



**COMMENT RESPONSE DOCUMENT (CRD)  
TO NOTICE OF PROPOSED AMENDMENT (NPA) 2008-17c**

**for an Agency Opinion on a Commission Regulation establishing the Implementing  
Rules for the medical certification of pilots**

**and**

**a draft Decision of the Executive Director of the European Aviation Safety Agency on  
Acceptable Means of Compliance and Guidance Material on the medical certification  
of pilots**

*“Implementing Rules for Pilot Licensing - Medical Certification”*

**CRD c. 2 – Comments and Responses to AMCs**

## IV. CRD table of comments, responses and resulting text

C. Draft Decision Part-MED - Subpart A: General Requirements - Section 1:  
General - AMC to MED.A.020: Medical certification

p. 22

comment	358	comment by: <i>Teh Danish Organisation of Flight Surgeons (DAFLO)</i>
	<p><b>Objection:</b> Disagree</p> <p><b>Reasons:</b> Generally DAFLO does not recommend the introduction of LAPL medical certificate.</p> <p><b>Suggestions:</b> LAPL in text is to be deleted.</p>	
response	<i>Not accepted</i>	
	The Basic Regulation (Article 7) allows a GMP to issue a medical certificate for a LAPL licence (if permitted under national law). This has to be taken into account in the implementing rules.	
comment	452	comment by: <i>UK CAA</i>
	<p><b>AMC to MED.A.020 (2)</b></p> <p><b>Comment:</b> More appropriate in IR.</p> <p><b>Justification:</b> This should apply to all certificates issued</p> <p><b>Proposed Text:</b> Move to IR MED.A.020 as '(i) A Class 1 medical certificate includes the privileges of Class 2 and LPL medical certificates. and (j) A Class 2 medical certificate includes the privileges of a LPL medical certificate. and delete from AMC.</p>	
response	<i>Noted</i>	
	See response to comment No 250 to MED.A.020.	
comment	453	comment by: <i>UK CAA</i>
	<p><b>AMC to MED.A.020 (2)</b></p> <p><b>Comment:</b> Validities also should be mentioned.</p> <p><b>Justification:</b> Clarity regarding the validity of a medical certificate.</p> <p><b>Proposed Text:</b> Amend text suggested for IR MED.A.020 above to '(i) A Class 1 medical</p>	

	certificate includes the privileges <b>and validities</b> of Class 2 and LPL medical certificates. and (j) A Class 2 medical certificate includes the privileges <b>and validities</b> of a LPL medical certificate.'	
response	<i>Partially accepted</i>	
	The AMC text will be amended as proposed in the comment.  See also response to comment No 250 to MED.A.020	
comment	454	comment by: UK CAA
	<b>AMC to MED.A.020 (1)</b>	
	<b>Comment:</b> The compatibility of medication with flying should be mentioned here.	
	<b>Justification:</b> This is a safety issue that is not covered elsewhere in 17c.	
	<b>Proposed Text:</b> Add: '...to fly <b>and before flying whilst taking medication.</b> '	
response	<i>Not accepted</i>	
	The issue is covered in MED.A.025(b) and (c).	
comment	553	comment by: British Microlight Aircraft Association
	Strongly agree	
response	<i>Noted</i>	
	Thank you for the positive comment.	
comment	1777	comment by: Norwegian Association of Aviation Medicine
	Keep only: A Class 1 medical certificate includes the privileges of Class 2.	
response	<i>Not accepted</i>	
	The Basic Regulation (Article 7) establishes the LAPL which has to be taken into account.	
comment	2014	comment by: Lars Tjensvoll
	remove LPL medical certificate	
response	<i>Noted</i>	
	See response to comment No 1777.	

<b>General - AMC to MED.A.025: Decrease in medical fitness</b>
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comment	91	comment by: <i>Dr.Beiderwellen, Secretary of GAAME</i>
	<p>Author: : Dr.Beiderwellen,AME member of the AB of ESAM  Section: <b>AMC to Med A 025 2.</b>  <b>Page: 22</b></p> <p>Relevant Text:  GMP</p> <p><b>Comment:</b>  s. above</p> <p><b>Proposal:</b>  Delete " or GMP"</p>	
response	<i>Noted</i>	
	<p>The Basic Regulation (Article 7) allows a GMP to issue a medical certificate for a LAPL licence (if permitted under national law). This has to be taken into account in the implementing rules.</p> <p>The possibility to seek the advice from a GMP should be limited to the GMP who issued the holder's medical certificate and has the full medical history of the holder. The text will be amended accordingly.</p> <p>The requirements in MED.A.060 for suspension of exercise of privileges will also be amended for LAPL to be in line with class 1 and class 2.</p>	
comment	98	comment by: <i>British Gliding Association</i>
	<p>Page 22 of 66  <b>AMC to MED.A.025</b>  <b>Decrease in medical fitness</b></p> <p>1. Holders of class 1 or class 2 medical certificates should seek the advice of an AeMC or AME if in any doubt about their fitness to fly.  2. Holders of LPL medical certificates should seek the advice of an AeMC, AME or GMP.</p> <p><i>Comment: This minimal advice seems inadequate and does not implement the requirements of 216/2008 where there is a need for all pilots to know of "human performance and limitations". Pilots are responsible for their fitness to fly between periodic medical certification and in the case of the LPL, this could exceed thirty years. Unfitness can arise from fatigue, minor infections or even unwise indulgence. However there should be no obligation for an AME to be informed of minor unfitness. Rules are required to define the responsibilities and powers of pilots, AMEs and GMPs in these circumstances. Lawyers and Authorities need to recognise that informal measures must be permitted, otherwise any requirement to report decreased fitness may be ignored.</i></p> <p><b>BGA Proposals:</b></p> <p><b>1. Pilots may ground or limit themselves for a period of up to 21 days at their own discretion. After 21 days an AME or the certifying GMP must be informed.</b></p> <p><b>2. Pilots are responsible to ensure that any Over the Counter (OTC)</b></p>	

*medicine does not adversely affect flight.*

*3. Pilots receiving treatment or medication from any doctor are to enquire of possible adverse effects on flight.*

*4. AMEs or certifying GMPs may informally suspend or limit a medical certificate for up to 90 days. This would include the recovery period from most surgical operations.*

*5. After full recovery within 90 days, an AME or certifying GMP can lift any suspension or limitation. If there is a permanent change in health status a revalidation becomes necessary and this may impose a limitation. If the pilot remains unfit for any flight, the Authority must be informed whether or not a revalidation medical examination took place.*

*Reference: Regulation (EC) No 216/2008 of the European Parliament and of the Council on common rules in the field of civil aviation... Annex 111, 1.b.1 (v).*

response *Not accepted*

1. Pilots may ground or limit themselves if they wish to do so. In any case they should seek aeromedical advice before resuming flight duties.

2. Pilots who use over the counter medication shall discontinue flying and seek aeromedical advice immediately.

3. Advice on the possible adverse effects of the medication or treatment for pilots may be provided only by the specialists in aviation medicine. Other medical practitioners may not sufficiently evaluate these effects, because they do not receive training in human physiology changes in flight environment.

4 and 5. There is no 'informal' suspension of the medical certificate. Requirements with regard to the suspension of the medical certificate and lifting the suspension are proposed in Subpart A Section 3.

Basic Regulation Annex III 1.b.1(v) is a requirement for the training of pilots. Requirements proposed in AMC to MED.A.025 determine decision making on the medical fitness, therefore, reference shall be made to paragraph 4 of Annex III.

See also response to comment No 91 of this segment.

comment 359 comment by: *Teh Danish Organiation of Flight Surgeons (DAFLO)*

Item: dot 2

**Objection:** Disagree

**Reasons:** Generally DAFLO does not recommend the introduction of LAPL medical certificate.

**Suggestions:** Item to be excluded

response *Noted*

See response to comment No 91.

comment 455 comment by: *UK CAA*

**AMC to MED.A.025 (2)**

**Comment:**

A holder of a medical certificate should seek the advice of the GMP who signed the LPL medical report.

**Justification:**

The GMP who signed the medical report will have knowledge of the medical certificate holder's history and medical licensing system.

**Proposed Text:**

Insert `...AeMC, AME or **the GMP who signed the holder's medical certificate.**'

response

*Accepted*

Thank you for your contribution.

The Agency recognises this to be an important safety issue that should be reflected in the requirement. The text will be amended accordingly.

comment

554

comment by: *British Microlight Aircraft Association*

Strongly agree

response

*Noted*

Thank you for the positive comment.

comment

693

comment by: *Robert Cronk*

'decrease in medical fitness' is not defined which could lead to difficulties. I suggest that pilots are themselves responsible for effectively self-certifying before flight, subject to not knowingly being in charge of an aircraft whilst unwell or suffering from a known medical problem that is likely to decrease the performance of the pilot. For an illness/injury lasting more than say one month, the pilot should be encouraged to refer to an AME or GMP as appropriate.

response

*Noted*

See responses to comments No 98 and 91 of this segment.

comment

799

comment by: *George Rowden*

*Comment: The advice given in the NPA is incorrect as it ignores the comparable requirements of 216/2008 where there is a need for all pilots to know of "human performance and limitations". Unfitness can arise from fatigue, minor infections or even unwise indulgence but it is pilots who are responsible for determining their fitness to fly between medical examinations not AME's. Rules are required to define the responsibilities and powers of pilots, AMEs and GMPs in these circumstances. Lawyers and Authorities need to recognise that informal measures must be permitted, otherwise any requirement to report decreased fitness will be ignored..*

I propose that the while informal, pilot based self assessment is the basis for daily decisions to fly between medical examinations, the responsibilities of pilots and medical practitioners should be made clearer.

response	<i>Noted</i>	
	<p>Rules with regard to the decrease in medical fitness are transposed from JAR FCL 3 provisions. These provisions are harmonised and implemented in all Member States.</p> <p>See also responses to comments No 98 and 91 of this segment.</p>	
comment	1183	comment by: <i>Ray Partridge</i>
	<p>It is vital to be able to ground oneself in a simple and easily reversible way. This provides the maximum encouragement to self-declare of non-fitness. I have given a personal example above. Adopt the BGA proposal.</p>	
response	<i>Noted</i>	
	See response to comment No 98.	
comment	1237	comment by: <i>Swedish Transport Agency, Civil Aviation Department (Transportstyrelsen, Luftfartsavdelningen)</i>
	<p><b>Comment:</b> It should always be possible to seek the advice of a medical assessor at the licensing authority. 2. is incomplete and should have the same, full sentence as 1.</p> <p><b>Proposal:</b> Amend AMC to MED.A.025: <b>Decrease in medical fitness</b> 1. Holders of class 1 or class 2 medical certificates should seek the advice of the licensing authority, an AeMC or AME if in any doubt about their fitness to fly. 2. Holders of LPL medical certificates should seek the advice of the licensing authority, an AeMC, AME or GMP if in any doubt about their fitness to fly.</p>	
response	<i>Partially accepted</i>	
	<p>The text will be amended to reflect your proposal for harmonised text for class 1, class 2 and LAPL. See also response to comment No 71 of this segment. The licensing authority should not be included because an AeMC, AME or GMP always has the possibility to refer to the licensing authority according to AMC to MED.A.045.</p>	
comment	1319	comment by: <i>Vincent EARL</i>
	<p>Part 2</p> <p>This requirement is entirely inappropriate.</p> <p>While leisure pilots are not professionally qualified they do have a professional attitude to their fitness to fly. Training in airmanship leading to solo standard includes performance limitations. GPL and LPL(S) holders are well aware of their capabilities given their current medical condition. There are also extended periods between medical renewals where leisure pilots routinely ground</p>	

	<p>themselves for minor illnesses.</p> <p>This could be taken as advice rather than a requirement as it states that pilots "should seek advice" rather than 'must' seek advice and I suspect that without a revision, this is how it will be interpreted.</p>	
response	Noted	
	<p>See responses to comments No 98 and 91 of this segment.</p> <p>Safety objective is determined in the implementing rule (MED.A.025). AMC establish the way how to achieve the safety objective. It means that the requirement laid down in AMC to MED.A.025 is a rule, not an advice.</p>	
comment	1779	comment by: <i>Norwegian Association of Aviation Medicine</i>
	cancel the whole point 2.	
response	Noted	
	See response to comment No 91.	
comment	1794	comment by: <i>Paul Morrison</i>
	<p>The minimal advice contained within this proposal seems inadequate and does not implement the requirements of 216/2008 where there is a need for all pilots to know of "human performance and limitations". Pilots are responsible for their fitness to fly between periodic medical certification and in the case of the LPL, this could exceed thirty years.</p> <p>Unfitness can arise from fatigue, minor infections or even unwise indulgence. However there should be no obligation for an AME to be informed of minor unfitness. Rules are required to define the responsibilities and powers of pilots, AMEs and GMPs in these circumstances. Lawyers and Authorities need to recognise that informal measures must be permitted, otherwise any requirement to report decreased fitness may be ignored.</p> <p>I therefore fully support the proposals submitted by the BGA:</p> <ol style="list-style-type: none"> <li>1. <i>Pilots may ground or limit themselves for a period of up to 21 days at their own discretion. After 21 days an AME or the certifying GMP must be informed.</i></li> <li>2. <i>Pilots are responsible to ensure that any Over the Counter (OTC) medicine does not adversely affect flight.</i></li> <li>3. <i>Pilots receiving treatment or medication from any doctor are to enquire of possible adverse effects on flight.</i></li> <li>4. <i>AMEs or certifying GMPs may informally suspend or limit a medical certificate for up to 90 days. This would include the recovery period from most surgical operations.</i></li> <li>5. <i>After full recovery within 90 days, an AME or certifying GMP can lift any suspension or limitation. If there is a permanent change in health status are validation becomes necessary and this may impose a limitation. If the pilot remains unfit for any flight, the Authority must be informed whether or not are validation medical examination took place.</i></li> </ol>	
response	Noted	

	See response to comment No 98.	
comment	2015	comment by: <i>Lars Tjensvoll</i>
	remove item 2.	
response	<i>Noted</i>	
	See response to comment No 91.	
comment	2089	comment by: <i>Royal Swedish Aeroclub</i>
	<p>The meaning is ambiguous. We suppose it means that a pilot that you need to consult the AMsC, AME or GMP only if you intend to go flying and not otherwise.</p> <p>We should be allowed to declare ourselves "un fit" from time to time. Like when having a cold.</p>	
response	<i>Noted</i>	
	See responses to comments No 98 and 91 of this segment.	
comment	2112	comment by: <i>Light Aircraft Association UK</i>
	<p>This advice needs to be expanded: it should note that the pilot may 'self-declare' themselves to be temporarily unfit, advice as to what would be appropriate with regards longer term (but temporary) conditions, as well as the existing advice to seek clarification from the AME/GMP if in doubt.</p>	
response	<i>Noted</i>	
	See responses to comments No 98 and 91 of this segment.	
comment	2128	comment by: <i>Croft Brown</i>
	<p>Page 22 of 66  AMC to MED.A.025  Decrease in medical fitness</p> <ol style="list-style-type: none"> <li>1. Holders of class 1 or class 2 medical certificates should seek the advice of an AeMC or AME if in any doubt about their fitness to fly.</li> <li>2. Holders of LPL medical certificates should seek the advice of an AeMC, AME or GMP.</li> </ol> <p>Comment: This minimal advice seems inadequate and does not implement the requirements of 216/2008 where there is a need for all pilots to know of "human performance and limitations". Pilots are responsible for their fitness to fly between periodic medical certification and in the case of the LPL, this could exceed thirty years.</p> <p>Unfitness can arise from fatigue, minor infections or even unwise indulgence. However there should be no obligation for an AME to be informed of minor unfitness. Rules are required to define the responsibilities and powers of pilots, AMEs and GMPs in these circumstances. Lawyers and Authorities need to recognise that informal measures must be permitted, otherwise any requirement to report decreased fitness may be ignored.</p> <p>BGA Proposals:</p> <ol style="list-style-type: none"> <li>1. Pilots may ground or limit themselves for a period of up to 21 days at their</li> </ol>	

own discretion. After 21 days an AME or the certifying GMP must be informed.  
 2. Pilots are responsible to ensure that any Over the Counter (OTC) medicine does not adversely affect flight.  
 3. Pilots receiving treatment or medication from any doctor are to enquire of possible adverse effects on flight.  
 4. AMEs or certifying GMPs may informally suspend or limit a medical certificate for up to 90 days. This would include the recovery period from most surgical operations.  
 5. After full recovery within 90 days, an AME or certifying GMP can lift any suspension or limitation. If there is a permanent change in health status a revalidation becomes necessary and this may impose a limitation. If the pilot remains unfit for any flight, the Authority must be informed whether or not a revalidation medical examination took place.  
 Reference: Regulation (EC) No 216/2008 of the European Parliament and of the Council on common rules in the field of civil aviation...  
 Annex 111, 1.b.1 (v).

response

*Noted*

See response to comment No 98.

comment

2138

comment by: *Diana King*

AMC to MED.A.025  
 Page 22

2. Holders of LPL medical certificates should seek the advice of an AeMC, AME or GMP.

Comment:

Pilots may need more detailed and realistic advice than this on the action they should take if they have any medical problems or decrease in their level of fitness, which may arise from minor ailments or injuries as well as from more significant factors. Pilots need to understand their responsibility for their fitness to fly between periodic medical examinations and they should have appropriate advice on how to ensure that they can remain fit for flying, who to should consult if they are in any doubt and how to monitor their own levels of health and fitness.

An informal system involving the pilot, the GP and the pilot's CFI is more likely to be effective than a complicated and expensive system, which is likely to be ignored except in extreme cases.

response

*Noted*

See responses to comments No 98 and 91 of this segment.

comment

2347

comment by: *Graham Bishop*

Pilots are responsible for grounding themselves between medical periods, There are so many reasons for this state to arise. More precise instructions are required to cover this area.

response

*Noted*

See responses to comments No 98 and 91 of this segment.

comment	2462	comment by: <i>Paul Mc G</i>
<p>This advice needs to be expanded: it should note that the pilot may 'self-declare' themselves to be temporarily unfit but can they then re-declare? Advice as to what would be appropriate with regards longer term temporary conditions, as well as the existing advice to seek clarification from the AME/GMP if in doubt. Actually this is a mess and needs a rewrite.</p> <p>Decrease in medical fitness</p> <ol style="list-style-type: none"> <li>1. Holders of class 1 or class 2 medical certificates should seek the advice of an AeMC or AME if in any doubt about their fitness to fly.</li> <li>2. Holders of LPL medical certificates should seek the advice of an AeMC, AME or GMP.</li> </ol> <p>This minimal advice seems inadequate and does not implement the requirements of 216/2008 where there is a need for all pilots to know of "human performance and limitations". Pilots are responsible for their fitness to fly between periodic medical certification. Unfitness can arise from fatigue, minor infections or even unwise indulgence. However there should be no obligation for an AME to be informed of minor unfitness. Rules are required to define the responsibilities and powers of pilots, AMEs and GMPs in these circumstances. Lawyers and Authorities need to recognise that informal measures must be permitted, otherwise any requirement to report decreased fitness may be ignored.</p> <p>BGA Proposals:</p> <ol style="list-style-type: none"> <li>1. Pilots may ground or limit themselves for a period of up to 21 days at their own discretion. After 21 days an AME or the certifying GMP must be informed. However, this could cause problems with recency if not careful and in very bad weather recency could fall foul of a 21 day rule where no illness occurs. Consistency can become a problem.</li> <li>2. Pilots are responsible to ensure that any Over the Counter (OTC) medicine does not adversely affect flight.</li> <li>3. Pilots receiving treatment or medication from any doctor are to enquire of possible adverse effects on flight.</li> <li>4. AMEs or certifying GMPs may informally suspend or limit a medical certificate for up to 90 days. This would include the recovery period from most surgical operations.</li> <li>5. After full recovery within 90 days, an AME or certifying GMP can lift any suspension or limitation. If there is a permanent change in health status a revalidation becomes necessary and this may impose a limitation. If the pilot remains unfit for any flight, the Authority must be informed whether or not a revalidation medical examination took place.</li> </ol>		
response	<i>Noted</i>	
See responses to comments No 98 and 91 of this segment.		

<b>C. Draft Decision Part-MED - Subpart A: General Requirements - Section 2: Issuance, revalidation and renewal of medical certificates</b>	p. 22
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comment	1560	comment by: <i>Swiss Association of Aviation Medicine</i>
LPL Medical Report		

Like we stated above we prefer a questionnaire that can be filled in by the pilot himself. We propose to cancel it completely. Some questions/decisions are not ethically. They would allow pilots to fly with diseases that normally would be treated in the normal population because there is evidence that mortality and morbidity will be reduced.

response *Partially accepted*

As a result of the comments received, both the provisions for a GMP and the medical requirements for LAPL will be amended. The medical requirements for a LAPL will appear as MED.B.090 and AMC to MED.B.090. The examination form established for class 1 and class 2 examinations will also be used for LAPL, where the boxes which are non-compulsory for LAPL will be shaded out.

comment 1776 comment by: *Norwegian Association of Aviation Medicine*

According to earlier arguments we suggest to remove the whole **AMC to Med.A.040**

response *Noted*

See response to comment No 1560 of this segment.

comment 1915 comment by: *Andrew BARDGETT*

The medical report for a LPL seems excessive in relation to the requirement for simple measures for non commercial activities. In my opinion it will lead to much increased costs as the fees to complete such a record will be far higher than the present fees charged by GMPs. Such legislation is no more safe, and indeed could be less safe than present standards and introduces unnecessary and costly bureaucracy.

response *Noted*

See response to comment No 1560 of this segment.

**C. Draft Decision Part-MED - Subpart A: General Requirements - Section 2: Issuance, revalidation and renewal of medical certificates - AMC to MED.A.040: Requirements for the issue, revalidation and renewal of medical certificates – Limitations to LPL medical certificates** p. 22-29

comment 32 comment by: *Neil Broughton*

Para 3.2 is ridiculous. There is no way a medical examiner can be aware of this exact figure - and in any case it is irrelevant. As long as a pilot is below the blood alcohol limit at the time of flight it is not important if they have had a drink in the past week or month or year. There is an entirely separate and proper question elsewhere about alcohol dependency.

response *Noted*

The 'Leisure Pilot's Licence Medical Report' in AMC to MED.A.40 has been replaced by a reduced version of the medical application and examination forms for class 1 and class 2. The form will be in Authority Requirements.

comment	33	comment by: <i>Neil Broughton</i>
response	<p>There appears to be no justification for changing the format of the UK NPPL GP process - i.e a medical signed on the basis of fitness to drive. This is a process which is well understood by GPs and has proven to be safe and effective. The National format for LPL medical issue should remain.</p> <p><i>Noted</i></p> <p>UK NPPL process may be well understood in UK, but is not clear for GMPs from other Member States. When proposing LAPL medical certification rules, we had to take into account medical issues in all 27 Member States. The BR allows GMPs to assess the medical fitness of LAPL holders if permitted under national law, but it does not exempt LAPL from holding a medical certificate.</p>	
comment	92	comment by: <i>Dr.Beiderwellen, Secretary of GAAME</i>
response	<p>Author: : Dr.Beiderwellen, AME member of the AB of ESAM  Section: <b>AMC to Med.A 040</b>  Page: 23 - 28</p> <p>Relevant Text:  Complete LAPL medical report</p> <p><b>Comment:</b>  Specific medical terms are not understandable for applicants.  Relevance of some diseases are not clear to applicants</p> <p><b>Proposal:</b>  Delete complete report or translate into understandable terms for applicants, if you want self declaration. Remove doctors certificate and add in a certification by government.</p> <p><i>Noted</i></p> <p>A self-declaration was not considered as a choice for LAPL medical because the Basic Regulation states that a GMP may act as an AME for the issue of a LAPL medical certificate, if permitted under national law. A medical certificate cannot be issued on the basis of a self-declaration only, but that also an appropriate medical assessment is needed.  Also see response to comment No 248.</p>	
comment	99	comment by: <i>British Gliding Association</i>
<p>Page 22 of 66  <b>AMC to MED.A.040</b>  <b>Requirements for the issue, revalidation and renewal of medical certificates - Limitations to LPL medical certificates</b>  LPL medical certificates should be issued following examination in accordance with the following report:  Page 23/66  This report consists of questions that have 'yes' or 'no' answers that are indicated by ticking boxes. If all ticks are in clear boxes the medical certificate can be</p>		

issued immediately by the doctor undertaking this examination. If any of the ticks are in a shaded box the medical report should be referred to an AME or AeMC for further assessment.

*Comment: This lengthy report form for the LPL does not meet the requirement in the preamble of 216/2008 to achieve simple measures for non commercial activities. The LPL compares quote unfavourably with the Sport Pilot Licence of the USA and the existing UK NPPL - both of which provide valuable working approaches. The medical form proposed for the LPL is complicated in the extreme. Our suggestion is that it could benefit from reviewing the experiences of Road Transport Authorities in Europe who require a similar standard as that required for the LPL. It should make use of the universally available individual national/public health records. It should also not attempt to incorporate the actual standards into the form.*

*It has been said that the basic regulation 216/2008 requires a physical examination for the LPL prior to certification by a GMP but this has not been identified in the text. There seems little usefulness in requiring applicants to demonstrate that they can extract a cork using a corkscrew with either hand! The cost difference of these approaches (ie: record examination vs. actual examination) to the applicant can be considerable; the British Medical Association web site suggests for members a charge of £15 for a validation from records but £169.50 for a report such as that required by EASA.*

*The BGA is very concerned that the complexity and thereby potential cost of the process for an applicant to obtain medical clearance through a GMP will create a significant barrier to entry to the sport of gliding for young people, and indeed a barrier to older, retired people on lower incomes to continue in gliding, where the periodicity of medical renewal decreases with age. As an example, the British Medical Association suggested charge of £169.50 for an examination rather than validation from medical records could constitute typically 15% to 30% on top of the total cost of a young applicant's course for learning to fly gliders to a licence level in a volunteer club environment.*

**BGA Proposals:**

- 1. That the proposed LPL form be simplified in a similar fashion to that used by the New Zealand Gliding Association and which permits either validation by reference to records or by a physical examination.**
- 2. That when records are not available and a physical examination is required, the EASA Class 2 form is used.**
- 3. That separate guidance material is prepared.**
- 4. That air sports associations nominate doctors to their Authority who comply with the requirements for AMEs especially in respect of having practical knowledge and experience of the air sport concerned. These can advise both GMPs and AMEs on difficult cases.**

*References:*

- 1. Regulation (EC) No 216/2008 of the European Parliament and of the Council on common rules in the field of civil aviation...*

*Preamble (7-8)*

- 2. United States House of Representatives; Committee on Transportation and Infrastructure. FAA Oversight of falsifications on airman medical certificate applications. Released March 27, 2007.*
- 3. BMA -Suggested fees for services that can only be provided by the patient's own GP. [www.bma.org.uk/ap.nsf/Content/noagreement~onlybygp](http://www.bma.org.uk/ap.nsf/Content/noagreement~onlybygp)*
- 4. International Centre for Alcohol Policies. [www.icap.org/PolicyIssues/drinkingGuidelines/StandardUnitsTable/](http://www.icap.org/PolicyIssues/drinkingGuidelines/StandardUnitsTable/)*
- 5. GLIDING NEW ZEALAND INC. MEDICAL REQUIREMENTS.*

	<a href="http://www.glidering.co.nz/sites/glidering.co.nz/downloads/MOAP/Forms/OPS/OPS%201.pdf">www.glidering.co.nz/sites/glidering.co.nz/downloads/MOAP/Forms/OPS/OPS%201.pdf</a>
response	Noted
	<p>See also response to comment No 248 of this segment.</p> <p>1. The LAPL report form has been withdrawn following the comments received. The application and examination forms for class 1 and class 2 will be used, but with shaded areas that will not be applicable to the LAPL holder. The new form will appear in an AMC in the Authority Requirements.</p> <p>A medical certificate for a pilot flying an aircraft up to a max t/o weight of 2000 kg cannot be issued on the basis of an evaluation of the medical records alone. It is regrettable that the cost difference between record evaluation and medical assessment is so substantial in the UK, but an aeromedical examination <u>and</u> assessment is considered to be necessary for a medical certificate confirming fitness to fly. It would also be difficult to estimate whether medical records are available or not, because if a person states that there are no records because he/she is completely healthy this may be true – or not, depending on the national health system.</p> <p>There are only very few European Member States where 'universally available individual national/public health records' exist. This is why a new sub-paragraph has been included in D.001 saying that a GMP can act as AME only in those States where he/she has appropriate access to the full medical records of pilots.</p> <p>The medical provisions have been revised to make them clearer; they are still below ICAO standards.</p> <p>2. Following (1), physical examination is always a part of LAPL medical assessment.</p> <p>3. Separate guidance material may be considered at a later stage.</p> <p>4. A GMP will refer a pilot to an AME or AeMC if the pilot presents with a condition where fitness to fly is in doubt. If an AME or AeMC needs further advice they can contact the licensing authority. Nothing prevents an air sports association to point out AMEs to the authority who have specific knowledge and experience in the air sport concerned. The authority may, or may not, accept the offer. The creation of rules for a parallel system of reporting lines for doctors to the one that is already in place is not planned.</p>

comment	100	comment by: <i>British Gliding Association</i>
	<p>Page 23/66</p> <p><b>Section 2 Issuance, revalidation and renewal of medical certificates.</b></p> <p>On occasions licences may need to be restricted. Examples of restrictions are the prohibition of passenger carriage, or in the case of a disabled pilot, a restriction to a demonstrated aircraft type with approved modifications</p> <p><b><i>Comment: A list of possible limitations and associated codes is to be found in JAR-FCL 3. These are satisfactory and cover all possible contingencies. However they do apply to all medical certificates and should be in a general section. Limitations provide the tool by which mitigating measures described in 216/2008 are implemented. Rules and guidance are also needed on the application of these limitations.</i></b></p> <p><b><i>Proposals:</i></b></p>	

**1. On a revalidation of a medical certificate, a previous limitation may be carried forward without question.**

**2. On initial issue of an LPL following denial of a Class 1 or medical certificate, a limitation is to be expected.**

**3. Any AME or GMP may impose any limitation.**

**4. Following evidence of recovery, a limitation may be rescinded.**

**5. Temporary and time limited limitations may be applied.**

**6. Guidance for limitations:**

**CODES with LIMITATIONS as set out in JAR-FCL 3.**

**TML VALID ONLY FOR ..... MONTHS**

**This limitation is applied when the applicant is suffering from a condition that may deteriorate prior to the next routine periodic review. It can also be used when the condition may improve when it is usually associated with another limitation, although there is nothing to prevent a pilot with a limitation from seeking a review at any date.**

**VDL SHALL WEAR CORRECTIVE LENSES**

**The applicant requires a refractive correction of vision in order to meet the prescribed standard. With this limitation it is also a requirement that a spare pair of spectacles is carried.**

**VNL SHALL HAVE AVAILABLE CORRECTIVE LENSES**

**The applicant has good distance vision but requires correction for certain close tasks such as map reading. It is the usual limitation for older pilots suffering presbyopia.**

**VCL FLIGHTS ONLY WITHIN FIRS OF A MEMBER STATE, VFR FLIGHTS BY DAY ONLY.**

**The applicant does not meet ICAO standards, usually in respect of the ability to discriminate colour. For an EASA licence, this would be within the Flight Information Regions of EASA member nations.**

**OML VALID ONLY AS OR WITH QUALIFIED CO-PILOT**

**This limitation is applied when there is a risk of incapacity that is greater than normal but not so high as to warrant grounding. It only applies to pilots flying aircraft certified for two pilot operation and would be unusual for non commercial pilots.**

**OCL VALID ONLY AS CO-PILOT**

**A similar limitation to OML, but this limitation also precludes flying as aircraft captain.**

**OSL VALID ONLY AS SAFETY PILOT AND IN AIRCRAFT WITH DUAL CONTROLS.**

**A pilot with this limitation has few privileges over an unlicensed pilot and it is not an equivalent to the OML for private pilots. It can be applied as a temporary limitation while recovering from illness.**

**OAL RESTRICTED TO A DEMONSTRATED AIRCRAFT TYPE**

**This limitation is applicable to a pilot with an anthropometric or orthopaedic limitation that might make control difficult. Commonly pilots with a lower limb abnormality find the operation of the wheel brakes is difficult with some designs but not others. Pilots with such a limitation must seek flying instructor clearance and an entry in their flying log book for each type that is to be flown.**

**OPL VALID ONLY WITHOUT PASSENGERS**

**This limitation is applied when there is a risk of incapacity that is greater than normal but not so high as to warrant grounding. By excluding inexperienced passengers the major third party risk is removed, the ground risk being very remote following incapacity. Continued solo flight or flying with another pilot is permitted with this limitation. Unless there is evidence that the disqualifying disease has improved, this limitation should be applied to all LPL pilots who have**

*been previously denied a Class 2. Elderly pilots can expect to be limited OPL as they age.*

***APL VALID ONLY WITH APPROVED PROSTHESIS***

*This limitation is to be applied to pilots with a prosthesis that could affect their ability to control an aircraft. It would commonly be combined with an OAL limitation.*

***AHL VALID ONLY WITH APPROVED HAND CONTROLS***

*This limitation is applied to paraplegic pilots or those with lower limb defects that prohibit normal rudder pedal control. In this case the aircraft has to be modified to meet the needs of that pilots and only aircraft so modified may be flown.*

***AGL VALID ONLY WITH APPROVED EYE PROTECTION***

*This limitation has been applied to monocular pilots flying open cockpit aircraft. However dust or debris can adversely affect both eyes and protective goggles are recommended for all pilots in these aircraft.*

***SSL SPECIAL RESTRICTIONS AS SPECIFIED***

*This limitation permits any restriction to be written in. These could be geographical, climatic or altitude limits. One useful application concerns suspected or minor psychiatric disease when a recreational pilot can be restricted to a named club where responsible officials have been informed, in confidence and with the consent of the applicant, of possible problems. Subsequent reports from these officials become a vital contribution to a sensible and fair medical decision.*

***SIC SPECIAL INSTRUCTIONS - CONTACT AMS***

*This does not affect the privileges of a licence but is a warning to an AME not to revalidate without consulting the AMS. This limitation might be applied in a case of past psychiatric disease or previous misdemeanour by the applicant.*

***VAR VARIATION - ICAO ANNEX 1 PARA 1.2.4.8***

*This does not affect the privileges of a licence but indicates that the provisions of ICAO are not met, although the pilot is considered fit. It is only applicable to ICAO compliant licences.*

***AMS ISSUED BY AMS***

*This does not affect the privileges of a licence but is a hint to an AME that there may have been some special consideration in the past.*

response *Noted*

Thank you for your elaborate comment. When possible, your proposals will be considered in redrafting the medical requirements for LAPL.

