indicated in this Subpart, evaluate whether the applicant is able to perform his/her duties safely when complying with one or more limitations endorsed on the medical certificate, and issue the medical certificate with limitation(s) as necessary;
 - (iii) in the case of applicants for a ~~Class 2~~ medical certificate, evaluate, in consultation with the licensing authority as indicated in this Subpart, whether the applicant is able to perform his/her duties safely when complying with one or more limitations endorsed on the medical certificate, and issue the medical certificate, as necessary with limitation(s) as necessary with limitation(s), in consultation with the licensing authority;
- (2iv) The AeMC or AME may revalidate or renew a medical certificate with the same limitation(s) without referring the applicant to or consulting with the licensing authority.

(b) *Limitations to LAPL medical certificates*

- (1) Where a fitness assessment may be considered, if a GMP, after due consideration of the applicant's medical history, concludes that the applicant does not fully meet the requirements for medical fitness, the GMP shall refer the applicant to an AeMC or AME, except those requiring a limitation related only to the use of corrective lenses or to the period of validity of the medical certificate.
- (2) If an applicant for an LAPL medical certificate has been referred, the AeMC or AME shall give due consideration to MED.B.005 and MED.B.095, evaluate whether the applicant is able to perform their duties safely when complying with one or more limitations endorsed on the medical certificate and issue the medical certificate with limitation(s) as necessary. The AeMC or AME shall always consider the need to restrict the pilot from carrying passengers (Operational Passenger Limitation, OPL).
- (3) The GMP may revalidate or renew an LAPL medical certificate with the same limitation without referring the applicant to an AeMC or AME.

(c) When assessing whether a limitation is necessary, particular consideration shall be given to:

- (1) whether accredited medical conclusion indicates that in special circumstances the applicant's failure to meet any requirement, whether numerical or otherwise, is such that



the exercise of the privileges of the licence applied for is not likely to jeopardise flight safety;

(2) the applicant's ability, skill and experience relevant to the operation to be performed.

(d) *Operational limitation codes*

(1) Operational multi-pilot limitation (OML – Class 1 only)

(i) When the holder of a CPL, ATPL or MPL does not fully meet the requirements for a Class 1 medical certificate and has been referred to the licensing authority, it shall be assessed whether the medical certificate may be issued with an OML 'valid only as or with qualified co-pilot'. This assessment shall be performed by the licensing authority.

(ii) The holder of a medical certificate with an OML shall only operate an aircraft in multi-pilot operations when the other pilot is fully qualified on the relevant class and type of aircraft, is not subject to an OML and has not attained the age of 60 years.

(iii) The OML for Class 1 medical certificates ~~may only~~ shall be initially imposed and only removed by the licensing authority.

(2) Operational Safety Pilot Limitation (OSL – Class 2 and LAPL privileges)

(i) The holder of a medical certificate with an OSL ~~limitation~~ shall only operate an aircraft if another pilot fully qualified to act as pilot-in-command on the relevant class ~~or~~ and type of aircraft is carried on board, the aircraft is fitted with dual controls and the other pilot occupies a seat at the controls.

(ii) The OSL for Class 2 medical certificates may be imposed ~~or~~ and removed by an AeMC or AME in consultation with the licensing authority.

(iii) The OSL for LAPL medical certificates may be imposed and removed by an AeMC or AME.

(3) Operational Passenger Limitation (OPL – Class 2 and LAPL privileges)

(i) The holder of a medical certificate with an OPL ~~limitation~~ shall only operate an aircraft without passengers on board.

(ii) ~~An~~ The OPL for Class 2 medical certificates may be imposed and removed by an AeMC or AME in consultation with the licensing authority.

(iii) ~~An~~ The OPL for a LAPL medical certificates ~~limitation~~ may be imposed and removed by an AeMC or AME.

(4) Operating Pilot Restriction Limitation (ORL – Class 2 and LAPL privileges)

(i) The holder of a medical certificate with an ORL shall only operate an aircraft;

(A) if another pilot fully qualified to act as pilot-in-command on the relevant class and type of aircraft is carried on board, the aircraft is fitted with dual controls and the other pilot occupies a seat at the controls; or

(B) without passengers on board.

(ii) The ORL for class 2 medical certificates may be imposed and removed by an AeMC or AME in consultation with the licensing authority.



(iii) The ORL for LAPL medical certificates may be imposed and removed by an AeMC or AME.

(5) Special Restriction as Specified (SSL)

The SSL on a medical certificate shall be followed by a description of the limitation.

- (e) Any other limitation may be imposed on the holder of a medical certificate if required to ensure flight safety.
- (f) Any limitation imposed on the holder of a medical certificate shall be specified therein.

SECTION 2

Medical requirements for Class 1 and Class 2 medical certificates

MED.B.005 General medical requirements

(a) Applicants for a medical certificate shall be free from any:

- (a1) abnormality, congenital or acquired;
- (b2) active, latent, acute or chronic disease or disability;
- (c3) wound, injury or sequelae from operation;
- (d4) effect or side effect of any prescribed or non-prescribed therapeutic, diagnostic or preventive medication taken;

that would entail a degree of functional incapacity which is likely to interfere with the safe exercise of the privileges of the applicable licence(s) or could render the applicant likely to become suddenly unable to exercise the privileges of the licence(s) safely.

- (b) ~~In cases where the decision on medical fitness of an applicant for a Class 1 medical certificate is referred to the licensing authority, this authority may delegate such a decision to an AeMC, except in cases where an OML is needed.~~
- (c) ~~In cases where the decision on medical fitness of an applicant for a Class 2 medical certificate is referred to the licensing authority, this authority may delegate such a decision to an AeMC or an AME, except in cases where an OSL or OPL is needed.~~

SECTION 2

Medical requirements for class 1 and class 2 medical certificates

MED.B.010 Cardiovascular System

(a) *Examination*

- (1) A standard 12-lead resting electrocardiogram (ECG) and report shall be completed on clinical indication, and:
- (i) for a ~~Class 1~~ class 1 medical certificate, at the ~~initial~~ initial examination ~~for the first issue of a medical certificate~~, then every 5 years until age 30, every 2 years until age 40, annually until age 50, and at all revalidation or renewal examinations thereafter;
- (ii) for a ~~Class 2~~ class 2 medical certificate, at the ~~first initial~~ first initial examination, then at the first examination after age 40 and then every 2 years after ~~at the first examination after~~ age 50, and every 2 years thereafter.



- (2) An Extended cardiovascular assessment shall be required when clinically indicated.
- (3) For a Class 1 medical certificate, an extended cardiovascular assessment shall be completed at the first revalidation or renewal examination after age 65 and every 4 years thereafter.
- (4) For a Class 1 medical certificate, estimation of serum lipids, including cholesterol, shall be required at the initial examination for the first issue of a medical certificate, and at the first examination after having reached the age of 40.

(b) *Cardiovascular System – General*

- (1) Applicants shall not suffer from any cardiovascular disorder which is likely to interfere with the safe exercise of the privileges of the applicable licence(s).
- (12) Applicants for a Class 1 medical certificate with any of the following conditions shall be assessed as unfit:
 - (i) aneurysm of the thoracic or supra-renal abdominal aorta, before or after surgery;
 - (ii) significant functional or symptomatic abnormality of any of the heart valves;
 - (iii) heart or heart/lung transplantation.
- (23) Applicants for a Class 1 medical certificate with an established history or diagnosis of any of the following conditions shall be referred to the licensing authority before a fit assessment may be considered:
 - (i) peripheral arterial disease before or after surgery;
 - (ii) aneurysm of the thoracic or supra-renal abdominal aorta, before or after surgery;
 - (iii) aneurysm of the infra-renal abdominal aorta before or after surgery;
 - (iv) functionally insignificant cardiac valvular abnormalities;
 - (v) after cardiac valve surgery;
 - (vi) abnormality of the pericardium, myocardium or endocardium;
 - (vii) congenital abnormality of the heart, before or after corrective surgery;
 - (viii) recurrent vasovagal syncope of uncertain cause;
 - (ix) arterial or venous thrombosis;
 - (x) pulmonary embolism;
 - (xi) cardiovascular condition requiring systemic anticoagulant therapy.
- (34) Applicants for a Class 2 medical certificate with an established diagnosis of one of the conditions specified in (b)(21) and (b)(32) above shall be assessed evaluated by a cardiologist before a fit assessment can may be considered in consultation with the licensing authority.
- (4) Applicants with cardiac disorders other than those specified in (b)(1) and (b)(2) may be assessed as fit subject to satisfactory cardiological assessment.

(c) *Blood Pressure*

- (1) The blood pressure shall be recorded at each examination.
- (2) The applicant's blood pressure shall be within normal limits.



- (3) Applicants for a ~~Class~~ class 1 medical certificate:
- (i) with symptomatic hypotension; or
 - (ii) whose blood pressure at examination consistently exceeds 160 mmHg systolic and/or 95 mmHg diastolic, with or without treatment;
- shall be assessed as unfit.
- (4) ~~The Applicants initiation who have commenced the use of medication for the control of blood pressure shall require a period of temporary suspension of the medical certificate to establish~~ be assessed as unfit until the absence of significant side effects ~~has been established~~.

(d) *Coronary Artery Disease*

- (1) Applicants for a ~~Class~~ class 1 medical certificate with:
- (i) suspected myocardial ischaemia;
 - (ii) asymptomatic minor coronary artery disease requiring no anti-anginal treatment;
- shall be referred to the licensing authority and undergo cardiological evaluation to exclude myocardial ischaemia before a fit assessment ~~can~~ may be considered.
- (2) Applicants for a ~~Class~~ class 2 medical certificate with any of the conditions detailed in (d)(1) shall undergo cardiological evaluation before a fit assessment ~~can~~ may be considered.
- (3) Applicants with any of the following conditions shall be assessed as unfit:
- (i) myocardial ischaemia;
 - (ii) symptomatic coronary artery disease;
 - (iii) symptoms of coronary artery disease controlled by medication.
- (4) Applicants for the initial issue of a ~~Class~~ class 1 medical certificate with a history or diagnosis of any of the following conditions shall be assessed as unfit:
- (i) myocardial ischaemia;
 - (ii) myocardial infarction;
 - (iii) revascularisation ~~or stenting~~ for coronary artery disease.
- (5) Applicants for a ~~Class~~ class 2 medical certificate who are asymptomatic following myocardial infarction or surgery for coronary artery disease shall undergo satisfactory cardiological evaluation before a fit assessment ~~can~~ may be considered in consultation with the licensing authority. Applicants for the revalidation of a ~~Class~~ class 1 medical certificate shall be referred to the licensing authority.

(e) *Rhythm/Conduction Disturbances*

- (1) Applicants for a ~~Class~~ class 1 medical certificate shall be referred to the licensing authority when they have any significant disturbance of cardiac conduction or rhythm, including any of the following:
- (i) disturbance of supraventricular rhythm, including intermittent or established sinoatrial dysfunction, atrial fibrillation and/or flutter and asymptomatic sinus pauses;
 - (ii) complete left bundle branch block;



- (iii) Mobitz type 2 atrioventricular block;
 - (iv) broad and/or narrow complex tachycardia;
 - (v) ventricular pre-excitation;
 - (vi) asymptomatic QT prolongation;
 - (vii) Brugada pattern on electrocardiography.
- (2) Applicants for a Class 2 medical certificate with any of the conditions detailed in (e)(1) shall undergo satisfactory cardiological evaluation before a fit assessment in consultation with the licensing authority ~~can~~ **may** be considered.
- (3) Applicants with any of the following:
- (i) incomplete bundle branch block;
 - (ii) complete right bundle branch block;
 - (iii) stable left axis deviation;
 - (iv) asymptomatic sinus bradycardia;
 - (v) asymptomatic sinus tachycardia;
 - (vi) asymptomatic isolated uniform supra-ventricular or ventricular ectopic complexes;
 - (vii) first degree atrioventricular block;
 - (viii) Mobitz type 1 atrioventricular block;
- may be assessed as fit in the absence of any other abnormality and subject to satisfactory cardiological evaluation.
- (4) Applicants with a history of:
- (i) ablation therapy;
 - (ii) pacemaker implantation;
- shall undergo satisfactory cardiovascular evaluation before a fit assessment ~~can~~ **may** be considered. Applicants for a Class 1 medical certificate shall be referred to the licensing authority. Applicants for a Class 2 medical certificate shall be assessed in consultation with the licensing authority.
- (5) Applicants with any of the following conditions shall be assessed as unfit:
- (i) symptomatic sinoatrial disease;
 - (ii) symptomatic hypertrophic cardiomyopathy;
 - (iii) complete atrioventricular block;
 - (iv) symptomatic QT prolongation;
 - (v) an automatic implantable defibrillating system;
 - (vi) a ventricular anti-tachycardia pacemaker.

MED.B.015 Respiratory System

- (a) Applicants with significant impairment of pulmonary function shall be assessed as unfit. A fit assessment may be considered once pulmonary function has recovered and is satisfactory.



- (b) For a ~~€~~class 1 medical certificate, applicants are required to undertake pulmonary morphological or functional tests at the initial examination and ~~on clinical indication when clinically indicated.~~
- (c) For a ~~€~~class 2 medical certificate, applicants are required to undertake pulmonary morphological or functional tests ~~on clinical indication when clinically indicated.~~
- (d) Applicants with a history or established diagnosis of:
- (1) asthma requiring medication;
 - (2) active inflammatory disease of the respiratory system;
 - (3) active sarcoidosis;
 - (4) pneumothorax;
 - (5) sleep apnoea syndrome;
 - (6) major thoracic surgery;
 - (7) pneumonectomy;
 - (8) chronic obstructive pulmonary disease
- shall undergo respiratory evaluation with a satisfactory result before a fit assessment ~~can~~ may be considered. Applicants with an established diagnosis of the conditions specified in (d)(3) and (d)(5) shall undergo satisfactory cardiological evaluation before a fit assessment ~~can~~ may be considered.
- (e) Aero-medical assessment:
- (1) applicants for a ~~€~~class 1 medical certificate with any of the conditions detailed in (d) ~~above~~ shall be referred to the licensing authority.
 - (2) applicants for a ~~€~~class 2 medical certificate with any of the conditions detailed in (d) ~~above~~ shall be assessed in consultation with the licensing authority.
- (f) Applicants for a class 1 medical certificate who have undergone a ~~total~~ pneumonectomy shall be assessed as unfit.

MED.B.020 Digestive System

- (a) ~~Applicants shall not possess any functional or structural disease of the gastro-intestinal tract or its adnexa which is likely to interfere with the safe exercise of the privileges of the applicable licence(s).~~
- (ab) Applicants with any sequelae of disease or surgical intervention in any part of the digestive tract or its adnexa likely to cause incapacitation in flight, in particular any obstruction due to stricture or compression shall be assessed as unfit.
- (be) Applicants shall be free from herniae that might give rise to incapacitating symptoms.
- (cd) Applicants with disorders of the ~~gastro-intestinal~~ gastrointestinal system including:
- (1) recurrent dyspeptic disorder requiring medication;
 - (2) pancreatitis;
 - (3) symptomatic gallstones;
 - (4) an established diagnosis or history of chronic inflammatory bowel disease;



- (5) after surgical operation on the digestive tract or its adnexa, including surgery involving total or partial excision or a diversion of any of these organs;

~~shall be assessed as unfit. A fit assessment may be considered after successful treatment or full recovery after surgery and subject to satisfactory gastroenterological evaluation.~~ may be assessed as fit subject to satisfactory gastrointestinal evaluation after successful treatment or full recovery after surgery.

(de) Aero-medical assessment:

- (1) applicants for a ~~€~~class 1 medical certificate with the diagnosis of the conditions specified in (c)(2), (c)(4) and (c)(5) shall be referred to the licensing authority;
- (2) fitness of ~~€~~class 2 applicants with pancreatitis shall be assessed in consultation with the licensing authority.

MED.B.025 Metabolic and Endocrine Systems

~~(a) Applicants shall not possess any functional or structural metabolic, nutritional or endocrine disorder which is likely to interfere with the safe exercise of the privileges of the applicable licence(s).~~

(ab) Applicants with metabolic, nutritional or endocrine dysfunction may be assessed as fit subject to demonstrated stability of the condition and satisfactory aero-medical evaluation.

(be) *Diabetes mellitus*

- (1) Applicants with diabetes mellitus requiring insulin shall be assessed as unfit.
- (2) Applicants with diabetes mellitus not requiring insulin shall be assessed as unfit unless it can be demonstrated that blood sugar control has been achieved and is stable.

(cd) Aero-medical assessment:

- (1) applicants for a ~~€~~class 1 medical certificate requiring medication other than insulin for blood sugar control shall be referred to the licensing authority;
- (2) fitness of ~~€~~class 2 applicants requiring medication other than insulin for blood sugar control shall be assessed in consultation with the licensing authority.

MED.B.030 Haematology

~~(a) Applicants shall not possess any haematological disease which is likely to interfere with the safe exercise of the privileges of the applicable licence(s).~~

(ab) For a ~~€~~class 1 medical certificate, haemoglobin shall be tested at each examination for the issue of a medical certificate.

(be) Applicants with a haematological condition, such as:

- (1) coagulation, haemorrhagic or thrombotic disorder;
- (2) ~~chronic~~ leukaemia;

may be assessed as fit subject to satisfactory aero-medical evaluation.

(cd) Aero-medical assessment:

- (1) applicants for a ~~€~~class 1 medical certificate with ~~one~~ any of the conditions specified in (eb) ~~above~~ shall be referred to the licensing authority;



- (2) fitness of Class 2 applicants with ~~one~~ any of the conditions specified in (e) above shall be assessed in consultation with the licensing authority.
- (de) Class 1 applicants with one of the haematological conditions specified below shall be referred to the licensing authority:
- (1) abnormal haemoglobin, including, but not limited to anaemia, erythrocytosis polycythaemia or haemoglobinopathy;
 - (2) significant lymphatic enlargement;
 - (3) enlargement of the spleen.

MED.B.035 Genitourinary System

- (a) ~~Applicants shall not possess any functional or structural disease of the renal or genitourinary system or its adnexa which is likely to interfere with the safe exercise of the privileges of the applicable licence(s).~~
- (ab) Urinalysis shall form part of every aero-medical examination. The urine shall contain no abnormal element considered to be of pathological significance.
- (be) Applicants with any sequelae of disease or surgical procedures on the genitourinary system or its adnexa kidneys or the urinary tract likely to cause incapacitation, in particular any obstruction due to stricture or compression, shall be assessed as unfit.
- (cd) Applicants with a genitourinary disorder, such as:
- (1) renal disease;
 - (2) one or more urinary calculi, or a history of renal colic;
- may be assessed as fit subject to satisfactory renal and urological evaluation as applicable.
- (de) Applicants who have undergone a major surgical operation in the genitourinary system or its adnexa urinary apparatus involving a total or partial excision or a diversion of its organs shall be assessed as unfit, and be re-assessed a After full recovery, before a fit assessment can may be considered. Applicants for a Class 1 medical certificate shall be referred to the licensing authority. for the re-assessment.

MED.B.040 Infectious Disease

- (a) Applicants shall have no established medical history or clinical diagnosis of any infectious disease which is likely to interfere with the safe exercise of the privileges of the applicable licence(s) held.
- (b) Applicants who are HIV positive may be assessed as fit subject to satisfactory aero-medical evaluation. Applicants for a Class 1 medical certificate shall be referred to the licensing authority.

MED.B.045 Obstetrics and Gynaecology

- (a) ~~Applicants shall not possess any functional or structural obstetric or gynaecological condition which is likely to interfere with the safe exercise of the privileges of the applicable licence(s).~~
- (ab) Applicants who have undergone a major gynaecological operation shall be assessed as unfit until full recovery.



(be) *Pregnancy*

- (1) ~~In the case of pregnancy, if the AeMC or AME considers that the licence holder is fit to exercise her privileges, he/she shall limit the validity period of the medical certificate to the end of the 26th week of gestation. After this point, the certificate shall be suspended. The suspension shall be lifted after full recovery following the end of the pregnancy.~~
- (2) ~~Holders of Class 1 medical certificates shall only exercise the privileges of their licences until the 26th week of gestation with an OML. Notwithstanding MED. B.001 in this case, the OML may be imposed and removed by the AeMC or AME.~~

In the case of pregnancy, an applicant may continue to exercise her privileges until the end of the 26th week of gestation, only if the AeMC or AME considers that the licence holder is fit to do so. For holders of a class 1 medical certificate, an OML shall apply. Notwithstanding MED.B.001 in this case, the OML may be imposed and removed by the AeMC or AME. An applicant may resume exercising her privileges after recovery following the end of the pregnancy.

MED.B.050 Musculoskeletal System

- (a) Applicants shall not possess any abnormality of the bones, joints, muscles or tendons, congenital or acquired which is likely to interfere with the safe exercise of the privileges of the applicable licence(s).
- (b) An applicant shall have sufficient sitting height, arm and leg length and muscular strength for the safe exercise of the privileges of the applicable licence(s).
- (c) An applicant shall have satisfactory functional use of the musculoskeletal system to enable them to safely exercise of the privileges of the applicable licence(s). In case of doubt, Fitness of the applicants for a class 1 medical certificate shall be referred to assessed-in consultation with the licensing authority and applicants for a class 2 medical certificate shall be assessed in consultation with the licensing authority.

MED.B.055 Psychiatry

- (a) ~~Applicants shall have no established medical history or clinical diagnosis of any psychiatric disease or disability, condition or disorder, acute or chronic, congenital or acquired, which is likely to interfere with the safe exercise of the privileges of the applicable licence(s).~~
- (ab) Applicants with a mental or behavioural disorder due to use or misuse of alcohol or other use or abuse of psychotropic psychoactive substances shall be assessed as unfit pending recovery and freedom from psychoactive substance use or misuse and subject to satisfactory psychiatric evaluation after successful treatment. Applicants for a Class 1 medical certificate shall be referred to the licensing authority. Fitness of Class 2 applicants shall be assessed in consultation with the licensing authority.
- (be) Applicants with a psychiatric condition such as:
- (1) mood disorder;
 - (2) neurotic disorder;
 - (3) personality disorder;
 - (4) mental or behavioural disorder;



shall undergo satisfactory psychiatric evaluation before a fit assessment ~~can~~ **may** be ~~made~~ **considered**.

- (~~cd~~) Applicants with a history of a single or repeated acts of deliberate self-harm shall be assessed as unfit. ~~Applicants shall undergo satisfactory psychiatric evaluation before a fit assessment can be considered.~~ **A fit assessment may be considered after satisfactory psychiatric evaluation.**
- (~~de~~) Aero-medical assessment:
- (1) applicants for a ~~C~~ **E** class 1 medical certificate with ~~one~~ **any** of the conditions detailed in (~~ba~~), (~~eb~~) or (~~dc~~) ~~above~~ shall be referred to the licensing authority;
 - (2) fitness of ~~C~~ **E** class 2 applicants with ~~one~~ **any** of the conditions detailed in (~~ba~~), (~~eb~~) or (~~dc~~) ~~above~~ shall be assessed in consultation with the licensing authority.
- (~~ef~~) Applicants with an established history or clinical diagnosis of schizophrenia, schizotypal or delusional disorder shall be assessed as unfit.

MED.B.060 Psychology

- (a) Applicants shall have no established psychological deficiencies, which are likely to interfere with the safe exercise of the privileges of the applicable licence(s).
- (b) A psychological evaluation may be required as part of, or complementary to, a specialist psychiatric or neurological examination.

MED.B.065 Neurology

- (~~a~~) ~~Applicants shall have no established medical history or clinical diagnosis of any neurological condition which is likely to interfere with the safe exercise of the privileges of the applicable licence(s).~~
- (~~ab~~) Applicants with an established history or clinical diagnosis of:
- (1) epilepsy, **except in the cases mentioned in (b)(1) and (b)(2);**
 - (2) recurring episodes of disturbance of consciousness of uncertain cause;
- shall be assessed as unfit.
- (~~be~~) Applicants with an established history or clinical diagnosis of:
- (1) epilepsy without recurrence after age 5;
 - (2) epilepsy without recurrence and off all treatment for more than 10 years;
 - (3) epileptiform EEG abnormalities and focal slow waves;
 - (4) progressive or non-progressive disease of the nervous system;
 - (5) **inflammatory disease of the central or peripheral nervous system;**
 - (6) **migraine;**
 - (~~7~~) a single episode of disturbance of consciousness of uncertain cause;
 - (~~8~~) loss of consciousness after head injury;
 - (~~9~~) penetrating brain injury;
 - (~~10~~) spinal or peripheral nerve injury;



- (11) disorders of the nervous system due to vascular deficiencies including haemorrhagic and ischaemic events

shall undergo further evaluation before a fit assessment can may be considered. Applicants for a Class 1 medical certificate shall be referred to the licensing authority. Fitness of Class 2 applicants shall be assessed in consultation with the licensing authority.

MED.B.070 Visual System

- (a) ~~Applicants shall not possess any abnormality of the function of the eyes or their adnexa or any active pathological condition, congenital or acquired, acute or chronic, or any sequelae of eye surgery or trauma, which is likely to interfere with the safe exercise of the privileges of the applicable licence(s).~~
- (ab) *Examination*
- (1) For a Class 1 medical certificate:
- (i) a comprehensive eye examination shall form part of the initial examination and shall be undertaken when clinically indicated and periodically depending on the refraction and the functional performance of the eye; and
- (ii) a routine eye examination shall form part of all revalidation and renewal examinations.
- (2) For a Class 2 medical certificate:
- (i) a routine eye examination shall form part of the initial and all revalidation and renewal examinations; and
- (ii) a comprehensive eye examination shall be undertaken when clinically indicated.
- (c) ~~Distant visual acuity, with or without correction, shall be:~~
- (1) ~~in the case of Class 1 medical certificates, 6/9 (0,7) or better in each eye separately and visual acuity with both eyes shall be 6/6 (1,0) or better;~~
- (2) ~~in the case of Class 2 medical certificates, 6/12 (0,5) or better in each eye separately and visual acuity with both eyes shall be 6/9 (0,7) or better. An applicant with substandard vision in one eye may be assessed as fit in consultation with the licensing authority subject to satisfactory ophthalmic assessment;~~
- (3) ~~applicants for an initial Class 1 medical certificate with substandard vision in one eye shall be assessed as unfit. At revalidation, applicants with acquired substandard vision in one eye shall be referred to the licensing authority and may be assessed as fit if it is unlikely to interfere with safe exercise of the licence held.~~
- (d) ~~An applicant shall be able to read an N5 chart (or equivalent) at 30-50 cm and an N14 chart (or equivalent) at 100 cm, with correction, if prescribed.~~
- (e) ~~Applicants for a Class 1 medical certificate shall be required to have normal fields of vision and normal binocular function.~~
- (f) ~~Applicants who have undergone eye surgery may be assessed as fit subject to satisfactory ophthalmic evaluation.~~
- (g) ~~Applicants with a clinical diagnosis of keratoconus may be assessed as fit subject to a satisfactory examination by an ophthalmologist. Applicants for a Class 1 medical certificate shall be referred to the licensing authority.~~



- (h) Applicants with:
- (1) astigmatism;
 - (2) anisometropia;
- may be assessed as fit subject to satisfactory ophthalmic evaluation.
- (i) Applicants with diplopia shall be assessed as unfit.
- (j) ~~Spectacles and contact lenses. If satisfactory visual function is achieved only with the use of correction:~~
- (1)
 - (i) ~~for distant vision, spectacles or contact lenses shall be worn whilst exercising the privileges of the applicable licence(s);~~
 - (ii) ~~for near vision, a pair of spectacles for near use shall be kept available during the exercise of the privileges of the licence;~~
 - (2) ~~a spare set of similarly correcting spectacles shall be readily available for immediate use whilst exercising the privileges of the applicable licence(s);~~
 - (3) ~~the correction shall provide optimal visual function, be well tolerated and suitable for aviation purposes;~~
 - (4) ~~if contact lenses are worn, they shall be for distant vision, monofocal, non-tinted and well tolerated;~~
 - (5) ~~applicants with a large refractive error shall use contact lenses or high index spectacle lenses;~~
 - (6) ~~no more than one pair of spectacles shall be used to meet the visual requirements;~~
 - (7) ~~orthokeratological lenses shall not be used.~~
- (be) Visual acuity
- (1) Class 1 medical certificates:
 - (i) Distant visual acuity, with or without correction, shall be 6/9 (0,7) or better in each eye separately and visual acuity with both eyes shall be 6/6 (1,0) or better.
 - (ii) Initial examination: Applicants with substandard vision in one eye shall be assessed as unfit.
 - (iii) Revalidation and renewal examinations: Notwithstanding (b)(1)(i), applicants with acquired substandard vision in one eye or acquired monocular vision shall be referred to the licensing authority and may be assessed as fit subject to a satisfactory ophthalmological evaluation.
 - (2) Class 2 medical certificates:
 - (i) Distant visual acuity, with or without correction, shall be 6/12 (0,5) or better in each eye separately and visual acuity with both eyes shall be 6/9 (0,7) or better.
 - (ii) Notwithstanding (b)(2)(i), applicants with substandard vision in one eye or monocular vision may be assessed as fit in consultation with the licensing authority and subject to a satisfactory ophthalmic evaluation.
 - (3) Applicants shall be able to read an N5 chart or equivalent at 30-50 cm and an N14 chart or equivalent at 100 cm, if necessary with correction.



(ch) Refractive error and anisometropia

- (1) Applicants with refractive errors or anisometropia may be assessed as fit subject to satisfactory ophthalmic evaluation.
- (2) Notwithstanding (c)(1), applicants for a class 1 medical certificate with:
 - (i) myopia exceeding -6.0 dioptres;
 - (ii) astigmatism exceeding 2.0 dioptres;
 - (iii) anisometropia exceeding 2.0 dioptresshall be referred to the licensing authority and may be assessed as fit subject to a satisfactory ophthalmological evaluation.
- (2) Notwithstanding (c)(1), applicants for a class 1 medical certificate with hypermetropia exceeding $+5.0$ dioptres shall be referred to the licensing authority and may be assessed as fit subject to a satisfactory ophthalmological evaluation provided there are adequate fusional reserves, normal intraocular pressures and anterior angles and no significant pathology has been demonstrated. Notwithstanding (b)(1)(i), corrected visual acuity in each eye shall be $6/6$ or better.
- (4) Applicants with a clinical diagnosis of keratoconus may be assessed as fit subject to a satisfactory examination by an ophthalmologist. Applicants for a class 1 medical certificate shall be referred to the licensing authority.

(dei) Binocular function

- (1) Applicants for a class 1 medical certificate shall have normal binocular function.
- (2) Applicants with diplopia shall be assessed as unfit.

(e) Visual fields

Applicants for a class 1 medical certificate shall have normal fields of vision.

(f) Eye surgery

Applicants who have undergone eye surgery shall be assessed as unfit until full recovery of visual function. A fit assessment may be considered subject to satisfactory ophthalmological evaluation.

(gj) Spectacles and contact lenses

- (1) If satisfactory visual function is achieved only with the use of correction, the spectacles or contact lenses shall provide optimal visual function, be well-tolerated and suitable for aviation purposes.
- (2) No more than one pair of spectacles shall be used to meet the visual requirements when exercising the privileges of the applicable licence(s).
- (3) For distant vision, spectacles or contact lenses shall be worn when exercising the privileges of the applicable licence(s).
- (4) For near vision, a pair of spectacles shall be kept available when exercising the privileges of the applicable licence(s).
- (5) A spare set of similarly correcting spectacles, for distant or near vision as applicable, shall be readily available for immediate use when exercising the privileges of the applicable licence(s).



- (6) If contact lenses are worn when exercising the privileges of the applicable licence(s), they shall be for distant vision, monofocal, and non-tinted and well-tolerated.
- (7) Applicants with a large refractive error shall use contact lenses or high-index spectacle lenses.
- (8) Orthokeratological lenses shall not be used.

MED.B.075 Colour vision

- (a) Applicants shall be required to demonstrate the ability to perceive readily perceive the colours that are necessary for the safe performance of duties exercise of the privileges of the applicable licence(s).
- ~~(b) Examination~~
 - ~~(1) Applicants shall pass the Ishihara test for the initial issue of a medical certificate.~~
 - ~~(2) Applicants who fail to pass in the Ishihara test shall undergo further colour perception testing to establish whether they are colour safe.~~
- ~~(c) In the case of Class 1 medical certificates, applicants shall have normal perception of colours or be colour safe. Applicants who fail further colour perception testing shall be assessed as unfit. Applicants for a Class 1 medical certificate shall be referred to the licensing authority.~~
- ~~(d) In the case of Class 2 medical certificates, when the applicant does not have satisfactory perception of colours, his/her flying privileges shall be limited to daytime only.~~

(b) Examination and assessment

- (1) Applicants shall pass the Ishihara test for the initial issue of a medical certificate.
- (2) Class 1 medical certificates:
 - (i) Notwithstanding (b)(1), applicants for a class 1 medical certificate who do not pass the Ishihara test shall be referred to the licensing authority and shall undergo further colour perception testing to establish whether they are colour safe.
 - (ii) Applicants for a class 1 medical certificate shall be normal trichromats or shall be colour safe.
 - (iii) Applicants who fail further colour perception testing shall be assessed as unfit.
- (3) Class 2 medical certificates:
 - (i) Notwithstanding (b)(1), applicants for a class 2 medical certificate who do not pass the Ishihara test shall undergo further colour perception testing to establish whether they are colour safe.
 - (ii) Applicants who do not have satisfactory perception of colours shall be limited to exercising the privileges of the applicable licence(s) in daytime only.

MED.B.080 ~~Otorhino-laryngology~~ Otorhinolaryngology (ENT)

- ~~(a) Applicants shall not possess any abnormality of the function of the ears, nose, sinuses or throat, including oral cavity, teeth and larynx, or any active pathological condition, congenital or acquired, acute or chronic, or any sequelae of surgery or trauma which is likely to interfere with the safe exercise of the privileges of the applicable licence(s).~~
- ~~(b) Hearing shall be satisfactory for the safe exercise of the privileges of the applicable licence(s).~~



(ae) Examination

- (1) Hearing shall be tested at all examinations.
 - (i) ~~In the case of~~ For a ~~Class 1~~ Class 1 medical certificates, and for a ~~Class 2~~ Class 2 medical certificates, when an instrument rating or en route instrument rating is to be added to the licence held, hearing shall be tested with ~~pure~~ pure-tone audiometry at the initial examination and, at subsequent revalidation or renewal examinations, then every 5 years until the age 40 and every 2 years thereafter.
 - (ii) When tested on a pure-tone audiometer, initial applicants shall not have a hearing loss of more than 35 dB at any of the frequencies 500, 1 000 or 2 000 Hz, or more than 50 dB at 3 000 Hz, in either ear separately. Applicants for revalidation or renewal, with greater hearing loss shall demonstrate satisfactory functional hearing ability.
 - (iii) ~~Applicants with hypoacusis shall demonstrate satisfactory functional hearing ability.~~
- (2) A comprehensive ear, nose and throat examination shall be undertaken for the initial issue of a ~~Class 1~~ Class 1 medical certificate and periodically thereafter when clinically indicated.

(be) Applicants for a ~~Class 1~~ Class 1 medical certificate with:

- (1) hypoacusis;
- (2) an active pathological process, ~~acute or chronic~~, of the internal or middle ear;
- (3) unhealed perforation or dysfunction of the tympanic membrane(s);
- (4) dysfunction of the Eustachian tube(s);
- (5) disturbance of vestibular function;
- (6) significant restriction of the nasal passages;
- (7) sinus dysfunction;
- (8) significant malformation or significant, ~~acute or chronic~~ infection of the oral cavity or upper respiratory tract;
- (9) significant disorder of speech or voice;
- (10) any sequelae of surgery of the internal or middle ear

shall undergo further ~~medical examination and assessment~~ to establish that the condition does not interfere with the safe exercise of the privileges of the applicable licence(s) held.

(ce) Aero-medical assessment:

- (1) applicants for a ~~Class 1~~ Class 1 medical certificate with ~~the disturbance of vestibular function~~ a medical condition specified in (b)(1), (b)(4), or (b)(5) shall be referred to the licensing authority;
- (2) fitness of ~~Class 2~~ Class 2 applicants with ~~the disturbance of vestibular function~~ a medical condition specified in (b)(4) or (b)(5) shall be assessed in consultation with the licensing authority.



- (3) fitness of class 2 applicants for an instrument rating or en route instrument rating with the condition specified in (b)(1) shall be assessed in consultation with the licensing authority.

MED.B.085 Dermatology

Applicants shall have no established dermatological condition likely to interfere with the safe exercise of the privileges of the applicable licence(s) held.

MED.B.090 Oncology

- (a) Applicants shall have no established primary or secondary malignant disease likely to interfere with the safe exercise of the privileges of the applicable licence(s).
- (b) ~~After treatment for~~ Applicants with primary or secondary malignant disease, applicants shall undergo satisfactory oncological evaluation before a fit assessment ~~can~~ may be made considered. Applicants for a ~~Class 1 medical certificate~~ applicants shall be referred to the licensing authority. Fitness of ~~Class 2~~ applicants shall be assessed in consultation with the licensing authority.
- (c) Applicants with an established history or clinical diagnosis of an intracerebral malignant tumour shall be assessed as unfit.



SECTION 3***Specific requirements for LAPL medical certificates*****MED.B.095 Medical examination and/or assessment of applicants for LAPL medical certificates**

- (a) An applicant for a LAPL medical certificate shall be assessed based on aero-medical best practice.
- (b) Special attention shall be given to the applicant's complete medical history.
- (c) The initial assessment, all subsequent re-assessments after age 50 and assessments in cases where the medical history of the applicant is not available to the examiner shall include at least the following:
 - (1) clinical examination;
 - (2) blood pressure;
 - (3) urine test;
 - (4) vision;
 - (5) hearing ability.
- (d) After the initial assessment, subsequent re-assessments until age 50 shall include:
 - (1) an assessment of the LAPL holder's medical history; and
 - (2) the items specified in ~~paragraph~~ (c) as deemed necessary by the AeMC, AME or GMP in accordance with aero-medical best practice.



SUBPART D

**AERO-MEDICAL EXAMINERS (AME), GENERAL MEDICAL PRACTITIONERS (GMP),
OCCUPATIONAL HEALTH MEDICAL PRACTITIONERS (OHMP)**

SECTION 1

*Aero-Medical Examiners***MED.D.001 Privileges**

- (a) The privileges of an AME are to issue, revalidate and renew Part-MED class 2 medical certificates and Part-MED LAPL medical certificates, and to conduct the relevant medical examinations and assessments.
- (b) Holders of an AME certificate may apply for an extension of their privileges to include medical examinations for the revalidation and renewal of Part-MED class 1 medical certificates, if they comply with the requirements in MED.D.015.
- (c) The privileges of a holder of an AME certificate referred to in (a) and (b) include the privileges to conduct cabin crew members' aero-medical examinations and assessments and to provide the related cabin crew members' medical reports, as applicable, in accordance with Part-MED.
- (de) The scope of the privileges of the AME, and any condition thereof, shall be specified in the certificate.
- (e) An AME certificate holder shall not at any time hold more than one AME certificate issued in accordance with this Part.
- (fd) Holders of an AME certificate ~~as an AME~~ shall not undertake aero-medical examinations and assessments in a Member State other than the Member State that issued their AME certificate ~~as an AME~~, unless they have:
 - (1) been granted access by the host Member State to exercise their professional activities as a specialised doctor;
 - (2) informed the competent authority of the host Member State of their intention to conduct aero-medical examinations and assessments, and to issue medical certificates within the scope of their privileges as AME; and
 - (3) received a briefing from the competent authority of the host Member State.

MED.D.005 Application

- (a) An Application for an AME certificate, or for an extension of the privileges of the AME certificate, ~~as an AME~~ shall be made in a form and manner specified by the competent authority.
- (b) Applicants for an AME certificate shall provide the competent authority with:
 - (1) personal details and professional address;
 - (2) documentation demonstrating that they comply with the requirements established in MED.D.010, including a ~~certificate~~ evidence of successful completion of the training course in aviation medicine appropriate to the privileges they apply for;



- (3) a written declaration that the AME will issue medical certificates on the basis of the requirements of this Part.
- (c) When the AME undertakes aero-medical examinations in more than one location, they shall provide the competent authority with relevant information regarding all practice locations and practice facilities.

MED.D.010 Requirements for the issue of an AME certificate

Applicants for an AME certificate with the privileges for the initial issue, revalidation and renewal of Part-MED class 2 medical certificates and Part-MED LAPL medical certificates shall:

- (a) be fully qualified and licensed for the practice of medicine and have evidence of completion hold a Certificate of Completion of specialist medical training;
- (b) have undertaken successfully completed a basic training course in aviation medicine, including practical training in the examination methods and aero-medical assessments;
- (c) demonstrate to the competent authority that they:
- (1) have adequate facilities, procedures, documentation and functioning equipment suitable for aero-medical examinations; and
 - (2) have in place the necessary procedures and conditions to ensure medical confidentiality.

MED.D.015 Requirements for the extension of privileges

Applicants for an AME certificate extending their privileges to the revalidation and renewal of class 1 medical certificates shall hold a valid certificate as an AME and have:

- (a) conducted at least 30 examinations for the issue, revalidation or renewal of Part-MED class 2 medical certificates over a period of no more than 5-3 years preceding the application;
- (b) undertaken successfully completed an advanced training course in aviation medicine, including practical training in the examination methods and aero-medical assessments; and
- (c) undergone practical training of a duration of 2 to 4 days at an AeMC or under supervision of the licensing competent authority.

MED.D.020 Training courses in aviation medicine

- (a) Training courses in aviation medicine shall be approved by the competent authority of the Member State where the organisation providing it training provider has its principal place of business. The organisation providing the course training provider shall demonstrate that the course syllabus is adequate contains the learning objectives to acquire the necessary competencies and that the persons in charge of providing the training have adequate knowledge and experience.
- (b) Except in the case of refresher training, the courses shall be concluded by a written examination on the subjects included in the course content.
- (c) The organisation providing the course training provider shall issue a certificate of completion to applicants when they have obtained a pass in the examination.



MED.D.025 Changes to the AME certificate

- (a) AMEs shall notify the competent authority of the following ~~changes~~ ~~circumstances~~ which could affect their certificate:
- (1) the AME is subject to disciplinary proceedings or investigation by a medical regulatory body;
 - (2) there are ~~any~~ changes to the conditions ~~on~~ ~~under~~ which the certificate was granted, including the content of the statements provided with the application;
 - (3) the requirements for the issue of the AME certificate are no longer met;
 - (4) there is a change ~~of~~ ~~to~~ the aero-medical examiner's practice location(s) or correspondence address.
- (b) Failure to inform the competent authority shall result in the suspension or revocation of the privileges of the AME certificate, on the basis of the decision of the competent authority that suspends or revokes the AME certificate.

MED.D.030 Validity of AME certificates

An AME certificate shall be ~~issued~~ ~~valid~~ for a period not exceeding 3 years. It shall be revalidated ~~subject to~~ ~~providing~~ the holder:

- (a) ~~continuing~~ ~~continues~~ to fulfil the general conditions required for medical practice and ~~maintaining~~ ~~maintains~~ their licence for the practice of medicine ~~registration as a medical practitioner according to national law~~;
- (b) ~~undertaking~~ ~~has undertaken~~ refresher training in aviation medicine within the last 3 years;
- (c) ~~having~~ ~~has~~ performed at least 10 aero-medical examinations every year;
- (d) ~~remaining~~ ~~remains~~ in compliance with the terms of their certificate; and
- (e) ~~exercising their~~ ~~exercises~~ their AME privileges in accordance with this Part.

SECTION 2**General Medical Practitioners (GMPs)****MED.D.035 Requirements for general medical practitioners**

~~(a)~~ GMPs shall act as AMEs for issuing LAPL medical certificates only:

- ~~(a1)~~ if they exercise their activity in a Member State where GMPs have ~~appropriate~~ access to the full medical records of applicants; ~~and~~
- ~~(b2)~~ in accordance with any additional requirements established under national law;;
- ~~(cb)~~ ~~In order to issue LAPL medical certificates, general medical practitioners (GMP) shall be if they are~~ fully qualified and licensed for the practice of medicine in accordance with national law; ~~and~~
- ~~(e)~~ ~~GMPs acting as AMEs shall notify their activity to the competent authority.~~
- ~~(d)~~ they have notified the competent authority before starting such activity.

SECTION 3

Occupational Health Medical Practitioners (OHMPs)

MED.D.040 Requirements for occupational health medical practitioners

~~OHMPs shall only conduct aero-medical assessments of cabin crew if:~~

- ~~(a) the competent authority is satisfied that the relevant national occupational health system can ensure compliance with the applicable requirements of this Part;~~
- ~~(b) they are licensed in the practice of medicine and qualified in occupational medicine in accordance with national law; and~~
- ~~(c) have acquired knowledge in aviation medicine as relevant to the operating environment of cabin crew.~~

In Member States where the competent authority is satisfied that the relevant national occupational health system can ensure compliance with the applicable requirements of this Part, OHMPs may conduct aero-medical assessments of cabin crew if:

- (a) they are fully qualified and licensed in the practice of medicine and qualified in occupational medicine;
- (b) the in-flight working environment and safety duties of the cabin crew were included in their occupational medicine qualification syllabus, or other training or operational experience; and
- (c) they have notified the competent authority before starting such activity.



3.2. Draft AMC and GM (Draft ED Decision)

SUBPART A

General requirements

Section 1

General

AMC1 MED.A.015 Medical confidentiality

To ensure medical confidentiality, all medical reports and records should be securely held with accessibility restricted to personnel authorised by the medical assessor.

~~AMC1 MED.A.020 Decrease in medical fitness~~

~~If in any doubt about their fitness to fly, use of medication or treatment:~~

- ~~(a) holders of class 1 or class 2 medical certificates should seek the advice of an AeMC or AME;~~
- ~~(b) holders of LAPL medical certificates should seek the advice of an AeMC, AME, or of the GMP who issued the holder's medical certificate;~~
- ~~(c) suspension of exercise of privileges: holders of a medical certificate should seek the advice of an AeMC or AME when they have been suffering from any illness involving incapacity to function as a member of the flight crew for a period of at least more than 21 days.~~

GM1 MED.A.020 Decrease in medical fitness

MEDICATION — GUIDANCE FOR PILOTS AND CABIN CREW MEMBERS

- (a) Any medication can cause side effects, some of which may impair the safe performance of flying duties. Equally, symptoms of colds, sore throats, diarrhoea and other abdominal upsets may cause little or no problem whilst on the ground but may distract the pilot or cabin crew member and degrade their performance whilst on duty. The in-flight environment may also increase the severity of symptoms which may only be minor whilst on the ground. Therefore, one issue with medication and flying is the underlying condition and, in addition, the symptoms may be compounded by the side effects of the medication prescribed or bought over the counter for treatment. This guidance material provides some help to pilots and cabin crew in deciding whether expert aero-medical advice by an AME, AeMC, GMP, OHMP or Medical Assessor is needed.
- (b) Before taking any medication and acting as a pilot or cabin crew member, the following three basic questions should be satisfactorily answered:
 - (1) Do I feel fit to fly?
 - (2) Do I really need to take medication at all?
 - (3) Have I given this particular medication a personal trial on the ground to ensure that it will not have any adverse effects on my ability to fly?
- (c) Confirming the absence of adverse effects may well need expert aero-medical advice.
- (d) The following are some widely used medicines with a description of their compatibility with flying duties:



- (1) Antibiotics. Antibiotics may have short-term or delayed side effects which can affect pilot or cabin crew performance. More significantly, however, their use usually indicates that an infection is present and, thus, the effects of this infection may mean that a pilot or cabin crew member is not fit to fly and should obtain expert aero-medical advice.
- (2) Anti-malaria drugs. The decision on the need for anti-malaria drugs depends on the geographical areas to be visited, and the risk that the pilot or cabin crew member has of being exposed to mosquitoes and of developing malaria. An expert medical opinion should be obtained to establish whether anti-malaria drugs are needed and what kind of drugs should be used. Most of the anti-malaria drugs (atovaquone plus proguanil, chloroquine, doxycycline) are compatible with flying duties. However, adverse effects associated with mefloquine include insomnia, strange dreams, mood changes, nausea, diarrhoea and headaches. In addition, mefloquine may cause spatial disorientation and lack of fine coordination and is, therefore, not compatible with flying duties.
- (3) Antihistamines. Antihistamines can cause drowsiness. They are widely used in 'cold cures' and in treatment of hay fever, asthma and allergic rashes. They may be in tablet form or a constituent of nose drops or sprays. In many cases, the condition itself may preclude flying, so that, if treatment is necessary, expert aero-medical advice should be sought so that so-called non-sedative antihistamines, which do not degrade human performance, can be prescribed.
- (4) Cough medicines. Antitussives often contain codeine, dextromethorfan or pseudo-ephedrine which are not compatible with flying duties. However, mucolytic agents (e.g. carbocysteine) are well-tolerated and are compatible with flying duties.
- (5) Decongestants. Nasal decongestants with no effect on alertness may be compatible with flying duties. However, as the underlying condition requiring the use of decongestants may be incompatible with flying duties, expert aero-medical advice should be sought. For example, oedema of the mucosal membranes causes difficulties in equalising the pressure in the ears or sinuses.
- (6) Nasal corticosteroids are commonly used to treat hay fever, and they are compatible with flying duties.
- (7) (i) Common pain killers and antifebrile drugs. Non-Steroidal Anti-Inflammatory Drugs (NSAIDs) and paracetamol, commonly used to treat pain, fever or headaches, may be compatible with flying duties. However, the pilot or cabin crew member should give affirmative answers to the three basic questions listed in (b) before using the medication and carrying out flying duties.

(ii) Strong analgesics. The more potent analgesics including codeine are opiate derivatives, and may produce a significant decrement in human performance and, therefore, are not compatible with flying duties.
- (8) Anti-ulcer medicines. Gastric secretion inhibitors such as H₂ antagonists (e.g. ranitidine, cimetidine) or proton pump inhibitors (e.g. omeprazole) may be acceptable after diagnosis of the pathological condition. It is important to seek for the medical diagnosis and not to only treat the dyspeptic symptoms.
- (9) Anti-diarrhoeal drugs. Loperamide is one of the more common anti-diarrhoeal drugs and is usually safe to take whilst flying. However, the diarrhoea itself often makes the pilot and cabin crew member unfit for flying duties.



- (10) Hormonal contraceptives and hormone replacement therapy usually have no adverse effects and are compatible with flying duties.
- (11) Erectile dysfunction medication. This medication may cause disturbances in colour vision and dizziness. There should be at least 6 hours between taking sildenafil and flying duty; and 36 hours between taking vardenafil or tadalafil and flying duty.
- (12) Smoking cessation. Nicotine replacement therapy may be acceptable. However, other medication affecting the central nervous system (bupropion, varenicline) is not acceptable for pilots.
- (13) High blood pressure medication. Most anti-hypertensive drugs are compatible with flying duties. However, if the level of blood pressure is such that drug therapy is required, the pilot or cabin crew member should be monitored for any side effects before carrying out flying duties. Therefore, consultation with the AME, AeMC, GMP, OHMP or Medical Assessor as applicable, is needed.
- (14) Asthma medication. Asthma has to be clinically stable before a pilot or cabin crew member can return to flying duties. The use of respiratory aerosols or powders, such as corticosteroids, beta-2-agonists or chromoglycic acid may be compatible with flying duties. However, the use of oral steroids or theophylline derivatives is incompatible with flying duty. Pilots or cabin crew members using medication for asthma should consult the AME, AeMC, GMP, OHMP or Medical Assessor, as applicable.
- (15) Tranquillisers, anti-depressants and sedatives. The inability to react, due to the use of this group of medicines, has been a contributory cause to fatal aircraft accidents. In addition, the underlying condition for which these medications have been prescribed will almost certainly mean that the mental state of a pilot or cabin crew member is not compatible with flying duties.
- (16) Sleeping tablets. Sleeping tablets dull the senses, may cause confusion and slow reaction times. The duration of effect may vary from individual to individual and may be unduly prolonged. Expert aero-medical advice should be obtained before using sleeping tablets.
- (17) Melatonin. Melatonin is a hormone that is involved with the regulation of the circadian rhythm. In some countries it is a prescription medicine, whereas in most other countries it is regarded as a 'dietary supplement' and can be bought without any prescription. The results from the efficiency of melatonin in treatment of jet lag or sleep disorders have been contradictory. Expert aero-medical advice should be obtained.
- (18) Coffee and other caffeinated drinks may be acceptable, but excessive coffee drinking may have harmful effects, including disturbance of the heart's rhythm. Other stimulants including caffeine pills, amphetamines, etc. (often known as 'pep' pills) used to maintain wakefulness or suppress appetite can be habit forming. Susceptibility to different stimulants varies from one individual to another, and all may cause dangerous overconfidence. Overdosage causes headaches, dizziness and mental disturbance. These other stimulants should not be used.
- (19) Anaesthetics. Following local, general, dental and other anaesthetics, a period of time should elapse before returning to flying. The period will vary considerably from individual to individual, but a pilot or cabin crew member should not fly for at least 12 hours after a local anaesthetic, and for at least 48 hours after a general, spinal or epidural anaesthetic (see MED.A.020).



(e) Many preparations on the market nowadays contain a combination of medicines. It is, therefore, essential that if there is any new medication or dosage, however slight, the effect should be observed by the pilot or the cabin crew member on the ground prior to flying. It should be noted that medication which would not normally affect pilot or cabin crew performance may do so in individuals who are 'oversensitive' to a particular preparation. Individuals are, therefore, advised not to take any medicines before or during flight unless they are completely familiar with their effects on their own bodies. In cases of doubt, pilots and cabin crew members should consult an AME, AeMC, GMP, OHMP or Medical Assessor, as applicable.

(f) Other treatments

Alternative or complementary medicine, such as acupuncture, homeopathy, hypnotherapy and several other disciplines, is developing and gaining greater credibility. Such treatments are more acceptable in some States than others. There is a need to ensure that 'other treatments', as well as the underlying condition, are declared and considered by the AME, AeMC, GMP, OHMP or Medical Assessor, as applicable, for assessing fitness.

AMC1 MED.A.025 Obligations of the AeMC, AME, GMP and OHMP

- (a) ~~The report required in MED.A.025 (b)(4) should detail the results of the examination and the evaluation of the findings with regard to medical fitness.~~
- (b) ~~The report may be submitted in electronic format, but adequate identification of the examiner should be ensured.~~
- (ae) If the medical examination is carried out by two or more AMEs or GMPs, only one of them should be responsible for coordinating the results of the examination, evaluating the findings with regard to medical fitness, and signing the report.
- (b) The applicant should be made aware that the associated medical certificate or cabin crew attestation may be suspended or revoked if the applicant provides incomplete, inaccurate or false statements on their medical history to the AeMC, AME, GMP or OHMP.
- (c) In cases where the AeMC or AME is required to assess the fitness of an applicant for a class 2 medical certificate in consultation with the licensing authority, they should document the consultation in accordance with the procedure established by the competent authority.
- (d) The AeMC, AME, GMP or OHMP should give advice to the applicant on treatment and preventive measures if, during the course of the examination, medical conditions are found which may endanger the medical fitness of the applicant in the future.

GM1 MED.A.025 Obligations of the AeMC, AME, GMP and OHMP

GUIDELINES FOR THE AeMC, AME OR GMP CONDUCTING THE MEDICAL EXAMINATIONS AND ASSESSMENTS FOR MEDICAL CERTIFICATION OF PILOTS

- (a) Before performing the medical examination, the AeMC, AME or GMP should:
 - (1) verify the applicant's identity by checking their identity card, passport, driving licence or other official document containing a photograph of the applicant;
 - (2) obtain details of the applicant's flight crew licence from the applicant's licensing authority if they do not have their licence with them;



- (3) except for initial applicants, obtain details of the applicant's most recent medical certificate from the applicant's licensing authority if they do not have their certificate with them;
 - (4) in the case of an SIC on the existing medical certificate, obtain details of the specific medical condition and any associated instructions from the applicant's licensing authority. This could include, for example, a requirement to undergo a specific examination or test;
 - (5) except for initial applicants, ascertain, from the previous medical certificate, which routine medical test(s) should be conducted, for example ECG;
 - (6) provide the applicant with the application form for a medical certificate and the instructions for completion and ask the applicant to complete the form but not to sign it yet;
 - (7) go through the form with the applicant and give information to help the applicant understand the significance of the entries and ask any questions which might help the applicant to recall important historical medical data;
 - (8) verify that the form is complete and legible, ask the applicant to sign and date the form and then sign it as well. If the applicant declines to complete the application form fully or declines to sign the declaration on consent to the release of medical information, inform the applicant that it may not be possible to issue a medical certificate regardless of the outcome of the clinical examination and assessment.
- (b) Once all the items in (a) have been addressed, the AeMC, AME or GMP should:
- (1) perform the medical examination of the applicant in accordance with the applicable rules;
 - (2) arrange for additional specialist medical examinations, such as otorhinolaryngology (ENT) or ophthalmology, to be conducted as applicable and obtain the associated report forms or reports;
 - (3) complete the medical examination report form in accordance with the associated instructions for completion;
 - (4) ensure that all of the report forms are complete, accurate and legible.
- (c) Once all the actions in (b) have been carried out, the AeMC, AME or GMP should review the report forms and:
- (1) if satisfied that the applicant meets the applicable medical requirements as set out in Part-MED, issue a medical certificate for the appropriate class, with limitations if necessary. The applicant should sign the certificate once signed by the AeMC, AME or GMP; or
 - (2) if the applicant does not meet the applicable medical requirements, or if the fitness of the applicant for the class of medical certificate applied for is in doubt:
 - (i) refer the decision on medical fitness to, or consult the decision on medical fitness with, the licensing authority or AME in compliance with MED.B.001; or
 - (ii) deny issuance of a medical certificate, explain the reason(s) for denial to the applicant and inform them of their right of a review according to the procedures of the competent authority.
- (d) The AeMC, AME or GMP should send the documents as required by MED.A.025(b) to the applicant's licensing authority within 5 days from the date of the medical examination. If a medical certificate has



been denied or the decision has been referred, the documents should be sent to the licensing authority on the same day that the denial or referral decision is reached.

Section 2

Requirements for medical certificates

AMC1 MED.A.030 Medical certificates

- (a) A class 1 medical certificate includes the privileges and validities of class 2 and LAPL medical certificates.
- (b) A class 2 medical certificate includes the privileges and validities of a LAPL medical certificate.

AMC1 MED.A.035 Application for a medical certificate

Except for initial applicants, when applicants do not present a current or previous the most recent medical certificate to the AeMC, AME or GMP prior to the relevant examinations, the AeMC, AME or GMP should not issue the medical certificate unless relevant information is received from the licensing authority.

~~AMC1 MED.A.045 Validity, revalidation and renewal of medical certificates~~

~~The validity period of a medical certificate (including any associated examination or special investigation) is determined by the age of the applicant at the date of the medical examination.~~



SUBPART B

Specific requirements for class 1, class 2 and LAPL medical certificates

AMC for class 1, class 2 and LAPL medical certificates

Section 1

General

AMC1 MED.B.001 Limitations to class 1, class 2 and LAPL medical certificates**GENERAL**

- (a) An AeMC or AME may refer the decision on fitness of the applicant to the licensing authority in borderline cases or where fitness is in doubt.
- (b) In cases where a fit assessment can only be considered with a limitation, the AeMC, AME, GMP or the licensing authority should evaluate the medical condition of the applicant in consultation with flight operations and other experts, if necessary.
- (c) Limitation codes:

	Code	Limitation
1	TML	restriction of the period of validity of the medical certificate
2	VDL	correction for defective distant vision
3	VML	correction for defective distant, intermediate and near vision
4	VNL	correction for defective near vision
5	CCL	correction by means of contact lenses only
6	VCL	valid by day only
7	HAL	valid only when hearing aids are worn
8	APL	valid only with approved prosthesis
9	ØCL	valid only as co-pilot
10	ØPL	valid only without passengers (PPL and LAPL only)
11	SSL	special restriction as specified
12	ØAL	restricted to demonstrated aircraft type
13	AHL	valid only with approved hand controls
14	SIC	specific regular medical examination(s) – contact licensing authority
15	RXØ	specialist ophthalmological examination

(cd) Entry Initial application of limitations

- (1) The limitations 1 to 4 TML, VDL, VML, VNL and VCL may be imposed by an AME or an AeMC for class 1, class 2, and LAPL medical certificates, or a GMP for LAPL medical certificates.
- (2) Limitations 5 to 15 All other limitations listed in AMC2 MED.B.001(a) should only be imposed:
- (i) for class 1 medical certificates, by the licensing authority where a referral is required according to MED.B.001;



- (ii) for class 2 medical certificates, by the AME or AeMC in consultation with the licensing authority where consultation is required according to MED.B.001;
- (iii) for LAPL medical certificates, by an AME or AeMC.

(de) Removal of limitations

- (1) For class 1 medical certificates, all limitations should only be removed by the licensing authority.
- (2) For class 2 medical certificates, limitations may be removed by the licensing authority or by an AeMC or AME in consultation with the licensing authority.
- (3) For LAPL medical certificates, limitations may be removed by an AeMC or AME.

AMC2 MED.B.001 Limitations to medical certificates**LIMITATION CODES**

- (ae) The following abbreviations for limitations codes should be used on the medical certificates as applicable:

Code	Limitation
TML	restriction of the Limited period of validity of the medical certificate
VDL	Valid only with correction for defective distant vision
VML	Valid only with correction for defective distant, intermediate and near vision
VNL	Valid only with correction for defective near vision
CCL	Correction by means of contact lenses only
VCL	Valid by day only
RXO	s Specialist ophthalmological examination(s)
SIC	s Specific regular medical examination(s) contact licensing authority
HAL	Valid only when hearing aids are worn
APL	Valid only with approved prosthesis
AHL	Valid only with approved hand controls
OML	Valid only as, or with, a qualified co-pilot
OCL	Valid only as a qualified co-pilot
OSL	Valid only with a safety pilot and in aircraft with dual controls
OPL	Valid only without passengers (PPL and LAPL only)
ORL	Valid only with a safety pilot if passengers are carried
OAL	Restricted to demonstrated aircraft type
SSL	s Special restriction(s) as specified



(b) The abbreviations for the limitation codes should be explained to the holder of a medical certificate as follows:

(1) TML Time limitation

The period of validity of the medical certificate is limited to the duration as shown on the medical certificate. This period of validity commences on the date of the medical examination. Any period of validity remaining on the previous medical certificate is no longer valid. The pilot holder of the medical certificate should present themselves for re-examination when advised and should follow any medical recommendations.

(2) VDL Wear corrective lenses and carry a spare set of spectacles

Correction for defective distant vision: whilst exercising the privileges of the licence, the pilot holder of the medical certificate should wear spectacles or contact lenses that correct for defective distant vision as examined and approved by the AeMC, AME or GMP. Contact lenses may not be worn until cleared to do so by the AeMC, AME or GMP. If contact lenses are worn, a spare set of spectacles, approved by the AeMC, AME or GMP, should be carried readily available.

(3) VML Wear multifocal spectacles and carry a spare set of spectacles

Correction for defective distant, intermediate and near vision: whilst exercising the privileges of the licence, the pilot holder of the medical certificate should wear spectacles that correct for defective distant, intermediate and near vision as examined and approved by the AeMC, AME or GMP. Contact lenses or full frame spectacles, when either correct for near vision only, may not be worn. A spare set of spectacles, approved by the AeMC, AME or GMP, should be readily available.

(4) VNL Have available corrective spectacles and carry a spare set of spectacles

Correction for defective near vision: whilst exercising the privileges of the licence, the pilot holder of the medical certificate should have readily available spectacles that correct for defective near vision as examined and approved by the AeMC, AME or GMP. Contact lenses or full frame spectacles, when either correct for near vision only, may not be worn. A spare set of spectacles, approved by the AeMC, AME or GMP, should be readily available.

(5) CCL Wear contact lenses that correct for defective distant vision

Correction for defective distant vision: whilst exercising the privileges of the licence, the holder of a medical certificate should wear contact lenses that correct for defective distant vision, as examined and approved by the AeMC or AME. A spare set of similarly correcting spectacles, approved by the AeMC, AME or GMP, should be readily available for immediate use whilst exercising the privileges of the licence.

(6) VCL Valid by day only

~~The This limitation allows private pilots holders of a class 2 or LAPL medical certificate with varying degrees of colour deficiency, to exercise the privileges of their licence by daytime only. Applicable to class 2 medical certificates only.~~



(7) RXO Specialist ophthalmological examination(s)

Specialist ophthalmological examination(s), other than the examinations stipulated in Part-MED, are required for a significant reason. The limitation may be applied by an AME but should only be removed by the licensing authority.

(8) SIC Specific regular medical examination(s) contact licensing authority

This limitation requires the AeMC, or AME to contact the licensing authority before embarking upon a revalidation or renewal or recertification aero-medical assessment. The limitation is likely to concern a medical history or additional examination(s) of which the AeMC or AME should be aware of prior to undertaking the assessment.

(9) HAL Wear hearing aid(s)

Whilst exercising the privileges of the licence, the holder of the medical certificate should use hearing aid(s) that compensate for defective hearing as examined and approved by the AeMC or AME. A spare set of batteries should be readily available.

(10) APL Valid only with approved prosthesis

This limitation applies to the holder of a medical certificate with a musculoskeletal condition when a medical flight test or a flight simulator test has shown that the use of a prosthesis is required to safely exercise the privileges of the licence. The prosthesis to be used should be approved.

(11) AHL Valid only with approved hand controls

This limitation applies to the holder of a medical certificate who has a limb deficiency or other anatomical problem which had been shown by a medical flight test or flight simulator testing to be acceptable but to require the aircraft to be equipped with suitable, approved hand controls.

(12) OML Valid only as or with a qualified co-pilot

This limitation applies to crew members holders of a class 1 medical certificate who do not fully meet the aero-medical requirements for single-pilot crew operations, but are fit for multi-pilot crew operations. Refer to MED.B.001(d)(1).

(13) OCL Valid only as a qualified co-pilot

This limitation is an further extension of the OML limitation and is applied when, and applies to holders of a class 1 medical certificate who, for some well-defined medical reason(s), the pilot is assessed as safe to operate in a are restricted to the role of co-pilot, role but not in command. Applicable to class 1 medical certificates only.

(14) OSL Valid only with a safety pilot and in aircraft with dual controls

This limitation applies to holders of a class 2 or a LAPL medical certificate only. The safety pilot is qualified as PIC on the class/type of aircraft and rated for the flight conditions. He/she occupies a control seat, is The safety pilot should be made aware of the type(s) of possible incapacity that the pilot whose medical certificate has been issued with this limitation may suffer and is should be prepared to take over the aircraft controls during flight. Refer to MED.B.001(d)(2). Applicable to class 2 and LAPL medical certificates only.



(15) OPL Valid only without passengers

This limitation ~~may be considered when a pilot with a musculoskeletal problem, or some other~~ applies to holders of a class 2 or LAPL medical certificate with a medical condition, ~~that may involve lead to~~ an increased ~~element~~ level of risk to flight safety when exercising the privileges of the licence. ~~which might be acceptable to the pilot but~~ This limitation is to be applied when this risk ~~which is not acceptable for the carriage of passengers. Applicable to class 2 and LAPL medical certificates only.~~ Refer to MED.B.001(d)(3).

(16) ORL Valid only with a safety pilot if passengers are carried and in aircraft with dual controls

This limitation applies to holders of a class 2 or LAPL medical certificate with a medical condition that may lead to an increased level of risk to flight safety when exercising the privileges of the licence. The safety pilot, if carried, should be made aware of the type(s) of possible incapacity that the pilot whose medical certificate has been issued with this limitation may suffer and should be prepared to take over the aircraft controls during flight. Refer to MED.B.001(d)(4).

(17) OAL Restricted to demonstrated aircraft type

This limitation ~~may apply~~ applies to a pilot ~~the holder of a medical certificate~~ who has a limb deficiency or ~~some other anatomical~~ medical problem which had been shown by a medical flight test or flight simulator testing to be acceptable but to require a restriction to a specific class and type of aircraft.

(18) SSL Special restriction(s) as specified

This limitation may be considered when an individually specified limitation, not defined in this AMC, is appropriate to mitigate an increased level of risk to flight safety. The description of the SSL should be entered on the medical certificate or in a separate document to be carried with the medical certificate.



Section 2

Specific requirements for class 1 medical certificates

AMC1 MED.B.010 Cardiovascular system

(a) Examination

Exercise electrocardiography

An exercise ECG when required as part of a cardiovascular assessment should be symptom limited and completed to a minimum of Bruce Stage IV or equivalent.