1: Agreed; will be included in the amended text.

2: Agreed in principle, but will not be included in the text as there will be a need for individualised assessments.

3, 4, 5, and 6: See the amended text of MED.A.045 and the AMC to MED.A.045.

comment

134

comment by: *Civil Aviation Authority - The Netherlands*

**BLz. 23, het LPL medical report form**

De zinsnede "Therefore the doctor completing this report should have good knowledge of the pilot's medical history", acht de CAA-The Netherlands, vanwege het medisch beroepsgeheim, niet uitvoerbaar.

In Nederland is de desbetreffend keuringsarts afhankelijk van hetgeen de kandidaat aan hem mededeelt over zijn medisch verleden. Een arts heeft in

	<p>Nederland geen plicht tot het toezenden van een medisch dossier. Nederlandse wet- en regelgeving wordt op dit punt niet aangepast.</p> <p>De CAA-The Netherlands ziet niet in waarom uitsluitend voor het LPL een standaardformulier wordt voorgeschreven. Voor klasse 1 en 2 zou tevens een formulier moeten worden voorgeschreven</p>	
response	<p><i>Noted</i></p> <p>We understand the difficulty in some Member States to transfer medical information from one medical professional to another. But in each Member State the pilot (applicant) has an access to his/her medical history and has legal right to obtain it for a medical examination by GMP, AME or AeMC. Our proposals do not prevent the use of standard forms for class 1 and 2 aeromedical examinations which are already used by Member States.</p> <p>See also response to comment No 248 of this segment.</p>	
comment	135	comment by: <i>Civil Aviation Authority - The Netherlands</i>
	<p><b>Blz. 25, onderdeel 6, 8</b></p> <p>De CAA-The Netherlands merkt op dat onderdeel 7 in het formulier ontbreekt.</p>	
response	<p><i>Noted</i></p> <p>See response to comment No 248 of this segment.</p>	
comment	136	comment by: <i>Civil Aviation Authority - The Netherlands</i>
response	<p><i>Noted</i></p> <p>There is no comment.</p>	
comment	137	comment by: <i>Civil Aviation Authority - The Netherlands</i>
	<p><b>Blz. 26, onderdeel 13.</b></p> <p>De CAA-The Netherlands merkt op dat in onderdeel 13 wordt verwezen naar "further details below". Deze details ontbreken. Het verzoek van de CAA-The Netherlands is om deze details alsnog in het formulier op te nemen.</p> <p><b>Blz. 26 van 66, onderdeel 13.1</b></p> <p>De CAA-The Netherlands merkt op dat 13.2, 13.3 etc. niet bestaan. Het is daarom niet nodig om onderdeel 13.1 op te nemen.</p>	
response	<p><i>Noted</i></p> <p>See response to comment No 248 of this segment.</p>	
comment	138	comment by: <i>Civil Aviation Authority - The Netherlands</i>
	<p><b>onderdeel 16.1 (Blz. 27 van 66)</b></p> <p>De CAA-The Netherlands acht 6/9 een te lichte eis. Om veiligheidsredenen kan</p>	

volgens de CAA-The Netherlands niet minder worden geëist dan een "visual acuity" van 6/6 (1.0) met twee ogen. De CAA-The Netherlands verzoekt om onderdeel 16.1 conform Nederlandse opvatting aan te passen.

**onderdeel 17 (Blz. 27 van 66)**

De CAA-The Netherlands kan zich niet vinden in hetgeen aan onderzoek wordt geëist in onderdeel 17. Volgens de CAA-The Netherlands komt hetgeen in onderdeel 17 niet overeen met hetgeen normaliter in de medische wereld onder lichamelijk onderzoek wordt verstaan. Als voorbeelden worden genoemd het ontbreken van hart- en longonderzoek.

De CAA-The Netherlands merkt op dat het voorschrift in 17.3 vreemd is. Wat te doen als een arts geen trappen in de buurt heeft? Iedere medische onderbouw van 17.3 ontbreekt.

Volgens de CAA-The Netherlands moet de inhoud van onderdeel 17 worden vervangen met eisen die voortkomen uit elementen uit gangbare medische onderzoeken.

response *Noted*

See response to comment No 248 of this segment.

Visual acuity of 6/9 binocularly is the ICAO Standard for class 2 and will be retained in the amended LAPL requirements.

comment

248

comment by: *Lufthansa German Airlines*

Author: Prof. Dr. U. Stüben Head of AMC Frankfurt - Germany  
 Head of Lufthansa Medical Services  
 Head of German Academy of Aviation and Travel Medicine  
 Section: **AMC/GM to part - medical**  
**Subpart A Section2**  
**AMC to MED.A.040 Leisure Pilot`s License Medical Report**  
**Page: 23 -- 29**

Relevant Text:  
 the whole medical report

**Comment:**

Why shall a medical doctor sign this report?

1) If doctors sign this report they testify that the pilot understood the questions ,or it was explained by the doctor in a way that he could understand the questions. If it is asked e.g. Does the pilot have a psychological or psychiatric illness and quick answers like yes or no are possible, nobody will find out the answer of question 4.4 - alcohol dependency in the past 3 years. If the pilot is ok at the age of 17 nobody will ask him again until 45.This means the doctor who signed the fist LPL medical must give a prognosis of medical fitness for 28 years. But during this time the occurrence of many psychiatric disorders ,alcohol and drug dependency have its peak. Who will be accused, if the worst case will happen that a pilot with a bipolar disorder , unable to realize his situation, flying with a valid medical certificate , will have an accident with a commercial aircraft while violating a controlled airspace? - the medical doctor or the competent authority.

2.) We tested the medical report form in our Academy in an advanced course of aviation medicine with 25 AMEs who know the medical terminology very well. The best performer needed 35 minutes to fill out the report correctly, at

average it took 45 minutes to perform the LPL questions and the medical examinations. Who believes that this will be a cheaper way to enter a cockpit as it was under JAA requirements with a class 2 medical is mistaken. Even GPs need salary for 45 minutes to work .  
 The whole medical part of the LPL seems to be very problematic, far under ICAO standard, for European standards and narrow airspace structures **not safety!**

**Proposal:**

- 1) For LPL medical standard the same standard as class 2 medical standard shall be recommended.
- 2) If the political guidelines for EASA do not allow class 2 Medicals for LPL pilots we propose a self assessment every 2 years by the LPL pilot. For this purpose EASA or the national competent authorities shall provide an internet solution where pilots can fill out the LPL medical report and automatically receive by internet their medical certificate if no grey shaded tick box was ticked. If such a box was ticked it shall be the responsibility of the authority to send the pilot to a specialist or an AME for an assessment. If it is regulated in this way the authority is definitely responsible for the lack of safety in such a system and medical doctors are not used as an alibi for good medical assessment. This might be important in case of accidents when insurances are looking for responsibilities.
- 3) If proposal 1 and 2 will not be respected by EASA and the LPL medical requirements will be implemented as it is now, the medical societies should give advice to their doctors to refuse the collaboration in all cases of medical advice, reports and assessment relating to LPL.

response *Noted*

Based on the comments received on the LAPL medical requirements and the examination form in AMC to MED.A.040, the Agency has decided to withdraw its original proposal. As a consequence of the Agency’s decision, comments to specific details of the withdrawn text will not receive individual responses.

The Agency agrees with the comments that the requirements proposed in the NPA did not properly reflect safety objectives in the implementing rules and they were not fully tailored to the aviation safety risks related to various medical conditions. The Agency also agrees that the examination form proposed in the NPA was too complicated for the examination and assessment for a LAPL.

A new proposal will be presented together with the Agency’s responses to the comments received on NPA 2008-17 C (Medical). The new proposal has been discussed and revised by an EASA Review group consisting of medical experts from authorities, scientific aeromedical organisations and pilot organisations.

The new proposal will be based on the general safety objectives in MED.B.001 and an amended MED.B.090, and the detailed requirements will appear in an AMC to MED.B.090. The AMC to MED.B.090 will have the same structure as the AMCs for class 2, but with less details in order to provide a standard below ICAO class 2 tailored to the risks related to the privileges of a LAPL. The examination form for class 1 and class 2 will be retained also for LAPL, but with the areas non-mandatory for LAPL being shaded.

comment 

280
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 comment by: *Lufthansa German Airlines*

**Author:** Dr. Ulrike Springer AMC Frankfurt

**Section:** 2

Subpart A

AMC to MED.A.040 - Instruction for completion of LPL report

**Page:** 27

**Relevant Text:**

ENT chapter has been forgotten in the LPL report form

**Comment:**

The report details the medical standard required for a pilot to hold a Light Aircraft Pilots' Licence. It should be completed by the doctor, in the presence of the pilot. This report requires some physical examination.

In the LAPL Medical Report there is no chapter for ENT.

**Proposal:**

15 ENT

Ear

Does the pilot have a history of:

15.1 Impaired hearing or hearing loss

Y

N

15.2 Eustachian tube dysfunction

15.3 Suppurative or non suppurative disease of middle ear

15.4 Middle ear surgery

Tympanoplasty

Stapedectomy

15.5 Disease of inner ear

Temporal bone fracture

Acoustic trauma

Perilymph fistula

Menière disease

Acoustic neuroma

Vestibular system:

Does the pilot have a history of:

15.6 Infective labyrinthitis

Y

N

15.7 Menière disease

15.8 Head trauma

15.9 Acute vestibular dysfunction

15.10 Chronic vestibular hypofunction

with incomplete compensation

with episodic decompensation

15.11 Perilymph fistula

response	<i>Partially accepted</i>	
	See response to comment No 248 of this segment. The amended requirements for LAPL will include a section for ENT.	
comment	313	comment by: <i>Alexander DONALD</i>
	<p>I believe the LPL medical arrangements would benefit from following those used for the UK NPPL, where the applicant's GP endorses a self declaration of medical fitness based on driving licence medical standards. In making this endorsement, the GP can draw on their personal knowledge of the applicant's medical history, has access to relevant medical notes from consultants or other specialists, and can undertake medical examination of the applicant as they see fit.</p> <p>The EASA LPL medical proposals indicate that a GP may make the medical assessment, but must be experienced in aviation or qualified in aviation medicine. Additionally, the assessment will be made on the basis of a questionnaire. A tick in any of the shaded boxes requires the GP to refer the applicant to an AME for assessment at that point. Both of these issues mean that I would need to attend an AME for assessment. This I believe will be a more time consuming, expensive and ultimately less effective process than the GP-endorsed self declaration.</p> <p>Incidentally, the LPL Medical Report asks about valvular disease, but Section 2, Specific requirements for LPL medical certificates makes no mention of this.</p>	
response	<i>Noted</i>	
	Concerning the report form, please, see response to comment No 248 of this segment. Regarding the GMPs, please see responses in Section D.	
comment	317	comment by: <i>Aero-Club of Switzerland</i>
	<p>LPL Medical Report/Questionnaire</p> <p>The medical specialists of the Aero-Club of Switzerland is of the opinion that the proposed questionnaire has to be redone completely and that the old JAR FCL Medical Questionnaire for a class 2 medical certificate was better. Alternatively the Club proposes to take into consideration the use of the class 2 medical certificate questionnaire of France.</p> <p>Justification: All questions must be asked in a form a pilot can understand. Secondly, the questionnaire has to include all aspects of medicine, the proposed one goes too far on the one hand, is too superficial on the other. Thirdly, to our specialists it is quite clear that the proposed questionnaire was not established on evidence-based medicine.</p>	
response	<i>Noted</i>	
	See response to comment No 248 of this segment.	
comment	338	comment by: <i>FOCA Switzerland</i>
	AMC to MED.A.040 This questionnaire proposed as medical report for LPL	

holders is not an usable tool at all. There are many medical mistakes in it (only some exemples: no 3: numbers of alcohol units inappropriate) no 5: eye surgery is missing , no 7: text not existing , no 10: aneurysms as described are too dangerous, 16: color vision not adressed, but mandatory for a night rating as mentioned in AMC to MED.B.090 and many more) . The time to fill in this really inappropriate questionnaire takes more time than the normal time of an aeromedical exam and is therefore more expensive for pilots. In addition, there is no reporting system established in case of unfitness. Nearly every pilot that fills in the questionnaire correctly will need to be deferred to an AME.

Proposal: **replace requirements for LPL pilots by class 2 requirements**

response *Noted*

See response to comment No 248 of this segment.

comment

345

comment by: *Medical Officer BBAC*

The present JAR-FCL medical form has a list of questions the pilot answers and then signs to confirm truth. This should be retained. This would reduce the number of questions the GP has to ask during completion of this form e.g alcohol history, history of cancer, diabetes, anti-convulsant medication, renal stone, diplopia, head injury, epilepsy,. The questions on hypoglycaemia only relate to pilots on insulin.

response *Noted*

See response to comment No 248 of this segment.

comment

346

comment by: *Medical Officer BBAC*

17. Part B

Many of these questions relate to physical ability and should be assessed by the instructor during flight training and have nothing to do with medical incapacity. These would stop access for disabled people wanting to undergo air sports.

response *Noted*

See response to comment No 248 of this segment.

Assessment of the physical ability is the primary task of the GMP or AME. In borderline cases a medical flight test may be used and our proposal does not prevent the instructor to add his/her assessment during flight training.

comment

360

comment by: *Teh Danish Organisation of Flight Surgeons (DAFLO)*

Objection: Disagree

Reasons: The LAPL Medical Report and the limited examinations have no objective value and as such provide no basis for proper assessment of the health state of the applicant in a perspective of flight safety. The applicant has no chance of giving reliable responses because of insufficient insight, e.g. item 14.1 ("Does the pilot have a liability to a medical condition that puts them at an increased risk of developing pneumothorax?")

Ideally all items should be discussed with the applicant. This would, however,

	<p>imply a time consumptions considerably exceeding that of a Class 2 examination today.</p> <p>Suggestions: In case of introduction of LAPL it is strongly recommended the helath requirements as a minimum are equal to ICAO standards.</p>	
response	<p><i>Noted</i></p> <p>See response to comment No 248 of this segment.</p>	
comment	456	comment by: UK CAA
	<p><b>AMC to MED.A.040</b>  <b>Item 1</b>  <b>Page: 23</b></p> <p><b>Comment:</b>  Meaning of word 'identity' unclear.</p> <p><b>Justification:</b>  Not all citizens have Identity Numbers.</p> <p><b>Proposed Text:</b>  Change 'Identity' to '<b>Reference</b>'.</p>	
response	<p><i>Noted</i></p> <p>See response to comment No 248 of this segment.</p>	
comment	457	comment by: UK CAA
	<p><b>AMC to MED.A.040</b>  <b>Item 2</b>  <b>Page: 23</b></p> <p><b>Comment:</b>  Meaning of word 'identity' unclear.</p> <p><b>Justification:</b>  Not all doctors have Identity Numbers.</p> <p><b>Proposed Text:</b>  Change 'Identity' to '<b>Registration</b>'</p>	
response	<p><i>Noted</i></p> <p>See response to comment No 248 of this segment.</p>	
comment	458	comment by: UK CAA
	<p><b>AMC to MED.A.040</b>  <b>Item 3.2</b>  <b>Page: 23</b></p> <p><b>Comment:</b>  Very proscriptive requirement.</p>	

	<p><b>Justification:</b> Limits stated are recommendations from a public health standpoint and are not relevant to fitness for a medical certificate.</p> <p><b>Proposed Text:</b> Delete question 3.2.</p>	
response	<i>Noted</i>	
	See response to comment No 248 of this segment.	
comment	459	comment by: UK CAA
	<p><b>AMC to MED.A.040</b> <b>Item 3.3</b> Page: 24</p> <p><b>Comment:</b> Question would benefit from amendment.</p> <p><b>Justification:</b> All applicants with a history of a cancer with a liability to metastasise to the brain should be referred to an AME or AeMC for assessment.</p> <p><b>Proposed Text:</b> Delete 'significant'.</p>	
response	<i>Noted</i>	
	See response to comment No 248 of this segment.	
comment	460	comment by: UK CAA
	<p><b>AMC to MED.A.040</b> <b>Item 6.2</b> Page: 24</p> <p><b>Comment:</b> Question to be refined.</p> <p><b>Justification:</b> Cough syncope liable to recur unless risk factors corrected.</p> <p><b>Proposed Text:</b> Delete 'and cough syncope'.</p>	
response	<i>Noted</i>	
	See response to comment No 248 of this segment.	
comment	461	comment by: UK CAA
	<p><b>AMC to MED.A.040 Item 8</b> Page: 25</p>	

**Comment:**  
There is an error in the question stems in this section.

**Justification:**  
Applicants would be referred with conditions that are satisfactory for a LPL medical certificate if the questions are not amended.

**Proposed Text:**  
Change to:  
**8 Coronary artery disease.**  
**Does the pilot have coronary artery disease?**  
**Yes (in box) If yes, answer the questions below.**  
**If no, go to section 9.**

**Has the pilot had an acute coronary syndrome, including myocardial infarction:**  
**8.1 Within the last 6 weeks? Yes (shaded box) No (unshaded box)**  
**8.1.1 More than 6 weeks ago with a subsequent satisfactory cardiological evaluation including an exercise electrocardiogram? Yes (unshaded box) No (shaded box)**  
**Has the pilot had angina:**  
**8.2 Within the last 6 weeks? Yes (shaded box) No (unshaded box)**  
**8.2.1 More than 6 weeks ago with a subsequent satisfactory cardiological evaluation including an exercise electrocardiogram? Yes (unshaded box) No (shaded box)**  
**Has the pilot had angioplasty and/or stenting:**  
**8.3 Within the last 6 weeks? Yes (shaded box) No (unshaded box)**  
**8.3.1 More than 6 weeks ago with a subsequent satisfactory cardiological evaluation including an exercise electrocardiogram, and been free of angina since the procedure? Yes (unshaded box) No (shaded box)**  
**Has the pilot had coronary artery bypass grafting:**  
**8.4 Within the last 3 months? Yes (shaded box) No (unshaded box)**  
**8.4.1 More than 3 months ago with a subsequent satisfactory cardiological evaluation including an exercise electrocardiogram conducted at least 3 months post operatively? Yes (unshaded box) No (shaded box)**

response *Noted*

See response to comment No 248 of this segment.

comment

462

comment by: UK CAA

**AMC to MED.A.040**  
**Item 10.1**  
**Page: 26**

**Comment:**  
Numerical error.

**Justification:**  
Value should be higher and consistent with AMC to MED.B.090 1.2 and 1.3.

**Proposed Text:**  
Change '5cm' to '5.5 cm.'

response	<i>Noted</i>	
	See response to comment No 248 of this segment.	
comment	463	comment by: UK CAA
	<p><b>AMC to MED.A.040</b>  <b>Item 13.1</b>  <b>Question stem</b>  <b>Page: 26</b></p> <p><b>Comment:</b>  Question stem is complicated.</p> <p><b>Justification:</b>  Clarity.</p> <p><b>Proposed Text:</b>  Change 'not including' to '<b>other than</b>'</p>	
response	<i>Noted</i>	
	See response to comment No 248 of this segment.	
comment	464	comment by: UK CAA
	<p><b>AMC to MED.A.040</b>  <b>Item 13.1</b>  <b>6<sup>th</sup> and 7<sup>th</sup> bullet points</b>  <b>Page: 26</b></p> <p><b>Comment:</b>  Terms could be clarified.</p> <p><b>Justification:</b>  Rightward and leftward axes are not necessarily pathological.</p> <p><b>Proposed Text:</b>  Change 'rightward axis' to '<b>right axis deviation</b>' and 'leftward axis' to '<b>left axis deviation</b>'.</p>	
response	<i>Noted</i>	
	See response to comment No 248 of this segment.	
comment	465	comment by: UK CAA
	<p><b>AMC to MED.A.040</b>  <b>Doctor's declaration</b>  <b>Page: 29</b>  <b>Comment:</b>  There is no need for the GMP to refer to the Regulation and AMC as applicants with any relevant medical condition are automatically referred to an AME or AeMC.</p>	

response	<p><b>Justification:</b> The form is designed to be 'standalone' and is to be used by the GMP without having to refer to other documents.</p> <p><b>Proposed Text:</b> Change declaration wording to: '<b>I declare that the information given on this report is correct to the best of my knowledge and belief.</b>'</p> <p><i>Noted</i></p> <p>See response to comment No 248 of this segment.</p>
comment	<p>466 <span style="float: right;">comment by: UK CAA</span></p> <p><b>AMC to MED.A.040</b> <b>Page: 29</b></p> <p><b>Comment:</b> There is no statement of whether the certificate has been issued or the application referred to an AME or AeMC. There needs to be a mechanism for reporting the outcome of a LPL medical.</p> <p><b>Justification:</b> Disposal (ie GMP's decision) needs to be clear. Compliance with MED.A.050 (b) (4).</p> <p><b>Proposed Text:</b> On the LPL report form a question stem needs to be inserted and "yes" and "no" boxed replies are needed between the title "Doctor's declaration" and the sentence beginning "I declare that I have examined.." Add: '<b>Complete the boxes as indicated</b>'. Boxes to be added for '<b>Certificate Issued</b>' and '<b>Application referred</b>'.</p> <p><i>Noted</i></p> <p>See response to comment No 248 of this segment.</p>
comment	<p>555 <span style="float: right;">comment by: British Microlight Aircraft Association</span></p> <ol style="list-style-type: none"> <li>1. "Identity No: "The UK does not allocate citizens with identity numbers and so this part of the form is irrelevant to the UK</li> <li>2. "Identity No: "The UK does not allocate citizens with identity numbers and so this part of the form is irrelevant to the UK</li> <li>3. 3.2 UK recommended maximum Alcohol limits are 21 units for female and 28 units for male and are so more lenient than those suggested by this question. Has there been an investigation to prove that the proposed lower limits are justified?</li> <li>4. No comment</li> <li>5. No comment</li> <li>6. Below the header "Nervous System" "Does the pilot have a history of" spurious wording that should be removed. After the "Yes" box "does the pilot have a history of" wording should be removed</li> <li>7. No section 7</li> <li>8. No question included after the header to answer. 8.1.1 If the pilot has not had an ACS more than six weeks before and answers No he is penalized for not having a medical problem. The question needs to be phrased with</li> </ol>

an "if" For example "If the pilot has had an ACS more than six weeks ago has he had a satisfactory cardiological evaluation including a normal exercise tolerance test and since the ACS?" The same comment applies to 8.2.1 - 8.3.1 - 8.4.1

9. No comment  
 10. No comment  
 11. No comment  
 12. No comment  
 13. To answer this question is it required that the pilot has had to have had a resting electrocardiogram. This is not part of the requirement for examination for the LPL medical certificate.  
 14. No comment  
 15. Should this read, "Do you feel that the pilot has an important condition that has **not** been addressed in the questions above?"  
 16. No comment  
 17. **17.3** requires that the examination room has stairs! **17.4** does it have to be a pencil? **17.8** Disagree that the lower limb strength required to fly an aircraft is as much as required to ride a bicycle.

**Repeated questions before Pilot's Declaration**" If the pilot has previously undergone examination for a pilots licence, state when, where and with what result."  
 and  
 "Has the pilot ever had a medical certificate denied suspended or revoked? If so, give details bellow."

**Spelling** error "bellow" should be "below"

General comment  
 The proposed form should be considered by organisations representing the members of the medical profession who will be asked to carry out these examinations. It should not be entirely designed by doctors who are experienced in aviation medical practices.

response

*Noted*

See response to comment No 248 of this segment.

3. Standard recommended maximum alcohol units (expressed in grams of ethanol) are 8 in UK; 9,9 in Netherlands; 10 in Australia, Austria, New Zealand, Poland and Spain; 11 in Finland; 12 in Denmark, France, Italy, South Africa; 13,6 in Canada; 14 in Portugal and United States. Internationally the average standard alcohol unit is higher than in the UK.

comment

578

comment by: *Florian Söhn*

Getting the history:

In a medical system where a centralized medical database exists it maybe possible for a GP to obtain extended history data. In GERmany this is NOT possible due data protction "Datenschutz" and the "Schweigepflicht. Therefor a way more dietailed examination to ensure not medical risk for flight safty is present seems absolutly necessary. t least ICAO standards should be met all the time.

point 13. cardiac investigations:

the LPL examination part does not include a restiing electrocardiogram.

	Therefore Question 13 can not be answered.
response	<i>Noted</i>
	See response to comment No 248 of this segment.

comment	614	comment by: <i>Lufthansa German Airlines</i>
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Author: Dr. Christine Huber, Cardiologist, AMC Frankfurt  
 Section: AMC/GM to Part Medical  
 Draft Version 3.0  
**Page: 25**

**Relevant Text: 8 ) Coronary Artery Disease**  
 8.1 Has the pilot had an acute coronary syndrome (ACS) including myocardial infarction (heart attack) within the last six weeks?  
 8.11 Has the pilot had an ACS more than six weeks ago and since the ACS they have had a satisfactory cardiological evaluation including a normal exercise tolerance test?  
 8.2 Has the pilot had angina within the last six weeks?  
 8.2.1 Has the pilot had angina more than six weeks ago and since this time they have had a satisfactory cardiological evaluation including a normal exercise tolerance test?  
 8.3 Has the pilot had angioplasty and/or stenting within the last six weeks?  
 8.3.1 Has the pilot had angioplasty and/or stenting more than six weeks ago and since the procedure they have been free from angina and have had a satisfactory cardiological evaluation including a normal exercise tolerance test?  
 8.4 Has the pilot had coronary bypass crafting within the last three months?  
 8.4.1 Has the pilot had coronary bypass crafting more than 3 months ago and an exercise tolerance test conducted 3 months post operatively was normal and also a post cardiological evaluation was satisfactory?

**Comment:** A differentiation between „within" or „more than" 6 weeks or 3 month in myocardial infarction/ACS, angiopalstyTstent or coronary bypass grafting is not useful for the evaluation of pilots:

- - the disease is relevant anyway
- - the issue CAD with or without intervention/surgery has to lead to a deferral to the licensing authority

**Proposal: 8 ) Coronary Artery Disease**  
 8.1 Has the pilot ever had angina, acute coronary syndrome or myocardial infarction?  
 8.2 Has the pilot had any coronary intervention (angioplasty/stent) or coronary baypass grafting?

response	<i>Noted</i>
	See response to comment No 248 of this segment.

comment	615	comment by: <i>Lufthansa German Airlines</i>
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Author: Dr. Christine Huber, Cardiologist, AMC Frankfurt  
 Section: AMC/GM to Part Medical  
 Draft Version 3.0  
**Page: 25**

Relevant Text: **8 ) Coronary Artery Disease**  
 8.5 Is the pilot known to have a left ventricular ejection fraction of less than 0.4?

**Comment:** an LV- ejection fraction of less than 40% is too low as a limit and bears a high risk for significant ventricular rhythm disorders.

**Proposal: 8 ) Coronary Artery Disease**  
 8.5 Is the pilot 's left ventricular ejection fraction less than 0.5?

response *Noted*

See response to comment No 248 of this segment.

comment 616 comment by: *Lufthansa German Airlines*

Author: Dr. Christine Huber, Cardiologist, AMC Frankfurt  
 Section: AMC/GM to Part Medical  
 Draft Version 3.0  
**Page:** 25

Relevant Text: **9 ) Cardiac Arrhythmia**  
 9.1 Is it the case that the pilot 's heart rhythm is abnormal?

**Comment:** is it useful not to differentiate between different heart rhythm abnormalities here?

**Proposal: 9 ) Cardiac Arrhythmia**  
 9.1 Is there any pilot 's history of syncope, palpitations?  
 9.2 Is there a history of relevant bradycardia or tachycardia?  
 9.3 Is there a history of extrasystoly?

response *Noted*

See response to comment No 248 of this segment.

comment 617 comment by: *Lufthansa German Airlines*

Author: Dr. Christine Huber, Cardiologist, AMC Frankfurt  
 Section: AMC/GM to Part Medical  
 Draft Version 3.0  
**Page:** 26

Relevant Text: **11) Valvular/Congenital Heart Disease**  
 11.4 Does the pilot currently have significant symptoms due to valvular/congenital heart disease or is the pilot likely to develop such symptoms?  
 11.5 Has there been any progression of valvular/congenital heart disease since the last medical report?  
 (if relevant)

**Comment:** there is no definition of "significant symptoms" - who decides upon the degree (GMP?) and who decides upon the "relevant progression"?