(b) General

(1) Cardiovascular risk factor assessment

- (i) Serum lipid estimation is case finding and significant abnormalities should ~~require be reviewed, investigated and supervised~~ by the AeMC or AME in consultation with the licensing authority.
- (ii) ~~An~~ Applicants with an accumulation of risk factors (smoking, family history, lipid abnormalities, hypertension, etc.) should ~~require undergo a~~ cardiovascular evaluation by the AeMC or AME, ~~if necessary~~ in consultation with the licensing authority.

(2) Cardiovascular assessment

- (i) Reporting of resting and exercise electrocardiograms should be by the AME or an accredited specialist.
- (ii) The extended cardiovascular assessment should be undertaken at an AeMC or may be delegated to a cardiologist.

(c) Peripheral arterial disease

If there is no significant functional impairment, a fit assessment may be considered ~~by the licensing authority,~~ provided:

- (1) applicants without symptoms of coronary artery disease have reduced any vascular risk factors to an appropriate level;
- (2) applicants should be on ~~acceptable appropriate~~ secondary prevention treatment;
- (3) exercise electrocardiography is satisfactory. Further tests may be required which should show no evidence of myocardial ischaemia or significant coronary artery stenosis.

(d) Aortic aneurysm

- (1) Applicants with an aneurysm of the infra-renal abdominal aorta ~~of less than 5 cm in diameter may be assessed as fit before surgery, with an OML multi-pilot limitation subject to satisfactory evaluation by a cardiologist by the licensing authority.~~ Follow-up by ultra-sound scans or other imaging techniques, as necessary, should be determined by the licensing authority.
- (2) Applicants may be assessed as fit ~~with an OML by the licensing authority~~ after surgery for an ~~aneurysm of the thoracic or abdominal aorta infra-renal aortic aneurysm with a multi-pilot limitation at revalidation~~ if the blood pressure and cardiovascular ~~assessment evaluation are is~~



satisfactory. Regular ~~cardiological review~~ evaluations by a cardiologist should be required ~~carried out~~.

(e) Cardiac valvular abnormalities

- (1) Applicants with previously unrecognised cardiac murmurs should undergo evaluation by a cardiologist and assessment by the licensing authority. If considered significant, further investigation should include at least 2D Doppler echocardiography or equivalent imaging.
- (2) Applicants with minor cardiac valvular abnormalities may be assessed as fit ~~by the licensing authority~~. Applicants with significant abnormality of any of the heart valves should be assessed as unfit.
- (3) Aortic valve disease
 - (i) Applicants with a bicuspid aortic valve may be assessed as fit if no other cardiac or aortic abnormality is demonstrated. Follow-up with echocardiography, as necessary, should be determined by the licensing authority.
 - ~~(ii) Applicants with aortic stenosis require licensing authority review. Left ventricular function should be intact. A history of systemic embolism or significant dilatation of the thoracic aorta is disqualifying. Those with a mean pressure gradient of up to 20 mmHg may be assessed as fit. Those with mean pressure gradient above 20 mmHg but not greater than 40 mmHg may be assessed as fit with a multi-pilot limitation. A mean pressure gradient up to 50 mmHg may be acceptable. Follow-up with 2D Doppler echocardiography, as necessary, should be determined by the licensing authority. Alternative measurement techniques with equivalent ranges may be used.~~
 - (ii) Applicants with aortic stenosis may be assessed as fit provided the left ventricular function is intact and the mean pressure gradient is less than 20 mmHg. Applicants with an aortic valve orifice with indexation on the body surface of more than 0.6 cm²/m² and a mean pressure gradient above 20 mmHg, but not greater than 50 mmHg, may be assessed as fit with an OML. Follow-up with 2D Doppler echocardiography, as necessary, should be determined by the licensing authority in all cases. Alternative measurement techniques with equivalent ranges may be used. Regular evaluation by a cardiologist should be considered. Applicants with a history of systemic embolism or significant dilatation of the thoracic aorta should be assessed as unfit.
 - (iii) Applicants with trivial aortic regurgitation may be assessed as fit. A greater degree of aortic regurgitation should require an OML ~~multi-pilot limitation~~. There should be no demonstrable abnormality of the ascending aorta on 2D Doppler echocardiography. Follow-up, as necessary, should be determined by the licensing authority.
- (4) Mitral valve disease
 - (i) Asymptomatic applicants with an isolated mid-systolic click due to mitral leaflet prolapse may be assessed as fit.
 - (ii) Applicants with rheumatic mitral stenosis should normally be assessed as unfit.
 - (iii) Applicants with ~~uncomplicated~~ minor regurgitation may be assessed as fit. Periodic ~~cardiological~~ review should be determined by the licensing authority.



- (iv) Applicants with ~~uncomplicated~~ moderate mitral regurgitation may be considered as fit with an ~~OML multi-pilot limitation~~ if the 2D Doppler echocardiogram demonstrates satisfactory left ventricular dimensions and satisfactory myocardial function is confirmed by exercise electrocardiography. Periodic cardiological review should be required, as determined by the licensing authority.
- (v) Applicants with evidence of volume overloading of the left ventricle demonstrated by increased left ventricular end-diastolic diameter or evidence of systolic impairment should be assessed as unfit.

(f) Valvular surgery

Applicants ~~with~~ who have undergone cardiac valve replacement ~~or~~ repair should be assessed as unfit. A fit assessment may be considered ~~by the licensing authority~~ in the following cases:

~~(1) Aortic valvotomy should be disqualifying.~~

~~(2)~~ Mitral leaflet repair for prolapse is compatible with a fit assessment, provided post-operative investigations reveal satisfactory left ventricular function without systolic or diastolic dilation and no more than minor mitral regurgitation.

~~(3)~~ Asymptomatic applicants with a tissue valve or with a mechanical valve who, at least 6 months following surgery, are taking no cardioactive medication may be considered for a fit assessment with an ~~OML multi-pilot limitation by the licensing authority~~. Investigations which demonstrate normal valvular and ventricular configuration and function should have been completed as demonstrated by:

- (i) a satisfactory symptom limited exercise ECG. Myocardial perfusion imaging/stress echocardiography should be required if the exercise ECG is abnormal or any coronary artery disease ~~has been demonstrated~~ is suspected;
- (ii) a 2D Doppler echocardiogram showing no significant selective chamber enlargement, a tissue valve with minimal structural alteration and a normal Doppler blood flow, and no structural or functional abnormality of the other heart valves. Left ventricular fractional shortening should be normal.

Follow-up with exercise ECG and 2D echocardiography, as necessary, should be determined by the licensing authority.

~~(34)~~ Where anticoagulation is needed after valvular surgery, a fit assessment with an ~~OML multi-pilot limitation~~ may be considered ~~after review by the licensing authority~~ if the haemorrhagic risk is acceptable. ~~The review should show that~~ and the anticoagulation is stable. Anticoagulation should be considered stable if, within the last 6 months, at least 5 INR values are documented, of which at least 4 are within the INR target range. ~~The INR target range should be determined by the type of surgery performed.~~ In cases of anticoagulation medication not requiring INR monitoring, a fit assessment with an OML may be considered after review by the licensing authority after a stabilisation period of 3 months.

~~(g) Thromboembolic disorders~~

~~Arterial or venous thrombosis or pulmonary embolism are disqualifying whilst anticoagulation is being used as treatment. After 6 months of stable anticoagulation as prophylaxis, a fit assessment with multi-~~



~~pilot limitation may be considered after review by the licensing authority. Anticoagulation should be considered stable if, within the last 6 months, at least 5 INR values are documented, of which at least 4 are within the INR target range. Pulmonary embolus should require full evaluation. Following cessation of anti-coagulant therapy, for any indication, applicants should require review by the licensing authority.~~

(g) Thromboembolic disorders

Applicants with arterial or venous thrombosis or pulmonary embolism should be assessed as unfit. A fit assessment with an OML may be considered after a period of stable anticoagulation as prophylaxis, after review by the licensing authority. Anticoagulation should be considered stable if, within the last 6 months, at least 5 INR values are documented, of which at least 4 are within the INR target range and the haemorrhagic risk is acceptable. In cases of anticoagulation medication not requiring INR monitoring, a fit assessment with an OML may be considered after review by the licensing authority after a stabilisation period of 3 months. Applicants with pulmonary embolism should also be evaluated by a cardiologist. Following cessation of anticoagulant therapy, for any indication, applicants should undergo a re-assessment by the licensing authority.

(h) Other cardiac disorders

(1) Applicants with a primary or secondary abnormality of the pericardium, myocardium or endocardium should be assessed as unfit. A fit assessment may be considered ~~by the licensing authority~~ following complete resolution and satisfactory cardiological evaluation which may include 2D Doppler echocardiography, exercise ECG and/or myocardial perfusion imaging/stress echocardiography and 24-hour ambulatory ECG. Coronary angiography may be indicated. Frequent review and an OML ~~multi-pilot limitation~~ may be required after fit assessment.

(2) Applicants with a congenital abnormality of the heart, ~~including those who have undergone surgical correction~~, should be assessed as unfit. Applicants following surgical correction or with minor abnormalities that are functionally unimportant may be assessed as fit ~~by the licensing authority~~ following cardiological ~~assessment~~ evaluation. No cardioactive medication is acceptable. Investigations may include 2D Doppler echocardiography, exercise ECG and 24-hour ambulatory ECG. The potential hazard of any medication should be considered as part of the assessment. Particular attention should be paid to the potential for the medication to mask the effects of the congenital abnormality before or after surgery. Regular cardiological ~~reviews~~ evaluations should be ~~required~~ carried out.

(i) Syncope

(1) In the case of a single episode of vasovagal syncope which can be satisfactorily explained, a fit assessment may be considered.

(2) Applicants with a history of recurrent vasovagal syncope should be assessed as unfit. A fit assessment may be considered ~~by the licensing authority~~ after a 6-month period without recurrence, provided cardiological evaluation is satisfactory. Such evaluation should include:

- (i) a satisfactory symptom limited 12 lead exercise ECG to Bruce Stage IV, or equivalent. If the exercise ECG is abnormal, myocardial perfusion imaging/stress echocardiography or equivalent test should be ~~required~~ carried out;
- (ii) a 2D Doppler echocardiogram showing neither significant selective chamber enlargement nor structural or functional abnormality of the heart, valves or myocardium;



- (iii) a 24-hour ambulatory ECG recording showing no conduction disturbance, complex or sustained rhythm disturbance or evidence of myocardial ischaemia.
 - (32) A tilt test, or equivalent, carried out to a standard protocol showing no evidence of vasomotor instability may be required.
 - (43) Neurological review should be required.
 - (54) An OML multi-pilot limitation should be required until a period of 5 years has elapsed without recurrence. The licensing authority may determine a shorter or longer period of OML multi-pilot limitation according to the individual circumstances of the case.
 - (65) Applicants who experienced loss of consciousness without significant warning should be assessed as unfit.
- (j) Blood pressure
- (1) The diagnosis of hypertension should require cardiovascular review evaluation to include potential vascular risk factors.
 - (2) Anti-hypertensive treatment should be agreed by the licensing authority. Acceptable medication may include:
 - (i) non-loop diuretic agents;
 - (ii) ACE inhibitors;
 - (iii) angiotensin II/AT1 receptor blocking agents (sartans);
 - (iv) slow-channel calcium blocking agents;
 - (v) certain (generally hydrophilic) beta-blocking agents.
 - (3) Following initiation of medication for the control of blood pressure, applicants should be re-assessed to verify that satisfactory control has been achieved and the treatment is compatible with the safe exercise of the privileges of the applicable licence(s) held.
- (k) Coronary artery disease
- (1) Chest pain of uncertain cause should require full investigation. Applicants with angina pectoris should be assessed as unfit, whether or not it is alleviated by medication.
 - (2) In suspected asymptomatic coronary artery disease, exercise electrocardiography should be required. Further tests may be required, which should show no evidence of myocardial ischaemia or significant coronary artery stenosis.
 - (3) Applicants with Evidence of exercise-induced myocardial ischaemia should be disqualifying assessed as unfit.
 - (4) After an ischaemic cardiac event, including or revascularisation procedure, applicants without symptoms should have reduced any cardiovascular risk factors to an appropriate level. Medication, when used to control cardiac symptoms, is not acceptable. All applicants should be on acceptable appropriate secondary prevention treatment.



- (i) A coronary angiogram obtained around the time of, or during, the ischaemic myocardial event or revascularisation procedure and a complete, detailed clinical report of the ischaemic event and of any operative procedures should be made available to the licensing authority:
- (A) there should be no stenosis more than 50 % in any major untreated vessel, in any vein or artery graft or at the site of an angioplasty/stent, except in a vessel subtending a myocardial infarction. ~~More than two stenoses between 30 % and 50 % within the vascular tree should not be acceptable;~~
 - (B) the whole coronary vascular tree should be assessed as satisfactory by a cardiologist, and particular attention should be paid to multiple stenoses and/or multiple revascularisations;
 - (C) Applicants with ~~A~~ an untreated stenosis greater than 30 % in the left main or proximal left anterior descending coronary artery should ~~not be acceptable~~ ~~assessed as unfit.~~
- (ii) At least 6 months from the ischaemic myocardial event, ~~including or~~ revascularisation procedure, the following investigations should be completed (equivalent tests may be substituted):
- (A) an exercise ECG showing neither evidence of myocardial ischaemia nor rhythm or conduction disturbance;
 - (B) an echocardiogram showing satisfactory left ventricular function with no important abnormality of wall motion (such as dyskinesia or akinesia) and a left ventricular ejection fraction of 50 % or more;
 - (C) in cases of angioplasty/stenting, a myocardial perfusion scan or stress echocardiogram, or equivalent test, which should show no evidence of reversible myocardial ischaemia. If there is any doubt about myocardial perfusion in other cases (infarction or bypass grafting) a perfusion scan, or equivalent test, should also be ~~required~~ carried out;
 - (D) further investigations, such as a 24-hour ECG, may be necessary to assess the risk of any significant rhythm disturbance.
- (iii) Follow-up should be annually (or more frequently, if necessary) to ensure that there is no deterioration of the cardiovascular status. It should include a review by a cardiologist, exercise ECG and cardiovascular risk assessment. Additional investigations may be required by the licensing authority.
- (A) After coronary artery ~~vein~~ bypass grafting, a myocardial perfusion scan, or equivalent test, should be performed if there is any indication, and in all cases within 5 years from the procedure.
 - (B) In all cases, coronary angiography should be considered at any time if symptoms, signs or non-invasive tests indicate myocardial ischaemia.
- (iv) Successful completion of the 6-month or subsequent review will allow a fit assessment with an OML ~~multi-pilot limitation.~~



(l) Rhythm and conduction disturbances

- (1) ~~Any~~ Applicants with significant rhythm or conduction disturbance should ~~require~~ undergo evaluation by a cardiologist and appropriate follow-up in the case of ~~before~~ a fit assessment with an OML, as necessary, may be considered. Appropriate follow-up should be carried out at regular intervals. Such evaluation should include:
- (i) exercise ECG to the Bruce protocol or equivalent. Bruce stage 4 should be achieved and no significant abnormality of rhythm or conduction, or evidence of myocardial ischaemia should be demonstrated. Withdrawal of cardioactive medication prior to the test should normally be required;
 - (ii) 24-hour ambulatory ECG which should demonstrate no significant rhythm or conduction disturbance;
 - (iii) 2D Doppler echocardiogram which should show no significant selective chamber enlargement or significant structural or functional abnormality, and a left ventricular ejection fraction of at least 50 %.

Further evaluation may include (equivalent tests may be substituted):

- (iv) 24-hour ECG recording repeated as necessary;
 - (v) electrophysiological study;
 - (vi) myocardial perfusion imaging;
 - (vii) cardiac magnetic resonance imaging (MRI);
 - (viii) coronary angiogram.
- (2) Applicants with frequent or complex forms of supra ventricular or ventricular ectopic complexes require full cardiological evaluation.
- (3) Where anticoagulation is needed for a rhythm disturbance, a fit assessment with an OML may be considered if the haemorrhagic risk is acceptable and the anticoagulation is stable. Anticoagulation should be considered stable if, within the last 6 months, at least 5 INR values are documented, of which at least 4 are within the INR target range. In cases of anticoagulation medication not requiring INR monitoring, a fit assessment with an OML may be considered after review by the licensing authority after a stabilisation period of 3 months.

(43) Ablation

Applicants who have undergone ablation therapy should be assessed as unfit. A fit assessment may be considered ~~by the licensing authority~~ following successful catheter ablation and should require an OML ~~multi-pilot limitation~~ for at least one year, unless an electrophysiological study, undertaken at a minimum of 2 months after the ablation, demonstrates satisfactory results. For those whose long-term outcome cannot be assured by invasive or non-invasive testing, an additional period with an OML ~~multi-pilot limitation~~ and/or observation may be necessary.

(54) Supraventricular arrhythmias



Applicants with significant disturbance of supraventricular rhythm, including sinoatrial dysfunction, whether intermittent or established, should be assessed as unfit. A fit assessment may be considered ~~by the licensing authority~~ if cardiological evaluation is satisfactory.

- (i) Atrial fibrillation/flutter
 - (A) For initial applicants, a fit assessment should be limited to those with a single episode of arrhythmia which is considered by the licensing authority to be unlikely to recur.
 - (B) For revalidation, applicants may be assessed as fit if cardiological evaluation is satisfactory and the stroke risk is sufficiently low. A fit assessment with an OML may be considered after a period of stable anticoagulation as prophylaxis, after review by the licensing authority. Anticoagulation should be considered stable if, within the last 6 months, at least 5 INR values are documented, of which at least 4 are within the INR target range. In cases of anticoagulation medication not requiring INR monitoring, a fit assessment with an OML may be considered after review by the licensing authority after a stabilisation period of 3 months.
- (ii) Applicants with asymptomatic sinus pauses up to 2.5 seconds on resting electrocardiography may be assessed as fit if exercise electrocardiography, echocardiography and 24-hour ambulatory ECG are satisfactory.
- (iii) Applicants with Symptomatic sino-atrial disease should be ~~disqualifying~~ assessed as unfit.

(65) Mobitz type 2 atrio-ventricular block

Applicants with Mobitz type 2 AV block should require full cardiological evaluation and may be assessed as fit in the absence of distal conducting tissue disease.

(76) Complete right bundle branch block

- (i) Applicants with complete right bundle branch block should ~~require~~ undergo a cardiological evaluation on first presentation. A fit assessment may be considered if there is no underlying pathology, and subsequently:
 - (i) ~~for initial applicants under age 40, a fit assessment may be considered by the licensing authority. Initial applicants over age 40 should demonstrate a period of stability of 12 months;~~
 - (ii) ~~for revalidation, a fit assessment may be considered if the applicant is under age 40 there is no underlying pathology. A multi-pilot limitation should be applied for 12 months for those over age 40.~~
- (ii) Applicants with bifascicular block may be assessed as fit with an OML after a satisfactory cardiological evaluation. The OML may be considered for removal if an electrophysiological study demonstrates no infra-Hissian block, or a 3-year period of satisfactory surveillance has been completed.

(87) Complete left bundle branch block

- (i) A fit assessment may be considered ~~by the licensing authority;~~ subject to satisfactory cardiological evaluation and a 3-year period with an OML, and without an OML after 3 years of surveillance and satisfactory cardiological evaluation.



- ~~(i) Initial applicants should demonstrate a 3 year period of stability.~~
- ~~(ii) For revalidation, after a 3 year period with a multi pilot limitation applied, a fit assessment without multi pilot limitation may be considered.~~
- (iii) Investigation of the coronary arteries is necessary for applicants over age 40.

(98) Ventricular pre-excitation

~~A fit assessment may be considered by the licensing authority:~~

- (i) Asymptomatic initial applicants with pre-excitation may be assessed as fit if an electrophysiological study, including adequate drug-induced autonomic stimulation reveals no inducible re-entry tachycardia and the existence of multiple pathways is excluded.
- (ii) Asymptomatic applicants with pre-excitation may be assessed as fit at revalidation with a ~~multi pilot limitation~~ limitation(s) as appropriate. Limitations may not be necessary if an electrophysiological study, including adequate drug-induced autonomic stimulation, reveals no inducible re-entry tachycardia and the existence of multiple accessory pathways is excluded.

(109) Pacemaker

Applicants with a subendocardial pacemaker should be assessed as unfit. A fit assessment ~~with an OML~~ may be considered at revalidation ~~by the licensing authority~~ no sooner than 3 months after insertion ~~and should require~~ provided:

- (i) ~~there is~~ no other disqualifying condition;
- (ii) a bipolar lead system, programmed in bipolar mode without automatic mode change ~~of the device~~ has been used;
- (iii) ~~that~~ the applicant is not pacemaker dependent; ~~and~~
- (iv) ~~the applicant has a regular~~ follow-up at least every 12 months, including a pacemaker check; ~~and~~
- ~~(v) a multi-pilot limitation.~~

~~(1110)~~ (11) QT prolongation

~~Prolongation of the QT interval on the ECG associated with symptoms should be disqualifying. Asymptomatic applicants require cardiological evaluation for a fit assessment and a multi pilot limitation may be required.~~

Applicants with asymptomatic QT prolongation may be assessed as fit with an OML subject to satisfactory cardiological evaluation.

(12) Brugada pattern on electrocardiography

Applicants with a Brugada pattern Type 1 should be assessed as unfit. Applicants with Type 2 or Type 3 may be assessed as fit, with limitations as appropriate, subject to satisfactory cardiological evaluation.



GM1 MED.B.010 Cardiovascular system**MITRAL VALVE DISEASE**

- (a) Minor regurgitation should have evidence of no thickened leaflets or flail chordae and left atrial internal diameter of less than or equal to 4.0 cm.
- (b) The following may indicate severe regurgitation:
- (1) LV internal diameter (diastole) > 6.0 cm; or
 - (2) LV internal diameter (systole) > 4.1 cm; or
 - (3) Left atrial internal diameter > 4.5 cm.
- (c) Doppler indices, such as width of jet, backwards extension and whether there is flow reversal in the pulmonary veins may be helpful in assessing severity of regurgitation.

GM2 MED.B.010 Cardiovascular system**VENTRICULAR PRE-EXCITATION**

Asymptomatic applicants with pre-excitation may be assessed as fit if they meet the following criteria, which may also indicate a satisfactory electrophysiological evaluation:

- (a) refractory period > 300 ms;
- (b) no induced atrial fibrillation.

GM3 MED.B.010 Cardiovascular system**ANTICOAGULATION**

Applicants and licence holders taking anticoagulant medication which requires monitoring with INR testing, should measure their INR on a 'near patient' testing system within 12 hours prior to flight and the privileges of the applicable licence(s) should only be exercised if the INR is within the target range. The INR result should be recorded and the results should be reviewed at each aero-medical assessment.

AMC1 MED.B.015 Respiratory system

- (a) Examination
- (1) Spirometry

A Spirometric examination is required for initial examination and on clinical indication. Applicants with an FEV1/FVC ratio of less than 70 % at initial examination should be evaluated by a specialist in respiratory disease.
 - (2) Chest radiography

Posterior/anterior chest radiography may be required at initial, revalidation or renewal examinations when if clinically or epidemiologically indicated on clinical or epidemiological grounds.
- (b) Chronic obstructive airways-pulmonary disease
- Applicants with chronic obstructive airways-pulmonary disease should be assessed as unfit. Applicants with only minor impairment of their pulmonary function may be assessed as fit.



(c) Asthma

Applicants with asthma requiring medication or experiencing recurrent attacks of asthma may be assessed as fit if the asthma is considered stable with satisfactory pulmonary function tests and medication is compatible with flight safety. Applicants requiring systemic steroids are disqualifying and should be assessed as unfit.

(d) Inflammatory disease

For applicants with active inflammatory disease of the respiratory system a fit assessment may be considered when the condition has resolved without sequelae and no medication is required.

(e) Sarcoidosis

(1) Applicants with active sarcoidosis should be assessed as unfit. Investigation should be undertaken with respect to the possibility of systemic, particularly cardiac, involvement. A fit assessment may be considered if no medication is required, and the disease is investigated and shown to be limited to hilar lymphadenopathy and inactive.

(2) Applicants with cardiac or neurological sarcoid should be assessed as unfit.

(f) Pneumothorax

(1) Applicants with a spontaneous pneumothorax should be assessed as unfit. A fit assessment may be considered if respiratory evaluation is satisfactory:

(i) 1 year following full recovery from a single spontaneous pneumothorax;

(ii) at revalidation, 6 weeks following full recovery from a single spontaneous pneumothorax, with an OML multi-pilot limitation for at least a year after full recovery;

(iii) following surgical intervention in the case of a recurrent pneumothorax provided there is satisfactory recovery.

(2) Applicants with a recurrent spontaneous pneumothorax that has not been surgically treated is disqualifying and should be assessed as unfit.

(3) A fit assessment following full recovery from a traumatic pneumothorax as a result of an accident or injury may be acceptable once full absorption of the pneumothorax is demonstrated.

(g) Thoracic surgery

(1) Applicants requiring major thoracic surgery should be assessed as unfit for a minimum of 3 months following operation or until such time as the effects of the operation are no longer likely to interfere with the safe exercise of the privileges of the applicable licence(s) until recovery is complete, the applicant is asymptomatic, and the risk of secondary complication is minimal.

(2) A fit assessment following lesser chest surgery may be considered by the licensing authority after satisfactory recovery and full respiratory evaluation.

(h) Sleep apnoea syndrome/sleep disorder

Applicants with unsatisfactorily treated sleep apnoea syndrome should be assessed as unfit.



AMC1 MED.B.020 Digestive system

(a) Oesophageal varices

Applicants with oesophageal varices should be assessed as unfit.

(b) Pancreatitis

Applicants with pancreatitis should be assessed as unfit pending assessment. A fit assessment may be considered if the cause (~~e.g. gallstone, other obstruction, medication~~) is removed.

(c) Gallstones

(1) Applicants with a single asymptomatic large gallstone discovered incidentally may be assessed as fit if not likely to cause incapacitation in flight.

(2) ~~An~~ Applicants with asymptomatic multiple gallstones may be assessed as fit with an ~~OML multi-pilot limitation~~.

(d) Inflammatory bowel disease

Applicants with an established diagnosis or history of chronic inflammatory bowel disease should be assessed as fit if the inflammatory bowel disease is in established remission and stable and ~~that~~ if systemic steroids are not required for its control.

(e) Peptic ulceration

Applicants with peptic ulceration should be assessed as unfit pending full recovery and demonstrated healing.

(f) ~~Abdominal~~ Digestive tract and abdominal surgery

(1) ~~Abdominal surgery is disqualifying for a minimum of 3 months. An earlier fit assessment may be considered if recovery is complete, the applicant is asymptomatic and there is only a minimal risk of secondary complication or recurrence.~~

(2) ~~Applicants who have undergone a surgical operation on the digestive tract or its adnexa, involving a total or partial excision or a diversion of any of these organs, should be assessed as unfit for a minimum period of 3 months or until such time as the effects of the operation are no longer likely to interfere with the safe exercise of the privileges of the applicable licence(s).~~

Applicants who have undergone a surgical operation:

(1) for herniae; or

(2) on the digestive tract or its adnexa, including a total or partial excision or a diversion of any of these organs

should be assessed as unfit. A fit assessment may be considered if recovery is complete, the applicant is asymptomatic, and there is only a minimal risk of secondary complication or recurrence.

(g) Liver disease

Applicants with morphological or functional liver disease, or after surgery, including liver transplantation, may be assessed as fit subject to satisfactory gastroenterological evaluation.



AMC1 MED.B.025 Metabolic and endocrine systems

(a) Metabolic, nutritional or endocrine dysfunction

Applicants with metabolic, nutritional or endocrine dysfunction may be assessed as fit if the condition is asymptomatic, clinically compensated and stable with or without replacement therapy, and regularly reviewed by an appropriate specialist.

(b) Obesity

Applicants with a Body Mass Index ≥ 35 may be assessed as fit only if the excess weight is not likely to interfere with the safe exercise of the applicable licence(s) and the results of a satisfactory cardiovascular risk review has been undertaken risk assessment, including evaluation of the cardiovascular system and evaluation of the possibility of sleep apnoea, are satisfactory.

(c) Addison's disease

Applicants with Addison's disease is disqualifying should be assessed as unfit. A fit assessment with an OML may be considered, provided that cortisone is carried and available for use whilst exercising the privileges of the applicable licence(s). Applicants may be assessed as fit with a multi-pilot limitation.

(d) Gout

Applicants with acute gout should be assessed as unfit. A fit assessment may be considered once asymptomatic, after cessation of treatment or the condition is stabilised on anti-hyperuricaemic therapy.

(e) Thyroid dysfunction

Applicants with hyperthyroidism or hypothyroidism should be assessed as unfit. A fit assessment may be considered when a stable euthyroid state is attained.

(f) Abnormal glucose metabolism

Glycosuria and abnormal blood glucose levels require investigation. A fit assessment may be considered if normal glucose tolerance is demonstrated (low renal threshold) or impaired glucose tolerance without diabetic pathology is fully controlled by diet and regularly reviewed.

(g) Diabetes mellitus

Subject to good control of blood sugar with no hypoglycaemic episodes:

- (1) applicants with diabetes mellitus not requiring medication may be assessed as fit;
- (2) the use of antidiabetic medications that are not likely to cause hypoglycaemia may be acceptable for a fit assessment with an OML multi-pilot limitation.

AMC1 MED.B.030 Haematology

(a) Abnormal haemoglobin

Applicants with abnormal haemoglobin should be investigated.

(b) Anaemia

- (1) Applicants with anaemia demonstrated by a reduced haemoglobin level or require investigation. Applicants with an haematocrit of less than 32 % should be assessed as unfit and require



investigation. A fit assessment may be considered in cases where the primary cause, such as iron or B12 deficiency, has been treated (e.g. iron or B12 deficiency) and the haemoglobin or haematocrit has stabilised at a satisfactory level.

- (2) Applicants with Anaemia which is unamenable to treatment is disqualifying should be assessed as unfit.

(c) Erythrocytosis Polycythaemia

Applicants with polycythaemia-erythrocytosis should be assessed as unfit and require investigation. A fit assessment with an OML multi-pilot limitation may be considered if investigation establishes that the condition is stable and no associated pathology is demonstrated.

(d) Haemoglobinopathy

- (1) Applicants with a haemoglobinopathy should be assessed as unfit. A fit assessment may be considered where minor thalassaemia or other haemoglobinopathy is diagnosed without a history of crises and where full functional capability is demonstrated. The haemoglobin level should be satisfactory.

- (2) Applicants with sickle cell disease (homozygote) should be assessed as unfit.

(e) Coagulation disorders

- (1) Applicants with a coagulation disorder should be assessed as unfit. A fit assessment may be considered if there is no history of significant bleeding episodes.

- (2) Applicants with thrombocytopenia with a platelet count less than $75 \times 10^9/L$ should be assessed as unfit. A fit assessment may be considered once the platelet count is above $75 \times 10^9/L$ and stable.

(f) Haemorrhagic disorders

Applicants with a haemorrhagic disorder require investigation. A fit assessment with an OML multi-pilot limitation may be considered if there is no history of significant bleeding.

(g) Thrombo-embolic disorders Thromboembolic disorders

- (1) Applicants with a thrombotic disorder require investigation. A fit assessment with a multi-pilot limitation may be considered if there is no history of significant clotting episodes when the applicant is asymptomatic and there is only minimal risk of secondary complication or recurrence.

- (2) If anticoagulation is used as treatment, refer to AMC1 MED.B.010(g).

- (32) An Applicants with arterial embolus is disqualifying should be assessed as unfit. A fit assessment may be considered once recovery is complete, the applicant is asymptomatic, and there is only minimal risk of secondary complication or recurrence.

(h) Disorders of the lymphatic system

Applicants with significant localised and generalised enlargement of the lymphatic glands and/or haematological diseases of the blood should be assessed as unfit and require investigation. A fit assessment may be considered in cases of an acute infectious process which is fully recovered or Hodgkin's lymphoma or other lymphoid malignancy which has been treated and is in full remission.



- (i) Leukaemia
- (1) Applicants with acute leukaemia should be assessed as unfit. Once in established remission, applicants may be assessed as fit.
 - (2) Applicants with chronic leukaemia should be assessed as unfit. After a period of demonstrated stability a fit assessment may be considered.
 - (3) Applicants with a history of leukaemia should have no history of central nervous system involvement and no continuing side-effects from treatment of flight safety importance. Haemoglobin and platelet levels should be satisfactory. Regular follow-up is required.

(j) Splenomegaly

Applicants with splenomegaly should be assessed as unfit and require investigation. A fit assessment may be considered when the enlargement is minimal, stable and no associated pathology is demonstrated, or if the enlargement is minimal and associated with another acceptable condition.

AMC1 MED.B.035 Genitourinary system

(a) Abnormal urinalysis

Investigation is required if there is any abnormal finding on urinalysis.

(b) Renal disease

- (1) Applicants presenting with any signs of renal disease should be assessed as unfit. A fit assessment may be considered if blood pressure is satisfactory and renal function is acceptable.
- (2) ~~The requirement for~~ Applicants requiring dialysis ~~is disqualifying~~ should be assessed as unfit.

(c) Urinary calculi

- (1) Applicants with an asymptomatic calculus or a history of renal colic require investigation.
- (2) Applicants presenting with one or more urinary calculi should be assessed as unfit and require investigation.
- (3) ~~Whilst awaiting assessment or treatment, A~~ a fit assessment with an OML ~~multi-pilot limitation~~ may be considered ~~whilst awaiting assessment or treatment~~.
- (4) ~~After successful treatment for a calculus A~~ a fit assessment without an OML ~~multi-pilot limitation~~ may be considered ~~after successful treatment for a calculus~~.
- (5) Applicants ~~with~~ ~~parenchymal~~ residual calculi, ~~a fit assessment with a multi-pilot limitation~~ may be considered for a fit assessment with an OML.

(d) Renal and ~~urological~~ surgery

- (1) Applicants who have undergone a major surgical operation on the ~~genitourinary system or its adnexa~~ ~~urinary tract or the urinary apparatus~~ involving a total or partial excision or a diversion of any of its organs, should be assessed as unfit ~~for a minimum period of 3 months or until such time as the effects of the operation are no longer likely to cause incapacity in flight~~ ~~until recovery is complete, the applicant is asymptomatic, and the risk of secondary complication is minimal.~~



- (2) After other urological surgery, a fit assessment may be considered if when the applicant is completely asymptomatic and there is only minimal risk of secondary complication or recurrence.
- (32) Applicants with compensated nephrectomy without hypertension or uraemia may be considered for a fit assessment.
- (43) Applicants who have undergone renal transplantation may be considered for a fit assessment with an OML if it is fully compensated and tolerated with only minimal immuno-suppressive therapy after at least 12 months. Applicants may be assessed as fit with a multi-pilot limitation.
- (54) Applicants who have undergone total cystectomy may be considered for a fit assessment with an OML if there is satisfactory urinary function, no infection and no recurrence of primary pathology. Applicants may be assessed as fit with a multi-pilot limitation.

AMC1 MED.B.040 Infectious disease

(a) Infectious disease General

In cases of infectious disease, consideration should be given to a history of, or clinical signs indicating, underlying impairment of the immune system.

(b) Tuberculosis

- (1) Applicants with active tuberculosis should be assessed as unfit. A fit assessment may be considered following completion of therapy.
- (2) Applicants with quiescent or healed lesions may be assessed as fit. Specialist evaluation should consider the extent of the disease, the treatment required and possible side effects of medication.

(c) Syphilis

Applicants with acute syphilis is disqualifying should be assessed as unfit. A fit assessment may be considered in the case of those fully treated and recovered from the primary and secondary stages.

(d) HIV infection positivity

- (1) Applicants who are HIV positive may be assessed as fit is positivity is disqualifying. A fit assessment with an OML multi-pilot limitation may be considered for individuals with stable, non-progressive disease if a full investigation provides no evidence of HIV associated diseases that might give rise to incapacitating symptoms. Frequent review of the immunological status and neurological evaluation by an appropriate specialist is required should be carried out. A cardiological evaluation may also be required, depending on the medication.
- (2) The occurrence Applicants with signs or symptoms of AIDS or an AIDS-related complex-defining condition is disqualifying should be assessed as unfit.

(e) Infectious hepatitis

Applicants with infectious hepatitis is disqualifying should be assessed as unfit. A fit assessment may be considered after full recovery once the applicant has become asymptomatic. Regular review of the liver function should be carried out.



AMC1 MED.B.045 Obstetrics and gynaecology

(a) Gynaecological surgery

~~An applicant who has have~~ undergone a major gynaecological operation should be assessed as unfit for a period of 3 months or until such time as the effects of the operation are not likely to interfere with the safe exercise of the privileges of the licence(s) if the holder ~~A fit assessment may be considered if recovery is complete, the applicant is completely asymptomatic, and there is only a minimal the~~ risk of secondary complication or recurrence ~~is minimal.~~

(b) Severe menstrual disturbances

~~An applicant with a history of severe menstrual disturbances unamenable to treatment should be assessed as unfit.~~

(be) Pregnancy

- (1) A pregnant licence holder may be assessed as fit with an ~~OML multi-pilot limitation~~ during the first 26 weeks of gestation, following review of the obstetric evaluation by the AeMC or AME who should inform the licensing authority.
- (2) The AeMC or AME should provide written advice to the applicant and the supervising physician regarding potentially significant complications of pregnancy.

AMC1 MED.B.050 Musculoskeletal system

- (a) ~~An applicant with any significant sequela~~ ~~sequelae~~ from disease, injury or congenital abnormality affecting the bones, joints, muscles or tendons with or without surgery requires full evaluation prior to a fit assessment.
- (b) In cases of limb deficiency, a fit assessment may be considered following a satisfactory medical flight test or simulator testing.
- (c) ~~An applicant with inflammatory, infiltrative, traumatic or degenerative disease of the musculoskeletal system may be assessed as fit, provided the condition is in remission or is stable and the applicant is taking no disqualifying medication and has satisfactorily completed a medical flight or simulator flight test. Appropriate limitation(s) to specified aircraft type(s) may be required apply.~~
- (d) Abnormal physique, including obesity, or muscular weakness may require medical flight or flight simulator testing. Particular attention should be paid to emergency procedures and evacuation. ~~Appropriate limitations to specified aircraft type(s) may be required apply.~~

AMC1 MED.B.055 Psychiatry

(a) Psychotic disorder

~~An applicant with a history of, or the occurrence, of, a functional psychotic disorder is disqualifying should be assessed as unfit. A fit assessment may be considered if unless a cause can be unequivocally identified as one which is transient, has ceased and will not recur the risk of recurrence is minimal.~~

(b) Organic mental disorder

~~Applicants with An organic mental disorder is disqualifying should be assessed as unfit. Once the cause has been treated, an applicant may be assessed as fit following satisfactory psychiatric review evaluation.~~



(c) ~~Psychotropic~~ Psychoactive substances

~~Use or abuse of psychotropic substances likely to affect flight safety is disqualifying.~~

Applicants who use or misuse psychoactive substances or psychoactive medication likely to affect flight safety should be assessed as unfit. If stability on maintenance psychoactive medication is confirmed, a fit assessment with an OML may be considered. If the dosage or type of medication is changed, a further period of unfit assessment should be required until stability is confirmed.

(d) Schizophrenia, schizotypal or delusional disorder

Applicants with an established history or clinical diagnosis of schizophrenia, schizotypal or delusional disorder ~~should~~ may only be considered for a fit assessment if the licensing authority concludes that the original diagnosis was inappropriate or inaccurate as confirmed by psychiatric evaluation, or, in the case of a single episode of delirium, provided that the applicant has suffered no permanent impairment.

(e) Mood disorder

Applicants with ~~A~~ an established mood disorder ~~is disqualifying~~ should be assessed as unfit. After full recovery and after full consideration of ~~an~~ the individual case, a fit assessment may be considered, depending on the characteristics and gravity of the mood disorder. If ~~a stable~~ stability on maintenance ~~psychotropic~~ psychoactive medication is confirmed, a fit assessment ~~should require~~ with an OML may be considered ~~multi pilot limitation~~. If the dosage or type of medication is changed, a further period of unfit assessment should be required until stability is confirmed.

(f) Neurotic, stress-related or somatoform disorder

Where there ~~is suspicion~~ are signs or is established evidence that an applicant ~~has~~ may have a neurotic, stress-related or somatoform disorder, the applicant should be referred for psychiatric opinion and advice.

(g) Personality or behavioural disorders

Where there ~~is suspicion~~ are signs or is established evidence that an applicant ~~has~~ may have a personality or behavioural disorder, the applicant should be referred for psychiatric opinion and advice.

(h) Disorders due to alcohol or other psychoactive substance use or misuse

(1) Applicants with ~~M~~ mental or behavioural disorders due to alcohol or other psychoactive substance use or misuse, with or without dependency, ~~are disqualifying~~ should be assessed as unfit.

(2) A fit assessment may be considered after a period of two years of documented sobriety or freedom from psychoactive substance use or misuse. At revalidation or renewal, a fit assessment may be considered earlier with an OML ~~multi pilot limitation~~. Depending on the individual case, treatment and ~~review~~ evaluation may include: in-patient treatment of some weeks followed by ongoing checks, including blood testing and peer reports, which may be required indefinitely.

(i) ~~in-patient treatment of some weeks followed by:~~

~~(A) review by a psychiatric specialist; and~~

~~(B) ongoing review including blood testing and peer reports, which may be required indefinitely.~~



(i) Deliberate self-harm

Applicants who have carried out a single self-destructive action or repeated acts of deliberate self-harm are ~~disqualifying~~ should be assessed as unfit. A fit assessment may be considered after full consideration of an individual case and may require psychiatric or psychological ~~review~~ evaluation. Neuropsychological ~~assessment~~ evaluation may also be required.

AMC1 MED.B.060 Psychology

- (a) Where there is ~~suspicion~~ are signs or is established evidence that an applicant ~~may have~~ has a psychological disorder, the applicant should be referred for psychological opinion and advice.
- (b) Established evidence should be verifiable information from an identifiable source ~~which evokes doubts concerning~~ related to the mental fitness or personality of a particular individual. Sources for this information can be accidents or incidents, problems in training or proficiency checks, ~~delinquency behaviour~~ or knowledge relevant to the safe exercise of the privileges of the applicable licence(s).
- (c) The psychological evaluation may include a collection of biographical data, the administration of aptitude as well as personality tests and psychological interview.
- (d) The psychologist should submit a written report to the AME, AeMC or licensing authority as appropriate, detailing his/her opinion and recommendation.

AMC1 MED.B.065 Neurology

(a) Epilepsy

(1) Applicants with A a diagnosis of epilepsy is ~~disqualifying~~ should be assessed as unfit, unless there is unequivocal evidence of a syndrome of benign childhood epilepsy associated with a very low risk of recurrence, and unless the applicant has been free of recurrence and off treatment for more than 10 years. One or more convulsive episodes after the age of 5 ~~are~~ is disqualifying. In the case of an acute symptomatic seizure, which is considered to have a very low risk of recurrence, a fit assessment may be considered after neurological ~~review~~ evaluation.

(2) ~~An a~~ Applicants may be assessed as fit by the ~~licensing authority~~ with an OML ~~multi-pilot limitation~~ if:

- (i) there is a history of a single afebrile epileptiform seizure;
- (ii) there has been no recurrence after at least 10 years off treatment;
- (iii) there is no evidence of continuing predisposition to epilepsy.

~~(b) Conditions with a high propensity for cerebral dysfunction~~

~~An applicant with a condition with a high propensity for cerebral dysfunction should be assessed as unfit. A fit assessment may be considered after full evaluation.~~

~~(be) Clinical EEG abnormalities~~

- (1) Electroencephalography is required when indicated by the applicant's history or on clinical grounds.
- (2) Applicants with ~~E~~epileptiform paroxysmal EEG abnormalities and focal slow waves should be ~~disqualifying~~ assessed as unfit.



(cd) Neurological disease

Applicants with ~~any stationary or progressive~~ disease of the nervous system which ~~has caused or is likely to cause a significant disability~~ hazard to flight safety ~~is disqualifying~~ should be assessed as unfit. However, in certain cases, including cases of minor functional losses associated with ~~stationary~~ stable disease, a fit assessment may be considered after full evaluation which should include a medical flight test which may be conducted in a flight simulation training device.

(d) Migraine

Applicants with an established diagnosis of migraine or other severe periodic headaches likely to cause a hazard to flight safety should be assessed as unfit. A fit assessment may be considered after full evaluation. The evaluation should take into account at least the following: auras, visual field loss, frequency, severity, therapy. Appropriate limitation(s) may apply.

(e) Episode of disturbance of consciousness

In the case of a single episode of disturbance of consciousness, which can be satisfactorily explained, a fit assessment may be considered, but applicants experiencing a recurrence should be ~~disqualifying~~ assessed as unfit.

(f) Head injury

~~An a~~ Applicants with a head injury which was severe enough to cause loss of consciousness or is associated with penetrating brain injury should be ~~reviewed~~ evaluated by a ~~consultant~~ neurologist. A fit assessment may be considered if there has been a full recovery and the risk of epilepsy is sufficiently low.

(g) Spinal or peripheral nerve injury, ~~myopathies~~

~~An a~~ Applicants with a history or diagnosis of spinal or peripheral nerve injury or a disorder of the nervous system due to a traumatic injury or ~~myopathy~~ should be assessed as unfit. A fit assessment may be considered if neurological ~~review~~ evaluation is satisfactory and the provisions of AMC1 MED.B.050 are met ~~and musculoskeletal assessments are satisfactory~~.

(h) Vascular deficiencies

Applicants with a disorder of the nervous system due to vascular deficiencies including haemorrhagic and ischaemic events should be assessed as unfit. A fit assessment may be considered if neurological evaluation is satisfactory and the provisions of AMC1 MED.B.050 are met. A cardiological evaluation and medical flight test should be undertaken for applicants with residual deficiencies.

AMC1 MED.B.070 Visual system

(a) Eye examination

- (1) At each aero-medical ~~revalidation~~ examination, an assessment of the visual fitness should be undertaken and the eyes should be examined with regard to possible pathology.
- (2) All abnormal and doubtful cases should be referred to an ophthalmologist. Conditions which indicate ophthalmological examination include, but are not limited to, a substantial decrease in the uncorrected visual acuity, any decrease in best corrected visual acuity and/or the occurrence of eye disease, eye injury, or eye surgery.



- (3) Where specialist ophthalmological examinations are required for any significant reason, this should be imposed as a limitation on the medical certificate.
- (4) The possible cumulative effect of more than one eye condition should be evaluated by an ophthalmologist.

(b) Comprehensive eye examination

A comprehensive eye examination by an eye specialist is required at the initial examination. All abnormal and doubtful cases should be referred to an ophthalmologist. The examination should include:

- (1) history;
- (2) visual acuities - near, intermediate and distant vision (uncorrected and with best optical correction if needed);
- (3) examination of the external eye, anatomy, media (slit lamp) and funduscopy;
- (4) ocular motility;
- (5) binocular vision;
- (6) visual fields;
- (7) tonometry on clinical indication; and
- (8) objective refraction: hyperopic initial applicants with a hyperopia of more than +2 dioptres and under the age of 25 should undergo objective refraction in cycloplegia;
- (9) assessment of mesopic contrast sensitivity; and
- (10) colour vision;

(c) Routine eye examination

A routine eye examination may be performed by an AME and should include:

- (1) history;
- (2) visual acuities - near, intermediate and distant vision (uncorrected and with best optical correction if needed);
- (3) examination of the external eye, anatomy, media and funduscopy; and
- (4) further examination on clinical indication.

~~(d) Refractive error~~

~~(1) At initial examination an applicant may be assessed as fit with:~~

- ~~(i) hypermetropia not exceeding +5.0 dioptres;~~
- ~~(ii) myopia not exceeding -6.0 dioptres;~~
- ~~(iii) astigmatism not exceeding 2.0 dioptres;~~
- ~~(iv) anisometropia not exceeding 2.0 dioptres~~

~~provided that optimal correction has been considered and no significant pathology is demonstrated.~~



- ~~(2) Initial applicants who do not meet the requirements in (1)(ii), (iii) and (iv) above should be referred to the licensing authority. A fit assessment may be considered following review by an ophthalmologist.~~
- ~~(3) At revalidation an applicant may be assessed as fit with:~~
- ~~(i) hypermetropia not exceeding +5.0 dioptres;~~
 - ~~(ii) myopia exceeding -6.0 dioptres;~~
 - ~~(iii) astigmatism exceeding 2.0 dioptres;~~
 - ~~(iv) anisometropia exceeding 2.0 dioptres~~
- ~~provided that optimal correction has been considered and no significant pathology is demonstrated.~~
- ~~(4) If anisometropia exceeds 3.0 dioptres, contact lenses should be worn.~~
- ~~(5) If the refractive error is +3.0 to +5.0 or -3.0 to -6.0 dioptres, there is astigmatism or anisometropia of more than 2 dioptres but less than 3 dioptres, a review should be undertaken 5 yearly by an eye specialist.~~
- ~~(6) If the refractive error is greater than -6.0 dioptres, there is more than 3.0 dioptres of astigmatism or anisometropia exceeds 3.0 dioptres, a review should be undertaken 2 yearly by an eye specialist.~~
- ~~(7) In cases (5) and (6) above, the applicant should supply the eye specialist's report to the AME. The report should be forwarded to the licensing authority as part of the medical examination report. All abnormal and doubtful cases should be referred to an ophthalmologist.~~

(d) Refractive error and anisometropia

(1) Applicants with:

- (i) hypermetropia not exceeding +5.0 dioptres;**
- (ii) myopia not exceeding -6.0 dioptres;**
- (iii) astigmatism not exceeding 2.0 dioptres;**
- (iv) anisometropia not exceeding 2.0 dioptres**

may be assessed as fit subject to satisfactory ophthalmic evaluation and provided that optimal correction has been considered and no significant pathology is demonstrated.

(2) Applicants should wear contact lenses if:

- (i) hypermetropia exceeds +5.0 dioptres;**
- (ii) anisometropia exceeds 3.0 dioptres.**

(3) An evaluation by an eye specialist should be undertaken 5-yearly if:

- (i) the refractive error is between -3.0 and -6.0 dioptres or +3 and +5 dioptres;**
- (ii) astigmatism or anisometropia is between 2.0 and 3.0 dioptres.**

(4) An evaluation by an eye specialist should be undertaken 2-yearly if:



- (i) the refractive error is greater than -6.0 dioptres or $+5.0$ dioptres;
- (ii) astigmatism or anisometropia exceeds 3.0 dioptres.

(e) Uncorrected visual acuity

No limits apply to uncorrected visual acuity.

(f) ~~Substandard vision~~ Visual acuity

(1) ~~Reduced vision in one eye or monocularly:~~ Applicants for revalidation or renewal with reduced central vision or acquired loss of vision in one eye may be assessed as fit if the binocular visual field is normal and the underlying pathology is acceptable according to ophthalmological assessment. A satisfactory medical flight test and a ~~with an OML multi-pilot limitation~~ are required, if:

- (i) the binocular visual field or, in the case of monocularly, the monocular visual field is acceptable;
- (ii) in the case of monocularly, a period of adaptation time has passed from the known point of visual loss, during which the applicant should be assessed as unfit;
- (iii) the unaffected eye achieves distant visual acuity of $6/6$ ($1,0$) corrected or uncorrected;
- (iv) the unaffected eye achieves intermediate visual acuity of $N14$ and $N5$ for near;
- (v) the underlying pathology is acceptable according to ophthalmological assessment and there is no significant ocular pathology in the unaffected eye; and
- (vi) a medical flight test is satisfactory.

(2) ~~An applicant with acquired substandard vision in one eye may be assessed as fit with a multi-pilot limitation if:~~

- (i) ~~the better eye achieves distant visual acuity of $6/6$ ($1,0$), corrected or uncorrected;~~
- (ii) ~~the better eye achieves intermediate visual acuity of $N14$ and $N5$ for near;~~
- (iii) ~~in the case of acute loss of vision in one eye, a period of adaptation time has passed from the known point of visual loss, during which the applicant should be assessed as unfit;~~
- (iv) ~~there is no significant ocular pathology; and~~
- (v) ~~a medical flight test is satisfactory.~~

(23) Visual fields

~~An~~ Applicants with a visual field defect, who do not have reduced central vision or acquired loss of vision in one eye, may be assessed as fit if the binocular visual field is normal ~~and the underlying pathology is acceptable to the licensing authority.~~

(g) Keratoconus

Applicants with keratoconus may be assessed as fit if the visual requirements are met with the use of corrective lenses and periodic ~~review~~ evaluation is undertaken by an ophthalmologist.

(h) ~~Heterophoria~~ Binocular function

Applicants with heterophoria (imbalance of the ocular muscles) exceeding:

- (1) at 6 metres:
 - 2.0 prism dioptres in hyperphoria,
 - 10.0 prism dioptres in esophoria,
 - 8.0 prism dioptres in exophoria
 and
- (2) at 33 centimetres:
 - 1.0 prism dioptre in hyperphoria,
 - 8.0 prism dioptres in esophoria,
 - 12.0 prism dioptres in exophoria

should be assessed as unfit. A fit assessment may be considered if an orthoptic evaluation demonstrates that the applicant should be reviewed by an ophthalmologist and if the fusional reserves are sufficient to prevent asthenopia and diplopia a fit assessment may be considered.

(i) Eye surgery

The assessment after eye surgery should include an ophthalmological examination.

- (1) After refractive surgery, a fit assessment may be considered, provided that:
 - (i) pre-operative refraction was not greater than did not exceed +5.0 dioptres;
 - (ii) post-operative stability of refraction has been achieved (of less than 0.75 dioptres variation diurnally) has been achieved;
 - (iii) examination of the eye shows no post-operative complications;
 - (iv) glare sensitivity is within normal standards;
 - (v) mesopic contrast sensitivity is not impaired;
 - (vi) review an evaluation is undertaken by an eye specialist.
- (2) Following intraocular lens surgery, including cataract surgery, entails unfitness. A fit assessment may be considered after 3 months once recovery is complete and the visual requirements are met with or without correction. Intraocular lenses should be monofocal and should not impair colour vision and night vision.
- (3) Retinal surgery entails unfitness. A fit assessment may be considered 6 months after successful surgery, or earlier if recovery is complete. A fit assessment may also be acceptable considered earlier after retinal laser therapy. Regular follow-up by an ophthalmologist should may be required carried out.
- (4) Glaucoma surgery entails unfitness. A fit assessment may be considered 6 months after successful surgery or earlier if recovery is complete. Regular follow-up by an ophthalmologist should may be required carried out.



(5) For (2), (3) and (4) above, a fit assessment may be considered earlier if recovery is complete.

(j) Correcting lenses-Visual correction

Correcting lenses should permit the licence holder to meet the visual requirements at all distances.

GM1 MED.B.070 Visual system

COMPARISON OF DIFFERENT READING CHARTS (APPROXIMATE FIGURES)

(a) Test distance: 40 cm

Decimal	Nieden	Jäger	Snellen	N	Parinaud
1,0	1	2	1,5	3	2
0,8	2	3	2	4	3
0,7	3	4	2,5		
0,6	4	5	3	5	4
0,5	5	5		6	5
0,4	7	9	4	8	6
0,35	8	10	4,5		8
0,32	9	12	5,5	10	10
0,3	9	12		12	
0,25	9	12		14	
0,2	10	14	7,5	16	14
0,16	11	14	12	20	

(b) Test distance: 80 cm

Decimal	Nieden	Jäger	Snellen	N	Parinaud
1,2	4	5	3	5	4
1,0	5	5		6	5
0,8	7	9	4	8	6
0,7	8	10	4,5		8
0,63	9	12	5,5	10	10
0,6	9	12		12	10
0,5	9	12		14	10
0,4	10	14	7,5	16	14
0,32	11	14	12	20	14

AMC1 MED.B.075 Colour vision

- (a) At revalidation and renewal examinations, colour vision should be tested on clinical indication.
- (b) The Ishihara test (24 plate version) is considered passed if the first 15 plates, presented in a random order, are identified without error.
- (c) Those failing the Ishihara test should be examined either by:
- (1) anomaloscopy (Nagel or equivalent). This test is considered passed if the colour match is trichromatic and the matching range is 4 scale units or less, or if the anomalous quotient is acceptable; or by



- (2) lantern testing with a Spectrolux, Beynes or Holmes-Wright lantern. This test is considered passed if the applicant passes without error a test with accepted lanterns; or by
- (3) Colour Assessment and Diagnosis (CAD) test. This test is considered passed if the threshold is less than 6 standard normal (SN) units for deutan deficiency, or less than 12 SN units for protan deficiency. A threshold greater than 2 SN units for tritan deficiency indicates an acquired cause which should be investigated.

AMC1 MED.B.080 ~~Otorhino-laryngology~~ Otorhinolaryngology (ENT)

(a) Hearing

- (1) ~~The a~~Applicants should understand correctly conversational speech when tested with each ear at a distance of 2 metres from and with the applicant's back turned towards the AME.
- (2) ~~The pure tone audiogram should cover the 500 Hz, 1 000 Hz, 2 000 Hz and 3 000 Hz frequency thresholds.~~
- (23) ~~An a~~Applicants with hypoacusis ~~should be referred to the licensing authority. A~~ may be assessed as fit ~~assessment may be considered~~ if a speech discrimination test or functional flight deck hearing test demonstrates satisfactory hearing ability. A vestibular function test may be appropriate.
- (34) If the hearing requirements can only be met with the use of hearing aids, the hearing aids should provide optimal hearing function, be well tolerated and suitable for aviation purposes.

(b) Comprehensive ~~otorhinolaryngological~~ ENT examination

A comprehensive ~~otorhino-laryngological~~ ENT examination should include:

- (1) history;
- (2) clinical examination including otoscopy, rhinoscopy, and examination of the mouth and throat;
- (3) tympanometry or equivalent;
- (4) clinical ~~assessment~~ examination of the vestibular system.

(c) Ear conditions

- (1) ~~An a~~Applicants with an active pathological process, ~~acute or chronic~~, of the internal or middle ear should be assessed as unfit. A fit assessment may be considered once the condition has stabilised or there has been a full recovery.
- (2) ~~An a~~Applicants with an unhealed perforation or dysfunction of the tympanic membranes should be assessed as unfit. An applicant with a single dry perforation of non-infectious origin and which does not interfere with the normal function of the ear may be considered for a fit assessment.

(d) Vestibular disturbance

~~An a~~Applicants with disturbance of vestibular function should be assessed as unfit. A fit assessment may be considered after full recovery. The presence of spontaneous or positional nystagmus requires complete vestibular evaluation by an ~~ENT~~ specialist. Applicants with ~~S~~ significant abnormal caloric or rotational vestibular responses ~~are disqualifying~~ should be assessed as unfit. Abnormal vestibular responses should be assessed in their clinical context.



(e) Sinus dysfunction

~~An~~ Applicants with any dysfunction of the sinuses should be assessed as unfit until there has been full recovery.

(f) Oral/upper respiratory tract infections

Applicants with ~~A~~ a significant, ~~acute or chronic~~ infection of the oral cavity or upper respiratory tract ~~is~~ disqualifying should be assessed as unfit. A fit assessment may be considered after full recovery.

(g) Speech disorder

Applicants with ~~a~~ A significant disorder of speech or voice ~~is~~ disqualifying should be assessed as unfit.

(h) Air passage restrictions

Applicants with significant restriction of the nasal air passage on either side, or significant malformation of the oral cavity or upper respiratory tract may be assessed as fit if ENT evaluation is satisfactory.

(i) Eustachian tube(s) dysfunction

Applicants with permanent dysfunction of the Eustachian tube(s) may be assessed as fit if ENT evaluation is satisfactory.

(j) Sequelae of surgery of the internal or middle ear

Applicants with sequelae of surgery of the internal or middle ear should be assessed as unfit until recovery is complete, the applicant is asymptomatic, and the risk of secondary complication is minimal.

GM1 MED.B.080 Otorhinolaryngology (ENT)**PURE TONE AUDIOGRAM**

The pure tone audiogram may also cover the 4 000 Hz frequency for early detection of decrease in hearing.

AMC1 MED.B.085 Dermatology

- (a) Referral to the licensing authority should be made if doubt exists about the fitness of ~~an~~ applicants with eczema (exogenous and endogenous), severe psoriasis, bacterial infections, drug induced, or bullous eruptions or urticaria.
- (b) Systemic effects of radiant or pharmacological treatment for a dermatological condition should be considered before a fit assessment ~~can~~ may be considered.
- (c) In cases where a dermatological condition is associated with a systemic illness, full consideration should be given to the underlying illness before a fit assessment may be considered.

AMC1 MED.B.090 Oncology

- (a) Applicants who ~~underwent treatment for~~ have been diagnosed with a malignant disease may be assessed as fit by the licensing authority if provided that:
 - (1) ~~after primary treatment,~~ there is no evidence of residual malignant disease ~~after treatment~~ likely to jeopardise flight safety;
 - (2) time appropriate to the type of tumour ~~and primary treatment~~ has elapsed ~~since the end of treatment~~;



-
- (3) the risk of inflight incapacitation from a recurrence or metastasis is sufficiently low;
 - (4) there is no evidence of short or long-term sequelae from treatment. Special attention should be paid to applicants who have received anthracycline chemotherapy;
 - (5) satisfactory oncology follow-up reports are provided to the licensing authority.
- (b) An OML ~~multi-pilot limitation~~ should be applied as appropriate.
- (c) Applicants receiving ongoing chemotherapy or radiation treatment should be assessed as unfit.
- (de) Applicants with pre-malignant conditions of the skin may be assessed as fit if treated or excised as necessary and there is regular follow-up.



Section 3

Specific requirements for class 2 medical certificates

AMC2 MED.B.010 Cardiovascular system

(a) Examination

Exercise electrocardiography

An exercise ECG when required as part of a cardiovascular assessment should be symptom-limited and completed to a minimum of Bruce Stage IV or equivalent.

(b) General

(1) Cardiovascular risk factor assessment

Applicants with an accumulation of risk factors (smoking, family history, lipid abnormalities, hypertension, etc.) should require undergo a cardiovascular evaluation by the AeMC or AME.

(2) Cardiovascular assessment

Reporting of resting and exercise electrocardiograms should be by the AME or an accredited specialist.

(c) Peripheral arterial disease

A fit assessment may be considered for an applicant with peripheral arterial disease, or after surgery for peripheral arterial disease, provided there is no significant functional impairment, any vascular risk factors have been reduced to an appropriate level, the applicant is receiving acceptable secondary prevention treatment, and there is no evidence of myocardial ischaemia.

(d) Aortic aneurysm

(1) Applicants with an aneurysm of the infra-renal abdominal aorta of less than 5 cm in diameter may be assessed as fit, subject to satisfactory cardiological evaluation. Regular cardiological evaluations should be carried out.

~~(2)~~ Applicants with an aneurysm of the thoracic or supra-renal abdominal aorta of less than 5 cm in diameter may be assessed as fit with an OSL, subject to satisfactory cardiological evaluation, and ~~and~~ Regular follow-up should be carried out.

(3) Applicants may be assessed as fit after surgery for an infra-renal abdominal aortic aneurysm, subject to satisfactory cardiological evaluation. Regular cardiological evaluations should be carried out.

~~(4)~~ Applicants may be assessed as fit with an OSL after surgery for a thoracic or supra-renal abdominal aortic aneurysm, subject to satisfactory cardiological evaluation ~~to exclude the presence of coronary artery disease.~~ Regular cardiological evaluations should be carried out.

(e) Cardiac valvular abnormalities

(1) Applicants with previously unrecognised cardiac murmurs ~~require~~ should undergo further cardiological evaluation.

(2) Applicants with minor cardiac valvular abnormalities may be assessed as fit.



(3) Aortic valve disease

- (i) Applicants with a bicuspid aortic valve may be assessed as fit if no other cardiac or aortic abnormality is demonstrated. Follow-up with echocardiography, as necessary, should be determined in consultation with the licensing authority.
- (ii) Applicants with aortic stenosis may be assessed as fit provided the left ventricular function is intact and the mean pressure gradient is less than 20 mmHg. Applicants with an aortic valve orifice of more than 1 cm² and a mean pressure gradient above 20 mmHg, but not greater than 50 mmHg, may be assessed as fit with an ORL. Follow-up with 2D Doppler echocardiography, as necessary, should be determined in consultation with the licensing authority in all cases. Alternative measurement techniques with equivalent ranges may be used. Regular cardiological evaluation should be considered. Applicants with a history of systemic embolism or significant dilatation of the thoracic aorta should be assessed as unfit.
- (iii) Applicants with trivial aortic regurgitation may be assessed as fit. Applicants with a greater degree of aortic regurgitation may be assessed as fit with an OSL. There should be no demonstrable abnormality of the ascending aorta on 2D Doppler echocardiography. Follow-up, as necessary, should be determined in consultation with the licensing authority.

(4) Mitral valve disease

- (i) Asymptomatic applicants with an isolated mid-systolic click due to mitral leaflet prolapse may be assessed as fit.
- (ii) Applicants with rheumatic mitral stenosis should normally be assessed as unfit.
- (iii) Applicants with minor regurgitation may be assessed as fit. Periodic cardiological review should be determined in consultation with the licensing authority.
- (iv) Applicants with moderate mitral regurgitation may be considered as fit with an ORL if the 2D Doppler echocardiogram demonstrates satisfactory left ventricular dimensions and satisfactory myocardial function is confirmed by exercise electrocardiography. Periodic cardiological review should be determined in consultation with the licensing authority.
- (v) Applicants with evidence of volume overloading of the left ventricle demonstrated by increased left ventricular end-diastolic diameter or evidence of systolic impairment should be assessed as unfit.

(f) Valvular surgery

- (1) Applicants who have undergone cardiac valve replacement or repair may be assessed as fit without limitations subject to satisfactory post-operative cardiological evaluation and if ~~post-operative cardiac function and investigations are satisfactory and~~ no anticoagulants are needed.
- (2) Where anticoagulation is needed after valvular surgery, a fit assessment with an ~~ORL OSL or OPL limitation~~ may be considered after cardiological ~~review~~ evaluation if the haemorrhagic risk is acceptable. The review should show that the anticoagulation is stable. Anticoagulation should be considered stable if, within the last 6 months, at least 5 INR values are documented, of which at least 4 are within the INR target range. The INR target range should be determined by the type of surgery performed. Applicants who measure their INR on a 'near patient' testing system within 12



hours prior to flight and only exercise the privileges of their licence(s) if the INR is within the target range, may be assessed as fit without the above-mentioned limitation. The INR results should be recorded and the results should be reviewed at each aero-medical assessment. Applicants taking anticoagulation medication not requiring INR monitoring, may be assessed as fit without the above-mentioned limitation in consultation with the licensing authority after a stabilisation period of 3 months.

(g) Thromboembolic disorders

Applicants with Arterial or venous thrombosis or pulmonary embolism should be assessed as unfit. ~~are disqualifying whilst anticoagulation is being used as treatment. After 6 months of stable anticoagulation as prophylaxis, a~~ A fit assessment with an ~~ORL OSL or OPL limitation~~ may be considered after a period of stable anticoagulation as prophylaxis ~~after review~~ in consultation with the licensing authority. Anticoagulation should be considered stable if, within the last 6 months, at least 5 INR values are documented, of which at least 4 are within the INR target range and the haemorrhagic risk is acceptable. Applicants who measure their INR on a 'near patient' testing system within 12 hours prior to flight and only exercise the privileges of their licence(s) if the INR is within the target range may be assessed as fit without the above-mentioned limitation. The INR results should be recorded and the results should be reviewed at each aero-medical assessment. Applicants taking anticoagulation medication not requiring INR monitoring, may be assessed as fit without the above-mentioned limitation in consultation with the licensing authority after a stabilisation period of 3 months. Applicants with ~~Pulmonary embolus~~ embolism should ~~require~~ also undergo a cardiological ~~full~~ evaluation. Following cessation of anticoagulant therapy for any indication, applicants should undergo a re-assessment in consultation with the licensing authority.

(h) Other cardiac disorders

- (1) Applicants with a primary or secondary abnormality of the pericardium, myocardium or endocardium may be assessed as ~~unfit pending~~ subject to satisfactory cardiological evaluation.
- (2) Applicants with a congenital abnormality of the heart, including those who have undergone surgical correction, may be assessed as fit subject to satisfactory cardiological ~~assessment~~ evaluation. Cardiological follow-up may be necessary and should be determined in consultation with the licensing authority.

(i) Syncope

- (1) In the case of a single episode of vasovagal syncope which can be satisfactorily explained, a fit assessment may be considered.
- (2) Applicants with a history of recurrent vasovagal syncope ~~may be assessed as fit~~ should be assessed as unfit. A fit assessment may be considered after a 6-month period without recurrence, ~~providing that~~ cardiological evaluation is satisfactory. Neurological review may be indicated.

(j) Blood pressure

- (1) When the blood pressure at examination consistently exceeds 160 mmHg systolic and/or 95 mmHg diastolic, with or without treatment, the applicant should be assessed as unfit.
- (2) The diagnosis of hypertension requires review of other potential vascular risk factors.
- (3) Applicants with symptomatic hypotension should be assessed as unfit.



- (4) Anti-hypertensive treatment should be compatible with flight safety.
- (5) Following initiation of medication for the control of blood pressure, applicants should be re-assessed to verify that **satisfactory control has been achieved and that** the treatment is compatible with the safe exercise of the privileges of the **applicable licence(s) held**.
- (k) Coronary artery disease
- (1) Chest pain of uncertain cause requires full investigation.
- (2) **Applicants with** ~~an~~ suspected asymptomatic coronary artery disease **should undergo** cardiological evaluation **which** should show no evidence of myocardial ischaemia or significant coronary artery stenosis.
- (3) **Applicants with evidence of exercise-induced myocardial ischaemia should be assessed as unfit.**
- (4) After an ischaemic cardiac event, or revascularisation, applicants without symptoms should have reduced ~~any~~ **cardiovascular** risk factors to an appropriate level. Medication, when used to control angina pectoris, is not acceptable. All applicants should be on ~~acceptable~~ **appropriate** secondary prevention treatment.
- (i) A coronary angiogram obtained around the time of, or during, the ischaemic myocardial event and a complete, detailed clinical report of the ischaemic event and of any operative procedures should be available to the AME.
- (A) There should be no stenosis more than 50 % in any major untreated vessel, in any vein or artery graft or at the site of an angioplasty/stent, except in a vessel subtending a myocardial infarction. ~~More than two stenoses between 30 % and 50 % within the vascular tree should not be acceptable.~~
- (B) The whole coronary vascular tree should be assessed as satisfactory **by a cardiologist** and particular attention should be paid to multiple stenoses and/or multiple revascularisations.
- (C) **Applicants with An** untreated stenosis greater than 30 % in the left main or proximal left anterior descending coronary artery should ~~not be acceptable~~ **assessed as unfit.**
- (ii) At least 6 months from the ischaemic myocardial event, including revascularisation, the following investigations should be completed (equivalent tests may be substituted):
- (A) an exercise ECG showing neither evidence of myocardial ischaemia nor rhythm disturbance;
- (B) an echocardiogram showing satisfactory left ventricular function with no important abnormality of wall motion and a satisfactory left ventricular ejection fraction of 50 % or more;
- (C) in cases of angioplasty/stenting, a myocardial perfusion scan or stress echocardiogram, **or equivalent test**, which should show no evidence of reversible myocardial ischaemia. If there is doubt about revascularisation in myocardial infarction or bypass grafting, a perfusion scan, **or equivalent test**, should also be **required carried out**;



- (D) further investigations, such as a 24-hour ECG, may be necessary to assess the risk of any significant rhythm disturbance.
- (iii) Periodic follow-up should include a ~~cardiological review~~ evaluation.
- (A) After coronary artery bypass grafting, a myocardial perfusion scan (or ~~satisfactory~~ equivalent test) should be performed if there is any indication, and in all cases within five years from the procedure for a fit assessment without an ~~OSL, OPL or ORL safety~~ pilot limitation.
- (B) In all cases, coronary angiography should be considered at any time if symptoms, signs or non-invasive tests indicate myocardial ischaemia.
- (iv) Successful completion of the six-month or subsequent review will allow a fit assessment. Applicants may be assessed as fit with an ~~ORL safety pilot limitation~~ having successfully completed only an exercise ECG.
- (54) Applicants with ~~A~~ angina pectoris ~~is disqualifying~~ should be assessed as unfit, whether or not it is ~~abolished~~ alleviated by medication.
- (l) Rhythm and conduction disturbances
- (1) ~~Any Applicants with~~ significant rhythm or conduction disturbance should ~~require~~ undergo cardiological evaluation and an appropriate follow-up before a fit assessment may be considered. ~~with A an ORL-OSL or OPL limitation should be considered as appropriate.~~ Such evaluation should include:
- (i) exercise ECG to the Bruce protocol or equivalent. Bruce stage 4 should be achieved and no significant abnormality of rhythm or conduction, or evidence of myocardial ischaemia should be demonstrated. Withdrawal of cardioactive medication prior to the test should normally be required;
- (ii) 24-hour ambulatory ECG which should demonstrate no significant rhythm or conduction disturbance;
- (iii) 2D Doppler echocardiogram which should show no significant selective chamber enlargement or significant structural or functional abnormality, and a left ventricular ejection fraction of at least 50 %.
- Further evaluation may include (equivalent tests may be substituted):
- (iv) 24-hour ECG recording repeated as necessary;
- (v) electrophysiological study;
- (vi) myocardial perfusion imaging;
- (vii) cardiac magnetic resonance imaging (MRI);
- (viii) coronary angiogram.
- (2) Where anticoagulation is needed for a rhythm disturbance, a fit assessment with an ORL may be considered, if the haemorrhagic risk is acceptable and the anticoagulation is stable. Anticoagulation should be considered stable if, within the last 6 months, at least 5 INR values are documented, of which at least 4 are within the INR target range. Applicants who measure their

INR on a 'near patient' testing system within 12 hours prior to flight and only exercise the privileges of their licence(s) if the INR is within the target range may be assessed as fit without the above-mentioned limitation. The INR results should be recorded and the results should be reviewed at each aero-medical assessment. Applicants taking anticoagulation medication not requiring INR monitoring, may be assessed as fit without the above-mentioned limitation in consultation with the licensing authority after a stabilisation period of 3 months.

~~(31)~~ Ablation

A fit assessment may be considered following successful catheter ablation subject to satisfactory cardiological review undertaken at a minimum of 2 months after the ablation.

~~(42)~~ Supraventricular arrhythmias

(i) Applicants with significant disturbance of supraventricular rhythm, including sinoatrial dysfunction, whether intermittent or established, may be assessed as fit if cardiological evaluation is satisfactory.

(ii) Applicants with atrial fibrillation/flutter may be assessed as fit if cardiological evaluation is satisfactory and the stroke risk is sufficiently low. Where anticoagulation is needed, a fit assessment with an ORL may be considered after a period of stable anticoagulation as prophylaxis, in consultation with the licensing authority. Anticoagulation should be considered stable if, within the last 6 months, at least 5 INR values are documented, of which at least 4 are within the INR target range. Applicants who measure their INR on a 'near patient' testing system within 12 hours prior to flight and only exercise the privileges of their licence(s) if the INR is within the target range may be assessed as fit without the above-mentioned limitation. The INR results should be recorded and the results should be reviewed at each aero-medical assessment. Applicants taking anticoagulation medication not requiring INR monitoring, may be assessed as fit without the above-mentioned limitation in consultation with the licensing authority after a stabilisation period of 3 months.

(iii) Applicants with asymptomatic sinus pauses up to 2.5 seconds on resting electrocardiography may be assessed as fit if cardiological evaluation is satisfactory.

~~(53)~~ Heart block

(i) Applicants with first degree and Mobitz type 1 AV block may be assessed as fit.

(ii) Applicants with Mobitz type 2 AV block may be assessed as fit in the absence of distal conducting tissue disease.

~~(64)~~ Complete right bundle branch block

Applicants with complete right bundle branch block may be assessed as fit with appropriate limitations, such as an ORL, and subject to satisfactory cardiological evaluation.

~~(75)~~ Complete left bundle branch block

Applicants with complete left bundle branch block may be assessed as fit with appropriate limitations, such as an ORL, and subject to satisfactory cardiological assessment-evaluation.

~~(86)~~ Ventricular pre-excitation



Asymptomatic applicants with ventricular pre-excitation may be assessed as fit with limitation(s) as appropriate, subject to satisfactory cardiological evaluation. Limitations may not be necessary if an electrophysiological study is conducted and the results are satisfactory.

(97) Pacemaker

Applicants with a subendocardial pacemaker ~~may~~ should be assessed as unfit. A fit assessment may be considered no sooner than 3 months after insertion, provided:

- (i) there is no other disqualifying condition;
- (ii) a bipolar lead system ~~is used~~, programmed in bipolar mode without automatic mode change, ~~of the device~~ has been used;
- (iii) the applicant is not pacemaker dependent; and
- (iv) the applicant has a ~~regular~~ follow-up at least every 12 months, including a pacemaker check.

(10) QT prolongation

Applicants with asymptomatic QT prolongation may be assessed as fit with an ORL subject to satisfactory cardiological evaluation.

(11) Brugada pattern on electrocardiography

Applicants with a Brugada pattern Type 1 should be assessed as unfit. Applicants with Type 2 or Type 3 may be assessed as fit, with limitation(s) as appropriate, subject to satisfactory cardiological evaluation.

(m) Heart or heart/lung transplantation

(1) Applicants who have undergone heart or heart/lung transplantation may be assessed as fit, with appropriate limitation(s) such as an ORL, no sooner than 12 months after transplantation, provided that cardiological evaluation is satisfactory with:

- (i) no rejection in the first year following transplantation;
- (ii) no significant arrhythmias;
- (iii) a left ventricular ejection fraction $\geq 50\%$;
- (iv) a symptom limited exercise ECG; and
- (v) a coronary angiogram if indicated;

(2) Regular cardiological evaluations should be carried out.

GM4 MED.B.010 Cardiovascular system

MITRAL VALVE DISEASE

(a) Minor regurgitation should have evidence of no thickened leaflets or flail chordae and left atrial internal diameter of less than or equal to 4.0 cm.

(b) The following may indicate severe regurgitation:

- (1) LV internal diameter (diastole) > 6.0 cm; or



(2) LV internal diameter (systole) > 4.1 cm; or

(3) Left atrial internal diameter > 4.5 cm.

(c) Doppler indices, such as width of jet, backwards extension and whether there is flow reversal in the pulmonary veins may be helpful in assessing severity of regurgitation.

GM5 MED.B.010 Cardiovascular system

VENTRICULAR PRE-EXCITATION

Asymptomatic applicants with pre-excitation may be assessed as fit if they meet the following criteria:

(a) no inducible re-entry tachycardia;

(b) refractory period > 300 ms;

(c) no induced atrial fibrillation;

(d) no evidence of multiple accessory pathways.

AMC2 MED.B.015 Respiratory system

(a) ~~Chest radiography~~ Examination

(1) A spirometric examination should be performed on clinical indication. Applicants with an FEV1/FVC ratio of less than 70 % should be evaluated by a specialist in respiratory disease.

(2) Posterior/anterior chest radiography may be required if ~~indicated on clinical grounds~~ clinically or epidemiologically indicated.

(b) Chronic obstructive ~~airways~~ pulmonary disease

Applicants with only minor impairment of pulmonary function may be assessed as fit.

(c) Asthma

Applicants with asthma may be assessed as fit if the asthma is considered stable with satisfactory pulmonary function tests and medication is compatible with flight safety. Applicants requiring systemic steroids should be ~~disqualifying~~ assessed as unfit.

(d) Inflammatory disease

Applicants with active inflammatory disease of the respiratory system should be assessed as unfit pending resolution of the condition.

(e) Sarcoidosis

(1) Applicants with active sarcoidosis should be assessed as unfit. Investigation should be undertaken with respect to the possibility of systemic involvement. A fit assessment may be considered once the disease is inactive.

(2) Applicants with cardiac sarcoid should be assessed as unfit.

(f) Pneumothorax

(1) Applicants with spontaneous pneumothorax should be assessed as unfit. A fit assessment may be considered if respiratory evaluation is satisfactory:

(i) six weeks following full recovery from a single spontaneous pneumothorax;



~~(ii) or following recovery from surgical intervention in the case of treatment for a recurrent pneumothorax, provided there is satisfactory recovery.~~

(2) A fit assessment following full recovery from a traumatic pneumothorax as a result of an accident or injury may be acceptable once full absorption of the pneumothorax is demonstrated.

(g) Thoracic surgery

~~Applicants requiring major thoracic surgery should be assessed as unfit until such time as the effects of the operation are no longer likely to interfere with the safe exercise of the privileges of the applicable licence(s) until recovery is complete, the applicant is asymptomatic, and the risk of secondary complication is minimal.~~

(h) Sleep apnoea syndrome

Applicants with unsatisfactorily treated sleep apnoea syndrome should be assessed as unfit.

AMC2 MED.B.020 Digestive system

(a) Oesophageal varices

Applicants with oesophageal varices should be assessed as unfit.

(b) Pancreatitis

Applicants with pancreatitis should be assessed as unfit pending satisfactory recovery.

(c) Gallstones

(1) Applicants with a single asymptomatic large gallstone or asymptomatic multiple gallstones may be assessed as fit.

(2) Applicants with symptomatic single or multiple gallstones should be assessed as unfit. A fit assessment may be considered following gallstone removal.

(d) Inflammatory bowel disease

Applicants with an established diagnosis or history of chronic inflammatory bowel disease may be assessed as fit provided that the disease is stable and not likely to interfere with the safe exercise of the privileges of the applicable licence(s).

(e) Peptic ulceration

Applicants with peptic ulceration should be assessed as unfit pending full recovery.

(f) ~~Abdominal~~ Digestive tract and abdominal surgery

~~(1) Abdominal surgery is disqualifying. A fit assessment may be considered if recovery is complete, the applicant is asymptomatic and there is only a minimal risk of secondary complication or recurrence.~~

~~(2) Applicants who have undergone a surgical operation on the digestive tract or its adnexa, involving a total or partial excision or a diversion of any of these organs, should be assessed as unfit until such time as the effects of the operation are no longer likely to interfere with the safe exercise of the privileges of the applicable licence(s).~~

Applicants who have undergone a surgical operation:



- (1) for herniae; or
- (2) on the digestive tract or its adnexa, including a total or partial excision or diversion of any of these organs

should be assessed as unfit. A fit assessment may be considered if recovery is complete, the applicant is asymptomatic, and there is only a minimal risk of secondary complication or recurrence.

(g) Liver disease

Applicants with morphological or functional liver disease, or after surgery, including liver transplantation, may be assessed as fit subject to satisfactory gastroenterological evaluation.

AMC2 MED.B.025 Metabolic and endocrine systems

(a) Metabolic, nutritional or endocrine dysfunction

Applicants with ~~M~~ metabolic, nutritional or endocrine dysfunction is ~~disqualifying~~ should be assessed as unfit. A fit assessment may be considered if the condition is asymptomatic, clinically compensated and stable.

(b) Obesity

~~Obese applicants may be assessed as fit only if the excess weight is not likely to interfere with the safe exercise of the applicable licence(s).~~

Applicants with a Body Mass Index ≥ 35 may be assessed as fit only if the excess weight is not likely to interfere with the safe exercise of the applicable licence(s) and the results of a risk assessment, including evaluation of the cardiovascular system and evaluation of the possibility of sleep apnoea, are satisfactory.

(c) Addison's disease

Applicants with Addison's disease may be assessed as fit provided that cortisone is carried and available for use whilst exercising the privileges of the applicable licence(s).

(d) Gout

Applicants with acute gout should be assessed as unfit until asymptomatic.

(e) Thyroid dysfunction

Applicants with thyroid disease may be assessed as fit once a stable euthyroid state is attained.

(f) Abnormal glucose metabolism

Glycosuria and abnormal blood glucose levels require investigation. A fit assessment may be considered if normal glucose tolerance is demonstrated (low renal threshold) or impaired glucose tolerance is fully controlled by diet and regularly reviewed.

(g) Diabetes mellitus

Applicants with diabetes mellitus may be assessed as fit. The use of antidiabetic medications that are not likely to cause hypoglycaemia may be acceptable.



AMC2 MED.B.030 Haematology

(a) Abnormal haemoglobin

Haemoglobin should be tested when clinically indicated.

(b) Anaemia

Applicants with anaemia demonstrated by a reduced haemoglobin level or low haematocrit may be assessed as fit once the primary cause has been treated and the haemoglobin or haematocrit has stabilised at a satisfactory level.

(c) ~~Erythrocytosis~~ Polycythaemia

Applicants with ~~polycythaemia~~ erythrocytosis may be assessed as fit if the condition is stable and no associated pathology is demonstrated.

(d) Haemoglobinopathy

Applicants with a haemoglobinopathy may be assessed as fit if minor thalassaemia or other haemoglobinopathy is diagnosed without a history of crises and where full functional capability is demonstrated.

(e) Coagulation and haemorrhagic disorders

Applicants with a coagulation or haemorrhagic disorder may be assessed as fit if there is no likelihood of significant bleeding.

(f) ~~Thrombo-embolic disorders~~ Thromboembolic disorders

Applicants with a thrombotic disorder may be assessed as fit if there is ~~no~~ minimal likelihood of significant clotting episodes. ~~If anticoagulation is used as treatment, refer to AMC2 MED.B.010(g).~~

(g) Disorders of the lymphatic system

Applicants with significant enlargement of the lymphatic glands or haematological disease may be assessed as fit if the condition is unlikely to interfere with the safe exercise of the privileges of the applicable licence(s). Applicants may be assessed as fit in cases of acute infectious process which is fully recovered or Hodgkin's lymphoma or other lymphoid malignancy which has been treated and is in full remission.

(h) Leukaemia

(1) Applicants with acute leukaemia may be assessed as fit once in established remission.

(2) Applicants with chronic leukaemia may be assessed as fit after a period of demonstrated stability.

(3) In cases (h)(1) and (h)(2), ~~above~~ there should be no history of central nervous system involvement and no continuing side effects from treatment of flight safety importance. Haemoglobin and platelet levels should be satisfactory. Regular follow-up is required.

(i) Splenomegaly

Applicants with splenomegaly may be assessed as fit if the enlargement is minimal, stable and no associated pathology is demonstrated, or if the enlargement is minimal and associated with another acceptable condition.



AMC2 MED.B.035 Genitourinary system

(a) Renal disease

Applicants presenting with renal disease may be assessed as fit if blood pressure is satisfactory and renal function is acceptable. Applicants requiring dialysis should be assessed as unfit.

(b) Urinary calculi

- (1) Applicants presenting with one or more urinary calculi should be assessed as unfit.
- (2) Applicants with an asymptomatic calculus or a history of renal colic require investigation.
- (3) While awaiting assessment or treatment, a fit assessment with an OSL safety pilot limitation may be considered.
- (4) After successful treatment the applicant may be assessed as fit.
- (5) Applicants with parenchymal residual calculi may be assessed as fit.

(c) Renal and urological surgery

- (1) Applicants who have undergone a major surgical operation on the genitourinary system or its adnexa urinary tract or the urinary apparatus involving a total or partial excision or a diversion of any of its organs, should be assessed as unfit until such time as the effects of the operation are no longer likely to cause incapacity in flight. recovery is complete, the applicant is asymptomatic, and the risk of secondary complication is minimal.
- (2) After other urological surgery, a fit assessment may be considered when if the applicant is completely asymptomatic, and there is only minimal risk of secondary complication or recurrence presenting with renal disease, if blood pressure is satisfactory and renal function is acceptable. The requirement for dialysis is disqualifying.
- (32) Applicants with compensated nephrectomy without hypertension or uraemia may be assessed as fit.
- (43) Applicants who have undergone renal transplantation may be considered for a fit assessment if it is fully compensated and with only minimal immuno-suppressive therapy.
- (54) Applicants who have undergone total cystectomy may be considered for a fit assessment if there is satisfactory urinary function, no infection and no recurrence of primary pathology.

AMC2 MED.B.040 Infectious diseases

(a) Tuberculosis

- (1) Applicants with active tuberculosis should be assessed as unfit. until A fit assessment may be considered following completion of therapy.
- (2) Applicants with quiescent or healed lesions may be assessed as fit. Specialist evaluation should consider the extent of the disease, the treatment required and possible side effects of medication.



(b) ~~HIV infection~~ HIV positivity

~~A fit assessment may be considered for HIV positive individuals with stable, non progressive disease if full investigation provides no evidence of HIV associated diseases that might give rise to incapacitating symptoms.~~

(1) Applicants who are HIV positive may be assessed as fit if a full investigation provides no evidence of HIV associated diseases that might give rise to incapacitating symptoms. Frequent review of the immunological status and neurological evaluation by an appropriate specialist should be carried out. A cardiological evaluation may be required, depending on the medication.

(2) Applicants with signs or symptoms of an AIDS-defining condition should be assessed as unfit.

AMC2 MED.B.045 Obstetrics and gynaecology

(a) Gynaecological surgery

~~An~~ Applicants who ~~has~~ have undergone a major gynaecological operation should be assessed as unfit until such time as the effects of the operation are not likely to interfere with the safe exercise of the privileges of the licence(s) recovery is complete, the applicant is asymptomatic, and the risk of secondary complication or recurrence is minimal.

(b) Pregnancy

(1) A pregnant licence holder may be assessed as fit during the first 26 weeks of gestation following satisfactory obstetric evaluation.

(2) Licence privileges may be resumed upon satisfactory confirmation of full recovery following confinement or termination of pregnancy.

AMC2 MED.B.050 Musculoskeletal system

(a) ~~An~~ Applicants with any significant ~~sequela~~ sequelae from disease, injury or congenital abnormality affecting the bones, joints, muscles or tendons with or without surgery should require full evaluation prior to a fit assessment.

(b) In cases of limb deficiency, a fit assessment may be considered following a satisfactory medical flight test.

(c) ~~An~~ Applicants with inflammatory, infiltrative, traumatic or degenerative disease of the musculoskeletal system may be assessed as fit, provided the condition is in remission or is stable and the applicant is taking no disqualifying medication and has satisfactorily completed a medical flight test. Appropriate limitation(s) to specified aircraft type(s) may be required apply.

(d) Abnormal physique or muscular weakness may require a satisfactory medical flight test. Appropriate limitation(s) to specified aircraft type(s) may be required apply.

AMC2 MED.B.055 Psychiatry

(a) Psychotic disorder

~~A~~ Applicants with a history of, or the occurrence, of, a functional psychotic disorder is disqualifying should be assessed as unfit. A fit assessment may be considered if ~~unless in certain rare cases~~ a cause



can be unequivocally identified as one which is transient, has ceased and ~~will not recur~~ the risk of recurrence is minimal.

(b) Organic mental disorder

Applicants with an organic mental disorder should be assessed as unfit. Once the cause has been treated, an applicant may be assessed as fit following satisfactory psychiatric evaluation.

(c) ~~Psychotropic~~ Psychoactive substances

~~Use or abuse of psychotropic substances likely to affect flight safety is disqualifying. If a stable maintenance psychotropic medication is confirmed, a fit assessment with an OSL limitation may be considered.~~

Applicants who use or misuse psychoactive substances or psychoactive medication likely to affect flight safety should be assessed as unfit. If stability on maintenance psychoactive medication is confirmed, a fit assessment with appropriate limitation(s) may be considered. If the dosage or type of medication is changed, a further period of unfit assessment should be required until stability is confirmed.

(d) Schizophrenia, schizotypal or delusional disorder

~~An~~ Applicants with an established history or clinical diagnosis of schizophrenia, schizotypal or delusional disorder may only be considered fit if the original diagnosis was inappropriate or inaccurate as confirmed by psychiatric evaluation or, in the case of a single episode of delirium, provided that the applicant has suffered no permanent impairment.

(e) Mood disorder

Applicants with an established mood disorder should be assessed as unfit. After full recovery and after full consideration of the individual case, a fit assessment may be considered, depending on the characteristics and gravity of the mood disorder. If stability on maintenance psychoactive medication is confirmed, a fit assessment with appropriate limitation(s) may be considered. If the dosage or type of medication is changed, a further period of unfit assessment should be required until stability is confirmed.

(f) Neurotic, stress-related or somatoform disorder

Where there are signs or is established evidence that an applicant may have a neurotic, stress-related or somatoform disorder, the applicant should be referred for psychiatric opinion and advice.

(g) Personality or behavioural disorders

Where there are signs or is established evidence that an applicant may have a personality or behavioural disorder, the applicant should be referred for psychiatric opinion and advice.

(h) Disorders due to alcohol or other psychoactive substance use or misuse

(1) Applicants with ~~M~~ mental or behavioural disorders due to alcohol or other psychoactive substance use or misuse, with or without dependency, ~~are disqualifying~~ should be assessed as unfit.

(2) A fit assessment may be considered ~~in consultation with the licensing authority~~ after a period of two years of documented sobriety or freedom from psychoactive substance use or misuse. A At



revalidation or renewal, a fit assessment may be considered earlier with an OSL or OPL limitation. Depending on the individual case, treatment and review evaluation may include: in-patient treatment of some weeks followed by ongoing checks, including blood testing and peer reports, which may be required indefinitely.

(i) in-patient treatment of some weeks followed by:

(A) review by a psychiatric specialist; and

(B) ongoing review including blood testing and peer reports, which may be required indefinitely.

(i) Deliberate self-harm

Applicants who have carried out a single self-destructive action or repeated acts of deliberate self-harm should be assessed as unfit. A fit assessment may be considered after full consideration of an individual case and may require psychiatric or psychological evaluation or both. Neuropsychological assessment may also be required. Psychiatric evaluations may include reports from the applicant's flight instructor.

AMC2 MED.B.060 Psychology

Applicants with a psychological disorder may need to be referred for psychological or neuropsychiatric opinion and advice.

AMC2 MED.B.065 Neurology

(a) Epilepsy

Applicants may be assessed as fit if:

- (1) there is a history of a single afebrile epileptiform seizure, considered to have a very low risk of recurrence;
- (2) there has been no recurrence after at least 10 years off treatment;
- (3) there is no evidence of continuing predisposition to epilepsy.

~~(b) Conditions with a high propensity for cerebral dysfunction~~

~~An applicant with a condition with a high propensity for cerebral dysfunction should be assessed as unfit. A fit assessment may be considered after full evaluation.~~

(be) Neurological disease

Any stationary or progressive Applicants with any disease of the nervous system which has caused or is likely to cause a significant disability is disqualifying hazard to flight safety should be assessed as unfit. However, in certain cases, including cases of minor functional loss associated with stationary stable disease, a fit assessment may be considered after full evaluation which should include a medical flight test which may be conducted in a flight simulation training device.

(c) Migraine

Applicants with an established diagnosis of migraine or other severe periodic headaches likely to cause a hazard to flight safety should be assessed as unfit. A fit assessment may be considered after full



evaluation. The evaluation should take into account at least the following: auras, visual field loss, frequency, severity, therapy. Appropriate limitation(s) may apply.

(d) Head injury

~~An~~ Applicants with a head injury which was severe enough to cause loss of consciousness or is associated with penetrating brain injury may be assessed as fit if there has been a full recovery and the risk of epilepsy is sufficiently low. An evaluation by a neurologist may be required depending on the staging of the original injury.

(e) Spinal or peripheral nerve injury

Applicants with a history or diagnosis of spinal or peripheral nerve injury or a disorder of the nervous system due to a traumatic injury should be assessed as unfit. A fit assessment may be considered if neurological evaluation is satisfactory and the provisions of AMC2 MED.B.050 are met.

(f) Vascular deficiencies

Applicants with a disorder of the nervous system due to vascular deficiencies including haemorrhagic and ischaemic events should be assessed as unfit. A fit assessment may be considered if neurological evaluation is satisfactory and the provisions of AMC2 MED.B.050 are met. A cardiological evaluation and medical flight test should be undertaken for applicants with residual deficiencies.

AMC2 MED.B.070 Visual system

(a) Eye examination

- (1) At each aero-medical revalidation examination an assessment of the visual fitness of the licence holder should be undertaken and the eyes should be examined with regard to possible pathology. Conditions which indicate further ophthalmological examination include, but are not limited to, a substantial decrease in the uncorrected visual acuity, any decrease in best corrected visual acuity and/or the occurrence of eye disease, eye injury, or eye surgery.
- (2) At the initial assessment, the examination should include:
 - (i) history;
 - (ii) visual acuities - near, intermediate and distant vision (uncorrected and with best optical correction if needed);
 - (iii) examination of the external eye, anatomy, media and funduscopy;
 - (iv) ocular motility;
 - (v) binocular vision;
 - (vi) ~~colour vision and~~ visual fields;
 - (vii) colour vision;
 - (viii) further examination on clinical indication.
- (3) At the initial assessment the applicant should submit a copy of the recent spectacle prescription if visual correction is required to meet the visual requirements.



(b) Routine eye examination

A routine eye examination should include:

- (1) history;
- (2) visual acuities - near, intermediate and distant vision (uncorrected and with best optical correction if needed);
- (3) examination of the external eye, anatomy, media and funduscopy;
- (4) further examination on clinical indication.

~~(c) Visual acuity~~

~~In an applicant with amblyopia, the visual acuity of the amblyopic eye should be 6/18 (0,3) or better. The applicant may be assessed as fit, provided the visual acuity in the other eye is 6/6 (1,0) or better, with or without correction, and no significant pathology can be demonstrated.~~

~~(d) Substandard vision~~

- ~~(1) Reduced stereopsis, abnormal convergence not interfering with near vision and ocular misalignment where the fusional reserves are sufficient to prevent asthenopia and diplopia may be acceptable.~~
- ~~(2) An applicant with substandard vision in one eye may be assessed as fit subject to a satisfactory flight test if the better eye:

 - ~~(i) achieves distant visual acuity of 6/6 (1,0), corrected or uncorrected;~~
 - ~~(ii) achieves intermediate visual acuity of N14 and N5 for near;~~
 - ~~(iii) has no significant pathology.~~~~
- ~~(3) An applicant with a visual field defect may be considered as fit if the binocular visual field is normal and the underlying pathology is acceptable.~~

(c) Visual acuity

Reduced vision in one eye or monocularly: Applicants with reduced vision or loss of vision in one eye may be assessed as fit if:

- (1) the binocular visual field or, in the case of monocularly, the monocular visual field is acceptable;
- (2) in the case of monocularly, a period of adaptation time has passed from the known point of visual loss, during which the applicant should be assessed as unfit;
- (3) the unaffected eye achieves distant visual acuity of 6/6 (1,0), corrected or uncorrected;
- (4) the unaffected eye achieves intermediate visual acuity of N14 or equivalent and N5 or equivalent for near (Refer to GM1 MED.B.070);
- (5) there is no significant ocular pathology in the unaffected eye; and
- (6) a medical flight test is satisfactory.



(d) Binocular function

Reduced stereopsis, abnormal convergence not interfering with near vision and ocular misalignment where the fusional reserves are sufficient to prevent asthenopia and diplopia may be acceptable.

(e) Eye surgery

- (1) The assessment after eye surgery should include an ophthalmological examination.
- (2) After refractive surgery a fit assessment may be considered provided that there is satisfactory stability of refraction, there are no post-operative complications and no increase in glare sensitivity.
- (3) After cataract, retinal or glaucoma surgery a fit assessment may be considered once recovery is complete and the visual requirements are met with or without correction.

(f) ~~Correcting lenses~~ Visual correction

Correcting lenses should permit the licence holder to meet the visual requirements at all distances.

AMC2 MED.-B.075 Colour vision

- (ae)** Colour vision should be tested on clinical indication at revalidation ~~or~~ and renewal examinations.
- (ba)** The Ishihara test (24 plate version) is considered passed if the first 15 plates, presented in a random order, are identified without error.
- (cb)** Those failing the Ishihara test should be examined either by:
- (1) anomaloscopy (Nagel or equivalent). This test is considered passed if the colour match is trichromatic and the matching range is 4 scale units or less, or if the anomalous quotient is acceptable; or by
 - (2) lantern testing with a Spectrolux, Beynes or Holmes-Wright lantern. This test is considered passed if the applicant passes without error a test with accepted lanterns; or by
 - (3) Colour Assessment and Diagnosis (CAD) test. This test is considered passed if the threshold is less than 6 standard normal (SN) units for deutan deficiency, or less than 12 SN units for protan deficiency. A threshold greater than 2 SN units for tritan deficiency indicates an acquired cause which should be investigated.

AMC2 MED.B.080 ~~Otorhino-laryngology~~ Otorhinolaryngology (ENT)**(a) Hearing**

- (1) ~~The a-~~ Applicants should understand correctly conversational speech when tested with each ear at a distance of 2 metres from and with the applicant's back turned towards the AME.
- (2) ~~An a-~~ Applicants with hypoacusis may be assessed as fit if a speech discrimination test or functional cockpit hearing test demonstrates satisfactory hearing ability. ~~An applicant for an instrument rating with hypoacusis should be assessed in consultation with the licensing authority.~~
- (3) If the hearing requirements can be met only with the use of hearing aids, the hearing aids should provide optimal hearing function, be well tolerated and suitable for aviation purposes.



- (4) Applicants with profound deafness or major disorder of speech, or both, may be assessed as fit with an SSL, such as 'limited to areas and operations where the use of radio is not mandatory'. The aircraft should be equipped with appropriate alternative warning devices in lieu of sound warnings.
- (b) Examination
An ~~ear, nose and throat (ENT)~~ examination should form part of all initial, revalidation and renewal examinations.
- (c) Ear conditions
- (1) ~~An a~~ Applicants with an active pathological process, ~~acute or chronic~~, of the internal or middle ear should be assessed as unfit until the condition has stabilised or there has been a full recovery.
 - (2) ~~An a~~ Applicants with an unhealed perforation or dysfunction of the tympanic membranes should be assessed as unfit. An applicant with a single dry perforation of non-infectious origin which does not interfere with the normal function of the ear may be considered for a fit assessment.
- (d) Vestibular disturbance
~~An a~~ Applicants with disturbance of vestibular function should be assessed as unfit pending full recovery.
- (e) Sinus dysfunction
~~An a~~ Applicants with any dysfunction of the sinuses should be assessed as unfit pending full recovery.
- (f) Oral/upper respiratory tract infections
~~Applicants with A~~ a significant, ~~acute or chronic~~ infection of the oral cavity or upper respiratory tract ~~is disqualifying~~ should be assessed as unfit. A fit assessment may be considered after full recovery.
- (g) Speech disorder
~~Applicants with a~~ A significant disorder of speech or voice should be ~~disqualifying~~ assessed as unfit.
- (h) Air passage restrictions
~~An a~~ Applicants with significant restriction of the nasal air passage on either side, or significant malformation of the oral cavity or upper respiratory tract may be assessed as fit if ENT evaluation is satisfactory.
- (i) Eustachian tube dysfunction
~~An a~~ Applicants with ~~significant~~ permanent dysfunction of the Eustachian tube(s) may be assessed as fit ~~in consultation with the licensing authority~~ if ENT evaluation is satisfactory.
- (j) Sequelae of surgery of the internal or middle ear
Applicants with sequelae of surgery of the internal or middle ear should be assessed as unfit until recovery is complete, the applicant is asymptomatic, and the risk of secondary complication is minimal.

GM2 MED.B.080 Otorhinolaryngology (ENT)**PURE TONE AUDIOGRAM**

The pure tone audiogram may also cover the 4 000 Hz frequency for early detection of decrease in hearing.

AMC2 MED.B.085 Dermatology

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

AMC2 MED.B.090 Oncology

- (a) Applicants who have been diagnosed with a malignant disease may be considered for a fit assessment after treatment for malignant disease if provided that:
- (1) after primary treatment, there is no evidence of residual malignant disease after treatment likely to jeopardise flight safety;
 - (2) time appropriate to the type of tumour and primary treatment has elapsed since the end of 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 jeopardise flight safety;
 - (5) special attention is paid to applicants who have received anthracycline chemotherapy;
 - (5) arrangements for an oncological follow-up have been made for an appropriate period of time.
- (b) Applicants receiving ongoing chemotherapy or radiation treatment should be assessed as unfit.
- (c) Applicants with pre-malignant conditions of the skin may be assessed as fit if treated or excised as necessary and there is a regular follow-up.



Section 4

Specific requirements for LAPL medical certificates

AMC1 MED.B.095 Medical examination and/or assessment of applicants for LAPL medical certificates

When a specialist evaluation is required under this section, the aero-medical assessment of the applicant should be performed by an AeMC, an AME or, in the case of AMC-5 MED.B.095(d), by the licensing authority.

AMC2 MED.B.095 Cardiovascular system

(a) Examination

Pulse and blood pressure should be recorded at each examination.

(b) General

(1) Cardiovascular risk factor assessment

An accumulation of risk factors (smoking, family history, lipid abnormalities, hypertension, etc.) requires cardiovascular evaluation.

(2) Aortic aneurysm

Applicants with an aortic aneurysm may be assessed as fit subject to satisfactory cardiological evaluation and a regular follow-up.

(3) Cardiac valvular abnormalities

(i) Applicants with a cardiac murmur may be assessed as fit if the murmur is assessed as being of no pathological significance.

(ii) Applicants with a cardiac valvular abnormality may be assessed as fit subject to satisfactory cardiological evaluation.

(4) Valvular surgery

After cardiac valve replacement or repair, a fit assessment may be considered, with an ORL if anticoagulation is needed, if subject to satisfactory post-operative cardiological evaluation cardiac function and investigations are satisfactory. Anticoagulation, if needed, should be stable and the haemorrhagic risk should be acceptable. Anticoagulation should be considered stable if, within the last 6 months, at least 5 INR values are documented, of which at least 4 are within the INR target range. The INR target range should be determined by the type of surgery performed. Applicants who measure their INR on a 'near patient' testing system within 12 hours prior to flight and only exercise the privileges of their licence if the INR is within the target range, may be assessed as fit without the above-mentioned limitation. The INR results should be recorded and the results should be reviewed at each aero-medical assessment. Applicants taking anticoagulation medication not requiring INR monitoring, may be assessed as fit without the above-mentioned limitation in consultation with the licensing authority after a stabilisation period of 3 months.

(5) Other cardiac disorders:

(i) Applicants with other cardiac disorders may be assessed as fit subject to satisfactory cardiological assessment-evaluation. A fit assessment may be considered, with an ORL if



anticoagulation is needed. Anticoagulation should be stable and the haemorrhagic risk should be acceptable. Anticoagulation should be considered stable if, within the last 6 months, at least 5 INR values are documented, of which at least 4 are within the INR target range. The INR target range should be determined by the type of surgery performed. Applicants who measure their INR on a 'near patient' testing system within 12 hours prior to flight and only exercise the privileges of their licence if the INR is within the target range, may be assessed as fit without the above-mentioned limitation. The INR results should be recorded and the results should be reviewed at each aero-medical assessment. Applicants taking anticoagulation medication not requiring INR monitoring, may be assessed as fit without the above-mentioned limitation in consultation with the licensing authority after a stabilisation period of 3 months.

(ii) Applicants with symptomatic hypertrophic cardiomyopathy should be assessed as unfit.

(c) Blood pressure

- (1) When the blood pressure consistently exceeds 160 mmHg systolic and/or 95 mmHg diastolic, with or without treatment, the applicant should be assessed as unfit.
- (2) ~~The Applicants initiating initiation of medication for the control of blood pressure should require a period of temporary suspension of the medical certificate to establish~~ Applicants initiating initiation of medication for the control of blood pressure should require a period of temporary suspension of the medical certificate to establish ~~be assessed as unfit until the absence of significant side effects has been established.~~

(d) Coronary artery disease

- (1) Applicants with suspected myocardial ischaemia ~~should be investigated~~ ~~can~~ ~~may~~ undergo a cardiological evaluation before a fit assessment ~~can~~ ~~may~~ be considered.
- (2) Applicants with angina pectoris requiring medication for cardiac symptoms should be assessed as unfit.
- (3) After an ischaemic cardiac event, including myocardial infarction or revascularisation, applicants without symptoms should have reduced ~~any~~ cardiovascular risk factors to an appropriate level. Medication, when used to control cardiac symptoms, is not acceptable. All applicants should be on ~~acceptable~~ appropriate secondary prevention treatment.
- (4) In cases ~~under (d)(1), (d)(2) and (d)(3) above,~~ applicants who have had a satisfactory cardiological evaluation to include an exercise test or equivalent that is negative for ischaemia may be assessed as fit.

(e) Rhythm and conduction disturbances

- (1) Applicants with a significant disturbance of cardiac rhythm or conduction should be assessed as unfit unless a cardiological evaluation concludes that the disturbance is not likely to interfere with the safe exercise of the privileges of the ~~LAPL~~ licence. ~~A fit assessment may be considered, with an ORL if anticoagulation is needed. Anticoagulation should be stable and the haemorrhagic risk should be acceptable. Anticoagulation should be considered stable if, within the last 6 months, at least 5 INR values are documented, of which at least 4 are within the INR target range. The INR target range should be determined by the type of surgery performed. Applicants who measure their INR on a 'near patient' testing system within 12 hours prior to flight and only exercise the privileges of their licence if the INR is within the target range, may be assessed as fit without the~~



above-mentioned limitation. The INR results should be recorded and the results should be reviewed at each aero-medical assessment. Applicants taking anticoagulation medication not requiring INR monitoring, may be assessed as fit without the above-mentioned limitation in consultation with the licensing authority after a stabilisation period of 3 months.

(2) Pre-excitation

Applicants with ventricular pre-excitation may be assessed as fit subject to satisfactory cardiological evaluation. Applicants with ventricular pre-excitation associated with a significant arrhythmia should be assessed as unfit.

(3) Automatic implantable defibrillating system

Applicants with an automatic implantable defibrillating system should be assessed as unfit.

~~(4)~~ Pacemaker

A fit assessment may be considered subject to satisfactory cardiological evaluation.

AMC3 MED.B.095 Respiratory system

(a) Applicants should undergo pulmonary morphological or functional tests when clinically indicated.

~~(b)~~ Asthma and chronic obstructive ~~airways~~ pulmonary disease

Applicants with asthma or ~~minor~~ impairment of pulmonary function may be assessed as fit if provided that the condition is considered stable with satisfactory pulmonary function and medication is compatible with flight safety. Systemic steroids may be ~~disqualifying~~ acceptable depending on provided that the dosage ~~needed~~ required is acceptable and ~~corresponding~~ there are no adverse side effects.

~~(c)~~ Sarcoidosis

(1) Applicants with active sarcoidosis should be assessed as unfit. Investigation should be undertaken with respect to the possibility of systemic involvement. A fit assessment may be considered once the disease is inactive.

(2) Applicants with cardiac sarcoidosis should be assessed as unfit.

~~(d)~~ Pneumothorax

(1) Applicants with spontaneous pneumothorax may be assessed as fit subject to satisfactory respiratory evaluation following ~~full~~ recovery from a single spontaneous pneumothorax or following recovery from surgical ~~treatment~~ intervention for a recurrent pneumothorax.

(2) Applicants with traumatic pneumothorax may be assessed as fit following ~~full~~ recovery.

~~(e)~~ Thoracic surgery

Applicants who have undergone ~~major~~ thoracic surgery may be assessed as fit following ~~full~~ recovery.

~~(f)~~ Sleep apnoea syndrome/sleep disorder

Applicants with unsatisfactorily treated sleep apnoea syndrome should be assessed as unfit.



AMC4 MED.B.095 Digestive system

(a) Gallstones

Applicants with symptomatic gallstones should be assessed as unfit. A fit assessment may be considered following gallstone removal.

(b) Inflammatory bowel disease

Applicants with an established diagnosis or history of chronic inflammatory bowel disease may be assessed as fit provided that the disease is stable and not likely to interfere with the safe exercise of the privileges of the licence.

(c) Peptic ulceration

Applicants with peptic ulceration may be assessed as fit subject to satisfactory gastroenterological evaluation.

(d) Digestive tract and Abdominal surgery

~~Applicants who have undergone a surgical operation on the digestive tract or its adnexae may be assessed as fit provided recovery is complete, they are asymptomatic and there is only a minimal risk of secondary complication or recurrence.~~

Applicants who have undergone a surgical operation:

(1) for herniae; or

(2) on the digestive tract or its adnexa, including a total or partial excision or diversion of any of these organs,

should be assessed as unfit. A fit assessment may be considered if recovery is complete, the applicant is asymptomatic, and there is only a minimal risk of secondary complication or recurrence.

(e) Pancreatitis

Applicants with pancreatitis may be assessed as fit after satisfactory recovery.

(f) Liver disease

Applicants with morphological or functional liver disease or after surgery, including liver transplantation, may be assessed as fit subject to satisfactory gastroenterological evaluation.

AMC5 MED.B.095 Metabolic and endocrine systems

(a) Metabolic, nutritional or endocrine dysfunction

Applicants with metabolic, nutritional or endocrine dysfunction may be assessed as fit subject to demonstrated stability of the condition and satisfactory aero-medical evaluation.

(b) Obesity

Obese applicants may be assessed as fit if the excess weight is not likely to interfere with the safe exercise of the licence.

(c) Thyroid dysfunction

Applicants with thyroid disease may be assessed as fit once a stable euthyroid state is attained.



- (d) Diabetes mellitus
- (1) ~~The use of Applicants using~~ antidiabetic medications that are not likely to cause hypoglycaemia ~~should be acceptable for a~~ ~~may be assessed as~~ fit assessment.
 - (2) Applicants with diabetes mellitus Type 1 should be assessed as unfit.
 - (3) Applicants with diabetes mellitus Type 2 treated with insulin may be assessed as fit with limitations for revalidation if blood sugar control has been achieved and the process under (e) and (f) ~~below~~ is followed. An ~~ORL-OSL~~ limitation is required. A TML ~~limitation~~ for 12 months may be needed to ensure compliance with the follow-up requirements below. Licence privileges should ~~not include rotary aircraft flying~~ ~~be restricted to aeroplanes and sailplanes only.~~
- (e) Aero-medical assessment by, or under the guidance of, the licensing authority:
- (1) A diabetology review at yearly intervals, including:
 - (i) symptom review;
 - (ii) review of data logging of blood sugar;
 - (iii) cardiovascular status. Exercise ECG at age 40, at 5-yearly intervals thereafter and on clinical indication, including an accumulation of risk factors;
 - (iv) ~~nephropathy/~~ nephropathy status.
 - (2) Ophthalmological review at yearly intervals, including:
 - (i) visual fields— ~~—~~ Humphrey-perimeter;
 - (ii) retinae— ~~—~~ full dilatation slit lamp ~~examination and documentation;~~
 - (iii) cataract— ~~—~~ clinical screening.

The development of retinopathy requires a full ophthalmological review.
 - (3) Blood testing at 6-monthly intervals:
 - (i) HbA1c; target is 7,5–8,5 %;
 - (ii) renal profile;
 - (iii) liver profile;
 - (iv) lipid profile.
 - (4) Applicants should be assessed as temporarily unfit after:
 - (i) changes of medication/insulin leading to a change to the testing regime until stable blood sugar control can be demonstrated;
 - (ii) a single unexplained episode of severe hypoglycaemia until stable blood sugar control can be demonstrated.
 - (5) Applicants should be assessed as unfit in the following cases:
 - (i) loss of hypoglycaemic awareness;
 - (ii) development of retinopathy with any visual field loss;



- (iii) significant nephropathy;
 - (iv) any other complication of the disease where flight safety may be jeopardised.
- (f) Pilot responsibility
- Blood sugar testing is carried out during non-operational and operational periods. A whole blood glucose measuring device with memory should be carried and used. Equipment for continuous glucose monitoring (CGMS) should not be used. Pilots should prove to the AME or AeMC or licensing authority that testing has been performed as indicated below and with which results.
- (1) Testing during non-operational periods: normally 3–4 times/day or as recommended by the treating physician, and on any awareness of hypoglycaemia.
 - (2) Testing frequency during operational periods:
 - (i) 120 minutes before departure;
 - (ii) <30 minutes before departure;
 - (iii) 60 minutes during flight;
 - (iv) 30 minutes before landing.
 - (3) Actions following glucose testing:
 - (i) 120 minutes before departure: if the test result is >15 mmol/l, piloting should not be commenced.
 - (ii) 10–15g of carbohydrate should be ingested and a re-test performed within 30 minutes if:
 - (A) any test result is <4,5 mmol/l;
 - (B) the pre-landing test measurement is missed or a subsequent go-around/diversion is performed.

GM1 MED.B.095 ~~Diabetes mellitus Type 2 treated with insulin~~ Metabolic and endocrine systems**DIABETES MELLITUS TYPE 2 TREATED WITH INSULIN — GENERAL**

- (a) Pilots and their treating physician should be aware that if the HbA1c target level was set to normal (non-diabetic) levels, this will significantly increase the chance of hypoglycaemia. For safety reasons the target level of HbA1c is therefore set to 7,5–8,5 % even though there is evidence that lower HbA1c levels are correlated with fewer diabetic complications.
- (b) The safety pilot should be briefed pre-flight on the potential condition of the pilot. The results of blood sugar testing before and during flight should be shared with the safety pilot for the acceptability of the values obtained.



GM2 MED.B.095 Metabolic and endocrine systems**DIABETES MELLITUS TYPE 2 TREATED WITH INSULIN — CONVERSION TABLE FOR HbA1c IN % AND MMOL/MOL**

HbA1c in %	HbA1c in mmol/mol
4,7	28
5,0	31
5,3	34
5,6	38
5,9	41
6,2	44
6,5	48
6,8	51
7,4	57
8,0	64
8,6	70
9,2	77
9,8	84
10,4	90
11,6	103

AMC6 MED.B.095 Haematology

Applicants with a haematological condition, such as:

- (a) abnormal haemoglobin including, but not limited to, anaemia, erythrocytosis ~~polycythaemia~~ or haemoglobinopathy;
- (b) coagulation, haemorrhagic or thrombotic disorder;
- (c) significant lymphatic enlargement;
- (d) acute or chronic leukaemia;
- (e) enlargement of the spleen ~~splenomegaly~~;

may be assessed as fit subject to satisfactory aero-medical evaluation. If anticoagulation is being used as treatment, refer to AMC2 MED.B.095(b)(4).

AMC7 MED.B.095 Genitourinary system

(a) Applicants with a genitourinary disorder, such as:

- (1) renal disease; or
- (2) one or more urinary calculi, or a history of renal colic

may be assessed as fit subject to satisfactory renal and urological evaluation, as applicable.



- (b) Applicants who have undergone a major surgical operation ~~in~~ on the genitourinary apparatus system or its adnexa may be assessed as fit following full recovery.
- (c) Applicants who have undergone renal transplantation may be assessed as fit subject to satisfactory renal evaluation.

AMC8 MED.B.095 Infectious disease

- (a) ~~HIV infection: a~~ Applicants who are HIV positive may be assessed as fit ~~if investigation provides no evidence of clinical disease~~ subject to satisfactory aero-medical evaluation.
- (b) Applicants with other chronic infections may be assessed as fit provided the infections are not likely to interfere with the safe exercise of the privileges of the licence.

AMC9 MED.B.095 Obstetrics and gynaecology

- (a) Pregnancy
Holders of a LAPL medical certificate should only exercise the privileges of their licences until the end of the 26th week of gestation under routine antenatal care.
- (b) Applicants who have undergone a major gynaecological operation may be assessed as fit after full recovery.

AMC10 MED.B.095 Musculoskeletal system

Applicants should have satisfactory functional use of the musculoskeletal system to enable the safe exercise of the privileges of the licence.

AMC11 MED.B.095 Psychiatry

- (a) Applicants with a mental or behavioural disorder due to use or misuse of alcohol or other psychoactive substances use, with or without dependency, should be assessed as unfit. ~~pending recovery and freedom from substance use and subject to satisfactory psychiatric evaluation after treatment.~~ A fit assessment may be considered after a period of two years of documented sobriety or freedom from psychoactive substance use or misuse, subject to satisfactory psychiatric evaluation after successful treatment. At revalidation or renewal, a fit assessment may be considered earlier. Depending on the individual case, treatment and evaluation may include in-patient treatment of some weeks followed by ongoing checks, including blood testing and peer reports, which may be required indefinitely.
- (b) Applicants with a history of, or the occurrence of, a functional psychotic disorder should be assessed as unfit. A fit assessment may be considered if a cause can be unequivocally identified as one which is transient, has ceased, and the risk of recurrence is minimal.
- (c) Applicants with an established history or clinical diagnosis of schizophrenia, schizotypal or delusional disorder should be assessed as unfit. A fit assessment may only be considered if the original diagnosis was inappropriate or inaccurate as confirmed by psychiatric evaluation or, in the case of a single episode of delirium, provided that the applicant has suffered no permanent impairment.
- (d) ~~Psychotropic~~ Psychoactive substances
Use or abuse of psychotropic substances likely to affect flight safety should be disqualifying. ~~If a stable maintenance psychotropic medication is confirmed, a fit assessment with an appropriate limitation may be considered.~~



Applicants who use or misuse psychoactive substances or psychoactive medication likely to affect flight safety should be assessed as unfit. If stability on maintenance psychoactive medication is confirmed, a fit assessment with appropriate limitation(s) may be considered. If the dosage or type of medication is changed, a further period of unfit assessment should be required until stability is confirmed.

~~(ed)~~ Applicants with a psychiatric condition, such as:

- (1) mood disorder;
- (2) neurotic disorder;
- (3) personality disorder;
- (4) mental or behavioural disorder

should undergo satisfactory psychiatric evaluation before a fit assessment may be considered.

~~(fe)~~ Applicants with a history of significant or repeated acts of deliberate self-harm should undergo satisfactory psychiatric ~~and/or~~ psychological evaluation ~~or both~~ before a fit assessment ~~can~~ **may** be considered.

~~(g)~~ Psychiatric evaluations and reviews may include reports from the applicant's flight instructor.

GM3 MED.B.095 Psychiatry

MOOD DISORDER

After full recovery from a mood disorder and after full consideration of the individual case, a fit assessment may be considered, depending on the characteristics and gravity of the mood disorder. If stability on maintenance psychoactive medication is confirmed, a fit assessment may be considered. If the dosage or type of medication is changed, a further evaluation may be required until stability is confirmed.

AMC12 MED.B.095 Psychology

Applicants with a psychological disorder may need to be referred for psychological opinion and advice.

AMC13 MED.B.095 Neurology

(a) Epilepsy and seizures

- (1) Applicants with an established diagnosis of and under treatment for epilepsy should be assessed as unfit. A re-assessment after all treatment has been stopped for at least 5 years should include a **review of neurological-evaluation reports**.
- (2) Applicants may be assessed as fit if:
 - (i) there is a history of a single afebrile epileptiform seizure considered to have a very low risk of recurrence; ~~and~~
 - (ii) there has been no recurrence after at least 5 years off treatment; ~~or~~
 - (iii) a cause has been identified and treated and there is no evidence of continuing predisposition to epilepsy.

(b) Neurological disease

~~(1)~~ — Applicants with any ~~stationary or progressive~~ disease of the nervous system which ~~has caused~~ ~~or~~ is likely to cause a **hazard to flight safety-significant disability** should be assessed as unfit. ~~The AME or~~



AeMC should assess these applicants taking into account the privileges of the licence held and the risk involved. An OPL limitation may be appropriate if a fit assessment is made. (2) — However, in certain cases, including cases of minor functional loss associated with stationary stable disease, a fit assessment may be considered after full evaluation including, if necessary, a medical flight test.

(c) Migraine

Applicants with an established diagnosis of migraine or other severe periodic headaches likely to cause a hazard to flight safety should be assessed as unfit. A fit assessment may be considered after full evaluation. The evaluation should take into account at least the following: auras, visual field loss, frequency, severity, therapy. Appropriate limitation(s) may apply.

(de) Head injury

Applicants with a head injury which was severe enough to cause loss of consciousness or is associated with penetrating brain injury may be assessed as fit if there has been a full recovery and the risk of epilepsy is sufficiently low. An evaluation by a neurologist may be required depending on the staging of the original injury.

(ed) Spinal or peripheral nerve injury

Applicants with a history or diagnosis of spinal or peripheral nerve injury or a disorder of the nervous system due to a traumatic injury may be assessed as fit if neurological review evaluation is satisfactory and the provisions of AMC10 MED.B.095 are met and musculoskeletal assessments are satisfactory.

(f) Vascular deficiencies

Applicants with a disorder of the nervous system due to vascular deficiencies including haemorrhagic and ischaemic events should be assessed as unfit. A fit assessment may be considered if neurological evaluation is satisfactory and the provisions of AMC10 MED.B.095 are met. A cardiological evaluation and medical flight test should be undertaken for applicants with residual deficiencies.

AMC14 MED.B.095 Visual system

(a) Applicants should not possess any abnormality of the function of the eyes or their adnexa or any active pathological condition, congenital or acquired, acute or chronic, or any sequelae of eye surgery or trauma, which is likely to interfere with the safe exercise of the privileges of the applicable licence(s).

(b) Eye examination

The examination should include visual acuities (near, intermediate and distant vision) and visual field.

(c) Visual acuity

- (1) Visual acuity with or without corrective lenses should be 6/9 (0,7) binocularly and 6/12 (0,5) in each eye.
- (2) Applicants who do not meet the required visual acuity should be assessed by an AME or AeMC, taking into account the privileges of the licence held and the risk involved.
- (3) Applicants should be able to read, binocularly, an N5 chart (or equivalent) at 30-50 cms and an N14 chart (or equivalent) at 100 cms, with correction if prescribed (Refer to GM1 MED.B.070).

(de) Visual acuity Substandard vision

Applicants with substandard vision in one eye may be assessed as fit if the better eye:



- (1) achieves distant visual acuity of 6/6 (1,0), corrected or uncorrected;
- (2) achieves distant visual acuity less than 6/6 (1,0) but not less than 6/9 (0,7), after ophthalmological evaluation.

(ed) Visual field defects

Applicants with a visual field defect may be assessed as fit if the binocular visual field or, in the case of monocular visual field defects, the monocular visual field is normal acceptable.

(fe) Eye surgery

- (1) After refractive surgery, a fit assessment may be considered, provided that there is satisfactory stability of refraction, there are no post-operative complications and no significant increase in glare sensitivity.
- (2) After cataract, retinal or glaucoma surgery a fit assessment may be considered once recovery is complete.

(gf) ~~Correcting lenses~~ Visual correction

Correcting lenses should permit the licence holder to meet the visual requirements at all distances.

AMC15 MED.B.095 Colour vision

Applicants for a night rating should correctly identify 9 of the first 15 plates of the 24-plate edition of Ishihara pseudoisochromatic plates or should be colour safe.

AMC16 MED.B.095 ~~Otorhino-laryngology~~ Otorhinolaryngology (ENT)**(a) Hearing**

- (1) Applicants should understand correctly conversational speech when tested with or without hearing aids at a distance of 2 metres from and with the applicant's back turned towards the examiner.
- (2) If the hearing requirements can only be met with the use of hearing aid(s), the hearing aid(s) should provide optimal hearing function, be well-tolerated, and be suitable for aviation purposes.
- (3) Applicants with hypoacusis should demonstrate satisfactory functional hearing ability.
- (4) Applicants with profound deafness or major disorder of speech, or both, may be assessed as fit with an SSL such as 'limited to areas and operations where the use of radio is not mandatory'. The aircraft should be equipped with appropriate alternative warning devices in lieu of sound warnings.

(b) Ear conditions

Applicants for a LAPL medical certificate with:

- (1) an active pathological process, acute or chronic, of the internal or middle ear;
- (2) unhealed perforation or dysfunction of the tympanic membrane(s);
- (3) disturbance of vestibular function;
- (4) significant restriction of the nasal passages;



- (5) sinus dysfunction;
- (6) significant malformation or significant, ~~acute or chronic~~ infection of the oral cavity or upper respiratory tract; or
- (7) significant disorder of speech or voice

should undergo further ~~medical~~ examination and ~~assessment~~ to establish that the condition does not interfere with the safe exercise of the privileges of the licence.

AMC17 MED.B.095 Dermatology

In cases where a dermatological condition is associated with a systemic illness, 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~~ jeopardise flight safety.
- (b) Arrangements for an oncological follow-up should be made for an appropriate period of time.
- (c) Applicants with an established history or clinical diagnosis of intracerebral malignant tumour should be assessed as unfit.



SUBPART C**Requirements for medical fitness of cabin crew****Section 1****General requirements****AMC1 MED.C.005 Aero-medical assessments**

- (a) When conducting aero-medical examinations and/or assessments of cabin crew members, as applicable, their medical fitness should be assessed with particular regard to their physical and mental ability to:
- (1) undergo the training required for cabin crew to acquire and maintain competence, e.g. actual fire-fighting, slide descending, using Protective Breathing Equipment (PBE) in a simulated smoke-filled environment, providing first aid;
 - (2) manipulate the aircraft systems and emergency equipment to be used by cabin crew, e.g. cabin management systems, doors/exits, escape devices, fire extinguishers, taking also into account the class and type of aircraft operated, e.g. narrow-bodied or wide-bodied, single/multi-deck, single/multi-cabin crew operation;
 - (3) continuously ~~sustain~~ tolerate the aircraft environment whilst performing duties, e.g. altitude, pressure, re-circulated air, noise; and the type of operations such as short/medium/long/~~ultra long~~ ultra long haul; and
 - (4) perform the required duties and responsibilities efficiently during normal and abnormal operations, and in emergency situations and psychologically demanding circumstances, e.g. assistance to crew members and passengers in case of decompression; stress management, decision-making, crowd control and effective crew coordination, management of disruptive passengers and of security threats. When relevant, operating as single cabin crew should also be taken into account when assessing the medical fitness of cabin crew.
- (b) Intervals
- (1) The interval between aero-medical assessments should be determined by the competent authority. The intervals established by the competent authority apply to cabin crew members who:
 - (i) undergo aero-medical assessments by an AME, AeMC or OHMP under the oversight of that competent authority;
 - (ii) are employed by an operator under the oversight of that competent authority.
 - (2) The interval between aero-medical assessments may be reduced by the AME, AeMC or OHMP for medical reasons and in accordance with MED.C.035.
 - (3) Aero-medical assessments for the revalidation of a cabin crew medical report may be undertaken up to 45 days prior to the expiry date of the previous medical report. The validity period of the aero-medical assessment shall be calculated from the expiry date of the previous aero-medical assessment.



Section 2

Requirements for aero-medical assessment of cabin crew

AMC1 MED.C.025 Content of aero-medical assessments

Aero-medical examinations and/or assessments of cabin crew members should be conducted according to the specific medical requirements in AMC2 to AMC18 MED.C.025.

GM1 MED.C.025 Content of aero-medical assessments *(Previously positioned after AMC18 MED.C.025)*

- (a) When conducting aero-medical examinations and/or assessments, typical cabin crew duties as listed in (b) and (c), particularly those to be performed during abnormal operations and emergency situations, and cabin crew responsibilities to the travelling public should be considered in order to identify:
 - (1) any physical and/or mental conditions that could be detrimental to the performance of the duties required from cabin crew; and
 - (2) which examination(s), test(s) or investigation(s) should be undergone to complete an appropriate aero-medical assessment.
- (b) Main cabin crew duties and responsibilities during day-to-day normal operations
 - (1) During pre/post-flight ground operations with/without passengers on board:
 - (i) monitoring of situation inside the aircraft cabin and awareness of conditions outside the aircraft including observation of visible aircraft surfaces and information to flight crew of any surface contamination such as ice or snow;
 - (ii) assistance to special categories of passengers (SCPs) such as infants and children (accompanied or unaccompanied), persons with disabilities or reduced mobility, medical cases with or without medical escort, and inadmissible persons, deportees and passengers in custody;
 - (iii) observation of passengers (any suspicious behaviour, passengers under the influence of alcohol and/or drugs, mentally disturbed), observation of potential able-bodied persons, crowd control during boarding and disembarkation;
 - (iv) safe stowage of cabin luggage, safety demonstrations and cabin secured checks, management of passengers and ground services during re-fuelling, observation of use of portable electronic devices;
 - (v) preparedness to carry out safety and emergency duties at any time, and security alertness.
 - (2) During flight:
 - (i) operation and monitoring of aircraft systems, surveillance of the cabin, lavatories, galleys, crew areas and flight crew compartment;
 - (ii) coordination with flight crew on situation in the cabin and turbulence events/effects;
 - (iii) management and observation of passengers (consumption of alcohol, behaviour, potential medical issues), observation of use of portable electronic devices;
 - (iv) safety and security awareness and preparedness to carry out safety and emergency duties at any time, and cabin secured checks prior to landing.



- (c) Main cabin crew duties and responsibilities during abnormal and emergency operations
- (1) In case of planned or unplanned emergency evacuation: briefing and/or commands to passengers including SCPs and selection and briefing to able-bodied persons; crowd control monitoring and evacuation conduct including in the absence of command from the flight crew; post-evacuation duties including assistance, first aid and management of survivors and survival in particular environments; activation of applicable communication means towards search and rescue services.
 - (2) In case of decompression: checking of crew members, passengers, cabin, lavatories, galleys, crew rest areas and flight crew compartment, and administering oxygen to crew members and passengers as necessary.
 - (3) In case of pilot incapacitation: secure pilot in his/her seat or remove from flight crew compartment; administer first aid and assist operating pilot as required.
 - (4) In case of fire or smoke: identify source/cause/type of fire/smoke to perform the necessary required actions; coordinate with other cabin crew members and flight crew; select appropriate extinguisher/agent and fight the fire using portable breathing equipment (PBE), gloves, and protective clothing as required; management of necessary passengers' movement if possible; instructions to passengers to prevent smoke inhalation/suffocation; give first aid as necessary; monitor the affected area until landing; preparation for possible emergency landing.
 - (5) In case of first aid and medical emergencies: assistance to crew members and/or passengers; correct assessment and correct use of therapeutic oxygen, defibrillator, first-aid kits/emergency medical kit contents as required; management of events, of incapacitated person(s) and of other passengers; coordination and effective communication with other crew members, in particular when medical advice is transmitted by frequency to flight crew or by a telecommunication connection.
 - (6) In case of disruptive passenger behaviour: passenger management as appropriate including use of restraint technique as considered required.
 - (7) In case of security threats (bomb threat on ground or in-flight and/or hijack): control of cabin areas and passengers' management as required by the type of threat, management of suspicious device, protection of flight crew compartment door.
 - (8) In case of handling of dangerous goods: observing safety procedures when handling the affected device, in particular when handling chemical substances that are leaking; protection and management of self and passengers and effective coordination and communication with other crew members.

AMC2 MED.C.025 Cardiovascular system

- (a) Examination
- (1) A standard 12-lead resting electrocardiogram (ECG) and report should be completed on clinical indication, at the first examination after the age of 40 and then at least every five years after the age of 50. If cardiovascular risk factors such as smoking, abnormal cholesterol levels or obesity are present, the intervals of resting ECGs should be reduced to two years.
 - (2) Extended cardiovascular assessment should be required when clinically indicated.



(b) Cardiovascular system - general

(1) Cabin crew members with any of the following conditions:

- (i) aneurysm of the thoracic or supra-renal abdominal aorta, before surgery;
- (ii) significant functional abnormality of any of the heart valves; or
- (iii) heart or heart/lung transplantation

should be assessed as unfit.

(2) Cabin crew members with an established diagnosis of one of the following conditions:

- (i) peripheral arterial disease before or after surgery;
- (ii) aneurysm of the abdominal aorta, before or after surgery;
- (iii) minor cardiac valvular abnormalities;
- (iv) after cardiac valve surgery;
- (v) abnormality of the pericardium, myocardium or endocardium;
- (vi) congenital abnormality of the heart, before or after corrective surgery;
- (vii) a cardiovascular condition requiring systemic anticoagulant therapy anticoagulation;
- (viii) recurrent vasovagal syncope of uncertain cause;
- (ix) arterial or venous thrombosis; or
- (x) pulmonary embolism

should be evaluated by a cardiologist before a fit assessment can may be considered.

(c) Thromboembolic disorders

Whilst anticoagulation therapy is initiated, cabin crew members should be assessed as unfit. After a period of stable anticoagulation, a fit assessment may be considered with limitation(s), as appropriate. Anticoagulation should be considered stable if, within the last 6 months, at least 5 INR values are documented, of which at least 4 are within the INR target range and the haemorrhagic risk is acceptable. In cases of anticoagulation medication not requiring INR monitoring, a fit assessment may be considered after a stabilisation period of 3 months. Cabin crew members with pulmonary embolism should also be evaluated by a cardiologist. Following cessation of anticoagulant therapy, for any indication, cabin crew members should undergo a re-assessment.

(d) Syncope

- (1) In the case of a single episode of vasovagal syncope which can be satisfactorily explained, a fit assessment may be considered.
- (2) Cabin crew members with a history of recurrent vasovagal syncope should be assessed as unfit. A fit assessment may be considered after a 6-month period without recurrence, provided cardiological evaluation is satisfactory. Neurological review may be indicated.

(ee) Blood pressure

Blood pressure should be recorded at each examination.