**Proposal:** Is there any history of congenital or valvular heart disease?

response	- if the answer is "yes" -> deferral to the licensing authority	
	<i>Noted</i>	
	See response to comment No 248 of this segment.	
comment	618	comment by: <i>Lufthansa German Airlines</i>
	<p>Author: Dr. Christine Huber, Cardiologist, AMC Frankfurt  Section: AMC/GM to Part Medical  Draft Version 3.0  <b>Page:</b> missing!</p> <p>Relevant Text: missing!</p> <p><b>Comment:</b> Epi-/Myo-/Pericarditis is missing  Pacemaker/ defibrillator/HF-ablation is missing</p> <p><b>Proposal:</b> Is there any history of epi-/myo-/pericarditis?  Does the pilot have an implanted pacemaker or defibrillator?  Did the pilot ever have an HF-ablation?</p>	
response	<i>Noted</i>	
	See response to comment No 248 of this segment.	
comment	619	comment by: <i>Lufthansa German Airlines</i>
	<p>Author: Dr. Christine Huber, Cardiologist, AMC Frankfurt  Section: AMC/GM to Part Medical  Draft Version 3.0  <b>Page:</b> 26</p> <p>Relevant Text: <b>13) Cardiac investigations - Has the pilot had</b>  13.1 an abnormal resting ecg but not including:  - RBBB  - LBBB subsequently evaluated with a satisfactory cardiological evaluation including an exercise tolerance test  - suspected myocardial infarction evaluated with a satisfactory cardiological evaluation including an exercise tolerance test  - pre-excitation without an associated arrhythmia or likelihood of developing an arrhythmia  - voltage criteria for left ventricular hypertrophy without clinical or echocardiographic evidence of left ventricular hypertrophy  - rightward axis  - leftward axis</p> <p><b>Comment:</b> - unprecise definitions "abnormal ecg not including abnormalities" like BBB  - LBBB: "satisfactory evaluation including an exercise test" -&gt; the exercise test is a minimum exam level in cardiology and requires no specific naming, however in LBBB it does/can not exclude CAD and is therefore insufficient !  - "pre-excitation without associated arrhythmia or likelihood of developing an arrhythmia" -&gt; this cannot be defined by an ecg, and an EP-study is not explicitly questioned or stated as an requirement, insufficient definition  - what is a "clinical evidence of LV hypertrophy" - there are no specific</p>	

symptoms directly and only related to this issue  
 - the necessity for specific investigations in cases of leftward axis is questionable

**Proposal: 13) Cardiac investigations - Has the pilot had**

- 13.1 a normal resting ecg
  - 13.1.1 a RBBB in the resting ecg
  - 13.1.2 a LBBB in the resting ecg
  - 13.1.3 a suspected myocardial infarction
  - 13.1.4 pre-excitation in the resting ecg
- If the answer is "yes" -> deferral to the licensing authority.

13.1.5. voltage criteria for left ventricular hypertrophy, rightward axis (or leftward axis) in the resting ecg need further cardiological investigation including echocardiography in case of pathological results -> deferral to the licensing authority.

response *Noted*

See response to comment No 248 of this segment.

comment

649

comment by: *Royal Danish Aeroclub*

**Leisure Pilot's License Medical Report (page 23-30)**

This is really good. The medical report is understandable and very easy to comply with. Any doctor (GMP) can deal with it. It is self explaining and it is obvious when to refer the applicant to the AME or AeMC. The report is much simpler than an ordinary certificate for e.g. life insurance companies that any doctor (GMP) deals with.

One thing: It says: "has the pilot ever..."

Suggestion:

It should read: "has the pilot since last aeromedical examination..." on page 28, for simplicity

response *Noted*

Thank you for the comment.  
 See response to comment No 248 of this segment.

comment

694

comment by: *Robert Cronk*

This list is much more extensive than the current requirements for a doctor to certify fitness for private leisure flight under the UK's NPPL, or US Sport Pilot Licence. It would be much better - and entirely suitable for the purpose of the Leisure Pilots Licence - to relate the medical requirements for the LPL to the medical requirements of a driver of a commercial vehicle.

Many of the questions on the form seem irrelevant to the actual requirements of the leisure pilot - eg, at 17.7, it is not relevant for a pilot to be able to row a boat or screw a corkscrew with either hand! Disabled pilots do fly in suitably adapted aircraft!

The cost of a medical certificate from the patient's records - which cannot lie - is very much less than the cost of an examination of the type proposed, and is

	no less accurate or meaningful.
response	<i>Noted</i>
	See response to comment No 248 of this segment.

comment	753	comment by: <i>Swiss Association of Aviation Medicine</i>
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**Comment:**  
 The working group of European Cardiologists in Aviation Medicine reached consensus, that the LPL requirements are medically - cardiologically critical for human safety for the pilot himself and for aviation safety. Furthermore multiple international study results prove the danger and risks of the requirements and limits set up in the LPL requirements (like for instance a left ventricular ejection fraction below 50%). It would be dangerous as well as stupid to assess cardiological and aeromedical "fitness" under such regulations. It would rather be an assessment and documentation of "sickness" than of fitness, ready for use against consultants by any lawyer or judge in the European Union.  
 Therefore the working group of cardiologists will refuse to check LPL pilots under these regulations.

**Proposal:**  
 Private Pilots should be checked for their fitness to fly according to AMC class 2 medical regulations.  
 LPL requirements should be deleted.

response	<i>Noted</i>
	See response to comment No 248 of this segment.

comment	757	comment by: <i>Swiss Association of Aviation Medicine</i>
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**Comment:**  
 The report details the medical standard required for a pilot to hold a light aircraft pilot`s licence. Medical history of an applicant is important to prevent any kind of disqualifying ENT conditions, because there are many issues in the ENT subject which potentially can cause sudden incapacitation in flight.

**Proposal:**  
 15 ENT  
Does the pilot have a history of:

15.1 Impaired hearing or hearing loss	Y/N
15.2 Eustachian tube dysfunction	Y/N
15.3 Diseases of the middle ear	Y/N
15.4 Middle ear surgery	Y/N
15.5 Disease of the inner ear	Y/N
15.6 Vestibular dysfunction	Y/N
15.7 Disease of head neck, face and scalp	Y/N
15.8 Disease of the upper airway or oral cavity	Y/N
15.9 Sinus dysfunction	Y/N

response	<i>Noted</i>
	See response to comment No 248 of this segment. The amended requirements for LAPL will include a section for ENT.

comment	766	comment by: <i>European Society of Space and Aviation Medicine (ESAM)</i>
<p><b>Author: European Society of Space and Aviation Medicine (ESAM) - Internal Medicine Group -</b></p> <p><b>Section: AMC to MED.A.040</b></p> <p><b>Page: 22</b></p> <p><b>Relevant Text: LPL medical certificates should be issued following examination in accordance with the following report (...).</b></p> <p><b>Comment:</b> The issue of any medical testimony about a general physical condition requires state-of-the-art evaluation of the patient's history and a complete physical examination in accordance with medical good-practice. Without a sound taking of history and examination no medical certification can be done legally.</p> <p><b>Proposal:</b> LPL medical certificates shall be issued only following complete evaluation of the applicant's medical history and following a complete physical examination according to medical good-practice.</p>		
response	<i>Noted</i>	
<p>Thank you for the comment. Both the evaluation of the applicant's medical history and a physical examination are essential parts of any aeromedical assessment.</p> <p>See also response to comment No 248 of this segment.</p>		
comment	767	comment by: <i>European Society of Space and Aviation Medicine (ESAM)</i>
<p><b>Author: European Society of Space and Aviation Medicine (ESAM) - Internal Medicine Group -</b></p> <p><b>Section: AMC to MED.A.040</b></p> <p><b>Page: 22</b></p> <p><b>Relevant Text: LPL medical certificates should be issued following examination in accordance with the following report (...).</b></p> <p><b>Comment:</b> The issue of any medical testimony about a general physical condition requires state-of-the-art evaluation of the patient's history and a complete physical examination in accordance with medical good-practice. Without a sound taking of history and examination no medical certification can be done legally.</p> <p><b>Proposal:</b> LPL medical certificates shall be issued only following complete evaluation of the applicant's medical history and following a complete physical examination according to medical good-practice.</p>		
response	<i>Noted</i>	

Thank you for the comment. Both the evaluation of the applicant's medical history and a physical examination are essential parts of any aeromedical assessment.

See also response to comment No 248 of this segment.

comment

800

comment by: George Rowden

*Comment: This lengthy medical report form required to be completed for the LPL has singularly failed to abide by the emphasis in 216/2008 to achieve simple measures for non commercial activities and compares very unfavourably with the medical requirements for non commercial pilots in a number of other countries. Adoption of the current proposals would significantly increase costs to the applicant without any perceivable safety benefit. As noted elsewhere in this response, pilot medicals should preferably be based on individual public health records held by the applicants GMP. Further, the experiences of the European Road Transport Authorities in certifying drivers appears very relevant as drivers are required to achieve a similar medical standard as pilots.*

I propose that the form proposed be replaced by a much simpler form that permits validation by either reference to records or a physical examination. The form used by the New Zealand Gliding Association is suggested as an example.

response

Noted

See response to comment No 248 of this segment.

comment

809

comment by: Swiss Association of Aviation Medicine

**The Swiss Society of Aviation Medicine supports the following comments of the german colleagues**

**Comment:**

Why should a medical doctor sign this report?

1) If doctors sign this report they testify that the pilot understood the questions ,or it was explained by the doctor in a way that he could understand the questions. If it is asked e.g. Does the pilot have a psychological or psychiatric illness and quick answers like yes or no are possible, nobody will find out the answer of question 4.4 - alcohol dependency in the past 3 years. If the pilot is ok at the age of 17 nobody will ask him again until 45.This means the doctor who signed the fist LPL medical must give a prognosis of medical fitness for 28 years. But during this time the occurrence of many psychiatric disorders ,alcohol and drug dependency have its peak. Who will be accused, if the worst case will happen that a pilot with a bipolar disorder , unable to realize his situation, flying with a valid medical certificate , will have an accident with a commercial aircraft while violating a controlled airspace? - the medical doctor or the competent authority.

2.) We tested the medical report form in the German Academy of Aviation Medicine in an advanced course of aviation medicine with 25 AMEs who know the medical terminology very well. The best performer needed 35 minutes to fill out the report correctly, at average it took 45 minutes to perform the LPL questions and the medical examinations. Who believes that this will be a cheaper way to enter a cockpit as it was under JAA requirements with a class 2 medical is mistaken. Even GPs need salary for 45 minutes to work .

The whole medical part of the LPL seems to be very problematic, far under ICAO standard, for European standards and narrow airspace structures are **not safety!**

**Proposal:**

1) For LPL medical standard the same standard as class 2 medical standard shall be recommended.

2) If the political guidelines for EASA do not allow class 2 Medicals for LPL pilots, we propose a self assessment every 2 years by the LPL pilot. For this purpose EASA or the national competent authorities shall provide an internet solution where pilots can fill out the LPL medical report and automatically receive by internet their medical certificate if no grey shaded tick box was ticked.

If such a box was ticked it shall be the responsibility of the authority to send the pilot to a specialist or an AME for an assessment. If it is regulated in this way the authority is definitely responsible for the lack of safety in such a system and medical doctors are not used as an alibi for good medical assessment.

This might be important in case of accidents when insurances are looking for responsibilities.

3) If proposal 1 and 2 will not be respected by EASA and the LPL medical requirements will be implemented as it is now, the medical societies should give advice to their doctors to refuse the collaboration in all cases of medical advice, reports and assessment relating to LPL.

response

*Noted*

See response to comment No 248 of this segment.

comment

814

comment by: *Swiss Association of Aviation Medicine*

**Comment:**

The issue of any medical testimony about a general physical condition requires state-of-the-art evaluation of the patient's history and a complete physical examination in accordance with medical good-practice. Without a sound taking of history and examination no medical certification can be done legally.

**Proposal:**

LPL medical certificates shall be issued only following complete evaluation of the applicant's medical history and following a complete physical examination according to medical good-practice.

response

*Noted*

Thank you for the comment. Both the evaluation of the applicant's medical history and a physical examination are essential parts of any aeromedical assessment.

See also response to comment No 248 of this segment.

comment

815

comment by: *Swiss Association of Aviation Medicine*

**Comment:**

If our comments are not accepted, the responsibility for issuing the LPL licence and for aeromedical consequences must be taken by the licensing authorities. The Internal Medicine working group would strongly recommend to any medical doctor not to issue a LPL-medical certification as a legal document under the existing conditions.

**Proposal:**  
Set Class 2 standards and certification procedures as a reasonable, minimum, safe and acceptable standard for any Aeromedical certification.

response *Noted*

See response to comment No 248 of this segment.

comment 835 comment by: *Thomas Cook Airlines UK*

Does this mean that even visual limitations have to be referred to an AME? Surely this is not the case. The limitations that are or are not permissible for GMPs to authenticate need to be clearly indicated.

response *Noted*

In the case of any limitation, the applicant shall be referred to an AME or AeMC.

comment 836 comment by: *Thomas Cook Airlines UK*

**Commentator: The UK Association of Aviation Medical Examiners**

**Paragraph:** II Draft Decision AMC and GM for Part-medical Subpart A General Requirements

**Page Number:** 27

**Comment:** Section 15 There are words missing here. The sentence should read "Do you feel that the pilot has an important condition that has not been addressed in the questions above?"

The word "feel" is a bad choice of English. It would be better to say ""In your opinion has the pilot....."

**Justification:** Document should not have missing words and poor choice of English syntax should be avoided

**Proposed text:** Section 15  
In your opinion has the pilot an important condition that has not been addressed in the questions above?

response *Noted*

See response to comment No 248 of this segment.

comment 843 comment by: *European Society of Space and Aviation Medicine (ESAM)*

**Author: European Society of Space and Aviation Medicine (ESAM) - Group ENT -**

**Section:**  
**2 Subpart A AMC to MED.A.040 - Instruction for completion of LPL report**

**Page:** 27

**Relevant Text:**  
 ENT chapter has been forgotten in the LPL report form

**Comment:**  
 The report details the medical standard required for a pilot to hold a light aircraft pilot`s licence. Medical history of an applicant is important to prevent any kind of disqualifying ENT conditions, because there are many issues in the ENT subject which potentially can cause sudden incapacitation in flight.

**Proposal:**  
 15 ENT  
Does the pilot have a history of:  
 15.1 Impaired hearing or hearing loss Y/N  
 15.2 Eustachian tube function Y/N  
 15.3 Diseases of the middle ear Y/N  
 15.4 Middle ear surgery Y/N  
 15.5 Disease of the inner ear Y/N  
 15.6 Vestibular disfunction Y/N  
 15.7 Disease of head neck, face and scalp Y/N  
 15.8 Disease of the upper airway or oral cavity Y/N  
 15.9 Sinus dysfunction Y/N

response *Noted*

See response to comment No 248 of this segment.

The amended requirements for LAPL will include a section for ENT.

comment 864

comment by: *Swiss Association of Aviation Medicine*

**Comment:**  
 4. Even the psychologist in the group could not define what a psychological illness is. Illness describes a medical and not primarily a psychological problem.

Two points to be added:  
 4.7 - 4.8 = Aeromedical psychiatric experience has proven that histories concerning the past six months are too short and not representative. 'psychotic illness/disorder' are easily misunderstood by pilots/applicants. The questions concerning treatment and medication in this context help for clarification.

**Proposal:**  
 4. Does the pilot/applicant have history of psychiatric illness or psychological deficiency .

Two points are to be added:  
 4.7 significant psychiatric disorder which needed treatment  
 4.8 does or did the pilot take any psychotropic medication

response	<p><i>Noted</i></p> <p>See response to comment No 248 of this segment.</p>				
comment	<table border="1"> <tr> <td data-bbox="343 342 470 392">892</td> <td data-bbox="470 342 1445 392">comment by: <i>European Society of Space and Aviation Medicine (ESAM)</i></td> </tr> <tr> <td colspan="2" data-bbox="343 392 1445 1585"> <p><b>Author: European Society of Space and Aviation Medicine (ESAM) - Group Neurology Psychiatry-</b></p> <p><b>Section: 1</b>  <b>II Draft decision AMC and GM for Part-Medical AMC/GM to Part-Medical</b>  <b>Subpart A</b>  <b>General Requirements</b></p> <p><b>Leisure Pilot's Licence Medical Report</b>  <b>4. Psychiatric illness</b>  4.1 - 4.6 = no comments</p> <p><b>Page: 24</b></p> <p><b>Relevant Text:</b>  Does the pilot have history of psychological or psychiatric illness?</p> <p><b>Comment:</b>  4. Even the psychologist in the group could not define what a psychological illness is. Illness describes a medical and not primarily a psychological problem.</p> <p>Two points to be added:  4.7 - 4.8 = Aeromedical psychiatric experience has proven that histories concerning the past six months are too short and not representative. 'psychotic illness/disorder' are easily misunderstood by pilots/applicants. The questions concerning treatment and medication in this context help for clarification.</p> <p><b>Proposal:</b>  4. Does the pilot/applicant have history of psychiatric illness or psychological deficiency .</p> <p>Two points are to be added:  4.7 significant psychiatric disorder which needed treatment  4.8 does or did the pilot take any psychotropic medication</p> </td> </tr> </table>	892	comment by: <i>European Society of Space and Aviation Medicine (ESAM)</i>	<p><b>Author: European Society of Space and Aviation Medicine (ESAM) - Group Neurology Psychiatry-</b></p> <p><b>Section: 1</b>  <b>II Draft decision AMC and GM for Part-Medical AMC/GM to Part-Medical</b>  <b>Subpart A</b>  <b>General Requirements</b></p> <p><b>Leisure Pilot's Licence Medical Report</b>  <b>4. Psychiatric illness</b>  4.1 - 4.6 = no comments</p> <p><b>Page: 24</b></p> <p><b>Relevant Text:</b>  Does the pilot have history of psychological or psychiatric illness?</p> <p><b>Comment:</b>  4. Even the psychologist in the group could not define what a psychological illness is. Illness describes a medical and not primarily a psychological problem.</p> <p>Two points to be added:  4.7 - 4.8 = Aeromedical psychiatric experience has proven that histories concerning the past six months are too short and not representative. 'psychotic illness/disorder' are easily misunderstood by pilots/applicants. The questions concerning treatment and medication in this context help for clarification.</p> <p><b>Proposal:</b>  4. Does the pilot/applicant have history of psychiatric illness or psychological deficiency .</p> <p>Two points are to be added:  4.7 significant psychiatric disorder which needed treatment  4.8 does or did the pilot take any psychotropic medication</p>	
892	comment by: <i>European Society of Space and Aviation Medicine (ESAM)</i>				
<p><b>Author: European Society of Space and Aviation Medicine (ESAM) - Group Neurology Psychiatry-</b></p> <p><b>Section: 1</b>  <b>II Draft decision AMC and GM for Part-Medical AMC/GM to Part-Medical</b>  <b>Subpart A</b>  <b>General Requirements</b></p> <p><b>Leisure Pilot's Licence Medical Report</b>  <b>4. Psychiatric illness</b>  4.1 - 4.6 = no comments</p> <p><b>Page: 24</b></p> <p><b>Relevant Text:</b>  Does the pilot have history of psychological or psychiatric illness?</p> <p><b>Comment:</b>  4. Even the psychologist in the group could not define what a psychological illness is. Illness describes a medical and not primarily a psychological problem.</p> <p>Two points to be added:  4.7 - 4.8 = Aeromedical psychiatric experience has proven that histories concerning the past six months are too short and not representative. 'psychotic illness/disorder' are easily misunderstood by pilots/applicants. The questions concerning treatment and medication in this context help for clarification.</p> <p><b>Proposal:</b>  4. Does the pilot/applicant have history of psychiatric illness or psychological deficiency .</p> <p>Two points are to be added:  4.7 significant psychiatric disorder which needed treatment  4.8 does or did the pilot take any psychotropic medication</p>					
response	<p><i>Noted</i></p> <p>See response to comment No 248 of this segment.</p>				
comment	<table border="1"> <tr> <td data-bbox="343 1738 470 1787">993</td> <td data-bbox="470 1738 1445 1787">comment by: <i>European Society of Space and Aviation Medicine (ESAM)</i></td> </tr> <tr> <td colspan="2" data-bbox="343 1787 1445 2033"> <p><b>Author:</b>  <b>Group General Requirements - European Society of Space and Aviation Medicine (ESAM) - Wiesbaden August 23<sup>rd</sup>- 24<sup>th</sup> 2008</b></p> <p><b>Section:AMC/GM to part - medical</b>  <b>Subpart A Section2</b>  <b>AMC to MED.A.040 Leisure Pilot`s License Medical Report</b></p> </td> </tr> </table>	993	comment by: <i>European Society of Space and Aviation Medicine (ESAM)</i>	<p><b>Author:</b>  <b>Group General Requirements - European Society of Space and Aviation Medicine (ESAM) - Wiesbaden August 23<sup>rd</sup>- 24<sup>th</sup> 2008</b></p> <p><b>Section:AMC/GM to part - medical</b>  <b>Subpart A Section2</b>  <b>AMC to MED.A.040 Leisure Pilot`s License Medical Report</b></p>	
993	comment by: <i>European Society of Space and Aviation Medicine (ESAM)</i>				
<p><b>Author:</b>  <b>Group General Requirements - European Society of Space and Aviation Medicine (ESAM) - Wiesbaden August 23<sup>rd</sup>- 24<sup>th</sup> 2008</b></p> <p><b>Section:AMC/GM to part - medical</b>  <b>Subpart A Section2</b>  <b>AMC to MED.A.040 Leisure Pilot`s License Medical Report</b></p>					

**Page:** 23-29

**Relevant Text:**

The whole medical report.

**Comment:**

Why should a medical doctor sign this report?

1) If doctors sign this report they testify that the pilot understood the questions ,or it was explained by the doctor in a way that he could understand the questions. If it is asked e.g. Does the pilot have a psychological or psychiatric illness and quick answers like yes or no are possible, nobody will find out the answer of question 4.4 - alcohol dependency in the past 3 years. If the pilot is ok at the age of 17 nobody will ask him again until 45.This means the doctor who signed the fist LPL medical must give a prognosis of medical fitness for 28 years. But during this time the occurrence of many psychiatric disorders ,alcohol and drug dependency have its peak. Who will be accused, if the worst case will happen that a pilot with a bipolar disorder , unable to realize his situation, flying with a valid medical certificate , will have an accident with a commercial aircraft while violating a controlled airspace? - the medical doctor or the competent authority.

2.) We tested the medical report form in the German Academy of Aviation Medicine in an advanced course of aviation medicine with 25 AMEs who know the medical terminology very well. The best performer needed 35 minutes to fill out the report correctly, at average it took 45 minutes to perform the LPL questions and the medical examinations. Who believes that this will be a cheaper way to enter a cockpit as it was under JAA requirements with a class 2 medical is mistaken. Even GPs need salary for 45 minutes to work .

The whole medical part of the LPL seems to be very problematic, far under ICAO standard, for European standards and narrow airspace structures are **not safety!**

**Proposal:**

1) For LPL medical standard the same standard as class 2 medical standard shall be recommended.

2) If the political guidelines for EASA do not allow class 2 Medicals for LPL pilots, we propose a self assessment every 2 years by the LPL pilot.

For this purpose EASA or the national competent authorities shall provide an internet solution where pilots can fill out the LPL medical report and automatically receive by internet their medical certificate if no grey shaded tick box was ticked.

If such a box was ticked it shall be the responsibility of the authority to send the pilot to a specialist or an AME for an assessment. If it is regulated in this way the authority is definitely responsible for the lack of safety in such a system and medical doctors are not used as an alibi for good medical assessment.

This might be important in case of accidents when insurances are looking for responsibilities.

3) If proposal 1 and 2 will not be respected by EASA and the LPL medical requirements will be implemented as it is now, the medical societies should give advice to their doctors to refuse the collaboration in all cases of medical advice, reports and assessment relating to LPL.

response	<p><i>Noted</i></p> <p>See response to comment No 248 of this segment.</p>	
comment	1017	comment by: <i>European Society of Space and Aviation Medicine (ESAM)</i>
<p><b>Author: European Society of Space and Aviation Medicine (ESAM) - Cardiology Group -</b></p> <p><b>Comment LPL</b></p> <p><b>Page: 23 - 26 and 60 - 61</b></p> <p><b>Comment:</b>  The working group of European Cardiologists in Aviation Medicine reached consensus, that the LPL requirements are medically - cardiologically critical for human safety for the pilot himself and for aviation safety. Furthermore multiple international study results prove the danger and risks of the requirements and limits set up in the LPL requirements (like for instance a left ventricular ejection fraction below 50%). It would be dangerous as well as stupid to assess cardiological and aeromedical "fitness" under such regulations. It would rather be an assessment and documentation of "sickness" than of fitness, ready for use against consultants by any lawyer or judge in the European Union.  Therefore the working group of cardiologists will refuse to check LPL pilots under these regulations.</p> <p><b>Proposal:</b>  Private Pilots should be checked for their fitness to fly according to AMC class 2 medical regulations.  LPL requirements should be deleted.</p>		
response	<p><i>Noted</i></p> <p>See response to comment No 248 of this segment.</p>	
comment	1026	comment by: <i>Ilse Janicke Heart Center Duisburg</i>
<p>Author: Janicke Ilse, Senior MD, AME I and II, Cardiologist and Angiologist at Heart Center Duisburg  Section: <b>II Draft Decision AMC and GM for Part-Medical Subpart A General Requirements</b>  Section 2: Issuance, revalidation and renewal of medical certificates  <b>AMC to MED.A.040</b>  Leisure Pilot`s License Medical Report  <b>Page: 25 (NPA 2008-17c)</b></p> <p>Relevant Text: <b>9 Cardiac Arrhythmia</b>  9.1 Is the pilot`s heart rhythm abnormal?</p> <p><b>Comment:</b> An abnormal heart rhythm is common in normal individuals too, e.g. premature atrial or ventricular beats. With increasing age the probability of rhythm disturbance increases. With this question truly answered a lot of validations must send to the licensing authority and often this is not needed.</p>		

	<p><b>Proposal:</b> Is the pilot`s heart rhythm significantly abnormal (ie bradycardia or tachycardia, frequent and complex forms of supraventricular or ventricular ectopic complexes) ? In case of "yes" have had the pilot a satisfactory cardiological evaluation?</p>	
response	Noted	
	See response to comment No 248 of this segment.	
	1027	comment by: <i>Ilse Janicke Heart Center Duisburg</i>
comment	<p>Author: Janicke Ilse, Senior MD, AME I and II, Cardiologist and Angiologist at Heart Center Duisburg Section: <b>II Draft Decision AMC and GM for Part-Medical Subpart A General Requirements</b> Section 2: Issuance, revalidation and renewal of medical certificates <b>AMC to MED.A.040</b> Leisure Pilot`s License Medical Report <b>Page:</b> 25 (NPA 2008-17c)</p> <p>Relevant Text: <b>10 Peripheral Arterial Disease</b> .... Some relevant text is missing</p> <p><b>Comment:</b> Peripheral vascular disease powerfully predicts the presence of a generalized arteriopathy that is likely to involve the coronary and cerebral circulations. Patients with PAOD are at high risk (5,4% per year) of cardiovascular death, myocardial infarction or apoplex (REACH-Registry) <i>Steg et al. JAMA 2007; 297(11)</i> The 12 year mortality risk in symptomatic or asymptomatic PAOD is up to 50% The risk for fatal MI or CHD death is for times higher. <i>Criqui MH et al. N Engl J Med 1992; 326: 381-386.</i> This is likely to jeopardize flight safety.</p> <p><b>Proposal:</b> supply 10.3 Does the pilot have had symptomatic or asymptomatic cerebral or peripheral artery obstructive disease?</p>	
response	Noted	
	See response to comment No 248 of this segment.	
	1028	comment by: <i>Ilse Janicke Heart Center Duisburg</i>
comment	<p>Author: Janicke Ilse, Senior MD, AME I and II, Cardiologist and Angiologist at Heart Center Duisburg Section: <b>II Draft Decision AMC and GM for Part-Medical Subpart A General Requirements</b> Section 2: Issuance, revalidation and renewal of medical certificates <b>AMC to MED.A.040</b> Leisure Pilot`s License Medical Report <b>Page:</b> 26 (NPA 2008-17c)</p> <p>Relevant Text: <b>13 Cardiac Investigations</b></p>	

**13.1** an abnormal resting electrocardiogram not including  
 .....  
 • LBBB subsequently evaluated with a satisfactory cardiological evaluation including an exercise tolerance test  
 • suspected myocardial infarction evaluated with a satisfactory cardiological evaluation including an exercise tolerance test  
 • pre-excitation without an associated arrhythmia or likelihood of developing an arrhythmia

**Comment:**

The exercise test is a minimum exam level in cardiology and requires no specific naming, however in LBBB it does/can not exclude CAD and is therefore insufficient !

Only a symptom limited exercise test will be of useful value to detect CAD and other diseases.

This sentence "pre-excitation without an associated arrhythmia or likelihood of developing an arrhythmia" is equivocally: *The preexcitation pattern is seen in 1,6 per 1000 routine resting ECGs. In a study of WPW pattern in 238 military aviators of mean age 34,3 years, 17,6 % were symptomatic against 82,4 % asymptomatic pilots. 15 % of pilots with pattern alone developed the syndrome over a mean of 22 years.* The risk of supraventricular tachycardia is 1,5-2 per cent per year. Here exist no certain possibility to check the risk who will develop arrhythmia and who not.

An EP-study is not explicitly questioned or stated as an requirement and ethically not to accepted.