- (1) The blood pressure should be within normal limits and should not consistently exceed 160 mmHg systolic and/or 95 mmHg diastolic, with or without treatment, taking into account other risk factors.
 - (2) ~~The initiation of Cabin crew members initiating~~ medication for the control of blood pressure should require a period of temporary suspension of fitness to establish the absence of any significant side effects be assessed as unfit until the absence of any significant side effects has been established and verification that the treatment is compatible with the safe exercise of cabin crew duties has been achieved.
- (fd) Coronary artery disease
- (1) Cabin crew members with:
 - (i) cardiac ischaemia;
 - (ii) symptomatic coronary artery disease; or
 - (iii) symptoms of coronary artery disease controlled by medicationshould be assessed as unfit.
 - (2) Cabin crew members who are asymptomatic after myocardial infarction or surgery for coronary artery disease should have fully recovered before a fit assessment ~~can~~ may be considered. The affected cabin crew members should be on appropriate secondary prevention treatment.
- (ge) Rhythm/conduction disturbances
- (1) Cabin crew members with any significant disturbance of cardiac conduction or rhythm should undergo cardiological evaluation before a fit assessment ~~can~~ may be considered.
 - (2) Cabin crew members with a history of:
 - (i) ablation therapy; or
 - (ii) pacemaker implantationshould undergo satisfactory cardiovascular evaluation before a fit assessment ~~can~~ may be made.
 - (3) Cabin crew members with:
 - (i) symptomatic sinoatrial disease;
 - (ii) symptomatic hypertrophic cardiomyopathy
 - (iii) complete atrioventricular block;
 - (iv) symptomatic QT prolongation;
 - (v) an automatic implantable defibrillating system; or
 - (vi) a ventricular anti-tachycardia pacemakershould be assessed as unfit.

AMC3 MED.C.025 Respiratory system

- (a) Cabin crew members with significant impairment of pulmonary function should be assessed as unfit. A fit assessment may be considered once pulmonary function has recovered and is satisfactory.



- (b) Cabin crew members should ~~be required to~~ undergo pulmonary ~~function~~ morphological or functional tests on ~~clinical indication~~ when clinically indicated.
- (c) Cabin crew members with a history or established diagnosis of:
- (1) asthma;
 - (2) active inflammatory disease of the respiratory system;
 - (3) active sarcoidosis;
 - ~~(4)~~ pneumothorax;
 - ~~(5)~~ sleep apnoea syndrome/sleep disorder; or
 - ~~(6)~~ major thoracic surgery
- should undergo respiratory evaluation with a satisfactory result before a fit assessment ~~can~~ ~~may~~ be considered.
- (d) Cabin crew members who have undergone a pneumonectomy should be assessed as unfit.

AMC4 MED.C.025 Digestive system

- (a) Cabin crew members with any ~~sequelae of~~ disease or ~~sequelae of~~ surgical intervention in any part of the digestive tract or its adnexa likely to cause incapacitation in flight, in particular any obstruction due to stricture or compression, should be assessed as unfit.
- (b) Cabin crew members should be free from herniae that might give rise to incapacitating symptoms.
- (c) Cabin crew members with disorders of the gastro-intestinal system, including:
- (1) recurrent ~~severe~~ dyspeptic disorder requiring medication;
 - (2) ~~peptic ulceration~~;
 - ~~(3)~~ pancreatitis;
 - ~~(4)~~ symptomatic gallstones;
 - ~~(5)~~ an established diagnosis or history of chronic inflammatory bowel disease; ~~or~~
 - ~~(6)~~ after surgical operation on the digestive tract or its adnexa, including surgery involving total or partial excision or a diversion of any of these organs;
 - (7) ~~morphological or functional liver disease~~; or
 - (8) ~~after surgery, including liver transplantation~~
- may be assessed as fit subject to satisfactory ~~gastroenterological~~ evaluation ~~after successful treatment and full recovery after surgery~~.

AMC5 MED.C.025 Metabolic and endocrine systems

- (a) Cabin crew members should not possess any functional or structural metabolic, nutritional or endocrine disorder which is likely to interfere with the safe exercise of their duties and responsibilities.
- (b) Cabin crew members with metabolic, nutritional or endocrine dysfunction may be assessed as fit, subject to demonstrated stability of the condition and satisfactory aero-medical evaluation.



- (c) Diabetes mellitus
- (1) Cabin crew members with diabetes mellitus requiring insulin may be assessed as fit:
- (i) if it can be demonstrated that adequate blood sugar control has been achieved and hypoglycaemia awareness is established and maintained; and
 - (ii) in the absence, within the preceding 12 months, of any;
 - (A) hospitalisation related to diabetes; or
 - (B) hypoglycaemia that resulted in a seizure, loss of consciousness, impaired cognitive function or that required the intervention by another party; or
 - (C) episode of hypoglycaemia unawareness.
- (2) Limitations should be imposed as appropriate. A ~~requirement~~ limitation to undergo specific ~~regular~~ medical examinations (SIC) and a restriction to operate only in multi-cabin crew operations (MCL) should be placed as a minimum.
- (32) Cabin crew members with diabetes mellitus not requiring insulin may be assessed as fit if it can be demonstrated that adequate blood sugar control has been achieved and hypoglycaemia awareness, if applicable considering the medication, is achieved.

GM2 MED.C.025 Metabolic and endocrine systems

DIABETES MELLITUS TREATED WITH INSULIN

When considering a fit assessment for cabin crew with diabetes mellitus requiring insulin, account should be taken of the IATA Guidelines on Insulin-Treated Diabetes (Cabin Crew), as last amended.

AMC6 MED.C.025 Haematology

Cabin crew members with a haematological condition, such as:

- (a) abnormal haemoglobin including, but not limited to, anaemia, ~~polycythaemia~~ erythrocytosis or haemoglobinopathy;
- (b) coagulation, haemorrhagic or thrombotic disorder;
- (c) significant lymphatic enlargement;
- (d) acute or chronic leukaemia; or
- (e) ~~enlargement of the spleen~~ splenomegaly

may be assessed as fit subject to satisfactory aero-medical evaluation. If anticoagulation is being used as treatment, refer to AMC2 MED.C.025(c).

AMC7 MED.C.025 Genitourinary system

- (a) Urine analysis should form part of every aero-medical examination and/or assessment. The urine should not contain any abnormal element(s) considered to be of pathological significance.
- (b) Cabin crew members with any ~~disease or~~ sequelae of ~~disease or~~ surgical procedures on the kidneys or the urinary tract, in particular any obstruction due to stricture or compression likely to cause incapacitation should be assessed as unfit.



- (c) Cabin crew members with a genitourinary disorder, such as:
- (1) renal disease; or
 - (2) a history of renal colic due to one or more urinary calculi
- may be assessed as fit subject to satisfactory renal/urological evaluation.
- (d) Cabin crew members who have undergone a major surgical operation in the genitourinary apparatus involving a total or partial excision or a diversion of its organs should be assessed as unfit and be re-assessed after full-recovery before a fit assessment can be made.
- (e) Cabin crew members who have undergone renal transplantation may be considered for a fit assessment if it is fully compensated and tolerated with only minimal immuno-suppressive therapy after at least 12 months. A requirement to undergo specific medical examinations (SIC) and a restriction to operate only in multi-cabin crew operations (MCL) should be considered.
- (f) Cabin crew members requiring dialysis should be assessed as unfit.

AMC8 MED.C.025 Infectious disease

Cabin crew members who are HIV positive may be assessed as fit if investigation provides no evidence of clinical disease and subject to satisfactory aero-medical evaluation.

AMC9 MED.C.025 Obstetrics and gynaecology

- (a) Cabin crew members who have undergone a major gynaecological operation should be assessed as unfit until full after recovery.
- (b) Pregnancy
- (1) A pregnant cabin crew member may be assessed as fit only during the first 16 weeks of gestation following review of the obstetric evaluation by the AME or OHMP.
 - (2) A limitation not to perform duties as single cabin crew member should be considered.
 - (3) The AME or OHMP should provide written advice to the cabin crew member and supervising physician regarding potentially significant complications of pregnancy resulting from flying duties.

AMC10 MED.C.025 Musculoskeletal system

- (a) Cabin crew members should have sufficient standing height, arm and leg length and muscular strength for the safe exercise of their duties and responsibilities.
- (b) Cabin crew members should have satisfactory functional use of the musculoskeletal system. Particular attention should be paid to emergency procedures and evacuation, and related training.
- (c) Cabin crew members with any significant sequelae from disease, injury or congenital abnormality affecting the bones, joints, muscles or tendons with or without surgery requires full evaluation prior to a fit assessment.
- (d) Cabin crew members with inflammatory, infiltrative, traumatic or degenerative disease of the musculoskeletal system may be assessed as fit provided the condition is in remission or is stable and the affected cabin crew member is taking no disqualifying medication.



AMC11 MED.C.025 Psychiatry

- (a) Cabin crew members with a mental or behavioural disorder due to use or misuse of alcohol or other problematic psychoactive substances ~~use~~ should be assessed as unfit pending recovery and freedom from problematic psychoactive substance use or misuse and subject to satisfactory psychiatric evaluation after successful treatment.
- (b) Cabin crew members with an established history or clinical diagnosis of schizophrenia, schizotypal or delusional disorder should be assessed as unfit.
- (c) Cabin crew members with a psychiatric condition such as:
- (1) mood disorder;
 - (2) neurotic disorder;
 - (3) personality disorder; or
 - (4) mental or behavioural disorder
- should undergo satisfactory psychiatric evaluation before a fit assessment ~~can~~ may be made considered.
- (d) Cabin crew members with a history of a single or repeated acts of deliberate self-harm should be assessed as unfit. Cabin crew members should undergo satisfactory psychiatric evaluation before a fit assessment ~~can~~ may be considered.

AMC12 MED.C.025 Psychology

- (a) Where there is established evidence that a cabin crew member has a psychological disorder, he/she should be referred for psychological opinion and advice.
- (b) The psychological evaluation may include a collection of biographical data, the review of aptitudes, and personality tests and psychological interview.
- (c) The psychologist should submit a report to the AME or OHMP, detailing the results and recommendation.
- (d) The cabin crew member may be assessed as fit to perform cabin crew duties, with limitation(s) if and as appropriate.

AMC13 MED.C.025 Neurology

- (a) Cabin crew members with an established history or clinical diagnosis of:
- (1) epilepsy; or
 - (2) recurring episodes of disturbance of consciousness of uncertain cause
- should be assessed as unfit.
- (b) Cabin crew members with an established history or clinical diagnosis of:
- (1) epilepsy without recurrence after five 5 years of age and without treatment for more than ten 10 years;
 - (2) epileptiform EEG abnormalities and focal slow waves;
 - (3) progressive or non-progressive disease of the nervous system;



- (4) inflammatory disease of the central or peripheral nervous system;
- (5) migraine;
- (64) a single episode of disturbance of consciousness of uncertain cause;
- (75) loss of consciousness after head injury;
- (86) penetrating brain injury; or
- (97) spinal or peripheral nerve injury

should undergo further evaluation before a fit assessment can may be considered.

- (c) Cabin crew members with a disorder of the nervous system due to vascular deficiencies including haemorrhagic and ischaemic events should be assessed as unfit. A fit assessment may be considered if neurological review and musculoskeletal assessments are satisfactory.

AMC14 MED.C.025 Visual system

- (a) Examination
 - (1) a routine eye examination should form part of the initial and all further examinations and assessments and/or examinations; and
 - (2) an extended eye examination should be undertaken by an eye specialist when clinically indicated.
- (b) Distant visual acuity, with or without correction, should be with both eyes 6/9 (0,7) or better.
- (c) Cabin crew members should be able to read an N5 chart (or equivalent) at 30–50 cm, with correction if prescribed (Refer to GM1 MED.B.070).
- (d) Cabin crew members should be required to have normal fields of vision and normal binocular function. The binocular visual field or, in the case of monocularity, the monocular visual field should be acceptable.
- (e) Cabin crew members who have undergone refractive surgery may be assessed as fit subject to satisfactory ophthalmic evaluation.
- (f) Cabin crew members with diplopia should be assessed as unfit.
- (g) Spectacles and contact lenses:

If satisfactory visual function is achieved only with the use of correction:

 - (1) in the case of myopia or hyperopia or both, spectacles or contact lenses should be worn whilst on duty;
 - (2) in the case of hyperopia presbyopia, spectacles or contact lenses should be readily available for immediate use;
 - (3) the correction should provide optimal visual function and be well tolerated well-tolerated;
 - (4) a spare set of similarly correcting spectacles should be readily available for immediate use whilst on duty;
 - (54) orthokeratologic lenses should not be used.



AMC15 MED.C.025 Colour vision

Cabin crew members should be able to correctly identify 9 of the first 15 plates of the 24-plate edition of Ishihara pseudoisochromatic plates. Alternatively, cabin crew members should demonstrate ~~that they are colour safe~~ the ability to readily perceive those colours of which the perception is required for the safe performance of their duties.

GM3 MED.C.025 Colour vision

GENERAL

Examples of colours of which the perception is required for the safe performance of cabin crew members' duties are: cabin crew indication panels, pressure gauges of emergency equipment (e.g. fire extinguishers) and cabin door status.

AMC16 MED.C.025 ~~Otorhino-laryngology~~ Otorhinolaryngology (ENT)

- (a) Hearing should be satisfactory for the safe exercise of cabin crew duties and responsibilities. Cabin crew with hypoacusis should demonstrate satisfactory functional hearing abilities.
- (b) Examination
- (1) An ear, nose and throat (ENT) examination should form part of all examinations and/or assessments. A tympanometry or equivalent should be performed at the initial examination and when clinically indicated.
 - (2) Hearing should be tested at all examinations and assessments ~~and/or examinations~~:
 - (i) the cabin crew member should understand correctly conversational speech when tested with each ear at a distance of 2 meters metres from and with the cabin crew member's back turned towards the examiner;
 - (ii) notwithstanding (b)(2)(i) above, hearing should be tested with pure tone audiometry at the initial examination and when clinically indicated;
 - (iii) at initial examination the cabin crew member should not have a hearing loss of more than 35 dB at any of the frequencies 500 Hz, 1 000 Hz or 2 000 Hz, or more than 50 dB at 3 000 Hz, in either ear separately.
 - (3) If the hearing requirements can be met only with the use of hearing aid(s), the hearing aid(s) should provide optimal hearing function, be well-tolerated, and suitable for aviation purposes.
- (c) Cabin crew members with:
- (1) an active pathological process, ~~acute or chronic~~, of the internal or middle ear;
 - (2) unhealed perforation or dysfunction of the tympanic membrane(s);
 - (3) disturbance of vestibular function;
 - (4) significant restriction of the nasal passages;
 - (5) sinus dysfunction;
 - (6) significant malformation or significant, ~~acute or chronic~~ infection of the oral cavity or upper respiratory tract;
 - (7) significant disorder of speech or voice



should undergo further ~~medical examination and assessment~~ to establish that the condition does not interfere with the safe exercise of their duties and responsibilities.

GM4 MED.C.025 Otorhinolaryngology (ENT)**PURE TONE AUDIOGRAM**

The pure tone audiogram may also cover the 4 000 Hz frequency for early detection of decrease in hearing.

AMC17 MED.C.025 Dermatology

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

AMC18 MED.C.025 Oncology

- (a) After treatment for malignant disease, cabin crew members should undergo satisfactory oncological and aero-medical evaluation before a fit assessment may be considered.
- (b) Cabin crew members with an established history or clinical diagnosis of intracerebral malignant tumour should be assessed as unfit. Considering the histology of the tumour, a fit assessment may be considered after successful treatment and ~~full~~ recovery.

~~GM1 MED.C.025 Content of aero-medical assessments~~

Paragraph moved to follow AMC1 MED.C.025



Section 3

Additional requirements for applicants for, and holders of, a cabin crew attestation

AMC1 MED.C.030 Cabin crew medical report

The cabin crew medical report to be provided in writing to the applicants for, and holders of, a cabin crew attestation after completion of each aero-medical assessment should be issued:

- (a) should be issued in the national language(s) and/or in English; and
- (b) according to the format below, or another format if all, and only, should include the following elements: specified below are provided.

CABIN CREW MEDICAL REPORT FOR CABIN CREW ATTESTATION (CCA) APPLICANT OR HOLDER		
(1)	State where the aero-medical assessment of the CCA applicant/holder was conducted:	
(2)	Name of CCA applicant/holder:	
(3)	Nationality of CCA applicant/holder:	
(4)	Date and place of birth of CCA applicant/holder: (dd/mm/yyyy)	
(5)	Expiry date of the previous aero-medical assessment: (dd/mm/yyyy)	
(6)	Date of the aero-medical assessment: (dd/mm/yyyy)	
(7)	Aero-medical assessment: (fit or unfit)	
(8)	Limitation(s) if applicable:	
(9)	Date of the next required aero-medical assessment: (dd/mm/yyyy)	
(10)	Date of issue and signature of the AME, or OHMP, who issued the cabin crew medical report:	
(11)	Seal or stamp:	
(12)	Signature of CCA applicant/holder:	

- (b) should include the following elements:

- (1) The State where the aero-medical assessment of the Cabin Crew Attestation (CCA) applicant/holder was conducted (I);
- (2) Last and first name of the CCA applicant/holder (IV);



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<p>I The State where the aero-medical assessment is conducted:</p> <p>III Cabin crew attestation reference number:</p> <p>IV Last and first name:</p> <p>XIV Date of birth (dd/mm/yyyy):</p> <p>VI Nationality:</p> <p>VII Signature of CCA applicant/holder:</p>	<p>II Aero-medical assessment result (fit/unfit):</p> <p>Expiry date of the previous cabin crew medical report (dd/mm/yyyy):</p> <p>Date of aero-medical assessment (dd/mm/yyyy):</p> <p>X Date of issue* (dd/mm/yyyy):</p> <p>X Signature of the AeMC, AME or OHMP:</p> <p>XI Seal or stamp of the AeMC, AME or OHMP:</p>
2	3

* Date of issue is the date the Cabin Crew Medical Report is issued and signed.



<p>XII Limitation(s), if applicable:</p> <p>Code:</p> <p>Description:</p> <p>Code:</p> <p>Description:</p> <p>Code:</p> <p>Description:</p>	<p>IX Expiry date of this medical report (dd/mm/yyyy):</p>
4	5

AMC1 MED.C.035 Limitations

When assessing whether the holder of a cabin crew attestation may be able to perform cabin crew duties safely if complying with one or more limitations, the following possible limitations should be considered:

- (a) a restriction to operate only in multi-cabin crew operations (MCL);
- (b) a restriction to specified aircraft type(s) (OAL) or to a specified type of operation (OOL);
- (c) a requirement to undergo the next aero-medical examination and/or assessment at an earlier date than required by MED.C.005(b) (TML);
- (d) a requirement to undergo specific regular medical examination(s) (SIC);
- (e) a requirement for visual correction (CVL), or by means of contact lenses that corrective lenses only for defective vision (CCL);
- (f) a requirement to use hearing aids (HAL); and
- (g) special restriction as specified (SSL).



SUBPART D

Aero-Medical Examiners (AME), General Medical Practitioners (GMP), Occupational Health Medical Practitioners (OHMP)**Section 1****Aero-medical examiners (AMEs)****AMC1 MED.D.010 – Requirements for the issue of an AME certificate****AMC1 MED.D.020 Training courses in aviation medicine****BASIC TRAINING COURSE**

(a) Basic training course for AMEs

The basic training course for AMEs should consist of 60 hours of theoretical and practical training, including specific examination techniques.

(b) ~~The syllabus for the basic training course should cover at least the following subjects:~~ The learning objectives to acquire the necessary competencies should include theoretical knowledge, risk management and decision-making principles in the following subjects. Demonstrations and practical skills should also be included, where appropriate.

- (1) Introduction to aviation medicine;
Physics of atmosphere and space;
- (2) Basic aeronautical knowledge;
- (3) Aviation physiology;
- (4) Cardiovascular system ~~Cardiology and general medicine;~~
- (5) Respiratory system;
- (6) Digestive system;
- (7) Metabolic and endocrine systems;
- (8) Haematology;
- (9) Genitourinary system;
- (10) Obstetrics and gynaecology;
- (11) Musculoskeletal system;
- (12) ~~Psychiatry in aviation medicine;~~
- (13) Psychology;
Dentistry
- (14) Neurology;
- (15) Visual system and colour vision ~~Ophthalmology, including demonstration and practical;~~
- (16) Otorhinolaryngology, ~~including demonstration and practical;~~



- (17) Oncology;
- (18) Incidents and accidents-Accidents, escape and survival;
- (19) Medication and flying;
- (20) Legislation, rules and regulations;
Air evacuation, including demonstration and practical;
- (21) Cabin crew working environment;
- (22) In-flight environment; and
- (23) Space medicine.

GM1 MED.D.020 Training courses in aviation medicine**BASIC TRAINING COURSE**

- | | | |
|-----|--|----------|
| (a) | Basic training course in aviation medicine | 60 hours |
| | (1) | 2 hours |
| | (i) | |
| | (ii) | |
| | (iii) | |
| | (iv) | |
| | (v) | |
| | (2) | 2 hours |
| | (i) | |
| | (ii) | |
| | (iii) | |
| | (iv) | |
| | (v) | |
| | (vi) | |
| | (3) | 9 hours |
| | (i) | |
| | (A) | |



- (B) Divisions of the atmosphere
- (C) Gas laws — physiological significance
- (D) Physiological effects of decompression
- (ii) Respiration
 - (A) Blood gas exchange
 - (B) Oxygen saturation
- (iii) Hypoxia signs and symptoms
 - (A) Average time of useful consciousness (TUC)
 - (B) Hyperventilation signs and symptoms
 - (C) Barotrauma
 - (D) Decompression sickness
- (iv) Acceleration
 - (A) G-Vector orientation
 - (B) Effects and limits of G-load
 - (C) Methods to increase Gz-tolerance
 - (D) Positive/negative acceleration
 - (E) Acceleration and the vestibular system
- (v) Visual disorientation
 - (A) Sloping cloud deck
 - (B) Ground lights and stars confusion
 - (C) Visual autokinesis
- (vi) Vestibular disorientation
 - (A) Anatomy of the inner ear
 - (B) Function of the semicircular canals
 - (C) Function of the otolith organs



- (D) The oculogyral and coriolis illusion
- (E) 'Leans'
- (F) Forward acceleration illusion of 'nose up'
- (G) Deceleration illusion of 'nose down'
- (H) Motion sickness — causes and management
- (vii) Noise and vibration
 - (A) Preventive measures
- (4) Cardiovascular system 3 hours
 - (i) Relation to aviation; risk of incapacitation
 - (ii) Examination procedures: ECG, laboratory testing and other special examinations
 - (iii) Cardiovascular diseases:
 - (A) Hypertension, treatment and assessment
 - (B) Ischaemic heart disease
 - (C) ECG findings
 - (D) Assessment of satisfactory recovery from myocardial infarction, interventional procedures and surgery
 - (E) Cardiomyopathies; pericarditis; rheumatic heart disease; valvular diseases
 - (F) Rhythm and conduction disturbances, treatment and assessment
 - (G) Congenital heart disease: surgical treatment, assessment
 - (H) Cardiovascular syncope: single and repeated episodes
- Topics (5) to (11) inclusive and (17) 10 hours
- (5) Respiratory system
 - (i) Relation to aviation, risk of incapacitation



- (ii) Examination procedures: spirometry, peak flow, x-ray, other examinations
- (iii) Pulmonary diseases: asthma, chronic obstructive pulmonary diseases
- (iv) Infections, tuberculosis
- (v) Bullae, pneumothorax
- (vi) Obstructive sleep apnoea
- (vii) Treatment and assessment

(6) Digestive system

- (i) Relation to aviation, risk of incapacitation
- (ii) Examination of the system
- (iii) Gastro-intestinal disorders: gastritis, ulcer disease
- (iv) Biliary tract disorders
- (v) Hepatitis and pancreatitis
- (vi) Inflammatory bowel disease, irritable colon/irritable bowel disease
- (vii) Herniae
- (viii) Treatment and assessment including post-abdominal surgery

(7) Metabolic and endocrine systems

- (i) Relation to aviation, risk of incapacitation
- (ii) Endocrine disorders
- (iii) Diabetes mellitus Type 1 & 2
 - (A) Diagnostic tests and criteria
 - (B) Anti-diabetic therapy
 - (C) Operational aspects in aviation
 - (D) Satisfactory control criteria for aviation



(iv) Hyper/hypothyroidism

(v) Pituitary and adrenal glands disorders

(vi) Treatment and assessment

(8) Haematology

(i) Relation to aviation, risk of incapacitation

(ii) Blood donation aspects

(iii) Erythrocytosis; anaemia; leukaemia; lymphoma

(iv) Sickle cell disorders

(v) Platelet disorders

(vi) Haemoglobinopathies; geographical distribution; classification

(vii) Treatment and assessment

(9) Genitourinary system

(i) Relation to aviation, risk of incapacitation

(ii) Action to be taken after discovery of abnormalities in routine dipstick urinalysis, e.g. haematuria; albuminuria

(iii) Urinary system disorders:

(A) Nephritis; pyelonephritis; obstructive uropathies

(B) Tuberculosis

(C) Lithiasis: single episode; recurrence

(D) Nephrectomy, transplantation, other treatment and assessment

(10) Obstetrics and gynaecology

(i) Relation to aviation, risk of incapacitation

(ii) Pregnancy and aviation

(iii) Disorders, treatment and assessment

(11) Musculoskeletal system



- (i) Vertebral column diseases
 - (ii) Arthropathies and arthroprosthesis
 - (iii) Pilots with a physical impairment
 - (iv) Treatment of musculoskeletal system, assessment for flying
- (12) Psychiatry 2 hours
- (i) Relation to aviation, risk of incapacitation
 - (ii) Psychiatric examination
 - (iii) Psychiatric disorders: neurosis; personality disorders; psychosis; organic mental illness
 - (iv) Alcohol and other psychoactive substance use
 - (v) Treatment, rehabilitation and assessment
- (13) Psychology 2 hours
- (i) Introduction to psychology in aviation as a supplement to neuropsychiatric assessment
 - (ii) Methods of psychological examination
 - (iii) Behaviour and personality
 - (iv) Workload management and situational awareness
 - (v) Flight motivation and suitability
 - (vi) Group social factors
 - (vii) Psychological stress, stress coping, fatigue
 - (viii) Psychomotor functions and age
 - (ix) Mental fitness and training
- (14) Neurology 3 hours
- (i) Relation to aviation, risk of incapacitation
 - (ii) Examination procedures
 - (iii) Neurological disorders



- (A) Seizures — assessment of single episode
- (B) Epilepsy
- (C) Multiple sclerosis
- (D) Head trauma
- (E) Post-traumatic states
- (F) Vascular diseases
- (G) Tumours
- (H) Disturbance of consciousness — assessment of single and repeated episodes
- (iv) Degenerative diseases
- (v) Sleep disorders
- (vi) Treatment and assessment
- (15) Visual system and colour vision 4 hours
 - (i) Anatomy of the eye
 - (ii) Relation to aviation duties
 - (iii) Examination techniques
 - (A) Visual acuity assessment
 - (B) Visual aids
 - (C) Visual fields — acceptable limits for certification
 - (D) Ocular muscle balance
 - (E) Assessment of pathological eye conditions
 - (F) Glaucoma
 - (iv) Monocularity and medical flight tests
 - (v) Colour vision
 - (vi) Methods of testing: pseudoisochromatic plates, lantern tests, anomaloscopy



- (vii) Importance of standardisation of tests and of test protocols
- (viii) Assessment after eye surgery
- (16) Otorhinolaryngology 3 hours
 - (i) Anatomy of the systems
 - (ii) Clinical examination in ORL
 - (iii) Functional hearing tests
 - (iv) Vestibular system; vertigo, examination techniques
 - (v) Assessment after ENT surgery
 - (vi) Barotrauma ears and sinuses
 - (vii) Aeronautical ENT pathology
 - (viii) ENT requirements
- (17) Oncology
 - (i) Relation to aviation, risk of metastasis and incapacitation
 - (ii) Risk management
 - (iii) Different methods of treatment and assessment
- (18) Incidents and accidents, escape and survival 1 hour
 - (i) Accident statistics
 - (ii) Injuries
 - (iii) Aviation pathology, post-mortem examination, identification
 - (iv) Aircraft evacuation
 - (A) Fire
 - (B) Ditching
 - (C) By parachute
- (19) Medication and flying 2 hours
 - (i) Hazards of medications



- (ii) Common side effects; prescription medications; over-the-counter medications; herbal medications; 'alternative' therapies
 - (iii) Medication for sleep disturbance
- (20) Legislation, rules and regulations 4 hours
- (i) ICAO Standards and Recommended Practices, European provisions (Implementing Rules, AMCs and GM)
 - (ii) Incapacitation: acceptable aero-medical risk of incapacitation; types of incapacitation; operational aspects
 - (iii) Basic principles in assessment of fitness for aviation
 - (iv) Operational and environmental conditions
 - (v) Use of medical literature in assessing medical fitness; differences between scientific study populations and licensed populations
 - (vi) Flexibility
 - (vii) Annex 1 to the Chicago Convention, paragraph 1.2.4.9
 - (viii) Accredited Medical Conclusion; consideration of knowledge, skill and experience
 - (ix) Trained versus untrained crews; incapacitation training
 - (x) Medical flight tests
- (21) Cabin crew working environment 1 hour
- (i) Cabin environment, workload, duty and rest time, fatigue risk management
 - (ii) Cabin crew safety duties and associated training
 - (iii) Types of aircraft and types of operations
 - (iv) Single-cabin crew and multi-cabin crew operations
- (22) In-flight environment 1 hour
- (i) Hygiene aboard aircraft: water supply, oxygen supply, disposal of waste, cleaning, disinfection and disinfection
 - (ii) Catering



(iii) Crew nutrition	
(iv) Aircraft and transmission of diseases	
(23) Space medicine	1 hour
(i) Microgravity and metabolism, life sciences	
(24) Practical demonstrations of basic aeronautical knowledge	8 hours
(25) Concluding items	2 hours
(i) Final examination	
(ii) De-briefing and critique	

AMC1 MED.D.015 – Requirements for the extension of privileges

AMC2 MED.D.020 Training courses in aviation medicine

ADVANCED TRAINING COURSE

(a) Advanced training course for AMEs

The advanced training course for AMEs should consist of another 60 hours of theoretical and practical training, including specific examination techniques.

(b) ~~The syllabus for the advanced training course should cover at least the following subjects:~~ The learning objectives to acquire the necessary competencies should include theoretical knowledge, risk management and decision-making principles in the following subjects. Demonstrations and practical skills should also be included, where appropriate.

- (1) Pilot working environment;
 - (2) Aerospace physiology, ~~including demonstration and practical;~~
 - (3) Clinical medicine;
 - (4) Cardiovascular system ~~Cardiology and general medicine, including demonstration and practical;~~
 - (5) Neurology/psychiatry, ~~including demonstration and practical;~~
 - (6) Visual system and colour vision ~~Ophthalmology, including demonstration and practical;~~
 - (7) Otorhinolaryngology, ~~including demonstration and practical;~~
 - (8) Dentistry;
 - (9) Human factors in aviation, ~~including demonstration and practical;~~
 - (10) Incidents and accidents, escape and survival; and
 - (11) Tropical medicine;
- Hygiene, ~~including demonstration and practical;~~



~~Space medicine.~~

- (c) Practical training in an AeMC should be under the guidance and supervision of the head of the AeMC.
- (d) After the successful completion of the practical training, a report of demonstrated competency should be issued.

GM2 MED.D.020 Training courses in aviation medicine**ADVANCED TRAINING COURSE**

- | | |
|--|----------|
| (a) Advanced training course in aviation medicine | 60 hours |
| (1) Pilot working environment | 6 hours |
| (i) Commercial aircraft flight crew compartment | |
| (ii) Business jets, commuter flights, cargo flights | |
| (iii) Professional airline operations | |
| (iv) Fixed wing and helicopter, specialised operations including aerial work | |
| (v) Air traffic control | |
| (vi) Single-pilot/multi-pilot | |
| (vii) Exposure to radiation and other harmful agents | |
| (2) Aerospace physiology | 4 hours |
| (i) Brief review of basics in physiology (hypoxia, rapid/slow decompression, hyperventilation, acceleration, ejection, spatial disorientation) | |
| (ii) Simulator sickness | |
| (3) Clinical medicine | 5 hours |
| (i) Complete physical examination | |
| (ii) Review of basics with relationship to commercial flight operations | |
| (iii) Class 1 requirements | |
| (iv) Clinical cases | |
| (4) Cardiovascular system | 4 hours |



- (i) Cardiovascular examination and review of basics
 - (ii) Class 1 requirements
 - (iii) Diagnostic steps in cardiovascular system
 - (iv) Clinical cases
- (5) Neurology/psychiatry 5 hours
- (i) Brief review of basics (neurological and psychiatric examination)
 - (ii) Alcohol and other psychoactive substance use
 - (iii) Class 1 requirements
 - (iv) Clinical cases
- (6) Visual system and colour vision 5 hours
- (i) Brief review of basics (visual acuity, refraction, colour vision, visual fields, night vision, stereopsis, monocularitày)
 - (ii) Class 1 visual requirements
 - (iii) Implications of refractive and other eye surgery
 - (iv) Clinical cases
- (7) Otorhinolaryngology 4 hours
- (i) Brief review of basics (barotrauma — ears and sinuses, functional hearing tests)
 - (ii) Noise and its prevention
 - (iii) Vibration, kinetosis
 - (iv) Class 1 hearing requirements
 - (v) Clinical cases
- (8) Dentistry 2 hours
- (i) Oral examination including dental formula
 - (ii) Oral cavity, dental disorders and treatment, including implants,



fillings, prosthesis, etc.

(iii) Barodontalgia

(iv) Clinical cases

(9) Human factors in aviation, including 8 hours demonstration and practical experience 19 hours

(i) Long haul flight operations

(A) Flight time limitations

(B) Sleep disturbance

(C) Extended/expanded crew

(D) Jet lag/time zones

(ii) Human information processing and system design

(A) Flight Management System (FMS), Primary Flight Display (PFD), datalink, fly by wire

(B) Adaptation to the glass cockpit

(C) Crew Coordination Concept (CCC), Crew Resource Management (CRM), Line Oriented Flight Training (LOFT) etc.

(D) Practical simulator training

(E) Ergonomics

(iii) Crew commonality

(A) Flying under the same type rating, e.g. A-318, A-319, A-320, A-321

(iv) Human factors in aircraft incidents and accidents

(v) Flight safety strategies in commercial aviation

(vi) Fear and refusal of flying

(vii) Psychological selection criteria

(viii) Operational requirements (flight time limitation, fatigue risk)



management, etc.)

(10) Incidents and accidents, escape and survival 2 hours

(i) Accident statistics

(ii) Types of injuries

(iii) Aviation pathology, post-mortem examination related to aircraft accidents, identification

(iv) Rescue and emergency evacuation

(11) Tropical medicine 2 hours

(i) Endemicity of tropical disease

(ii) Infectious diseases (communicable diseases, sexual transmitted diseases, HIV etc.)

(iii) Vaccination of flight crew and passengers

(iv) Diseases transmitted by vectors

(v) Food and water-borne diseases

(vi) Parasitic diseases

(vii) International health regulations

(viii) Personal hygiene of aviation personnel

(12) Concluding items 2 hours

(i) Final examination

(ii) De-briefing and critique

GM3 MED.D.020 Training courses in aviation medicine

GENERAL

(a) Principles of training:

To acquire knowledge and skills for the aero-medical examination and assessment, the training should be:

(1) based on regulations;

(2) based on general clinical skills and knowledge necessary to conduct relevant examinations for the different medical certificates;



- (3) based on knowledge of the different risk assessments required for various types of medical certification;
 - (4) based on an understanding of the limits of the decision-making competences of an AME in assessing safety-critical medical conditions for when to defer and when to deny;
 - (5) based on knowledge of the aviation environment; and
 - (6) exemplified by clinical cases and practical demonstrations.
- (b) Training outcomes:
- The trainee should demonstrate a thorough understanding of:
- (1) the aero-medical examination and assessment process:
 - (i) principles, requirements and methods;
 - (ii) ability to investigate all clinical aspects that present aero-medical risks, the reasonable use of additional investigations;
 - (iii) the role in the assessment of the ability of the pilot or cabin crew member to safely perform their duties in special cases, such as the medical flight test;
 - (iv) aero-medical decision-making based on risk management;
 - (v) medical confidentiality; and
 - (vi) correct use of appropriate forms, and the reporting and storing of information;
 - (2) the conditions under which the pilots and cabin crew carry out their duties; and
 - (3) principles of preventive medicine, including aero-medical advice in order to help prevent future limitations.

GM1 MED.D.030 – Refresher training in aviation medicine

AMC1 MED.D.030 Validity of AME certificates

REFRESHER TRAINING

- (a) It is the responsibility of the AME to continuously maintain and improve their competencies.
- (b) During the period of authorisation, an AME should attend 20 hours of refresher training.
- (c) A proportionate number of refresher training hours should be provided by, or conducted under the direct supervision of, the competent authority or the Medical Assessor.
- (d) Attendance at scientific meetings and, congresses, and flight deck experience may be approved credited by the competent authority for a specified number of hours against the training obligations of the AME, provided the competent authority has assessed it in advance as being relevant for crediting purposes.
- (e) Scientific meetings that should be accredited by the competent authority are:
 - (1) International Academy of Aviation and Space Medicine Annual Congresses;
 - (2) Aerospace Medical Association Annual Scientific Meetings; and
 - (3) other scientific meetings, as organised or approved by the Medical Assessor.



~~(e) Other refresher training may consist of:~~

- ~~(1) flight deck experience;~~
- ~~(2) jump seat experience;~~
- ~~(3) simulator experience; and~~
- ~~(4) aircraft piloting.~~

GM2 MED.D.030 Validity of AME certificates

REFRESHER TRAINING

Scientific meetings, congresses or flight deck experience that may be credited by the competent authority:

(a)	International Academy of Aviation and Space Medicine Annual Congresses (ICASM)	4 days – 10 hours credit
(b)	European Conference of Aerospace Medicine (ECAM)	4 days – 10 hours credit
(c)	Aerospace Medical Association Annual Scientific Meetings (AsMA)	4 days – 10 hours credit
(d)	Other scientific meetings (A minimum of 6 hours to be under the direct supervision of the medical assessor of the competent authority)	4 days – 10 hours credit
(e)	Flight crew compartment experience (a maximum of 5 hours credit per 3 years):	
(1)	Jump seat	5 sectors - 1 hour credit
(2)	Simulator	4 hours - 1 hour credit
(3)	Aircraft piloting	4 hours - 1 hour credit



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)

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comment	6	comment by: <i>EUROCONTROL</i>
	Attachment #1	
	EUROCONTROL comments on EASA NPA 2013-15	
response	<i>Noted</i> Thank you for the information.	
comment	8	comment by: <i>AECA(SPAIN)</i>
	<p>Proposal 1. The concepts developed in paragraph 2.3.1 (1), (2) and (3) must be transferred to MED A. 010: Definitions.</p> <p>Reason: these elements are used in the text to specify the actions of aeromedical system participants and have to be translated into different national languages with the meaning that wants to give them in the regulation. The definition of each of them help for its proper translation.</p>	
response	<i>Not accepted</i> The expressions 'to evaluate' and 'to assess' are mainly used in the acceptable means of compliance (ED Decision) while definitions are in the Implementing Rule (EU Regulation). The status of the AMCs would be changed by adding a definition to the rule. The obligations of AMEs, AeMCs, GMPs, OHMPs and Medical Assessors are laid down in the rules in Part-MED and ARA.MED (Annex IV and Annex VI to the Aircrew Regulation respectively).	
comment	9	comment by: <i>AECA(SPAIN)</i>
	In several places the rule refers to 'specialists'. For example: "to evaluate" is used where a	



specialist, e.g a cardiologist, evaluates the medical situation of a pilot and provides the findings to the AME, AeMCs, or licensing authority as appropriate for the class of medical certificate'. But regulation does not refer to any condition of specialists. Should meet some specific aeromedical condition to this function or is not required?

Proposal 2. Reference is made to specific conditions for specialists in Section regarding the persons involved in aeromedical system. These conditions could be: training in aviation medicine related to their specialty, do their work in the environment of AeMCs.

response *Not accepted*

According to the Basic Regulation (and ICAO Annex 1) the AME, AeMC, GMP or the Medical Assessor decides on the medical fitness of a pilot. The specialists (e.g. cardiologist, neurologist, etc.) provide a specialist medical opinion on the medical situation of the pilot concerned. The AME, etc. will then assess the medical fitness of the pilot according to the requirements, taking into account the specialist report including its relevance to aviation medicine.

comment 10

comment by: AECA(SPAIN)

There is sometime a clear disparity between the provisions of the Regulations and what develops in the AMC. For example: are times when the regulation, regarding certain disease or injury, clear states that the sufferer should be declared 'unfit', however the corresponding AMC provide methods that even in such cases can be certified as fit a person with this disease or injury, which means a real collision with the rules.

Proposal 3. In cases in which wants to liberalize a requirement leading to 'unfit' with conditions therein regulation, should be opened the possibility of this circumstance, adding, for example, a phrase such as: "However, in cases it ... can be described as fit if ... "

response *Partially accepted*

For conditions which inevitably lead to an unfit assessment, the Regulation clearly states 'unfit', e.g. heart/lung transplantation (class 1) and schizophrenia. For conditions which could either lead to a fit or an unfit assessment, the Regulation cannot state 'unfit', as the AMC giving the possibility for a fit assessment would be contradictory. In these cases, the rules state 'a fit assessment may be considered' and the AMC provides criteria for that assessment, depending on the individual case.

comment 11

comment by: AECA(SPAIN)

There are States where, for reasons of national legislation or procedures of the health system, cannot be implemented the GMP or OHMP figure. In these cases is necessary that the Regulation refers to the validity of medical certificates issued by these medical professionals in other States.

Proposal 4: To include in the Regulation a reference indicating that medical certificates issued by GMPs or OHMPs not be valid in relation with licenses or certificates issued by the States in which these figures cannot be implemented for reasons of national legislation.

response *Noted*

Medical certificates issued by GMPs or OHMPs in countries where this is allowed under national law are valid in all Member States for persons who hold their licence in these



countries. In countries where the GMP or OHMP is not allowed to issue medical certificates, these certificates do not have to be accepted in cases where a licence/attestation holder of this same country gets a medical certificate /report from a GMP or OHMP abroad. For example: A Spanish LAPL holder transfers his licence to the UK and gets a medical certificate issued by a GMP in the UK. This medical certificate (and licence) is valid in Spain and the pilot can fly a Spanish registered aircraft everywhere in Europe. If the same pilot holds a licence issued in Spain and has a medical certificate issued by a GMP in UK, the Spanish authority is not obliged to accept that medical certificate. This is not mentioned in Part-MED because the Basic Regulation already provides for this in Article 7.

comment 22 comment by: AECA(SPAIN)

Why not include Subpart C to the requirements of the CC?

response *Noted*

Whilst developing Part-MED, the Agency endeavoured to position all medical requirements within one document. Furthermore, the medical certification requirements for air traffic controllers may also be incorporated into this document in the future.

comment 49 comment by: Light Aircraft Association UK

These comments are made by the Light Aircraft Association in the UK, based on the review of the NPA by our Medical Advisor, who is an AME.

response *Noted*

Thank you for the information.

comment 68 comment by: Federal Office of Civil Aviation FOCA

It is important that the level of detail is proportionate and adequate by leaving enough room for individual (expert) judgement. As a general remark, FOCA considers that some regulations do not meet this criterion by being too detailed. In the present MED-Requirements the level of detail and the room for individual (expert) judgement are rather well balanced. It is important that this concept is not abandoned now and in the future.

response *Noted*

The Agency agrees that it is important to strike the right balance between the level of detail and room for individual judgement. This was given priority during the development of the provisions with the medical experts on the Rulemaking group.

comment 76 comment by: The Norwegian Air Sports Federation

GENERAL REMARKS
Norges Luftsportforbund (The Norwegian Air Sports Federation / NLF) welcomes NPA 2013-



	<p>15, as it corrects editorial errors and covers gaps in the current regulation. Furthermore, the NPA introduces some new alleviations, making flying accessible to persons who are currently barred from flying, while maintaining a high level of safety.</p> <p>However, despite the fact that the NPA according to the Executive Summary is not supposed to introduce any major changes to Part-MED, we regret that the Agency suggests new limitations without providing information about the safety case (AMC2 MED.B.010 (d)).</p> <p>NLF would also have welcomed alternative guidance on how a Member State could allow their GMPs to perform the medical examinations for LAPL holders. This is an acute matter, which can hit the Norwegian air sports activities in an irreversible manner from 2015 onwards.</p>
response	<p><u>First comment in this field</u></p> <p><i>Noted</i></p> <p>Thank you for your support.</p> <p><u>Second comment in this field</u></p> <p><i>Noted</i></p> <p>See response to comment No 78.</p> <p><u>Third comment in this field</u></p> <p><i>Noted</i></p> <p>The GMP is only allowed to carry out aero-medical examinations and assessments if permitted under national law. If national law permits GMPs to do so, these GMPs have to follow the rules just as AMEs have to.</p>
comment	<p>89 comment by: ESAM</p> <p>Attachments #2 #3</p> <p>The following comments have been submitted on behalf of: Dr. René Maire, MD Cardiological Expert and AME of the Federal Office for Civil Aviation, Switzerland Member of the Advisory board of ESAM Vice President of SSAVMED</p>
response	<p><i>Noted</i></p> <p>Thank you for your detailed comments on GM1 MED.A.020 and MED.B.010 which ESAM uploaded onto the Comment-Response Tool (CRT) as two identical attachments from ESAM and SSAVMED.</p> <p>All comments have been seen and taken into account. However, comments which have not been entered into the corresponding segments in the Agency's comment response tool cannot be answered individually.</p> <p>Nevertheless, the following remarks are offered in response to your comments:</p> <ol style="list-style-type: none"> 1. It is sound aero-medical practice not to fly if the type or dose of blood pressure



medication is changed. It is up to the licensing authority to decide whether the pilot is formally assessed as unfit whilst any potential side effects are monitored and until blood pressure control is regained.

2. 'Cardioactive' is a term used in aero-medical practice and is listed in the Oxford Medical Dictionary.
3. The suggested investigations for congenital heart disease are in AMC material and are intended as examples for aero-medically relevant investigations.
4. 'Potential hazard' refers here to aero-medical risk.
5. The cardiac dimensions mentioned in relation to mitral valve disease were specifically put in the GM on the suggestion of the Rulemaking group.
6. Similarly, the electro-physiological parameters were listed in the GM for ventricular pre-excitation on the suggestion of the Rulemaking group. As a general rule, numerical limits are placed in GM rather than AMC.
7. The ejection fraction limit in AMC2 MED.B.010(m) has been corrected to $\geq 50\%$.

comment

92

comment by: EFLEVA

These comments are posted on behalf of the European Federation of Light Experimental and Vintage Aircraft (EFLEVA).

response

Noted

Thank you for the information.

comment

125

comment by: *Swedish Transport Agency, Civil Aviation Department
(Transportstyrelsen, Luftfartsavdelningen)*

Section: [Part-MED](#)

Page: [General comment](#)

Comment:

When preparing this NPA for Part-MED a harmonisation with the NPA for Part-ATCO.MED was sought. The CRD for Part-ATCO.MED now has been published with some amendments to the NPA, including a number of improvements regarding structure, wordings and expressions which contribute to a clearer understanding of the rules without changing their content.

The main users of both Part-MED for aircrew and Part-ATCO.MED are the Aero-Medical Examiners and the Aero-Medical Centres. Differences between Part-MED for aircrew and Part-ATCO.MED with regards to structure, wordings and expressions used might create difficulties in interpretation for the users with risks of mistakes in medical assessments. A harmonisation of structure, wordings and expressions used in Part-MED and Part-ATCO.MED will simplify the work of the AMEs and AeMCs and reduce the risk for incorrect medical assessments.

Proposal:

Cross-check the whole NPA Part-MED with the CRD Part-ATCO.MED to create harmonised structure, wording and expressions wherever possible.



response	<i>Partially accepted</i>	
	A harmonisation of structure, wording and expressions used in Part-MED and Part-ATCO.MED has been applied. Further alignment, where appropriate, will be considered once the two sets of provisions have stabilised.	
comment	220	comment by: CAA-NL
	<p>The proposed amendments are in general an improvement, text more clear, more uniform. Our compliments for the authors.</p> <p>There is less unnecessary work for the license holder as well as the authority where in pregnancy the license is no longer suspended. We are less happy with the additional workload due to an unnecessary renewal examination after pregnancy. Also we have the opinion that in the new text there is an overshoot regarding vasovagal syncope. Please also see our detailed comments.</p>	
response	<i>Noted</i>	
	Thank you for this information. Responses to the comments on pregnancy and vasovagal syncope are provided in the relevant sections.	
comment	223	comment by: Luftfahrt-Bundesamt
	The LBA has no comments on NPA 2013-15.	
response	<i>Noted</i>	
	Thank you for your support.	
comment	236	comment by: French main military Aeromedical Center (CEMPN)
	<p>This is a general presentation of our comments about the updated version of part-Med to EU and updated AMC/GM to part-Med.</p> <p>These comments are the expression in the name of the 20 physicians, specialist of aviation medicine who have been working in the French main military aeromedical center (CEMPN) of Clamart (PARIS) for years.</p> <p>Adress of the AeMC is :</p> <p style="text-align: center;">HIA PERCY DEPARTEMENT D'EXPERTISE AERONAUTIQUE CENTRE PRINCIPAL D'EXPERTISE MEDICALE DU PERSONNEL NAVIGANT 101 Avenue Henri Barbusse – BP 406 92141 CLAMART Cedex</p> <p>Details of the authors are :</p> <p>Med General V. MARTEL Director of AeMC Percy MD, Specialist of Aviation Medicine Military National Consultant for aviation medicine Member of the French Aeromedical Authority</p> <p>Med Col E. PERRIER</p>	



	<p>Head of Medicine and Cardiology Department - AeMC Percy Professor of Aviation Medicine Military National aeromedical expert Med Col P. CREPY Head of Ophthalmology Department - AeMC Percy MD, Specialist of Ophthalmology Military National aeromedical expert Med Col O. MANEN Medicine and Cardiology Department - AeMC Percy MD, Specialist of Aviation Medicine</p>
response	<p><i>Noted</i></p> <p>Thank you for the information. Responses to the comments provided by the CPEMPN are given in the corresponding segments in this document.</p>

comment	<p>332 comment by: <i>Austro Control</i></p> <p style="text-align: center;">COMMENTS OF AUSTRO CONTROL to NPA 2013-15 concerning Part-MED of Commission Regulation (EU) 1178/2011 and Acceptable Means of Compliance (AMC) and Guidance Material (GM)</p> <p><u>General comments:</u> In general Austro Control is of the opinion that relevant rules (eg. limitation codes, cabin crew medical report and syllabus of training courses in aviation medicine ...) should be stated fully in the regulation and not within the AMC. Some parts should be transferred from AMC into PART-MED. The guidance material should only consist of actually explanatory contents. Some GM should be transferred to AMC (eg training courses in aviation medicine) – see the referring remarks below.</p> <p><u>Subpart A:</u> The amendments in subpart B are generally supported by Austro Control. Nevertheless we suggest the following changes:</p> <p><u>MED.A.025</u></p> <p>MED.A.025 (a)(3) <i>“... notify the licensing authority, or, in the case of cabin crew attestation holders, notify the competent authority if the applicant provides incomplete, inaccurate or false statements on their medical history”</i> Concerning cabin crew it is not absolutely comprehensible, why the notification should only go to the competent authority - especially in member states where cabin crew examinations are undergone only by aeromedical examiners (result of MED.A.025(b)(4)). In our opinion there should be not a difference between Cabin crew examinations and pilot examinations concerning the authority.</p> <p><u>MED.A.025 (b)(4)</u> <i>“in the case of applicants for a medical certificate, submit without delay to the licensing</i></p>
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authority a signed, or electronically authenticated, report containing the detailed results of the aero-medical examination and assessment as required for the class of medical certificate and a copy of the application form, the examination form, and the medical certificate to the licensing authority; ...”

Austro Control suggests the following wording:

“in the case of applicants for a medical certificate, submit without delay to the licensing authority **(in the way defined by the licensing authority)** a signed, or electronically authenticated, report containing the detailed results of the aero-medical examination and assessment as required for the class of medical certificate **or denial** and a copy of the application form, the examination forms– **according to PART-ARA**, and the medical certificate to the licensing authority; **if the licensing authority is responsible for the medical assessment, the AME shall submit all other relevant medical reports. ...”**

MED.A.035

Austro Control recommends integrating all forms (application, examination reports, certificates etc.) into the rule (it should not be published only in the AMC). This could be done either via a reference to the forms in PART-ARA or an integration of the forms into PART-MED. (Forms like licenses, application etc. are part of the rule in other cases – see for example Regulation (EC) 2042/2003 and 748/2012, etc.)

Austro Control suggests the following phrasing:

“Applications for a medical certificate shall be made in a format **according to PART-ARA** and established by the competent authority.”

Subpart B:

The amendments in subpart B are generally supported by Austro Control. Nevertheless we suggest the following changes:

MED.B.001 (d) (2) (iii)

Austro Control recommends not deleting the phrase “with limitation(s), in consultation with the licensing authority” because the medical requirements for LAPL are even now very open and the possibility for AMEs and AeMCs to impose and remove “OSL” without consultation of the competent authority could lead to inconsistent assessments depending from the AME or AeMC.

MED.B.010 (a)(1)(ii)

The proposal in MED.B.010 (a)(1)(ii) requiring a 12-lead resting ECG at the initial examination for a class 2 medical certificate and deleting the ECG at the first examination after age 40 could mean that in some cases a young applicant for class 2 gets an ECG at the age of 17 or 18 years and afterwards for a timeframe of more than 32 years no ECG. Reason: the next ECG has to be performed at the first examination after the age of 50!

Conclusively in our opinion there is no safety background in deleting the requirement getting an ECG at the first examination after age 40.

The proposal in AMC 2 MED.B.095 (d)(2) concerning the LAPL-medical allowing pilots to fly with AP requiring medication in our eyes is **not acceptable** from the point of flight safety, because medication to control serious symptoms of coronary hypoxia is able to disguise symptoms of myocardial infarction before and during flight, especially because of the fact, that decrease of oxygen in the atmosphere at high altitudes and without pressure cabin, as it commonly occurs in LAPL-A/C, during climbing is able to aggravate hypoxia of the heart.

Furthermore pilots are normally amateurs in medical questions and are not able to make a



difference between stable AP, which normally does not require further medication, and an unstable AP, which needs quick medical treatment and is definitely not compatible with flying.

AMC MED:

The amendments in AMC1 are generally supported by Austro Control. Nevertheless we suggest the following changes:

AMC 1 MED.B.010 (d)(1)

Austro Control fully agrees with the proposal to AMC 1 MED.B.010 (d)(1), but in our opinion the phrasing “*It is proposed to clarify in the AMC that the diameter of the aneurysm should not be greater than 5cm²...*” describes not the correct metric unit for the diameter, it should be “**5 cm**” and not “5cm²”.

AMC 1 MED.B.020, AMC 2 MED.B.020 and AMC 4 MED.B.095

In regard to the proposed changes in AMC 1 MED.B.020, AMC 2 MED.B.020 and AMC 4 MED.B.095 we think, that it **could be useful to add the sentence “Applicants after liver transplantation because of a history of alcohol abuse should be assessed as unfit”**, because in rare cases and under very certain conditions liver transplantations are made also under these circumstances.

AMC 1 MED.B.095 (a) (1)

The proposal for AMC 16 MED.B.095 (a) (1) **should be amended with the following sentence:**

“In the case of acoustic feedbacks pilots with hearing aids are permitted to take down the device(s) during flight, when the on-board-intercom- and-radio-communication-system is able to enhance the sound level individually with the result, that radio-communication without a hearing aid is still possible and not jeopardizing flight safety. Hearing aids should always be reachable in the cockpit.”

Conclusively also the deletion of the paragraphs MED.B.005 (b) and (c) is not recommended.

AMC1 MED.D.020

The content of this AMC concerning the syllabus of training courses in aviation medicine should be regulated in PART MED and not in the AMC because of harmonization reasons.

AMC2 MED.B.001

Limitations should be only regulated in PART-MED and not in the AMC because of harmonization reasons.

AMC 2 MED.D.020

The content of this AMC concerning the syllabus of training courses in aviation medicine should be regulated in PART MED and not in the AMC because of harmonization reasons.

AMC.1.MED.D.030

The content of this AMC concerning the syllabus of training courses in aviation medicine should be regulated in PART MED and not in the AMC because of harmonization reasons.

Guidance Material:

GM1 MED.D.020 – Training courses in aviation medicine



	<p>The content of this GM should be transferred to the AMC because of harmonization reasons.</p> <p><u>GM2 MED.D.020</u> – Training courses in aviation medicine The content of this GM should be transferred to the AMC because of harmonization reasons.</p> <p><u>GM3 MED.D.020</u> – Training courses in aviation medicine The content of this GM should be transferred to the AMC because of harmonization reasons.</p> <p><u>GM1 MED.D.030</u> – Training courses in aviation medicine The content of this GM should be transferred to the AMC because of harmonization reasons.</p>
response	<p><i>Noted</i></p> <p><u>General comments:</u></p> <p>The Agency, together with the Rulemaking drafting group tried to balance the distribution of the regulatory material. The basic principle is to state in the regulation what has to be done (for example, training course in aviation medicine), to explain in the AMCs how it should be done (duration of the course, list of content) and to provide further details in GM. Considering the comments received to NPA 2008-17c and NPA 2009-02e and this NPA, the Agency has the impression that the aim of a balanced distribution has been achieved.</p> <p><u>Further comments:</u></p> <p>All comments have been seen and taken into account. However, comments which have not been entered into the corresponding segments in the Agency’s comment response tool cannot be answered individually.</p>
comment	<p>333 comment by: <i>ITALIAN AIR FORCE MEDICAL SERVICE</i></p> <p>Attachment #4</p> <p>Mr Silvio Porcu, ENAC, Italy</p>
response	<p><i>Noted</i></p> <p>Thank you for your detailed comments which the Italian Air Force Medical Service uploaded onto the Comment-Response Tool (CRT) as an attachment.</p> <p>All comments have been seen and taken into account. However, comments which have not been entered into the corresponding segments in the Agency’s comment response tool cannot be answered individually.</p> <p>Nevertheless, the following comments are offered in response to your suggested changes:</p> <ol style="list-style-type: none"> 1. The regulatory basis of Part-MED is not to delegate fitness assessments for class 1 applicants who do not fully comply with class 1 requirements to aero-medical centres. Additionally, only the licensing authority should add or remove OMLs. 2. In order to preserve proportionate regulations, the Agency has not accepted the proposed increased frequency of ECGs for class 2 certificate holders, nor has it accepted the proposal to have the haemoglobin checked at all class 2 certificate examinations. 3. With regard to the proposal that class 1 initial applicants undergo a psychiatric and



psychological assessment, the Agency is not aware that these tests have sufficient sensitivity or specificity to have an impact on civil aviation safety.

4. Text covering migraine has now been added to the AMC material.
5. The requirement for certificate holders with a CCL to carry a spare set of spectacles is to allow for a rapid correction of defective vision if a contact lens is dislodged or the lenses need to be removed due to contamination such as may occur in a smoke event.
6. The pressure gradient limit for aortic stenosis has been set to have an acceptable risk of incapacitation whereas the ESC guidelines have been determined so that surgery can be considered at this level of severity.
7. New text has been added concerning anticoagulants, which includes the use of NOACs.
8. The Rulemaking group was of the opinion that a sufficient description of the type of pacemaker acceptable for certification is already in PART-MED.
9. In the case of Brugada pattern ECGs, type 3 pattern has been added to the text. The decision to proceed to challenge testing with sodium blocking drugs and electrophysiological testing has been left to the cardiologist, because at present there is still controversy about the value, specificity and sensitivity of these procedures.
10. Contrast sensitivity has now been included in the comprehensive eye examination. If anisometropia exceeds 3 dioptres, then it is expected that during the ophthalmic evaluation, binocular function will be assessed.
11. Tympanometry is included in the comprehensive ENT examination.
12. Routine drug testing may be considered in a future rulemaking task.

comment 69

comment by: René Meier, Europe Air Sports

Europe Air Sports wishes to thank the Agency for the development of NPA 2013-15. Our medical specialists studied the proposals of the NPA.

We understand that for Part-MED it was the objective to transpose the JAR-FCL 3 material, particularly amendment 5, into European Rules. Direct changes to JARFCL 3, including the medical technical requirements were to be avoided in order to facilitate implementation in the Member States. This has led to medical rules in Part-MED that have not been technically updated since 2006 when JAR-FCL 3, amendment 5, was published. As medical knowledge has further developed since that time it was necessary to update the medical rules at the earliest possible stage, as proposals made by stakeholders during the consultation phase of NPA 2008-18 (c) have not been considered for Part-MED to avoid drastic changes.

We also discussed if the proposals of this NPA do represent major changes. You will find later that we do not fully agree with the Agency's position. Particularly our Norwegian friends regret that the Agency suggests new limitations without providing information on an eventual safety case [(AMC2 MED.B.010 (d))].

Pilots and their organisations from several countries would have welcomed guidance on how GMP could be allowed to perform medical assessments for LAPL holders. Such a guidance could be helpful to maintain the number of active pilots throughout Europe.



	<p>And, at last, a general remark: The comments of Europe Air Sports are supported by the European Powered Flying Union (EPFU), by the Aero-Club of Switzerland and by the Norwegian Air Sports Federation.</p>
response	<p><i>Noted</i></p> <p>The Agency understands that the commentator does not support the introduction of new limitations in the NPA, with the example of an OSL for applicants with an aortic aneurysm.</p> <p>However, the OSL is not new, as it was suggested for class 2 applicants with infra-renal aortic aneurysm in the former JAA manual of civil aviation medicine. About half of all aortic aneurysms in the abdomen >6,0 cm rupture within one year, while one sixth rupture over a similar period if the diameter is <6,0 cm. Data is less for thoracic aortic aneurysm but about two thirds only survive five years, rupture occurring in one third of those dying over this period. Surgical correction may stabilise the situation but does not correct remote pathology. In the JAA manual, class 2 applicants with a thoracic or supra-renal aortic aneurysm before or after surgery should be assessed as unfit. A fit assessment is possible in the current provisions, but mitigation such as 'less than 5 cm in diameter' and 'with an OSL' was missing, hence, the correction in the NPA.</p> <p>However, the AMC has been refined so that a fit assessment for a class 2 applicant with an infra-renal abdominal aortic aneurysm of less than 5 cm in diameter, or having had surgery for it, may be considered, without an OSL or OPL.</p> <p>On the comment about GMPs, the GMP is only allowed to carry out aero-medical examinations and assessments if permitted under national law. If national law permits GMPs to do so, these GMPs have to follow the rules just as AMEs do.</p>
comment	<p><i>111</i> comment by: <i>AMCS - Thomas Syburra</i></p> <p><u>GENERAL REMARKS</u></p> <p>The European Association for Cardio-Thoracic Surgery EACTS (www.eacts.org) is the leading and largest association for cardiac, thoracic and vascular surgeons in Europe. EACTS is committed to advance education in the field of cardiac, thoracic and vascular interventions; and promote research into cardiovascular and thoracic physiology, pathology and therapy, with the aim to correlate and disseminate the results for the public benefit. Together with the European Society of Cardiology ESC, EACTS' working groups are editing the guidelines on myocardial revascularisation, on valvular heart disease management, on aortic surgery and on arrhythmia management (http://www.escardio.org/guidelines-surveys/esc-guidelines/Pages/GuidelinesList.aspx).</p> <p>Within the EACTS, we looked through EASA's standards, and we noticed a potential for improvement in the coordination of the EACTS/ESC rulemaking groups and EASA's rulemaking policies on the domain of cardiac surgery. As cardiac surgeons, we feel there is a lack of current guidance when we operate on flight crews, based on our current practice, knowledge, evidence and non-aeronautical guidelines. Therefore, we constituted a new committee within EACTS:</p> <p><u>Aviation Medicine and Cardiac Surgery AMCS.</u></p> <p>The mission of AMCS is to offer to EASA a service in the writing of guidance over cardiac surgery.</p> <p>We aim to join the efforts of our professional sections to promote coordinated and regular</p>



updates in the rulemaking for flight crew licensing in the context of cardiac surgery, supporting both the cardiac surgeon and the flight surgeon in the best interest of safety and sustainability for the flight crews undergoing cardiac surgery.

The first meeting of the AMCS was held during the 27th EACTS annual meeting this October in Vienna.

AMCS has the full support of the president of EACTS for his mission.

The AMCS committee is constituted as follow:

1. Thomas Syburra, MD FETCS: Cardiac Surgeon at the Royal Brompton Hospital London and Flight Surgeon in the Swiss Air Force - AMCS Chairman / person of contact
2. John Pepper, MD FRCS: Cardiac Surgeon at the Royal Brompton Hospital London - AMCS Co-Chairman and EACTS Acquired Cardiac Disease Chairman
3. Ulrich Rosendahl, MD FECS: Senior Aortic Surgeon at the Royal Brompton Hospital London
4. Wg Cdr Ed Nicol, MD: Aviation Cardiology in the UK Royal Air Force and Consultant Cardiologist (cardiovascular CT) at the Royal Brompton Hospital
5. Stuart Mitchell, MD: Head Authority Medical Section at the UK Civil Aviation Authority CAA
6. Denis Bron, MD: Head Aviation Medicine at the Swiss Air Force Aeromedical Institute

response *Noted*

The contribution by the AMCS committee of the EACTS is acknowledged by the Agency. Responses to the comments provided by the AMCS are given in the corresponding segments in this document.

2 Explanatory Note — 2.3 Overview of the proposed amendments — 2.3.1 Editorial corrections and changes for clarification and consistency

p. 7

comment 7

comment by: ICAO

I have a comment on the proposed use of certain terms that may be confused with ICAO terminology already in use by States. The relevant text in Part-Med is:

"For clarification, the words are now used as follows:

- (1) 'to evaluate' is used where a specialist, e.g. a cardiologist, evaluates the medical situation of a pilot and provides the findings to the AME, AeMC, or licensing authority as appropriate for the class of medical certificate;
- (2) 'to assess' is used when the AME, AeMC, or licensing authority assesses the specific findings and the 'evaluation' of a specialist and uses the information for the decision on medical fitness;
- (3) 'to review' has been replaced in most cases by either of the two terms above, as appropriate."

ICAO has specific definitions in ICAO Annex 1 - *Personnel Licensing* for "medical assessment" and "medical assessor" as follows:

"Medical Assessment. The evidence issued by a Contracting State that the licence holder meets specific requirements of medical fitness.

Medical assessor. A physician, appointed by the Licensing Authority, qualified and experienced in the practice of aviation medicine and competent in evaluating and assessing



medical conditions of flight safety significance.

Note 1. — Medical assessors evaluate medical reports submitted to the Licensing Authority by medical examiners.

Note 2. — Medical assessors are expected to maintain the currency of their professional knowledge.”

I don't know if it is possible to be consistent with ICAO, without involving major changes to Part-MED. Perhaps a consultant “reviews” a case and provides a specialist report, a medical examiner designated to be able to issue an assessment (certificate) “evaluates” the data and issues or declines issuance of an assessment/certificate.

The use of the term “medical assessment” as a noun (“the evidence issued”....rather than an action) by ICAO may not be the commonest use of terminology, but I feel that the wording proposed by EASA may not make things clearer.

response

Noted

The Agency is aware of the ICAO terms and follows ICAO wording where possible. However, in the cases referred to in the comment, this has not been possible.

The term ‘medical certificate’ is used instead of the ICAO equivalent ‘medical assessment’ because the Basic Regulation requires pilots to hold a medical certificate and the same expression must be used in the Aircrew Regulation.

Some Member States prefer that a difference is made between ‘medical examination’ and ‘assessment’. ‘Medical examination’ is meant to say that an applicant for a medical certificate is medically/clinically examined and the result assessed before a medical certificate can be issued, while in other cases the possibility is to be given to ‘assess’ only the medical history and then issue the certificate.

The medical rules and the administrative procedures do follow ICAO Annex 1. The Agency is of the opinion that the terms used are clear and consistent and lead to full ICAO compliance.

comment

251

comment by: UK CAA

Page No: 7

Paragraph No: Explanatory Note – 2.3.1(b)

Comment: The definitions of ‘to evaluate’, ‘to assess’ and ‘to review’ differ from ICAO definitions.

Justification: Clarity and ICAO compliance.

Proposed Text: EASA definitions should be aligned with ICAO definitions.

response

Noted

The explanations were given to indicate how the wording has been aligned in Part-MED rather than to serve as definitions. The alignment had been requested by the EASA Committee during the adoption process of Part-MED.