**Proposal:**

**13.1** an abnormal resting electrocardiogram not including  
 • LBBB subsequently evaluated with a satisfactory cardiological evaluation Including ischemia tests  
 • suspected myocardial infarction evaluated with a satisfactory cardiological evaluation including a symptom limited exercise tolerance test  
 • pre-excitation without an associated arrhythmia

response *Noted*

See response to comment No 248 of this segment.

comment

1029

comment by: *Ilse Janicke Heart Center Duisburg*

Author: Janicke Ilse, Senior MD, AME I and II, Cardiologist and Angiologist at Heart Center Duisburg

Section: : **II Draft Decision AMC and GM for Part-Medical**

**Subpart A General Requirements**

Section 2: Issuance, revalidation and renewal of medical certificates

**AMC to MED.A.040**

Leisure Pilot`s License Medical Report

**Page:** missing

Relevant Text: missing

**Comment:**

The spontaneously bleeding rate within normal INR range 2,0 - 3,0 extends up to 2 % per year. Any underlying disorder needing anticoagulant therapy will probably enhance the risk of sudden incapacitation. All together this is likely to

	jeopardize flight safety.
	<b>Proposal:</b> Text will be good fitted in chapter 11: valvular/congenital heart diseases Is there any systemic anticoagulant therapy currently or in the past? And why?
response	Noted
	See response to comment No 248 of this segment.

comment	1050	comment by: Ilse Janicke Heart Center Duisburg
	<p><b>Question 8:</b> The questions include only the interval of the last 6 weeks or the last 3 months. The time between two medical assessments will not be mentioned. Therefore the cardiovascular risk can not be estimated. The situation will be another if the doctor should have knowledge of the entire pilots history! <b>Proposal:</b> to delete the times "more then six weeks ago" or "more than 3 months ago" in the questions.</p> <p><b>Question 8.1.1</b> ...and since the ACS they have had a satisfactory cardiological evaluation including a normal symptom limited exercise tolerance test." The exercise ECG has little sensitivity and specificity for detecting CHD (coronary heart disease), this can be increased to 60-70 % sensitivity and 95 % specificity if symptom limited established.</p> <p><b>Question 8.5:</b> "Is the pilot known to have a left ventricular ejection fraction of less than 0,4"?</p> <p>A lot of studies in the past and recently describe that a significantly independent predictor of death or myocardial infarction in CHD with following sudden incapacitation will be the resting left ventricular ejection below 50 % (1). Poststress EF is the best predictor of cardiac death, whereas the amount of ischemia is the best predictor of nonfatal Myocardial infarction (2). One recently published big study showed in 8290 patients with stable CHD and preserved ejection fraction, that independent determinants of sudden cardiac death include an ejection fraction &gt; 40% and &lt; 50 % as opposed to &gt; 50 %, and this is highly significant (3) (1)Tsutsui JM et al.: Prognostic value of dobutamine stress myocardial contrast perfusion echocardiography. Circulation 2005 Sep 6; 112(10): 1382-3. (2) Sharir T et al: Prediction of myocardial infarction versus cardiac death by gated myocardial perfusion SPECT: risk stratification by the amount of stress-induced ischemia and the poststress ejection fraction. (3) Hsia J et al: Sudden cardiac death in patients with stable coronary artery disease and preserved left ventricular systolic function. Am J Cardiol.2008 Feb15; 101(4):457-61. An ejection fraction below 50 % without and especially with CHD is likely to jeopardize flight safety. This Value should be part of the questions.</p>	
response	Noted	
	See response to comment No 248 of this segment.	

comment	1056	comment by: Dr Michel Kossowski AeMC Clamart
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	<p>in the report ENT is not mentioned!!! At least must be mentioned :          have you an history of vertigo? or diziness?          Have you an history of deafness or of pathology of the ear ?          have you an history of ENT surgery?          Have you an history of cranial trauma?</p>
response	Noted
	<p>See response to comment No 248 of this segment.</p> <p>The amended requirements for LAPL will include a section for ENT.</p>
comment	<p>1074 <span style="float: right;">comment by: Dr. Ludger Beyerle</span></p>
	<p><b>Section:AMC/GM to part - medical</b>  <b>Subpart A Section2</b>  <b>AMC to MED.A.040 Leisure Pilot`s License Medical Report</b></p> <p><b>Page: 23-29</b></p> <p><b>Relevant Text:</b>          The whole medical report.</p> <p><b>Comment:</b></p> <p>1) If doctors sign this report they testify that the pilot understood the questions ,or it was explained by the doctor in a way that he could understand the questions. If it is asked e.g. Does the pilot have a psychological or psychiatric illness and quick answers like yes or no are possible, nobody will find out the answer of question 4.4 - alcohol dependency in the past 3 years. If the pilot is ok at the age of 17 nobody will ask him again until 45.This means the doctor who signed the fist LPL medical must give a prognosis of medical fitness for 28 years. But during this time the occurrence of many psychiatric disorders ,alcohol and drug dependency have its peak. Who will be accused, if the worst case will happen that a pilot with a bipolar disorder , unable to realize his situation, flying with a valid medical certificate , will have an accident with a commercial aircraft while violating a controlled airspace? - the medical doctor or the competent authority.</p> <p>2. The whole medical part of the LPL seems to be very problematic, far under ICAO standard. Concerning the traffic jammed airspace in middle Europe it the LPL chapter is jeopardizing the air safety.</p> <p><b>Proposal:</b></p> <p>1. For LPL medical standard the same standard as class 2 medical standard shall be recommended.</p> <p>2. If the proposal will not be respected by EASA and the LPL medical requirements will be implemented as it is now, the medical societies will give advice to their doctors to refuse the collaboration as the responsibility cannot be accepted.</p>
response	Noted
	See response to comment No 248 of this segment.

comment	1085	comment by: <i>Roger Anderson</i>
	<p>Leisure Pilot's Medical Report</p> <p>As a result of my personal experiences of obtaining a GP's countersignature to a National Pilot's License medical declaration I am concerned that it will not be feasible to persuade the average GP to conduct the very comprehensive medical that is proposed under NPA 2008-17c. The countersignature for a NPPL medical declaration does not mandate a medical examination and the GP is at liberty to countersign the declaration on the basis of his/her knowledge of the applicant's general health. When I asked my GP for a countersignature she was clearly not pleased at having to take time to facilitate what she considered to be a frivolous hobby, and would almost certainly not entertain carrying out an extensive report for such a purpose.</p> <p>I am also concerned that even if one is fortunate enough to have a GP who is prepared to undertake such a report they will be concerned about the liability aspect of putting their signature to such a report.</p> <p>In order to cover the liability aspect they will no doubt insist on subsidiary reports to protect their position. This will lead to an inordinate expense for even a perfectly healthy pilot and will prevent many pilots from continuing to fly.</p> <p>My personal experience is that although my GP had been content to add her countersignature to my annual declaration (I am over 60) for three years she refused to do so this year when the practice manager pointed out the possible liability aspect.</p> <p>My declaration has now been countersigned but only after I obtained a specialist's report that cost me nearly £1,500.00p.</p> <p>My personal opinion is that the requirements of the proposed LPL medical are disproportionate to the concept of a leisure pilot and that the British national system is more than adequate to meet all reasonable safety requirements.</p>	
response	<i>Noted</i>	
	See responses to the comments No 248 and 33 of this segment.	
	1087	comment by: <i>Robert Corbin</i>
	<p>The questionnaire contained in this section is very detailed and is intended to provide evidence to the aviation authority. From the perspective of a Medical certificate for a LPL(S) sailplane pilot in the UK this is a significant change as at present a signed certificate to a standard that is equivalent to UK Driving group 2 (professional driving) is all that is required.</p> <p>As the General Medical Practitioner is expected to have competence in aero medical examination (MED.D.001) the questionnaire in this section should be recommendations and not requirements. The GMP shall only be required to retain such evidence he deems necessary for the issuance of a Medical certificate.</p> <p>The questionnaire also implies a need for an electrocardiogram. That and other tests will add to the burden that a GMP has and so it will increase costs to</p>	

	<p>sporting aviators.</p> <p>In the UK there are very few accidents which are medically related and none in 2007 (BGA accident statistics). Even for those accidents that are due to medical factors the risk to third parties is negligible. The balance of risk mitigation through a thorough medical examination is disproportionate. The existing arrangements in the UK are more than adequate and do not require all the bureaucratic form filling proposed here.</p> <p><b>Propose</b> That the requirement for the report for LPL(S) should be dropped.</p>	
response	Noted	
	See response to comment No 248 of this segment.	
comment	1089	comment by: Richard WHITAKER
	<p>AMC to MED.A.040</p> <p>The proposed medical form for sporting pilots is very complex and onerous and will result in the imposition of yet another unnecessary expense. A simpler form should be introduced in line with current UK NPPL or US Sport Pilots Licence. The primary evidence should be reference to medical records; an examination would be needed if records for, say, 3 years were not available. If this were the case, why not use the EASA Class 2 form which is proven and well known already.</p>	
response	Noted	
	See response to comment No 248 of this segment.	
comment	1107	comment by: George Knight
	<p>There are drafting errors in this Medical Report form. No section 7 - although referenced in section 6. The "NO goto" text is missing the reference in many cases.</p>	
response	Noted	
	See response to comment No 248 of this segment.	
comment	1108	comment by: George Knight
	<p>This form is overly complex and will result in GMPs charging as much, if not more, for an LPL medical than AMEs for Class 2 medicals. It is also several pages longer than the existing JAA Class 2 medical form in use by AMEs in the UK today.</p> <p><b>SUGGESTION</b> Simplify and remove guidance material.</p>	
response	Noted	
	See response to comment No 248 of this segment.	

comment	1124	comment by: <i>Pete STARTUP</i>
	<p>With respect to the issue of a valid medical certificate to obtain a LPL(S) or SPL, the current proposals are overly excessive for what is required. A routine examination of the applicants medical records and maybe a basic physical examination would suffice. This can be carried out quite competently by my GMP. The cost of this has been about UK£20 in the past. The recommended fee for the required examination and completion of the documentation by an AME is an excessive UK£169! This cannot be justified for non-commercial sport aviation and needs urgent reviewing. Additionally, the medical declaration form requires an excessive medical history search to enable completion when a more suitable for purpose certificate would be a simple declaration by the GMP having carried out the necessary checks, that there are no medical reasons to his knowledge that he could establish as to why the applicant cannot be considered fit to pilot a sailplane for non-profit sport aviation purposes. Please review the medical examination standards required, the validity of a GMP to be acceptable to do this and not an AME, and at a cost in line with the purpose of the certificate. Please review urgently before proceeding with the NPA.</p>	
response	<i>Noted</i>	
	<p>See response to comment No 248 of this segment.</p> <p>Please note that the SPL is an ICAO compliant licence and an ICAO compliant class 2 medical certificate is needed.</p>	
comment	1135	comment by: <i>jim white</i>
	<p>I think that this approach is too prescriptive and that it is sufficient that the pilot meets the medical standard for driving as well understood by all GPs.</p> <p>The questionnaire here will be costly to implement and unnecessarily complicated for the LPL or SPL rating.</p> <p>However, the following comments are made:</p> <p>Alcohol. Weekly consumption levels may be predictors of disease but are not evidence of it nor evidence that the pilot is able to fly safely whilst not under the influence of alcohol, or not. Nor does the amount of alcohol consumed each week say much about the pattern of drinking or the pilots attitudes and responsibility.</p> <p>An electrocardiogram has limited predictive utility and is disproportionately expensive and complicated for this class of licence.</p>	
response	<i>Noted</i>	
	<p>See response to comment No 248 of this segment.</p>	
comment	1154	comment by: <i>Keith WHITE</i>
	<p><b>Add LPL(S) and SPL</b></p>	
response	<i>Noted</i>	
	<p>Requirements for LAPL are applicable to all LAPL applicants including LAPL(S). Applicants for SPL have to meet Class 2 requirements.</p>	

comment	1155	comment by: Keith WHITE
	Pilot's name, address, and age should be mandatory. In the UK there is no identity number. Telephone numbers and e-mail addresses should be marked as <b>optional entries</b> . In the box of 'Instructions', add <b>LPL(S) and SPL</b> .	
response	Noted	
	See response to comment No 248 of this segment.	
	Requirements for LAPL are applicable to all LAPL applicants including LAPL(S). Applicants for SPL have to meet Class 2 requirements.	
comment	1156	comment by: Keith WHITE
	6 Nervous system. Seems muddled and repetitive.	
response	Noted	
	See response to comment No 248 of this segment.	
comment	1157	comment by: Keith WHITE
	15. Should probably read '... has <b>not been</b> addressed ...'	
response	Noted	
	See response to comment No 248 of this segment.	
comment	1158	comment by: Keith WHITE
	<b>Delete 16.3.</b>	
response	Noted	
	Urine testing for glucose is important for aeromedical decision making.	
	See also response to comment No 248 of this segment.	
comment	1159	comment by: Keith WHITE
	<b>Delete repetition of '... previously ...' and '... denied ...'.</b>	
response	Noted	
	See response to comment No 248 of this segment.	
comment	1168	comment by: D.Hahn, class I AME
	again there seem to be no rules for the minimal extent of physical examination nor for the minimal methods and equipment of the GP to be applied. Should he be able to use ECG, oxygensaturation, bloodtesting, Röntgen or is all that not needed at all ? In the text it is just said "this just requires some physical examination ".	

	Is that enough to rule out dangerous organical malfunction-caused situations e.g. after two hours of circling in the heat of a summerday together with 15 other gliders in a thermic some 15 or 20 meters apart from each other ?	
response	<i>Noted</i>	
	See response to comment No 248 of this segment.	
comment	1169	comment by: <i>D.Hahn, class I AME</i>
	no rules for the minimal extent of physical examination nor equipment and methods to be applied seem to exist for the aeromedical GP. ECG, ophthalmologic equipment, Audiometer, bloodtesting Roentgenthorax all not necessary for daily aeronautical decisionmaking? regarding physical examination it is just said that "this report requires some physical examination". Is that enough to rule out hidden organical malfunction causing dangerous situations e.g. after two hours of circling in the summerheat together with 15 other competing gliders in the same thermic some 20 or 30 meters apart from each other, as it usually occurs around many german airfields.	
response	<i>Noted</i>	
	See response to comment No 248 of this segment.	
comment	1170	comment by: <i>D.Hahn, class I AME</i>
	Question 5.1 and 5.2 are not sufficient to rule out 1. deficiencies in the ability to estimate distances, very important for every pilot. 2. absence of visus of less then 1.0 on one or both eyes. 3. perimetric defects of visionfield	
response	<i>Noted</i>	
	See response to comment No 248 of this segment.	
comment	1171	comment by: <i>D.Hahn, class I AME</i>
	regarding 6 or 14 more important than question after Nephrolithiasis seem questions to rule out sleepapnea, causing tiredness at daytime. 1.have there been complaints of others about you snoring. 2.often tired in the morning or at daytime despite sufficient sleeping time ? 3.frequent headache, sleepiness or fall asleep during watching television ?  regarding 14 O2- Saturation 98% or below? over 15 cigarettes/day or more than 20 pack-years ?	
response	<i>Noted</i>	
	See response to comment No 248 of this segment.	
comment	1180	comment by: <i>FAI</i>

(CIMP)  
Page 23 of 66

The form of application for the LPL medical certificate in 17c (3) is extraordinarily complex and unrelated to any other in aero-medical use. To demand of experienced pilots that they have to demonstrate their ability to row a boat and use a corkscrew with either hand will expose EASA to international ridicule. The difference between an LPL medical certificate and a Class 2 or higher should lie in simpler procedures and greater ability to apply mitigating limitations as well as fitness levels. All medical certification can have a similar first page to be completed by the applicant and to copy the existing French Class 2 (14) would serve this purpose well.

**CIMP CONCLUSION**  
-All medical certification should have a similar first page to be completed by the applicant prior to any examination or endorsement. A copy of the existing French Class 2 (14) would serve this purpose well.

References:  
3. EASA NPA 2008-17c Part-Medical  
14. Conseil Médicale de l'Aéronautique Civile, 93 Boulevard Montparnasse, 75006 PARIS

response

*Noted*

See response to comment No 248 of this segment.

comment

1181 comment by: FAI

[Attachment #20](#)

(CIMP)  
Page 23 of 66

Alcohol abuse is a difficult problem to manage in aviation but is unlikely to be resolved by simply asking the applicant the number of units consumed. The term 'unit' is unscientific and is not a constant measure (16). In the UK it is 8gms ethanol but 9.9gms in the Netherlands; 10gms in Hungary; Ireland and Spain; 11gms in Finland, 12gms in Denmark, France and Italy; 14gms in Portugal. It is bad psychology to start the medical history with this question because it may initiate evasive responses. Finally there is no scientific evidence to support the figures cited, they were mere recommendations and are subject to criticism.

**CIMP CONCLUSION**  
-Questions to applicants concerning ethanol consumption require great medical skill if the truth is to be exposed and any limits specified must use scientific definitions.

Reference:  
16. International Centre for Alcohol Policies. [www.icap.org/](http://www.icap.org/) Home>Policy Issues>drinking guidelines>Standard Units Table.

response

*Noted*

See response to comment No 248 of this segment.

comment	1184	comment by: <i>Ray Partridge</i>
	This is far too complex. Like the EASA Certificate of Airworthiness requirements, the focus is on documentation. Last year the CoA process took much longer than previously and all the energy goes on completing forms so that the physical examination almost becomes secondary. Please do not lose sight of the fact that you are making proposals which relate to sport aviation. Adopt the BGA proposals.	
response	<i>Noted</i>	
	See response to comment No 248 of this segment.	

comment	1238	comment by: <i>Swedish Transport Agency, Civil Aviation Department (Transportstyrelsen, Luftfartsavdelningen)</i>
	<p><b>Comment:</b></p> <p>It is not appropriate to have the examination form for LPL included in an AMC to MED.A., whereas the examination forms for class 1 and class 2 are not included in an AMC but might be part of the GM.</p> <p><u>The proposed examination report form is totally inadequate.</u></p> <p>Generally, there is an unacceptable bad handling of the English language resulting in numerous ambiguities which should not appear in a regulatory text/document.</p> <p>The examination report form focuses only on previous medical history, not on the present medical status, which is inappropriate.</p> <p>Some <u>examples</u> of additional inappropriate text:</p> <p>In several sections of the questionnaire, for example regarding the nervous system, the doctor is instructed to carry on to the next section if the <u>first</u> question ('Does the pilot have a history of problems with the nervous system?') is answered with a "No". This is not adequate, because to be able to answer the first question the doctor first has to go through <u>every</u> question of that section as the applicant can not be expected to have sufficient medical knowledge to exclude any condition possible. One example is question 6.2, which is very specific and must be asked as it is written.</p> <p>This comment is relevant to most sections and not only for neurology, since the examiner is presumed to be a GMP of any single speciality and also cannot be expected to have good knowledge of all specialist areas.</p> <p>The first question of each section could possibly be used at the end of the section as a summary of the information gained concerning that section.</p> <p>3.2 is inappropriate, because the important issue is the assessment of possible abuse and/or dependency and not the amount of alcohol ingested.</p> <p>3.3 is inappropriate, as a correct answer requires the examining GMP to have a thorough knowledge of oncology which is seldom the case.</p> <p>In 4.3 - 4.6 it is inappropriate to have specified time limits because a</p>	

dependency or abuse should always require additional investigation; the questions should be asked if the applicant ever had ...

To include 'is the pilot known to have' in the questions 8.5 and 10.1 will imply that the examining GMP will always give the (possibly incorrect) answer 'NO', unless the GMP requests all previous medical files of the applicant or performs an ultrasound examination of the applicant. This type of questions is inappropriate in a regulatory text /document.

The initial question of section 13 is another example of an inappropriate question: if the applicant never had a resting electrocardiogram performed, the answer will always be 'NO'. This does not exclude the fact that the applicant might have several of the following ECG abnormalities, if being examined. To give an appropriate answer to the question, an ECG recording will be an absolute necessity.

The text of 13.1 is totally confusing and impossible to interpret.

The binding Implementing Rule MED.B.090 requires an examination of the musculoskeletal system to be performed. However, there is no corresponding requirement in the AMC to MED.B.090. According to Examination Part B of the examination report form, including the questions 17.4 - 17.8 on the musculoskeletal system, the doctor will only need to examine the pilot if uncertain of the answer. This is not according to the IR and has to be revised.

**Proposal:**

If there should be any separate examination report form at all for a LPL medical certificate, the proposed form must be totally revised by an independent group of competent experts in aviation medicine and general medicine with thorough knowledge of aeromedical risk assessment.

response

*Noted*

See response to comment No 248 of this segment.

comment

1299

comment by: *David Chapman*

Consideration should be given to making the form much much much easier for the GMP to process. This form will be used 10,000's of times, but any one GMP may only see the form once or twice. There will be considerable expense to pilots and the medical profession. the form is fully out of proportion to the task at hand.

It is too long and too confusing, the form should have a summary section with a few basic questions, and as long as those are answered "no" then probably no need for a physical examination. Remember the GMP will have thier own records to hand. In most cases pilots have no significant medical history, so why does a GMP have to read 100's of detailed questions. So 10 or 15 basic subject questions should be enough? All subsidiary questions should be in an appendix section.

Most important - if a GMP knowing the pilots medical history is available, then this is the safest and most appropriate route to medical certification for all GA. The key to be sure it is the pilots normal GMP, and that the GMP is guided to confirm what medical fitness level is required. Fitness for GA is not far different to driving a car, and, like cars, gliders can be adapted to cope with

less abled persons.

If the GMP is led to medical areas that may be marginal or not clear cut, the GMP should be advised to refer the pilot of a AME, and consult with the AME in an appropriate way.

All of the above will involve changes borne by the pilot, even in the UK, so again the complexity must be appropriate to the sailplane aviation sector.

Some details below, but remain focused on the above, !!!!!!!!!!!

in the long form, section 7 seems to be missing,...

Also some formatting problems recur several times, e.g. ....

13 Cardiac Investigations  
 Has the pilot had an abnormal resting electrocardiogram?  
 Yes If Yes refer to further details below No If No go to section 14,

but in PDF document it reads, ..

13 Cardiac Investigations  
 Has the pilot had an abnormal resting electrocardiogram?  
 Yes If Yes refer to further details below No If No go to section **1**

5 Vision  
 Does the pilot:  
 5.1 experience diplopia?  
 5.2 have any other significant ophthalmic condition?

What is significant? - make it clear that glasses to correct normal near/far sightedness is okay. A simple eye test/report is covered later.

response

*Noted*

See response to comment No 248 of this segment.

comment

1320	comment by: <i>Vincent EARL</i>
This form is not simple or easy to use as promised in the preamble of 216/2008 to achieve simple measures for non commercial activities.  It must be simplified along the lines of already effective measures being used in America (Sport Pilot Licence) and the UK (NPPL).	

response

*Noted*

See response to comment No 248 of this segment.

comment

1412	comment by: <i>Prutech Innovation Services Ltd.</i>
<b>AMC to MED.A.040-"Instructions for completion of this report":</b> The automatic requirement to refer answers to shaded questions to an AME or AeMC is excessive and totally patronising to GMPs. It should be obvious that GMPs are highly motivated professionals dealing with life and death situations daily and who are very experienced at judging when something is outside their	

area of competence. Many (or almost all?) of the shaded areas could very confidently be adjudicated on by a GMP in the vast majority of cases and they will know when to refer a specific candidate onwards to an AME, an AeMC or for another medical specialist's opinion.

Just a few examples at random from one area where the GMP could easily make its own decision and make direct referrals for opinions to (non-aero) medical expertise are 3.3, 3.8 and 3.9. Referral to an AME or AeMC should be limited to the few cases where the GMP is satisfied it needs this specialist aeromedical expertise i.e. far, far fewer cases than the shaded boxes.. What is therefore needed is only the production (by EASA) of a short booklet containing a clear set of guidelines for direct decision-making by the GMP, including a listing of those very few cases where referral to AME/AeMC is absolutely essential.

This is an essential change of approach, which has very significant implications for the cost to participants (financial, administrative and time/convenience) of European leisure flying. It therefore has corresponding implications for the success of EASA's and the European Community's objectives of growing European GA to match its potential and to match the levels that exist in North America. EASA must not water down the role of the GMP to appease any sector, as the use of GMPs at a much higher level of responsibility in leisure aviation certification is already well proven.

response *Noted*

See response to comment No 248 of this segment.

comment

1413

comment by: *Prutech Innovation Services Ltd.*

AMC to MED.A.040 final section in box "If all the questions ... for further evaluation." The second sentence, when taken in conjunction with the list of shaded questions, makes a mockery of the role of the GMP. As suggested strongly above, this whole section should be revised, recognising the wide expertise and professionalism of GMPs and their ability to judge for themselves when AME experience is essential (as opposed to non-aero specialist medical expertise that they can contact for themselves). The role of the GMP at a considerably higher level of responsibility has already been proven in several countries and this cannot and should not be swept under the carpet. A genuine risk-based analysis, taking account of past experience, would inevitably lead to such a leading role for the GMP.

response *Noted*

See response to comment No 248 of this segment.

comment

1451

comment by: *Michel KOSSOWSKI*

AMC to MED.A.040: in the report, ENT is not mentionned!!!  
At least must be mentionned :have you an history of vertigo or diziness?, have you an history of deafness or of ear pathology?, Have you an history of ent surgery? , Have you an history of cranial trauma?

response *Noted*

See response to comment No 248 of this segment.

The amended requirements for LAPL will include a section for ENT.

comment 1471 comment by: Trevor Wilcock

AMC to MED.A.040: this lengthy form is more comprehensive than that used by my AME for my JAA Class 2 medical! This is totally inappropriate for an LPL. Also some statements are absurdly incorrect. For example 17.6 "The upper limb strength.....required to fly an aircraft is similar to that required to row a boat". - not in any powered aircraft or glider that I fly! I fully support the proposals from the BGA.

response Noted

See response to comment No 248 of this segment.

comment 1566 comment by: Steve BARBER

The process for issuing a medical certificate in respect of an LPL is far too complicated. There is a stated aim to keep the rules for LPL as simple as possible; the proposed process and form clearly fails to meet that objective. It has been proved by many years of the British Gliding Association's experience, the experience in other countries, and the acceptance in some EU member states that self-certification is appropriate, that a medical standard similar to drivers' licences is satisfactory. There is no need to make it any more complex.

response Noted

See response to comment No 248 of this segment.

comment 1618 comment by: Ulster Gliding Club

This seven page report form is much too complex for SPL purposes.

A form similar to that used by the New Zealand Gliding Association should be adopted by EASA. See 'Medical Certificate & Declaration' at <http://www.gliding.co.nz/moap> which gives a link to [www.gliding.co.nz/sites/gliding.co.nz/downloads/MOAP/Forms/OPS/OPS%201.pdf](http://www.gliding.co.nz/sites/gliding.co.nz/downloads/MOAP/Forms/OPS/OPS%201.pdf)

A general medical practitioner (GMP) in the UK will charge from £10 to £15 for completing a New Zealand type report, but around £170 for the lengthy report set out in pp 23-29 of NPA 17c.

27 of the Ulster Gliding Club's members are over 60, and will require a medical certificate every two years. Most of them are retired, and have reduced incomes by way of pension. £85 pa would be a heavy increase in their fixed costs. For most of the nine members over 70, it would represent a 55 per cent increase in those costs, since they enjoy a reduced club membership fee of £150. With gliding becoming increasingly expensive, an increase of that order might cause some older members in clubs such as ours to resign.

response Noted

See response to comment No 248 of this segment.

comment	1646	comment by: <i>Medical Officer BBAC</i>
	Question 5.1 is included in 5.2 and should be combined.	
response	<i>Noted</i>	
	See response to comment No 248 of this segment.	
comment	1647	comment by: <i>Medical Officer BBAC</i>
	There is no section 8. Section 9 Cardiac arrhythmia repeats question 13 on ecg.	
response	<i>Noted</i>	
	See response to comment No 248 of this segment.	
comment	1648	comment by: <i>Medical Officer BBAC</i>
	Question 10, 12 and 14 are overtly complex and could be combined into an overarching question answered by the pilot at the beginning (as with the JAR-FCL) such as - Have you undergone any significant investigations, received treatment or are receiving treatment for any cardiac, respiratory or vasculature condition.	
response	<i>Noted</i>	
	See response to comment No 248 of this segment.	
comment	1663	comment by: <i>Deutscher Aero Club (DAeC)</i>
	<p>Comment:</p> <p>In their comments the BGA proposes a list of possible limitations and associated codes coming from JAR-FCL 3. These are satisfactory and cover all possible contingencies. However they do not apply to all medical certificates and should be in a general section. Limitations provide the tool by which mitigating measures described in 216/2008 are implemented. Rules and guidance are also needed on the application of these limitations.</p> <p>DAeC Proposal:</p> <p>DAeC supports the limitations and associated codes proposed by the BGA</p>	
response	<i>Noted</i>	
	See response to comment No 100 of this segment.	
comment	1664	comment by: <i>Deutscher Aero Club (DAeC)</i>
	<p>Comment:</p> <p>This lengthy report form for the LPL does not meet the requirement in the preamble of 216/2008 to achieve simple measures for non commercial activities. The medical form proposed for the LPL is complicated in the extreme.</p> <p>The DAeC is very concerned that the complexity and thereby potential cost of the process for an applicant to obtain medical clearance through a GMP will create a significant barrier to entry to the sport of gliding for young people, and indeed a barrier to older, retired people on lower incomes to continue in</p>	

gliding, where the periodicity of medical renewal decreases with age. DAeC see a risk, that the acceptance of the LPL medical is decreased due to high level of complexity and the acceptance by applicants and practitioners is diminished .  
DAeC Proposals:  
1. That the proposed LPL form be simplified and permits either validation by reference to records or by a physical examination.  
2. That when records are not available and a physical examination is required, the EASA Class 2 form is used.  
3. That separate guidance material is prepared.

response *Noted*

See response to comment No 248 of this segment.

comment

1691

comment by: UK CAA MEDICAL ADVISORY PANEL

**Paragraph** AMC to MED.A.040 8  
**Page** 25

**Comment**

Replace *had* with *suffered*....coronary

**Justification**

Preferred usage

**Proposed Text**

Replace *had* with *suffered*....coronary

response *Noted*

See response to comment No 248 of this segment.

comment

1692

comment by: UK CAA MEDICAL ADVISORY PANEL

**Paragraph** AMC to MED.A.040 11.4  
**Page** 26

**Comment**

Delete *significant*... insert ....*within the certificatory interval*

**Justification**

Any symptom in this context is not acceptable ..... better usage

**Proposed Text**

Delete *significant*... insert ....*within the certificatory interval*

response *Noted*

See response to comment No 248 of this segment.

comment

1709

comment by: Deutscher Aero Club

Section 2 Issuance, revalidation and renewal of medical certificates.  
On occasions licences may need to be restricted. Examples of restrictions are the prohibition of passenger carriage, or in the case of a disabled pilot, a restriction to a demonstrated aircraft type with approved modifications  
Comment:  
In their comments the BGA proposes a list of possible limitations and associated codes coming from JAR-FCL 3. These are satisfactory and cover all possible contingencies. However they do apply to all medical certificates and

	<p>should be in a general section. Limitations provide the tool by which mitigating measures described in 216/2008 are implemented. Rules and guidance are also needed on the application of these limitations.                  EGU Proposal:                  The EGU supports the limitations and associated codes proposed by the BGA</p>
response	<p><i>Noted</i></p>
	<p>See response to comment No 100 of this segment.</p>

comment	<p>1710</p>	<p>comment by: <i>Deutscher Aero Club</i></p>
	<p>AMC to MED.A.040                  Requirements for the issue, revalidation and renewal of medical certificates -                  Limitations to LPL medical certificates                  LPL medical certificates should be issued following examination in accordance with the following report:                  Page 23/66                  This report consists of questions that have 'yes' or 'no' answers that are indicated by ticking boxes. If all ticks are in clear boxes the medical certificate can be issued immediately by the doctor undertaking this examination. If any of the ticks are in a shaded box the medical report should be referred to an AME or AeMC for further assessment.                  Comment:                  This lengthy report form for the LPL does not meet the requirement in the preamble of 216/2008 to achieve simple measures for non commercial activities. The medical form proposed for the LPL is complicated in the extreme. Our suggestion is that it could benefit from reviewing the experiences of Road Transport Authorities in Europe who require a similar standard as that required for the LPL. It should make use of the universally available individual national/public health records. It should also not attempt to incorporate the actual standards into the form.                   The EGU is very concerned that the complexity and thereby potential cost of the process for an applicant to obtain medical clearance through a GMP will create a significant barrier to entry to the sport of gliding for young people, and indeed a barrier to older, retired people on lower incomes to continue in gliding, where the periodicity of medical renewal decreases with age.                   EGU Proposals:                  1. That the proposed LPL form be simplified in a similar fashion to that used by the New Zealand Gliding Association and which permits either validation by reference to records or by a physical examination.                  2. That when records are not available and a physical examination is required, the EASA Class 2 form is used.                  3. That separate guidance material is prepared.                  References:                  GLIDING NEW ZEALAND INC. MEDICAL REQUIREMENTS.  <a href="http://www.gliding.co.nz/sites/gliding.co.nz/downloads/MOAP/MOAP/Forms/OPS/OPS%201.pdf">www.gliding.co.nz/sites/gliding.co.nz/downloads/MOAP/MOAP/Forms/OPS/OPS%201.pdf</a></p>	
response	<p><i>Noted</i></p>	
	<p>See response to comment No 248 of this segment.</p>	

comment	<p>1737</p>	<p>comment by: <i>DCA Malta</i></p>
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	AMC to MED.A.040 Delete The LPL should have Class 2 requirements
response	<i>Noted</i>
	See response to comment No 248 of this segment.
comment	1748 <span style="float: right;">comment by: <i>Ralph ERSKINE</i></span>
	<p>The proposed medical report form will entail substantial extra expense for glider pilots in the UK, especially pilots over 65, who will need a medical once every two years.</p> <p>The British Medical Association recommends British doctors to charge about GBP 170 for this type of report. The annual medical costs of pilots over 65 will therefore increase by at least GBP 85 each year, for no real gain in safety. The report form proposed by NPA 17 therefore represents a disproportionate approach.</p> <p>EASA should also allow a report on the lines adopted by the New Zealand Gliding Association. See-  <a href="http://www.gliding.co.nz/sites/gliding.co.nz/downloads/MOAP/Forms/OPS/OPS%201.pdf">www.gliding.co.nz/sites/gliding.co.nz/downloads/MOAP/Forms/OPS/OPS%201.pdf</a>.</p>
response	<i>Noted</i>
	See response to comment No 248 of this segment.
comment	1805 <span style="float: right;">comment by: <i>CAA Belgium</i></span>
	<p>Relevant Text: AMC to MED.A.040  LPL medical certificates should be issued following examination in accordance with the following report :</p> <p>Comment: The requirements for LPL medical certificates are unacceptable. They are so deteriorated that they lead to a marked decrease in aviation safety.</p> <p>8 The cardiological part of the questionnaire is amazing : a coronary disease is not a temporary illness ; why this time limitation in the anamnesis (six weeks – 3 months)?</p> <p>9 If a cardiac arrhythmia is present, the diagnosis should be specified.</p> <p>10.1 A thoracic or abdominal aortic aneurysm of 5 cm entails an inadmissible risk of dissection or rupture.</p> <p>Proposal: Specific medical requirements for LPL should be deleted and the same requirements as those of class 2 should be applied.</p>
response	<i>Noted</i>
	See response to comment No 248 of this segment.
comment	1833 <span style="float: right;">comment by: <i>CAA Belgium</i></span>
	<p>Comment: For a complete information about Psychiatric history of a pilot there are necessary also the 2 additional questions: 4.7, 4.8.</p> <p>Proposal:</p> <p>4.1significant psychiatric disorder within the past 6 months (no change)?</p>

	4.2 no change 4.3 no change 4.4 no change 4.5 no change 4.6 no change 4.7 does or did the pilot take any psychotropic medication? 4.8 significant psychiatric disorder which needed medical treatment?	
response	<i>Noted</i>	
	See response to comment No 248 of this segment.	
comment	1856	comment by: Alan Morton
	As I am now over sixty years of age and retired I do worry about the proposed requirement for a medical examination (as opposed to medical validation by my own GP from my patient records). This would surely cost me considerably more and, from what I have read in many aviation journals, would provide little or no improvement in safety terms.	
response	<i>Noted</i>	
	See response to comment No 248 of this segment.	
comment	1860	comment by: Dr Stephen Gibson
	re page 28 LPL medical report pilots declaration	
	The form Med A 040 needs a clause inserted to be signed by the applicant authorising the giving of ALL RELEVANT information if LPL certificate is based on GMP examination or review of medical records and pilot declaration without examination.	
response	<i>Noted</i>	
	See response to comment No 248 of this segment.	
comment	1861	comment by: Dr Stephen Gibson
	re LPL medical report. page22-28	
	This report format seems to be introducing standards that are somewhat different from those detailed in the "specific requirements for LPL medical certificates", AMC to Med B.090.	
	I suggest standards should be established and the process of showing these are met should then follow, not vice versa. The process should be consistent with the standards and for the LPL as simple and low cost as reasonably demonstrates that the standards have been met.	
response	<i>Noted</i>	
	See response to comment No 248 of this segment.	
comment	1863	comment by: Sally Woolrich

Examination parts A & B

As far as I am aware GPs are not usually equipped to examine sight, therefore I would also be having to visit my optician.

BMI - the average gliding club has a large number of pilots who are likely to have a BMI over 35, and so far as I am aware that has never cause a problem. Obviously the glider should be flown within it's correct CoG limits and weight limits, but so long as the pilot comfortably fits their glider I cannot see a problem.

Upper body strength. I have rowed boats and flown gliders and the strength needed to row is vastly more, as is the range of movement. In addition a great many GPs have probably never rowed a boat, so I cannot see how this is a useful comment to them. (on the other hand the strength required to rig a glider is considerable for the average woman)

response *Noted*

See response to comment No 248 of this segment.

Our information is that GPs can test vision (information from the UK and the Internet).

BMI over 35 is statistically related to medical conditions which are potentially dangerous for flight safety and an OPL limitation may have to be considered.

comment

1883

comment by: *Phil King*

The LPL medical report appears to be excessively long and complex. In comparison the medical reports required for the UK NPPL or the USA Sport Pilot Licence are much shorter and simpler. There would seem to be good reason to use one of these existing reports as a basis for the LPL instead of creating a new and apparently excessive form.

The instructions for completion of this report "require some physical examination". Whilst this may be necessary in specific circumstances, it may not be necessary where the doctor has access to the pilot's medical history and can complete the report without further examination. Requiring some physical examination will inevitably increase costs unnecessarily.

I support the BGA proposals that:

1. *That the proposed LPL form be simplified in a similar fashion to that used by the New Zealand Gliding Association and which permits either validation by **reference to records or by a physical examination.***
2. *That when records are not available and a physical examination is required, the EASA Class 2 form is used.*
3. *That separate guidance material is prepared.*
4. *That air sports associations nominate doctors to their Authority who comply with the requirements for AMEs especially in respect of having practical knowledge and experience of the air sport concerned. These can advise both GMPs and AMEs on difficult cases.*

response *Noted*

See response to comment No 248 of this segment.

comment	1896	comment by: <i>Belgian Gliding Federation</i>
<p><i>AMC to MED.A.040</i>  <i>Requirements for the issue, revalidation and renewal of medical certificates -</i>  <i>Limitations to LPL medical certificates</i>  <i>LPL medical certificates should be issued following examination in accordance</i>  <i>with the following report:</i>  <i>Page 23/66</i>  <i>This report consists of questions that have 'yes' or 'no' answers that are</i>  <i>indicated by ticking boxes. If all ticks are in clear boxes the medical certificate</i>  <i>can be issued immediately by the doctor undertaking this examination. If any of</i>  <i>the ticks are in a shaded box the medical report should be referred to an AME</i>  <i>or AeMC for further assessment.</i></p> <p>Comment:  This lengthy report form for the LPL does not meet the requirement in the preamble of 216/2008 to achieve simple measures for non commercial activities. The medical form proposed for the LPL is complicated in the extreme. Our suggestion is that it could benefit from reviewing the experiences of Road Transport Authorities in Europe who require a similar standard as that required for the LPL. It should make use of the universally available individual national/public health records. It should also not attempt to incorporate the actual standards into the form.</p> <p>The BGF is very concerned that the complexity and thereby potential cost of the process for an applicant to obtain medical clearance through a GMP will create a significant barrier to entry to the sport of gliding for young people, and indeed a barrier to older, retired people on lower incomes to continue in gliding, where the periodicity of medical renewal decreases with age.</p> <p><b><u>The BGF seconds the EGU Proposals:</u></b>  <b>1. That the proposed LPL form be simplified in a similar fashion to that used by the New Zealand Gliding Association and which permits either validation by reference to records or by a physical examination.</b>  <b>2. That when records are not available and a physical examination is required, the EASA Class 2 form is used.</b>  <b>3. That separate guidance material is prepared.</b></p> <p><i>References:</i>  <i>GLIDING NEW ZEALAND INC. MEDICAL REQUIREMENTS.</i>  <a href="http://www.gliding.co.nz/sites/gliding.co.nz/downloads/MOAP/MOAP/Forms/OPS/OPS%201.pdf">www.gliding.co.nz/sites/gliding.co.nz/downloads/MOAP/MOAP/Forms/OPS/OPS%201.pdf</a></p>		
response	<i>Noted</i>	
See response to comment No 248 of this segment.		
comment	1963	comment by: <i>Carol Smith</i>
<p>The added complexity of the proposed medical form will mean an increase in charges from the pilot's GMP to a level equivalent to using an AME. This defeats the whole object of using GMPs for issue of medicals. There appears to be no evidence that the current BGA or NPPL requirements, consisting of a single page form often signed by a GMP at no charge, are inadequate.</p>		
response	<i>Noted</i>	

See response to comment No 248 of this segment.

comment	1990	comment by: CAA Belgium
	<p>p.27</p> <p><b>Relevant Text:</b> 17.2 In a quiet room, can the pilot hear a whispered voice?</p> <p><b>Comment:</b> In this report, the ENT has to be more detailed.</p> <p><b>Proposal:</b> 15 or 17. .... Does the pilot have a history of:</p> <p>15.1 Impaired hearing or hearing loss Y N</p> <p>15.2 Eustachian tube dysfunction</p> <p>15.3 Suppurative or non suppurative disease of middle ear</p> <p>15.4 Middle ear surgery Tympanoplasty Stapedectomy</p> <p>15.5 Disease of inner ear Temporal bone fracture Acoustic trauma Perilymph fistula Menière disease Acoustic neuroma</p> <p>15.6 Infective labyrinthitis Y N</p> <p>15.7 Menière disease</p> <p>15.8 Head trauma</p> <p>15.9 Acute vestibular dysfunction</p> <p>15.10 Chronic vestibular hypofunction with episodic decompensation</p>	
response	<p><i>Noted</i></p> <p>See response to comment No 248 of this segment.</p> <p>The amended requirements for LAPL will include a section for ENT.</p>	
comment	2016	comment by: Lars Tjensvoll
	<p>remove the whole part MED.A:040.</p>	
response	<p><i>Noted</i></p> <p>See response to comment No 248 of this segment.</p>	

comment

2129

comment by: *Croft Brown*

Page 22 of 66

AMC to MED.A.040

Requirements for the issue, revalidation and renewal of medical certificates  
-Limitations to LPL medical certificates

LPL medical certificates should be issued following examination in accordance with the following report:

Page 23/66

This report consists of questions that have 'yes' or 'no' answers that are indicated by ticking boxes. If all ticks are in clear boxes the medical certificate can be issued immediately by the doctor undertaking this examination. If any of the ticks are in a shaded box the medical report should be referred to an AME or AeMC for further assessment.

Comment: This lengthy report form for the LPL does not meet the requirement in the preamble of 216/2008 to achieve simple measures for non commercial activities. The LPL compares quite unfavorably with the Sport Pilot Licence of the USA and the existing UK NPPL - both of which provide valuable working approaches. The medical form proposed for the LPL is complicated in the extreme. Our suggestion is that it could benefit from reviewing the experiences of Road Transport Authorities in Europe who require a similar standard as that required for the LPL. It should make use of the universally available individual national/public health records. It should also not attempt to incorporate the actual standards into the form.

It has been said that the basic regulation 216/2008 requires a physical examination for the LPL prior to certification by a GMP but this has not been identified in the text. There seems little usefulness in requiring applicants to demonstrate that they can extract a cork using a corkscrew with either hand! The cost difference of these approaches (ie: record examination vs. actual examination) to the applicant can be considerable; the British Medical Association web site suggests for members a charge of £15 for a validation from records but £169.50 for a report such as that required by EASA. Croft Brown endorses the BGA Proposals:

1. That the proposed LPL form be simplified in a similar fashion to that used by the New Zealand Gliding Association and which permits either validation by reference to records or by a physical examination.
2. That when records are not available and a physical examination is required, the EASA Class 2 form is used.
3. That separate guidance material is prepared.
4. That air sports associations nominate doctors to their Authority who comply with the requirements for AMEs especially in respect of having practical knowledge and experience of the air sport concerned. These can advise both GMPs and AMEs on difficult cases.

References:

1. Regulation (EC) No 216/2008 of the European Parliament and of the Council on common rules in the field of civil aviation...

Preamble (7-8)

2. United States House of Representatives; Committee on Transportation and Infrastructure. FAA Oversight of falsifications on airman medical certificate applications.

Released March 27, 2007.

3. BMA -Suggested fees for services that can only be provided by the patient's own GP.

[www.bma.org.uk/ap.nsf/Content/noagreement~onlybygp](http://www.bma.org.uk/ap.nsf/Content/noagreement~onlybygp)

4. International Centre for Alcohol Policies.

[www.icap.org/PolicyIssues/drinkingGuidelines/StandardUnitsTable/](http://www.icap.org/PolicyIssues/drinkingGuidelines/StandardUnitsTable/)

response	<p>5. GLIDING NEW ZEALAND INC. MEDICAL REQUIREMENTS.  <a href="http://www.gliding.co.nz/sites/gliding.co.nz/downloads/MOAP/MOAP/Forms/OPS/OPS%201.pdf">www.gliding.co.nz/sites/gliding.co.nz/downloads/MOAP/MOAP/Forms/OPS/OPS%201.pdf</a></p> <p><i>Noted</i></p> <p>See response to comment No 248 of this segment.</p>
comment	<p>2130 <span style="float: right;">comment by: <i>Croft Brown</i></span></p> <p>Page 23/66  Section 2 Issuance, revalidation and renewal of medical certificates.  On occasions licences may need to be restricted. Examples of restrictions are the prohibition of passenger carriage, or in the case of a disabled pilot, a restriction to a demonstrated aircraft type with approved modifications  Comment: A list of possible limitations and associated codes is to be found in JAR-FCL 3. These are satisfactory and cover all possible contingencies. However they do apply to all medical certificates and should be in a general section. Limitations provide the tool by which mitigating measures described in 216/2008 are implemented. Rules and guidance are also needed on the application of these limitations.  Proposals:  1. On a revalidation of a medical certificate, a previous limitation may be carried forward without question.  2. On initial issue of an LPL following denial of a Class 1 or medical certificate, a limitation is to be expected.  3. Any AME or GMP may impose any limitation.  4. Following evidence of recovery, a limitation may be rescinded.  5. Temporary and time limited limitations may be applied.  6. Guidance for limitations:  CODES with LIMITATIONS as set out in JAR-FCL 3.  TML VALID ONLY FOR ..... MONTHS  This limitation is applied when the applicant is suffering from a condition that may deteriorate prior to the next routine periodic review. It can also be used when the condition may improve when it is usually associated with another limitation, although there is nothing to prevent a pilot with a limitation from seeking a review at any date.  VDL SHALL WEAR CORRECTIVE LENSES  The applicant requires a refractive correction of vision in order to meet the prescribed standard. With this limitation it is also a requirement that a spare pair of spectacles is carried.  VNL SHALL HAVE AVAILABLE CORRECTIVE LENSES  The applicant has good distance vision but requires correction for certain close tasks such as map reading. It is the usual limitation for older pilots suffering presbyopia.  VCL FLIGHTS ONLY WITHIN FIRS OF A MEMBER STATE, VFR FLIGHTS BY DAY ONLY.  The applicant does not meet ICAO standards, usually in respect of the ability to discriminate colour. For an EASA licence, this would be within the Flight Information Regions of EASA member nations.  OML VALID ONLY AS OR WITH QUALIFIED CO-PILOT  This limitation is applied when there is a risk of incapacity that is greater than normal but not so high as to warrant grounding. It only applies to pilots flying aircraft certified for two pilot operation and would be unusual for non commercial pilots.  OCL VALID ONLY AS CO-PILOT</p>

A similar limitation to OML, but this limitation also precludes flying as aircraft captain.

**OSL VALID ONLY AS SAFETY PILOT AND IN AIRCRAFT WITH DUAL CONTROLS.**

A pilot with this limitation has few privileges over an unlicensed pilot and it is not an equivalent to the OML for private pilots. It can be applied as a temporary limitation while recovering from illness.

**OAL RESTRICTED TO A DEMONSTRATED AIRCRAFT TYPE**

This limitation is applicable to a pilot with an anthropometric or orthopaedic limitation that might make control difficult. Commonly pilots with a lower limb abnormality find the operation of the wheel brakes is difficult with some designs but not others. Pilots with such a limitation must seek flying instructor clearance and an entry in their flying log book for each type that is to be flown.

**OPL VALID ONLY WITHOUT PASSENGERS**

This limitation is applied when there is a risk of incapacity that is greater than normal but not so high as to warrant grounding. By excluding inexperienced passengers the major third party risk is removed, the ground risk being very remote following incapacity. Continued solo flight or flying with another pilot is permitted with this limitation. Unless there is evidence that the disqualifying disease has improved, this limitation should be applied to all LPL pilots who have been previously denied a Class 2. Elderly pilots can expect to be limited OPL as they age.

**APL VALID ONLY WITH APPROVED PROSTHESIS**

This limitation is to be applied to pilots with a prosthesis that could affect their ability to control an aircraft. It would commonly be combined with an OAL limitation.

**AHL VALID ONLY WITH APPROVED HAND CONTROLS**

This limitation is applied to paraplegic pilots or those with lower limb defects that prohibit normal rudder pedal control. In this case the aircraft has to be modified to meet the needs of that pilots and only aircraft so modified may be flown.

**AGL VALID ONLY WITH APPROVED EYE PROTECTION**

This limitation has been applied to monocular pilots flying open cockpit aircraft. However dust or debris can adversely affect both eyes and protective goggles are recommended for all pilots in these aircraft.

**SSL SPECIAL RESTRICTIONS AS SPECIFIED**

This limitation permits any restriction to be written in. These could be geographical, climatic or altitude limits. One useful application concerns suspected or minor psychiatric disease when a recreational pilot can be restricted to a named club where responsible officials have been informed, in confidence and with the consent of the applicant, of possible problems. Subsequent reports from these officials become a vital contribution to a sensible and fair medical decision.

**SIC SPECIAL INSTRUCTIONS - CONTACT AMS**

This does not affect the privileges of a licence but is a warning to an AME not to revalidate without consulting the AMS. This limitation might be applied in a case of past psychiatric disease or previous misdemeanour by the applicant.

**VAR VARIATION - ICAO ANNEX 1 PARA 1.2.4.8**

This does not affect the privileges of a licence but indicates that the provisions of ICAO are not met, although the pilot is considered fit. It is only applicable to ICAO compliant licences.

**AMS ISSUED BY AMS**

This does not affect the privileges of a licence but is a hint to an AME that there may have been some special consideration in the past.

response *Noted*

See response to comment No 100 of this segment.

comment 2143 comment by: AMS Denmark

LPL medical report is a questionnaire should never be taken in use for certification purposes. It gives no meaning to discuss with a doctor or any professional medical person a questionnaire of this sort and adds almost no extra to a selfdeclaration.

We suggest responsible testing identical with ICAO class 2 and including the same examination and periodicity

response Noted

See response to comment No 248 of this segment.

comment 2148 comment by: Tom GARDNER

This form is excessively complex for an LPL medical certificate.

Based on one experience with a GMP in the past, they may well take one look at such a form and refuse to even consider signing it. Reason? Nothing to do with my medical fitness, but because it would distract them from their primary medical duties!

It will be too expensive. My daughter could not afford the fees associated with having a GMP complete such a form

response Noted

See response to comment No 248 of this segment.

comment 2151 comment by: Tom GARDNER

The double/triple negatives could be misinterpreted

An X not including:

- a Y evaluated as not significant yes/no
- a Z evaluated as not significant yes/no

The "acceptable" answers should be made clearer

response Noted

See response to comment No 248 of this segment.

comment 2197 comment by: Tom GARDNER

The requirements for a sailplane medical should be stated in terms with which the GMP is already familiar - something equivalent to the UK's "is safe to drive a car" requirement.

response Noted

The medical requirements for the LAPL applicants also include LAPL(S). Applicants for a sailplane pilot licence (SPL) shall meet Class 2 medical requirements.

See also response to comment No 248 of this segment.

comment 2205 comment by: *Royal Netherlands Aeronautical Association*

LPL's Medical Report:

Questionnaire content:

This proposed questionnaire will take a lot of time to be filled in by the doctor in the presence of the pilot. Many questions are not relevant to the different classes.

Some questions do not reflect the content of the IR, AMC or GM for the specific class, e.g. the BMI, diplopia, lung transplant, pneumothorax.

There is no definition of a number of medical conditions, like heart failure, angina (pectoris?). What criteria are used?

If in any case of a ticked box, the applicant has to be referred to an AME or AMC. Very few applicants will have a complete blank questionnaire, so many LPL applicant have to be referred. In The Netherlands and other countries there are only a few AME's and AMC's, so the assessments will be impossible practically. The assessments will become very expensive and time spending. A solution for this problem can be: to authorize other medical doctors for the LPL, like qualified sport doctors and medical officers.

KNVvL PROPOSAL:

-The questionnaire can be filled in by the pilot prior to the assessment, in the same way as now in the JAR or ICAO or comparable systems.

-These questionnaires are proven to be complete, relevant and accurate, so the proposal is to copy one of these questionnaires.

-Authorisation of qualified sport medical doctors, medical officers and other doctors with relevant specialty, next to GMPs

response *Noted*

See response to comment No 248 of this segment.

comment 2206 comment by: *Royal Netherlands Aeronautical Association*

Regarding Alcohol

Alcohol abuse is a difficult problem to manage in aviation but is unlikely to be resolved by simply asking the applicant the number of units consumed. The term 'unit' is unscientific and is not a constant measure (16). In the UK it is 8gms ethanol but 9.9gms in the Netherlands; 10gms in Hungary; Ireland and Spain; 11gms in Finland, 12gms in Denmark, France and Italy; 14gms in Portugal. It is bad psychology to start the medical history with this question because it may initiate evasive responses. Finally there is no scientific evidence to support the figures cited, they were mere recommendations and are subject to criticism.

KNVvL PROPOSAL:

-Questions to applicants concerning ethanol consumption require great medical skill if the truth is to be exposed and any limits specified must use scientific definitions.

Reference:

International Centre for Alcohol Policies. [www.icap.org/](http://www.icap.org/) Home>Policy Issues>drinking guidelines>Standard Units Table.

response *Noted*

See response to comment No 248 of this segment.

comment 2210 comment by: Roger STARLING

AMC to MED.A.040

The suggested report is excessively complex for leisure flying such as gliding. It is totally disproportionate to the need. The existing requirements for a UK NPPL (validation from medical records) are sufficient.

response Noted

See response to comment No 248 of this segment.

comment 2237 comment by: Douglas Gardner

Completing the "Leisure Pilot's Licence Medical Report" form is far too complicated a procedure for medical certification for leisure activity such as gliding. It would be burdensome, inefficient and expensive because it does not utilise the applicant's available medical records and the existing Knowledge of his/her GMP. These are all that are required, together with the applicant's self-certification.

response Noted

See response to comment No 248 of this segment.

comment 2246 comment by: Andrew Sampson

This form appears excessively complex.

response Noted

See response to comment No 248 of this segment.

comment 2249 comment by: A.Garside

The detailed report required as opposed to a record check will increase the cost to the pilot greatly to the extent it could deter youngsters from starting to fly or older pilots from continuing to fly

response Noted

See response to comment No 248 of this segment.

comment 2256 comment by: Martyn Johnson

Page 22 of 66  
AMC to MED.A.040

This lengthy report form for the LPL does not meet the requirement in the preamble of 216/2008 to achieve simple measures for non commercial activities. The LPL compares quote unfavourably with the Sport Pilot Licence of the USA and the existing UK NPPL - both of which provide valuable working approaches. The medical form proposed for the LPL is complicated in the

extreme. Our suggestion is that it could benefit from reviewing the experiences of Road Transport Authorities in Europe who require a similar standard as that required for the LPL. It should make use of the universally available individual national/public health records. It should also not attempt to incorporate the actual standards into the form.

It has been said that the basic regulation 216/2008 requires a physical examination for the LPL prior to certification by a GMP but this has not been identified in the text. There seems little usefulness in requiring applicants to demonstrate that they can extract a cork using a corkscrew with either hand! The cost difference of these approaches (ie: record examination vs. actual examination) to the applicant can be considerable; the British Medical Association web site suggests for members a charge of £15 for a validation from records but £169.50 for a report such as that required by EASA.

I am very concerned that the complexity and thereby potential cost of the process for an applicant to obtain medical clearance through a GMP will create a significant barrier to entry to the sport of gliding for young people, and indeed a barrier to older, retired people on lower incomes to continue in gliding, where the periodicity of medical renewal decreases with age. As an example, the British Medical Association suggested charge of £169.50 for an examination rather than validation from medical records could constitute typically 15% to 30% on top of the total cost of a young applicant's course for learning to fly gliders to a licence level in a volunteer club environment.

A safe, cheaper and more practical way forward is:

1. That the proposed LPL form be simplified in a similar fashion to that used by the New Zealand Gliding Association and which permits either validation by reference to records or by a physical examination.
2. That when records are not available and a physical examination is required, the EASA Class 2 form is used.
3. That separate guidance material is prepared.
4. That air sports associations nominate doctors to their Authority who comply with the requirements for AMEs especially in respect of having practical knowledge and experience of the air sport concerned. These can advise both GMPs and AMEs on difficult cases.

response

*Noted*

See response to comment No 248 of this segment.

comment

2259

comment by: *Roger Hurley*

The proposed form to complete is far too complex, and will as a result be prohibitively expensive. The difference in cost between asking your GMP to review your medical fitness to fly, and asking him to fill in this form could easily be a factor of 10 times or more!

The "extra" information gleaned from the completed form, over a Doctor's simple review, says little or nothing concerning a pilot's fitness to fly.

response

*Noted*

See response to comment No 248 of this segment.

comment

2283

comment by: *Mike Armstrong*

Page 22 of 66 AMC to MED.A.040

As previously stated, a GMP review of patient medical records may be sufficient to allow a GMP to complete and sign the medical report without examination, assuming he has known the patient for several (3+?) years or has adequate medical records. These could include eye test reports from opticians who are better qualified than a GMP for eye examinations.

response *Noted*

See response to comment No 248 of this segment.

comment 2288 comment by: Dick Dixon

As I have already suggested, I believe that the medical requirements for glider pilots should be kept straightforward and inexpensive. The current arrangements in the UK qualify under this description and have proved to be perfectly adequate. By far the majority of glider pilots are participating in the sport as amateurs and as a hobby. We are not generally wealthy individuals, and it would be a tragedy if a large proportion of glider pilots were to be forced to give up the sport due to unnecessary and heavy handed regulation.

response *Noted*

See response to comment No 248 of this segment.

comment 2313 comment by: Mike Armstrong

P23 Medical Report

This is a very detailed report that will almost certainly incur the pilot in significant charges from a GMP, AME or AeMC. This is against the premise that LPL medical requirements shall be as simple and basic as possible, commensurate with flight safety.

Without being a medical specialist I can't make detailed proposals but a few general questions such as "Is there any evidence or history of unresolved heart, circulatory or respiratory conditions that could impair the patient's ability to fly the aircraft?" could be prepared. If, for example, the answer is "no" then a medical could be issued but if the answer is "yes" then the further questions in the currently proposed report could be introduced where relevant.

This should mean that the majority of medicals could be issued with nominal charge from the GMP, AME or AeMC. This would be appropriate for a sporting licence.

response *Noted*

See response to comment No 248 of this segment.

comment 2330 comment by: Tim FREEGARDE

AMC to MEDA040

This is an unnecessarily long and detailed form. EASA should consider instead the medical certificate adopted by the UK NPPL - which I believe to be based upon that for HGV drivers - in which the exhaustive lists are limited to

	accompanying documentation.	
response	<i>Noted</i>	
	See response to comment No 248 of this segment.	
comment	2350	comment by: <i>Graham Bishop</i>
	The form for LPL is too lengthy for purpose and does not match the intent of 216/2008 to achieve simple measures. Review of the Road Transport Authorities of Europe which are similar in standard to the LPL requirements is suggested.	
response	<i>Noted</i>	
	See response to comment No 248 of this segment.	
comment	2366	comment by: <i>Federal Ministry of Transport, Austria (BMVIT)</i>
	The report for the issuance of the LPL medical certificate seems to be fairly complex considering the stated intention that examinations of LPL pilots should be simple.	
response	<i>Noted</i>	
	See response to comment No 248 of this segment.	
comment	2425	comment by: <i>Frank birlison</i>
	I support the use of a GP (GMP in Euro speak) for ascertaining fitness to fly but suggest that the check list form for the GMP is too long and will cost almost as much as an AME medical	
response	<i>Noted</i>	
	See response to comment No 248 of this segment.	
comment	2430	comment by: <i>John HINCHLIFFE</i>
	In response to the consultation opportunity in respect of NPA 2008 17, I am writing to express my strong support for the arguments promulgated by EASA against making more onerous the medical certification requirements for LPL licence holders. As a UK NPPL holder I think the new proposals represent a disincentive to participating in EU GA by introducing proposals that are more difficult and more expensive to operate, with no evidence based justification in terms of increased air safety.	
response	<i>Noted</i>	
	See response to comment No 248 of this segment.	
comment	2438	comment by: <i>James Hunneman</i>
	If implemented without modification, these proposals would effectively stop cross-country glider flights in the UK, and likely greatly reduce the number of pilots already flying. Not to mention "putting off" potential new pilots. The pilot	

medical costs alone would greatly increase the average pilot's yearly expenditure - for no proven increase in safety.  
Surely new regulations should only be implemented if they are likely to improve safety, or reduce complexity / confusion for pilots looking to fly in other member states. They should not effectively stop what is a safe and rewarding sport for many.

[comment is also copied to NPA 2008-17a - para 48 p. 29]

response *Noted*

See response to comment No 248 of this segment.

comment

2463

comment by: *Paul Mc G*

Requirements for the issue, revalidation and renewal of medical certificates  
Limitations to LPL medical certificates

This report consists of questions that have 'yes' or 'no' answers that are indicated by ticking boxes. If all ticks are in clear boxes the medical certificate can be issued immediately by the doctor undertaking this examination. If any of the ticks are in a shaded box the medical report should be referred to an AME or AeMC for further assessment.

This reads like a university computer marked assessment. It will be possible for someone to have a problem which produces a tick in the box and yet on examination the problem can prove to be irrelevant. Unfortunately this plan will result in continuous unnecessary referral!

This lengthy report form for the LPL does not meet the requirement in the preamble of 216/2008 to achieve simple measures for non commercial activities. The LPL compares quote unfavourably with the Sport Pilot Licence of the USA and the existing UK NPPL - both of which provide valuable working approaches. The Road Transport Authorities in Europe require a similar standard to that required for the LPL. It should make use of the universally available individual national/public health records. It has been said that the basic regulation 216/2008 requires a physical examination for the LPL prior to certification by a GMP but this has not been identified in the text.

The cost difference of these approaches (ie: record examination vs. actual examination) to the applicant can be considerable; the British Medical Association web site suggests for members a charge of £15 for a validation from records but £169.50 for a report such as that required by EASA.