ICAO uses the term ‘medical assessment’ for what is the ‘medical certificate’ in Part-MED. ‘Medical assessment’ is used in ICAO Annex 1 because it is up to the Contracting States to issue a medical certificate or to have a tick box on the licence indicating fitness to fly. A change from medical certificate to medical assessment will not be done because it would cause confusion.



2 Explanatory Note — 2.3 Overview of the proposed amendments — 2.3.2 Subpart A

p. 7-10

comment	<p>5 comment by: <i>Dr.Beiderwellen, Vice President of GAAME</i></p> <p>Page 10, (5) certainly, there is no "general understanding worldwide" about submitting personal data to the licensing authority. There are many countries, where the protection of personal data is a highly respected right and submitting such individual data will interfere with national law. Personal data should not be given to any third person, if not necessary for higher reasons e.g. Flight Safety or in case of mandatory referral to the licencing authority. If AME/AeMC have assessed an applicant as fit, following all rules given in the 1178/2011 and connected papers, there is no reason to submit any individual data to a third person. The " fit assessment " is documented by the medical certificate, which is the only document, that has to be send to the licensing authority.</p>
response	<p><i>Not accepted</i></p> <p>Based on ICAO Annex 1, it is worldwide practice to submit the results of the medical examination(s) and the assessment to the Medical Assessor of the aviation authority. The authority is responsible for ensuring medical confidentiality. The data provides evidence for the outcome of 'fit' or 'unfit' and is needed by the authority in order to conduct oversight activities and to identify any erroneous results which may in turn directly affect flight safety.</p>
comment	<p>70 comment by: <i>René Meier, Europe Air Sports</i></p> <p>2.3.2 Subpart A (d) Medical certificates Thank you for explicitly including the new en-route instrument rating (EIR). Rationale: Having it mentioned here it makes clear to everyone what is required.</p>
response	<p><i>Noted</i></p> <p>Thank you for your support.</p>
comment	<p>168 comment by: <i>DGAC FRANCE</i></p> <p>The NPA 2013-15 is proposing deletion of § MED.A.025 (b)(3) which was intending to inform the "flight crew assessed as unfit about his right of a secondary review."</p> <p>1°) The first general comment consists in highlighting, as a major issue, that France does not support such a working method which consists in amending a rule shortly after publication when the NAA have just put in place their new organisation in order to comply with this new rule.</p>



As a matter of fact, the implementation of the new organisation required by Aircrew led the NAA to amend its organisation ; to proceed such an organisation amendment, a high level decree was necessary leading to other ministries involvement.

In this context, to propose an amendment to a European regulation without any very accurate explanation leads to requests of clarification and, in any case, leads to put in question the regulation amendment.

In addition, the amendment to (EU) no 1178/2011 (particularly MED.A.025(b)(3)) will have potential impact upon requirement (EU) no 290/2012 (particularly Part ARA.MED.315, .325) and on Part ORA, i.e. will impact organisation and procedures of NAAs and stakeholders.

It is neither possible nor acceptable to change those requirements (EU) no 1178 and (EU) no 290 without having a global and comprehensive approach that would help understanding and assessing the complete picture. Except in case of an urgent amendment the cause of which would be clear and understood by all parties (NAAs and stakeholders) it would be more adequate to let the rule as it is during some time and make a global modification covering all aspects in one shot. If current regulation leads to harmonisation difficulties between member states it is suggested that EASA and the Commission make use of some flexibility in their standardisation assessment.

Also, it is not possible to draft an amendment to no 1178/2011 regulation which will have an impact on the rights given to any flight crew (in this case visibility given on rights) without identifying accurately the consequences upon Part ORA and ARA, which are the relevant requirements dealing with organisational aspects.

2°) the second detailed comment consists in indicating that it is of major importance that the fundamental right for flight crew personnel , freely moving within Europe, to be informed of the possibility to ask for revision of their medical dossier if they are declared unfit; this right must be kept in the European regulation.

It is necessary to ensure that each European country applies the same principle and the same rule and recognizes decisions taken by other countries in similar situations.

3°) Finally, and it is the third part of DGAC FR comment; it is requested to get further detailed explanation upon the note 2.3.2 c) 4), since this note is the basis of the proposal for amendment to § MED.A.025 (b)(3)

a) to detail any problems which were put in evidence when the draft regulation was established and the rationale for having replaced the wording “right of appeal” by the wording “right of secondary review”;

b) to explain what is exactly meant by the « secondary review » and what is the difference between the “appeal” and the « secondary review ».

c) to draft a regulation wording which is not letting an open door for various interpretations and implementations; otherwise, it would be expected that every national Authority is totally free to manage the “border line” cases and the “appeal” cases.

response *Noted*

See response to comment No 90.



comment 169

comment by: DGAC FRANCE

Do not delete the paragraph (3) (b) to MED.A.025 “Obligations of AeMC, AME, GMP and OHMP” - PART-MED - ANNEX IV.

The DGAC wants to keep this paragraph for the following reasons :

The suppression of the secondary review from MED.A.025 - PART MED - Annex IV of 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, in order to favour the administrative appeals according to the national law, bring the following remarks :

- when aero-medical examiners and the aero-medical centres are in front of a medical situation requiring a decision of the authority, they have to refer to the medical assessor. This referral is not an appeal to a decision ;

- in French law, any applicant who disagrees with an administrative decision, including a medical assessor decision, must be able to have the right of appeal against this decision.

The appeal could be made in front of the administrative courts, however the lack of responsiveness of this courts (3-4 months) does not seem appropriate and returns the very long and impractical appeal procedure. Furthermore, the number of predictable appeals (e.g. 40 new cases per year for air traffic controllers) may increase the existing congestion of the courts, what would have catastrophic consequences in the operational and financial plan.

It is thus essential to keep the current procedure which allows the candidate, in disagreement with a decision concerning the medical capacity, to make an appeal with an independent medical committee so that this collective authority studies the medical record for a revaluation of its case, ending in a new decision replacing the decision of the doctor assessor.

This constitutes the first level of the administrative appeal process, considering that a formal decision was initially issued (the administrative court being the second level). The interest is the speed of the procedure (appeal in 15 days following the notification of the decision of the medical assessor), financially less expensive for the member states, more suited to the operational plan and to the human plan.

Doctor Marie-Christine Monchalin, head doctor DGAC and Weather report-France.

response *Noted*

See response to comment No 90.

2 Explanatory Note — 2.3 Overview of the proposed amendments — 2.3.3 Subpart B, Section 1, General

p. 10-11

comment 112

comment by: AMCS - Thomas Syburra

On behalf of the AMCS committee within EACTS I report the following comments:

- > class 1/2/LAPL: non-consistent wording, need for standardisation of wording, sentences and criteria



> caveat on cardiac surgery guidelines: EACTS/ESC guidelines are looking at long-term outcomes, not at incapacitating events per annum, therefore there is a bias risk to consider. Furthermore: our population is older and not selected the same way as flight crews are. but: large amount of data is available, waiting to be processed.

> definition of 1% - 2% safety criteria may apply in the context of cardiac surgery and arrhythmia surgery

> EACTS/ESC guidelines to be considered as base for further focussed assessment of flight crews, taking in account the selection of this particular population

> surgery on the tricuspid valve lacks guidance material

> surgery on the thoracic aorta lacks guidance material

> aortic dimensions and management/surgery: lack of guidance material

> recent updates on genetic disorders and aortic surgery: lack of guidance material

> last update EACTS/ESC on aortic valve surgery in asymptomatic patients: lack of guidance material

response *Partially accepted*

Thank you for your detailed comments.

The wording for class 1, class 2 and LAPL medical certification has been standardised where appropriate. However, standardisation of the criteria would not support the principle of proportionality between risks associated with privileges of a commercial pilot licence holder and those of a private pilot licence holder or a light aircraft pilot licence holder.

On the comments about providing guidance material for certain medical conditions and surgery, the objective of the aero-medical examination and assessment is to verify that the pilot is fit to exercise the privileges of their licence, also taking into account the risk of sudden incapacitation, rather than considering for clinical management.

2 Explanatory Note — 2.3 Overview of the proposed amendments — 2.3.4 Subpart B, Medical requirements for class 1, class 2, and LAPL medical certificates — 2.3.4.1 General

p. 11

comment 184

comment by: Jörg SIEDENBURG

For reasons of consistency the terms mentioned should either be deleted throughout the requirements or left in place where they have been deleted. If not deleted everywhere a deletion in a couple of paragraphs makes no sense. The reason why the deletion takes place in some chapters and not in others remains unclear.

response *Partially accepted*

The status of IR text that is repeated in AMC would be unclear. Nevertheless, the proposed deletions have been reviewed and changed in some individual cases.

2 Explanatory Note — 2.3 Overview of the proposed amendments — 2.3.4 Subpart B, Medical requirements for class 1, class 2, and LAPL medical certificates — 2.3.4.2 Cardiovascular system — (a) Class 1

p. 11-12



comment	71	comment by: <i>René Meier, Europe Air Sports</i>
	<p>2.3.4.2 Cardiovascular system (c) LAPL</p> <p>We thank the Agency for the proposal made. With this new regulation there is the possibility for applicants with angina pectoris requiring medication to undergo a cardiologic evaluation. Rationale: Certain pilots now can be declared fit after such an evaluation, so this rule is less stringent, this is good for the members of our community.</p>	
response	<p><i>Noted</i></p> <p>See response to comment No 110.</p>	
comment	77	comment by: <i>The Norwegian Air Sports Federation</i>
	<p>MED.B.010 (b) (2) and AMC1 MED.B.010 (d) (2)</p> <p>Aortic aneurysm after surgery for Class 1: NLF welcomes this change, as it allows Class 1 certificates to be issued to persons without compromising flight safety.</p>	
response	<p><i>Noted</i></p> <p>Thank you for your support.</p>	

<p>2 Explanatory Note — 2.3 Overview of the proposed amendments — 2.3.4 Subpart B, Medical requirements for class 1, class 2, and LAPL medical certificates — 2.3.4.2 Cardiovascular system — (b) Class 2</p>	<p>p. 12</p>
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comment	78	comment by: <i>The Norwegian Air Sports Federation</i>
	<p>AMC2 MED.B.010 (d) (2)</p> <p>Aortic aneurysm after surgery for Class 2: NLF is opposed to the addition of the OSL, which is not in the current rule. As the Agency points out in 2.3.4.5 (a) (1) of the NPA, an OSL prevents pilots from exercising their privileges in single pilot aircraft. This will in particular affect SPL-rated glider pilots, but also a number of other license holders. It is surprising that this limitation is added without a medical justification or a verified safety case.</p>	
response	<p><i>Partially accepted</i></p> <p>The OSL is not new, as it was suggested for class 2 applicants with infra-renal aortic aneurysm in the former JAA manual of civil aviation medicine. About half of all aortic aneurysms in the abdomen >6 cm rupture within one year, while one sixth rupture over a similar period if the diameter is <6 cm. Data is less for thoracic aortic aneurysm but about two thirds only survive five years, rupture occurring in one third of those dying over this period. Surgical correction may stabilise the situation but does not correct pre-existing pathology. In the JAA manual, class 2 applicants with a thoracic or supra-renal aortic aneurysm before or after surgery should be assessed as unfit. A fit assessment is possible in the current provisions, but mitigation such as ‘less than 5 cm in diameter’ and ‘with an OSL’</p>	



was missing, hence, the correction in the NPA.

However, the AMC has been refined so that a fit assessment for a class 2 applicant with an infra-renal abdominal aortic aneurysm of less than 5 cm in diameter, or having had surgery for it, may be considered, without an OSL or OPL.

Regarding the comment on OSL preventing pilots from exercising their privileges in single pilot aircraft, this has been addressed by the introduction of a new paragraph (d)(4) in MED.B.001.

comment 241

comment by: René Meier, Europe Air Sports

AMC2 MED.B.010(d)(2)

Europe Air Sports received comments signalling opposition to the introduction of the OSL in the case of aortic aneurysm after surgery, this not being the case with the current rules. Several categories of licence holders could not continue their activities.

Rationale:

We are not sure if this measure is appropriate for holders of a Class 2 medical, we heard that this limitation is not evidence-based and was not introduced on the basis of a verified safety case.

response *Noted*

See response to comment No 78.

2 Explanatory Note — 2.3 Overview of the proposed amendments — 2.3.4 Subpart B, Medical requirements for class 1, class 2, and LAPL medical certificates — 2.3.4.2 Cardiovascular system — (c) LAPL p. 12

comment 113

comment by: AMCS - Thomas Syburra

this should be unacceptable

response *Noted*

See response to comment No 110.

2 Explanatory Note — 2.3 Overview of the proposed amendments — 2.3.4 Subpart B, Medical requirements for class 1, class 2, and LAPL medical certificates — 2.3.4.5 Metabolic and endocrine systems — (a) LAPL p. 13

comment 72

comment by: René Meier, Europe Air Sports

2.3.4.5 Metabolic and endocrine systems

(a) LAPL

Many thanks for including OPL, next to OSL, in LAPL provisions.



<p>response</p>	<p>Rationale: An extension with OPL limitation gives more flexibility for LAPL pilots and reflects better the safety requirements for diabetic pilots.</p> <p><i>Noted</i></p> <p>Thank you for your support. However, please note: In response to comments received, a new limitation, coded 'ORL' (Operating pilot Restriction Limitation) has been introduced (new (d)(4)) to allow a class 2 or LAPL medical certificate holder to apply either an Operational Safety Pilot Limitation (OSL) or an Operational Passenger Limitation (OPL). In other words, if passengers are carried, an OSL will apply.</p>
<p>comment</p>	<p>166 comment by: <i>Swedish Transport Agency, Civil Aviation Department (Transportstyrelsen, Luftfartsavdelningen)</i></p> <div style="border: 1px solid black; padding: 5px; margin: 5px 0;"> <p>Section: Explanatory Note, paragraph 2.3.4.5</p> <p>Relevant Text: Proposal to amend AMC5 MED.B.095 (d)(3) to allow a combination of OSL and OPL for LAPL. The same possibility should be available not only for diabetic LAPL pilots but also for other medical problems and also for class 2.</p> <p>Comment: The same possibility should be available not only for diabetic LAPL pilots but also for other medical problems and also for class 2.</p> <p>Proposal: An amendment to MED.B.001 and/or AMC2 MED.B.001 should be made to allow a flexible use of both OSL and OPL for a specified pilot.</p> </div>
<p>response</p>	<p><i>Accepted</i></p> <p>A new paragraph (d)(4) has been inserted under MED.B.001 which takes this comment into account.</p>

2 Explanatory Note — 2.3 Overview of the proposed amendments — 2.3.4 Subpart B, Medical requirements for class 1, class 2, and LAPL medical certificates — 2.3.4.11 Psychiatry — (b) LAPL p. 14-15

<p>comment</p>	<p>73 comment by: <i>René Meier, Europe Air Sports</i></p> <p>2.3.4.11 Psychiatry (b) LAPL</p> <p>We welcome this text because it is simple and leaves room for personalized decisions to be made by an AME.</p> <p>Rationale: In the view of our experts this text gives details clear enough to an AME to make well-</p>
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	founded decision on the fitness to fly.
response	<i>Noted</i> Thank you for your support.

2 Explanatory Note — 2.3 Overview of the proposed amendments — 2.3.4 Subpart B, Medical requirements for class 1, class 2, and LAPL medical certificates — 2.3.4.14 Otorhinolaryngology (ENT) — (d) LAPL p. 16

comment	74	comment by: <i>René Meier, Europe Air Sports</i>
	<p>2.3.4.14 Otorhinolaryngology (c) Class 2, and (d) LAPL We believe that (c) Class 2 (2) and the provisions for (d) LAPL represents a major change. We welcome this risk-based decision. Rationale: The affected pilot's good airmanship will enable him or her to exercise aeronautical activities in accordance with the requirements of the airspace flown.</p>	
response	<i>Noted</i> Thank you for your support.	

2 Explanatory Note — 2.3 Overview of the proposed amendments — 2.3.5 Subpart C, Requirements for medical fitness of cabin crew — 2.3.5.1 General p. 17

comment	167	comment by: <i>Swedish Transport Agency, Civil Aviation Department (Transportstyrelsen, Luftfartsavdelningen)</i>
	<p>Section: Explanatory Note, paragraph 2.3.5.1</p> <p>Relevant Text: Clarification in AMC1 MED.C.005 that the interval between aeromedical assessments of CC can be reduced to less than 60 months by the competent authority.</p> <p>Comment: The competent authority of the examining physician may be different to both the competent authority responsible for the CC attestation, and the competent authority where the operator employing the CC holds its AOC. In this case, the differences in national practices do not relate to the medical practices, but to the <u>operational</u> practices regulated in Part-OPS and the operator's Operations Manual.</p> <p>Proposal: The reference to national practices should be specified to the national <u>OPS</u> practices for the state where the employer holds its AOC.</p>	



response *Partially accepted*

The text has been amended to provide clarification on who may reduce the interval between aero-medical assessments.

2 Explanatory Note — 2.3 Overview of the proposed amendments — 2.3.5 Subpart C, Requirements for medical fitness of cabin crew — 2.3.5.12 Cabin crew medical report

p. 19

comment 56

comment by: *Ryanair*

In 2.3.5.12 Cabin crew medical report; (d) what guidance is given in relation to how long before expiry can the medical be done. Will there be a specified limit as in the Pilot case of 45 days before expiry?

response *Accepted*

Text has been added to allow aero-medical assessments to be undertaken up to 45 days prior to the expiry date of the medical report.

3 Proposed amendments — 3.1 Draft Regulation (Draft EASA Opinion) — ANNEX IV — [PART-MED] — SUBPART A — GENERAL REQUIREMENTS — SECTION 1 — General — MED.A.010 Definitions

p. 22

comment

126

comment by: *Swedish Transport Agency, Civil Aviation Department (Transportstyrelsen, Luftfartsavdelningen)*

Section: [MED.A.010](#)

Comment:

In the CRD Part-ATCO.MED the definition of ‘Accredited medical conclusion’ has been amended with an addition of ‘and including an operational risk assessment’.

The definition should be identical in Part-Med and Part-ACO.MED.

The definition should be amended to be consistent with Part-ATCO.MED.

Proposal:

Amend MED.A.010:

‘Accredited medical conclusion’ means ... / ... or other experts as necessary and including an operational risk assessment.’

response *Accepted*



The text has been amended accordingly.

comment

252

comment by: UK CAA

Page No: 22**Paragraph No:** MED.A.010

Comment: The text “*Examination’ means an inspection, palpation, percussion, auscultation or any other means of investigation especially for ~~diagnosing disease~~ determining the medical fitness to exercise the privileges of the licence, or to carry out cabin crew safety duties;*” includes the reason for examination.

Justification: The reason for examination should not be included in a definition.

Proposed Text: “*Examination’ means an inspection, palpation, percussion, auscultation or any other means of investigation. ~~especially for diagnosing disease determining the medical fitness to exercise the privileges of the licence, or to carry out cabin crew safety duties;~~*”

response

Not accepted

To include the aim of the examination in the definition provides clarity. The NPA text is aligned with that in the ATCO.MED Opinion.

comment

253

comment by: UK CAA

Page No: 22**Paragraph No:** MED.A.010

Comment: The sentence could be made more consistent with other parts of the text.

Justification: To increase clarity.

Proposed Text: “*Significant’ means a ~~the~~ degree of a medical condition, the effect of which would **be likely to** prevent the safe exercise of the privileges of the licence or of the cabin crew safety duties.*”

response

Not accepted

The definition in the NPA was aligned with the definition in the ATCO.MED Opinion. To say ‘the effect of which would be likely to prevent the safe exercise of the privileges of the licence or of the cabin crew safety duties’ may even raise the need for a definition of ‘likely’.

3 Proposed amendments — 3.1 Draft Regulation (Draft EASA Opinion) — ANNEX IV — [PART-MED] — SUBPART A — GENERAL REQUIREMENTS — SECTION 1 — General — MED.A.020
Decrease in medical fitness

p. 23

comment

127

comment by: Swedish Transport Agency, Civil Aviation Department
 (Transportstyrelsen, Luftfartsavdelningen)



response	<p>Section: MED.A.020</p> <p>Comment: In the CRD Part-ATCO.MED, A.020 (b) has been amended with the addition of ‘and before exercising the privileges of their licence’ to clearly define that exercising the privileges of a licence is not allowed under the circumstances mentioned. MED.A.020 (b) should be amended to be consistent with Part-ATCO.MED.</p> <p>Proposal: Amend MED.A.020: (b) ‘In addition, holders of a medical certificate shall, without undue delay and before exercising the privileges of their licence, seek aeromedical advice when they: ...’</p> <p><i>Accepted</i></p> <p>The text has been amended accordingly.</p>
comment	<p>254 comment by: UK CAA</p> <p>Page No: 23 Paragraph No: MED.A.020 (c) Comment: The actions referred to in (c) to be taken in the event of a decrease in medical fitness should also be performed in the cases referred to in (a) as well as (b). Justification: All decrease of medical fitness needs to be reported. Proposed Text: ‘In these cases referred to in (a) and (b):’</p> <p>response <i>Not accepted</i></p> <p>Subparagraph (a) states under which conditions a pilot shall not exercise the privileges of his/her licence. Subparagraph (b) states what the pilot has to do and subparagraph (c) provides detail about who to contact for the aero-medical advice referred to in (b). A decrease in fitness could also be a common cold or a stomach upset where it is not necessary to contact an AME, but the licence holder shall not exercise the privileges of their licence if the condition renders them unable to safely exercise those privileges.</p>
comment	<p>255 comment by: UK CAA</p> <p>Page No: 23 Paragraph No: MED.A.020 (c) (3) Comment: A privilege of a student pilot with a Class 1, 2, or LAPL medical certificate is to fly solo. Justification: Subparagraph 3 is not required as student pilot privileges are covered by (c)(1) or (2). Proposed Text: Delete paragraph (c) (3) in its entirety.</p> <p>response <i>Accepted</i></p> <p>The subparagraph has been deleted accordingly.</p>



comment	339	comment by: <i>Trond-Eirik Strand</i>
	<p>MED.A.020 (b)(2) Holders of a medical certificate shall seek aeromedical advice when «have commenced the regular use of any medication». What about periodic use of opioids or erectile dysfunction medicines for examples? In GM1 MED.A.020 (b) there are questions to be answered before taking <u>any</u> medication.</p>	
response	<p><i>Not accepted</i></p> <p>GM1 MED.A.020(b) is intended to address (a)(2) as well as (b)(2) of MED.A.020. Under (a)(2), licence holders shall not exercise the privileges of their licence when they take any prescribed or non-prescribed medication. They may refer to the GM to establish whether or not to seek aero-medical advice. If they have commenced regular use of any medication they must seek aero-medical advice. The GM also covers this aspect.</p>	

<p>3 Proposed amendments — 3.1 Draft Regulation (Draft EASA Opinion) — ANNEX IV — [PART-MED] — SUBPART A — GENERAL REQUIREMENTS — SECTION 1 — General — MED.A.025 Obligations of AeMC, AME, GMP and OHMP</p>	p. 24
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comment	2	comment by: <i>Dr.Beiderwellen, Vice President of GAAME</i>
	<p>MED.A.025 (3) Due to several reasons, there is no need to submit the complete medical history of an applicant -fully meeting al requirements- to the licensing authority: - no impact on flight safety - severe violation of protection of personal data - licensing authority should show more confidence in the expertise of AME and AeMC Proposed amendment: (3) in case of applicants for a medical certificate - meeting all requirements and no referral is mandatory - submit a copy of the medical certificate to the licensing authority.</p>	
response	<p><i>Not accepted</i></p> <p>This subparagraph is to ensure ICAO compliance. Please see ICAO Annex 1, 1.2.4.7.</p>	
comment	13	comment by: <i>AECA(SPAIN)</i>
	<p>Paragraph (b)(3) Add assessment to read <i>examinations and assessments</i> Introduction of paragraph (b) states 'After completion of aero-medical examinations and assessments...', so it must keep the consistency of text</p>	
response	<p><i>Accepted</i></p> <p>The text has been amended accordingly.</p>	



comment 90

comment by: DGAC FRANCE

Do not delete the paragraph (3) (b) to MED.A.025 “Obligations of AeMC, AME, GMP and OHMP” - PART-MED - ANNEX IV.

The DGAC wants to keep this paragraph for the following reasons :

The suppression of the secondary review from MED.A.025 - PART MED - Annex IV of 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, in order to favour the administrative appeals according to the national law, bring the following remarks :

- when aero-medical examiners and the aero-medical centres are in front of a medical situation requiring a decision of the authority, they have to refer to the medical assessor. This referral is not an appeal to a decision ;

- In French law, any applicant who disagrees with an administrative decision, including a medical assessor decision, must be able to have the right of appeal against this decision. The appeal could be made in front of the administrative courts, however the lack of responsiveness of this courts (3-4 months) does not seem appropriate and returns the very long and impractical appeal procedure. Furthermore, the number of predictable appeals (e.g. 40 new cases per year for air traffic controllers) may increase the existing congestion of the courts, what would have catastrophic consequences in the operational and financial plan. It is thus essential to keep the current procedure which allows the candidate, in disagreement with a decision concerning the medical capacity, to make an appeal with an independent medical committee so that this collective authority studies the medical record for a reevaluation of its case, ending in a new decision replacing the decision of the doctor assessor.

This constitutes the first level of the administrative appeal process, considering that a formal decision was initially issued (the administrative court being the second level). The interest is the speed of the procedure (appeal in 15 days following the notification of the decision of the medical assessor), financially less expensive for the member states, more suited to the operational plan and to the human plan.

Doctor Marie-Christine Monchalin, head doctor DGAC and Weather report-France

response *Partially accepted*

The subparagraph concerning the review has been reinstated with minor changes to the original text to solve the apparent confusion between referral, secondary review and appeal.

comment 182

comment by: Jörg SIEDENBURG

(3) in the case of applicants for a medical certificate, submit without delay to the licensing authority a signed, or electronically authenticated [] copy of the application form and the examination form, **containing the detailed results of the aero-medical examination and assessment as required for the class of medical certificate to include the assessment results**, and the medical certificate to the licensing authority; and ...

The examination form includes the required information, another report is not necessary and increases the burden of paper work, both for the examining physician and the authority.



As we can see with this system (CRT), good software appliances are possible to further reduce bureaucratic burden and create smart solutions. Therefore, it might be a good idea to have an electronic, internet based transmission system and electronic form for such data in place, which could probably be developed by the IT people of EASA.

response *Noted*

The application form includes the medical history and is, therefore needed for a review of the paperwork. As for the IT system: there is software currently available that is already being used by many EASA Member States. However, Member States are also free to develop their own IT system.

comment

256

comment by: UK CAA

Page No: 24

Paragraph No: MED.A.025 (a) (4)

Comment: It is unclear what is meant by 'at any stage of the process'. An AMC is required to explain what is meant.

Justification: Clarity.

Proposed Text: 'AMC MED.A.025 (a)(4): The process of applying for a medical certificate is considered to start at the commencement of the first assessment or examination at the AME or AeMC practice.'

response *Not accepted*

Applicants who realise that they might be assessed as unfit could withdraw their application and then re-apply with another AME, possibly in another Member State, to try to obtain a fit assessment. Subparagraph (a)(4) was added in the NPA in order to prevent a medical certificate based on incomplete medical information from being issued. The AME will now be required to inform the licensing authority if an applicant withdraws the application for a medical certificate at any stage of the process, which could also include the moment when the application form is being completed.

comment

257

comment by: UK CAA

Page No: 24

Paragraph No: MED.A.025 (b)

Comment: The UK CAA supports the changes in this section.

Justification: The changes provide clarity and consistency for Member States and enable national appeal systems to reflect national processes and law.

response

Noted

The UK CAA's support is noted by the Agency. However, in response to other comments, the subparagraph concerning the right of a review has been reinstated with minor changes to the original text to solve the apparent confusion between referral, secondary review and appeal.

comment

338

comment by: Federal Ministry of Transport, Austria (BMVIT)



MED.A.025 (b) (3)

While we have in general no objection to a transfer of important requirements from AMC to the Implementing Rules, we however do not believe that the approach by EASA as laid out in the NPA will serve the stated purpose of achieving better compliance with data protection law.

The competent authorities for data protection in Austria have already stated their opinion that the current system of reporting of medical data by AMEs to the competent authority is not in accordance with the relevant data protection clauses in European law (EASA has received a copy of the official statement by the Austrian Data Protection Council of 23 April 2013).

By simply transferring the existing rules from AMC to IR without evaluating the substance of relevant legal issues the problem at hand will in our opinion not be adequately addressed. We therefore suggest a thorough evaluation in consultation with data protection experts.

response *Noted*

This rule follows ICAO Annex 1 and it may be necessary to contact ICAO and propose a change to the standard 1.2.4.7 in order to remain ICAO compliant. However, the Agency acknowledges the comment and the Agency's legal department is currently consulting with the European Data Protection Supervisor on this matter.

3 Proposed amendments — 3.1 Draft Regulation (Draft EASA Opinion) — ANNEX IV — [PART-MED] — SUBPART A — GENERAL REQUIREMENTS — SECTION 2 — Requirements for medical certificates — MED.A.030 Medical certificates

p. 25

comment 12

comment by: *AECA(SPAIN)*

Should be noted that in the case of MPL Licenses no solo flight. Should be established criterion for the moment when required medical certificate to these student pilots. It is not very successful to propose the time of 'solo flight' as one in which the medical certificate is required, it may be the circumstances of what the student pilot is declared unfit and be lost time and money expended until the time of first flight only.

response *Accepted.*

The text has been amended taking this comment into account.

comment 50

comment by: *Light Aircraft Association UK*

MED.A.030 g): We feel that the requirement for an audiogram is excessive for an 'en route instrument rating' as this rating confers fewer privileges than a full instrument rating. There is no evidence to suggest that the standard hearing test is insufficient to discriminate for the ability to hear radio communications and identifying nav aids. We would therefore propose to delete the change and retain the original wording.

response *Not accepted*

Pilots flying with the En route Instrument Rating (EIR) operate in the same airspace as holders of an Instrument Rating (IR). En route, they have to hear and understand air traffic



control and other traffic the same way as IR holders.

comment	79	comment by: <i>The Norwegian Air Sports Federation</i>
	<p>MED.A.030 (g) NLF would like to question if the addition of the en route instrument rating to a PPL should require the license holder to undertake pure tone audiometry examinations in accordance with class 1 requirements. Since IFR approaches and departures are not included in the privileges of the EIR, this requirement seems to be disproportionate. Furthermore, a similar requirement does understandably not exist for the VFR night rating. It is hard to understand how an EIR operation would be so different in nature to an N-VFR operation that such an audiometry examination requirement should be considered mandatory. The requirement also makes the EIR less accessible, as it means that another medical examination will be required once a pilot decides to "upgrade" from VFR to EIR.</p>	
response	<i>Noted</i>	
	See response to comment No 50.	
comment	93	comment by: <i>EFLEVA</i>
	<p>MED.A.030g): EFLEVA are of the view that the requirement for an audiogram is excessive in the case of the En-Route IR, as this rating carries reduced privileges from an IR. A standard hearing test should be adequate to determine that the applicant has the ability to hear radio communication and navigation aids. This change should be removed and the original text retained.</p>	
response	<i>Noted</i>	
	See response to comment No 50.	
comment	242	comment by: <i>René Meier, Europe Air Sports</i>
	<p>MED.A.030 Medical certificates (g) Pure tone audiometry The requirement for a pure tone audiometry examination for EIR holders is challenged by a considerable number of our members, they propose to differentiate between EIR and CB-IR rating holders. Rationale: The EIR becomes less accessible when the pure tone audiometry requirement is maintained.</p>	
response	<i>Noted</i>	
	See response to comment No 50.	



certificates — MED.A.035 Application for a medical certificate

comment 340

comment by: *Trond-Eirik Strand*

In (a) it reads “Applications for a medical certificate shall be made in a format established by the competent authority.”. If one could interpret from this rule that a competent authority could decide a format to be an electronically, online submission system this is satisfactory. Otherwise the term “format” should be described in AMC1 MED.A.035 to give NPAs the opportunity to demand applicants to be submitted in such a system which is widespread in use in many member states.

response *Noted*

The competent authority can choose the form and manner in which applications for a medical certificate shall be made. ‘Format’ has been changed to ‘form and manner’ for clarification. However, the application form is in an AMC to Part-ARA (Annex VI to the Aircrew Regulation) to support harmonised formats across the EASA Member States. This will help, e.g. competent authority of EASA Member State (A), if a pilot who holds their licence with competent authority of EASA Member State (A), but undergoes the aero-medical examination and assessment in, e.g. competent authority of EASA Member State (B). Whether or not the application form is sent electronically or otherwise is for the individual authority to decide; please see MED.A.025(b)(4).

3 Proposed amendments — 3.1 Draft Regulation (Draft EASA Opinion) — ANNEX IV — [PART-MED] — SUBPART A — GENERAL REQUIREMENTS — SECTION 2 — Requirements for medical certificates — MED.A.040 Issue, revalidation and renewal of medical certificates

p. 26

comment

128

comment by: *Swedish Transport Agency, Civil Aviation Department (Transportstyrelsen, Luftfartsavdelningen)*Section: [MED.A.040](#)**Comment:**

In Part-ATCO.MED, A.040 (a) has been amended to give a better English without changing the content of the requirement.

MED.A. 040 (a) should be amended to be consistent with Part-ATCO.MED.

MED.A.040 (d)(2) has a grammatical error using ‘have’ instead of ‘has’.

Proposal:

Amend MED.A.040:

(a) ‘A medical certificate shall only be issued, revalidated or renewed once the required aero-medical examinations and assessments, as applicable, have been completed and the applicant has been assessed as fit.’

(d)(2) ‘the AME, AeMC or GMP has conducted .../’



response *Accepted*

The text has been amended accordingly.

comment 258

comment by: UK CAA

Page No: 26

Paragraph No: MED.A.040 (f) (2)

Comment: If a medical certificate is reissued because a correction was required, correspondence from the Licensing Authority will indicate and determine that the old certificate is invalid. It does not need to be returned to the Licensing Authority.

Justification: This would create an increased burden on medical certificate holders and the Licensing Authority. The UK has not routinely required certificate return in non-contentious cases. Where a potential risk to flight safety is identified e.g. a medical condition with lack of insight, the certificate return can be demanded. There has been no adverse safety events identified as a result of this procedure.

Proposed Text: 'it has identified that corrections to the information on the certificate are necessary in which case the incorrect medical certificate shall be ~~revoked~~ **returned to the Licensing Authority or destroyed by the holder.**'

response *Accepted.*

The text has been amended to require the certificate holder to either destroy an incorrect medical certificate or return it to the licensing authority, as determined by the authority.

3 Proposed amendments — 3.1 Draft Regulation (Draft EASA Opinion) — ANNEX IV — [PART-MED] — SUBPART A — GENERAL REQUIREMENTS — SECTION 2 — Requirements for medical certificates — MED.A.045 Validity, revalidation and renewal of medical certificates p. 26-27

comment 14

comment by: AECA(SPAIN)

No indication of the period of validity of medical evaluations of the CC.

If it is intended to unify the regulation should indicate here the validity of these documents.

On the other hand, should be made an indication of validity period closed for all states. That is a number of months equal for all.

The reason is that CC certificates can be used in any State or the medical certificate can be obtained from a State other than that issued the CC certificate, which could not be accepted different validity of medical certificates.

response *Not accepted*

The validity periods referred to in MED.A.045 apply to medical certificates required for pilots. Cabin crew members are not required to hold a medical certificate. According to MED.C.030, applicants for or holders of a cabin crew attestation shall be provided with a cabin crew medical report after completion of each aero-medical assessment. Aero-medical



assessments shall be conducted at intervals of maximum 60 months (refer to MED.C.005). 'Maximum 60 months' means that an authority may apply shorter intervals, if required by national medical practices. This has been clarified in AMC1 MED.C.005.

comment 15 comment by: AECA(SPAIN)

Paragraph (c)
Should be included reference to renewal of CC assessments.
For consistency reasons.

response *Not accepted*

Each aero-medical assessment for cabin crew members after the initial assessment shall involve an assessment of the cabin crew member's medical history and a clinical examination if deemed necessary (refer to MED.C.025). Therefore, a specific reference to renewal of cabin crew member's assessments is not appropriate.

comment 129 comment by: Swedish Transport Agency, Civil Aviation Department (Transportstyrelsen, Luftfartsavdelningen)

Section: [MED.A.045](#)

Comment:

[MED.A.045 \(c\)\(3\) contains the expression and/or which should be avoided](#)

Proposal:

[Amend MED.A.045 \(c\)\(3\) trying to find a wording without using the expression and/or.](#)

response *Accepted*

The text has been amended accordingly.

3 Proposed amendments — 3.1 Draft Regulation (Draft EASA Opinion) — ANNEX IV — [PART-MED] — SUBPART A — GENERAL REQUIREMENTS — SECTION 2 — Requirements for medical certificates — MED.A.046 Suspension and revocation of medical certificates

p. 27

comment 51 comment by: Light Aircraft Association UK

MED.A.046: Medicals regularly get suspended, often for minor things such as chest infections, broken bones, etc. It is an unnecessary regulatory burden to require certificates to be returned to the licensing authority for temporary suspensions and then to be re-issued when the condition has passed. We propose that in the case of minor and temporary conditions, the medical certificate need not be returned to the licensing authority. We agree that where medical certificates have been revoked, these should be returned.



response	<p><i>Accepted</i></p> <p>The text has been amended to provide one subparagraph on revocation and one on suspension, to indicate that ‘upon suspension of the medical certificate, the holder shall return the medical certificate to the licensing authority on request of the authority’. This allows the authority to ask the pilot to return the suspended medical certificate, if deemed necessary. Otherwise, it will not need to be returned. However, medical certificates that are revoked do need to be returned to the licensing authority to prevent the possible continuation of the non-compliance that triggered the revocation.</p>
comment	<p>94 comment by: EFLEVA</p> <p>MED.A.046: EFLEVA are of the view that returning the medical certificate to the authority in the event of suspension is an unnecessary requirement. If a medical certificate is temporarily suspended for a minor ailment there is little point in returning the certificate to the authority as it will need to be re-issued after a short period. However we agree that where a certificate is revoked then it should be returned to the authority.</p>
response	<p><i>Noted</i></p> <p>See response to comment No 51.</p>
comment	<p>130 comment by: Swedish Transport Agency, Civil Aviation Department (Transportstyrelsen, Luftfartsavdelningen)</p> <div style="border: 1px solid black; padding: 5px; margin-top: 10px;"> <p>Section: MED.A.046</p> <p>Comment: The headline reads ‘Suspension and revocation of medical certificates’ Part-ATCO.MED and Part-ARA use the wording ‘or’ instead of ‘and’. MED.A. 046 should be amended to be consistent with Part-ATCO.MED and Part-ARA.</p> <p>Proposal: Amend MED.A.046 headline: MED.A.046 Suspension or revocation of medical certificates</p> </div>
response	<p><i>Accepted</i></p> <p>The text has been amended accordingly.</p>
comment	<p>237 comment by: ENAC Aeromedical Section-Italy</p> <p>Licensing Authority could have large burden if the text of MED.A.046 is not better specified. The burden would arise if this requirement is intended as an obligation for the pilot to return the medical certificate also in case of unfitness for medical reason. The suggestion is to clarify in the MED.A.046 text that the medical certificate must be returned to Licensing Authority in case of "legal" suspension or revocation as per Part</p>



response	<p>ARA.GEN.355(b)(1).</p> <p><i>Noted</i></p> <p>See response to comment No 51.</p>
comment	<p>259 comment by: UK CAA</p> <p>Page No: 27 Paragraph No: MED.A.046 Comment: There is no flight safety justification for all certificates to be returned to the Licensing Authority. It is only necessary in cases where there is a risk of non-compliance. This paragraph was amended with a view to relate to Part ARA.GEN.355(b): <i>'(b) When such finding is raised, the competent authority shall carry out an investigation. If the finding is confirmed, it shall:</i> <i>(1) limit, suspend or revoke the licence, certificate, rating or attestation as applicable, when a safety issue has been identified; and</i> <i>(2) take any further enforcement measures necessary to prevent the continuation of the non-compliance.'</i> Justification: There would be a substantial administrative and cost burden if all certificates were to be returned. A certificate should only be required to be returned to the Licensing Authority if the potential risk to flight safety warrants this action. This action is already covered in Part ARA GEN. Proposed Text: Delete MED.A.046 in its entirety. If a rule is required we suggest the alternative text: 'MED.A.046 Suspension and revocation of medical certificates Upon suspension or revocation of the medical certificate, the holder shall immediately return the medical certificate to the licensing authority or be destroyed by the holder.'</p>
response	<p><i>Noted</i></p> <p>See response to comment No 51.</p>
comment	<p>341 comment by: Trond-Eirik Strand</p> <p>This proposal in the new MED.A.046 could be more smoothly incorporated into FCL.070 which deals with revocation, suspension and limitation of licences, ratings and certificates. If certificate in this context could include medical certificate then in FCL.070 (b) this could be extended to also include medical certificate, alternatively in a new point (c).</p>
response	<p><i>Noted</i></p> <p>See response to comment No 51. In addition, the Agency's aim is to facilitate the application of the regulations by positioning all the provisions pertaining to medical certification in one 'book'.</p>
comment	<p>349 comment by: Jukka TERTTUNEN</p> <p>From CAA Finland AMS point of view this new regulation doesn't add anything to flight</p>



safety. In Finland we do not have knowledge of even a single case where this new proposed procedure would have inhibited a flight safety incident or accident. We should go on with the just culture principle.

On the contrary this new proposed regulation further adds the administrative task of the authority, adds costs to the airlines and the medical certificate holders.

We suggest that this new proposal could be deleted. If not, then a very clear definition on when the medical certificate should be mailed to the authority should be defined. Suspensions of medical certificates are daily routines, revocations happen seldom. If EASA feels that it has to take this new rule into action then we would like to narrow its use to the minimum. E.g. if the suspension of the medical certificate exceeds 6 (or 12) months, then the pilot should mail his/her medical certificate to the authority.

response *Noted*

See response to comment No 51.

3 Proposed amendments — 3.1 Draft Regulation (Draft EASA Opinion) — ANNEX IV — [PART-MED] — SUBPART A — GENERAL REQUIREMENTS — SECTION 2 — Requirements for medical certificates — MED.A.050 Referral

p. 28

comment 353

comment by: *Jukka TERTTUNEN*

In Finland the AME-community, AeMCs and the authority (AMS) together have agreed that there's a need for the AME's to have the opportunity in e.g. complex or time consuming cases to refer the applicant's case to one of the AeMCs or to the authority (AMS). Our AME's want the support that our national authority can offer and wants to offer. We have also "upgraded" our national Aviation Act Law also in this perspective. So by our national law, AMEs can refer all medical cases to the authority if needed. In reality this is seen only as a "overpressure valve", so we can't see this as a burden to the authority by now.

response *Noted*

The main objective of this provision is to ensure that the relevant medical documentation is transferred to facilitate the assessments for all of those cases which are referred.

3 Proposed amendments — 3.1 Draft Regulation (Draft EASA Opinion) — ANNEX IV — [PART-MED] — SUBPART B — REQUIREMENTS FOR PILOT MEDICAL CERTIFICATES — SECTION 1 — General — MED.B.001 Limitations to medical certificates

p. 29-30

comment

131

comment by: *Swedish Transport Agency, Civil Aviation Department (Transportstyrelsen, Luftfartsavdelningen)*

Section: [MED.B.001 \(a\)\(2\)](#)

Comment:

[In \(a\)\(2\) 'without referring the applicant to the licensing authority' has been changed to](#)



'without involving the licensing authority'. The word 'involving' is a bit dubious as the licensing authority always, in one way or another, is involved in the process even if the decision can be made by an AeMC/AME.
In the CRD ATCO.MED the original wording is retained.
A better solution in MED.B.001 would be to add 'or without consultation with' to the original wording, which also gives a consistency to ATCO.MED.B.001 (a)(2)

Proposal:

Amend MED.B.001 (a)(2):

'The AeMC or AME may revalidate or renew a medical certificate with the same limitation without referring the applicant to, or without consultation with, the licensing authority.'

response

Accepted

The text has been amended taking the comment into account.

comment

132

comment by: *Swedish Transport Agency, Civil Aviation Department
(Transportstyrelsen, Luftfartsavdelningen)*

Section: [MED.B.001 \(d\)](#)

Comment:

In AMC5 MED.B.095 (d)(3) the possible combination of OPL and OSL has been introduced for LAPL pilots with diabetes. This combination of OPL and OSL should in many cases also be available for class 2, permitting pilots to fly without passengers or, if passengers are carried, requiring a safety pilot.

Proposal:

Amend MED.B.001 (d) with a new subparagraph (4) explaining the possibility to combine OPL and OSL.

response

Accepted

A new paragraph (d)(4) has been introduced in MED.B.001 which takes this comment into account.

comment

260

comment by: *UK CAA***Page No:** 30**Paragraph No:** MED.B.001 (d) (2) (iii)

Comment: The Licensing Authority also needs to be able to impose or remove an OSL where applicable.

Justification: The Licensing Authority may be involved in a referral or secondary review of a LAPL application.

Proposed Text: 'The OSL for LAPL medical certificates may be imposed and removed by an



response	AeMC, or AME or Licensing Authority.'
response	<p><i>Not accepted</i></p> <p>The agreement in 2008 was to extend the privileges of the AMEs and AeMCs where LAPL medical certificates are concerned and that the authority should not be directly involved. The proposed addition would also raise the question about which cases should require the licensing authority to impose or remove the OSL.</p>
comment	<p>261 comment by: UK CAA</p>
	<p>Page No: 30 Paragraph No: MED.B.001 (d) (3) (iii) Comment: The Licensing Authority also needs to be able to impose or remove an OPL where applicable. Justification: The Licensing Authority may be involved in a referral or secondary review of a LAPL application. Proposed Text: 'The OPL for LAPL medical certificates may be imposed and removed by an AeMC, orAME or Licensing Authority.'</p>
response	<p><i>Noted</i></p> <p>See response to comment No 260.</p>
comment	<p>262 comment by: UK CAA</p>
	<p>Page No: 30 Paragraph No: MED.B.001 (d) Comment: As discussed at the Medical Expert Group in Feb 2013, there is a need for a limitation for Class 2 and LAPL privileges that combines the limitations OSL and OPL. See also UK CAA comment on AMC2 to MED.B.001(b). Justification: A combined limitation is appropriate where there is equivalent risk mitigation with use of either limitation. Proposed Text: New subparagraph: '(5) Operating-pilot Restriction Limitation (ORL — Class 2 and LAPL privileges) (i) The holder of a medical certificate with an ORL limitation shall only operate an aircraft if either; another pilot fully qualified to act as pilot-in-command on the relevant class/type of aircraft is carried on board, the aircraft is fitted with dual controls and the other pilot occupies a seat at the controls; or operate an aircraft solo without passengers on board. (ii) An ORL for Class 2 medical certificates may be imposed by an AeMC or AME in consultation with the licensing authority. (iii) An ORL for an LAPL medical certificate limitation may be imposed by the Licensing Authority, or an AeMC or AME.'</p>
response	<p><i>Accepted</i></p> <p>The review group discussed how to apply the OSL and the OPL for class 2 and LAPL medical certificates taking into account that a safety pilot is required if passengers are carried. The ORL was deemed to be the best way to incorporate this concept.</p>



comment	351	comment by: <i>Jukka TERTTUNEN</i>
	The medical assessors of the authority should also have the right if needed to issue or deny medical certificates of all EASA Part MED classes 1, 2, LAPL and Cabin Crew. Also the medical assessors of the authority should have the right if needed to add operational limitations or limitations concerning the next AME-examination.	
response	<i>Noted</i>	
	The licensing authority can issue medical certificates with corrections (MED.A.040(f)(2)), which can be done if the AME/AeMC issued a medical certificate with limitations that the Medical Assessor does not agree with. For LAPL, see response to comment No 260. Please note that cabin crew members are not issued with medical certificates (see Basic Regulation) and the authority is not directly involved.	

comment	352	comment by: <i>Jukka TERTTUNEN</i>
	Concerning medical certificate classes 2 and LAPL there should also be a possibility to combine OPL and OSL limitations.	
response	<i>Noted</i>	
	See response to comment No 132.	

**3 Proposed amendments — 3.1 Draft Regulation (Draft EASA Opinion) — ANNEX IV — [PART-MED] — SUBPART B — REQUIREMENTS FOR PILOT MEDICAL CERTIFICATES — SECTION 1 — p. 30-31
General — MED.B.005 General medical requirements**

comment	263	comment by: <i>UK CAA</i>
	Page No: 31 Paragraph No: MED.B.005 (b) and (c) Comment: UK CAA agree with the deletions.	
response	<i>Noted</i>	
	Thank you for your support.	

**3 Proposed amendments — 3.1 Draft Regulation (Draft EASA Opinion) — ANNEX IV — [PART-MED] — SUBPART B — REQUIREMENTS FOR PILOT MEDICAL CERTIFICATES — SECTION 2 — p. 31-34
Medical requirements for class 1 and class 2 medical certificates — MED.B.010 Cardiovascular System**



comment	3	comment by: <i>Dr.Beiderwellen, Vice President of GAAME</i>
	<p>MED.B.015 (d) There is no evidence, that a stable COPD is related with cardiological Diseases. If lung function and ECG are normal, there is no need for additional cardiological evaluation. propose amendment: cancel " and 8 " last paragraph</p>	
response	<p><i>Accepted</i></p> <p>As the AMC indicates, only applicants with minor impairment of pulmonary function may be considered for a fit assessment. As there is no evidence to suggest that this is related to cardiological diseases, a cardiological evaluation is not necessary and has therefore been deleted. If lung function and ECG are normal, there is no need for additional cardiological evaluation.</p>	
comment	16	comment by: <i>AECA(SPAIN)</i>
	<p>Paragraph (a)(1)(ii) According to medical statistics worldwide, heart disease appear increasingly at younger age. We believe that the text should be left as is in the original version.</p>	
response	<p><i>Partially accepted</i></p> <p>Multiple comments were received in support of the introduction of an ECG at the initial examination for class 2 applicants. Many commentators also asked for the ECG to be performed at the first examination after age 40 in line with the existing rules. Subparagraph (a)(1)(ii) of MED.B.010 has, therefore, been amended to require a standard 12-lead electrocardiogram at the initial examination, then at the first examination after age 40 and then at the first examination after age 50, and every 2 years thereafter. This is in line with the ICAO Annex 1 standard requiring an ECG at the first examination after age 40.</p>	
comment	17	comment by: <i>AECA(SPAIN)</i>
	<p>Do not modify this paragraph, leave as in original: <i>'before or after surgery'</i></p>	
response	<p><i>Not accepted</i></p> <p>A fit assessment should not be systematically denied if the outcome of the operation for a thoracic or supra-renal aortic aneurysm is favourable and regular follow-up of the medical condition ensures that any deterioration of the vascular situation is detected at an early stage.</p>	
comment	52	comment by: <i>Light Aircraft Association UK</i>
	<p>MED.B.010 a)1): We support the proposed changes and agree that they represent a good improvement to risk management.</p>	



response	<i>Noted</i> This paragraph has been re-discussed on the basis of comments received. Multiple comments were received in support of the introduction of an ECG at the initial examination for class 2 applicants. Many commentators also asked for the ECG to be performed at the first examination after age 40 in line with the existing rules. Subparagraph (a)(1)(ii) of MED.B.010 has, therefore, been amended to require a standard 12-lead electrocardiogram at the initial examination, then at the first examination after age 40 and then at the first examination after age 50, and every 2 years thereafter. This is in line with the ICAO Annex 1 standard requiring an ECG at the first examination after age 40.
comment	95 comment by: EFLEVA MED.B.010 a)1) : EFLEVA supports this revision.
response	<i>Noted</i> See response to comment No 52.
comment	103 comment by: AeMC, Toulon, France If the introduction of a standard 12-lead electrocardiogram for a class 2 medical certificate at the first examination is considered as a real benefit, the disappearance of this test for the first examination after age 40 seems inadequate. We could easily introduce an electrocardiogram at the first examination and keep the older recommendation.
response	<i>Noted</i> See response to comment No 16.
comment	114 comment by: AMCS - Thomas Syburra b-1 to be added: (iv) "genetic disorders as Marfan, Loeys Dietz, Ehlers-Danlos, TGFBR1/TGFBR2 gene mutations shall be assessed as unfit"
response	<i>Not accepted</i> The aero-medical examiner, with advice from an appropriate specialist, is expected to consider whether a specific genetic disorder in an individual case could entail a degree of functional incapacity which is likely to interfere with the safe exercise of the privileges of the applicable licence (MED.B.005(a)). The proposed addition is too specific for the rules in Part-MED, but it may be considered in a future rulemaking task.
comment	133 comment by: Swedish Transport Agency, Civil Aviation Department (Transportstyrelsen, Luftfartsavdelningen) Section: MED.B.010 (a)(1)(ii)



response	<p>Comment: The introduction of an ECG at the initial examination is supported. However, as Part-MED is required to meet the requirements in ICAO Annex 1, there shall also be an ECG at the first examination after age 40. After age 50 an ECG every 2 years is sufficient.</p> <p>Proposal: Amend MED.B.010 (a)(1)(iii): 'for a class 2 medical certificate, at the initial examination, at the first examination after age 40.'</p> <p><i>Accepted</i></p> <p>The text has been amended accordingly.</p>
comment	<p>134 comment by: <i>Swedish Transport Agency, Civil Aviation Department (Transportstyrelsen, Luftfartsavdelningen)</i></p> <p>Section: MED.B.010 (a)(4)</p> <p>Comment: The wording of (a)(4) is not consistent with the amended (a)(1)(i). The amended text should be reflected also in (a)(4).</p> <p>Proposal: Amend MED.B.010 (a)(4): '.../... shall be required at the initial examination and at the first examination after age 40.'</p>
response	<p><i>Accepted</i></p> <p>The text has been amended accordingly.</p>
comment	<p>135 comment by: <i>Swedish Transport Agency, Civil Aviation Department (Transportstyrelsen, Luftfartsavdelningen)</i></p> <p>Section: MED.B.010 (b)(1)(ii)</p> <p>Comment: In the CRD ATCO.MED the wording 'or symptomatic' has been added. The requirements for pilots should have the same wording.</p> <p>Proposal: Amend MED.B.010 (b)(1)(ii): 'significant functional or symptomatic abnormality of any of the heart valves;'</p>

response

Accepted

The text has been amended accordingly.

comment

136

comment by: *Swedish Transport Agency, Civil Aviation Department
(Transportstyrelsen, Luftfartsavdelningen)*Section: [MED.B.010 \(b\)\(2\)](#)**Comment:**

In the CRD ATCO.MED the sentence 'before a fit assessment may be considered' is included, which is also consistent with other subparagraphs of MED.B.010.
The sentence should be added also in MED.B.010 (b)(2).

Proposal:

Amend MED.B.010 (b)(2):

'Applicants for a class 1 medical certificate with an established history or diagnosis of any of the following conditions shall be referred to the licensing authority before a fit assessment may be considered.'

response

Accepted

The text has been amended accordingly.

comment

137

comment by: *Swedish Transport Agency, Civil Aviation Department
(Transportstyrelsen, Luftfartsavdelningen)*Section: [MED.B.010 \(c\)\(4\)](#)**Comment:**

The use of the word 'suspension' legally means that the licensing authority has to take the decision and the licence holder has to return his/her medical certificate to the licensing authority according to MED.A.046. This is not the intention, why the same expression already has been deleted in the requirements for pregnancy in MED.B.045.
A more correct expression should be 'assessment as temporary unfit'.

Proposal:

Amend MED.B.010 (c)(4):

'The initiation of medication for the control of blood pressure shall require a period of assessment as temporary unfit to establish the absence of significant side effects.'

response

Accepted

The text has been amended to avoid the expression ‘temporary suspension’.

comment

138

comment by: *Swedish Transport Agency, Civil Aviation Department
(Transportstyrelsen, Luftfartsavdelningen)*

Section: [MED.B.010 \(d\)](#)

Comment:

The order of subparagraphs should start with the most restrictive requirement ‘shall be assessed as unfit’. To achieve this, the order should be (3), (4), (1), (2), and (5), with subsequent renumbering. This change of order has been made in the CRD ATCO.MED.

Proposal:

Amend MED.B.010:

Change the order of subparagraphs to (3), (4), (1), (2), and (5), with subsequent renumbering.

response

Partially accepted

This proposal will be considered under the future rulemaking task RMT.0424 ‘Regular update of Part-MED’, where organ systems will be addressed in individual packages, e.g. ‘update cardiovascular system’ or ‘update respiratory system’, etc.

comment

139

comment by: *Swedish Transport Agency, Civil Aviation Department
(Transportstyrelsen, Luftfartsavdelningen)*

Section: [ATCO.MED.B.010 \(d\)\(4\)\(iii\)](#)

Comment:

In the CRD ATCO.MED the words ‘and stenting’ have been added. The requirements for pilots should have the same wording, however ‘and’ should be replaced by ‘or’.

Proposal:

Amend MED.B.010 (d)(4)(iii):

‘revascularisation or stenting for coronary disease .

response

Accepted

The text has been amended accordingly.



comment	<p>140 comment by: <i>Swedish Transport Agency, Civil Aviation Department (Transportstyrelsen, Luftfartsavdelningen)</i></p>
	<p>Section: MED.B.010 (e)</p> <p>Comment: The order of subparagraphs should start with the most restrictive requirement 'shall be assessed as unfit'. To achieve this, the order should be (5), (1), (2), (3), and (4), with subsequent renumbering. This change of order has been made in the CRD ATCO.MED.</p> <p>Proposal: Amend MED.B.010 (e): change the order of subparagraphs to (5), (1), (2), (3), and (4), with subsequent renumbering.</p>
response	<p><i>Noted</i></p> <p>See response to comment No 138.</p>
comment	<p>183 comment by: <i>Jörg SIEDENBURG</i></p>
	<p>The reason for the change - in contradiction to ICAO Annex 6 - remains unclear. At initial examination disorders like Brugada syndrome, long or short QT syndrome, pre-excitation etc. could be ruled out by resting ECG, but these disorders are very rare. However, a resting ECG after age 40 is intended to discover changes due to coronary artery disease, which are more common than the disorders mentioned before. The yield of the original requirement seems to be much higher. Therefore, the proposed change should be rejected.</p>
response	<p><i>Noted</i></p> <p>See response to comment No 16.</p>
comment	<p>185 comment by: <i>Jörg SIEDENBURG</i></p>
	<p>(2) ... (iv) functionally is significant cardiac valvular abnormalities; It makes no sense to assess insignificant valvular abnormalities. Only significant valvular abnormalities are clinically and safety relevant. The latter might have an impact on flight safety and need further examination and assessment, whereas the former are irrelevant.</p>
response	<p><i>Not accepted</i></p> <p>According to the existing published part-MED, under subparagraph (1) of MED.B.010, applicants for a class 1 medical certificate with significant functional or symptomatic abnormality of any of the heart valves shall be assessed as unfit. The reference to 'functionally insignificant cardiac valvular abnormalities' in subparagraph (2) is to ensure that affected applicants are referred to the licensing authority before a fit assessment may be considered.</p>



comment	<p data-bbox="363 271 411 309">186</p> <p data-bbox="1098 271 1498 309" style="text-align: right;">comment by: Jörg SIEDENBURG</p> <p data-bbox="363 360 1498 734"> (viiiiviii) recurrent vasovagal syncope; Hidden under the euphemism editorial change a significant change has taken place here and is not discussed anywhere properly. A single syncope is not an uncommon event in young people, especially in teenagers. When applying for a medical certificate years later this would bring them into trouble even though there was no clinical relevance and there is none any more, if the change would pass as intended. Recurrent syncopes give rise to concerns about a potential incapacitation in the future, indeed. The original requirement is in line with AMC 1 MED.B.065 (e) where an episode of disturbance of consciousness is covered as insignificant. Therefore the proposed change should be rejected. </p>
response	<p data-bbox="363 734 579 772"><i>Partially accepted</i></p> <p data-bbox="363 792 1498 869">The Agency agrees that a 'one-off' (insignificant) event should not systematically lead to an unfit assessment.</p> <p data-bbox="363 882 1498 958">The text has been amended to 'vasovagal syncope of uncertain cause', which also reflects 'a single episode of disturbance of consciousness of uncertain cause' in MED.B.065.</p> <p data-bbox="363 972 1182 1016">The AMC has also been further clarified to support the above intent.</p>
comment	<p data-bbox="363 1055 411 1093">221</p> <p data-bbox="1225 1055 1498 1093" style="text-align: right;">comment by: CAA-NL</p> <p data-bbox="363 1151 1498 1630"> Applicant with vasovagal syncope should be referred to, class 1, or in consultation with authority class 2 In the new text 'recurrent' is deleted for obvious reasons. But with the new text every fainting will lead to a no fly for 6 months and thorough assessment of specialists. This seems to be an overshoot. Proposal: Applicants with a history of repeated or unexplainable vasovagal syncope should be assessed as unfit. In the AMC should be mentioned that in case of vasovagal syncope an assessment by the AME is necessary. Depending on his conclusion a further assessment by medical specialist can be necessary. Explanation: In this way when there is a more or less simple explanation for the syncope and this could be prevented in the future the applicant may continue to fly without unnecessary specialist assessment </p>
response	<p data-bbox="363 1630 443 1668"><i>Noted</i></p> <p data-bbox="363 1688 778 1742">See response to comment No 186.</p>
comment	<p data-bbox="363 1780 411 1818">224</p> <p data-bbox="699 1780 1498 1818" style="text-align: right;">comment by: French main military Aeromedical Center (CEMPN)</p> <p data-bbox="363 1877 1498 2024">It is a good choice to propose a 12-lead resting ECG for a class 2 medical certificate at the initial examination whatever the age is. However, the second ECG will be performed after age 50, which means a pilot will not have ECG for several decades. This attitude is paradoxical because on the one hand a cardiovascular risk is recognized; on the other hand</p>

this risk is temporary forgotten.

As a logical solution, we propose to perform ECG at the initial examination, then every 5 years until age 40 and every 2 years thereafter.

This periodicity of systematic resting ECG should also be used in the requirements for cabin crew and for LAPL medical certificates. As a minimal requirement for LAPL medical certificates only, it could be proposed resting ECG at the initial examination.

These comments are justified by the ability of ECG to detect intermittent abnormalities in relation to the age and not only to detect in particular coronary artery disease. Some ECG syndromes (ventricular pre-excitation, Brugada syndrome, QT variations, premature ventricular beats...) may be associated with a heart disease and/or jeopardize flight safety.

response *Partially accepted*

For a class 2 medical certificate, see response to comment No 16. The proposal to perform routine ECGs for LAPL or cabin crew members is not accepted for the reason of proportionate regulation.

comment 264

comment by: UK CAA

Page No: 31

Paragraph No: MED.B.010 (a) (1) (ii)

Comment: UK CAA agree with the proposed changes.

response *Noted*

See response to comment No 16.

comment 342

comment by: Trond-Eirik Strand

In MED.B.010 (c)(4) the term temporary suspension is used for first time. Are there situations where a suspension is not temporary?

response *Noted*

See response to comment No 137.

3 Proposed amendments — 3.1 Draft Regulation (Draft EASA Opinion) — ANNEX IV — [PART-MED] — SUBPART B — REQUIREMENTS FOR PILOT MEDICAL CERTIFICATES — SECTION 2 — Medical requirements for class 1 and class 2 medical certificates — MED.B.015 Respiratory System

p. 34-35

comment

141

comment by: Swedish Transport Agency, Civil Aviation Department
(Transportstyrelsen, Luftfartsavdelningen)

Section: [MED.B.015 \(b\) and \(c\)](#)

Comment:



The wording 'on clinical indication' has been changed to 'when clinically indicated' throughout Part-MED and ATCO.MED, with the exception for MED.B.015 and ATCO.MED.B.015. For consistency, these paragraphs should be changed in the same way.

Proposal:

Amend MED.B.015:

change 'on clinical indication' to 'when clinically indicated'.

response *Accepted*

The text has been amended to 'when clinically indicated', for consistency.

comment *344*

comment by: *Trond-Eirik Strand*

In section 2.3.5.3 of the NPA (Respiratory system) the following explanation is found: "An amendment to AMC 3 MED.C.025 (b) is proposed to allow morphological testing, as well as functional testing, when required on clinical indication, as morphological tests, such as MRI scans, are known to be an effective mechanism for assessing respiratory conditions." With the same argumentation this should also be the case for class 1, 2 and LAPL.

response *Accepted*

The option for pulmonary morphological testing has been added for class 1 and class 2 medical certification. Also, a new subparagraph has been added to the LAPL AMC for the respiratory system to ensure pulmonary morphological or functional tests are undertaken when clinically indicated.

3 Proposed amendments — 3.1 Draft Regulation (Draft EASA Opinion) — ANNEX IV — [PART-MED] — SUBPART B — REQUIREMENTS FOR PILOT MEDICAL CERTIFICATES — SECTION 2 — Medical requirements for class 1 and class 2 medical certificates — MED.B.020 Digestive System

p. 35

comment

142

comment by: *Swedish Transport Agency, Civil Aviation Department (Transportstyrelsen, Luftfartsavdelningen)*

Section: [MED.B.020 \(c\) and \(d\)](#)

Comment:

In CRD Part-ATCO.MED the text has been amended to permit, under certain provisions, a fit assessment for all conditions under (c) as most of the conditions should not automatically lead to an unfit assessment.

Also, for class 3 there is no requirement to refer applicants with those conditions to the licensing authority.

[The text should be amended to be consistent with Part-ATCO.MED.](#)

Proposal:

Amend MED.B.020:



**‘ may be assessed as fit subject to a satisfactory gastroenterological evaluation after successful treatment or full recovery after surgery.’
Delete (d).**

response *Partially accepted*

The text in subparagraph (c) has been amended to reflect the comment.

Subparagraph (d) has not been deleted because an alignment with Part-ATCO.MED is primarily important for Subpart A and the Subpart on AME certification. The specific Subparts B (MED and ATCO.MED) on medical assessment of pilots/ATCOs are tailored to the different working environments and may be different.

comment 343

comment by: *Trond-Eirik Strand*

In the proposed MED.B.020 (d) it is referred to conditions specified in (2), (4) or (5) where it should be referred to (c) (2), (c) (4) or (c) 5.

response *Accepted*

The text has been corrected accordingly.

3 Proposed amendments — 3.1 Draft Regulation (Draft EASA Opinion) — ANNEX IV — [PART-MED] — SUBPART B — REQUIREMENTS FOR PILOT MEDICAL CERTIFICATES — SECTION 2 — Medical requirements for class 1 and class 2 medical certificates — MED.B.025 Metabolic and Endocrine Systems

p. 35-36

comment

143

comment by: *Swedish Transport Agency, Civil Aviation Department (Transportstyrelsen, Luftfartsavdelningen)*

Section: [MED.B.025 \(a\)](#)

Comment:

[The general requirements in \(a\) are covered in MED.B.005 and have been deleted from most paragraphs. They should be deleted also from MED.B.025.](#)

Proposal:

Amend MED.B.025:

Delete (a).

response *Accepted*

Subparagraph (a) has been deleted accordingly.



comment	<p>144 comment by: <i>Swedish Transport Agency, Civil Aviation Department (Transportstyrelsen, Luftfartsavdelningen)</i></p> <p>Section: MED.B.025 (c)(2)</p> <p>Comment: In CRD Part-ATCO.MED the text also includes that the blood sugar control shall be stable. The requirements for pilots should have the same wording.</p> <p>Proposal: Amend MED.B.025: (c)(2) .../... blood sugar control has been achieved and is stable.</p>
response	<p><i>Accepted</i></p> <p>The text has been amended accordingly.</p>
comment	<p>265 comment by: <i>UK CAA</i></p> <p>Page No: 35 Paragraph No: MED.B.025 (c) Comment: Allowing pilots treated with insulin should be accepted subject to compliance with safe AMC/GM. Justification: Appropriate mitigation is outlined in the AMC below and is further detailed in the UK guidance document on insulin treated pilots. Proposed Text: '(c) <i>Diabetes mellitus</i> (1) Applicants with diabetes mellitus requiring insulin shall be assessed as unfit. Individual asymptomatic uncomplicated cases with good blood sugar control, including acceptable blood sugar monitoring whilst exercising licence privileges, may be assessed as fit for restricted certification by the licensing authority. (2) Applicants with diabetes mellitus not requiring insulin shall be assessed as unfit unless it can be demonstrated that blood sugar control has been achieved. (d) Aero-medical assessment: (1) applicants for a Class 1 medical certificate requiring potentially hypoglycaemic medication other than insulin for blood sugar control shall be referred to the licensing authority; (2) fitness of Class 2 applicants requiring potentially hypoglycaemic medication other than insulin for blood sugar control shall be assessed in consultation with the licensing authority.'</p>
response	<p><i>Not accepted</i></p> <p>This paragraph will not be changed at this stage; the rule will remain ICAO compliant.</p> <p>However, the following solution has been proposed in a recent package of amendments for Part-ARA (Annex VI to the Aircrew Regulation). The proposal is to reintroduce the former paragraph JAR.FCL 3.046 'special medical circumstances' to Part-ARA. The aim is to allow competent authorities to consider medical advancements and to establish whether a fit</p>



assessment may be possible for certain medical conditions for which the existing provisions inevitably lead to an unfit assessment. Under new medical assessment protocols via research, it would be possible to collect specific data in a controlled aviation environment, and to develop specific risk assessments for certain medical conditions.

3 Proposed amendments — 3.1 Draft Regulation (Draft EASA Opinion) — ANNEX IV — [PART-MED] — SUBPART B — REQUIREMENTS FOR PILOT MEDICAL CERTIFICATES — SECTION 2 — p. 36
Medical requirements for class 1 and class 2 medical certificates — MED.B.030 Haematology

comment

145

comment by: *Swedish Transport Agency, Civil Aviation Department*
(Transportstyrelsen, Luftfartsavdelningen)

Section: [MED.B.030](#)

Comment:

In CRD Part-ATCO.MED the text also includes that applicants suffering from acute leukemia shall be assessed as unfit.

[The corresponding paragraph for pilots should include the same requirement.](#)

Proposal:

[Amend MED.B.030:](#)

[\(e\) Applicants suffering from acute leukemia shall be assessed as unfit.](#)

response

Accepted

The Implementing Rule has been changed from 'chronic leukaemia' to 'leukaemia', as the AMC for class 1 and class 2 provides fit and unfit criteria for both acute and chronic leukaemia. In addition, this will ensure licensing authority involvement for acute as well as chronic leukaemia.

3 Proposed amendments — 3.1 Draft Regulation (Draft EASA Opinion) — ANNEX IV — [PART-MED] — SUBPART B — REQUIREMENTS FOR PILOT MEDICAL CERTIFICATES — SECTION 2 — p. 37
Medical requirements for class 1 and class 2 medical certificates — MED.B.040 Infectious Disease

comment

146

comment by: *Swedish Transport Agency, Civil Aviation Department*
(Transportstyrelsen, Luftfartsavdelningen)

Section: [MED.B.040 \(a\)](#)

Comment:

[The general requirements in \(a\) are probably covered in MED.B.005 and have been deleted from most paragraphs. Unless needed to give a hook for the AMCs, \(a\) should be considered for deletion also from MED.B.025.](#)



Proposal:
 Amend MED.B.040:
Consider the possibility to delete (a).

response *Not accepted*

The paragraph 'infectious diseases' only mentions HIV. Subparagraph (a) is a reminder for all other infectious diseases that should be considered and it provides the hook for the AMC.

3 Proposed amendments — 3.1 Draft Regulation (Draft EASA Opinion) — ANNEX IV — [PART-MED] — SUBPART B — REQUIREMENTS FOR PILOT MEDICAL CERTIFICATES — SECTION 2 — Medical requirements for class 1 and class 2 medical certificates — MED.B.045 Obstetrics and Gynaecology

p. 37

comment

4

comment by: *Dr.Beiderwellen, Vice President of GAAME*

MED. B. 045 (b) (1)
 Pregnancy is no illness.
 After the end of an uncomplicated pregnancy and full recover license holders do not need a renewal examination.
 proposed amendment:
 delete: " licence holder shall undergo a renewal examination and assessment "
 place : " The suspension shall be lifted after assessment by the AME/AeMC after full recovery following the end of the pregnancy."

response

Accepted

All comments in this section propose not to require a renewal examination after pregnancy.
 The text has been amended so that pilot can only exercise the privileges of her licence until the end of the 26th week of gestation, and then resume exercising her privileges after recovery following the end of the pregnancy.

comment

18

comment by: *AECA(SPAIN)*

Paragraph (b)(2)
 Must keep the idea of '*suspension of the certificate*'.
 Pregnancy can occur during the validity of the certificate, especially taking into account that some are valid for five years.

response

Noted

See response to comment No 4.



comment	55	comment by: <i>Light Aircraft Association UK</i>
	MED.B.045 c)1): We can find no logic in requiring an examination after termination of pregnancy or normally completed pregnancies. We consider that a declaration by the treating physician that the patient has had an uncomplicated pregnancy, delivery (or caesarian section), and post partum period is all that is required. This would be common to aeromedical practice for other major medical issues and surgery.	
response	<i>Noted</i> See response to comment No 4.	
comment	96	comment by: <i>EFLEVA</i>
	MED.B.045 c)1) : EFLEVA are of the view that post pregnancy testing is unnecessary. A medical declaration by the physician that the patient has had an uncomplicated pregnancy, delivery and recovery period should suffice, as in the case of other medical issues such as surgery.	
response	<i>Noted</i> See response to comment No 4.	
comment	222	comment by: <i>CAA-NL</i>
	<p>'The license holder shall undergo a renewal examination and assessment after full recovery following the end of the pregnancy.'</p> <p>Proposal for changing the above text into: The license holder shall undergo a obstetric review by AME or OHMP after full recovery following the end of the pregnancy.</p> <p>Explanation: It seems wise to have a medical review after each pregnancy to see if the license holder is fit to fly. This review could be done by an AME as well as by the OHMP. If there is any doubt regarding the fitness of the candidate a full assessment should be done. In this way unnecessary examinations are prevented and the procedure is more close to all day practice. In uncomplicated pregnancy there is no need for a renewal examination.</p>	
response	<i>Noted</i> See response to comment No 4.	
comment	266	comment by: <i>UK CAA</i>
	<p>Page No: 37</p> <p>Paragraph No: MED.B.045 (b) (1)</p> <p>Comment: This paragraph does not take account of all combinations of medical examinations, certificate validity period and possible outcomes of any pregnancy e.g. a certificate holder attends a medical on date x. She then declares she is pregnant a week later but then has a miscarriage 3 weeks later. She should not be required to undergo a renewal examination in this scenario.</p> <p>Justification: The text needs to cover all scenarios.</p>	



Proposed Text: 'In the case of pregnancy, if the AeMC or AME shall assess the licence holder's fitness considers that the licence holder is fit to exercise her privileges, he/she shall limit the validity period of the medical certificate to the end of the 26th week of gestation, at which point she shall be assessed as unfit. Following the end of the pregnancy the licence holder shall undergo assessment by the AeMC or AME. and a renewal examination and assessment after full recovery following the end of the pregnancy.'

response *Noted*

See response to comment No 4.

comment 350

comment by: *Jukka TERTTUNEN*

From CAA Finland AMS perspective a new regulation that demands a renewal AME-examination seems as an overregulation. We would like to suggest that we continue as we have been doing for decades. The vast majority of female pilots have been fit before the pregnancy and will be fit after it. In Finland we do have, as I also believe in other Nordic countries, a good pregnancy healthcare, in some EU-countries the situation is maybe not the same.

We suggest that a proper aeromedical assessment should be sufficient and if based on individual risk assessment a full AME-driven renewal examination should only be demanded.

response *Noted*

See response to comment No 4.

3 Proposed amendments — 3.1 Draft Regulation (Draft EASA Opinion) — ANNEX IV — [PART-MED] — SUBPART B — REQUIREMENTS FOR PILOT MEDICAL CERTIFICATES — SECTION 2 — Medical requirements for class 1 and class 2 medical certificates — MED.B.050 Musculoskeletal System

p. 37

comment

147

comment by: *Swedish Transport Agency, Civil Aviation Department (Transportstyrelsen, Luftfartsavdelningen)*

Section: [MED.B.050](#)

Comment:

The general requirements in (a) are probably covered in MED.B.005 and have been deleted from most paragraphs. Unless needed to give a hook for the AMCs, (a) should be considered for deletion also from MED.B.050.

The details in subparagraph (b) are probably covered by subparagraph (c) and should be considered for deletion.

In CRD Part-ATCO.MED the text corresponding to MED.B.050 (c) has been amended to improve the English. The requirements for pilots should have the same wording.

Proposal:

[Amend MED.B.050:](#)

Consider the possibility to delete (a) and (b).



(c) 'Applicants shall have satisfactory functional use of the musculoskeletal system to enable them to safely exercise the privileges of the applicable license(s). In case of doubt, applicants for .../...'

response

Partially accepted

Subparagraph (a) is not deleted as it may serve as a hook for the AMCs as also indicated in the comment.

Subparagraph (b) is not deleted. The point is well-taken, but it has always been in JAR-FCL 3 and has never been challenged. It should therefore not be deleted if there is no urgent safety reason.

The text of subparagraph (c) has been corrected as proposed.

3 Proposed amendments — 3.1 Draft Regulation (Draft EASA Opinion) — ANNEX IV — [PART-MED] — SUBPART B — REQUIREMENTS FOR PILOT MEDICAL CERTIFICATES — SECTION 2 —
Medical requirements for class 1 and class 2 medical certificates — MED.B.055 Psychiatry

p. 38

comment

148

comment by: *Swedish Transport Agency, Civil Aviation Department
(Transportstyrelsen, Luftfartsavdelningen)*

Section: [MED.B.055 \(a\)](#)

Comment:

In CRD Part-ATCO.MED the corresponding text has been further amended to give more clarity to the requirements. The requirements for pilots should have the same wording.

Proposal:

Amend [MED.B.055 \(a\)](#):

'Applicants with a mental or behavioural disorder due to alcohol or other use or misuse of psychoactive substances, including recreational substances, with or without dependency, shall be assessed as unfit until after a period of documented sobriety or freedom from psychoactive substance use or misuse and subject to satisfactory psychiatric evaluation after successful treatment. Applicants for a class 1 .../...'

response

Partially accepted

The text has been refined and partially aligned with the proposed text for ATCO.MED. The exception is where the proposed text is already covered in the AMCs.

comment

149

comment by: *Swedish Transport Agency, Civil Aviation Department*



*(Transportstyrelsen, Luftfartsavdelningen)*Section: [MED.B.055](#)**Comment:**

The order of subparagraphs should start with the most restrictive requirement 'shall be assessed as unfit'. To achieve this, the order should be (e), (a), (b), (c), and (d), with subsequent renumbering.

Proposal:

Amend MED.B.055 (a):

change the order of subparagraphs to (e), (a), (b), (c), and (d), with subsequent renumbering.

response *Noted*

See response to comment No 138.

comment *187*comment by: *Jörg SIEDENBURG*

(cd) Applicants with a history of a single or repeated acts of deliberate self-harm shall be assessed as unfit. ~~Applicants shall undergo satisfactory psychiatric evaluation before a fit assessment can~~ **A fit assessment** may be considered **after satisfactory psychiatric assessment**.

More concise and clear.

response *Partially accepted*

The text has been amended as suggested, except it indicates a psychiatric evaluation which is necessary for the assessment.

comment *346*comment by: *Trond-Eirik Strand*

In the new proposed (a) one could read that «Applicants for a class 1 medical certificate shall be referred to the licensing authority. Fitness of class 2 applicants shall be assessed in consultation with the licensing authority.» In (d)(1) this is repeated.

response *Accepted*

Subparagraphs (a), (b) and (c) provide criteria for the assessment, whereas subparagraph (d) is a 'catch-all' requirement to ensure that affected applicants for a class 1 medical certificate are referred to the licensing authority and affected applicants for a class 2 medical certificate are assessed in consultation with the licensing authority. Where this was duplicated in other subparagraphs under psychiatry, it has been deleted.

3 Proposed amendments — 3.1 Draft Regulation (Draft EASA Opinion) — ANNEX IV — [PART-MED] — SUBPART B — REQUIREMENTS FOR PILOT MEDICAL CERTIFICATES — SECTION 2 — p. 38-39



Medical requirements for class 1 and class 2 medical certificates — MED.B.065 Neurology
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comment	30	comment by: <i>Federal Office of Civil Aviation FOCA</i>
	MED.B.065 paragraph (b) (Neurology). FOCA suggests to add sub-paragraph 10: inflammatory central and peripheral nerve diseases.	

response	<i>Accepted</i>	
	The text has been amended to take account of the comment.	

comment	150	comment by: <i>Swedish Transport Agency, Civil Aviation Department (Transportstyrelsen, Luftfartsavdelningen)</i>
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Section: [MED.B.065 \(a\)](#)

Comment:

MED.B.065 (a) contradicts (b)(1) and (b)(2). This has been corrected in CRD ATCO.MED amending (1) with the addition of 'except in cases in (b)(1) and (2) below.' The requirements for pilots should have the same wording.

Proposal:

Amend MED.B.065:

(a)(1) 'epilepsy except in cases in (b)(1) and (b)(2) below.'

response	<i>Accepted</i>	
	The text has been amended accordingly.	

3 Proposed amendments — 3.1 Draft Regulation (Draft EASA Opinion) — ANNEX IV — [PART-MED] — SUBPART B — REQUIREMENTS FOR PILOT MEDICAL CERTIFICATES — SECTION 2 — p. 39-42 Medical requirements for class 1 and class 2 medical certificates — MED.B.070 Visual System

comment	151	comment by: <i>Swedish Transport Agency, Civil Aviation Department (Transportstyrelsen, Luftfartsavdelningen)</i>
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Section: [MED.B.070 \(a\)](#)

Comment:

The general text in (a) is covered by MED.B.005 and has been deleted from all other paragraphs.

In CRD ATCO.MED the corresponding subparagraph has been deleted.

Proposal:

Amend MED.B.070 (a):
Delete (a).

response

Accepted
Subparagraph (a) has been deleted.

comment

152

comment by: *Swedish Transport Agency, Civil Aviation Department
(Transportstyrelsen, Luftfartsavdelningen)*

Section: MED.B.070 (b)(1)(i)

Comment:

The wording 'on clinical indication' has been changed to 'when clinically indicated' throughout Part-MED and ATCO.MED. For consistency, also MED.B.070 (b)(1)(i) should be changed in the same way.

Proposal:

Amend MED.B.070:
change 'on clinical indication' to 'when clinically indicated'.

response

Accepted
The text has been amended accordingly.

comment

153

comment by: *Swedish Transport Agency, Civil Aviation Department (Transportstyrelsen,
Luftfartsavdelningen)*

Section: MED.B.070 (f)

Comment:

The words 'be required to' are superfluous and should be deleted as they do not appear in other paragraphs.

Proposal:

Amend MED.B.070 (f):
**'Visual fields
Applicants for a class 1 medical certificate shall have normal fields of vision.'**

response

Accepted
The text has been amended accordingly.



comment 154 comment by: *Swedish Transport Agency, Civil Aviation Department (Transportstyrelsen, Luftfartsavdelningen)*

Section: [MED.B.070 \(h\)](#)

Comment:

In the wording 'correction spectacles or contact lenses' the word 'correction' is superfluous and should be deleted.

Proposal:

Amend MED.B.070 (h):

(1) If satisfactory visual function is achieved only with the use of correction, the spectacles or contact lenses .../...'

response *Accepted*

The text has been amended accordingly.

comment 188 comment by: *Jörg SIEDENBURG*

(c) Visual acuity [] **and** Substandard vision in one eye
or

(c) Visual acuity []

In the proposed form the title of the paragraph could be misunderstood as referring only to the aspect of substandard vision in one eye. However, most of the information refers to visual acuity

response *Accepted*

The text has been amended accordingly.

comment 189 comment by: *Jörg SIEDENBURG*

Remark: The possibility for a fit assessment in case of acquired substandard vision for Class 1 is a significant change. It is more or less hidden in editorial changes and not discussed in an appropriate way. Recalling the arguments when the discussions about substandard vision and monocular vision for Class 2 have been discussed, the renunciation for a mandatory backup of the critical visual system remains questionable.

response *Noted*

This amendment was extensively discussed with the medical experts in the Rulemaking group. Acquired substandard vision for class 1 revalidation or renewal applicants was regarded to be acceptable providing the mitigation of an OML was in place.

comment 190 comment by: *Jörg SIEDENBURG*



	<p>(d) Refractive error, astigmatism and anisometropia</p> <p>(1) Applicants with refractive errors, astigmatism or anisometropia may be assessed as fit subject to satisfactory ophthalmic evaluation.</p> <p>(2) Applicants with a clinical diagnosis of keratoconus may be assessed as fit subject to a satisfactory examination by an ophthalmologist. Applicants for a class 1 medical certificate shall be referred to the licensing authority. The medical condition of astigmatism has been omitted. However, it should be mentioned. The reason for the omission remains unclear. Just mentioning keratokonus does not cover minor or moderate degrees of astigmatism.</p>
response	<p><i>Partially accepted</i></p> <p>Astigmatism is a refractive error and therefore not mentioned in the header. It has been added as point (c)(2)(ii). In addition, it is referred to in the Acceptable Means of Compliance.</p>
comment	<p>191 comment by: Jörg SIEDENBURG</p> <p>(2) No more than one pair of spectacles shall be used to meet the visual requirements when exercising the privileges of the applicable licence(s). In case of myopia in combination with age related presbyopia a pair of spectacles for distant vision may be worn and an additional pair of glasses for near vision be kept available.</p> <p>The provision, in which the new proposed change would result, has proven to be safe after being in place for long time under jurisdiction of the FAA. The change of near vision correction (i.e. for studying maps, manuals etc.) to distant vision and vice versa is most likely not happening in phases of flight where a permanent distant vision alertness is required by both pilots in a multi-pilot setting. Furthermore, a pilot with distant vision contact lenses adding a pair of spectacles for near vision for reading a map is not different from a pilot with VNL having his glasses available.</p>
response	<p><i>Not accepted</i></p> <p>This is an interesting approach, but ICAO 6.3.3.4 states ‘... When near correction is required, the applicant shall demonstrate that one pair of spectacles is sufficient to meet both distant and near visual requirements.’ This is already required according to the currently applicable Part-MED.</p>
comment	<p>267 comment by: UK CAA</p> <p>Page No: 41 Paragraph No: MED.B.070 (g) Comment: The term “ophthalmic evaluation” has been changed to “ophthalmological evaluation”. Neither of these terms is defined but AMC1 MED.070 (a)(2) implies that ophthalmological evaluation is conducted by an ophthalmologist. There is no reason given in the explanatory notes. We suggest the text should not be changed. Justification: This is not always necessary following some eye surgery e.g. refractive surgery. Proposed Text: ‘A fit assessment may be considered subject to satisfactory ophthalmic</p>



	ophthalmological evaluation.'
response	<p><i>Not accepted</i></p> <p>Eye surgery may have consequences for the fitness to fly and in most EASA Member States an examination by an ophthalmologist is the best way to confirm full recovery and to determine whether or not complications are likely to arise.</p>

3 Proposed amendments — 3.1 Draft Regulation (Draft EASA Opinion) — ANNEX IV — [PART-MED] — SUBPART B — REQUIREMENTS FOR PILOT MEDICAL CERTIFICATES — SECTION 2 — Medical requirements for class 1 and class 2 medical certificates — MED.B.075 Colour vision	p. 42
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comment	<p>99</p> <p style="text-align: right;">comment by: <i>Del Monte</i></p> <p>Dear NPA team, Considering other Authorities in the world have a far more relax regulation over this matter, would the Agency consider aligning and updating this law to the like of the FAA, CASA and Transport Canada? Not only the Ishihara's plates are 100+ year old but also ALL current approved secondary tests (Lanterns and Anomaloscope) are rather outdated and frankly not very relevant to any 'daily pilot action'. In fact these tests seems to cause a lot of FALSE POSITIVES: Even mild cases of colour vision defect who are indeed well capable and safe to fly at night or commercially might be unable to pass a very limited choice of tests thus being discriminated.</p> <p>Also, not only any test should be carried out in accordance with the manufacturing instructions (Ishihara's plates aren't, please check manual!) but I do also believe we need a more practical, fairer and honest test based on real life/actions, NOT academic/clinical/computerised tests. In fact, the FAA allows up to 18 approved tests amongst which a practical test (TOWER SIGNAL LIGHT AND MFT) that has direct relation to flying. Would the Agency at least consider this?</p> <p>Also in Australia for 20 years, CASA has been allowing pilots with ANY degree of colour vision defect, from mild all the way to SEVERE like protanotopes, not only to fly at night but also to carry out Commercial Air Transport: These colour vision defect pilots are subject to any LPC/OPC like the 'normal' colleagues and clearly show that they are able to perform SAFELY and CORRECTLY both as single and multi crew: this, once again, highlights the discrimination issue! Would the Agency think about this problem, especially about the discrimination issue, considering that as we speak many colour vision defect pilots are flying in and out Europe's largest airports flying heavy/super category aircraft, at night perhaps, yet their European peers are not even allowed to fly at night on a single engine aircraft?!</p> <p>thank you</p>
response	<p><i>Partially accepted</i></p> <p>Thank you for your contribution. However, the European rules will remain ICAO compliant. The choice of colour vision tests has been broadened to include the UK CAD test.</p>



3 Proposed amendments — 3.1 Draft Regulation (Draft EASA Opinion) — ANNEX IV — [PART-MED] — SUBPART B — REQUIREMENTS FOR PILOT MEDICAL CERTIFICATES — SECTION 2 — Medical requirements for class 1 and class 2 medical certificates — MED.B.080 Otorhinolaryngology (ENT)

p. 42-43

comment	19	comment by: <i>AECA(SPAIN)</i>
	Paragraph (a)(1)(ii) Should be a provision for 4000 Hz frequency, because that is what defines the acoustic trauma	
response	<i>Partially accepted</i> New GM has been added for class 1 and class 2 medical certification, and for cabin crew aero-medical examinations and assessments to provide the option for the pure tone audiogram to cover the 4 000 Hz frequency for the early detection of a decrease in hearing.	
comment	20	comment by: <i>AECA(SPAIN)</i>
	Paragraph (b) The description of ENT problems of this paragraph clearly includes elements that interfere with the safe exercise of the privileges. Should therefore reworded the last sentence. Furthermore in paragraph 'shall undergo ...' (last sentence) should use the terms referred to on page 7 of the explanatory note, and should be deleted in this case, the word <i>assessment</i> . Who does this assessment, if maintained? One otolaryngologist? Another? Who?.	
response	<u>First comment in this field</u> <i>Not accepted</i> It is true that the medical conditions described in subparagraph (b) could interfere with the safe exercise of the privileges of the applicants licence. Examinations should be undertaken to ensure that applicants with any of the listed conditions can safely exercise of the privileges of their licence. <u>Second comment in this field</u> <i>Accepted</i> The text has been corrected to 'examination'. The examination should be conducted by a person suitably qualified to evaluate the condition, i.e. a specialist.	
comment	80	comment by: <i>The Norwegian Air Sports Federation</i>
	MED.B.080 NLF would like to question if the addition of the en-route instrument rating to a PPL should require the license holder to undertake pure tone audiometry examinations in accordance with class 1 requirements. Since IFR approaches and departures (the most critical phases of	



flight, during which any hearing anomalies would have the most serious effect on flight safety) are not included in the privileges of the EIR, this requirement seems to be disproportionate. Furthermore, a similar requirement does understandably not exist for the VFR night rating. It is hard to understand how an EIR operation would be so different in nature to an N-VFR operation that such an audiometry examination requirement should be considered mandatory. The requirement also makes the EIR less accessible, as it means that another medical examination will be required once a pilot decides to upgrade from VFR to EIR.

We understand that the rules for medical examinations in other countries (e.g. Canada) do not include pure-tone audiometry after the initial investigation unless other (simpler) hearing tests indicate a problem. As this methodology has been safely applied also for Class 1 ratings abroad, we would assume that the general hearing examination requirements for Class 2 would suffice for EIR rated pilots.

response *Not accepted.*

Pilots flying with the En route Instrument Rating (EIR) operate in the same airspace as holders of an Instrument Rating (IR). En route, they have to hear and understand air traffic control and other traffic the same way as IR holders.

comment

155

comment by: *Swedish Transport Agency, Civil Aviation Department (Transportstyrelsen, Luftfartsavdelningen)*

Section: [MED.B.080 \(b\)\(2\)](#)

Comment:

In CRD ATCO.MED the subparagraph has been amended to delete ‘acute’ which otherwise require applicants with any kind of ear infection to have a further examination and assessment.

The possibility to delete ‘acute’ should be considered also for pilots.

Proposal:

Amend MED.B.080 (b)(2):

The possibility to delete ‘acute’ should be considered.

response *Accepted*

As described in the AMC for class 1 and class 2 medical certification, applicants with an active pathological process of the internal or middle ear should be assessed as unfit, whether it is acute or chronic. For LAPL medical certification, affected applicants should undergo further examination to establish that the condition does not interfere with the safe exercise of the privileges of the licence. This is similar for cabin crew aero-medical examinations and assessments.

Therefore, the words ‘acute or chronic’ have been deleted from the Implementing Rules and AMC.



comment	243	comment by: René Meier, Europe Air Sports
	<p>MED.B.080 Otorhinolaryngology (ENT) (a) Examination As in the case of MED.A.030(g) a considerable number of our members is of the opinion that a difference should be made between the CB-IR and the EIR holders. Rationale: Access to the EIR should be as simple as possible to get the maximum safety gain stemming from this provision.</p>	
response	<p><i>Noted</i> See response to comment No 80.</p>	

3 Proposed amendments — 3.1 Draft Regulation (Draft EASA Opinion) — ANNEX IV — [PART-MED] — SUBPART B — REQUIREMENTS FOR PILOT MEDICAL CERTIFICATES — SECTION 2 — p. 43-44
Medical requirements for class 1 and class 2 medical certificates — MED.B.090 Oncology

comment	81	comment by: The Norwegian Air Sports Federation
	<p>MED.B.090 (b) NLF welcomes this change.</p>	
response	<p><i>Noted</i> Thank you for your support.</p>	

comment	156	comment by: Swedish Transport Agency, Civil Aviation Department (Transportstyrelsen, Luftfartsavdelningen)
	<p>Section: MED.B.090 (a)</p> <p>Comment: The general requirements in (a) are probably covered in MED.B.005 and have been deleted from most paragraphs. Unless needed to give a hook for the AMCs, (a) should be considered for deletion also from MED.B.090.</p> <p>Proposal: Amend MED.B.090 (a): Consider the possibility to delete (a).</p>	
response	<p><i>Not accepted</i> (b) is only on treatment of malignant disease and referral to/consultation with the licensing authority.</p>	



(c) mentions intracerebral tumours only.

In order to cover other malignancies and to serve as a hook for the AMCs, subparagraph (a) has not been deleted.

comment

157

comment by: *Swedish Transport Agency, Civil Aviation Department
(Transportstyrelsen, Luftfartsavdelningen)*

Section: [MED.B.090 \(b\)](#)

Comment:

In CRD ATCO.MED the subparagraph has been amended to give more clarity to the requirements. The requirements for pilots should have the same wording.

Proposal:

Amend [MED.B.090 \(b\)](#):

After diagnosis of primary or secondary malignant disease, applicants shall undergo satisfactory oncological evaluation before a fit assessment may be considered. Applicants for .../... ‘

response

Partially accepted

The wording of the sentence has not been changed because the aim of the editorial improvements was to have similar wording within Part-MED, where applicable. Therefore, paragraphs start with ‘Applicants with’. In this case, Part-ATCO.MED should be aligned with Part-MED. In addition, ‘applicants with...’ implies that it has been diagnosed.

comment

158

comment by: *Swedish Transport Agency, Civil Aviation Department
(Transportstyrelsen, Luftfartsavdelningen)*

Section: [MED.B.090 \(c\)](#)

Comment:

In CRD ATCO.MED ‘an’ has been added before intracerebral malignant tumour to improve the English. The requirements for pilots should have the same wording.

Proposal:

Amend [MED.B.090 \(c\)](#):

‘Applicants with an established history or clinical diagnosis of an intracerebral malignant tumour shall be assessed as unfit.’

response

Accepted

The text has been amended accordingly.

comment	244	comment by: <i>René Meier, Europe Air Sports</i>
	<p>MED.B.090(b) Our community welcomes the change proposed. Rationale: It is proportionate, we thank for this risk-based approach to such situations.</p>	
response	<p><i>Noted</i> Thank you for your support.</p>	

3 Proposed amendments — 3.1 Draft Regulation (Draft EASA Opinion) — ANNEX IV — [PART-MED] — SUBPART B — REQUIREMENTS FOR PILOT MEDICAL CERTIFICATES — SECTION 3 — Specific requirements for LAPL medical certificates — MED.B.095 Medical examination and/or assessment of applicants for LAPL medical certificates

p. 44

comment	21	comment by: <i>AECA(SPAIN)</i>
	<p>Paragraph (c)(3) Let this element</p>	
response	<p><i>Accepted</i> The requirement for LAPL applicants to undergo urine testing has been reinstated, as proposed by multiple commentators, as the test is simple, inexpensive and has its significance either for safety relevant conditions or for an early detection of metabolic or kidney conditions.</p>	
comment	23	comment by: <i>Federal Office of Civil Aviation FOCA</i>
	<p>Requirement for urine test needs to be maintained. Justification: Urine testing is a basic test according to ICAO SARPs and other relevant aviation authorities testing requirements. The test is simple, inexpensive and has its significance either for safety relevant conditions, i.e. for kidney stones which lead to sudden incapacitation or for an early detecting of metabolic or kidney conditions.</p>	
response	<p><i>Noted</i> See response to comment No 21.</p>	
comment	57	comment by: <i>DGAC FRANCE</i>



SECTION 3**Specific requirements for LAPL medical certificates****MED.B.095 Medical examination and/or assessment of applicants for LAPL medical certificates****Paragraph (c) (3) urine test;**

Do not delete the urine test. The urine test is a part of best practice regarding medical examination. This examination is necessary because it can detect numerous possible deficiencies (sugar, albumin, diabetes). The urine test must be kept to guarantee a complete medical examination. The pilots LAPL exercise one activity identical to the pilots subjected on examination of class 2, also pilots LAPL must be subjected to the same requirements of safety.

Doctor René GERMA, Head of the Medical Pole flight crews, DGAC

response

Noted

See response to comment No 21.

comment

159

comment by: *Swedish Transport Agency, Civil Aviation Department
(Transportstyrelsen, Luftfartsavdelningen)*

Section: [MED.B.095 \(c\)\(3\)](#)

Comment:

The urine test is proposed to be deleted from the examination for a LAPL medical certificate. However, a simple urine test might give the only sign of diabetes or serious urinary tract disease and should be kept.

Proposal:

[Amend MED.B.090:
\(c\)\(3\) should not be deleted.](#)

response

Noted

See response to comment No 21.

comment

192

comment by: *Jörg SIEDENBURG*

The omission of urine tests for LAPL pilots is a safety issue. The test can detect inter alia common disorders like diabetes and kidney disease, which are relevant for aviation safety, because they might result in incapacitations. The test is cheap and easy to perform. Therefore, there seems to be no obvious reason advantage to drop the requirement for such tests.

response

Noted

See response to comment No 21.



comment	225	comment by: <i>French main military Aeromedical Center (CPEMPN)</i>
	Urine test should not be deleted for LAPL medical certificates, as far as this test is useful to detect kidney stones that can jeopardize flight safety.	
response	<i>Noted</i> See response to comment No 21.	

3 Proposed amendments — 3.1 Draft Regulation (Draft EASA Opinion) — ANNEX IV — [PART-MED] — SUBPART D — AERO-MEDICAL EXAMINERS (AME), GENERAL MEDICAL PRACTITIONERS (GMP), OCCUPATIONAL HEALTH MEDICAL PRACTITIONERS (OHMP) — SECTION 1 — Aero-Medical Examiners — MED.D.005 Application

p. 45

comment	160	comment by: <i>Swedish Transport Agency, Civil Aviation Department (Transportstyrelsen, Luftfartsavdelningen)</i>
	Section: MED.D.005 (a)	
	Comment: In CRD ATCO.MED the corresponding subparagraph has been amended to clarify the requirements for submitting an application for an AME certificate. The same wording should be used in MED.D.005 (a).	
	Proposal: Amend MED.D.005 (a): 'Applications for an AME certificate, or for the extension of the privileges of the AME certificate, shall be submitted in accordance with the procedure established by the competent authority.'	
response	<i>Partially accepted</i> The text has been changed for consistency, although the expression 'form and manner specified by the competent authority' is retained, as it is used in the rest of Part-MED.	
comment	161	comment by: <i>Swedish Transport Agency, Civil Aviation Department (Transportstyrelsen, Luftfartsavdelningen)</i>
	Section: MED.D.005 (c)	
	Comment: In CRD ATCO.MED the corresponding subparagraph has been amended to add 'and practice facilities'. The same wording should be used in MED.D.005 (c).	
	Proposal:	



	<p>Amend MED.D.005 (c): ‘.../... information regarding all practice locations and practice facilities.’</p>
response	<p><i>Accepted</i></p> <p>The text has been amended accordingly.</p>

<p>3 Proposed amendments — 3.1 Draft Regulation (Draft EASA Opinion) — ANNEX IV — [PART-MED] — SUBPART D — AERO-MEDICAL EXAMINERS (AME), GENERAL MEDICAL PRACTITIONERS (GMP), OCCUPATIONAL HEALTH MEDICAL PRACTITIONERS (OHMP) — SECTION 1 — Aero-Medical Examiners — MED.D.010 Requirements for the issue of an AME certificate</p>	<p>p. 45</p>
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comment	<p>47 comment by: AECA(SPAIN)</p> <p>AMC not published setting out the technical means to require an AME.</p>
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response	<p><i>Noted</i></p> <p>There is no clear proposal provided by the commentator.</p>
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comment	<p>162 comment by: Swedish Transport Agency, Civil Aviation Department (Transportstyrelsen, Luftfartsavdelningen)</p>
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<p>Section: MED.D.010 (b)</p> <p>Comment: In CRD ATCO.MED the corresponding subparagraph has been amended to require an applicant to ‘have successfully completed’ a training course. The same wording should be used in MED.D.010 (b).</p> <p>Proposal: Amend MED.D.010 (b): ‘ have successfully completed a basic training course in aviation medicine;’</p>	
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response	<p><i>Accepted</i></p> <p>The text has been amended accordingly.</p>
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comment	<p>239 comment by: ENAC Aeromedical Section-Italy</p> <p>The philosophy of the new text in proposed MED.D.010 (a) should be also put in MED.D.010 (b).</p>
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In many country medical doctors working for years in civil or military aviation have very huge curricula in aviation medicine.
At discretion of the Licensing Authority a limited training on regulation and procedures could be asked to the candidate if needed.
The suggested **MED.D.010 (b)** text is: "have undertaken a basic training course in aviation medicine, or have other evidence of equivalent training"

response *Not accepted*

For harmonisation reasons, all AMEs should follow the basic training course as laid down in the AMC to Subpart D.

comment

268

comment by: UK CAA

Page No: 45

Paragraph No: MED.D.010 (a)

Comment: The phrase 'other evidence of specialist medical training' is broad and does not give enough assurance of the nature and extent of that training

Justification: There needs to be an equivalence of specialist training that is acceptable throughout Europe.

Proposed Text: 'Applicants for an AME certificate with the privileges for the initial issue, revalidation and renewal of Class 2 medical certificates shall:

(a) be fully qualified and licensed for the practice of medicine and **either** hold a Certificate of Completion of specialist training, **or a statement from the doctor's national regulatory body that the applicant is eligible to work as a specialist in that country;**'

response *Partially accepted*

The text has been amended to clarify the intent, which is that the applicant shall have evidence of completion of specialist medical training.

3 Proposed amendments — 3.1 Draft Regulation (Draft EASA Opinion) — ANNEX IV — [PART-MED] — SUBPART D — AERO-MEDICAL EXAMINERS (AME), GENERAL MEDICAL PRACTITIONERS (GMP), OCCUPATIONAL HEALTH MEDICAL PRACTITIONERS (OHMP) — SECTION 1 — Aero-Medical Examiners — MED.D.015 Requirements for the extension of privileges

p. 46

comment

24

comment by: Federal Office of Civil Aviation FOCA

FOCA suggests to delete MED.D.015 sub-paragraph c. Justification: AMEs are specialised doctors and do not need training in examination techniques. Furthermore, it is impossible to organise such training courses in AeMCs as they neither have any interest nor financial and personal resources to organise such training. If requested, such practical training should be rather included in the advanced training course. In many smaller countries the AeMCs only conduct one or two initial exams per week, therefore it would be an overkill to request a practical training to be conducted by these centers. The specific tasks of a center is known to the AMEs, there is no need of practical training. If the intention to request such a practical training is to be maintained, it should be replaced by a requirement as "for the first 50 class 1 assessments, the decision of fitness has to be made in consultation with the authority".



response	<p><i>Partially accepted</i></p> <p>A change of this magnitude would need to be properly consulted, for example through NPA consultation, so at this stage the compromise is to change it to 'between 2 and 4 days' to keep the minimum and maximum to a reasonable duration.</p>
comment	<p>163</p> <p>comment by: <i>Swedish Transport Agency, Civil Aviation Department (Transportstyrelsen, Luftfartsavdelningen)</i></p> <p>Section: MED.D.015 (a)</p> <p>Comment: MED.D.015 (a) does not clearly define that the class 2 medical certificates shall be issued according to Part-MED, with the implication that any class 2 examination according to non-EU or national rules might be counted. A specification to Part-MED class 2 medical certificates should be added.</p> <p>Proposal: Amend MED.D.015 (a): '.../... for the issue, revalidation or renewal of class 2 medical certificates according to this Part over a period .../...</p>
response	<p><i>Partially accepted</i></p> <p>Amendments have been applied taking this comment into account.</p>
comment	<p>164</p> <p>comment by: <i>Swedish Transport Agency, Civil Aviation Department (Transportstyrelsen, Luftfartsavdelningen)</i></p> <p>Section: MED.D.015 (b)</p> <p>Comment: In CRD ATCO.MED the corresponding subparagraph has been amended to require an applicant to 'have successfully completed' a training course. The same wording should be used in MED.D.015 (b).</p> <p>Proposal: Amend MED.D.015 (b): 'have successfully completed an advanced training course in aviation medicine; and</p>
response	<p><i>Accepted</i></p> <p>The text has been amended accordingly.</p>



comment	181	comment by: <i>Direction de l'Aviation Civile Luxembourg</i>
	<ul style="list-style-type: none"> • Agree with the all the propositions of modification of NPA 2013-15, except MED.D.015. • Disagree with MED.D.015: requirement for the extension of privileges, paragraph (c), which mentions: "undergone practical training at an AeMC, or under supervision of the licensing authority". It is evident that problems remain on how to expand the privilege of an AME class 2 to the privilege of an AME class 1. The idea of EASA that the AME has to do practical training at an AeMC will be difficult or impossible to do in a small country like Luxembourg. Our AeMC only performs between 300 and 400 aeromedical examinations per year, and there is no academic training in medicine (including aeromedical training) at the University of Luxembourg. This AeMC has not enough resources to do the training and it is a fact that afterwards, the different AMEs class 1 will be in competition. Our proposition is to delete the practical training at an AeMC for the extension of privileges, or to mention that the practical training at an AeMC should be done in a country that offers an academic training in aviation medicine. 	
response	<p><i>Noted</i></p> <p>See response to comment No 24.</p>	
comment	238	comment by: <i>ENAC Aeromedical Section-Italy</i>
	<p>Clarification is needed about the request of training in an AeMC for AMEs that intend to expand their privileges from Class 2 to Class 1. The duration of the training need to be standardised among States and it has to be considered that in many States AeMC are too small or have not enough resources or accepting AMEs for training is an additional burden. The suggestion is to include the practical training required in MED.D.015(c) into the advanced training course program.</p>	
response	<p><i>Noted</i></p> <p>See response to comment No 24.</p>	
comment	240	comment by: <i>ENAC Aeromedical Section-Italy</i>
	<p>The philosophy of the new text in proposed MED.D.010 (a) should be also put in MED.D.015 (b).</p> <p>In many country medical doctors working for years in civil or military aviation have very huge curricula in aviation medicine and/or pilot medical certification, in some cases, having been appointed for years (i.e.) in the position of Head of AeMCs well before the entry into force of EU Regulations n.1178/2011 and n.290/2012.</p> <p>At discretion of the Licensing Authority a training on regulation and procedures could be asked to the candidate if needed.</p> <p>The suggested MED.D.015 (b) text is: "have undertaken an advanced training course in aviation medicine, or have other evidence of equivalent training or experience, and:".</p>	
response	<p><i>Not accepted</i></p> <p>For harmonisation reasons, all AMEs applicants for an AME certificate extending their</p>	



privileges should follow the advanced training course as laid down in the AMC to Subpart D.

3 Proposed amendments — 3.1 Draft Regulation (Draft EASA Opinion) — ANNEX IV — [PART-MED] — SUBPART D — AERO-MEDICAL EXAMINERS (AME), GENERAL MEDICAL PRACTITIONERS (GMP), OCCUPATIONAL HEALTH MEDICAL PRACTITIONERS (OHMP) — SECTION 1 — Aero-Medical Examiners — MED.D.025 Changes to the AME certificate

p. 46

comment

165

comment by: *Swedish Transport Agency, Civil Aviation Department
(Transportstyrelsen, Luftfartsavdelningen)*

Section: [MED.D.025 \(a\)](#)

Comment:

The corresponding subparagraph in CRD ATCO.MED has been amended for clarification, changing the word 'changes' to 'circumstances'.
The same wording should be used in MED.D.025.

Proposal:

Amend MED.D.025 (a):

'AMEs shall notify the competent authority of the following circumstances which could affect their certificate: .../...'

response

Accepted

The text has been amended accordingly.

3 Proposed amendments — 3.1 Draft Regulation (Draft EASA Opinion) — ANNEX IV — [PART-MED] — SUBPART D — AERO-MEDICAL EXAMINERS (AME), GENERAL MEDICAL PRACTITIONERS (GMP), OCCUPATIONAL HEALTH MEDICAL PRACTITIONERS (OHMP) — SECTION 2 — General Medical Practitioners (GMPs) — MED.D.035 Requirements for general medical practitioners

p. 47

comment

82

comment by: *The Norwegian Air Sports Federation*

MED.D.035 (new a)

The conditions for GMPs to act as AMEs should be clarified to avoid that doubt is raised as to whether this can be allowed in Member States where GMPs don't have automatic access to the full and entire medical records of the applicants. It is extremely difficult, if at all possible, for a GMP to have access to a patient's "full medical records". To our knowledge, only the UK can currently satisfy this requirement, and then only if the person in question has exclusively visited GMPs and other medical personnel connected to NHS UK's medical record system throughout their entire life. The result is that in countries like Norway, where it is currently



possible to visit a GMP to perform a medical examination for a national sailplane or balloon license, pilots may be barred from continuing this practice from April 8th 2015 onwards, when Part-FCL will enter into force for this segment of air sports. In turn, this will mean reduced activity, defeating the objective of the new legislation.

Instead, the NLF would like to suggest that GMPs performing examinations of pilots need to be the current "personal GMP*" for the patient, and that the pilot needs to grant the GMP access to the medical records of the patient also from previous "personal GMPs", in case the patient has recently changed his or her GMP. To make such an arrangement practical, a time limit should be set for access to the records (for instance three or five years).

*) "Personal GMP" is a concept practiced in Norway and other states, where each citizen by law has an assigned GMP at all times. Each individual is free to change GMPs within certain boundaries, but the change is traceable and recorded at a central database. Through this mechanism, rather complete medical records will be available.

NLF believes this methodology could have a safety benefit, as GMPs are the closest to know their patients and their medical limitations. At the same time, medical examinations will be less costly and more accessible.

response *Not accepted*

According to MED.D.035(a) in the NPA, GMPs are only allowed to perform LAPL aero-medical examinations if they have access to the full medical records of the applicant. The concept of a 'personal GMP' only applies in certain EASA Member States and, therefore, would not allow GMPs to perform LAPL medical certificate examinations in all EASA Member States.

comment 245

comment by: *René Meier, Europe Air Sports*

MED.D.035

Requirements for general medical practitioners (GMP)

Europe Air Sports and EPFU propose to optimise the provisions as regards the requirements for GMP to the greatest possible extent, always considering national legislation.

Rationale:

We do not necessarily think that an absolutely level playing field must be created, national variations are justified, they developed during decades, forced uniformity does in no way increase safety. It is an urgent need to keep costs as low as possible to maintain the number of pilot licence holders on the one hand, on the other we understand the a GMP should be in regular contact with a minimum number of pilots every year.

Requirements for GMP are, however, not the appropriate vehicle to propose changes to national health systems.

response *Not accepted*

No change has been made, as the provision neither implies, nor is it the intention to propose changes to, national health systems. The requirements are there mainly to ensure that the GMPs have access to the full medical records of applicants and that they have notified the competent authority before starting to act as AMEs for issuing LAPL medical certificates.



3 Proposed amendments — 3.1 Draft Regulation (Draft EASA Opinion) — ANNEX IV — [PART-MED] — SUBPART D — AERO-MEDICAL EXAMINERS (AME), GENERAL MEDICAL PRACTITIONERS (GMP), OCCUPATIONAL HEALTH MEDICAL PRACTITIONERS (OHMP) — SECTION 3 — Occupational Health Medical Practitioners (OHMP) — MED.D.040 Requirements for occupational health medical practitioners

p. 47

comment 193

comment by: Jörg SIEDENBURG

When OHMPs have been introduced for conducting cabin crew medical assessments this was done under the pre-condition that sufficient knowledge about aero-medical issues is acquired beforehand (e.g. a 3 day course instead 120 hours as for Class 1 AMEs). By reducing this requirement to just 1 or 2 hours within a course covering the whole occupational medicine (which is the result of the proposed change according to this NPA) results in conducting examinations without proper background knowledge. OHMPs are primarily trained to conduct examinations with the background of occupational health. Their scope is the health of the working individual. A licensing examination is quite different and has a much different scope, i.e. occupational health. Furthermore, these differences are the background of the relevant European legislation discouraging the combination of occupational health examinations with licensing examinations, because both have different approaches. One reason is medical confidentiality. Therefore, the possible background of saving cost by imposing these changes is not relevant especially when discussing safety issues. As flight attendants are covered by this regulations because of their role in aviation safety and not to standardise their occupational health coverage the proposed change should be rejected.

response *Not accepted*

According to the Basic Regulation, cabin crew members shall be periodically assessed for medical fitness to safely exercise their assigned safety duties. This assessment is to be based on aero-medical best practice. No specific criteria for who should conduct the assessments are included. Acceptance of the principle of allowing OHMPs to conduct aero-medical assessments was indicated when the Part-MED Opinion was adopted. OHMPs may only conduct aero-medical assessments of cabin crew if the in-flight working environment, and safety duties of the cabin crew were included in their occupational medicine qualification syllabus, or other training or operational experience.

No significant changes to the rules on the OHMP's knowledge of aviation medicine were proposed in the NPA. The current applicable rules require the OHMP to have acquired knowledge in aviation medicine as relevant to the operating environment of cabin crew. There was no intention to change this requirement in the text proposals in the NPA.

3 Proposed amendments — 3.2 Draft Acceptable Means of Compliance and Guidance Material (Draft EASA Decision) — AMC/GM to PART-MEDICAL — SUBPART A — General requirements — Section 1 — General — AMC1 MED.A.020 Decrease in medical fitness

p. 48



comment	<p>48 comment by: <i>Swiss International Airlines / Bruno Pfister</i></p> <p>Comment by the Head of Medical Services, SWISS Intl. Air Lines Ltd Concerning GM1 MED A.020: We believe the new chapter on medication which is meant as guidance material is misleading primarily for the following reasons:</p> <ul style="list-style-type: none"> · - General and compact information can easily lead to wrong conclusions (e.g. “ most of the anti-malaria drugs are compatible with flying duties”) · - guidelines may quickly become obsolete as continuous pharmacologic developments and modified release formulations can lead to longer pharmacologic activity/side effects (e.g. erectile dysfunction medication) <p>Thus, concerning the use of medication, the former statement in chapter AMC1 MED A. 020 “holders of class 1 or 2 medical certificates should seek advice of an AeMC or MAE” is more effective as it generally implies the consultation with an AME to evaluate the underlying cause and appropriate treatment.</p>
response	<p><i>Not accepted</i></p> <p>The GM was already in place under the JAR system and was provided to reduce the number of unnecessary calls to the AME/AeMC. It was not included in the initial issue of Part-MED, but comments received indicated that it was needed. It was, therefore, reviewed and updated and introduced in the NPA.</p> <p>On the use of medication, the former statement in AMC1 MED A.020; ‘holders of class 1 or 2 medical certificates should seek advice of an AeMC or AME’ was deleted in the NPA because it was a duplicate of an Implementing Rule, i.e. MED.A.020(c).</p>

3 Proposed amendments — 3.2 Draft Acceptable Means of Compliance and Guidance Material (Draft EASA Decision) — AMC/GM to PART-MEDICAL — SUBPART A — General requirements — p. 48-51
Section 1 — General — GM1 MED.A.020 Decrease in medical fitness

comment	<p>61 comment by: <i>Federal Office of Civil Aviation FOCA</i></p> <p>GM1.MED.A.020 par. (d) (13): FOCA suggests to delete following passage: "If the level of blood pressure is such that drug therapy is required, the pilot should be temporarily grounded and monitored for any side effects. Any treatment instituted should, therefore, be discussed with the AME, AeMC, GMP, OHMP or Medical Assessor as applicable (see MED.B.010(j))."</p> <p>Justification: A change of medication or a change of the dosage of a given medication in hypertensive patients occur frequently. The proposed text leads to an unacceptable burden of work for AME and/or aeromedical authorities.</p>
response	<p><i>Not accepted</i></p> <p>This GM suggests that consultation with the AME is needed when drug therapy is first used. During this consultation, the AME, etc. is expected to establish the need for further consultations in case of a change to the medication or dosage.</p>

comment	<p data-bbox="363 237 411 271">104</p> <p data-bbox="1050 237 1498 271" style="text-align: right;">comment by: AeMC, Toulon, France</p> <p data-bbox="363 331 1498 555">In our opinion, concerning the sleeping tablets, the mention « this medication should be avoided at least the night before duty » is too much restrictive. Indeed, in our practice, we emphasize the importance of trying for the first time these medications during grounding time to verify tolerance and to observe a minimal period of 6 hours before duty. More over, in many times, pilots use them the night before duty to ensure a « good » night in bad conditions.</p>
response	<p data-bbox="363 566 579 600"><i>Partially accepted</i></p> <p data-bbox="363 622 1498 846">The text has been amended to avoid expressions such as 'night before duty' as well as quoting a number of hours, because the effect and duration of the effect varies from individual to individual. Indeed, it is difficult to decide on an appropriate number of hours before flying duties, as shown through the comments on this NPA, i.e. 8 hours proposed by one commentator and 6 hours proposed by another commentator. The important point retained is that expert aero-medical advice should be obtained by aircrew.</p>
comment	<p data-bbox="363 891 411 925">226</p> <p data-bbox="699 891 1498 925" style="text-align: right;">comment by: French main military Aeromedical Centre (CEMPN)</p> <p data-bbox="363 981 1498 1238">This part about medications is useful and well structured. We agree with all this GM except for two comments: (17) Some sleeping tablet medications present a very short duration of action and elimination, so that aeromedical examiners can advise pilots to use them the night before duty on the morning, as far as there is a period of 8 hours without any flying activities. (18) It should be added that Melatonin should not be recommended by aeromedical examiners for the reasons developed and the doubtful source of many molecules.</p>
response	<p data-bbox="363 1249 579 1283"><i>Partially accepted</i></p> <p data-bbox="363 1305 1498 1373">The support for this GM by the French main military Aeromedical Centre is noted by the Agency.</p> <p data-bbox="363 1395 1498 1641">Regarding the comment to subparagraph 17 in the NPA: The text has been amended to avoid expressions such as 'night before duty' as well as quoting a number of hours, because the effect and duration of the effect varies from individual to individual. Indeed, it is difficult to decide on an appropriate number of hours before flying duties, as shown through the comments on this NPA, i.e. 8 hours proposed by one commentator and 6 hours proposed by another commentator. The important point retained is that expert aero-medical advice should be obtained by the affected aircrew.</p> <p data-bbox="363 1664 1498 1888">Regarding the comment to subparagraph 18 in the NPA: Although the point about AMEs not recommending melatonin is well-taken, this has not been added to the text, because the GM is primarily for aircrew rather than a point of reference for AMEs. In addition, it would mean that such recommendations would need to be considered for other medications. In other words, it would set a precedent. Once more, the important point retained is that expert aero-medical advice should be obtained by aircrew.</p>
comment	<p data-bbox="363 1933 411 1966">269</p> <p data-bbox="1225 1933 1498 1966" style="text-align: right;">comment by: UK CAA</p>



	<p>Page No: 49 Paragraph No: GM1 MED.A.020 (d) (1) Comment: The list of antibiotics is not necessary and may confuse. Justification: The list of antibiotics is unhelpful e.g. 'gyrase inhibitors' is not a term used in the UK. Proposed Text: 'Antibiotics. Various Penicillins, Tetracyclines, macrolides, gyrase inhibitors and others may have short term or delayed side effects which can affect pilot or cabin crew performance. ...'</p>
response	<p><i>Accepted</i></p> <p>The text has been amended accordingly.</p>
comment	<p>270 comment by: UK CAA</p>
	<p>Page No: 49 Paragraph No: GM1 MED.A.020 (d) (2) Comment: Editorial. Justification: Spelling error. Proposed Text: 'atovagquone'</p>
response	<p><i>Accepted</i></p> <p>The text has been corrected accordingly.</p>
comment	<p>271 comment by: UK CAA</p>
	<p>Page No: 49 Paragraph No: GM1 MED.A.020 (d) (5) Comment: Clobutinol and Oxeladin should not be permitted. Justification: Neither of these medications are available in UK. Clobutinol has been banned in Germany and possibly other EU States. Oxeladin may be carcinogenic. Proposed Text: Delete whole paragraph and substitute with: 'Nasal decongestants are normally incompatible with flying duties due to the underlying condition. Aeromedical advice should be sought.'</p>
response	<p><i>Accepted</i></p> <p>The subparagraph has been reworded taking the comment into account.</p>
comment	<p>272 comment by: UK CAA</p>
	<p>Page No: 49 Paragraph No: GM1 MED.A.020 (d) (7) Comment: Reference to anti-headache medication should be removed. Substitute 'medication' for 'drugs' for consistency. Justification: Anti-headache treatment could include migraine medication. If this is to be addressed it needs to be in a separate paragraph and to include mention of e.g. triptans. Proposed Text: 'Painkillers, and antifebrile and anti-headache drugs, medication.'</p>



response

Accepted

The subparagraph has been reworded taking the comment into account.

comment

273

comment by: UK CAA

Page No: 49**Paragraph No:** GM1 MED.A.020 (d) (7)**Comment:** Text needs to be rearranged to be correct.**Justification:** Paracetamol is not a NSAID.**Proposed Text:** '... **Paracetamol and** the Non-Steroidal Anti-inflammatory Drugs (NSAIDs) (e.g. **aspirin and ibuprofen**), commonly used to treat pain, fever and headache, may be compatible with flying duties (~~paracetamol, aspirin, ibuprofen~~). However ...'

response

Accepted

The subparagraph has been reworded taking the comment into account.

comment

274

comment by: UK CAA

Page No: 49**Paragraph No:** GM1 MED.A.020 (d) (8)**Comment:** The term 'antacids' is not correct.**Justification:** The term 'antacids' is not a generic term for anti-ulcer medicines.**Proposed Text:** Remove (~~Antacids~~).

response

Accepted

The text has been amended accordingly.

comment

275

comment by: UK CAA

Page No: 49/50**Paragraph No:** GM1 MED.A.020 (d) (13)**Comment:** The sentence about intellectual performance should be removed. Most anti-hypertensives are compatible with flying and cardiovascular reflex changes do not need to be mentioned in guidance.**Justification:** Anti-hypertensives are not characterised as causing decreased intellectual performance.**Proposed Text:**

'High blood pressure medication. Antihypertensive drugs are compatible with flying duties only after consultation with the AME, AeMC, GMP, OHMP or Medical Assessor as applicable. ~~as some of these drugs can cause a change in the normal cardiovascular reflexes and impair intellectual performance which can seriously affect flight safety.~~ If the level of blood pressure is such that drug therapy is required, the pilot should be temporarily grounded and monitored for any side effects. Any treatment instituted should, therefore, be discussed with the AME, AeMC, GMP, OHMP or Medical Assessor as applicable (see MED.B.010(j)).'



response

Accepted

The subparagraph has been reworded taking the comment into account.

comment

276

comment by: UK CAA

Page No: 50**Paragraph No:** GM1 MED.A.020 (d) (14)**Comment:** The reference to anti-cholinergics and aerosols need to be changed.**Justification:** Anticholinergics are not usually compatible with flying duties. It is usually only appropriate for acute, severe, attacks. Powder forms of medication may be used as well as aerosols.**Proposed Text:**

'... The use of respiratory aerosols **or powders**, such as corticosteroids, beta-2-agonists, **or** chromoglycic acid ~~or anticholinergic drugs in low dose~~ may be compatible with flying duties. However ...'

response

Accepted

The text has been amended accordingly.

comment

277

comment by: UK CAA

Page No: 50**Paragraph No:** GM1 MED.A.020 (d) (15)**Comment:** UK CAA suggests that this section is moved to Paragraph 7.**Justification:** Analgesics are covered in Paragraph 7.**Proposed Text:** Keep text but move to paragraph 7.

response

Accepted

The text has been moved accordingly, with the addition of a reference to codeine.

comment

278

comment by: UK CAA

Page No: 50**Paragraph No:** GM1 MED.A.020 (d) (16)**Comment:** The reference contained in the paragraph is incorrect.**Justification:** Editorial**Proposed Text:** 'MED.B.0505'

response

Accepted

The text has been amended accordingly.

comment

279

comment by: UK CAA



	<p>Page No: 50 Paragraph No: GM1 MED.A.020 (d) (17) Comment: It is not always appropriate to avoid taking a hypnotic in the night before a duty period. Justification: Hypnotics used under aeromedical supervision may be prescribed for use the night before a duty period. Proposed Text: ‘...This medication should be avoided at least the night before duty, and Expert aero-medical advice should be obtained before using them.’</p>
response	<p><i>Accepted</i></p> <p>The text has been amended accordingly.</p>

comment	280	comment by: UK CAA
	<p>Page No: 50 Paragraph No: GM1 MED.A.020 (d) (19) Comment: The text as written is misleading. Justification: Caffeine is not usually referred to as a ‘pep pill’. The penultimate sentence is inappropriate in guidance on medication and the last sentence is not evidence based. The reference is incorrect. Proposed Text: ‘Stimulants. Caffeine pills, amphetamines, and other stimulant medication etc. (often known as ‘pep’ pills) used to maintain wakefulness or suppress appetite, are often habit forming. Susceptibility to different stimulants varies from one individual to another, and all may cause dangerous overconfidence. Overdosage causes headaches, dizziness and mental disturbance. The use of stimulant medication (or ‘pep’ pills) is not permitted while flying. Where coffee intake does not offer sufficient stimulation, then an individual is not fit to fly. Remember that excessive coffee drinking has harmful effects including disturbance of the heart’s rhythm (see MED.B.055(b)).’</p>	
response	<p><i>Accepted</i></p> <p>The subparagraph has been reworded taking the comment into account.</p>	

<p>3 Proposed amendments — 3.2 Draft Acceptable Means of Compliance and Guidance Material (Draft EASA Decision) — AMC/GM to PART-MEDICAL — SUBPART A — General requirements — Section 1 — General — AMC1 MED.A.025 Obligations of AeMC, AME, GMP and OHMP</p>	p. 51
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comment	281	comment by: UK CAA
	<p>Page No: 51 Paragraph No: AMC1 MED.A.025 (d) Comment: This sentence incorrectly implies that the AME may advise the applicant on which treatment to take/use. This is not the remit of the AME and may be contrary to good medical practice in individual States (including the UK) where this is the role of the applicant’s family physician / specialist. Clarification is required. Justification: AMEs are competent to give aeromedical advice but are not the primary carers</p>	



of the applicant.

Proposed Text: 'The AeMC, AME, GMP or OHMP should give **aeromedical** advice to the applicant on treatment and preventive measures. If, during the course of the examination, medical conditions are found which may endanger the medical fitness of the applicant in the future, **the applicant should be referred to their family physician or specialist as appropriate.**'

response *Not accepted*

The subparagraph on advice to the applicant was introduced in the NPA to reflect the philosophy in ICAO Doc 8984 of taking the opportunity to engage in discussions about important health-related issues and to encourage interventions which may prevent future deterioration of health.

The advice given on treatment and preventive measures could include lifestyle improvements as well recommending that the applicant follows-up on certain issues with their general practitioner.

No change has been made to the NPA text.

3 Proposed amendments — 3.2 Draft Acceptable Means of Compliance and Guidance Material (Draft EASA Decision) — AMC/GM to PART-MEDICAL — SUBPART A — General requirements — p. 51-52 Section 1 — General — GM1 MED.A.025 Obligations of AeMC, AME, GMP and OHMP

comment

31

comment by: AECA(SPAIN)

GM1 MED.A.025
First sentence
OHMP not included when it is in the title

response

Not accepted

The title of the GM correctly reflects that of the associated rule. However, the GM subheading indicates that the scope of this GM excludes OHMP. GM for the OHMP may be considered in a future rulemaking task.

comment

282

comment by: UK CAA

Page No: 51 and 52
Paragraph No: GM1 MED.A.025
Comment: The text needs to be amended to apply only to AeMCs and AMEs.
Justification: The process is not applicable to GMPs.
Proposed Text: Remove any reference to GMP throughout this section.

response

Not accepted

GMPs need to comply with the GM where relevant for the LAPL.



3 Proposed amendments — 3.2 Draft Acceptable Means of Compliance and Guidance Material (Draft EASA Decision) — AMC/GM to PART-MEDICAL — SUBPART A — General requirements — Section 2 — Requirements for medical certificates — AMC1 MED.A.045 Validity, revalidation and renewal of medical certificates

p. 53

comment

170 comment by: *Swedish Transport Agency, Civil Aviation Department (Transportstyrelsen, Luftfartsavdelningen)*

Section: [AMC1 MED.A.045](#)

Comment:

The subject is already covered by MED.A.045 (a)(5). The AMC should be deleted as has been done in CRD ATCO.MED.

Proposal:

Delete AMC1 MED.A.045

response

Accepted

AMC1 MED.A.045 has been deleted as it is already covered in (a)(5) of the Implementing Rule.

3 Proposed amendments — 3.2 Draft Acceptable Means of Compliance and Guidance Material (Draft EASA Decision) — AMC/GM to PART-MEDICAL — SUBPART B — Specific requirements for class 1, class 2 and LAPL medical certificates - AMC for class 1, class 2 and LAPL medical certificates — Section 1 — General — AMC1 MED.B.001 Limitations to class 1, class 2 and LAPL medical certificates

p. 54

comment

25

comment by: *Federal Office of Civil Aviation FOCA*

AMC1 MED.B.001 d (1) (new numbering): VDL, VML, VNL and TML should be allowed to be removed not only by the licensing authority, but also by AeMC and AMEs.

response

Not accepted

A change of this magnitude would need to be properly consulted, for example through NPA consultation. It could, however, be considered in a future rulemaking task if supported by detailed justification.

comment

172

comment by: *Swedish Transport Agency, Civil Aviation Department (Transportstyrelsen, Luftfartsavdelningen)*



response	<p>Section: AMC1 MED.B.001</p> <p>Comment: AMC1 ATCO.MED.B.001 has been amended to give permit AeMCs and AMEs to entry also the limitations CCL, HAL, and RXO. This possibility should also be given to the AeMCs and AMEs regarding pilots.</p> <p>Proposal: Amend AMC1 MED.B.001 (c)(1): 'The limitations TML, VDL, VML,VNL,VCL, CCL, HAL, and RXO may be imposed by an AME or an AeMC for class 1, class 2, and LAPL medical certificates, or a GMP for LAPL medical certificates.'</p> <p><i>Not accepted</i></p> <p>A change of this magnitude would need to be properly consulted, for example through NPA consultation. It could, however, be considered in a future rulemaking task if supported by detailed justification.</p>
comment	<p>32 comment by: UK CAA</p> <p>Page No: 54 Paragraph No: AMC1 MED.B.001 (b) Comment: A GMP would not undertake an accredited medical conclusion or be involved in making an aeromedical judgement based on external reports and should not be included in this AMC. Justification: The process is not applicable to GMPs. Proposed Text: 'In cases where a fit assessment may only be considered with a limitation, the AeMC, AME, GMP or the licensing authority should evaluate the medical condition of the applicant in consultation with flight operations and other experts, if necessary.'</p>
response	<p><i>Not accepted</i></p> <p>According to MED.B.001(b)(1), if a GMP, after due consideration of the applicant's medical history, concludes that the applicant does not fully meet the requirements for medical fitness, the GMP shall refer the applicant to an AeMC or AME, except those requiring a limitation related only to the use of corrective lenses or to the period of validity of the medical certificate.</p> <p>Therefore, the NPA text has not been changed.</p>
comment	<p>284 comment by: UK CAA</p> <p>Page No: 54 Paragraph No: AMC1 MED.B.001 (c) Comment: UK CAA suggests the title should be amended. Justification: To improve clarity and appropriateness. Proposed Text: 'Entry Initial application of limitations'</p>



response *Accepted*

The text has been amended accordingly.

3 Proposed amendments — 3.2 Draft Acceptable Means of Compliance and Guidance Material (Draft EASA Decision) — AMC/GM to PART-MEDICAL — SUBPART B — Specific requirements for class 1, class 2 and LAPL medical certificates - AMC for class 1, class 2 and LAPL medical certificates — Section 1 — General — AMC2 MED.B.001 Limitations to medical certificates

p. 55-57

comment 26

comment by: *Federal Office of Civil Aviation FOCA*

AMC2 MED.B.001: FOCA suggests to replace following limitation definitions:
 replace "VDL Correction for defective distant vision" with "VDL Holder must wear corrective lenses". Reasoning: This definition is printed on the medical certificate and should advise the pilot on his obligations. The same (or similar) wording is also used by the FAA. The abbreviations VDL/VML/SIC etc. must be explained and be clear for pilots. Use former text from IEM FCL3.100c.
 replace "VNL Correction for defective near vision" by "VNL Holder must have available corrective lenses for near vision"
 replace "CCL Correction by means of contact lenses" by "CCL Holder must wear contact lenses"
 replace "RXO Specialist ophthalmological examinations" by "RXO Specialist ophthalmological examinations requested"
 replace "SIC Specific medical examination(s)" by "SIC Specific medical examinations requested"
 replace "HAL Hearing aids" by "HAL Hearing aids must be worn"

response *Accepted*

The limitation table in subparagraph (a) has been reworded taking the comment into account.

comment 32

comment by: *AECA(SPAIN)*

Paragraph 10 APL Prothesis or prostheses.
 These two words mean the same (one singular and one plural). We think there may be a confusion with 'orthosis' of which is not reference in limitation.
orthosis: an orthopedic appliance or apparatus used to support, align, prevent, or correct deformities or to improve function of movable parts of the body.

response *Accepted*

To avoid any misunderstanding, the reference to prostheses (plural of prothesis) has been deleted.

comment 173

comment by: *Swedish Transport Agency, Civil Aviation Department*



(Transportstyrelsen, Luftfartsavdelningen)

Section: [AMC2 MED.B.001 \(b\)](#)**Comment:**

[AMC1 ATCO.MED.B.001](#) has been amended to give more clarity to the explanations of limitation codes. The limitation codes in question are common to Part-MED for aircrew and ATCO.MED and need to have the same explanation.

Proposal:

Amend AMC2 MED.B.001 (b)

(2) VDL ‘.../... A spare set of spectacles as approved by the AeMC, AME or GMP, should be readily available

(7) RXO ‘Specialist ophthalmological examination(s), other than the examinations stipulated in this Part, are required .../...’

(8) SIC delete ‘contact licensing authority’

(9) HAL ‘.../... as examined and approved by the AeMC or AME. A spare set of batteries should be available.’