The BGA is very concerned that the complexity and thereby potential cost of the process for an applicant to obtain medical clearance through a GMP will create a significant barrier to entry to the sport of gliding for young people, and indeed a barrier to older retired people on lower incomes to continue in gliding, where the periodicity of medical renewal decreases with age. As an example, the British Medical Association suggested charge of £169.50 for an examination rather than validation from medical records could constitute typically 15% to 30% on top of the total cost of a young applicant's course for learning to fly gliders to a licence level in a volunteer club environment.

The BGA Proposals are not bad??

1. The proposed LPL form should be simplified in a similar fashion to that used

by the New Zealand Gliding Association and which permits validation by reference to records.  
 2. When records are not available and a physical examination is required, the EASA Class 2 form is used.  
 3. Separate guidance material is prepared. BUT what does this entail?  
 4. Air sports associations nominate doctors to their Authority who comply with the requirements for AMEs especially in respect of having practical knowledge and experience of the air sport concerned. These can advise both GMPs and AMEs on difficult cases.

response

*Noted*

See response to comment No 248 of this segment.

comment

2464

comment by: *Paul Mc G*

On occasions licences may need to be restricted. Examples of restrictions are the prohibition of passenger carriage, or in the case of a disabled pilot, a restriction to a demonstrated aircraft type with approved modifications.

A list of possible limitations and associated codes is to be found in JAR-FCL 3. These seem satisfactory and seem to cover all possible contingencies. However they do apply to all medical certificates and should be in a general section. Limitations provide the tool by which mitigating measures described in 216/2008 are implemented. Rules and guidance are also needed on the application of these limitations.

Perhaps,

1. On a revalidation of a medical certificate, a previous limitation may be carried forward without question.
2. On initial issue of an LPL following denial of a Class 1 or medical certificate, a limitation is to be expected.
3. Any AME or GMP may impose any limitation.
4. Following evidence of recovery, a limitation may be rescinded.
5. Temporary and time limited limitations may be applied.
6. Guidance for limitations: BUT these could be a problem as some cases are very non standard!!!

Codes with limitations as set out in JAR-FCL 3.

TML VALID ONLY FOR ..... MONTHS

This limitation is applied when the applicant is suffering from a condition that may deteriorate prior to the next routine periodic review. It can also be used when the condition may improve when it is usually associated with another limitation, although there is nothing to prevent a pilot with a limitation from seeking a review at any date. This is reasonable

VDL shall wear corrective lenses

The applicant requires a refractive correction of vision in order to meet the prescribed standard. With this limitation it is also a requirement that a spare pair of spectacles is carried. Perhaps a magnifying glass might also be considered?

VNL shall have available corrective lenses

The applicant has good distance vision but requires correction for certain close tasks such as map reading. It is the usual limitation for older pilots suffering presbyopia. Will this also require the carrying of two pairs of spectacles or a magnifying glass in addition to the glasses?

VCL flights only within FIRs of a member state, VFR flights by day only.

The applicant does not meet ICAO standards, usually in respect of the ability to discriminate colour. For an EASA licence, this would be within the Flight

Information Regions of EASA member nations. To be honest I worry about colour vision problems to the point where I would consider disallowing solo privilege as certain colour vision problems could lead to danger? However, I am open to persuasion?

OML valid only as or with qualified co-pilot

This limitation is applied when there is a risk of incapacity that is greater than normal but not so high as to warrant grounding. It only applies to pilots flying aircraft certified for two pilot operation and would be unusual for non commercial pilots. However, contrary to the opinion of some objectors it can occur and should be maintained.

OCL valid only as co-pilot

A similar limitation to OML, but this limitation also precludes flying as aircraft captain. In most cases, should not this and the previous option be combined, except in unusual circumstances?

OSL valid only as safety pilot and in aircraft with dual controls.

A pilot with this limitation has few privileges over an unlicensed pilot and it is not an equivalent to the OML for private pilots. It can be applied as a temporary limitation while recovering from illness. This is so limited and really for certain purposes only that it makes sense

OAL restricted to a demonstrated aircraft type.

This limitation is applicable to a pilot with an anthropometric or orthopaedic limitation that might make control difficult. Commonly pilots with a lower limb abnormality find the operation of the wheel brakes is difficult with some designs but not others. Pilots with such a limitation must seek flying instructor clearance and an entry in their flying log book for each type that is to be flown. Actually this can apply to people recovering from certain conditions too! These last two could be simplified surely?

OPL valid only without passengers.

This limitation is applied when there is a risk of incapacity that is greater than normal but not so high as to warrant grounding. By excluding inexperienced passengers the major third party risk is removed, the ground risk being very remote following incapacity. Continued solo flight or flying with another pilot is permitted with this limitation. Unless there is evidence that the disqualifying disease has improved, this limitation should be applied to all LPL pilots who have been previously denied a Class 2. Elderly pilots can expect to be limited OPL as they age. Surely if there are serious health problems, then this will be a transitory situation and can be covered more effectively with an additional pilot on board?

APL valid only with approved prosthesis

This limitation is to be applied to pilots with a prosthesis that could affect their ability to control an aircraft. It would commonly be combined with an OAL limitation. Surely only with additional restrictions?

AHL valid only with approved hand controls

This limitation is applied to paraplegic pilots or those with lower limb defects that prohibit normal rudder pedal control. In this case the aircraft has to be modified to meet the needs of that pilots and only aircraft so modified may be flown. However, the security of the modifications is paramount.

AGL valid only with approved eye protection

This limitation has been applied to monocular pilots flying open cockpit aircraft. However dust or debris can adversely affect both eyes and protective goggles are recommended for all pilots in these aircraft. Does not depth perception matter here? I have no problems with a check pilot but solo?

SSL special restrictions as specified

This limitation permits any restriction to be written in. These could be geographical, climatic or altitude limits. One useful application concerns suspected or minor psychiatric disease when a recreational pilot can be

restricted to a named club where responsible officials have been informed, in confidence and with the consent of the applicant, of possible problems. Subsequent reports from these officials become a vital contribution to a sensible and fair medical decision. This could cover all of the above so why bother with al of the above codes?

In case anyone wonders of my attitude, I have medical restrictions! I have spoken to some of the very senior national AMEs and have some understanding of the situation and it need not be this complex!

SIC special instructions - contact AMS

This does not affect the privileges of a licence but is a warning to an AME not to revalidate without consulting the AMS. This limitation might be applied in a case of past psychiatric disease or previous misdemeanour by the applicant.

VAR variation - ICAO annex 1 para 1.2.4.8

This does not affect the privileges of a licence but indicates that the provisions of ICAO are not met, although the pilot is considered fit. It is only applicable to ICAO compliant licences. However more details should be appreciated.

AMS issued by AMS

This does not affect the privileges of a licence but is a hint to an AME that there may have been some special consideration in the past. This is most useful!

response *Noted*

See response to comment No 100 of this segment.

comment

2486

comment by: UK CAA MEDICAL ADVISORY PANEL

**Paragraph** AMC to MED.A.040 8.1.1  
**Page** 25

**Comment**

Replace *had* with *suffered.....and hada with undergone.... delete tolerance test*

**Justification**

Preferred usage

**Proposed Text**

Replace *had* with *suffered....* Replace *.hada* with *undergone*

Replace tolerance test with... *electrocardiogram to symptom limitation*

response *Noted*

See response to comment No 248 of this segment.

comment

2487

comment by: UK CAA MEDICAL ADVISORY PANEL

**Paragraph** AMC to MED.A.040 8.2  
**Page** 25

**Comment**

Replace *had* with *experienced*

**Justification**

Preferred usage

**Proposed Text**

Replace *had* with *experienced*

response *Noted*

See response to comment No 248 of this segment.

comment 2488 comment by: UK CAA MEDICAL ADVISORY PANEL

**Paragraph** AMC to MED.A.040 8.2.1  
**Page** 25

**Comment**

Replace *had* with *suffered....and* since this *undergone..... delete exercise tolerance test*

**Justification**

Preferred usage

**Proposed Text**

Replace *had* with *suffered..... ..undergone satisfactory.... insert exercise electrocardiogram*

response Noted

See response to comment No 248 of this segment.

comment 2489 comment by: UK CAA MEDICAL ADVISORY PANEL

**Paragraph** AMC to MED.A.040 8.3  
**Page** 25

**Comment**

Replace *had* with *undergone*

**Justification**

Preferred usage

**Proposed Text**

Replace *had* with *undergone*

response Noted

See response to comment No 248 of this segment.

comment 2490 comment by: UK CAA MEDICAL ADVISORY PANEL

**Paragraph** AMC to MED.A.040 8.3.1  
**Page** 25

**Comment**

Replace *had* with *undergone*

**Justification**

Preferred usage

**Proposed Text**

Replace *had* with *undergone..... If so has a satisfactory cardiological evaluation including a normal exercise electrocardiogram been completed?*

response Noted

See response to comment No 248 of this segment.

comment 2491 comment by: UK CAA MEDICAL ADVISORY PANEL

**Paragraph** AMC to MED.A.040 8.4

	<p><b>Page 25</b></p> <p><b>Comment</b> Replace <i>had</i> with <i>undergone</i></p> <p><b>Justification</b> Preferred usage</p> <p><b>Proposed Text</b> Replace <i>had</i> with <i>undergone</i></p>
response	<p><i>Noted</i></p> <p>See response to comment No 248 of this segment.</p>

comment	<p>2492</p> <p>comment by: UK CAA MEDICAL ADVISORY PANEL</p> <p><b>Paragraph</b> AMC to MED.A.040 8.4.1 <b>Page 25</b></p> <p><b>Comment</b> Replace <i>had</i> with <i>undergone.....etc</i></p> <p><b>Justification</b> Preferred usage</p> <p><b>Proposed Text</b> <i>Has the pilot undergone coronary artery bypass grafting more than 3 months ago and was has an exercise electrocardiogram been conducted not less than 6 months post operatively been normal, and the post operative cardiological evaluation satisfactory?</i></p>
response	<p><i>Noted</i></p> <p>See response to comment No 248 of this segment.</p>

comment	<p>2493</p> <p>comment by: UK CAA MEDICAL ADVISORY PANEL</p> <p><b>Paragraph</b> AMC to MED.A.040 8.4.1 <b>Page 25</b></p> <p><b>Comment</b> Ejection fraction of &lt; 0.4 is unsafe</p> <p><b>Justification</b> Event rate is too high</p> <p><b>Proposed Text</b> ..... Ejection fraction of &lt; 0.5 ?</p>
response	<p><i>Noted</i></p> <p>See response to comment No 248 of this segment.</p>

comment	<p>2494</p> <p>comment by: UK CAA MEDICAL ADVISORY PANEL</p> <p><b>Paragraph</b> AMC to MED.A.040 11.5 <b>Page 26</b></p> <p><b>Comment</b> Who is to judge the progression of symptoms?</p> <p><b>Justification</b></p>
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	This question does not identify the status of the opinion expressed <b>Proposed Text</b> <i>....as judged by an accredited cardilologist</i>	
response	<i>Noted</i>	
	See response to comment No 248 of this segment.	
comment	2495	comment by: UK CAA MEDICAL ADVISORY PANEL
	<b>Paragraph</b> AMC to MED.A.040 12.2 <b>Page</b> 26  <b>Comment</b> This statement is incomplete as it stands <b>Justification</b> Cardiomyopathy is unqualified <b>Proposed Text</b> <i>...insert hypertrophic, dilated or restrictive cardiomyopathy...</i>	
response	<i>Noted</i>	
	See response to comment No 248 of this segment.	
comment	2496	comment by: UK CAA MEDICAL ADVISORY PANEL
	<b>Paragraph</b> AMC to MED.A.040 13.1 <b>Page</b> 26  <b>Comment</b> <i>...left bundle branch block.....etc</i> <b>Justification</b> This is poor usage <b>Proposed Text</b> <i>Insert... bundle branch block with a satisfactory cardiological evaluation including an exercise electrocardiogram and echocardiography.</i>	
response	<i>Noted</i>	
	See response to comment No 248 of this segment.	
comment	2497	comment by: UK CAA MEDICAL ADVISORY PANEL
	<b>Paragraph</b> AMC to MED.A.040 13.1 <b>Page</b> 26  <b>Comment</b> <i>...suspected myocardial infarction...</i> <b>Justification</b> This is potentially unsafe and poor usage <b>Proposed Text</b> <i>Insert ... suspected myocardial infarction with a satisfactory cardiological evaluation including, at least, an exercise electrocardiogram</i>	
response	<i>Noted</i>	

See response to comment No 248 of this segment.

comment 2498 comment by: UK CAA MEDICAL ADVISORY PANEL

**Paragraph** AMC to MED.A.040 13.1  
**Page** 26

**Comment**  
 How is the likelihood of developing an arrhythmia judged?

**Justification**  
 It cannot be done reliably

**Proposed Text**  
*Insert ..... without any history of tachy-arrhythmia.*

response Noted

See response to comment No 248 of this segment.

comment 2499 comment by: UK CAA MEDICAL ADVISORY PANEL

**Paragraph** AMC to MED.A.040 13.1  
**Page** 26

**Comment**  
 rightward axis evaluated by a physician as not significant.

**Justification**  
 Physician has a number of definitions

**Proposed Text**  
 rightward axis evaluated by *an accredited* physician as not significant.

response Noted

See response to comment No 248 of this segment.

comment 2500 comment by: UK CAA MEDICAL ADVISORY PANEL

**Paragraph** AMC to MED.A.040 13.1  
**Page** 26

**Comment**  
 leftward axis evaluated by a physician as not significant.

**Justification**  
 Physician has a number of definitions. Left ward axis deviation is usually unimportant. Left axis deviation may be

**Proposed Text**  
*left axis* deviation evaluated by an *accredited* physician as not significant.

response Noted

See response to comment No 248 of this segment.

comment	93	comment by: <i>Dr.Beiderwellen, Secretary of GAAME</i>
	<p>Author: : Dr.Beiderwellen, AME member of the AB of ESAM  Section: <b>AMC to Med A 045 a) and b)</b>  <b>Page:</b></p> <p>Relevant Text:</p> <p><b>Comment:</b>  Licensing authority is not qualified and medical confidentiality is not insured  See also comment 11 shown above</p> <p><b>Proposal:</b></p> <ul style="list-style-type: none"> <li>• a) AME class 2 may refer the decision.... to AME class 1 or AMC, AME class 1 may.... to AMC</li> <li>• b) Remove " licensing authority "</li> </ul>	
response	<i>Noted</i>	
	<p>For qualification of the medical assessor, please see AR.MED.020.</p> <p>Part MED is based on JAR-FCL 3 and the licensing authority corresponds to what was the AMS. All NAAs presently have the necessary competence to assess the fitness of a pilot in complicated and borderline cases.</p>	
comment	139	comment by: <i>Civil Aviation Authority - The Netherlands</i>
	<p><b>MED.A.045. onder a. (Blz. 30 van 66)</b>  Volgens De CAA-The Netherlands moet het woord 'may' worden vervangen door 'shall'.</p> <p><b>MED.A.045. onder b. (Blz. 30 van 66)</b>  Volgens De CAA-The Netherlands moet het zinsdeel "in consultation with flight operations and other experts if necessary" vervallen, bij gebrek aan nut en noodzaak. De CAA-The Netherlands geeft aan dat bovendien onduidelijk is wat met 'operations' en 'experts' wordt bedoeld.</p>	
response	<i>Not accepted</i>	
	<p>a. In those circumstances when an AeMC or AME is permitted to impose a limitation, the AeMC or AME is supposed to take the decision. The AMC to MED.A.045 will also give them the possibility to refer the decision to the licensing authority. The use of "may" therefore is more appropriate in this context.</p> <p>b. The text is copied from ICAO Annex 1. The definition of "accredited medical conclusion" includes the use of consultation with flight operations and other experts if necessary.</p>	
comment	556	comment by: <i>British Microlight Aircraft Association</i>
	Accepted	
response	<i>Noted</i>	

Thank you for the positive comment.

comment 1239 comment by: *Swedish Transport Agency, Civil Aviation Department (Transportstyrelsen, Luftfartsavdelningen)*

**Comment:**

(a) should also include GMP. An intermediate referral from a GMP to an AME will commonly result in an unduly delay and additional costs for the applicant, especially when the applicant is not previously known by the AME, and in cases where the AME still needs to refer the case further to the authority.

**Proposal:**

Amend AMC to MED.A.045:

(a) An AeMC, AME or GMP may refer the decision on fitness of the applicant to the licensing authority in borderline cases or where fitness is in doubt.

response *Not accepted*

The first stage for the referral of the LAPL applicant by the GMP is an AME or AeMC. If the AME or AeMC may not give a definite answer, then the applicant should be referred to the licensing authority. AME and AeMC are sufficiently qualified to solve a majority of LAPL borderline cases thus decreasing the additional workload of the medical assessor of the licensing authority.

comment 1240 comment by: *Swedish Transport Agency, Civil Aviation Department (Transportstyrelsen, Luftfartsavdelningen)*

**Comment:**

(b) should be limited to the licensing authority in accordance with our proposal to amend MED.A.045 (a)(1)

**Proposal:**

Amend AMC to MED.A.045:

(b) In cases where a fit assessment can only be considered with a limitation, the licensing authority should evaluate the medical condition of the applicant in consultation with flight operations and other experts if necessary.

response *Noted*

See response to comment No 139 of this segment.

comment 1414 comment by: *Prutech Innovation Services Ltd.*

**AMC to MED.A.045:** A new sub-section (c) should be added, to obviate the likelihood of excessive caution, leading to outcomes that are not justified by the levels of risk involved, as follows: "(c) Limitations should not be placed on an applicant's certificate unless these are clearly essential to eliminate an unacceptable risk that would otherwise be posed by the applicant [to third parties]."

**Comments:** *Other things being equal, the natural instinct of examiners will be to err on the side of over-caution, rather than more carefully weighing the risks posed by some medical condition. The proposed extra sub-section will encourage examiners to not feel they are placing themselves at risk by being more precise in their judgements.*

*Note: the final term in square brackets is suggested as an addition that keeps*

	<i>in mind that it is not the role of certification personnel to protect citizens (including pilots) <u>from themselves</u>, but rather to protect other parties from them. This is too easily forgotten.</i>	
response	<i>Not accepted</i>	
	Limitations on the medical certificate are always entered after a thorough evaluation of the case. There is no need of additional regulation, especially if it is based on the 'natural instinct' of examiners and preventing them from 'being more precise in their judgements'. The rule shall ensure the quality of the decisions. Moreover, MED.A.045 and AMC to MED.A.045 are rules which allow flexibility in aeromedical decisions and give the possibility to keep pilots flying when they do not fully comply with the requirements. By limiting this possibility, fewer pilots with decreased medical fitness would be accepted for aeromedical certification.	
comment	1775	comment by: <i>Norwegian Association of Aviation Medicine</i>
	remove LPL	
response	<i>Not accepted</i>	
	The Basic Regulation (Article 7) allows a GMP to issue a medical certificate for a LPL licence (if permitted under national law). This has to be taken into account in the implementing rules.	
comment	2034	comment by: <i>Tomasz Gorzenski</i>
	The EASA should consider creating a waiver program, similar to that developed by the FAA. By the way of special medical certificate issuance, allowing applicants, who meet all but one requirement (provided additional medical examination is performed as necessary to assure adequate level of safety), to exercise privileges of class 1 or class 2 medical certificate holders, <u>without operational multi-pilot or safety pilot limitation</u> , EASA may create in future better medical standards, based more on medical facts, than some old, unnecessary standards. This is the only way to get rid of some unnecessary and unjustly discriminating regulations This is exactly what happened in the USA and later in world with uncorrected vision standard. Thanks to the FAA waiver program, by allowing thousands of pilots and ATC controller to excercises their privileges despite being unable to meet the standard, the FAA was able to observe, that they had performed their duties safely and proficiently. Consequently the FAA removed the uncorrected vision standard from FAR Part 67 and later the ICAO and other aviation authorities followed the FAA.	
response	<i>Noted</i>	
	Thank you for the information. The system of limitations proposed in the NPA is transposed from JAR FCL 3. This system proved itself as being flexible and provides the possibility to take into account the latest developments in medicine.	
comment	2378	comment by: <i>Ingo Wiebelitz</i>
	AMC to MED.A.045	

	Additional:
	(c) Mißbrauch oder falsche Beurteilung von Gesundheitsdaten zum Nachteil eines Piloten soll den Entzug der Zulassung eines AeMC zur Folge haben.
response	<i>Noted</i>
	Please, refer to Authority Requirements AR.MED.250 (NPA 2008-22b).

<b>C. Draft Decision Part-MED - Subpart A: General Requirements - Section 2: Issuance, revalidation and renewal of medical certificates - AMC to MED.A.050: Obligations of AeMC, AME and GMP – report to the licensing authority</b>	p. 30
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comment	94	comment by: <i>Dr.Beiderwellen, Secretary of GAAME</i>
	<p>Author: : Dr.Beiderwellen, AME member of the AB of ESAM                  Section: <b>AMC to Med A 050 4)</b>                  Page: 30</p> <p>Relevant Text:                  GMP</p> <p><b>Comment:</b>                  s. above, GMP not qualified</p> <p><b>Proposal:</b>                  Delete 4) completely</p>	
response	<i>Not accepted</i>	
	<p>The Basic Regulation (Article 7) allows a GMP to issue a medical certificate for a LPL licence (if permitted under national law). This has to be taken into account in the implementing rules.</p> <p>In those cases where more than one doctor has been involved in the examination, it is essential to define that only one of them should be responsible for the final assessment and signing of the report.</p>	

comment	115	comment by: <i>Aero-Club of Switzerland</i>
	<p>On the one hand the Agency writes of "obligations", on the other the Agency chooses "should" as verb. Is it not simpler and clearer, and more correct to use the verb "has to" or a similar one throughout the whole document when dealing with obligations?</p> <p>Justification: We think that the wording has to be very clear and must not leave room for interpretation.</p>	
response	<i>Noted</i>	
	<p>The wording 'shall' is used in implementing rules. Implementing rules are a safety objective. AMCs describe the way how to reach the safety objective (there may be more than one AMC), and, therefore, the wording 'should' is used.</p>	

comment	409	comment by: <i>European CMO Forum</i>
	<b>AMC A to MED.B.050 3</b>	
	Comment: Current wording does not cover all scenarios.	
	Justification: Clarity..	
	Proposed Text: Insert `...substances <b>likely to affect flight safety</b> is...' NB Such substances should be specified in Guidance Material.	
response	<i>Not accepted</i>	
	The issue is covered in MED.B.050(b).	
comment	557	comment by: <i>British Microlight Aircraft Association</i>
	Accepted	
response	<i>Noted</i>	
	Thank you for the positive comment.	
comment	1091	comment by: <i>Regierung von Oberbayern-Luftamt Südbayern</i>
	Es wird Bezug genommen zu unserer Anmerkung zu MED.A.050.	
response	<i>Noted</i>	
	Please, see the responses to your comments in MED.A.050 and MED.A.030.	
comment	1160	comment by: <i>Keith WHITE</i>
	<b>2. Add LPL(S) and SPL.</b>	
response	<i>Noted</i>	
	See response to comment No 1129.	
comment	1241	comment by: <i>Swedish Transport Agency, Civil Aviation Department (Transportstyrelsen, Luftfartsavdelningen)</i>
	<b>Comment:</b> For quality control and supervision of the AeMC, AME and GMP it is necessary that the report also includes the medical history signed by the applicant, which must also be included in the assessment, in accordance with our proposal to amend MED.A.050 (b)(4)	
	<b>Proposal:</b> Amend AMC to MED.A.050: The report required in MED.A.050 (b)(4) should detail the results of the examination and the assessment of the medical history and the findings with	

		regard to medical fitness.
response		<i>Partially accepted</i>
		The issue will be covered by amending MED.A.050(a)(4) to read 'a signed <u>full</u> report'.
comment	1242	comment by: <i>Swedish Transport Agency, Civil Aviation Department (Transportstyrelsen, Luftfartsavdelningen)</i>
		<b>Comment:</b> The report form in AMC to MED.A.040 is totally inadequate (see our comments to AMC to MED.A.040) and should either be deleted or replaced by a new and relevant form.
		<b>Proposal:</b> In AMC to MED.A.050, the section 2 should either be deleted, or the report form referred to has to be totally revised.
response		<i>Accepted</i>
		The standard application and examination form for class 1 and class 2 will be used also for LAPL, with the sections non-compulsory for LAPL greyed out. As a consequence, (2) in AMC to MED.A.050 will be deleted.
comment	1627	comment by: <i>Bayerisches Staatsministerium für Wirtschaft, Infrastruktur, Verkehr und Technologie</i>
		Es wird Bezug genommen zu die Anmerkung zu MED.A.050.
response		<i>Noted</i>
		Please, see the responses to your comments in MED.A.050 and MED.A.030.
comment	1781	comment by: <i>Norwegian Association of Aviation Medicine</i>
		Remove GMP and cancel point 2.
response		<i>Noted</i>
		See responses to comments No 94 and 1242 of this segment.
comment	1859	comment by: <i>Dr Stephen Gibson</i>
		The form Med A 040 or the declaration Med A .035 (2) needs a clause added to be signed by the applicant authorising the giving of this information.
response		<i>Partially accepted</i>
		The signed declaration described in MED.A.035 (b)(2) will be part of the application form that will also be used for LAPL. Signing the application form will also give the consent to release the information needed.
comment	2574	comment by: <i>Heinz Fricke-Bohl and Kirsten Bohl</i>

AMC to MED.A.050: (3) Es darf kein Untersuchungsbefund übermittelt werden. Es dürfen nur allgemeine Daten wie Name, Anschrift, Geburtsdatum, Lizenznummer ggf. Einschränkung wie VML übermittelt werden. DATENSCHUTZ HAT HÖCHSTE Priortität !!!  
Es fällt auf, dass das Wort licensing authority häufig vorkommt. Es sollte durch AME/AMC ersetzt werden.

response *Not accepted*

The provisions in Part Medical follow ICAO Annex I and JAR FCL 3. Under both standards/requirements, the AME is obliged to send the individual examination results to the medical assessor of the licensing authority/AMS. This procedure is implemented in the 26 EU Member States, the FAA, CASA Australia, etc.

**C. Draft Decision Part-MED - Subpart A: General Requirements - Section 2: Issuance, revalidation and renewal of medical certificates - AMC to MED.A.055: Validity, revalidation and renewal of medical certificates – validity period**

p. 30

comment 558 comment by: *British Microlight Aircraft Association*

Accepted

response *Noted*

Thank you for the positive answer.

comment 1243 comment by: *Swedish Transport Agency, Civil Aviation Department (Transportstyrelsen, Luftfartsavdelningen)*

**Comment:**

The understanding of 'the age' is somewhat unclear due to a missing reference to the applicant, which should be corrected.

**Proposal:**

Amend AMC to MED.A.055:

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 when the medical examination takes place.

response *Accepted*

Thank you for the proposal. The text will be changed accordingly and will be placed in the implementing rules because it is a transposition of the text from JAR FCL 3 Section 1.

**C. Draft Decision Part-MED - Subpart B: Requirements for Medical Certificates**

p. 31

comment 101 comment by: *British Gliding Association*

Page 31 of 66

**Subpart B REQUIREMENTS FOR MEDICAL CERTIFICATES**

*Comment: This long section fills the same function as Chapter 6 of ICAO Annex 1 in that it sets out disqualifying conditions. However while ICAO uses the term 'likely to interfere with the performance of duties', in most cases the NPA requires reference to a specialist. This avoids the question of quantifying unfitness. While defects of function are tested in training, the risk of sudden incapacity remains a medical problem. Following a classic paper by Peter Chapman, the JAR-FCL 3 defined aeromedical risk as the chance of incapacity occurring during the next year. By comparison with other airworthiness standards, the limit was set at 1% for both Class 1 and 2. Another reason for using numerical standards is that after a period of time, accident and incident data can confirm whether intended standards have actually been met.*

**BGA Proposal:**

**1. That the risk of sudden incapacity be defined in numerical terms and limits be set. Suggested limits are**

- Class 1**                      **1% (Existing JAA level)**
- Class 1 OML**                **2%**
- Class 2**                      **2%**
- Class 2 OPL**                **5%**
- LPL**                         **2% (Group 2 drivers in the UK)**
- LPL OPL**                 **20% (Group 1 drivers in the UK)**

*References:*

*1. Chapman P.J.C. (1984). The consequences of in flight incapacitation in civil aviation medicine. Journal of Aviation and Space Environmental Medicine, 55, 497-500*

response *Partially accepted*

The risk assessment will be included in the Guidance Material.

comment

1585

comment by: FAA

**General comments on Chapters A and B on the AMC for Class 1 and Class 2 medical certificates:**

While the ultimate aim of medically certificating pilots safely is the same, the United States notes differences in the methodology EASA, ICAO, and the United States use to set forth disqualification parameters.

response *Noted*

Thank you for studying our NPA and the information provided throughout the document.

comment

1666

comment by: Deutscher Aero Club (DAeC)

**Comment:**

This long section fills the same function as Chapter 6 of ICAO Annex 1 in that it sets out disqualifying conditions. However while ICAO uses the term 'likely to interfere with the performance of duties', in most cases the NPA requires reference to a specialist. This avoids the question of quantifying unfitness. While defects of function are tested in training, the risk of sudden incapacity remains a medical problem. Following a classic paper by Peter Chapman, the JAR-FCL 3 defined aeromedical risk as the chance of incapacity occurring during the next year. By comparison with other airworthiness standards, the

	<p>limit was set at 1% for both Class 1 and 2. Another reason for using numerical standards is that after a period of time, accident and incident data can confirm whether intended standards have actually been met.</p> <p>DAeC Proposal:</p> <p>1. That the risk of sudden incapacity be defined in numerical terms and limits be set. Suggested limits are</p> <table border="0"> <tr> <td>Class 1</td> <td>1% (Existing JAA level)</td> </tr> <tr> <td>Class 1 OML</td> <td>2%</td> </tr> <tr> <td>Class 2</td> <td>2%</td> </tr> <tr> <td>Class 2 OPL</td> <td>5%</td> </tr> <tr> <td>LPL</td> <td>2% (Group 2 drivers in the UK)</td> </tr> <tr> <td>LPL OPL</td> <td>20% (Group 1 drivers in the UK)</td> </tr> </table> <p>References:</p> <p>1. Chapman P.J.C. (1984). The consequences of in flight incapacitation in civil aviation medicine. Journal of Aviation and Space Environmental Medicine, 55, 497-500</p>	Class 1	1% (Existing JAA level)	Class 1 OML	2%	Class 2	2%	Class 2 OPL	5%	LPL	2% (Group 2 drivers in the UK)	LPL OPL	20% (Group 1 drivers in the UK)
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LPL	2% (Group 2 drivers in the UK)												
LPL OPL	20% (Group 1 drivers in the UK)												
response	<p><i>Noted</i></p> <p>Please see response to the same comment above (No 101).</p>												

comment	<p>1711</p> <p>comment by: <i>Deutscher Aero Club</i></p> <p>Subpart B REQUIREMENTS FOR MEDICAL CERTIFICATES</p> <p>Comment:</p> <p>This long section fills the same function as Chapter 6 of ICAO Annex 1 in that it sets out disqualifying conditions. However while ICAO uses the term 'likely to interfere with the performance of duties', in most cases the NPA requires reference to a specialist. This avoids the question of quantifying unfitness. While defects of function are tested in training, the risk of sudden incapacity remains a medical problem. Following a classic paper by Peter Chapman, the JAR-FCL 3 defined aeromedical risk as the chance of incapacity occurring during the next year. By comparison with other airworthiness standards, the limit was set at 1% for both Class 1 and 2. Another reason for using numerical standards is that after a period of time, accident and incident data can confirm whether intended standards have actually been met.</p> <p>EGU Proposal:</p> <p>1. That the risk of sudden incapacity be defined in numerical terms and limits be set. Suggested limits are</p> <table border="0"> <tr> <td>Class 1</td> <td>1% (Existing JAA level)</td> </tr> <tr> <td>Class 1 OML</td> <td>2%</td> </tr> <tr> <td>Class 2</td> <td>2%</td> </tr> <tr> <td>Class 2 OPL</td> <td>5%</td> </tr> <tr> <td>LPL</td> <td>2% (Group 2 drivers in the UK)</td> </tr> <tr> <td>LPL OPL</td> <td>20% (Group 1 drivers in the UK)</td> </tr> </table> <p>References:</p> <p>1. Chapman P.J.C. (1984). The consequences of in flight incapacitation in civil aviation medicine. Journal of Aviation and Space Environmental Medicine, 55, 497-500</p>	Class 1	1% (Existing JAA level)	Class 1 OML	2%	Class 2	2%	Class 2 OPL	5%	LPL	2% (Group 2 drivers in the UK)	LPL OPL	20% (Group 1 drivers in the UK)
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Class 2 OPL	5%												
LPL	2% (Group 2 drivers in the UK)												
LPL OPL	20% (Group 1 drivers in the UK)												
response	<p><i>Noted</i></p> <p>Please see response to the same comment (No 101). This comment has been entered twice from the same commentator.</p>												

comment	2132	comment by: <i>Croft Brown</i>
	<p>Page 31 of 66  Subpart B REQUIREMENTS FOR MEDICAL CERTIFICATES  Comment: This long section fills the same function as Chapter 6 of ICAO Annex 1 in that it sets out disqualifying conditions. However while ICAO uses the term 'likely to interfere with the performance of duties', in most cases the NPA requires reference to a specialist.  This avoids the question of quantifying unfitness. While defects of function are tested in training, the risk of sudden incapacity remains a medical problem. Following a classic paper by Peter Chapman, the JAR-FCL 3 defined aeromedical risk as the chance of incapacity occurring during the next year. By comparison with other airworthiness standards, the limit was set at 1% for both Class 1 and 2. Another reason for using numerical standards is that after a period of time, accident and incident data can confirm whether intended standards have actually been met.  Croft Brown endorses the BGA Proposal:  1. That the risk of sudden incapacity be defined in numerical terms and limits be set. Suggested limits are  Class 1 1% (Existing JAA level)  Class 1 OML 2%  Class 2 2%  Class 2 OPL 5%  LPL 2% (Group 2 drivers in the UK)  LPL OPL 20% (Group 1 drivers in the UK)  References:  1. Chapman P.J.C. (1984). The consequences of in flight incapacitation in civil aviation medicine. <i>Journal of Aviation and Space Environmental Medicine</i>, 55, 497-500</p>	
response	<i>Noted</i>	
	Please see response to the same comment (No 101).	

comment	2465	comment by: <i>Paul Mc G</i>
	<p>This could be combined elsewhere, as this long section has the same function as Chapter 6 of ICAO Annex 1 It sets out disqualifying conditions. However while ICAO uses the term 'likely to interfere with the performance of duties', in most cases the NPA requires reference to a specialist. This avoids the question of quantifying unfitness. While defects of function are tested in training, the risk of sudden incapacity remains a medical problem. The problem is that statistics are not used in calculation of the possibility of event, merely an arbitrary opinion. There has to be a better way?? Is it intended to use the same calculations are per driving licenses?</p>	
response	<i>Noted</i>	
	Please see response to comment No 101.	