(17) SSL delete ‘Refer to MED.B.001 (d)(4).’

response *Partially accepted*

The text has been amended taking the comment into account.

comment 194

comment by: Jörg SIEDENBURG

(3)

VML Wear multifocal spectacles and carry a spare set of spectacles

Correction for defective distant, intermediate and near vision: whilst exercising the privileges of the licence, the holder of the medical certificate should wear spectacles that correct for defective distant, intermediate and near vision as examined and approved by the AeMC, AME or GMP. ~~Contact lenses or full frame spectacles, when either correct for near vision only, may not be worn.~~ **Contact lenses or full frame spectacles may not be worn if one glass corrects for distant and the other for near vision.**

The original expression remains somehow unclear. Only with some exegesis it may or may not become clear what the intention of the sentence is. The proposed change creates more clarity.

response *Not accepted*

If the pilot needs correction for defective distant, intermediate and near vision, only full frame spectacles can be used, as only multifocal contact lenses are not permitted. If correction for defective distant, intermediate and near vision is needed, contact lenses and full frame spectacles for correction for near vision only are not permitted. The text in the NPA indicates this.

comment 195

comment by: Jörg SIEDENBURG



	<p>(4) VNL Have available corrective spectacles and carry a spare set of spectacles Correction for defective near vision: whilst exercising the privileges of the licence, the holder of the medical certificate should have readily available spectacles that correct for defective near vision as examined and approved by the AeMC, AME or GMP. Contact lenses or full frame spectacles, when either correct for near vision only, may not be worn. Contact lenses or full frame spectacles may not be worn if one glass corrects for distant and the other for near vision. The original expression remains somehow unclear. Only with some exegesis it may or may not become clear what the intention of the sentence is. The proposed change creates more clarity.</p>
response	<p><i>Not accepted</i></p> <p>If the pilot needs correction for defective near vision only, contact lenses and full frame spectacles are not permitted. The text in the NPA indicates this.</p>
comment	<p>227 comment by: French main military Aeromedical Center (CEMPN)</p> <p>(a) The OPL limitation poses an ethical problem to be applied and so should be deleted. (b) (7) We agree to let the AME or AeMC remove the RXO limitation.</p>
response	<p><u>First comment in this field</u></p> <p><i>Accepted</i></p> <p>A new limitation, encoded 'ORL' (Operating pilot Restriction Limitation), has been introduced to allow a class 2 or LAPL medical certificate holder to apply either an OSL or an Operational Passenger Limitation (OPL). In other words, if passengers are carried, an OSL applies.</p> <p><u>Second comment in this field</u></p> <p><i>Noted</i></p> <p>However, the deletion of the 'limitation may be applied by an AME but should only be removed by the licensing authority' in (b)(7) of AMC2 MED.B.001 does not imply that the AME or AeMC may remove the RXO limitation. Subparagraph (d) of AMC1 MED.B.001 applies.</p>
comment	<p>285 comment by: UK CAA</p> <p>Page No: 55 Paragraph No: AMC 2 MED.B.001 (a) Code SIC Comment: The requirement to contact the Licensing Authority should not be removed from the limitation code description. Justification: The text should mention the need to contact the Licensing Authority to remind AMEs to do this. Proposed Text: 'Specific medical examination(s) – contact licensing authority.'</p>
response	<p><i>Not accepted</i></p> <p>As the medical documents go to the new licensing authority if there is a change of state of</p>



licence issue, there is no need to add 'contact the licensing authority' as a reminder, as the licensing authority will anyway identify the need for specific regular medical examinations. Therefore, it is not needed on the medical certificate, as indicated in subparagraph (a). Nevertheless, it still remains under (b)(8) for the explanation to be given to the holder of a medical certificate.

comment

286

comment by: UK CAA

Page No: 56**Paragraph No:** AMC 2 MED.B.001 (b) (6)**Comment:** A VCL should not be limited to Class 2 or LAPL.**Justification:** Occasionally a VCL needs to be applied to a Class 1 certificate for flying instruction or aerial work.**Proposed Text:** 'The limitation allows holders of a **Class 1**, Class 2 or LAPL medical certificate with varying degrees of colour deficiency, to exercise the privileges of their licence by daytime only.'

response

Not accepted

A change of this magnitude would need to be properly consulted, for example through NPA consultation. It could, however, be considered in a future rulemaking task if supported by detailed risk assessment data and justification. However, it should be noted that paragraph 6.2.4.4 of ICAO Annex 1 allows this alleviation for class 2 only, i.e. not class 1.

comment

287

comment by: UK CAA

Page No: 57**Paragraph No:** AMC2 MED.B.001 (b) 15**Comment:** The pilot should not determine the acceptable level of risk.**Justification:** This risk may be acceptable to the pilot but not the Authority.**Proposed Text:** 'OPL **Valid only** without passengers

This limitation applies to holders of a class 2 or LAPL medical certificate with a medical condition that may lead to an increased level of risk to flight safety when exercising the privileges of the licence. This **limitation is to be applied when this risk might be acceptable to the pilot but** is not acceptable for the carriage of passengers. Refer to MED.B.001 (d)(3).'

response

Accepted

The text has been amended accordingly.

comment

288

comment by: UK CAA

Page No: 57**Paragraph No:** AMC2 to MED.B.001(b)**Comment:** As discussed at the Medical Expert Group in Feb 2013, there is a need for a limitation for Class 2 and LAPL privileges that combines the limitations OSL and OPL.**Justification:** A combined limitation is appropriate where there is equivalent risk mitigation with use of either limitation.

Proposed Text: Insert new subparagraph 16 shown below and renumber subsequent paragraphs
‘ORL Valid only with safety pilot and in aircraft with dual controls, or solo without passengers.
This limitation may be considered when a pilot with a medical condition, may involve an increased element of risk to flight safety which is acceptable for single pilot operations but not acceptable for the carriage of passengers unless a safety pilot is carried. A safety pilot is qualified as PIC on the class/type of aircraft and rated for the flight conditions. He/she occupies a control seat, is aware of the type(s) of possible incapacity that the pilot whose medical certificate has been issued with this limitation may suffer and is prepared to take over the aircraft controls during flight.
Applicable to class 2 and LAPL medical certificates only.’

response

Partially accepted

A new limitation, encoded ‘ORL’ (Operating pilot Restriction Limitation) has been introduced (new (d)(4)) to allow a class 2 or LAPL medical certificate holder to apply either an Operational Safety Pilot Limitation (OSL) or an Operational Passenger Limitation (OPL). In other words, if passengers are carried, an OSL will apply.

3 Proposed amendments — 3.2 Draft Acceptable Means of Compliance and Guidance Material (Draft EASA Decision) — AMC/GM to PART-MEDICAL — SUBPART B — Specific requirements for class 1, class 2 and LAPL medical certificates - AMC for class 1, class 2 and LAPL medical certificates — Section 2 — Specific requirements for class 1 medical certificates — AMC1 MED.B.010 Cardiovascular system p. 57-64

comment

33

comment by: *AECA(SPAIN)*

Paragraph (c)(2)

Leave the word 'acceptable' to avoid discussions on the concept of what is *appropriate* as it is not defined in regulation.

response

Not accepted

The word ‘appropriate’ is used so that clinicians can decide on the optimal treatment regime for the applicant rather than modifying the treatment regime in order for the applicant to gain certification.

comment

34

comment by: *AECA(SPAIN)*

Paragraph (l)(1)

Leave the word 'recurrent'.

Without it any motion sickness that may occur in a person, in a haphazard manner, for example by seeing blood, would compel the application of the measures outlined in this AMC. It is a bit excessive.

response

Noted



See response to comment No 186.

comment	35	comment by: <i>AECA(SPAIN)</i>
	Paragraph (K)(4) See comment 33	
response	<i>Noted</i> See response to comment No 33.	
comment	36	comment by: <i>AECA(SPAIN)</i>
	Paragraph (K)(4)(i)(A) We believe that paragraph that has been deleted should be kept for security reasons.	
response	<i>Not accepted</i> It is difficult to identify 30 % to 50 % stenosis. It is up to the cardiologist conducting the evaluation to assess the risks indicated by any stenosis.	
comment	62	comment by: <i>Federal Office of Civil Aviation FOCA</i>
	AMC1.MED.B.010 par. (h) (2): FOCA proposes to delete the following text: "No cardioactive medication is acceptable. Investigations may include 2D Doppler echocardiography, exercise ECG and 24-hour ambulatory ECG. The potential hazard of any medication should be considered as part of the assessment. Particular attention should be paid to the potential for the medication to mask the effects of the congenital abnormality before or after surgery." Justification: 1) The term cardioactive medication is generally not common. 2) It does not make sense to give details about examinations. 3) The comment „potential hazard of any medication“ has to be considered in all situations with cardiological diseases; thus this phrase is also redundant.	
response	<i>Not accepted</i> ‘Cardioactive medication’ is defined in medical dictionaries as medication which has an effect on the heart. It is also used elsewhere in Part-MED and no other comments were received indicating that the term should not be used. The details on types of investigations that may be undertaken are provided to inform the pilot of what they might expect. The details on the hazards of medication are included as this is a particular concern due to the potential for the medication to mask the effects of the congenital abnormality before or after surgery. Therefore, no change is made to the NPA text.	
comment	105	comment by: <i>AeMC, Toulon, France</i>
	If the new paragraph concerning aortic stenosis is a real benefit, we proposed to notify « Applicants with an aortic valve orifice of more than 0,6 cm²/m² ... ». This notification may be	



response	<p>helpful in case of very high or very low physical area.</p> <p><i>Accepted</i></p> <p>The text has been amended taking the comment into account.</p>
comment	<p>106 comment by: AeMC, Toulon, France</p> <p>The withdrawal of the term « recurrent » concerning the vasovagal syncope seems too much restrictive. Indeed, in very typical circumstances (for example blood test), the 6 month period without recurrence appears too severe. In the same way, our opinion is the same for the systematic period of 5 years with an OML after a single syncope, whatever the mechanism.</p> <p>Concerning the tilt-test, this exam has got a poor sensitivity and its indication is much more to help the diagnosis (vasovagal mechanism versus more pejorative aetiology) than to show vasomotor instability (which is expected in vasovagal mechanism).</p>
response	<p><u>First comment in this field</u></p> <p><i>Noted</i></p> <p>See response to comment No 186.</p> <p><u>Second comment in this field</u></p> <p><i>Partially accepted</i></p> <p>The experts consulted through the NPA review group appreciated the point made by the commentator questioning the value of the tilt test, but in the absence of an alternative test and without alternative text proposals from the commentator, a prescriptive change was not deemed possible by the Agency. Instead, the possibility for an ‘equivalent’ test has been introduced.</p>
comment	<p>107 comment by: AeMC, Toulon, France</p> <p>Concerning the complete right bundle branch block, we agree the withdrawal of the initial restriction (« fit assessment consider by the licensing authority for applicants, initial applicants with a period of stability of 12 months and OML for 12 months for applicants over age 40 »).</p>
response	<p><i>Noted</i></p> <p>Thank you for your support.</p>
comment	<p>115 comment by: AMCS - Thomas Syburra</p> <p>b-general-1-i: too unspecific e-cardiac valvular abnormalities-2: mild = fit, moderate = OML, severe = unfit</p>
response	<p><u>First comment in this field ‘b-general-1-i’</u></p>



Not accepted

It is not appropriate to regulate to a greater degree of detail. The specialists are expected to refer to suitable medical literature to conduct their evaluation effectively. Furthermore, no additional text is proposed by the commentator.

Second comment in this field 'e-cardiac valvular abnormalities-2'

Not accepted

The requirements already take into account the principle behind the comment regarding severity of the condition and the effect it may have on the risk of incapacitation in flight. In addition, it depends on the clinical situation of the individual, so it cannot be defined as such.

comment	<p>116 comment by: AMCS - Thomas Syburra</p> <p>e-cardiac valvular abnormalities-3-ii: "regular evaluation by a cardiologist <u>is mandatory</u>"</p>
response	<p><i>Not accepted</i></p> <p>To mandate regular evaluation by a cardiologist would need to be an Implementing Rule. However, the 'soft law' status of the acceptable means of compliance means that regular evaluation should take place, unless an alternative means of compliance is proposed, with an equivalent effect.</p>
comment	<p>117 comment by: AMCS - Thomas Syburra</p> <p>4-mitral valve disease-iv: "periodic cardiological review <u>is</u> required"</p> <p>MISSING ITEMS: - Tricuspid valve - Pulmonal valve</p>
response	<p><u>First comment in this field '4-mitral valve disease-iv'</u></p> <p><i>Not accepted</i></p> <p>To mandate periodic cardiological review would need to be in an Implementing Rule. However, the 'soft law' status of the acceptable means of compliance means that periodic cardiological review should take place, unless an alternative means of compliance is proposed, with an equivalent effect. The important element here is that the licensing authority determines this need depending on the individual case.</p> <p><u>Second comment in this field 'missing items - Tricuspid valve and pulmonal valve</u></p> <p><i>Not accepted</i></p> <p>The addition of tricuspid valve and pulmonary valve is not considered to be necessary here as cardiac valvular abnormalities are already covered under (e)(2).</p>
comment	<p>118 comment by: AMCS - Thomas Syburra</p>



	<p>f-valvular surgery-1: missing mention of concomitant left atrial appendage exclusion anymore; should be mentioned and exclusion recommended for reduction in thromboembolic risk (ICAO 2008: "LAA exclusion may be an advantage)</p> <p>f-valvular surgery-2: missing mention of valve type. valve type does matter: pericardial stented valves and stentless valves have better flow profiles under high cardiac output conditions (Kuehnel et al., EJTC 2005;27:450-5), and stentless valves are superior to stented ones regarding myocardial perfusion (Kleine et al., JCTS 2006;131:883-8)</p> <p>f-valvular surgery-3: oral anticoagulation monitoring is not sufficient, needs more values. furthermore the main risk of oral anticoagulation in mechanical prostheses is rather the thromboembolic risk above 1% than the hemorrhagic one.</p>
response	<p><u>First comment in this field 'f-valvular surgery-1'</u></p> <p><i>Not accepted</i></p> <p>It is not appropriate to regulate to this level of detail. The specialists are expected to refer to suitable medical literature to conduct their evaluation effectively.</p> <p><u>Second comment in this field 'f-valvular surgery-2'</u></p> <p><i>Not accepted</i></p> <p>It is not appropriate to regulate to this level of detail. The specialists are expected to consider different valve types and to refer to suitable medical literature to conduct their evaluation.</p> <p><u>Third comment in this field 'f-valvular surgery-3'</u></p> <p><i>Noted</i></p> <p>See response to comment No 289.</p>
comment	<p>119 comment by: AMCS - Thomas Syburra</p> <p>g-thromboembolic disorders: oral anticoagulation regimen too loosely monitored g-thromboembolic disorders: fit assessment OML only if no evidence of pulmonary hypertension</p>
response	<p><u>First comment in this field 'thromboembolic disorders'</u></p> <p><i>Noted</i></p> <p>See response to comment No 289.</p> <p><u>Second comment in this field 'thromboembolic disorders'</u></p> <p><i>Not accepted</i></p> <p>It is not appropriate to regulate to this level of detail. The specialists are expected to refer to suitable medical literature to conduct their evaluation effectively.</p>
comment	<p>120 comment by: AMCS - Thomas Syburra</p> <p>h-other cardiac disorders-2: investigations shall include cardiac MRI and/or CT angiogram</p>

response *Not accepted*

The text as it stands does not prevent the use of cardiac MRI and/or CT angiogram for the evaluation.

comment **121** comment by: AMCS - Thomas Syburra

i-syncope-2: define protocol, state about GTN use
 i-syncope-3: "neurological review is required"
 i-syncope-5: "should be assessed permanently as unfit"

response First comment in this field 'i-syncope-2'

Not accepted

It is not appropriate to regulate to this level of detail. The specialists are expected to know the standard protocol and about possible GTN use.

Second comment in this field 'i-syncope-3'

Not accepted

To mandate neurological review would need to be in an Implementing Rule. However, the 'soft law' status of the acceptable means of compliance means that neurological review should take place, unless an alternative means of compliance is proposed, with an equivalent effect.

Third comment in this field 'i-syncope-5'

Not accepted

The expression 'permanently unfit' is not used in Part-MED, as it does not support the possibility for a fit assessment where 'new' treatment may be effective in enabling the applicant to exercise the privileges of the licence safely.

comment **122** comment by: AMCS - Thomas Syburra

k-coronary artery disease-2: this is outdated. should be mentioned: CT / CCS / CTA
 k-coronary artery disease-4-i-A: why has the last sentence been removed? the 30 to 50% sentence did make sense indeed.

response First comment in this field 'k-coronary artery disease-2'

Partially accepted

The specialists are expected to ensure suitable further testing. However, this could be considered in a future rulemaking task to update Part-MED.

Second comment in this field 'k-coronary artery disease-4-i-A'

Noted

See response to comment No 36.



comment	<p>123 comment by: AMCS - Thomas Syburra</p> <p>i-rhythm and conduction disturbances-1-i: "withdrawal of cardioactive medication prior to the test <u>is always</u> required"</p> <p>i-rhythm and conduction disturbances-1-viii: add CTCA</p> <p>i-rhythm and conduction disturbances-4-i-B: OML after "successful" ablation</p> <p>i-rhythm and conduction disturbances-9-iv: follow-up must be annual, with testing of battery life and lead impedance</p>
response	<p><u>First comment in this field 'i- rhythm and conduction disturbances-1-l'</u></p> <p><i>Not accepted</i></p> <p>The Agency assumes that this comment refers to subparagraph 'l' and not 'i' as specified by the commentator. Requiring withdrawal of cardioactive medication prior to the exercise ECG test is up to the judgement of the cardiologist. There may be exceptional cases where the cardiologist would not ask for this.</p> <p><u>Second comment in this field 'i-rhythm and conduction disturbances-1-viii'</u></p> <p><i>Partially accepted</i></p> <p>The Agency assumes that this comment refers to subparagraph 'l' and not 'i' as specified by the commentator. The text as it stands does not prevent the use of CTCA for further evaluation. However, this addition could be considered in a future rulemaking task to update Part-MED.</p> <p><u>Third comment in this field 'i-rhythm and conduction disturbances-4-i-B'</u></p> <p><i>Partially accepted</i></p> <p>The Agency assumes that this comment refers to subparagraph 'l' and not 'i' as specified by the commentator. Successful ablation and OML are mentioned in the text as in the NPA under the subparagraph heading 'ablation'.</p> <p><u>Fourth comment in this field 'i-rhythm and conduction disturbances-9-iv'</u></p> <p><i>Not accepted</i></p> <p>The Agency assumes that this comment refers to subparagraph 'l' and not 'i' as specified by the commentator. The intervals for regular follow-up should be established by the cardiologist depending on the individual case. Specifying 'annual' would prevent the opportunity for more frequent follow-up intervals, which may be deemed necessary in a specific case.</p>
comment	<p>171 comment by: Swedish Transport Agency, Civil Aviation Department (Transportstyrelsen, Luftfartsavdelningen)</p> <p>Section: General comment to AMC 1 and AMC 2 MED.B.010 - 090.</p> <p>Comment: Several improvements have been made in this NPA to both Section 2 of Subpart B (AMC1 to MED.B) and Section 3 of Subpart B (AMC2 to MED.B), as well as in the corresponding AMCs to Subpart B in the NPA/CRD Part-ATCO.MED. However, the two NPAs have not been drafted at the same time and a number of wordings,</p>



expressions and sentences intended to have the same meaning are expressed differently in the two NPAs. Consistency should be sought between the documents wherever possible. If this is not possible during the present rulemaking process, it should be an urgent part of the upcoming rulemaking tasks RMT.0424 and RMT.0603.

Proposal:

Alignment of wordings, expressions and sentences should be sought between the AMCs of Subpart B to Part-MED and the AMCs to Subpart B to Part-ATCO.MED.

response *Partially accepted*

A harmonisation of structure, wording and expressions used in Part-MED and Part-ATCO.MED has been applied, where appropriate.

comment

174

comment by: *Swedish Transport Agency, Civil Aviation Department
(Transportstyrelsen, Luftfartsavdelningen)*

Section: [AMC1 MED.B.010 \(I\)](#)

Comment:

Means to handle anticoagulation are mentioned in AMC 1 MED.B.010 (f)(3) for valvular surgery and in AMC1 MED.B.010 (g) for thromboembolic disorders. However, anticoagulation is also frequently used for cardiac rhythm disturbances but is not mentioned in AMC1 MED.B.010 (I). The requirements in AMC1 MED.B.010 (f)(3) should be added as a new subparagraph to AMC1 MED.B.010 (I).

Proposal:

Amend AMC1 MED.B.010 (I):

(x) 'Where anticoagulation is needed for a rhythm disturbance, a fit assessment with an OML may be considered, if the haemorrhagic risk is acceptable and the anticoagulation is stable. Anticoagulation should be considered stable if, within the last 6 months, at least 5 INR values are documented, of which at least 4 are within the INR target range.'

response *Accepted*

The text has been added accordingly.

comment

196

comment by: *Jörg SIEDENBURG*

(e)
Cardiac valvular abnormalities

(1)

Applicants with previously unrecognised cardiac murmurs should **be examined by echocardiography.** **Applicants with other than functional valvular abnormalities** should undergo evaluation by a cardiologist ~~and assessment by the licensing authority.~~ If considered



significant, further investigation should include at least 2D Doppler echocardiography or equivalent imaging. **If these investigations show significant valvular abnormalities the applicant should be assessed by the licensing authority.**

Innocent murmurs are quite common and harmless. However, significant valvular abnormalities are much less common. Only the letter are relevant and in a certain proportion relevant for aviation safety. Echocardiography differs the one from the other. If all innocent murmurs would be referred to the licensing authority then its assessors would only deal with these. A possible filter would be to start the sequence of further processes by echocardiography, which has not necessarily to be performed by a cardiologist. Other than functional abnormalities of the valves should be seen by a cardiologist, who selects those applicants that have to be assessed by the licensing authority. Otherwise the unwanted consequence might be that innocent or minor or even moderate or severe murmurs might be overheard during the clinical examination, which would be a dire but likely consequence of over-regulation. Subparagraph (2) expresses the same rationale. At the end of the day conditions relevant for flight safety would be under control. A major task of regulatory medicine and of medicine in general is to separate irrelevant findings from the relevant ones.

response *Not accepted*

A change of this magnitude would need to be properly consulted, for example through NPA consultation. Furthermore, the proposed changes would be in conflict with the Implementing Rule, which requires licensing authority involvement for 'functionally insignificant cardiac valvular abnormalities'. It could, however, be considered in a future rulemaking task to update Part-MED.

comment 197

comment by: Jörg SIEDENBURG

i) Syncope
(1)

Applicants with a history of **recurrent** vasovagal syncope should be assessed as unfit. A fit assessment may be considered...

Hidden under the euphemism editorial change a significant change has taken place here and is not discussed anywhere properly. A single syncope is not an uncommon event in young people, especially in teenagers. When applying for a medical certificate years later this would bring them into trouble even though there was no clinical relevance and there is none any more, if the change would pass as intended. Recurrent syncopes give rise to concerns about a potential incapacitation in the future, indeed. The original requirement is in line with AMC 1 MED.B.065 (e) where an episode of disturbance of consciousness is covered as insignificant. Therefore the proposed change should be rejected.

response *Noted*

See response to comment No 186.

comment 228

comment by: French main military Aeromedical Center (CEMPN)

(d) The risk of rupture of an aneurysm of abdominal aorta is high before the **limit of 5 cm**; this limit should be discussed again for a fit evaluation, considering the potential fatal consequences of such an event, particularly in case of long-haul flights.

(e) (3) (ii) It should be used a limit for aortic valve orifice with indexation on body surface.



	<p>(i) (1) The word “recurrent” for vasovagal syncope must not be deleted, otherwise all the following evaluation is not appropriate for a single episode. Moreover, there are banal vasovagal reactions in typical situations such as medical circumstances which do not require investigations.</p> <p>(2) This sentence is strange considering the role of tilt-test in the diagnosis of vasovagal syncope. Tilt-test should be used only in case of a doubtful diagnosis or a suspected severe hypervagotonia.</p>
response	<p><u>First comment in this field (d)</u></p> <p><i>Not accepted</i></p> <p>The limit for the diameter of the infra-renal abdominal aorta was included in the NPA as additional mitigation. This has been discussed again with experts, who agree that the limit of 5 cm is appropriate. Additional mitigation (OML) was also introduced in the NPA.</p> <p><u>Second comment in this field (e)(3)(ii)</u></p> <p><i>Accepted</i></p> <p>The text has been added accordingly.</p> <p><u>Third comment in this field (i)(1)</u></p> <p><i>Noted</i></p> <p>See response to comment No 186.</p> <p><u>Fourth comment in this field (2)</u></p> <p><i>Noted</i></p> <p>See response to comment No 106.</p>
comment	<p>289 comment by: UK CAA</p> <p>Page No: 60 Paragraph No: AMC1 to MED.B.010 (f) (4) Comment: Monitoring of warfarin therapy after valvular surgery should include near patient testing prior to flight. Justification: To mitigate the bleeding risk of use of warfarin. Proposed Text: Add sentences:</p> <p>‘Class 1 applicants will be required to measure their INR on a ‘near patient’ testing system (such as CoaguChek S) 12 hours prior to flight and only fly if the INR is within the target range. The INR should be recorded in the Log Book. The Log Book should be reviewed at each medical certificate revalidation examination. ‘</p>
response	<p><i>Partially accepted</i></p> <p>The principal of ‘near patient’ testing just prior to flight is accepted and guidance material has been added accordingly. However, the recording of the INR does not necessarily need to be in the log book if there is concern about medical confidentiality.</p>



comment	<p>290 comment by: UK CAA</p> <p>Page No: 60 Paragraph No: AMC1 to MED.B.010 (g) Comment: Monitoring of warfarin therapy for thromboembolic disorders should include near patient testing prior to flight. Justification: To mitigate the bleeding risk of use of warfarin. Proposed Text: Add sentence:</p> <p>'Class 1 applicants will be required to measure their INR on a 'near patient' testing system (such as CoaguChek S) 12 hours prior to flight and only fly if the INR is within the target range. The INR should be recorded in the Log Book. The Log Book should be reviewed at each medical certificate revalidation examination.'</p>
response	<p><i>Noted</i></p> <p>See response to comment No 289.</p>
comment	<p>291 comment by: UK CAA</p> <p>Page No: 60 Paragraph No: AMC1 to MED.B.010 (g) Comment: UK CAA suggest consideration should be given to approving Novel AntiCoagulants (NOACs) where an equivalent level of safety can be demonstrated and to add NOACs to this paragraph if consensus on use is agreed. Justification: To allow consideration of NOACs where they are prescribed in clinical practice and there is no excess risk. Proposed Text: To be developed after European meeting on NOACs in November 2013.</p>
response	<p><i>Accepted</i></p> <p>In light of the conclusions of the dedicated workshop on 'new' oral anticoagulants with specialists in Berlin on 15th November 2013, the text, throughout Part-MED, on anticoagulation has been amended to take account of direct oral anticoagulants used as a prophylaxis (medication not needing INR monitoring).</p>
comment	<p>292 comment by: UK CAA</p> <p>Page No: 60 Paragraph No: AMC1 to MED.B.010 (i)(1) Comment: UK CAA believes reference to 'recurrent' syncope should be retained. Justification: A six month grounding period for syncope is too onerous in cases where the cause is known and is not relevant to flight safety. Six months grounding is only needed for cases of <u>recurrent</u> syncope. Proposed Text: 'Applicants with a history of recurrent vasovagal syncope should be assessed as unfit.'</p>
response	<p><i>Noted</i></p> <p>See response to comment No 186.</p>



comment	293	comment by: UK CAA
	<p>Page No: 61 Paragraph No: AMC1 to MED.B.010 (i) (4) Comment: UK CAA suggests the original text should be retained. Justification: A 5 years OML restriction is too onerous in explained cases of a single episode of syncope. 5 years OML is only needed for cases of recurrent syncope. Proposed Text: Suggest no change unless new text to MED.B.010 (i) (1) is adopted.</p>	
response	<p><i>Noted</i> See response to comment No 186.</p>	
comment	294	comment by: UK CAA
	<p>Page No: 61 Paragraph No: AMC1 to MED.B.010 (j) (2) (iii) Comment: UK CAA suggest delete '/AT1'. Justification: Incorrect abbreviation. Proposed Text: 'Angiotensin II/AT1 blocking agents (sartans)'</p>	
response	<p><i>Accepted</i> The text has been amended accordingly.</p>	
comment	295	comment by: UK CAA
	<p>Page No: 61 Paragraph No: AMC1 to MED.B.010 (k) (4) (i) Comment: The clinical report should include the report of the angiogram. Justification: Clear text ensures angiogram results are available. Proposed Text: 'A coronary angiogram obtained around the time of, or during, the ischaemic myocardial event and a complete, detailed clinical report of the ischaemic event and of any operative procedures (including angiogram) should be available to the licensing authority.'</p>	
response	<p><i>Not accepted</i> The existing text already states that a coronary angiogram should be available to the licensing authority.</p>	
comment	296	comment by: UK CAA
	<p>Page No: 62 Paragraph No: AMC1 to MED.B.010 (k) (4) (i) (A) Comment: UK CAA suggest there should be no change to the original text as there needs to be some assessment of overall disease burden. Justification: This proposed rule change increases the magnitude of overall disease burden that would be acceptable and is a potentially unsafe rule change.</p>	



Proposed Text: 'there should be no stenosis more than 50 % in any major untreated vessel, in any vein or artery graft or at the site of an angioplasty/stent, except in a vessel subtending a myocardial infarction. **More than 2 stenoses between 30% and 50% within the vascular tree should not be acceptable.'**

response *Noted*

See response to comment No 36.

comment 297

comment by: UK CAA

Page No: 64

Paragraph No: AMC1 to MED.B.010 (I) (7)

Comment: UK CAA suggests delete (i) and (ii) and replace with new subparagraphs.

Justification: There should be no differences between initial and revalidation standards. Applicants with LBBB should be followed for 3 years with an OML.

Proposed Text: Replace sub-paragraphs (i) and (ii) to read as follows:

'Complete Left Bundle Branch Block

A fit assessment may be considered:

i) subject to satisfactory cardiological evaluation and a 3 year period with an OML

ii) without an OML after 3 years of surveillance and satisfactory cardiological evaluation

iii) Investigation of the coronary arteries is necessary for applicants over age 40'

response *Accepted*

The text has been amended accordingly.

comment 329

comment by: Royal Danish Aeroclub

Comment to page 60, point (g). The following text should be added:

"In case of use of the newer anticoagulation drugs, which cannot be monitored by INR measurements, one should take into consideration, that no adverse effects compromise flight safety. In these cases one should check renal function regularly."

response *Noted*

See response to comment No 291.

3 Proposed amendments — 3.2 Draft Acceptable Means of Compliance and Guidance Material (Draft EASA Decision) — AMC/GM to PART-MEDICAL — SUBPART B — Specific requirements for class 1, class 2 and LAPL medical certificates - AMC for class 1, class 2 and LAPL medical certificates — Section 2 — Specific requirements for class 1 medical certificates — GM1 MED.B.010 Cardiovascular system p. 64-65

comment 63

comment by: Federal Office of Civil Aviation FOCA



	<p>GM1 MED.B.010: (mitral valve disease): The whole section should be rewritten and place to another section. Justification: 1) There is no need to create a specific section on mitral valve disease. Nevertheless, if it is to be adopted, then it should be incorporated into section AMC1 MED.B.010 (e) (4). 2) The level of detail on mitral valve findings is disproportionate. This section should be newly drafted, in a more simplified way.</p>
<p>response</p>	<p><i>Not accepted</i></p> <p>The guidance material has been added in the NPA for class 1 and 2 in order to provide indicators for harmonised assessments. The text should not be moved to AMC as, where possible, numerical criteria should be avoided at AMC level.</p>
<p>comment</p>	<p>124 comment by: AMCS - Thomas Syburra</p> <p>GM1 MED.B.010: where are the tricuspid, pulmonary and aortic diseases?</p>
<p>response</p>	<p><i>Not accepted</i></p> <p>Guidance material for tricuspid, pulmonary and aortic diseases, as well as other conditions, may be considered in future rulemaking tasks on Part-MED.</p>

3 Proposed amendments — 3.2 Draft Acceptable Means of Compliance and Guidance Material (Draft EASA Decision) — AMC/GM to PART-MEDICAL — SUBPART B — Specific requirements for class 1, class 2 and LAPL medical certificates - AMC for class 1, class 2 and LAPL medical certificates — Section 2 — Specific requirements for class 1 medical certificates — GM2 MED.B.010 Cardiovascular system p. 65

<p>comment</p>	<p>64 comment by: Federal Office of Civil Aviation FOCA</p> <p>GM2 MED.B.010: (ventricular pre-excitation): FOCA suggest to delete this requirement as it is too detailed. The content of the section AMC1 MED.B.010 (I) covers all forms of arrhythmias. If ventricular pre-excitation is mentioned especially then other forms of arrhythmias like for example AV re-entry tachycardia and many others should also be mentioned. And this would be far-reaching. If this section will not be deleted, then it should at the least be incorporated into section AMC1 MED.B.010 (I).</p>
<p>response</p>	<p><i>Partially accepted</i></p> <p>The guidance material has been added in the NPA for class 1 and 2 in order to provide indicators for harmonised assessments. Not all of the GM text should be moved to AMC as, where possible, numerical criteria should be avoided at AMC level.</p> <p>According to the AMC, a fit assessment may be considered without limitations for initial class 1 applicants whose electrophysiological study results are satisfactory. Therefore, the AMC text has been amended to also allow this for revalidation assessments. If the revalidation assessment does not include an electrophysiological study, a fit assessment may be</p>



considered with limitation(s) as appropriate.

comment 108

comment by: AeMC, Toulon, France

The systematic restriction OML in case of a ventricular pre-excitation, even when the following criteria are present (no inductible re-entry, refractory period > 300 ms, no induced atrial fibrillation and no multiple accessory pathways) could appear as too restrictive. We are in favour of a case by case decision by the licensing authority. Indeed, this new notification could expose to inadequate ablation in the objective of medical fitness.

response *Noted*

See response to comment No 64.

comment 229

comment by: French main military Aeromedical Center (CEMPN)

In case of ventricular pre-excitation in asymptomatic applicants, the electrophysiological criteria developed in (a) and (b) are such that an OML limitation is not justified. To the contrary, all these characteristics should be checked by the licensing authority to assess the applicant as fit **without any safety pilot**.

response *Noted*

See response to comment No 64.

3 Proposed amendments — 3.2 Draft Acceptable Means of Compliance and Guidance Material (Draft EASA Decision) — AMC/GM to PART-MEDICAL — SUBPART B — Specific requirements for class 1, class 2 and LAPL medical certificates - AMC for class 1, class 2 and LAPL medical certificates — Section 2 — Specific requirements for class 1 medical certificates — AMC1 MED.B.025 Metabolic and endocrine systems

p. 67

comment 298

comment by: UK CAA

Page No: 67

Paragraph No: AMC1 MED.B.025 (g)

Comment: Allowing pilots treated with insulin should be accepted subject to compliance with safe AMC/GM.

Justification: Appropriate mitigation is outlined in the AMC below and is further detailed in the UK Guidance document on insulin treated pilots.

Proposed Text: Amend paragraph (g) to read as follows:

‘Diabetes mellitus

Subject to **at least annual specialist assessment, absence of complications likely to interfere with licence privileges, evidence of** good control of blood sugar with no significant hypoglycaemic episodes, applicants with diabetes mellitus;

(1) not requiring medication may be assessed as fit **by the AME or AeMC;**

(2) **requiring the** use of antidiabetic medications that are not likely to cause hypoglycaemia



may be acceptable for a fit assessment with a multi-pilot limitation. **Individual asymptomatic applicants without complications using insulin shall be assessed by the licensing authority and comply with operational testing protocols to demonstrate acceptable blood sugar levels whilst exercising licence privileges.'**

response

Not accepted

This paragraph will not be changed at this stage; the rule will remain ICAO compliant.

However, the following solution has been proposed in a recent package of amendments for Part-ARA (Annex VI to the Aircrew Regulation). The proposal is to reintroduce the former paragraph JAR.FCL 3.046 'special medical circumstances' to Part-ARA. The aim is to allow competent authorities to consider medical advancements and to establish whether a fit assessment may be possible for certain medical conditions for which the existing provisions inevitably lead to an unfit assessment. Under new medical assessment protocols via research, it would be possible to collect specific data in a controlled aviation environment, and to develop specific risk assessments for certain medical conditions.

3 Proposed amendments — 3.2 Draft Acceptable Means of Compliance and Guidance Material (Draft EASA Decision) — AMC/GM to PART-MEDICAL — SUBPART B — Specific requirements for class 1, class 2 and LAPL medical certificates - AMC for class 1, class 2 and LAPL medical certificates — Section 2 — Specific requirements for class 1 medical certificates — AMC1 MED.B.030 Haematology p. 68-69

comment

198

comment by: Jörg SIEDENBURG

(b)
Anaemia

(1)

Applicants with anaemia demonstrated by a reduced haemoglobin level **requires investigation**. ~~or~~ **An applicant with a** haematocrit less than 32 % should be assessed as unfit and require investigation. A fit assessment may be considered in cases where ...

The proposed change reflects the intention of the previous JAR-FCL 3 text. Haematocrit is not required and the reason that it did not replace the requirement of haemoglobin was the allegedly high costs for that test. However, a numerical standard for "normal haemoglobin" could not be agreed upon. Therefore, either both test have to be required and normal limits to be defined or either of them with a normal standard each be required or the old JAR-FCL 3 sequence of both examinations be left in place in order to have a prudent provision.

response

Accepted

The text has been changed accordingly.

comment

199

comment by: Jörg SIEDENBURG

It is not a good idea to replace the term "polycythaemia" by the term "erythrocytosis". Throughout most parts of the world at least of Europe the disorder discussed about is called "polycythaemia", whereas "erythrocytosis" is used for a condition with a surplus of the mass



of red blood cells, which may be a small subgroup of "polycythaemia" but is in most cases secondary to a host of non-haematological causes like hypobaric hypoxia, dehydration etc. However, the latter is not what is discussed about in the paragraph. It deals about the haematological condition of "polycythaemia". It is a chronic myeloproliferative disorder, where the numbers of all three groups of blood cells, red and white blood cells and platelets are elevated. The term "erythrocytosis" may be readily understood only in the UK. For reasons of clarity the old term should be preferred. The proposed change should be rejected. This comment relates to all changes where "erythrocytosis" had replaced "polycythaemia".

response *Not accepted*

According to paragraph 5.4.2 of ICAO Doc 8984, traditionally, the term 'polycythaemia' has been used about several disorders with an increase in circulating red blood cells, but 'erythrocytosis' is a better and more correct term (it means a documented increase of red cell mass).

3 Proposed amendments — 3.2 Draft Acceptable Means of Compliance and Guidance Material (Draft EASA Decision) — AMC/GM to PART-MEDICAL — SUBPART B — Specific requirements for class 1, class 2 and LAPL medical certificates - AMC for class 1, class 2 and LAPL medical certificates — Section 2 — Specific requirements for class 1 medical certificates — AMC1 MED.B.035 Genitourinary system p. 69-70

comment 299

comment by: UK CAA

Page No: 70

Paragraph No: AMC 1 MED.B.035 (d) (4)

Comment: An annual exercise ECG test should be required for Class 1 certification after renal transplantation.

Justification: There is an increased risk of cardiovascular disease after renal transplantation.

Proposed Text: Add sentence: **'Annual exercise electrocardiography should be required.'**

response *Not accepted*

A change of this magnitude would need to be properly consulted, for example through NPA consultation. It could, however, be considered in a future rulemaking task on Part-MED if supported by detailed risk assessment data and justification. In the meantime, nothing prevents the licensing authority from requiring a cardiological evaluation and/or imposing a SIC (specific regular medical examination(s)) (see MED.B.001(e)), as this is a referral situation.

3 Proposed amendments — 3.2 Draft Acceptable Means of Compliance and Guidance Material (Draft EASA Decision) — AMC/GM to PART-MEDICAL — SUBPART B — Specific requirements for class 1, class 2 and LAPL medical certificates - AMC for class 1, class 2 and LAPL medical certificates — Section 2 — Specific requirements for class 1 medical certificates — AMC1 MED.B.040 Infectious disease p. 70



comment	37	comment by: AECA(SPAIN)
	<p>Paragraph (d)(1) In the phrase ... <i>and neurological evaluation</i> ... add and psychological. It should read: ... <i>and neurological and psychological evaluation</i>.</p>	
response	<p><i>Not accepted</i></p> <p>A change of this magnitude would need to be properly consulted, for example through NPA consultation. It could, however, be considered in a future rulemaking task on Part-MED if supported by detailed justification. In addition, a psychological evaluation is not mentioned in ICAO Doc 8984.</p>	
comment	300	comment by: UK CAA
	<p>Page No: 70 Paragraph No: AMC1 MED.B.040 (d)(2) Comment: "AIDS related complex" is a medical term that is no longer in regular clinical use. Justification: Use of the term "AIDS related complex" was widely discontinued in the year 2000. Its continued inclusion here gives the appearance of being out of date or not fully understanding the subject matter. Proposed Text: 'Applicants with signs or symptoms of an AIDS defining condition or AIDS-related complex is disqualifying should be assessed as unfit.'</p>	
response	<p><i>Accepted</i></p> <p>The text has been amended accordingly, as referred to in ICAO Doc 8984.</p>	

3 Proposed amendments — 3.2 Draft Acceptable Means of Compliance and Guidance Material (Draft EASA Decision) — AMC/GM to PART-MEDICAL — SUBPART B — Specific requirements for class 1, class 2 and LAPL medical certificates - AMC for class 1, class 2 and LAPL medical certificates — Section 2 — Specific requirements for class 1 medical certificates — AMC1 MED.B.055 Psychiatry p. 71-72

comment	301	comment by: UK CAA
	<p>Page No: 72 Paragraph No: AMC1 MED.B.055 (h) Comment: The term "psychoactive" has been added to similar text in AMC2 MED.B.055 (h) but not in AMC1 MED.B.055 (h). Justification: Maintain consistency Proposed Text: ' Disorders due to alcohol or other psychoactive substance use (1) Applicants with mental or behavioural disorders due to alcohol or other psychoactive substance use, with or without dependency, should be assessed as unfit. (2) A fit assessment may be considered after a period of two years of documented sobriety or freedom from psychoactive substance use. '</p>	



response *Accepted*

The text has been amended taking the comment into account.

3 Proposed amendments — 3.2 Draft Acceptable Means of Compliance and Guidance Material (Draft EASA Decision) — AMC/GM to PART-MEDICAL — SUBPART B — Specific requirements for class 1, class 2 and LAPL medical certificates - AMC for class 1, class 2 and LAPL medical certificates — Section 2 — Specific requirements for class 1 medical certificates — AMC1 MED.B.060 Psychology

p. 72

comment 302

comment by: UK CAA

Page No: 72

Paragraph No: AMC 1 MED.B.060

Comment: AMC needs to be developed for the assessment of applicants with dyslexia.

Justification: No AMC is available on the assessment of this condition.

response

Not accepted

Dyslexia has not be added to the AMC for class 1, as it is not an ICAO Annex 1 ‘medical’ standard and it would be challenging to provide fit/unfit criteria. Any safety issues caused by dyslexia would anyway be detected during flight crew training, e.g. the MCC course.

3 Proposed amendments — 3.2 Draft Acceptable Means of Compliance and Guidance Material (Draft EASA Decision) — AMC/GM to PART-MEDICAL — SUBPART B — Specific requirements for class 1, class 2 and LAPL medical certificates - AMC for class 1, class 2 and LAPL medical certificates — Section 2 — Specific requirements for class 1 medical certificates — AMC1 MED.B.070 Visual system

p. 74-77

comment 27

comment by: Federal Office of Civil Aviation FOCA

AMC1 MED.B.070 b (9): assessment of contrast only if indicated/prescribed by an ophthalmologic expert. If the test is requested for all pilots, then EASA Rulemaking should specify the requested method and define limits.

AMC1 MED.B.070 (f)(2): Monocularity: Applicants for revalidation or renewal who have an ~~with~~ acquired loss of vision....(typographical error)

response

First comment in this field AMC1 MED.B.070(b)(9)

Noted

See response to comment No 304.

Second comment in this field AMC1 MED.B.070(f)(2)

Accepted



The typographical error has been corrected and is now positioned under (f)(1) in the resulting text.

comment

38

comment by: *AECA(SPAIN)*

Paragraph (d)(2)(iii)

Complete the new sentence to read: Subject to satisfactory evaluation by ophthalmologist ophthalmic.

We see no other way to make this assessment and discussions are avoided saying it.

response

Not accepted

The Agency assumes that the comment means that applicants for a class 1 medical certificate who have anisometropia not exceeding 2.0 dioptres should be evaluated by an ophthalmologist rather than be subject to an ‘ophthalmic evaluation’. However, an evaluation by an ophthalmologist will be required for applicants with anisometropia exceeding 2.0 dioptres (refer to (d)(2)). The Agency finds that this is the most appropriate balance for the evaluations.

comment

176

comment by: *Swedish Transport Agency, Civil Aviation Department
(Transportstyrelsen, Luftfartsavdelningen)*

Section: [AMC1 MED.B.070 \(j\)](#)

Comment:

The AMC1 ATCO.MED.B.070 (j) has been amended to change the expression ‘correcting lenses’, which is incorrectly used in this context, to ‘spectacles’.

The same expression should be used also for pilots.

Proposal:

Amend AMC1 MED.B.070:

‘(j) Visual correction

Spectacles should permit the licence holder to meet the visual requirements at all distances.’

response

Not accepted

The subparagraph applies to spectacles and contact lenses.

comment

178

comment by: *Swedish Transport Agency, Civil Aviation Department
(Transportstyrelsen, Luftfartsavdelningen)*

Section: [GM1 MED.B.070 \(new\)](#)

Comment:

[A GM1 ATCO.MED.B.070 has been added with a table for comparison of the scales of](#)



different near vision charts to make it easier for AMEs to compare the charts they are using with the N charts referred to in the requirements. As the same reading charts are used also for pilots, this GM should be added as a GM1 MED.B.070.

Proposal:

Add GM1 ATCO.MED.B.070 as a new GM1 MED.B.070.

response *Accepted*

The comparison table from GM1 ATCO.MED.B.070 has been added as GM for class 1, 2, LAPL and Cabin crew.

comment

230

comment by: *French main military Aeromedical Center (CPEMPN)*

(c) On routine eye examination

Examination of anatomy, media and funduscopy should be asked **on clinical examination**, because in France only ophthalmologist practitioners (which means MD) are allowed to perform this evaluation.

response

Not accepted

The text states that the routine eye examination 'may' be performed by an AME, which means that the AME is free to refer the applicant to an ophthalmologist, for parts of the examination which are outside their area of competence. No change has been made to the text.

comment

303

comment by: *UK CAA*

Page No: 74

Paragraph No: AMC1 MED.B.070 (b)(8)

Comment: Objective refraction in cycloplegia is not indicated for all applicants with a hyperopia of more than 2 dioptres and under the age of 25.

Justification: The circumstances where it is not required to include applicants with a retinoscopy result of less than +5.00D (where all attempts should be made to prevent the applicant accommodating during retinoscopy), stable retinoscopy results, normal accommodation and no history of patching in childhood.

Proposed Text : 'objective refraction: Hyperopic initial applicants with a hyperopia of more than +2 dioptres and under the age of 25 ~~should~~ **may be required to** undergo objective refraction in cycloplegia;'

response

Not accepted

A change of this magnitude would need to be properly consulted, for example through NPA consultation. It could, however, be considered in a future rulemaking task on Part-MED. In the meantime, the EU system also allows for alternative means of compliance to be established by the competent authority, as long as the safety objectives of the Implementing Rule are still met.



comment	<p>304</p> <p>Page No: 74 Paragraph No: AMC1 MED.B.070 (b) (9) Comment: New text is introduced to indicate that “contrast...vision” should be examined at initial examination but no explanatory note is provided. Justification: There is no clear indication for including contrast sensitivity testing in all initial medical assessments. There is no internationally agreed standard for assessment. This will result in differing assessments and outcomes across member states. Proposed Text: ‘(9) assessment of contrast; and (109) colour vision.’</p>	comment by: UK CAA
response	<p><i>Partially accepted</i></p> <p>It is not appropriate to regulate to this level of detail. The specialists are expected to have the professional knowledge necessary to apply suitable methods and standards. Nevertheless, for clarification, the text has been amended to ‘assessment of mesopic contrast sensitivity’, as referred to in AMC1 MED.B.070(i)(1)(v). Another commentator (see comment 333) suggested ‘contrast sensitivity’.</p>	
comment	<p>305</p> <p>Page No: 74 Paragraph No: AMC1 MED.B.070 (d) (1) Comment: In certain circumstances hypermetropia beyond 5 dioptres should be allowed. Justification: Previous comments on this standard have raised concerns about the risk of angle closure glaucoma and diplopia in spectacle wearing applicants with a refractive error >+5 dioptres when tired. There is no evidence of increased accidents/incidents in high hypermetropes. The concerns can be mitigated through the assessment outlined below. Proposed Text : ‘(1) Applicants with hypermetropia exceeding +5.0 dioptres should be assessed as unfit may be assessed as fit subject to satisfactory ophthalmic evaluation and provided that there are adequate fusional reserves, normal intraocular pressures and anterior angles and that no significant pathology has been demonstrated. Visual acuity in each eye must be 6/6 or better corrected or uncorrected.’</p>	comment by: UK CAA
response	<p><i>Accepted</i></p> <p>The text has been restructured for clarification and changed so that applicants with hypermetropia exceeding +5.0 dioptres may be assessed as fit after evaluation by an ophthalmologist subject to certain criteria being met, as now prescribed in the Implementing Rule.</p>	
comment	<p>306</p> <p>Page No: 75 Paragraph No: AMC1 MED.B.070 (d) (4) Comment: The word “with” should be deleted. Justification: Typing error. Proposed Text: ‘Applicants who, for revalidation or renewal examinations do not meet the</p>	comment by: UK CAA



	<p>requirements in (2) above may be assessed as fit with: subject to satisfactory ophthalmic evaluation and provided that optimal correction has been considered and no significant pathology has been demonstrated.'</p>
response	<p><i>Accepted</i></p> <p>The typographical error has been resolved, as (d)(4) has been redrafted.</p>
comment	<p>307 comment by: UK CAA</p>
	<p>Page No: 75 Paragraph No: AMC1 MED.B.070 (d) (6) Comment: The word "to" should be deleted in two places. Justification: Typing error. Proposed Text: 'If the refractive error is between +3.0 to and +5.0 or between -3.0 to and -6.0 dioptres, or there is astigmatism or anisometropia between 2.0 dioptres and 3.0 dioptres, an evaluation should be undertaken 5 yearly by an eye specialist.'</p>
response	<p><i>Accepted</i></p> <p>The typographical error has been resolved, as (d)(4) has been redrafted and moved.</p>
comment	<p>308 comment by: UK CAA</p>
	<p>Page No: 75 and 76 Paragraph No: AMC1 MED.B.070 (f) (1), (2) and (3) Comment: UK CAA suggests the text should be amended to avoid duplication of text and the lowering of standard of visual field acceptable for monocular pilots compared to those with substandard vision in one eye. Justification: Class 1 applicants with substandard vision in one eye need to have normal binocular visual fields whilst monocular applicants need to have a normal monocular visual field. Any applicant with substandard vision who has an abnormal visual field by virtue of the substandard eye, but a normal monocular field in the better eye only will want to be assessed as monocular. Otherwise the AMC for both are very similar and could be combined which would simplify the text as the 6/18 standard would no longer be applicable. Proposed Text:</p> <p>' Substandard vision (1) Reduced vision in one eye or monocularly: Applicants for revalidation or renewal with reduced central vision or acquired loss of vision in one eye may be assessed as fit with an OML if: (i) the binocular visual field is acceptable normal according to satisfactory ophthalmic evaluation; (ii) the visual acuity of the affected eye is 6/18 (0.3) or better; (ii) in the case of monocularly, a period of adaptation time has passed from the known point of visual loss, during which the applicant should be assessed as unfit; (iii) the better unaffected eye achieves distant visual acuity of 6/6 (1.0) corrected or uncorrected; (iv) the better unaffected eye achieves intermediate visual acuity of N14 and N5 for near; (v) the underlying pathology is acceptable according to ophthalmological assessment; and</p>



there is no significant ocular pathology in the unaffected eye; and
 (vi) a medical flight test is satisfactory.
 (2) ~~Monocularity: Applicants for revalidation or renewal who have with acquired loss of vision in one eye may be assessed as fit with an OML if:~~
 (i) ~~the functional eye achieves distant visual acuity of 6/6 (1.0), corrected or uncorrected;~~
 (ii) ~~the functional eye achieves intermediate visual acuity of N14 and N5 for near;~~
 (iii) ~~a period of adaptation time has passed from the known point of visual loss, during which the applicant should be assessed as unfit;~~
 (iv) ~~there is no significant ocular pathology in the functional eye; and~~
 (v) ~~a medical flight test is satisfactory.~~
 (3) ~~Visual fields~~
 (i) ~~Applicants with a visual field defect, who do not have reduced central vision or acquired loss of vision in one eye, may be assessed as fit if the binocular visual field is normal.~~
 (ii) ~~In cases of monocularity, applicants for revalidation or renewal may be assessed as fit if the monocular field of vision is normal and subject to satisfactory ophthalmic evaluation.'~~

response

Accepted
 The text has been amended accordingly.

comment

347 comment by: *Trond-Eirik Strand*

Regarding refractive error and hypermetropia not exceeding +5.0 dioptries in (d)(1) the rationale for this is based on the small risk of incapacitation due to acute glaucoma and a potential functional decrease in fusional reserves. Both conditions could be ruled out and individual assessed from case to case. Progression could be monitored with ophthalmologic evaluation and eventually appropriate limitations to ensure proper ophthalmologic follow-up. The suggestion is therefore to replace (d)(1) with something such as "Applicants with hypermetropia exceeding +5.0 dioptrres may be assessed as fit following a satisfactory ophthalmologic evaluation and follow-up"

response

Noted
 See response to comment No 305.

comment

348 comment by: *Trond-Eirik Strand*

In (f)(2) there are a couple of spelling errors:
 "aApplicants" should be "Applicants"
 "... have with acquired ..." should be "...have acquired..."

response

Accepted
 The typographical error has been corrected.

3 Proposed amendments — 3.2 Draft Acceptable Means of Compliance and Guidance Material (Draft EASA Decision) — AMC/GM to PART-MEDICAL — SUBPART B — Specific requirements for class 1, class 2 and LAPL medical certificates - AMC for class 1, class 2 and LAPL medical certificates — Section 2 — Specific requirements for class 1 medical certificates — AMC1 MED p. 77



B.075 Colour vision

comment	28	comment by: <i>Federal Office of Civil Aviation FOCA</i>
	<p>AMC1 MED.B.075 c: FOCA suggests to add a sub-paragraph as follows: (3) CAD Color Vision Test. Justification: Insert AltMOC of CAA UK concerning CAD test in new AMC. There is sufficient scientific background available for this test, which is more reliable and state-of-the-art as the outdated "lantern testing".</p>	
response	<p><i>Accepted</i></p> <p>The choice of colour vision tests has been broadened to include the UK CAD test.</p>	
comment	100	comment by: <i>Del Monte</i>
	<p>Dear NPA team,</p> <p>Considering other Authorities in the world have a far more relax regulation over this matter, would the Agency consider aligning and updating this law to the like of the FAA, CASA and Transport Canada?</p> <p>Not only the Ishihara's plates are 100+ year old but also ALL current approved secondary tests (Lanterns and Anomaloscope) are rather outdated and frankly not very relevant to any 'daily pilot action'. In fact these tests seems to cause a lot of FALSE POSITIVES: Even mild cases of colour vision defect who are indeed well capable and safe to fly at night or commercially might be unable to pass a very limited choice of tests thus being discriminated. Also, not only any test should be carried out in accordance with the manufacturing instructions (Ishihara's plates aren't, please check manual!) but I do also believe we need a more practical, fairer and honest test based on real life/actions, NOT academic/clinical/computerised tests. In fact, the FAA allows up to 18 approved tests amongst which a practical test (TOWER SIGNAL LIGHT AND MFT) that has direct relation to flying. Would the Agency at least consider this?</p> <p>Also in Australia for 20 years, CASA has been allowing pilots with ANY degree of colour vision defect, from mild all the way to SEVERE like protanotopes, not only to fly at night but also to carry out Commercial Air Transport: These colour vision defect pilots are subject to any LPC/OPC like the 'normal' colleagues and clearly show that they are able to perform SAFELY and CORRECTLY both as single and multi crew: this, once again, highlights the discrimination issue! Would the Agency think about this problem, especially about the discrimination issue, considering that as we speak many colour vision defect pilots are flying in and out Europe's largest airports flying heavy/super category aircraft, at night perhaps, yet their European peers are not even allowed to fly at night on a single engine aircraft?!</p> <p>thank you</p>	
response	<p><i>Partially accepted</i></p> <p>A change of this magnitude would need to be properly consulted, for example through NPA consultation. It could, however, be considered in a future rulemaking task if supported by detailed risk assessment data and justification.</p> <p>However, the Agency acknowledges that new methods of testing colour vision have been introduced since publication of the initial issue of Part-MED. In light of this, the Colour</p>	



Assessment and Diagnosis (CAD) test has been added as an additional option in the AMCs for class 1 and 2. The EU system also allows for alternative means of compliance to be established by the competent authority, so other methods could be used as long as they are proved to be effective and provide equivalent check levels.

If a night rating is added to a PPL or LAPL, the Implementing Rule requires the licence holder to be colour safe. This can be determined by practical/functional testing.

comment 309

comment by: UK CAA

Page No: 77**Paragraph No:** AMC1 MED.B.075 (c)

Comment: There are methodological limitations to the use of the anomaloscope and lantern tests in determining whether an individual is 'colour safe'. A colour threshold determination test needs to be allowed as an alternative to, or more probably instead of, a lantern test.

Justification: The colour threshold determination test, known as the CAD test, is now in routine use in some States as the evidence for its use is far greater than the evidence for the use of any of the lantern tests. It is proposed that it should be included as being acceptable for a medical assessment for Class 1.

The task analysis that was undertaken as part of the research for the CAD test demonstrated that cockpit displays have sufficient redundancy cues so as not to be safety critical colour tasks. However the detection of coloured lights in the PAPI **IS** safety critical and this underpins the new test.

Proposed Text: Add new sub-paragraph as follows:

'(3) Colour threshold determination test (CAD or equivalent). This test is considered passed if the colour detection threshold is equivalent to that of an individual with normal trichromacy.'

response Noted

See response to comment No 28. The reference to 'normal trichromacy' has been added to the Implementing Rule.

3 Proposed amendments — 3.2 Draft Acceptable Means of Compliance and Guidance Material (Draft EASA Decision) — AMC/GM to PART-MEDICAL — SUBPART B — Specific requirements for class 1, class 2 and LAPL medical certificates - AMC for class 1, class 2 and LAPL medical certificates — Section 2 — Specific requirements for class 1 medical certificates — AMC1 MED.B.080 Otorhino-laryngology Otorhinolaryngology (ENT) p. 77-78

comment 39

comment by: AECA(SPAIN)

Paragraph (a)(2)

Editorial

Applicants with hypoacusis **should may be** assessed ...

Delete should



response *Accepted*
The typographical error has been corrected.

comment *310* comment by: *UK CAA*

Page No: 77
Paragraph No: AMC1 MED.B.080 (a) (2)
Comment: The word 'should' is superfluous and should be removed.
Justification: Editorial correction.
Proposed Text: 'Applicants with hypoacusis ~~should~~ **may** be assessed as fit if a speech discrimination test or functional flight deck hearing test demonstrates satisfactory hearing ability. A vestibular function test may be appropriate.'

response *Noted*
See response to comment No 39.

comment *311* comment by: *UK CAA*

Page No: 77
Paragraph No: AMC1 MED.B.080 (a) (4)
Comment: It is unclear whether this text refers to the use of noise reduction during audiometry or for operational use by the pilot. It is also unclear why/how the use of noise reducing devices would affect the assessment as to whether the requirements are met.
Justification: The meaning of the text is unclear.
Proposed Text: ~~(4) If noise reducing devices are used, it must be ensured that the requirements are met.~~

response *Accepted*
The text has been amended accordingly.

3 Proposed amendments — 3.2 Draft Acceptable Means of Compliance and Guidance Material (Draft EASA Decision) — AMC/GM to PART-MEDICAL — SUBPART B — Specific requirements for class 1, class 2 and LAPL medical certificates - AMC for class 1, class 2 and LAPL medical certificates — Section 2 — Specific requirements for class 1 medical certificates — AMC1 MED.B.090 Oncology

p. 79

comment *331* comment by: *Royal Danish Aeroclub*

Page 79, point (c) should be added this text:
"Therapy with hormones /antihormones (e.g mammacancer, prostatic cancer or other chemotherapeutica with milder effects can be accepted if there are no significant adverse effects jeopardising flight safety."



response *Not accepted*

Chemotherapy and radiation treatment are not meant to include other treatment such as hormone therapy.

3 Proposed amendments — 3.2 Draft Acceptable Means of Compliance and Guidance Material (Draft EASA Decision) — AMC/GM to PART-MEDICAL — SUBPART B — Specific requirements for class 1, class 2 and LAPL medical certificates - AMC for class 1, class 2 and LAPL medical certificates — Section 3 — Specific requirements for class 2 medical certificates — AMC2 MED.B.010 Cardiovascular system p. 80-84

comment

65

comment by: *Federal Office of Civil Aviation FOCA*

AMC 2 MED.B.010 (m): (heart or heart/lung transplantation): Why is this text in Class 2 Medical chapter and not also in the Class 1-Medical chapter?
Ejection fraction should be written as $\geq 50\%$

response

Partially accepted

There should be no AMC for class 1 applicants who have had a heart or heart/lung transplantation, as the Implementing Rule states that these applicants shall be assessed as unfit. However, class 2 applicants shall be evaluated by a cardiologist, and a fit assessment may be considered in consultation with the licensing authority. This follows the principle of proportionality between risks associated with privileges of a commercial pilot licence holder compared to a private pilot licence holder.

However, the NPA text for the class 2 AMC has been amended to align with the Implementing Rule, which states that applicants for a class 2 medical certificate who have undergone heart or heart/lung transplantation shall be evaluated by a cardiologist before a fit assessment may be considered. The NPA text was in conflict with this, as it indicated that applicants for a class 2 medical certificate who had undergone a combined heart and lung transplantation should be assessed as unfit.

The suggested editorial correction regarding ejection fraction has been applied.

comment

83

comment by: *The Norwegian Air Sports Federation*

AMC2 MED.B.010 (d) (2)

Aortic aneurysm after surgery for Class 2: NLF is strongly opposed to the addition of the OSL, which is not in the current rule. As the Agency points out in 2.3.4.5 (a) (1) of the NPA, an OSL prevents pilots from exercising their privileges in single pilot aircraft. This will in particular affect SPL-rated glider pilots, but also a number of other license holders. It is surprising that this limitation is added without a medical justification or a verified safety case.

response

Noted

See response to comment No 78.



comment	<p>84 comment by: <i>The Norwegian Air Sports Federation</i></p> <p>AMC1 (AMC2) MED.B.020, etc NLF welcomes this change. However, a more elaborate criterion than "satisfactory gastroenterological evaluation" would be beneficial to ensure a harmonised understanding among competent authorities and medical examiners.</p>
response	<p><i>Noted</i></p> <p>Thank you for your support. The Agency has noted that this comment refers to MED.B.020 as opposed to this section MED.B.010. Regarding the part of the comment requesting more criteria for the gastroenterological evaluation for class 1 and class 2 applicants, this may be considered in a future rulemaking task on Part-MED if supported by some text proposals.</p>
comment	<p>175 comment by: <i>Swedish Transport Agency, Civil Aviation Department (Transportstyrelsen, Luftfartsavdelningen)</i></p> <div style="border: 1px solid black; padding: 5px; margin-top: 10px;"> <p>Section: AMC2 MED.B.010 (I)</p> <p>Comment: Means to handle anticoagulation are mentioned in AMC 2 MED.B.010 (f)(2) for valvular surgery and in AMC2 MED.B.010 (g) for thromboembolic disorders. However, anticoagulation is also frequently used for cardiac rhythm disturbances but is not mentioned in AMC2 MED.B.010 (I). The requirements in AMC1 MED.B.010 (f)(2) should be added as a new subparagraph to AMC2 MED.B.010 (I).</p> <p>Proposal: Amend AMC2 MED.B.010 (I): (x) 'Where anticoagulation is needed for a rhythm disturbance, a fit assessment with an OML may be considered, if the haemorrhagic risk is acceptable and the anticoagulation is stable. Anticoagulation should be considered stable if, within the last 6 months, at least 5 INR values are documented, of which at least 4 are within the INR target range.'</p> </div>
response	<p><i>Accepted</i></p> <p>The text from AMC1 MED.B.010(f)(2) has been added to AMC2 MED.B.010(I) accordingly.</p>
comment	<p>200 comment by: <i>Jörg SIEDENBURG</i></p> <p>(i) Syncope Applicants with a history of recurrent vasovagal syncope...</p> <p>Hidden under the euphemism editorial change a significant change has taken place here and is not discussed anywhere properly. A single syncope is not an uncommon event in young people, especially in teenagers. When applying for a medical certificate years later this would bring them into trouble even though there was no clinical relevance and there is none any</p>

response	<p>more, if the change would pass as intended. Recurrent syncope give rise to concerns about a potential incapacitation in the future, indeed. The original requirement is in line with AMC 1 MED.B.065 (e) where an episode of disturbance of consciousness is covered as insignificant. Therefore the proposed change should be rejected.</p> <p><i>Noted</i></p> <p>See response to comment No 186.</p>
comment	<p>202 comment by: AMCS - Thomas Syburra</p> <p>e - cardiac valvular abnormalities - 3 - aortic valve disease - iii: "applicants with trivial aortic regurgitation may..." It should state: trivial/<u>mild</u></p>
response	<p><i>Not accepted</i></p> <p>No change has been made to the text as 'trivial aortic regurgitation' is a commonly used medical expression especially in the context of echocardiogram analysis.</p>
comment	<p>203 comment by: AMCS - Thomas Syburra</p> <p>g - thromboembolic disorders: the greater threat is the thromboembolic risk, and the proposed INR plan is not sufficient. pulmonal artery hypertension should be ruled out. same comments apply as for the class 1 section</p>
response	<p><i>Noted</i></p> <p>See response to comment No 119.</p>
comment	<p>204 comment by: AMCS - Thomas Syburra</p> <p>i - syncope: neurological review is <u>mandatory</u></p>
response	<p><i>Not accepted</i></p> <p>This addition would not support the principle of proportionate rules for Class 2 medical certification. It should not be mandated at AMC level which is 'soft law' and would, therefore, have to be added at Implementing Rule level.</p> <p>In addition, the licensing authority will be in a position to require neurological review where deemed necessary for certain cases, as the medical certification process requires consultation with the licensing authority, according to the Implementing Rule. A need for a neurological review should also be identified during the cardiological evaluation.</p> <p>Furthermore, this would be considered a major change and, therefore, cannot be inserted at this stage of the NPA.</p>
comment	<p>205 comment by: AMCS - Thomas Syburra</p>



	f - valvular surgery: the greater threat is the thromboembolic risk, and the proposed INR plan is not sufficient. same comments apply as for the class 1 section	
response	<i>Not accepted</i> As the commentator has not provided any proposed text to improve the INR plan, there will be no change to the text at this stage, although it could be considered in a future rulemaking task on Part-MED. In addition, it may not be appropriate to regulate to a greater level of detail. The specialists are expected to refer to suitable medical literature to conduct their evaluation effectively.	
comment	206 k - coronary artery disease - i - a: why was the last sentence removed? she does make sense indeed, as much as for class 1. particularly considering the fact that most of the class 2 operations are single pilot without the handover escape route.	comment by: AMCS - Thomas Syburra
response	<i>Noted</i> See response to comment No 36.	
comment	207 l - rhythm and conduction disturbances - 3 - heart block - i: upper limit 250ms should be mentioned here	comment by: AMCS - Thomas Syburra
response	<i>Not accepted</i> It is not appropriate to regulate to a greater degree of detail. The specialists are expected to refer to suitable medical literature to conduct their evaluation effectively. Furthermore, where feasible, values and numbers are excluded from AMC, as in many cases it cannot be a precise 'cut-off' as every individual is different.	
comment	208 l - rhythm and conduction disturbances - 4 - complete RBBB: same limitations as class 1 should apply	comment by: AMCS - Thomas Syburra
response	<i>Accepted</i> Limitations have been added for class 2 applicants with complete RBBB and LBBB.	
comment	209 l - rhythm and conduction disturbances - 5 - complete LBBB: same limitations as for class 1 should apply	comment by: AMCS - Thomas Syburra
response	<i>Noted</i>	



See response to comment No 208.

comment	210	comment by: AMCS - Thomas Syburra
	I - rhythm and conduction disturbances - 7 - pacemaker - iv: annual ppm check mandatory, query battery life and lead impedances	
response	<i>Partially accepted</i>	
	The text for class 1 and 2 has been amended to require a follow-up at least every 12 months, to take account of more frequent follow-up which may be suggested by the pacemaker manufacturer. No change for battery life and lead impedances, as this is already expected to be addressed during the pacemaker checks.	
comment	211	comment by: AMCS - Thomas Syburra
	m - heart or heart/lung transplantation - iii: use 50% as a matter of wording consistency	
response	<i>Accepted</i>	
	The text has been amended accordingly	
comment	231	comment by: French main military Aeromedical Center (CPEMPN)
	(f) and (g) The OPL limitation in case of anticoagulation after valvular surgery or thromboembolic disorder is not ethically possible (see Section 1). (i) The word " recurrent " for vasovagal syncope must not be deleted, otherwise all the following evaluation is not appropriate for a single episode. Moreover, there are banal vasovagal reactions in typical situations such as medical circumstances which do not require investigations.	
response	<p><u>First comment in this field</u></p> <p><i>Accepted</i></p> <p>A new limitation, encoded 'ORL' (Operating pilot Restriction Limitation), has been introduced to allow a class 2 or LAPL medical certificate holder to apply either an OSL or an Operational Passenger Limitation (OPL). In other words, if passengers are carried, an OSL applies.</p> <p><u>Second comment in this field</u></p> <p><i>Noted</i></p> <p>See response to comment No 186.</p>	
comment	246	comment by: René Meier, Europe Air Sports
	<p>AMC1, AMC2 MED.B.020</p> <p>Remark:</p> <p>The changes proposed are welcome and appropriate provided that there is common</p>	



response	understanding what a "satisfactory evaluation" is.
response	<p><i>Noted</i></p> <p>Thank you for your support.</p> <p>Regarding the part of the comment on 'satisfactory evaluation': According to Part-MED, the specialist, e.g. cardiologist, should evaluate the likely impact of the condition on the safe exercise of the privileges of the licence held or to be held by the applicant. A satisfactory evaluation means that the level of risk is acceptable. A common understanding is not achievable as the impact of medical conditions will vary from person to person. This concept will be covered during the AME training course(s).</p>
comment	<p>312 comment by: UK CAA</p> <p>Page No: 81 Paragraph No: AMC2 to MED.B.010 (e) (3) (iii) Comment: UK CAA suggests the text should be amended to replace 'OML' with 'OSL or OPL' Justification: Current text refers to inappropriate OML limitation for Class 2. Proposed Text: '... A greater degree of aortic regurgitation should require an OML limitation. For greater degrees of aortic regurgitation an OSL or OPL should be considered....'</p>
response	<p><i>Accepted</i></p> <p>OML was an error and the text has been amended to 'OSL'.</p>
comment	<p>313 comment by: UK CAA</p> <p>Page No: 81 Paragraph No: AMC2 to MED.B.010 (f) (2) Comment: Monitoring of warfarin therapy should include near patient testing prior to flight. Justification: To mitigate the bleeding risk of use of warfarin. Proposed Text: Add sentences:</p> <p>'Class 2 applicants will be required to measure their INR on a 'near patient' testing system (such as CoaguChek S) 12 hours prior to flight and only fly if the INR is within the target range. The INR should be recorded in the Log Book. The Log Book should be reviewed at each medical certificate revalidation examination. If near patient testing is not conducted an OSL or OPL would be appropriate.'</p>
response	<p><i>Noted</i></p> <p>See response to comment No 289.</p>
comment	<p>314 comment by: UK CAA</p> <p>Page No: 81 Paragraph No: AMC2 to MED.B.010 (g) Comment: Monitoring of warfarin therapy should include near patient testing prior to flight. Justification: To mitigate the bleeding risk of use of warfarin.</p>



Proposed Text: Add sentences at end of text:

'Class 1 applicants will be required to measure their INR on a 'near patient' testing system (such as CoaguChek S) 12 hours prior to flight and only fly if the INR is within the target range. The INR should be recorded in the Log Book. The Log Book should be reviewed at each medical certificate revalidation examination.'

response *Noted*

See response to comment No 289.

comment 315

comment by: UK CAA

Page No: 81

Paragraph No: AMC2 to MED.B.010 (g)

Comment: Consider approving Novel AntiCoagulant (NOACs) where an equivalent level of safety can be demonstrated.