<b>C. Draft Decision Part-MED - Subpart B: Requirements for Medical Certificates - Section 1: Specific requirements for class 1 and class 2 medical certificates - Chapter A: AMC for Class 1 medical certificates</b>	p. 31
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comment	559	comment by: <i>British Microlight Aircraft Association</i>
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	Medical requirements shall be equal to and not greater than those published as ICAO minimum requirements.	
response	<i>Noted</i>	
	<p>The requirements for the LAPL medical certificate are below ICAO standard; the requirements for class 2 medical certificates have been aligned with ICAO SARPs.</p> <p>Where considered necessary for safety reasons, medical rules for class 1 are, in some cases, higher than ICAO class 1 SARPs.</p>	
comment	998	comment by: <i>European Society of Space and Aviation Medicine (ESAM)</i>
	<p><b>Author: European Society of Space and Aviation Medicine (ESAM) - Cardiology Group -</b></p> <p><b>Subpart B Requirements for medical certificates</b>  <b>Section: 1 Specific requirements for class 1 and class 2 medical certificates</b>  <b>Chapter A AMC for class 1 medical certificates</b></p> <p><b>Page: 31</b></p> <p><b>Relevant Text:</b>  (b) General  1. Cardiovascular Risk Factor Assessment  1.2 An accumulation of risk factors (smoking, family history, lipid abnormalities, hypertension, etc.) should require cardiovascular evaluation by the AeMC or AME in conjunction with the licensing authority.</p> <p><b>Comment:</b> a conjunction with the licensing authority will not be necessary in all cases - only if necessary.</p> <p><b>Proposal:</b>  (b) General  1. Cardiovascular Risk Factor Assessment  1.2 An accumulation of risk factors (smoking, family history, lipid abnormalities, hypertension, etc.) should require cardiovascular evaluation by the AMC or AME in conjunction with the licensing authority if necessary.</p>	
response	<i>Not accepted</i>	
	Cardiovascular evaluation in conjunction with the licensing authority was a requirement in JAR-FCL 3 which was the basis for this document. The rule is now in an AMC which should provide the flexibility you propose while not abandoning the involvement of the licensing authority.	
comment	999	comment by: <i>European Society of Space and Aviation Medicine (ESAM)</i>
	<p><b>Author: European Society of Space and Aviation Medicine (ESAM) - Cardiology Group -</b></p> <p><b>Subpart B Requirements for medical certificates</b>  <b>Section: 1 Specific requirements for class 1 and class 2 medical certificates</b></p>	

**Chapter A AMC for class 1 medical certificates****Page:** 31**Relevant Text:**

(b) General

2. *Cardiovascular Assessment*

2.1. Reporting of resting and exercise electrocardiograms should be by the AME or other specialist.

**Comment:** not any other specialist, but a cardiologist**Proposal:**

(b) General

2. *Cardiovascular Assessment*

2.1. Reporting of resting and exercise electrocardiograms should be by the AME or cardiologist.

response *Not accepted*

The text is transposed from JAR FCL 3.130(d) where the full wording was: ‘... other specialists acceptable to the AMS’.

While JAR-FCL 3 was the basis for this NPA, some general changes were made, one of them being to delete ‘as acceptable to the AMS/Authority’. This text opens the door for different interpretations of the rules and was therefore deleted in order to provide rules and AMCs of one standard for all Europe.

In some cases an AME may not actually do the ECG but refer the pilot ‘to another specialist’ who will provide the ECG and the evaluation. It is not necessary to require a cardiologist to evaluate all routine ECGs.

comment

1244

comment by: *Swedish Transport Agency, Civil Aviation Department (Transportstyrelsen, Luftfartsavdelningen)***Comment:**

In different parts of AMC A to MED.B.005, e.g. 4.1 and 4.2, the basis for a decision is described in different manners which makes the text more complex and may lead to misinterpretations. In order to simplify the reading and interpretation of the text, each subparagraph of AMC A to MED.B should have a uniform basic structure.

**Proposal:**

The following uniform basic structure is proposed: definition of the condition - possible fit assessment - possible difference at initial and revalidation - level of decision (licensing authority/AeMC/AME) - possible limitations - follow-up required.

response *Partially accepted*

The text in the AMCs has been redrafted using JAR-FCL 3 as a basis. It seems sensible to revise the AMCs (and the rules) at close intervals to keep them updated. A change to the structure as mentioned in the comment could be considered at that stage.

**C. Draft Decision Part-MED - Subpart B: Requirements for Medical Certificates - Section 1: Specific requirements for class 1 and class 2 medical certificates - Chapter A: AMC for Class 1 medical certificates - AMC A to MED.B.005: Cardiovascular System** p. 31-37

comment	11	comment by: <i>GEMA</i>
	4.2.II Una disquinesia, habitual tras un IAM, no tiene por qué ser importante	
response	<i>Noted</i>	
comment	12	comment by: <i>GEMA</i>
	8 II. OML para siempre, o puede ser apto sin limitaciones tras un periodo determinado?	
	9.1 Tres meses para todo, da igual que sea un marcapasos que una resección intestinal o una colecistectomía laparoscópica	
response	<i>Noted</i>	
	8:II. It is correct that there is no rule to withdraw an OML limitation. But this is also true for JAR-FCL 3 which has been transposed to this Part Medical. A future RM task may cover this issue, if considered necessary.	
comment	38	comment by: <i>Dieter Bauereiss</i>
	<p><b>AMC for Class 1 medical certificates</b>  <b>AMC A to MED.B.005</b>  <b>CARDIOVASCULAR SYSTEM - Class 1 medical certificates</b></p> <p><b>(d) CORONARY ARTERY DISEASE</b>  4.2. At least 6 months from the ischaemic cardiac event, including revascularisation, the following investigations should be completed (equivalent tests may be substituted):</p> <p>(ii) 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 <u>50%</u> or more</p> <p><b>AMC for Class 2 medical certificates</b>  <b>AMC B to MED.B.005</b>  <b>CARDIOVASCULAR SYSTEM Class 2 medical certificates</b></p> <p><b>(d) CORONARY ARTERY DISEASE</b>  3.2. At least 6 months from the ischaemic cardiac event, including revascularisation, the following investigations should be completed (equivalent tests may be substituted):</p> <p>(ii) an echocardiogram showing satisfactory left ventricular function with no important abnormality of wall motion and a <u>satisfactory</u> left ventricular ejection fraction</p> <p><b><u>Comment</u></b></p>	

Unter (ii) findet man unterschiedliche Leistungsanforderungen bezüglich der linksventrikulären Auswurfraction. Die Forderungen an die Tauglichkeitsklasse 2 sind hierbei als absolut richtig anzusehen, erreichen nachweislich ca. 33% der Erdbevölkerung **nicht** die geforderten 50% linksventrikulären Ejakulation Fraction (obwohl nicht Herzkrank!!!). Sofern diese Forderung bezüglich der LVEF bestehen bleibt, ist dies im Sinne der Gleichbehandlung auch bei der periodischen Flugtauglichkeitsuntersuchung mit einzubeziehen.

Es wäre meiner Meinung nach sinnvoll, Herzspezialisten (Herzchirurgen) zu rate zu ziehen und anschliessend die Anforderungen an Class 1 auch mit "satisfactory left ventricular ejection fraction" zu beschreiben. Eine Messung des EF sollte unter Belastung erfolgen, dies zeigt, in wie weit das Herz noch "leistungsfähig" ist.

In der Hoffnung einen sinnvollen Beitrag erbracht zu haben, verbleibe ich

mit freundlichen Grüßen  
Dieter Bauereiss

response *Not accepted*

With very few exeptions, 'satisfactory', 'significant', 'normal' is the wording in the rules to give the basic outline of what is expected. Figures are then in the AMCs to provide the values that can be accepted for a fit assessment and at the same time a harmonised standard across Europe.

The text is transposed from JAR FCL 3 which was the basis of this document, a left ventricular ejection fraction of 50% or more was required in Appendix 1 (6)(b) which was a rule. The present text is in an AMC and changes to AMCs are considered necessary, proposals for rulemaking tasks are welcome by the Agency.

comment

140

comment by: *Civil Aviation Authority - The Netherlands*

**5.2.1, onder iii. (Blz. 32 van 66)**

De CAA-The Netherlands merkt op dat niet duidelijk is wat met 'trivial' en 'a greater' wordt bedoeld. De CAA-The Netherlands verzoekt EASA om deze termen met cijfers te verduidelijken.

**5.2.2, onder ii. (Blz. 32 van 66)**

De CAA-The Netherlands merkt op dat niet duidelijk is wat met 'normally' wordt bedoeld. De CAA-The Netherlands verzoekt EASA om aan te geven wanneer kandidaten met 'rheumatic mitral stenosis' niet als ongeschikt moeten worden gekwalificeerd.

**6.1. (Blz. 32 van 66)**

Deze eis is strenger ten opzichte van JAR-FCL. De CAA-The Netherlands acht kandidaten met een nieuwe hartklep onder omstandigheden geschikt.

response *Noted*

The text has been transposed from JAR-FCL 3, Appendix 1 to Subparts B & C, (9)(b)(3), where 'trivial' is also used.

The aim of the NPA was to transpose JAR-FCL 3 for class 1 with only minor changes, if at all. However, future rulemaking tasks will be initiated to amend and improve the text.

comment 141 comment by: *Civil Aviation Authority - The Netherlands*

**8.2. (Blz. 33 van 66)**

De CAA-The Netherlands merkt op dat niet duidelijk is wat met 'minor' wordt bedoeld. De CAA-The Netherlands verzoekt om deze term met cijfers te verduidelijken.

response *Noted*

It is not always possible to put numbers on a condition because in some cases the examinations needed to verify them in a pilot would be too demanding, or no numbers exist, or the same condition in 2 pilots needs to be assessed differently because of other present medical conditions.

In the case of this comment 'minor abnormalities of the heart' a clearer definition would be too long for an AMC. However, further clarification could be in the Guidance Material that will be drafted.

comment 339 comment by: *FOCA Switzerland*

AMC A to MED.B.005 add a consequence to accumulation of risk factors.

Proposal: **Add the following text**

**b) 1.2: If the risk assessment indicates a risk of more than 1% incapacitation risk per year, a OML limitation is mandatory.**

response *Partially accepted*

The risk assessment will be included in the Guidance Material.

comment 467 comment by: *UK CAA*

**AMC A to MED.B.005 (b) 2.1**

**Page: 31**

**Comment:**

Exercise electrocardiograms should be reported by a cardiologist.

**Justification:**

AMEs (unless accredited in cardiology) do not have the expertise to report exercise electrocardiograms.

**Proposed Text:**

Delete 'and exercise'.

response *Not accepted*

'other specialist' will be replaced by 'an accredited specialist'.

'cardiologist' is not used because e.g. an internist could evaluate a stress ECG and it may not be possible in all European countries to get easy access to a cardiologist for just one stress ECG .

The term 'accredited specialist' is also a valid term to determine who can evaluate a resting ECG and the paragraph does not have to be split.

An AME should be in a position to evaluate resting and stress ECGs if he/she has the corresponding qualification.

comment 468 comment by: UK CAA

**AMC A to MED.B.005 (b) 2.2 and new 2.3**

**Page: 31**

**Comment:**

Separate the reporting of electrocardiograms and exercise electrocardiograms into two requirements.

**Justification:**

The reporting of resting and exercise electrocardiograms requires different competencies.

**Proposed Text:**

Insert as 2.2' **Reporting of exercise electrocardiograms should be by a cardiologist.'**

response *Noted*

Please see response to comment No 467.

comment 469 comment by: UK CAA

**AMC A to MED.B.005 (b) 3 (ii)**

**Page: 31**

**Comment:**

Requirement should be broadened to include the fact that lifestyle factors should be addressed.

**Justification:**

Applicants with peripheral arterial disease should adjust lifestyle factors such as stopping smoking as well as be on an anti-platelet agent.

**Proposed Text:**

Delete 'be on acceptable' and 'treatment' and insert '**take measures directed towards**' as follows: 'All applicants should **take measures directed towards** secondary prevention.'

response *Not accepted*

The proposed NPA text is a transposition of the corresponding requirement from JAR FCL 3. The difference between the text in the NPA (and presently in JAR-FCL 3) and the one proposed seems to be significant. A lifestyle change can be recommended to a pilot but the aeromedical fit/unfit assessment cannot be based on lifestyle. Secondary prevention treatment can be required.

comment 470 comment by: UK CAA

**AMC A to MED.B.005 (b) 4.1**

**Comment:**

An upper limit should be specified for medical certification with an aortic aneurysm.

**Justification:**

The risk of rupture of an aneurysm with a diameter of more than 5.5cm is unacceptable for a fit assessment.

**Proposed Text:**

Add **'of up to 5.5 cm diameter'** as follows: **'...infra-renal abdominal aorta of up to 5.5cm diameter may be assessed...'**

response *Noted*

The proposed NPA text is a transposition of the corresponding requirement from JAR-FCL 3 where no maximal diameter for an infra-renal aneurysm was set and there may be different opinions of the specialists of what diameter can be tolerated for a fit assessment for a class 1 medical certificate. Therefore, no change to the text will be introduced at this stage.

However, the comment has been taken on for discussion during the next rulemaking task MED.001.

comment

471

comment by: UK CAA

**AMC A to MED.B.005 (b) 5.2.1 (ii)**

**Page: 32**

**Comment:**

Mean pressure gradients are not used in all States (eg UK), so this AMC should be amended to reflect different clinical practice in different States. It could refer to 'minor, moderate or severe aortic stenosis' and numerical measurements be confined to Guidance Material that is relevant for each State. All Member States will not be able to evaluate the aeromedical implications of aortic stenosis if mean pressure gradients are retained.

The proposed text is based on European Society of Cardiology guidelines that can be further elucidated in supplementary guidance material.

The use of the word 'intact' does not make sense in this context and should be replaced by 'satisfactory'.

**Justification:**

The optimum parameter for the assessment of aortic stenosis is considered to be 'aortic valve area' in the UK but it is not always possible to measure this in practice. And peak pressure gradient or peak velocity may be used as alternatives. Also, other clinical factors are very important in assessing the aeromedical relevance of the stenosis. These factors include left ventricular hypertrophy, left ventricular diastolic function, left ventricular ejection fraction, amount of calcification and degree of coincident regurgitation.

In addition, the measurement of mean or peak pressure gradient varies according to whether it is undertaken during a catheter study or as part of an echocardiographic study; the variation can be up to 15 mm Hg difference. The gradient also varies significantly depending on the cardiac output.

	<p><b>Proposed Text:</b> Amend to: 'Applicants with aortic stenosis require licensing authority review. Left ventricular function should be <b>satisfactory</b>. A history of systemic embolism or significant dilatation of the thoracic aorta is disqualifying. <b>An OML is required with moderate aortic stenosis. Severe aortic stenosis is disqualifying.</b>'</p>
response	<p><i>Not accepted</i></p>
	<p>The proposed NPA text is a transposition of the corresponding requirement from JAR-FCL 3 where these values were included in a rule. Other comments on this NPA (e.g. No 140 and 141 in this segment) pointed out that general expressions 'minor', 'trivial', 'normally', transposed from JAR-FCL 3, do not provide sufficient clarity for a medical assessment. These terms will remain in the AMCs at this moment with the justification given in the response. However, it does not seem adequate to replace clear limits that are presently implemented in a rule by very general expressions in the future AMC.</p> <p>We take note that the UK does not use mean pressure gradients to evaluate aortic stenosis. The paragraph will be amended with one sentence: 'Alternative measurement techniques with equivalent ranges may be used'.</p>
comment	<p>472 <span style="float: right;">comment by: UK CAA</span></p>
	<p><b>AMC A to MED.B.005 (b) 5.2.2 (v)</b> <b>Page: 32</b></p> <p><b>Comment:</b> Systolic impairment should also be included.</p> <p><b>Justification:</b> It is systolic impairment that is of particular aeromedical concern.</p> <p><b>Proposed Text:</b> Amend to '...left ventricular end-diastolic diameter <b>or evidence of systolic impairment</b> should be...'</p>
response	<p><i>Accepted</i></p>
	<p>The comment is accepted with the justification given in the comment.</p>
comment	<p>473 <span style="float: right;">comment by: UK CAA</span></p>
	<p><b>AMC A to MED.B.005 (b) 6.3.(i) etc</b> <b>Page: 33</b></p> <p><b>Comment:</b> Change of terminology required.</p> <p><b>Justification:</b> 'Myocardial scintigraphy' is an obsolete term.</p> <p><b>Proposed Text:</b> Change 'myocardial scintigraphy' to '<b>myocardial perfusion imaging</b>'.</p> <p>NB This change should be applied throughout the text.</p>

response	<i>Accepted</i>	
comment	474	comment by: UK CAA
	<p><b>AMC A to MED.B.005 (b) 7</b>  <b>Page: 33</b>  <b>Comment:</b>  The requirements should be flexible to facilitate certification on anticoagulants in low risk cases.</p> <p><b>Justification:</b>  Anticoagulation is now much easier to monitor and control with individual monitoring devices being widely available.</p> <p>Recently some genetic conditions have been described for which anticoagulation may be prescribed prophylactically eg Factor V Leiden deficiency.</p> <p><b>Proposed Text:</b>  Add further sentence: <b>'Use of anticoagulant therapy for prophylaxis may be compatible with a fit assessment subject to multi pilot limitation following review by the licensing authority'.</b></p>	
response	<i>Partially accepted</i>	
	<p>The rule has been amended to change a complete unfit assessment to the possibility of a fit assessment after review either by the licensing authority (class 1) or in consultation with the licensing authority (class 2). The AMC will be amended to take this change into account.</p>	
comment	475	comment by: UK CAA
	<p><b>AMC A to MED.B.005 (b) 9.3</b>  <b>Page: 33</b>  <b>Comment:</b>  Text change to clarify that neurological review is not always necessary.</p> <p><b>Justification:</b>  Recurrence of a simple faint would not justify neurological review.</p> <p><b>Proposed Text:</b>  Change 'should' to 'may'.</p>	
response	<i>Not accepted</i>	
	<p>The assessment is also needed to distinguish recurrent vasovagal syncope from recurrence of simple faint.</p>	
comment	476	comment by: UK CAA
	<p><b>AMC A to MED.B.005 (c) 1</b>  <b>Page: 34</b>  <b>Comment:</b></p>	

A commercial pilot who develops hypertension should have a cardiovascular review.

**Justification:**

Hypertension is a powerful risk factor for cardiovascular events.

**Proposed Text:**

Amend to: 'The diagnosis of hypertension should require **cardiovascular review to include** potential vascular risk factors'.

response *Accepted*

comment

477

comment by: UK CAA

**AMC A to MED.B.005 (d) 4.2 (i)**

Page: 34

**Comment:**

Text change to clarify.

**Justification:**

'Rhythm disturbance' does not cover all conduction disorders.

**Proposed Text:**

Amend to: '...myocardial ischaemia **or** rhythm **or** conduction disturbance;'

response *Accepted*

comment

478

comment by: UK CAA

**AMC A to MED.B.005 (e) 5**

Page: 36

**Comment:**

Heading incorrect.

**Justification:**

More appropriate heading.

**Proposed Text:**

Change heading to '**Mobitz type 2 Atrio-ventricular Block.**'

response *Accepted*

The text will be changed accordingly.

comment

479

comment by: UK CAA

**AMC A to MED.B.005 (e) 6 (i)**

Page: 36

**Comment:**

Text change to clarify.

**Justification:**

response	<p>No point in stating a time period if it is negated by the use of the word 'approximately'.</p> <p><b>Proposed Text:</b> Delete 'approximately'.</p> <p><i>Accepted</i></p> <p>Thank you for the comment. The text will be changed accordingly.</p>
comment	<p>626 <span style="float: right;">comment by: <i>Lufthansa German Airlines</i></span></p>
	<p>Author: Dr. Christine Huber, Cardiologist, AMC Frankfurt Section: 2 Specific requirements for class 1 and class 2 medical certificates Chapter A AMC for Class 1 medical certificate Draft Version 3.0 <b>Page:</b> 31</p> <p>Relevant Text: 4. Aortic Aneurysm 4.2. Applicants may be assessed as fit by the licensing authority after surgery for an infra-renal aortic aneurysm with a multi-pilot limitation at revalidation if the blood pressure, exercise electrocardiographic response and cardiovascular assessment are satisfactory. Regular cardiological review should be required.</p> <p><b>Comment:</b> 4.2.) why regular cardiological assessments and exercise ecgs after surgery for infrarenal aneurysms?</p> <p><b>Proposal:</b> 4.2. Applicants may be assessed as fit by the licensing authority after surgery for an infra-renal aortic aneurysm with a multi-pilot limitation at revalidation if there is a good postoperative outcome and the blood pressure is normal or well treated with medication.</p>
response	<p><i>Partially accepted</i></p> <p>The text of the NPA will be changed to retain a corresponding JAR FCL 3 requirement. This includes cardiovascular assessment but does not specifically mention exercise electrocardiographic response.</p> <p>The possibility to require additional medical examinations and investigations is in MED.B.001(d).</p>
comment	<p>627 <span style="float: right;">comment by: <i>Lufthansa German Airlines</i></span></p>
	<p>Author: Dr. Christine Huber, Cardiologist, AMC Frankfurt Section: 2 Specific requirements for class 1 and class 2 medical certificates Chapter A AMC for Class 1 medical certificate Draft Version 3.0 <b>Page:</b> 17</p> <p>Relevant Text: 5. Cardiac Valvular Abnormalities 5.1. Applicants with previously unrecognised cardiac murmurs should require evaluation by a cardiologist and assessment by the licensing authority. If considered significant, further investigation should include at least 2D Doppler echocardiography. 5.2. Applicants with minor cardiac valvular abnormalities may be assessed as fit by the licensing authority. Applicants with significant abnormality of any of</p>

the heart valves should be assessed as unfit.

#### 5.2.1. Aortic Valve Disease

(i) Applicants with 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 mm Hg may be assessed as fit. Those with mean pressure gradient above 20 mm Hg but no greater than 40 mm Hg may be assessed as fit with a multi-pilot limitation. A mean pressure gradient up to 50 mm Hg may be acceptable. Follow-up with 2D Doppler echocardiography, as necessary, should be determined by the licensing authority.

(iii) Applicants with trivial aortic regurgitation may be assessed as fit. A greater degree of aortic regurgitation should require a 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.

#### 5.2.2. 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 a 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 should be assessed as unfit.

**Comment:** "If considered significant, further investigation should include at least 2D Doppler echocardiography". - a thorough cardiological evaluation is necessary.

"(ii) Applicants with aortic stenosis require licensing authority review." - why a licensing authority review and not a cardiological review?

"2D Doppler echocardiography", simply echocardiography is enough.

"no demonstrable abnormality of the ascending aorta on 2D Doppler echocardiography" - what kind of definition is this?

5.2.1 (iii) "Follow-up, as necessary" - who defines the "necessity"?

5.2.2.) assessment of mitral valve prolapse through echo or auscultation here?

(iv) uncomplicated moderate mitral regurgitation does not necessarily need an OML limitation. The rest of the explanation is unnecessary: LV dimensions and EF are o.k. if MI is moderate and there is no additional CAD, otherwise the degree of MI is misjudged. Satisfactory myocardial function is determined by echocardiography not by exercise ecg!

(v) nonsense: main issue here is the degree of the valve insufficiency, not volume overload or diameters.

Proposal: 5.1. Applicants with previously unrecognised cardiac murmurs should require evaluation by a cardiologist and assessment by the licensing authority.

If considered significant, a thorough cardiological evaluation has to be performed.

(ii) Applicants with aortic stenosis require a cardiological examination.

(iii) Applicants with trivial aortic regurgitation may be assessed as fit. A greater degree of aortic regurgitation should require a multi-pilot limitation. Follow-up, as necessary, should be determined by the licensing authority.

(iv) Applicants with uncomplicated moderate mitral regurgitation may be considered as fit. Periodic cardiological review should be required, as determined by the cardiologist and the licensing authority.

(v) Applicants with evidence of higher degrees of mitral regurgitation are assessed as unfit.

response *Noted*

1. The wording 'further investigation' and 'at least 2D Doppler echocardiography' is considered to be flexible for the cardiologist to determine further examinations that may have to be done.

2. The text in JAR-FCL 3 was: 'Applicants with aortic stenosis require AMS review'. This text was amendmended in the last version of JAR-FCL 3 (Amendment 5) and carried over to Part Medical. Also, only a cardiologist will be in a position to do the examinations that are required (measurement of pressure gradients).

3. As above, 2D Doppler echocardiography stems from JAR-FCL 3.

4. Text in JAR-FCL 3: There shall be no demonstrable abnormality of the ascending aorta on 2D Doppler echocardiographie.

5. (5.2.1(iii)) The NPA text is: Follow-up, as necessary, should be determined by the licensing authority.

6. Mitral valve prolapse will normally be assessed by a cardiologist (See subparas (iii), (iv)).

7. The difference is made between 'minor' in (iii) (OML may be needed) and 'moderate' in (iv) (OML should be imposed). The rest of the text is there to give an indication of what should be judged as 'moderate'.

8. The 'nonsense' was already in JAR-FCL 3 and can be corrected in the follow-up rulemaking task MED.001.

comment 628

comment by: *Lufthansa German Airlines*

Author: Dr. Christine Huber, Cardiologist, AMC Frankfurt  
 Section: 2 Specific requirements for class 1 and class 2 medical certificates  
 Chapter A AMC for Class 1 medical certificate  
 Draft Version 3.0  
**Page:** 32 / 33

Relevant Text: 6. Valvular surgery

Applicants with cardiac valve replacement/repair should be assessed as unfit. A fit assessment may be considered by the licensing authority.

6.1. Aortic valvotomy should be disqualifying.

6.2. Mitral leaflet repair for prolapse is compatible with a fit assessment provided post-operative investigations are satisfactory.

6.3. Asymptomatic applicants with a tissue valve who, at least 6 months following surgery, are taking no cardioactive medication may be considered for a fit assessment with a 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 scintigraphy/stress echocardiography should be required if the exercise ECG is abnormal or any coronary artery disease has been demonstrated.  
 (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.

**Comment:** why do they name special surgical procedures like the valvotomy and special examinations here. The other topics only mentioned cardiological evaluations - even in heart transplantation. What changed the attitude here??? Cardioactive medication can be a  $\beta$ -blocker without problems for the fitness to fly. Before a valve replacement takes place, every patient is checked for CAD anyway, it is useless to name exercise ecg in (i) here.

**Proposal:** : 6. Valvular surgery  
 Applicants with cardiac valve replacement/repair should be assessed as unfit. A fit assessment may be considered by the licensing authority provided good postoperative cardiological results and no anticoagulants are necessary. An OML limitation may be applied.

response

*Not accepted*

The proposed NPA text is a transposition of the corresponding requirements in JAR-FCL 3. However, the comment is valid and has been added to the list of tasks in the new rulemaking task MED.001.

Anticoagulation: please see response to comment No 474.

comment

629

comment by: *Lufthansa German Airlines*

Author: Dr. Christine Huber, Cardiologist, AMC Frankfurt  
 Section: 2 Specific requirements for class 1 and class 2 medical certificates  
 Chapter A AMC for Class 1 medical certificate  
 Draft Version 3.0  
**Page:** 33

Relevant Text:

8.2. Applicants with a congenital abnormality of the heart, including those who have undergone surgical correction, should be assessed as unfit. Applicants with minor abnormalities that are functionally unimportant, may be assessed as fit by the licensing authority following cardiological assessment. No cardioactive medication is acceptable. Investigations may include 2D Doppler echocardiography, exercise ECG and 24-hour ambulatory ECG. Regular cardiological review should be required.