Justification: To allow consideration of NOACs where they are prescribed in clinical practice and there is no excess risk.

response *Noted*

See response to comment No 291.

comment 316

comment by: UK CAA

Page No: 81

Paragraph No: AMC2 to MED.B.010 (i)

Comment: UK CAA suggests the word 'recurrent' should be retained.

Justification: A six month grounding period for syncope is too onerous in explained cases. Six months grounding is only needed for cases of recurrent syncope.

Proposed Text: 'Applicants with a history of ~~recurrent~~ recurrent vasovagal syncope should be assessed as unfit.'

response *Noted*

See response to comment No 186.

comment 317

comment by: UK CAA

Page No: 82

Paragraph No: AMC1 to MED.B.010 (j) (5)

Comment: UK CAA suggests that satisfactory control should be emphasised in this paragraph.

Justification: Satisfactory control is key to recertification.

Proposed Text: 'Following initiation of medication for the control of blood pressure, applicants should be re-assessed to verify **that satisfactory control has been achieved and that the treatment is compatible with the safe exercise of the privileges of the licence.**'



response *Accepted*

The Agency assumes that the comment refers to AMC2 to MED.B.010(j)(5) as opposed to AMC1, as written. However, the text has been amended accordingly for both class 1 and class 2.

comment *318* comment by: *UK CAA*

Page No: 82
Paragraph No: AMC2 to MED.B.010 (k) (4) (i) (A)
Comment: UK CAA suggests the original text should be retained as there needs to be some assessment of overall disease burden
Justification: The proposed rule change increases the magnitude of overall disease burden that would be acceptable
Proposed Text: Suggest that no change is made to the original text.

response *Noted*

See response to comment No 36.

comment *330* comment by: *Royal Danish Aeroclub*

Comment to page 81, point (g). The following text should be added:

"In case of use of the newer anticoagulation drugs, which cannot be monitored by INR measurements, one should take into consideration, that no adverse effects compromise flight safety. In these cases one should check renal function regularly."

response *Noted*

See response to comment No 291.

In addition, the need to check renal function is really related to the clinical care of the pilot taking NOACs, as these drugs are mainly cleared by the kidney.

3 Proposed amendments — 3.2 Draft Acceptable Means of Compliance and Guidance Material (Draft EASA Decision) — AMC/GM to PART-MEDICAL — SUBPART B — Specific requirements for class 1, class 2 and LAPL medical certificates - AMC for class 1, class 2 and LAPL medical certificates — Section 3 — Specific requirements for class 2 medical certificates — GM3 MED.B.010 Cardiovascular system

p. 84

comment *66* comment by: *Federal Office of Civil Aviation FOCA*

GM3 MED.B.010: (mitral valve disease):

- 1) It does not make sense to create a specific section on mitral valve disease. If there is such a need, then it should be incorporated into section AMC1 MED.B.010 (e) (4).
- 2) The requirement on mitral valve findings is too detailed. It looks like a chapter in a



response	cardiological textbook. This section should be redrafted and simplified.	
	<i>Noted</i>	
	See response to comment No 63.	
comment	212	comment by: AMCS - Thomas Syburra
	statements regarding the tricuspid valve and the pulmonic valve are missing but should be added. our group offers to provide the service of writing those missing paragraphs.	
response	<i>Noted</i>	
	See response to comment No 124.	
comment	213	comment by: AMCS - Thomas Syburra
	b - the following may indicate severe regurgitation: please state the limitations if LA > 4.0cm but <4.5cm -> query OSL	
response	<i>Not accepted</i>	
	Limitations are indicated in the AMC for class 1 and class 2 applicants with moderate regurgitation associated with mitral valve disease. There is no limitation mentioned for applicants with severe regurgitation as this should lead to an unfit assessment for both class 1 and class 2 applicants.	

3 Proposed amendments — 3.2 Draft Acceptable Means of Compliance and Guidance Material (Draft EASA Decision) — AMC/GM to PART-MEDICAL — SUBPART B — Specific requirements for class 1, class 2 and LAPL medical certificates - AMC for class 1, class 2 and LAPL medical certificates — Section 3 — Specific requirements for class 2 medical certificates — GM4 MED.B.010 Cardiovascular system

p. 84

comment	40	comment by: AECA(SPAIN)
	Paragraph (a) ... with an OML... Must say OSL	
response	<i>Partially accepted</i>	
	OML was an error and GM is not the correct arena for imposing limitations. Therefore, the reference to limitations has been deleted from the GM. Furthermore, the associated AMC has been amended.	
comment	41	comment by: AECA(SPAIN)
	Paragraph (a)(2)	



	<p>This requirement can only be satisfied by an electrophysiological study and for Class 2 seems excessive.</p>
response	<p><i>Partially accepted</i></p> <p>It is true that the new GM would require an electrophysiological study to be conducted, but as this is introduced as guidance material rather than AMC or IR, it is not mandatory. The cardiologist should decide if it is needed for the evaluation, e.g. for borderline cases.</p> <p>However, the associated AMC has been amended, so that if the GM is applied and the results are satisfactory, limitations may not be necessary. If not, limitations as appropriate should be applied.</p>
comment	<p>67 comment by: <i>Federal Office of Civil Aviation FOCA</i></p> <p>It does not make sense to set up too detailed requirements on ventricular pre-excitation. The content of the section AMC1 MED.B.010 (I) covers all forms of arrhythmias. If ventricular pre-excitation is highlighted particularly then other forms of arrhythmias like for example AV-reentry tachycardia and many others should also be mentioned.</p> <p>If this section will not be deleted, then it should at least be incorporated into section AMC1 MED.B.010 (I).</p>
response	<p><i>Noted</i></p> <p>See response to comment No 64.</p>
comment	<p>109 comment by: <i>AeMC, Toulon, France</i></p> <p>The systematic restriction OML in case of a ventricular pre-excitation, even when the following criteria are present (no inductible re-entry, refractory period > 300 ms, no induced atrial fibrillation and no multiple accessory pathways) could appear as too restrictive. We are in favour of a case by case decision by the licensing authority. Indeed, this new notification could expose to inadequate ablation in the objective of medical fitness.</p>
response	<p><i>Partially accepted</i></p> <p>The associated AMC has been amended, so that if the GM is applied and the electrophysiological study results are satisfactory, limitations may not be necessary. If not, limitations as appropriate should be applied.</p>
comment	<p>214 comment by: <i>AMCS - Thomas Syburra</i></p> <p>ventricular pre-excitation: EP study mandatory</p>
response	<p><i>Noted</i></p> <p>It is not clear from the comment whether the commentator is suggesting that the new GM would require an electrophysiological study to be conducted or whether the commentator is suggesting that an electrophysiological study should be mandatory.</p> <p>However, as this is introduced as guidance material rather than AMC or IR, it is not</p>

mandatory. The cardiologist should decide if it is needed for the evaluation, e.g. for borderline cases.

Furthermore, the associated AMC has been amended, so that if the GM is applied and the electrophysiological study results are satisfactory, limitations may not be necessary. If not, limitations as appropriate should be applied.

comment	232	comment by: <i>French main military Aeromedical Center (CPEMPN)</i>
	In case of ventricular pre-excitation in asymptomatic applicants, the electrophysiological criteria developed in (a) and (b) are such that an OSL limitation (and not OML) is not justified. To the contrary, all these characteristics should be checked by the licensing authority to assess the applicant as fit without any safety pilot .	
response	<i>Noted</i> See response to comment No 109.	

3 Proposed amendments — 3.2 Draft Acceptable Means of Compliance and Guidance Material (Draft EASA Decision) — AMC/GM to PART-MEDICAL — SUBPART B — Specific requirements for class 1, class 2 and LAPL medical certificates - AMC for class 1, class 2 and LAPL medical certificates — Section 3 — Specific requirements for class 2 medical certificates — AMC2 MED.B.015 Respiratory system p. 84-85

comment	54	comment by: <i>Light Aircraft Association UK</i>
	AMC2 MED.B.015 a): We disagree that the proposed test is an appropriate way to assess this condition. It would be better if an appropriate assessment with an accredited specialist is required, as a spirometric examination does not assess gas transfer and is only a crude tool to manage asthma-type conditions.	
response	<i>Partially accepted</i> In the NPA, new text was proposed to state that a spirometric examination should be performed on clinical indication. This was intended to be a screening test and not as a tool for assessing respiratory diseases. If the FEV1/FVC ratio is <70 % a specialist evaluation is required and the specialist should then proceed to any further investigations deemed to be necessary such as a gas transfer factor estimation.	
comment	97	comment by: <i>EFLEVA</i>
	AMC2 MED.B.015 a): EFLEVA have received advice to the effect that a Spirometric examination is only a crude tool in the management of asthma. An assessment by a credited specialist would be a better alternative.	
response	<i>Noted</i> See response to comment No 54.	



3 Proposed amendments — 3.2 Draft Acceptable Means of Compliance and Guidance Material (Draft EASA Decision) — AMC/GM to PART-MEDICAL — SUBPART B — Specific requirements for class 1, class 2 and LAPL medical certificates - AMC for class 1, class 2 and LAPL medical certificates — Section 3 — Specific requirements for class 2 medical certificates — AMC2 MED.B.025 Metabolic and endocrine systems p. 86-87

comment	<p>201</p> <p style="text-align: right;">comment by: Jörg SIEDENBURG</p> <p>(b) Obesity</p> <p>Obese Applicants with a Body mass index ≥ 35 may be assessed as fit only if the excess weight is not likely to interfere with the safe exercise of the applicable licence(s) and a satisfactory cardiovascular risk review has been undertaken.</p> <p>Obesity and related disorders like diabetes, hypertension etc. (metabolic syndrome) show an increasing prevalence in the general population. Even though this appears like an epidemic, the affected individuals can do something very simple for prevention: reducing weight. The inherent cardiovascular risk in case of severe obesity is not less in Class 2 pilots in comparison with Class 1 pilots. Because of socioeconomic factors the prevalence of obesity is probably even higher in private pilots (no healthy worker effect). Furthermore, the inherent risk in case of an incapacitation is even higher in private pilots in comparison with a multi-pilot cockpit. By allowing severely obese patients to fly without ruling out a high potential of incapacitation due to cardiovascular events as sequelae of metabolic syndrome would be a wrong signal. The medically less controlled groups of pilots show higher fatality rates, not only in types of accidents related to operational factors, but also relating to medical causes. The proposed change increases the risk in the whole system. Therefore, it should be denied.</p>
response	<p><i>Accepted</i></p> <p>The subparagraph on obesity for class 2 medical certification has been amended to require a risk assessment, including evaluation of the cardiovascular system and evaluation of the possibility of sleep apnoea.</p>
comment	<p>319</p> <p style="text-align: right;">comment by: UK CAA</p> <p>Page No: 87 Paragraph No: AMC2 MED.B.025 (g) Comment: Allowing pilots treated with insulin should be accepted subject to compliance with safe AMC/GM. Justification: Appropriate mitigation is outlined in the AMC below and is further detailed in the UK guidance document on insulin treated pilots. Proposed Text: Amend paragraph (g) to read: 'Diabetes mellitus (1) Applicants with diabetes mellitus may be assessed as fit. The use of antidiabetic medications that are not likely to cause hypoglycaemia may be acceptable for a fit assessment. (2) Subject to at least annual specialist assessment, absence of complications likely to</p>



interfere with licence privileges, evidence of good control of blood sugar with no significant hypoglycaemic episodes, applicants with diabetes mellitus requiring the use of antidiabetic medications that may cause hypoglycaemia may be assessed as fit in consultation with the licencing authority and subject to testing whilst exercising licence privileges.'

response *Not accepted*

This paragraph will not be changed at this stage; the rule will remain ICAO compliant.

However, the following solution has been proposed in a recent package of amendments for Part-ARA (Annex VI to the Aircrew Regulation). The proposal is to reintroduce the former paragraph JAR.FCL 3.046 'special medical circumstances' to Part-ARA. The aim is to allow competent authorities to consider medical advancements and to establish whether a fit assessment may be possible for certain medical conditions for which the existing provisions inevitably lead to an unfit assessment. Under new medical assessment protocols via research, it would be possible to collect specific data in a controlled aviation environment, and to develop specific risk assessments for certain medical conditions.

3 Proposed amendments — 3.2 Draft Acceptable Means of Compliance and Guidance Material (Draft EASA Decision) — AMC/GM to PART-MEDICAL — SUBPART B — Specific requirements for class 1, class 2 and LAPL medical certificates - AMC for class 1, class 2 and LAPL medical certificates — Section 3 — Specific requirements for class 2 medical certificates — AMC2 MED.B.035 Genitourinary system

p. 88

comment 320

comment by: UK CAA

Page No: 88

Paragraph No: AMC 2 MED.B.035 (c) (4)

Comment: Cardiovascular risk assessment should be required for Class 2 certification after renal transplantation.

Justification: There is an increased risk of cardiovascular disease after renal transplantation.

Proposed Text: Add sentence: '**Cardiovascular risk assessment should be required.**'

response *Not accepted*

A change of this magnitude would need to be properly consulted, for example through NPA consultation. It could, however, be considered in a future rulemaking task on Part-MED if supported by detailed risk assessment data and justification. In the meantime, nothing prevents the AME from requesting a cardiological evaluation if deemed appropriate for the individual.

3 Proposed amendments — 3.2 Draft Acceptable Means of Compliance and Guidance Material (Draft EASA Decision) — AMC/GM to PART-MEDICAL — SUBPART B — Specific requirements for class 1, class 2 and LAPL medical certificates - AMC for class 1, class 2 and LAPL medical certificates — Section 3 — Specific requirements for class 2 medical certificates — AMC2 MED.B.040 Infectious diseases

p. 88-89



comment	321	comment by: UK CAA
	<p>Page No: 89 Paragraph No: AMC2 MED.B.040 (b)(2) Comment: “AIDS related complex” is a medical term that is no longer in regular clinical use. Justification: Use of the term “AIDS related complex” was widely discontinued in the year 2000. Its continued inclusion here gives the appearance of being out of date or not fully understanding the subject matter. Proposed Text: ‘Applicants with signs or symptoms of an AIDS defining condition or AIDS-related complex is disqualifying should be assessed as unfit.’</p>	
response	<p><i>Noted</i> See response to comment No 300.</p>	

3 Proposed amendments — 3.2 Draft Acceptable Means of Compliance and Guidance Material (Draft EASA Decision) — AMC/GM to PART-MEDICAL — SUBPART B — Specific requirements for class 1, class 2 and LAPL medical certificates - AMC for class 1, class 2 and LAPL medical certificates — Section 3 — Specific requirements for class 2 medical certificates — AMC2 MED.B.055 Psychiatry p. 89-90

comment	322	comment by: UK CAA
	<p>Page No: 89 Paragraph No: AMC 2 MED.B.055 (c) Comment: Limitations other than OSL may be appropriate. Justification: A limitation e.g. to fly with no passengers, or to fly from a named club may be more appropriate than a OSL. Proposed Text: ‘... If a stable maintenance psychotropic medication is confirmed, a fit assessment with an OSL or other limitation may be considered.’</p>	
response	<p><i>Partially accepted</i> The text has been amended taking the comment into account.</p>	

comment	323	comment by: UK CAA
	<p>Page No: 90 Paragraph No: AMC2 MED.B.055 (e) Comment: Confusion in the use of the terms “psychoactive” and “psychotropic”. Justification: These terms could be held to mean the same but in AMC1 MED.B.055 it appears that “psychotropic” is held to mean drugs prescribed with therapeutic intent and “psychoactive” refers to illegal/illicit substances. The wording in paragraphs (e) when read with (h) result in the unintended consequence that pilots on maintenance antidepressant medication require a period of “two years documented sobriety”. Change text in (e) to maintain consistency with AMC1 MED.B.055 (e).</p>	



Proposed Text: ‘... If a ~~stable~~ **stability on** maintenance ~~psychoactive~~ **psychotropic** medication is confirmed, a fit assessment with **appropriate limitation(s)** may be considered ...’

response *Partially accepted*

Subparagraph (c) and (e) both refer to maintenance medication. As the expression ‘psychoactive’ includes medication such as sedatives and opioids, this will be the term used throughout Part-MED, instead of ‘psychotropic’. Subparagraphs (c) and (e) have been amended accordingly, also with editorial improvements, alignment with AMC1 MED.B.055 and reference to appropriate limitations.

3 Proposed amendments — 3.2 Draft Acceptable Means of Compliance and Guidance Material (Draft EASA Decision) — AMC/GM to PART-MEDICAL — SUBPART B — Specific requirements for class 1, class 2 and LAPL medical certificates - AMC for class 1, class 2 and LAPL medical certificates — Section 3 — Specific requirements for class 2 medical certificates — AMC2 MED.B.065 Neurology p. 90-91

comment 85 comment by: *The Norwegian Air Sports Federation*

AMC2 MED.B.065 (e) (f), etc NLF welcomes the addition covering the possibility for a fit assessment despite traumatic injury and vascular deficiencies for both Class 2 and LAPL, while maintaining a high level of safety.

response *Noted*

Thank you for your support.

comment 247 comment by: *René Meier, Europe Air Sports*

AMC2 MED.B.065 Neurology
Our community welcomes the alleviations proposed.
Rationale:
Pilots as well as AME know about the responsibilities and will therefore maintain the highest possible level of safety while minimizing risks.

response *Noted*

Thank you for your support.

3 Proposed amendments — 3.2 Draft Acceptable Means of Compliance and Guidance Material (Draft EASA Decision) — AMC/GM to PART-MEDICAL — SUBPART B — Specific requirements for class 1, class 2 and LAPL medical certificates - AMC for class 1, class 2 and LAPL medical certificates — Section 3 — Specific requirements for class 2 medical certificates — AMC2 MED.B.070 Visual system p. 91-93



comment

177

comment by: *Swedish Transport Agency, Civil Aviation Department
(Transportstyrelsen, Luftfartsavdelningen)*Section: [AMC2 MED.B.070 \(j\)](#)**Comment:**

The AMC1 ATCO.MED.B.070 (j) has been amended to change the expression 'correcting lenses', which is incorrectly used in this context, to 'spectacles'.
The same expression should be used also for pilots.

Proposal:

Amend AMC2 MED.B.070:

'(j) Visual correction

Spectacles should permit the licence holder to meet the visual requirements at all distances.'

response

Not accepted

The subparagraph applies to spectacles and contact lenses.

comment

179

comment by: *Swedish Transport Agency, Civil Aviation Department
(Transportstyrelsen, Luftfartsavdelningen)*Section: [GM2 MED.B.070 \(new\)](#)**Comment:**

A GM1 ATCO.MED.B.070 has been added with a table for comparison of the scales of different near vision charts to make it easier for AMEs to compare the charts they are using with the N charts referred to in the requirements. As the same reading charts are used also for pilots, this GM should be added as a GM2 MED.B.070.

Proposal:

Add GM1 ATCO.MED.B.070 as a new GM2 MED.B.070.

response

Accepted

The comparison table from GM1 ATCO.MED.B.070 has been added as GM for class 1, 2, LAPL and cabin crew.

comment

324

comment by: *UK CAA***Page No:** 92**Paragraph No:** AMC2 MED.B.070 (c)

Comment: For Class 2, a visual field requirement is set for applicants with reduced visual acuity in one eye but there is no visual field requirement for applicants who are monocular.



There are also slight differences in the terminology used compared with AMC1 MED.B.070(f).
Justification: Class 2 applicants with reduced visual acuity in one eye need to have normal binocular visual fields whilst there is no standard for monocular applicants. Any pilot with reduced visual acuity who has an abnormal visual field will want to be assessed as monocular. Otherwise the AMC for both are very similar and could be combined to simplify the text and altered to ensure consistent terminology with AMC1 MED.B.070(f).

Proposed Text: Suggest amend the text as follows:

~~Visual acuity~~ **Substandard Vision**

(1) **Reduced vision in one eye or monocularly:** Applicants with reduced ~~visual acuity~~ **vision or loss of vision** in one eye may be assessed as fit if:

- (i) ~~the visual acuity of the affected eye is 6/18 (0.3) or better~~ **in the case of monocularly, a period of adaptation time has passed from the known point of visual loss, during which time the applicant should be assessed as unfit;**
- (ii) ~~the better~~ **unaffected** eye achieves distant visual acuity of 6/6 (1.0), corrected or uncorrected;
- (iii) ~~the better~~ **unaffected** eye achieves intermediate visual acuity of N14 and N5 for near;
- (iv) there is no significant ocular pathology in the ~~better~~ **unaffected** eye;
- (v) ~~the binocular~~ **visual field is normal acceptable;** and
- (vi) a medical flight test is satisfactory.

~~(2) Monocularly~~

~~Applicants with acquired loss of vision in one eye, may be assessed as fit if:~~

- ~~(i) a period of adaptation time has passed from the known point of visual loss, during which time the applicant should be assessed as unfit;~~
- ~~(ii) the functional eye achieves distant visual acuity of 6/6 (1.0), corrected or uncorrected;~~
- ~~(iii) the functional eye achieves intermediate visual acuity of N14 and N5 for near;~~
- ~~(iv) there is no significant ocular pathology in the functional eye; and~~
- ~~(v) a medical flight test is satisfactory.'~~

response

Accepted

The text has been amended accordingly.

3 Proposed amendments — 3.2 Draft Acceptable Means of Compliance and Guidance Material (Draft EASA Decision) — AMC/GM to PART-MEDICAL — SUBPART B — Specific requirements for class 1, class 2 and LAPL medical certificates - AMC for class 1, class 2 and LAPL medical certificates — Section 3 — Specific requirements for class 2 medical certificates — AMC2 MED B.075 Colour vision p. 93

comment

101

comment by: *Del Monte*

Dear NPA team,
 Considering other Authorities in the world have a far more relax regulation over this matter, would the Agency consider aligning and updating this law to the like of the FAA, CASA and Transport Canada?
 Not only the Ishihara's plates are 100+ year old but also ALL current approved secondary tests (Lanterns and Anomaloscope) are rather outdated and frankly not very relevant to any 'daily pilot action'. In fact these tests seems to cause a lot of FALSE POSITIVES: Even mild cases of colour vision defect who are indeed well capable and safe to fly at night or



commercially might be unable to pass a very limited choice of tests thus being discriminated. Also, not only any test should be carried out in accordance with the manufacturing instructions (Ishihara's plates aren't, please check manual!) but I do also believe we need a more practical, fairer and honest test based on real life/actions, NOT academic/clinical/computerised tests. In fact, the FAA allows up to 18 approved tests amongst which a practical test (TOWER SIGNAL LIGHT AND MFT) that has direct relation to flying. Would the Agency at least consider this?

Also in Australia for 20 years, CASA has been allowing pilots with ANY degree of colour vision defect, from mild all the way to SEVERE like protanotopes, not only to fly at night but also to carry out Commercial Air Transport: These colour vision defect pilots are subject to any LPC/OPC like the 'normal' colleagues and clearly show that they are able to perform SAFELY and CORRECTLY both as single and multi crew: this, once again, highlights the discrimination issue! Would the Agency think about this problem, especially about the discrimination issue, considering that as we speak many colour vision defect pilots are flying in and out Europe's largest airports flying heavy/super category aircraft, at night perhaps, yet their European peers are not even allowed to fly at night on a single engine aircraft?!

thank you

response *Partially accepted*

Thank you for your contribution. However, the European rules will remain ICAO compliant for the time being.

The choice of colour vision tests has been broadened to include the UK CAD test.

comment 325

comment by: UK CAA

Page No: 93

Paragraph No: AMC2 MED.B.075

Comment: There are methodological limitations to the use of the anomaloscope and lantern tests in determining whether an individual is 'colour safe'. A colour threshold determination test needs to be allowed as an alternative to, or more probably instead of, a lantern test.

Justification: The colour threshold determination test, known as the CAD test, is now in routine use in some States as the evidence for its use is far greater than the evidence for the use of any of the lantern tests. It is proposed that it should be included as being acceptable for a medical assessment for Class 2.

The task analysis that was undertaken as part of the research for the CAD test demonstrated that cockpit displays have sufficient redundancy cues so as not to be safety critical colour tasks. However the detection of coloured lights in the PAPI **IS** safety critical and this underpins the new test.

Proposed Text: Add new sub-paragraph as follows:

'(3) Colour threshold determination test (CAD or equivalent). This test is considered passed if the colour detection threshold is equivalent to that of an individual with normal trichromacy.'

response *Noted*

See response to comment No 28. The reference to 'normal trichromacy' has been added to the Implementing Rule.



3 Proposed amendments — 3.2 Draft Acceptable Means of Compliance and Guidance Material (Draft EASA Decision) — AMC/GM to PART-MEDICAL — SUBPART B — Specific requirements for class 1, class 2 and LAPL medical certificates - AMC for class 1, class 2 and LAPL medical certificates — Section 3 — Specific requirements for class 2 medical certificates — AMC2 MED.B.080 Otorhino-laryngology Otorhinolaryngology (ENT) p. 93-94

comment 86 comment by: *The Norwegian Air Sports Federation*

AMC2 MED.B.080 (a) (4) / AMC16 MED.B.095 (a) (4)
NLF welcomes the change, which allows for a fit assessment in cases of profound deafness. NLF has in the past issued licenses to such pilots for flying microlight aircraft, and no safety issue has been noted during these operations.

response *Noted*

Thank you for your support.

comment 248 comment by: *René Meier, Europe Air Sports*

AMC2 MED.B.080(a)(4) and AMC16 MED.B.095(a)(4)
Profound deafness or major disorder of speech
We welcome this provision allowing a fit assessment in cases of deafness or major disorder of speech. This, however, is in our opinion, a major change, not only a minor change.
Rationale:
Observing the requirements of the airspace flown deafness or speech disorder should not prevent a pilot from flying.

response *Noted*

Thank you for your support.

3 Proposed amendments — 3.2 Draft Acceptable Means of Compliance and Guidance Material (Draft EASA Decision) — AMC/GM to PART-MEDICAL — SUBPART B — Specific requirements for class 1, class 2 and LAPL medical certificates - AMC for class 1, class 2 and LAPL medical certificates — Section 4 — Specific requirements for LAPL medical certificates — AMC1 MED.B.095 Medical examination and/or assessment of applicants for LAPL medical certificates p. 96

comment 42 comment by: *AECA(SPAIN)*

In general these AMC corresponding to Section 4 seem inconsistent with the regulation. They carry far beyond what is required by regulation.
If you want to evaluate the level set in the AMC must be change the Regulation to include additional requirements. Otherwise be eliminated the majority of AMC of this section.



response *Not accepted*

In the NPA, there was a proposal to move the existing paragraph MED.B.005 from section 2 of Subpart B to section 1 of the same Subpart. MED.B.005 contains the very basic medical requirements and the result of including it in section 1 is that it will be applicable for LAPL medical certificates which is presently not the case.

This change was considered to be necessary because the rules for the LAPL medical certificate in paragraph MED.B.095 do not contain medical criteria for the assessment of applicants. The lack of a rule for specific LAPL medical requirements was considered to be a gap in Part-MED that should be covered without undermining the overall aim of not having strict rules for LAPL medical certificates. The inclusion of MED.B.005 in section 1 of Subpart B does not change the objective of lighter and flexible requirements for the LAPL medical certificate because this general paragraph that does not provide specific fit or unfit criteria.

The applicability of MED.B.005 for the LAPL medical certificate is supposed to provide the necessary basis on which to rely for the medical assessment of these applicants. Detailed medical criteria for the LAPL will remain in the AMCs to MED.B.095.

3 Proposed amendments — 3.2 Draft Acceptable Means of Compliance and Guidance Material (Draft EASA Decision) — AMC/GM to PART-MEDICAL — SUBPART B — Specific requirements for class 1, class 2 and LAPL medical certificates - AMC for class 1, class 2 and LAPL medical certificates — Section 4 — Specific requirements for LAPL medical certificates — AMC2 MED.B.095 Cardiovascular system p. 96-97

comment 53

comment by: *Light Aircraft Association UK*

AMC2 MED.B.095 d)2): We strongly support this proposal to allow people on anti-anginal medication to be assessed as fit to fly solo or with a safety pilot.

response *Noted*

See response to comment No 110.

comment 87

comment by: *The Norwegian Air Sports Federation*

AMC2 MED.B.095 (d) (2)

NLF welcomes the possibility for a fit assessment for persons with angina pectoris requiring medication after cardiological evaluation. As there are normally no restrictions for driving a car if the angina is well controlled, one would assume that the risk of a sudden incapacitation is rather remote. Unless it is possible to document that leisure flying – which LAPL holders are exclusively engaged in – poses special risks for angina patients compared to driving a car, no further restrictions should be added.

response *Noted*

See response to comment No 110.



comment	98	comment by: EFLEVA
	AMC2 MED.B.095 d)2) : EFLEVA welcomes the revision to allow people under treatment for angina to undergo cardiological evaluation and may be considered fit to fly.	
response	<i>Noted</i> See response to comment No 110.	
comment	110	comment by: AeMC, Toulon, France
	We are not in favour of a potential fit assessment in case of angina pectoris requiring medication for cardiac symptoms.	
response	<i>Accepted</i> The onset of angina during flight is likely to have significant flight safety implications which are not mitigated by the addition of an OSL or OPL, and the medication used to treat angina often has significant side effects. The text has, therefore, been changed back to the original text, which is as follows: 'Applicants with angina pectoris requiring medication for cardiac symptoms should be assessed as unfit'.	
comment	215	comment by: AMCS - Thomas Syburra
	b - general - 5 - other cardiac disorders - ii: this is not mentioned in class 1 / 2, so why here? please clarify	
response	<i>Partially accepted</i> 'Other cardiac disorders' is already addressed in the existing AMC for class 1 and 2. Nevertheless, a new subparagraph (b)(4) has been added to the Implementing Rule for class 1 and 2, for clarification.	
comment	216	comment by: AMCS - Thomas Syburra
	Attachment #5	
	b - general - 2 - aortic aneurysm: bear in mind the EACTS/ESC and ACC guidelines on the monitoring and treatment of aortic aneurysms. In particular consider to weight the value of the diameter against comorbidities such as bicuspid aortic valve, gender, underlying genetic disorders. the growth rate is also to be considered. those factors will determine the start of beta-blockers or recommendation for surgery at an earlier stage than the usual values.	
	references: ACC/AHA Guideline based on the 2010 ACCF / AHA / AATS / ACR / ASA / SCA / SCAI / SIR / STS / SVM Guidelines for the Diagnosis and Management of Patients With Thoracic Aortic Disease Hiratzka, Barkis, Beckman, Bersin, Carr, Casey, Eagle, Hermann, Isselbacher, Kazerooni,	



Kouchoukos, Lytle, Milewicz, Reich, Sen, Shinn, Svensson, Williams
Circulation 2010;121:1544-79

What is New in Dilatation of the Ascending Aorta? : Review of Current Literature and Practical Advice for the Cardiologist

Cozijnsen, Braam, Waalewijn, Shepens, Loeys, van Oosterhout, Barge-Schaapveld, Mulder
Circulation 2011;123:924-8

Natural History of thoracic aortic aneurysms: indications for surgery, and surgical versus nonsurgical risks.

John A. Elefteriades

Ann Thorac Surg 2002;74:1877-80

Yearly rupture or dissection rates for thoracic aortic aneurysms: simple prediction based on size.

R Davies, L Goldstein, M Coady, S Tittle, J Rizzo, G Kopf, J Elefteriades

Ann Thorac Surg 2002;73:17-28

The following link leads to a topic overview by Prof. J. A. Elefteriades from Yale university, he's one of the leading authorities on this topic:

<http://www.ncbi.nlm.nih.gov/pmc/articles/PMC2605304/>

I summarized the current recommendations in the attached Excel sheet "[121009 guidelines for surgery in ao asc](#)". They represent the current practice at the Royal Brompton Hospital London.

response *Not accepted*

The detailed guidance material on the monitoring and treatment of aortic aneurysms that the commentator has provided is appreciated by the Agency. However, this level of detail is not considered appropriate for LAPL medical certification, as it would not support the principle of proportionality. Indeed, the specialists are expected to refer to suitable medical literature to conduct effective evaluations. Furthermore, the objective of the aero-medical examination and assessment is to verify that the pilot is fit to exercise the privileges of their licence, also taking into account the risk of sudden incapacitation, rather than for consideration for clinical intervention.

comment 217

comment by: AMCS - Thomas Syburra

d - coronary artery disease - 2: unclear, so if controlled with medication are they fit?

response *Noted*

See response to comment No 110.

comment 218

comment by: AMCS - Thomas Syburra

e - rhythm and conduction disturbances - 3: specify after what time period and the subsequent follow-up intervals, or should it be straight away?



response	<p><i>Noted</i></p> <p>More flexibility was intended for applicants for the LAPL, so no specific time limits for certification or follow up are stipulated.</p>
comment	<p>233 comment by: <i>French main military Aeromedical Center (CEMPN)</i></p> <p>(b) (4) The requirements in case of anticoagulation are imprecise. Considering a so important problem, a sentence should refer to the same conditions as in sections 2 and 3. It should be written a periodicity for ECG as for class 2 pilots. Resting ECG is a simple, quick, cheap and non-invasive exam that is currently used particularly to detect coronary artery disease, left ventricular hypertrophy and different syndromes which can be intermittent (ventricular pre-excitation, Brugada syndrome, QT variations, premature ventricular beats...) These abnormalities and/or heart diseases may jeopardize flight safety as for class 1 and 2 pilots.</p>
response	<p><u>First comment in this field</u></p> <p><i>Accepted</i></p> <p>The text has been amended taking the comment into account.</p> <p><u>Second comment in this field</u></p> <p>This would be considered a major change and, therefore, cannot be introduced at this stage of the NPA.</p>
comment	<p>249 comment by: <i>René Meier, Europe Air Sports</i></p> <p>AMC2 MED.B.095 Cardiovascular system (d)(2) Our community welcomes these provisions. Rationale: Car driving is not a problem when angina is controlled, the risk of a sudden incapacitation is remote, therefore no additional restrictions are required.</p>
response	<p><i>Noted</i></p> <p>See response to comment No 110.</p>
comment	<p>326 comment by: <i>UK CAA</i></p> <p>Page No: 97 Paragraph No: AMC 2 to MED.B.095 (d) (2) Comment: UK CAA believes applicants with angina requiring medication should be restricted. Justification: An OSL or OPL is required in this circumstance to mitigate the increased risk. Proposed Text: 'Applicants with angina pectoris requiring medication for cardiac symptoms should undergo a cardiological evaluation before a fit assessment may be considered. Applicants who have been symptom free on medication for 6 weeks, including no symptoms on exercise testing, may be assessed as fit otherwise an OSL or OPL is</p>



	appropriate.'
response	<i>Noted</i> See response to comment No 110.

3 Proposed amendments — 3.2 Draft Acceptable Means of Compliance and Guidance Material (Draft EASA Decision) — AMC/GM to PART-MEDICAL — SUBPART B — Specific requirements for class 1, class 2 and LAPL medical certificates - AMC for class 1, class 2 and LAPL medical certificates — Section 4 — Specific requirements for LAPL medical certificates — AMC3 MED.B.095 Respiratory system p. 97

comment	345	comment by: <i>Trond-Eirik Strand</i>
	In section 2.3.5.3 of the NPA (Respiratory system) the following explanation is found: “An amendment to AMC 3 MED.C.025 (b) is proposed to allow morphological testing, as well as functional testing, when required on clinical indication, as morphological tests, such as MRI scans, are known to be an effective mechanism for assessing respiratory conditions.” With the same argumentation this should also be the case for class 1, 2 and LAPL.	
response	<i>Accepted</i> The option for pulmonary morphological testing has been added for class 1 and class 2 medical certification. Also, a new subparagraph has been added to the LAPL AMC for the respiratory system to ensure pulmonary morphological or functional tests are undertaken on clinical indication.	

3 Proposed amendments — 3.2 Draft Acceptable Means of Compliance and Guidance Material (Draft EASA Decision) — AMC/GM to PART-MEDICAL — SUBPART B — Specific requirements for class 1, class 2 and LAPL medical certificates - AMC for class 1, class 2 and LAPL medical certificates — Section 4 — Specific requirements for LAPL medical certificates — AMC5 MED.B.095 Metabolic and endocrine systems p. 98-100

comment	58	comment by: <i>DGAC FRANCE</i>
	<p>Section 4 Specific requirements for LAPL medical certificates AMC5 MED.B.095 Metabolic and endocrine systems Paragraph (d) Diabetes mellitus</p> <p>Delete the authorization of the diabetes insulin dependent for the pilots LAPL medical capacity.</p> <p>France has already let know its position concerning Diabetes mellitus as regard of Air traffic controllers.</p>	



As, EASA is fully aware France has let observed:

- That paragraph concerning diabetes mellitus requiring insulin disappears from different versions of NPA Part-MED (ATCO) due to disagreement within the expert group, as cause of unfitness.
- Those propositions of AMC and GM (see UK Proposals and ESAM recommendations) on this topic raise many comments and objections that the French expert (Ms Monchaline) has already brought up in front of the medical experts group on the ground that :
 - They lead to inadequate treatment,
 - It can affect ATCO health in middle and long term due to the fact that to reduce harmful effects of insulin treatment upon fly safety (faintness ...) it is proposed to impose target values higher than recommended by the consulting physicians (See Target ranges for clinical variables),
 - It interferes with therapeutic management,
 - It requires to air navigation services providers (DSNA), organizational and operational limitations which are not compatible with its management style (see Certification for Applicants with diabetes, Testing Protocol).

In France, registration to French Medical Association implies compliance with in force law:

- Code of Ethics :
 - o Medical confidentiality is mandatory to every physician. Communication between consulting physicians and AMEs is forbidden.
 - o Each physician is responsible for its decisions and actions. AMEs cannot interfere with treatment....
 - o Physician must not damage physical and mental health.
- Penal code :
 - o Aero medical experts and medical assessor will be personally responsible if they fail to their duties.

Moreover, the principle of free movement of citizens (ATCO) in Europe will be limited if some countries do not want to apply it.

Other countries also do not support the change concerning diabetes.

In these conditions, a change concerning the LAPL certificate is not acceptable without a global discussion (including pilots and ATCO) on the diabetes topic.

Sir Kneepens' letter informed France about a forum on the insulin dependent diabetes planned in February 2014 to Gatwick. It is advisable to wait for the notices and for conclusions of this forum and the European Commission before authorizing the insulin dependent diabetes at the pilots LAPL.

response

Not accepted

In the NPA, no substantial changes were proposed for the LAPL medical certification criteria for applicants with diabetes mellitus. The current AMCs allow for a fit assessment to be considered under a strict regime for applicants with diabetes mellitus Type 2 treated with insulin. The only changes proposed are for clarification, especially for the limitation(s) to be applied.

The Agency's proposal for ATCO medical certification requires applicants with diabetes mellitus requiring insulin to be assessed as unfit. This reflects the difference between the acceptable level of safety for privileges associated with the LAPL and the ATCO licence.



comment	75	comment by: <i>Uwe Höfinghoff</i>
	Why medical treatment with insulin is handled differently for Diabetes Type 1 and Diabetes Type 2. The general treatment with insulin for both types of Diabetes is comparable, isn't it?	
response	<i>Noted</i>	
	The hypoglycaemic risk is lower in Type 2 diabetics treated with insulin.	
comment	88	comment by: <i>The Norwegian Air Sports Federation</i>
	AMC5 MED.B.095 (d) (3) NLF welcomes the change from an OSL to an OPL. In general, NLF prefers the OPL over the OSL limitation for leisure flying, firstly because on OSL offers few advantages over being a regular passenger in a light aircraft, secondly because an OPL is well suited to protect third parties, who are less likely to be aware of the risks associated with the operations than the pilot in command.	
response	<i>Noted</i>	
	Thank you for your support. A new limitation, encoded ORL (Operating pilot Restriction Limitation), has been introduced (new (d)(4)) to allow a class 2 or LAPL medical certificate holder to apply either an OSL (Operational Safety Pilot Limitation) or an OPL (Operational Passenger Limitation). In other words, if passengers are carried, an OSL will apply. Therefore, pilots with medical certificates endorsed with an ORL will be able to operate single seat aircraft.	
comment	250	comment by: <i>René Meier, Europe Air Sports</i>
	AMC5 MED.B.095(d)(3) Proposed change from OSL to OPL Europe Air Sports and its members support this change. Rationale: It offers a higher degree of safety and of protection of third parties.	
response	<i>Noted</i>	
	Thank you for your support. A new limitation, encoded ORL (Operating pilot Restriction Limitation), has been introduced (new (d)(4)) to allow a class 2 or LAPL medical certificate holder to apply either an OSL (Operational Safety Pilot Limitation) or an OPL (Operational Passenger Limitation). In other words, if passengers are carried, an OSL will apply. Therefore, pilots with medical certificates endorsed with an ORL will be able to operate single seat aircraft.	
comment	334	comment by: <i>Jörg SIEDENBURG</i>
	(b) Obesity	



Obese applicants **with a Body mass index ≥ 35** may be assessed as fit only if the excess weight is not likely to interfere with the safe exercise of the applicable licence(s) **and a satisfactory cardiovascular risk review has been undertaken.**

Obesity and related disorders like diabetes, hypertension etc. (metabolic syndrome) show an increasing prevalence in the general population. Even though this appears like an epidemic, the affected individuals can do something very simple for prevention: reducing weight. The inherent cardiovascular risk in case of severe obesity is not less in LAPL pilots in comparison with Class 1 or Class 2 pilots. Because of socioeconomic factors the prevalence of obesity is probably even higher in private pilots (no healthy worker effect). Furthermore, the inherent risk in case of an incapacitation is even higher in private pilots in comparison with a multi-pilot cockpit. By allowing severely obese patients to fly without ruling out a high potential of incapacitation due to cardiovascular events as sequelae of metabolic syndrome would be a wrong signal. The medically less controlled groups of pilots show higher fatality rates, not only in types of accidents related to operational factors, but also relating to medical causes. The proposed change increases the risk in the whole system. Therefore, it should be denied.

response

Not accepted

This addition would not support the principle of proportionate rules for light aircraft pilots.

Furthermore, this would be considered a major change and, therefore, cannot be inserted at this stage of the NPA.

3 Proposed amendments — 3.2 Draft Acceptable Means of Compliance and Guidance Material (Draft EASA Decision) — AMC/GM to PART-MEDICAL — SUBPART B — Specific requirements for class 1, class 2 and LAPL medical certificates - AMC for class 1, class 2 and LAPL medical certificates — Section 4 — Specific requirements for LAPL medical certificates — GM1 MED.B.095 Diabetes mellitus Type 2 treated with insulin

p. 100

comment

59

comment by: DGAC FRANCE

GM1 MED.B.095 Diabetes mellitus Type 2 treated with insulin

Delete the authorization of the diabetes insulin dependent for the pilots LAPL medical capacity.

France has already let know its position concerning Diabetes mellitus as regard of Air traffic controllers.

As, EASA is fully aware France has let observed:

- That paragraph concerning diabetes mellitus requiring insulin disappears from different versions of NPA Part-MED (ATCO) due to disagreement within the expert group, as cause of unfitness.
- Those propositions of AMC and GM (see UK Proposals and ESAM recommendations) on this topic raise many comments and objections that the French expert (Ms Monchalín) has already brought up in front of the medical experts group on the ground that :
 - They lead to inadequate treatment,
 - It can affect ATCO health in middle and long term due to the fact that to reduce harmful



effects of insulin treatment upon fly safety (faintness ...) it is proposed to impose target values higher than recommended by the consulting physicians (See Target ranges for clinical variables),

- It interferes with therapeutic management,
- It requires to air navigation services providers (DSNA), organizational and operational limitations which are not compatible with its management style (see Certification for Applicants with diabetes, Testing Protocol).

In France, registration to French Medical Association implies compliance with in force law:

- Code of Ethics :
 - o Medical confidentiality is mandatory to every physician. Communication between consulting physicians and AMEs is forbidden.
 - o Each physician is responsible for its decisions and actions. AMEs cannot interfere with treatment....
 - o Physician must not damage physical and mental health.
- Penal code :
 - o Aero medical experts and medical assessor will be personally responsible if they fail to their duties.

Moreover, the principle of free movement of citizens (ATCO) in Europe will be limited if some countries do not want to apply it.

Other countries also do not support the change concerning diabetes.

In these conditions, a change concerning the LAPL certificate is not acceptable without a global discussion (including pilots and ATCO) on the diabetes topic.

Sir Kneepens' letter informed France about a forum on the insulin dependent diabetes planned in February 2014 to Gatwick. It is advisable to wait for the notices and for conclusions of this forum and the European Commission before authorizing the insulin dependent diabetes at the pilots LAPL.

response *Noted*

See response to comment No 58.

3 Proposed amendments — 3.2 Draft Acceptable Means of Compliance and Guidance Material (Draft EASA Decision) — AMC/GM to PART-MEDICAL — SUBPART B — Specific requirements for class 1, class 2 and LAPL medical certificates - AMC for class 1, class 2 and LAPL medical certificates — Section 4 — Specific requirements for LAPL medical certificates — GM2 MED.B.095 Diabetes mellitus Type 2 treated with insulin

p. 101

comment 60

comment by: *DGAC FRANCE*

GM1 MED.B.095 Diabetes mellitus Type 2 treated with insulin

Delete the authorization of the diabetes insulin dependent for the pilots LAPL medical capacity.



France has already let know its position concerning Diabetes mellitus as regard of Air traffic controllers.

As, EASA is fully aware France has let observed:

- That paragraph concerning diabetes mellitus requiring insulin disappears from different versions of NPA Part-MED (ATCO) due to disagreement within the expert group, as cause of unfitness.
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 - They lead to inadequate treatment,
 - It can affect ATCO health in middle and long term due to the fact that to reduce harmful effects of insulin treatment upon fly safety (faintness ...) it is proposed to impose target values higher than recommended by the consulting physicians (See Target ranges for clinical variables),
 - It interferes with therapeutic management,
 - It requires to air navigation services providers (DSNA), organizational and operational limitations which are not compatible with its management style (see Certification for Applicants with diabetes, Testing Protocol).

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 - o Physician must not damage physical and mental health.
- Penal code :
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Sir Kneepens' letter informed France about a forum on the insulin dependent diabetes planned in February 2014 to Gatwick. It is advisable to wait for the notices and for conclusions of this forum and the European Commission before authorizing the insulin dependent diabetes at the pilots LAPL.

response *Noted*

See response to comment No 58.



(Draft EASA Decision) — AMC/GM to PART-MEDICAL — SUBPART B — Specific requirements for class 1, class 2 and LAPL medical certificates - AMC for class 1, class 2 and LAPL medical certificates — Section 4 — Specific requirements for LAPL medical certificates — AMC15 MED.B.095 Colour vision

comment 102

comment by: *Del Monte*

Dear NPA team,
it's good to see some progress on this matter! The Agency is finally moving towards the end of this discrimination as Colour Vision Defect Pilots, or at least those mild if not ALL, are indeed safe and capable to fly at night! Australian Civil Aviation Authority (CASA) has in fact even allowed for 20 year Color Vision Defect Pilots to fly not only at night, but also for Commercial Air Transport! In fact as we speak many colour vision defect pilots are flying in and out Europe's largest airports flying heavy/super category aircraft.

The FAA accept also up to 18 tests, thus allowing a greater chance for a pass including a practical test (TOWER LIGHT SIGNAL) to make sure fairness and honesty are guaranteed.

On this matter, the Agency has started a good step in the right direction with the LAPL. Is the Agency planning to apply a similar concept to class one and two?

thank you

response *Noted*

Thank you for your support. However, it should be noted that there was no change to the LAPL AMC proposed in the NPA. The existing AMC requires LAPL holders applying for a night rating to correctly identify 9 of the first 15 plates of the 24-plate edition of Ishihara pseudo-isochromatic plates or to be colour safe.

The Agency acknowledges that new methods of testing colour vision have been introduced since publication of the initial issue of Part-MED. In light of this, the Colour Assessment and Diagnosis (CAD) test has been added as an additional option in the AMCs for class 1 and 2. The EU system also allows for alternative means of compliance to be established by the competent authority, so other methods could be used as long as they are proved to be effective and provide equivalent levels of safety.

3 Proposed amendments — 3.2 Draft Acceptable Means of Compliance and Guidance Material (Draft EASA Decision) — AMC/GM to PART-MEDICAL — SUBPART B — Specific requirements for class 1, class 2 and LAPL medical certificates - AMC for class 1, class 2 and LAPL medical certificates — Section 4 — Specific requirements for LAPL medical certificates — AMC16 MED.B.095 Otorhino-laryngology Otorhinolaryngology (ENT)

p. 105

comment 1

comment by: *Thomas GARDNER*

My interest is only in LAPL(S) medical certificates for solo flight in sailplanes. I wear hearing



aids and have successfully used them when conversing with other pilots in very noisy motor gliders. However I regard my hearing as sufficiently deficient that I have never and will never put myself in a position in which I have to use a radio in a sailplane. The sailplanes in which I fly solo do not even have radios fitted.

The previous versions of this document would have prevented me flying, even though my deficient hearing could not possibly have affected my ability to fly safely. That was irrational, disproportionate, and did not increase safety.

The new clauses allowing hearing aids to be used are rational, safe and proportionate.

The new clauses allowing an SSL limiting flying to locations and operations where radios are not necessary are rational, safe and proportionate.

I strongly support the new clauses in AMC16 MED.B.095 Otorhinolaryngology (ENT) (a) (1) to (4)

response *Noted*

Thank you for your support.

3 Proposed amendments — 3.2 Draft Acceptable Means of Compliance and Guidance Material (Draft EASA Decision) — AMC/GM to PART-MEDICAL — SUBPART C — Requirements for medical fitness of cabin crew — Section 1 — General requirements — AMC1 MED.C.005 Aero-medical assessments

p. 106

comment 43

comment by: *AECA(SPAIN)*

Comments cannot be made to the AMC of this section concerning CC, because it was not included the corresponding section of the Regulation in this NPA.

response *Noted*

As described in the published Terms of Reference, the scope of the task does not include a review of the Implementing Rules for medical fitness of cabin crew and these rules are therefore not included in the NPA. Comments have been made using the published Regulation as a reference for the changes proposed in the NPA to the AMC for cabin crew.

comment

180

comment by: *Swedish Transport Agency, Civil Aviation Department (Transportstyrelsen, Luftfartsavdelningen)*

Section: [AMC1 MED.C.005](#)

[Clarification in AMC1 MED.C.005 that the interval between aeromedical assessments of CC can be reduced to less than 60 months by the competent authority.](#)

Comment:

[The competent authority of the examining physician may be different to both the](#)



competent authority responsible for the CC attestation, and the competent authority where the operator employing the CC holds its AOC.
In this case, the differences in national practices do not relate to the medical practices, but to the operational practices regulated in Part-OPS and the operator's Operations Manual.

Proposal:

The reference to national practices should be specified to the national OPS practices for the state where the employer holds its AOC.

response *Noted*

See response to comment No 167.

comment 327

comment by: UK CAA

Page No: 106 to 119

Paragraph No: SUBPART C

Comment: Regulatory medical requirements for cabin crew are not required. The medical requirements should be operator based according to occupational health principles for fitness to work.

Justification: There is no medical evidence base for cabin crew medical assessments as the incapacitation of a cabin crew member will have a negligible effect on flight safety.

Proposed Text: Delete Subpart C.

response *Not accepted.*

According to paragraph 7.b. of the Essential Requirements for air operations in Annex IV to Regulation (EC) No 216/2008 (commonly referred to as the 'Basic Regulation') as last amended, cabin crew members must be periodically assessed for medical fitness to safely exercise their assigned safety duties. Compliance must be shown by appropriate assessment based on aero-medical best practice.

Article 8(5) of the Basic Regulation allows for the legislator to adopt supplementary provisions which describe in more detail how to comply with the Basic Regulation, including its Essential Requirements. These provisions are published in subpart C of Annex IV (Part-MED) to Regulation (EU) No 1178/2011 (Implementing Rules) and the associated ED Decision (AMC and GM).

comment 337

comment by: DGAC FRANCE

The paragraph (b) of the AMC 1 MED.C.005 Aero-medical assessments must be clarified.

Member States can set different intervals for aero-medical assessment of cabin crew members, with a maximum of 60 months between every aero-medical assessment. Due to the lack of harmonization, the AMC must specify the rules for cabin crew members as follows:



1) Of which Member State, the cabin crew member has to apply the rules of periodicity of its aero-medical assessments? Is it the fixed periodicity by the authority which issued the CTA to the operator for which he works?

2) In case of change of operator, the validity of the aero-medical assessment should it be aligned with the rules defined by the authority of the new operator uses its services?

The lack of defined rules entails a risk of "medical tourism". The cabin crew members can escape the periodicity decided by a Member State. It is advisable to fix criteria to avoid counterclaims of cabin crew members related to distortions of treatment, for example within the same airline company. The persistence of such requests eventually has the effect of removing any real scope for national rules made possible by the AMC.

response *Partially accepted*

The text has been amended for clarification.

3 Proposed amendments — 3.2 Draft Acceptable Means of Compliance and Guidance Material (Draft EASA Decision) — AMC/GM to PART-MEDICAL — SUBPART C — Requirements for medical fitness of cabin crew — Section 2 — Requirements for aero-medical assessment of cabin crew — p. 106-108
AMC2 MED.C.025 Cardiovascular system

comment 219

comment by: *AMCS - Thomas Syburra*

d - coronary artery disease - 1 - iii: "...controlled by medication"

if this is true, the cabin crew requirements are more restrictive than LAPL -> is this true/correct?

response *Accepted*

In response to requests from some members of the Rulemaking group, the NPA contained the possibility to consider a fit assessment for LAPL applicants with angina pectoris after cardiological evaluation. However, the risk of a sudden incapacitation during flight in a person with this condition was seen as unacceptable according to comments received from specialists. The Agency has therefore decided not to permit applicants with angina pectoris requiring medication to hold any class of certificate including the LAPL. Therefore, this is equivalent to 'applicants with symptoms of coronary artery disease controlled by medication should be assessed as unfit' which is in the AMC for cabin crew members.

comment 234

comment by: *French main military Aeromedical Center (CEMPN)*

(a) (1) **Periodicity of ECG** should be changed, as for class 2 and LAPL pilots. This comment is justified by the ability of ECG to detect intermittent abnormalities in relation to the age and not only to detect in particular coronary artery disease. Some ECG syndromes (ventricular pre-excitation, Brugada syndrome, QT variations, premature ventricular beats...) are important to detect not only among pilots (because they may be associated with a heart disease and/or jeopardize flight safety), but also among crew members because they may endanger their life and/or lead to flight rerouting. It is not acceptable that such syndromes



	are not detected in a population of professional aircrew that is followed by professional aeromedical experts.
response	<p><i>Not accepted</i></p> <p>A routine ECG is deemed to be necessary on clinical indication but not routinely for the initial assessment. Thereafter, it is required at the first examination after the age of 40 and then at least every five years after the age of 50. The objective of the aero-medical assessment for cabin crew is to verify that they are fit to perform their safety duties, rather than for detection of medical conditions as mentioned in the comment.</p> <p>Furthermore, this would be considered a major change and, therefore, cannot be inserted at this stage of the NPA.</p>
comment	<p>335 comment by: Jörg SIEDENBURG</p> <p>(c) Blood pressure Blood pressure should be recorded at each examination. (1) The blood pressure should be within normal limits (i.e. not exceeding 160 mm Hg systolic and / or 95 mm Hg diastolic) with or without treatment.</p> <p>The general term "normal" needs to be properly defined. In line with international recommendations and with other groups within this regulation the limits are the same.</p>
response	<p><i>Accepted</i></p> <p>The text has been amended to reflect the comment made.</p>

3 Proposed amendments — 3.2 Draft Acceptable Means of Compliance and Guidance Material (Draft EASA Decision) — AMC/GM to PART-MEDICAL — SUBPART C — Requirements for medical fitness of cabin crew — Section 2 — Requirements for aero-medical assessment of cabin crew — AMC5 MED.C.025 Metabolic and endocrine systems

p. 109

comment	<p>235 comment by: French main military Aeromedical Center (CPEMPN)</p> <p>(c) (ii) Requirements (B) and (C) in case of diabetes mellitus with insulin therapy are difficult to apply, because cabin crew will not declare a past medical history of hypoglycaemia. Moreover, it cannot be demonstrated with objectivity that hypoglycaemia awareness is established and maintained. Finally, a period of unfitness during 12 months is difficult to apply and also to understand...</p>
response	<p><i>Not accepted</i></p> <p>All aero-medical regulations rely on the probity of applicants in order to be effective. Many aero-medical regulations rely on the subjective reporting of symptoms rather than objective testing.</p> <p>With regard to demonstrating 'hypoglycaemia awareness is established and maintained', this is not strictly defined as it is important that each individual case is assessed on its own merits. The guidance material introduced in the NPA refers to the IATA Guidelines on Insulin-Treated Diabetes (Cabin Crew) which provides more detail on hypoglycaemia awareness,</p>



including mention of 12-month unfitness if an episode of hypoglycaemic unawareness occurs.

comment 336

comment by: Jörg SIEDENBURG

(c)

Obesity

Applicants with a Body mass index ≥ 35 may be assessed as fit only if the excess weight is not likely to interfere with the safe exercise of their duties and a satisfactory cardiovascular risk review has been undertaken.

Obesity and related disorders like diabetes, hypertension etc. (metabolic syndrome) show an increasing prevalence in the general population. Even though this appears like an epidemic, the affected individuals can do something very simple for prevention: reducing weight. The inherent cardiovascular risk in case of severe obesity is not less in cabin crew in comparison with pilots. However, obesity is a major safety issue in cabin crew as major tasks are emergency situations and evacuation of passengers in case of emergency. Extreme obesity may result in preventing cabin crew in performing those duties or even obstructing emergency exits. Furthermore, ventilation may be impeded and thus restrictive hypoventilation in combination with the inherent hypobaric hypoxia within the aircraft cabin may decrease aerobic performance, especially in emergency situations (e.g. working under smoke hoods). Emergency training with extreme obesity may result in an increased accident rate due to distortion of ankle joints and even fractures of this joint as experience has proven.

response *Not accepted*

Cabin crew members are considered to be fit to perform their relevant safety duties if they pass regular safety training exercises. Furthermore, during the aero-medical assessment, consideration should be given to subparagraph (a) of AMC5 MED.C.025 which states 'cabin crew members should not possess any functional or structural metabolic, nutritional or endocrine disorder which is likely to interfere with the safe exercise of their duties and responsibilities'.

3 Proposed amendments — 3.2 Draft Acceptable Means of Compliance and Guidance Material (Draft EASA Decision) — AMC/GM to PART-MEDICAL — SUBPART C — Requirements for medical fitness of cabin crew — Section 2 — Requirements for aero-medical assessment of cabin crew — AMC16 MED.C.025 Otorhinolaryngology

p. 113

comment 45

comment by: AECA(SPAIN)

Page 3 paragraph II:

We repeat what we have said on previous occasions. If the evaluation result is "unfit" certificate is not given, it is denied.

This happens in the case of certificate class 1, 2 and LAPL. Why in this case takes a different formula that all that will do is to generate confusion and facilitate the pitfalls?



response *Not accepted*

The outcome of the cabin crew aero-medical examination and assessment is a report to indicate whether the cabin crew member is fit or not to perform their safety duties. It is not the same principle as medical certification for pilots, which requires a certificate as proof of fitness to exercise the privileges of the licence held.

3 Proposed amendments — 3.2 Draft Acceptable Means of Compliance and Guidance Material (Draft EASA Decision) — AMC/GM to PART-MEDICAL — SUBPART C — Requirements for medical fitness of cabin crew — Section 3 — Additional requirements for applicants for, and holders of, a cabin crew attestation — GM1 MED.C.030(b) Cabin crew medical report p. 117-119

comment 44

comment by: AECA(SPAIN)

In general: This format change means that all software made or modified by States to suit regulations and all processed and printed formats are useless. I think you should take into consideration this circumstance because the change adds nothing to safety.

response *Not accepted*

In the NPA, the format for the cabin crew medical report was moved to GM, specifically to provide flexibility and to avoid the obligation to make changes. The design was supported by the drafting group which was composed of representatives from industry and authorities. It was based on computer applications already in use, and also reflects the style of the medical certificate for pilots.

comment 328

comment by: UK CAA

Page No: 117

Paragraph No: GM1 MED.C.030(b)

Comment: Notwithstanding the UK CAA comment on Subpart C, the competent authority may not supply the forms for cabin crew medical reports.

Justification: The competent authority logo should only be used on documents and stationery issued by the authority.

Proposed Text: 'Competent authority name and logo'

response *Partially accepted*

Competent authority name and logo has been changed to 'State of issue'.

3 Proposed amendments — 3.2 Draft Acceptable Means of Compliance and Guidance Material (Draft EASA Decision) — AMC/GM to PART-MEDICAL — SUBPART D — Aero-Medical Examiners (AME), General Medical Practitioners (GMP), Occupational Health Medical Practitioners (OHMP) — Section 1 — Aero-medical examiners (AMEs) — AMC1 MED.D.020 Training courses in aviation medicine p. 120-121



comment	46	comment by: AECA(SPAIN)
	The learning objectives cited in paragraph (b) actually exist?. If so should address this fact in the AMC.	
response	<i>Partially accepted</i>	
	The learning objectives stem from the computer-based training concept (CBT) which has been added to the AME training in light of developments by ICAO on the new approach, with the emphasis on individual training needs measured by performance rather than knowledge alone. This will be further developed for Part-MED during future rulemaking tasks. However, the foundations have been introduced in this NPA as a starting point, including a new paragraph, GM3 MED.D.020, which provides some associated guidance for the training providers.	

3 Proposed amendments — 3.2 Draft Acceptable Means of Compliance and Guidance Material (Draft EASA Decision) — AMC/GM to PART-MEDICAL — SUBPART D — Aero-Medical Examiners (AME), General Medical Practitioners (GMP), Occupational Health Medical Practitioners (OHMP) — Section 1 — Aero-medical examiners (AMEs) — AMC1 MED.D.030 Validity of AME certificates

p. 131

comment	29	comment by: Federal Office of Civil Aviation FOCA
	AMC1 MED.D.030 (d) (according to new numbering): FOCA suggests to delete this requirement. Reasoning: To assess such a meeting in advance is not practicable as it provokes too much administrative burden and there is no harmonisation within EASA Member States. Furthermore, clear criteria for crediting are missing.	
response	<i>Partially accepted</i>	
	The Agency agrees that more regulations may be needed with regard to crediting of hours at scientific meetings for AME refresher training in order to achieve a level playing field.	
	However, a change of this magnitude would need to be properly consulted, for example through NPA consultation, so it should be considered in a future rulemaking task on Part-MED.	
	In the meantime, the list of conferences in the GM is not exhaustive and the competent authority may authorise other appropriate events.	
	Lastly, the current text in the published Part-MED was amended in the NPA to ensure that the competent authority assesses the proposed training in advance rather than after the event, in response to requests from stakeholders.	



5. Appendix A — Attachments placed in the CRT

 [Eurocontrol comments on NPA 2013-15.pdf](#)

Attachment #1 to comment [#6](#)

 [NPA 2013.RM.SSAVmed.pdf](#)

Attachment #2 to comment [#89](#)

 [NPA 2013.RM.ESAM.pdf](#)

Attachment #3 to comment [#89](#)

 [IT AF INPUTS to ENAC EASA FOR NPA 2013-2015.pdf](#)

Attachment #4 to comment [#333](#)

 [121009 guidelines for surgery in ao asc.pdf](#)

Attachment #5 to comment [#216](#)



6. References

6.1. *Affected 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), as last amended by Commission Regulation (EU) No 245/2014 of 13 March 2014 (OJ L 74, 14.3.2014, p.33).

6.2. *Affected AMC and GM*

ED Decision 2011/015/R of 15 December 2011 on Acceptable Means of Compliance and Guidance Material to Commission Regulation (EU) No 1178/2011 laying down technical requirements and administrative procedures related to civil aviation aircrew pursuant to Regulation (EC) No 216/2008, as last amended by ED Decision 2013/016/R of 8 August 2013.

6.3. *Reference documents*

- ICAO Annex 1 'Personnel Licensing', eleventh edition, July 2011.
- ICAO Doc 8984 (AN/895) 'Manual of Civil Aviation Medicine', third edition, 2012.