**Comment:** 8.2.) why is a cardioactive medication not acceptable?  $\beta$ -blocker or ace-inhibitor? Why do they mention all the different cardiological examinations here again?

	<p><b>Proposal:</b> 8.2. Applicants with a congenital abnormality of the heart, including those who have undergone surgical correction, should be assessed as unfit. Applicants with minor abnormalities that are functionally unimportant, may be assessed as fit by the licensing authority following cardiological assessment. Regular cardiological review should be required.</p>
<p>response</p>	<p><i>Not accepted</i></p>
	<p>The proposed NPA text is a transposition of the corresponding requirement from JAR-FCL 3, Appendix 1 (12), which does not allow any medication. This has been amended in the NPA to read 'no cardioactive medication'.</p> <p>Further changes to the IRs/AMCs rule may be introduced through the new rulemaking task MED.001.</p>

<p>comment</p>	<p>631</p>	<p>comment by: <i>Lufthansa German Airlines</i></p>
	<p>Author: Dr. Christine Huber, Cardiologist, AMC Frankfurt</p> <p>Section: 2 Specific requirements for class 1 and class 2 medical certificates Chapter A AMC for Class 1 medical certificate Draft Version 3.0 <b>Page:</b> 36</p> <p>Relevant Text: 8. Ventricular preexcitation A fit assessment may be considered by the licensing authority. (i) Asymptomatic initial applicants with pre-excitation may be assessed as fit by the licensing authority 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 by the licensing authority at revalidation with a multi-pilot limitation.</p> <p>9. Pacemaker 9.1. Applicants with a subendocardial pacemaker should be assessed as unfit. A fit assessment may be considered at revalidation by the licensing authority no sooner than three months after insertion and should require: (i) no other disqualifying condition; (ii) a bipolar lead system; (iii) that the applicant is not pacemaker dependent; (iv) regular follow-up including a pacemaker check; and (v) a multi-pilot limitation. 9.2. Applicants with an anti-tachycardia pacemaker should be assessed as unfit.</p> <p>10. 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.</p> <p>11. Implantable Cardioverter Defibrillators Applicants with an automatic implantable defibrillating system should be assessed as unfit.</p> <p><b>Comment:</b> Preexcitation is enough, no "ventricular" in front necessary. 8(i) no inducible "sustained" re-entry tachycardia 9(ii) a bipolar lead system "programmed to bipolar not unipolar (new systems can be changed in lead polarity or might have an automatic change!)</p>	

9.2. there are atrial antitachycardia pacemakers as well - no chance for fitness according to this text

**Proposal: 8. Preexcitation**

A fit assessment may be considered by the licensing authority.

(i) Asymptomatic initial applicants with preexcitation may be assessed as fit by the licensing authority if an electrophysiological study, including adequate drug-induced autonomic stimulation reveals no inducible sustained reentry-tachycardia and the existence of multiple pathways is excluded.

(ii) Asymptomatic applicants with preexcitation may be assessed as fit by the licensing authority at revalidation with a multi-pilot limitation.

**9. Pacemaker**

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

(i) no other disqualifying condition;

(ii) a bipolar lead system, **programmed in bipolar mode without automatic mode change of the device**

(iii) that the applicant is not pacemaker dependent;

(iv) regular follow-up including a pacemaker check; and

(v) a multi-pilot limitation.

9.2. Applicants with a ventricular antitachycardia pacemaker should be assessed as unfit.

**10. 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.

**11. Implantable Cardioverter Defibrillators**

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

response *Partially accepted*

The proposed NPA text is a transposition of the corresponding requirement from JAR-FCL 3. However, the addition in 9.1 (ii) is accepted for clarity.

The justification to add 'ventricular' to 9.2 is not clear enough to amend the text.

comment

734

comment by: *Swiss Association of Aviation Medicine*

**Comment:** a conjunction with the licensing authority will not be necessary in all cases - only if necessary.

**Proposal:**

(b) General

1. Cardiovascular Risk Factor Assessment

1.2 An accumulation of risk factors (smoking, family history, lipid abnormalities, hypertension, etc.) should require cardiovascular evaluation by the AMC or AME in conjunction with the licensing authority if necessary.

response *Not accepted*

'In conjunction with the AMS' was added to appendix 1 of JAR-FCL 3 in the latest amendment. As JAR-FCL 3 is the basis of Part Medical, the text will not be changed at this stage.

The proposal of the comment will be considered in the coming rulemaking task MED.001.

comment	735	comment by: <i>Swiss Association of Aviation Medicine</i>
	<p><b>Comment:</b> not any other specialist, but a cardiologist</p> <p><b>Proposal:</b>          (b) General          2. <i>Cardiovascular Assessment</i>          2.1. Reporting of resting and exercise electrocardiograms should be by the AME or cardiologist.</p>	
response	Noted	
	Please see response to comment No 467.	

comment	736	comment by: <i>Swiss Association of Aviation Medicine</i>
	<p><b>Comment:</b> ultrasound is not always the best method for follow up, there are other imaging techniques available and this should be mentioned here. The exercise ecg is not the main issue after infra renal aneurysm surgery and cardiological reviews are not required here on a regular base.</p> <p><b>Proposal:</b>          (b) General          4. <i>Aortic Aneurysm</i>          4.1. Applicants with an aneurysm of the infra-renal abdominal aorta may be assessed as fit for class 1 with a multi-pilot limitation by the licensing authority. Follow-up by ultra-sound scans or other imaging techniques should be determined by the licensing authority.</p> <p>4.2. Applicants may be assessed as fit by the licensing authority after surgery for an infra-renal aortic aneurysm with a multi-pilot limitation at revalidation, if there is good postoperative outcome, the blood pressure is normal or well treated with medication and cardiovascular assessment is satisfactory.</p>	
response	Partially accepted	
	The text has been amended: 'Follow-up by ultra-sound scans or other imaging techniques as necessary ...'.	

comment	737	comment by: <i>Swiss Association of Aviation Medicine</i>
	<p><b>Comment:</b>Aortic and mitral valve disease are mentioned in a strange dimension into the depth of pressure gradients. This is unnecessary, it is the cardiologists work to judge on the severity of the disease and it does not have to be mentioned in that manner. The more precise and efficient version follows below.</p> <p><b>Proposal:</b>          5. <i>Cardiac Valvular Abnormalities</i>          5.1. Applicants for a class 1 medical certificate shall be assessed as unfit, when they have any significant valve disease including any of the following:</p>	

	(i) aortic stenosis (ii) aortic insufficiency (iii) mitral insufficiency (iv) mitral stenosis These applicants require a cardiological evaluation for a fit assessment by the licensing authority. A multipilot limitation may be applied. Periodic cardiological review should be required, as determined by the cardiologist and the licensing authority.
response	<i>Noted</i>
	The text was carried over from JAR-FCL 3 which was the basis for this NPA. The proposed text leads to a change that cannot be introduced at this stage.  The comment will be taken up in the rulemaking task MED.001.
comment	738 <i>comment by: Swiss Association of Aviation Medicine</i>
	<b>Comment:</b> specific cardiological parameters don't need to be mentioned here. Time frame is important as well as good postop results and OML might be necessary. Anticoagulants are no go items  <b>Proposal:</b> 6. <i>Valvular surgery</i> Applicants with cardiac valve replacement/repair should be assessed as unfit. A fit assessment may be considered by the licensing authority at a minimum of 6 month following surgery provided good postoperative cardiological results and no anticoagulants necessary. An multipilot limitation may be applied. Regular cardiological follow-up should be determined by the licensing authority.
response	<i>Noted</i>
	See response to comment No 628.
comment	739 <i>comment by: Swiss Association of Aviation Medicine</i>
	<b>Comment:</b> the above mentioned tests are included in a cardiological evaluation anyway and do not have to be mentioned. Cardioactive medications like $\beta$ -blocker or aspirin are acceptable in flying duty and might be necessary for secondary prevention. It is totally wrong to write "no cardioactive medication is acceptable".  <b>Proposal:</b> 8. <i>Other Cardiac Disorders</i> 8.1. 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. Periodic cardiological review and a multipilot limitation may be required. 8.2. Applicants with a congenital abnormality of the heart, including those who have undergone surgical correction, should be assessed as unfit. Applicants with abnormalities that are functionally unimportant, may be assessed as fit by the licensing authority following cardiological evaluation. Regular cardiological reviews should be required and a multipilot limitation may be applied.
response	<i>Noted</i>

Please see response to comment No 629.

comment 740 comment by: *Swiss Association of Aviation Medicine*

**Comment:** one single syncope is sufficient and relevant and needs further investigation neurologically and cardiologically. Special exams need not be mentioned here, but reviews and limitations.

**Proposal:**

*9. Syncope*

9.1. Applicants with a history of syncope should be assessed as unfit. A fit assessment may be considered by the licensing authority.

9.2. A cardiological and a neurological review should be required.

9.3. A multipilot limitation and periodical reviews may applied.

response *Noted*

The title wording will be changed to 'Syncope'.

The text of the AMC reflects the rule in Appendix 1 (13) in JAR-FCL 3. Further changes to the text may be discussed in a new rulemaking task.

comment 741 comment by: *Swiss Association of Aviation Medicine*

**Comment:** AT 1 blocking agents are missing, not vertain, but preferably hydrophilic  $\beta$ -blockers should be used.

**Proposal:**

**BLOOD PRESSURE**

1. The diagnosis of hypertension should require review of other potential vascular risk factors.

2. The initiation of hypertensive treatment requires the control of blood pressure and reassessment of the application, to verify that the treatment is compatible with the safe exercise of the privileges of the licence held.

3. Antihypertensive treatment should be agreed by the licensing authority.

Preferable medications for an antihypertensive treatment include:

(i) non loop diuretic agents;

(ii) ACE Inhibitors;

(iii) angiotensin II and AT 1 blocking agents;

(iv) slow channel calcium blocking agents;

(v) preferably hydrophilic) betablocking agents.

response *Noted*

'Certain (generally hydrophylic) beta-blocking agents' are included in paragraph (c) 2.(v) of the NPA.

comment 742 comment by: *Swiss Association of Aviation Medicine*

**Comment:** in English it is spelled "ischemia", not ischaemia! 1-4 only minor corrections for more precise definitions; more than two stenosis are relevant, if they are located in major coronary vessels and not in small, unimportant vessels.

There are several tests equivalent to perfusion scan, so the opportunity is necessary to use either one of them and to decide in each separate case which one will be best for a good evaluation.

**Proposal:**

**(d) CORONARY ARTERY DISEASE**

1. Chest pain of uncertain cause should require full cardiological investigation.
2. In suspected coronary artery disease, a cardiological evaluation is required.
3. Evidence of myocardial ischemia or significant coronary artery stenosis should be disqualifying.
4. After an ischemic cardiac event, including revascularisation, applicants without symptoms should have reduced any vascular risk and should be on acceptable secondary prevention treatment.
  - 4.1. unchanged
    - (i) 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 leading to an infarct. More than two stenoses between 30% and 50% within major coronary vessels should not be acceptable.
    - (ii) and (iii) unchanged
  - 4.2. and (i), (ii) unchanged
    - (iii) in cases of angioplasty/stenting, a myocardial perfusion scan or equivalent tests, which should show no evidence of reversible myocardial ischemia. If there is any doubt about myocardial perfusion in other cases (infarction or bypass grafting) a perfusion scan or equivalent tests should also be required;
    - (iv) further investigations, such as a 24 hour ECG, may be necessary to assess the risk of any significant rhythm disturbance.
  - 4.3. Follow up should be yearly (or more frequently, if necessary) to ensure that there is no deterioration of cardiovascular status.
  - 4.4. After coronary artery bypass grafting, a myocardial perfusion scan or equivalent tests should be performed if there is any indication, and in all cases within 5 years from the procedure.
  - 4.5. and 4.6. unchanged

response

*Not accepted*

**Spelling**

We took the spelling from the current version ICD - 10 (I20 - I25) and prefer not to change it.

**Proposal**

The proposed NPA text is a transposition of the corresponding requirement from JAR-FCL 3. The proposal in this comment (and numerous others) would lead to less prescriptive medical provisions. This may be an option for the future but it has to be taken into account that it would lead to different ways to assess medical fitness of pilots around Europe. Therefore, a careful analysis of the effect would be needed. However, the first step in this direction has already been done in this NPA by removing all rules in the Appendices in JAR-FCL 3 to AMCs.

The possibility to require additional medical examinations and investigations is proposed in MED.B.001(d).

comment

743

comment by: *Swiss Association of Aviation Medicine*

**Comment:** The first sentence is the relevant one, the others are unnecessary, as they routinely are required for a sufficient cardiological evaluation.

**Proposal:**

**(e) RHYTHM AND CONDUCTION DISTURBANCES**

response	<p>1. Any significant rhythm or conduction disturbance should require evaluation by a cardiologist and appropriate follow up in the case of a fit assessment.</p> <p><i>Noted</i></p> <p>Please see response to comment No 743.</p>	
comment	744	comment by: <i>Swiss Association of Aviation Medicine</i>
	<p><b>Comment:</b> An OML is not necessarily related to the age of 40 and might be necessary even below that age and in some cases will not be necessary above the age of 40. The sentence for the necessity of the cardiological evaluation is missing in the section for left bundle branch block.</p> <p><b>Proposal:</b> 6. and (i) unchanged (ii) For revalidation a fit assessment may be considered if the applicant is under 40 years. A multipilot limitation may be applied. 7. <i>Complete left bundle branch block</i> Applicants with complete left bundle branch block should require cardiological evaluation on first Presentation. A fit assessment may be considered by the licensing authority. (i), (ii), (iii) unchanged</p>	
response	<p><i>Not accepted</i></p> <p>The proposed NPA text is a transposition of the corresponding requirement from JAR-FCL 3.</p> <p>The comment on age will be taken up in the rulemaking task MDM.001</p>	
comment	745	comment by: <i>Swiss Association of Aviation Medicine</i>
	<p><b>Comment:</b> the inducibility of a <u>sustained</u> reentry tachycardia is relevant; if the tachycardia blocks after a few beats, it is irrelevant.</p> <p><b>Proposal:</b> (i) Asymptomatic initial applicants with preexcitation may be assessed as fit by the licensing authority if an electrophysiological study, including adequate drug induced autonomic stimulation reveals no inducible, sustained reentry tachycardia and the existence of multiple pathways is excluded.</p>	
response	<p><i>Not accepted</i></p> <p>The proposed NPA text is a transposition of the corresponding requirement in JAR-FCL 3. Further changes will be introduced in a future rulemaking task.</p>	
comment	746	comment by: <i>Swiss Association of Aviation Medicine</i>
	<p><b>Comment:</b> new pacemaker devices have a lot of automatic mode changes and some will have an automatic change between bipolar and unipolar sensing and pacing, so it is useless to insist on bipolar electrodes, if they are programmed to unipolar mode in the end. There seems to be a misunderstanding of antitachycardia pacemakers. Most pacemaker devices have some antitachycardia programme settings. Such a</p>	

device is not the same as an AICD. The sentence 9.2. should be deleted, it is nonsense.

**Proposal:**

9. *Pacemaker*

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

- (i) no other disqualifying condition;
- (ii) a bipolar lead system programmed in bipolar mode without automatic mode change of the device;
- (iii) that the applicant is not pacemaker dependent;
- (iv) regular followup including a pacemaker check;
- (v) a multipilot limitation.

9.2. deleted

response *Accepted*

Paragraph 9.2 will be deleted.

comment

1000

comment by: *European Society of Space and Aviation Medicine (ESAM)*

**Author: European Society of Space and Aviation Medicine (ESAM) - Cardiology Group -**

**Subpart B Requirements for medical certificates**

**Section: 1 Specific requirements for class 1 and class 2 medical certificates**

**Chapter A AMC for class 1 medical certificates**

**Page: 31 - 32**

**Relevant Text:**

(b) General

*4. Aortic Aneurysm*

4.1. Applicants with an aneurysm of the infra-renal abdominal aorta may be assessed as fit for class 1 with a multi-pilot () limitation by the licensing authority. Follow-up by ultra-sound scans, as necessary, should be determined by the licensing authority.

4.2. Applicants may be assessed as fit by the licensing authority after surgery for an infra-renal aortic aneurysm with a multi-pilot limitation at revalidation if the blood pressure, exercise electrocardiographic response and cardiovascular assessment are satisfactory. Regular cardiological review should be required.

**Comment:** ultrasound is not always the best method for follow up, there are other imaging techniques available and this should be mentioned here. The exercise ecg is not the main issue after infra renal aneurysm surgery and cardiological reviews are not required here on a regular base.

**Proposal:**

(b) General

*4. Aortic Aneurysm*

4.1. Applicants with an aneurysm of the infra-renal abdominal aorta may be assessed as fit for class 1 with a multi-pilot limitation by the licensing authority. Follow-up by ultra-sound scans or other imaging techniques should

be determined by the licensing authority.

4.2. Applicants may be assessed as fit by the licensing authority after surgery for an infra-renal aortic aneurysm with a multi-pilot limitation at revalidation, if there is good postoperative outcome, the blood pressure is normal or well treated with medication and cardiovascular assessment is satisfactory.

response *Noted*

Please see response to identical comment under No 736.

comment

1001

comment by: *European Society of Space and Aviation Medicine (ESAM)*

**Author: European Society of Space and Aviation Medicine (ESAM) - Cardiology Group -**

**Subpart B Requirements for medical certificates**

**Section: 1 Specific requirements for class 1 and class 2 medical certificates**

**Chapter A AMC for class 1 medical certificates**

**Page: 32**

**Relevant Text:**

*5. Cardiac Valvular Abnormalities*

5.1. Applicants with previously unrecognised cardiac murmurs should require evaluation by a cardiologist and assessment by the licensing authority. If considered significant, further investigation should include at least 2D Doppler echocardiography.

5.2. 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.

**5.2.1. Aortic Valve Disease**

(i) Applicants with 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 embol is mor significant dilatation of the thoracic aorta is disqualifying.

Those with a mean pressure gradient of up to 20 mm Hg may be assessed as fit. Those with mean pressure gradient above 20 mm Hg but no greater than 40 mm Hg may be assessed as fit with a multipilot limitation. A mean pressure gradient up to 50 mm Hg may be acceptable. Follow up with 2D Doppler echocardiography, as necessary, should be determined by the licensing authority.

(iii) Applicants with trivial aortic regurgitation may be assessed as fit. A greater degree of aortic regurgitation should require a multipilot limitation. There should be no demonstrable abnormality of the ascending aorta on 2D Doppler echocardiography. Followup, as necessary, should be determined by the licensing authority.

**5.2.2. Mitral Valve Disease**

- (i) Asymptomatic applicants with an isolated midsystolic 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 a multipilot 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 enddiastolic diameter should be assessed as unfit.

**Comment:** Aortic and mitral valve disease are mentioned in a strange dimension into the depth of pressure gradients. This is unnecessary, it is the cardiologists work to judge on the severity of the disease and it does not have to be mentioned in that manner. The more precise and efficient version follows below.

**Proposal:**

5. *Cardiac Valvular Abnormalities*

5.1. Applicants for a class 1 medical certificate shall be assessed as unfit, when they have any significant

valve disease including any of the following:

- (i) aortic stenosis
- (ii) aortic insufficiency
- (iii) mitral insufficiency
- (iv) mitral stenosis

These applicants require a cardiological evaluation for a fit assessment by the licensing authority. A multipilot limitation may be applied. Periodic cardiological review should be required, as determined by the cardiologist and the licensing authority.

response

*Noted*

Please see response to identical comment under No 737.

comment

1002      comment by: *European Society of Space and Aviation Medicine (ESAM)*

**Author: European Society of Space and Aviation Medicine (ESAM) - Cardiology Group -**

**Subpart B Requirements for medical certificates**

**Section: 1 Specific requirements for class 1 and class 2 medical certificates**

**Chapter A AMC for class 1 medical certificates**

**Page: 32 - 33**

**Relevant Text:**

6. *Valvular surgery*

Applicants with cardiac valve replacement/repair should be assessed as unfit.

A fit assessment may be considered by the licensing authority.

6.1. Aortic valvotomy should be disqualifying.

6.2. Mitral leaflet repair for prolapse is compatible with a fit assessment provided postoperative investigations are satisfactory.

6.3. Asymptomatic applicants with a tissue valve who, at least 6 months following surgery, are taking no cardioactive medication may be considered for fit assessment with a multipilot 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 scintigraphy/stress echocardiography should be required if the exercise ECG is abnormal or any coronary artery disease has been demonstrated.

(ii) a 2D Doppler echocardiogram showing no significant selective chamber enlargement, a tissue valve with minimal structural alteration and a normal Doppler bloodflow, 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.

**Comment:** specific cardiological parameters don't need to be mentioned here. Time frame is important as well as good postop results and OML might be necessary. Anticoagulants are no go items

**Proposal:**

6. *Valvular surgery*

Applicants with cardiac valve replacement/repair should be assessed as unfit. A fit assessment may be considered by the licensing authority at a minimum of 6 month following surgery provided good postoperative cardiological results and no anticoagulants necessary. An multipilot limitation may be applied. Regular cardiological follow-up should be determined by the licensing authority.

response *Noted*

Please see response to identical comment under No 738.

comment

1003

comment by: *European Society of Space and Aviation Medicine (ESAM)*

**Author: European Society of Space and Aviation Medicine (ESAM) - Cardiology Group -**

**Subpart B Requirements for medical certificates**

**Section: 1 Specific requirements for class 1 and class 2 medical certificates**

**Chapter A AMC for class 1 medical certificates**

**Page: 33**

**Relevant Text:**

8. *Other Cardiac Disorders*

8.1. 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 scintigraphy/stress

echocardiography and 24 hour ambulatory ECG. Coronary angiography may be indicated.

Frequent review and a multipilot limitation may be required after fit assessment.

8.2. Applicants with a congenital abnormality of the heart, including those who have undergone surgical correction, should be assessed as unfit. Applicants with minor abnormalities, that are functionally unimportant may be assessed as fit by the licensing authority following cardiological assessment. No cardioactive medication is acceptable. Investigations may include 2D Doppler echocardiography, exercise ECG and 24hour ambulatory ECG. Regular cardiological review should be required.

**Comment:** the above mentioned tests are included in a cardiological evaluation anyway and do not have to be mentioned. Cardioactive medications like  $\beta$ -blocker or aspirin are acceptable in flying duty and might be necessary for secondary prevention. It is totally wrong to write "no cardioactive medication is acceptable".

**Proposal:**

8. *Other Cardiac Disorders*

8.1. 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. Periodic cardiological review and a multipilot limitation may be required.

8.2. Applicants with a congenital abnormality of the heart, including those who have undergone surgical correction, should be assessed as unfit. Applicants with abnormalities that are functionally unimportant, may be assessed as fit by the licensing authority following cardiological evaluation. Regular cardiological reviews should be required and a multipilot limitation may be applied.

response

*Noted*

Please see response to identical comment under No 739.

comment

1004

comment by: *European Society of Space and Aviation Medicine (ESAM)*

**Author: European Society of Space and Aviation Medicine (ESAM) - Cardiology Group -**

**Subpart B Requirements for medical certificates**

**Section: 1 Specific requirements for class 1 and class 2 medical certificates**

**Chapter A AMC for class 1 medical certificates**

**Page: 33 - 34**

**Relevant Text:**

*9. Recurrent Vasovagal Syncope*

9.1. 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 scintigraphy/stress

echocardiography should be required.  
 (ii) a 2D Doppler echocardiogram showing no significant selective chamber enlargement nor structural or functional abnormality of the heart, valves or myocardium.  
 (iii) a 24hour ambulatory ECG recording showing no conduction disturbance, complex or sustained rhythm disturbance or evidence of myocardial ischemia.  
 9.2. A tilt test carried out to a standard protocol showing no evidence of vasomotor instability may be required.  
 9.3. Neurological review should be required.  
 9.4. A multipilot 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 multipilot limitation according to the individual circumstances of the case.  
 9.5. Applicants who experienced loss of consciousness without significant warning should be assessed as unfit.

**Comment:** one single syncope is sufficient and relevant and needs further investigation neurologically and cardiologically. Special exams need not be mentioned here, but reviews and limitations.

**Proposal:**

*9. Syncope*

- 9.1. Applicants with a history of syncope should be assessed as unfit. A fit assessment may be considered by the licensing authority.
- 9.2. A cardiological and a neurological review should be required.
- 9.3. A multipilot limitation and periodical reviews may be applied.

response

*Noted*

Please see response to identical comment under No 740.

comment

1005      comment by: *European Society of Space and Aviation Medicine (ESAM)*

**Author: European Society of Space and Aviation Medicine (ESAM) - Cardiology Group -**

**Subpart B Requirements for medical certificates**

**Section: 1 Specific requirements for class 1 and class 2 medical certificates**

**Chapter A AMC for class 1 medical certificates**

**Page: 34**

**Relevant Text:**

**© BLOOD PRESSURE**

- 1. The diagnosis of hypertension should require review of other potential vascular risk factors.
- 2. Antihypertensive treatment should be agreed by the licensing authority. Medication acceptable to the licensing authority may include:
  - (i) non loop diuretic agents;
  - (ii) ACE Inhibitors;
  - (iii) angiotensin II blocking agents(sartans);
  - (iv) slow channel calcium blocking agents;
  - (v) certain (generally hydrophilic) betablocking agents.
- 3. Following initiation of medication for the control of blood pressure,

applicants should be reassessed to verify that the treatment is compatible with the safe exercise of the privileges of the licence held.

**Comment:** AT 1 blocking agents are missing, not vertain, but preferably hydrophilic  $\beta$ -blockers should be used.

**Proposal:**

© **BLOOD PRESSURE**

1. The diagnosis of hypertension should require review of other potential vascular risk factors.

2. The initiation of hypertensive treatment requires the control of blood pressure and reassessment of the application, to verify that the treatment is compatible with the safe exercise of the privileges of the licence held.

3. Antihypertensive treatment should be agreed by the licensing authority. Preferable medications for an antihypertensive treatment include:

- (iv) non loop diuretic agents;
- (v) ACE Inhibitors;
- (vi) angiotensin II and AT 1 blocking agents;

(iv) slow channel calcium blocking agents;

(v) preferably hydrophilic) betablocking agents.

response *Noted*

Please see response to identical comment under No 741.

comment

1006

comment by: *European Society of Space and Aviation Medicine (ESAM)*

**Author: European Society of Space and Aviation Medicine (ESAM) - Cardiology Group -**

**Subpart B Requirements for medical certificates**

**Section: 1 Specific requirements for class 1 and class 2 medical certificates**

**Chapter A AMC for class 1 medical certificates**

**Page: 34 - 35**

**Relevant Text:**

**(d) CORONARY ARTERY DISEASE**

1. Chest pain of uncertain cause should require full investigation.

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. Evidence of exercise induced myocardial ischaemia should be disqualifying.

4. After an ischaemic cardiac event, including evascularisation, applicants without symptoms should have reduced any vascular risk factors to an appropriate level. Medication, when used to control cardiac symptoms, is not acceptable. All applicants should be on acceptable secondary prevention treatment.

4.1. A coronary angiogram obtained around the time of, or during, the ischaemic cardiac event and a complete, detailed clinical report of the ischaemic event, the angiogram and any operative procedures should be available to the licensing authority:

(i) 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 leading to an infarct. More than two stenoses between 30% and 50% within the vascular tree should not be acceptable.

(ii) 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.

(iii) An untreated stenosis greater than 30% in the left main or proximal left anterior descending coronary artery should not be acceptable.

4.2. At least 6 months from the ischaemic cardiac event, including revascularisation, the following investigations should be completed (equivalent tests may be substituted):

- (i) an exercise ECG showing no evidence of myocardial ischaemia nor rhythm disturbance;

(ii) 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;

- (ii) in cases of angioplasty/stenting, a myocardial perfusion scan or stress echocardiogram 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 should also be required;

(iv) further investigations, such as a 24 hour ECG, may be necessary to assess the risk of any significant rhythm disturbance.

- 4.3. Follow up should be yearly (or more frequently if necessary) to ensure that there is no deterioration of cardiovascular status. It should include a review by a cardiologist, exercise ECG and cardio-vascular risk assessment. Additional investigations may be required by the licensing authority.

4.4. 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.

4.5. In all cases coronary angiography shall be considered at any time if symptoms, signs or non invasive tests indicate cardiac ischemia.

4.6. Successful completion of the six month or subsequent review will allow a fit assessment with a multipilot limitation.

**Comment:** in English it is spelled "ischemia", not ischaemia! 1-4 only minor corrections for more precise definitions; more than two stenosis are relevant, if they are located in major coronary vessels and not in small, unimportant vessels.

There are several tests equivalent to perfusion scan, so the opportunity is necessary to use either one of them and to decide in each separate case which one will be best for a good evaluation.

**Proposal:**

**(d) CORONARY ARTERY DISEASE**

1. Chest pain of uncertain cause should require full cardiological investigation.
2. In suspected coronary artery disease, a cardiological evaluation is required.
3. Evidence of myocardial ischemia or significant coronary artery stenosis should be disqualifying.
4. After an ischemic cardiac event, including revascularisation, applicants without symptoms should have reduced any vascular risk and should be on acceptable secondary prevention treatment.

4.1. unchanged

(i) 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 leading to an infarct. More than two stenoses between 30% and 50% within major coronary vessels should not be acceptable.

(ii) and (iii) unchanged

- 4.2. and (i), (ii) unchanged

(iii) in cases of angioplasty/stenting, a myocardial perfusion scan or equivalent tests, which should show no evidence of reversible myocardial ischemia. If there is any doubt about myocardial perfusion in other cases (infarction or bypass grafting) a perfusion scan or equivalent tests should also be required;

(iv) further investigations, such as a 24 hour ECG, may be necessary to assess the risk of any significant rhythm disturbance.

- 4.4. Follow up should be yearly (or more frequently, if necessary) to ensure that there is no deterioration of cardiovascular status.

4.4. After coronary artery bypass grafting, a myocardial perfusion scan or equivalent test should be performed if there is any indication, and in all cases within 5years from the procedure.

4.5. and 4.6. unchanged

response *Noted*

Please see response to identical comment under No 742.

comment

1007

comment by: *European Society of Space and Aviation Medicine (ESAM)*

**Author: European Society of Space and Aviation Medicine (ESAM) - Cardiology Group -**

**Subpart B Requirements for medical certificates**

**Section: 1 Specific requirements for class 1 and class 2 medical certificates**

**Chapter A AMC for class 1 medical certificates**

**Page: 35**

**Relevant Text:**

**(e) RHYTHM AND CONDUCTION DISTURBANCES**

1. Any significant rhythm or conduction disturbance should require evaluation by a cardiologist and appropriate follow up in the case of a fit assessment. 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 be considered.

(ii) 24hour 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) Repeated 24hour ECG recording;

- (i) Electrophysiological study;
- (ii) Myocardial perfusion scanning;
- (iii) Cardiac MRI;

(viii) Coronary angiogram.

2. Applicants with frequent or complex forms of supra entricular or ventricular ectopic complexes require full cardiological evaluation.

**Comment:** The first sentence is the relevant one, the others are unnecessary, as they routinely are required for a sufficient cardiological evaluation.

**Proposal:**

**(e) RHYTHM AND CONDUCTION DISTURBANCES**

1. Any significant rhythm or conduction disturbance should require evaluation by a cardiologist and appropriate follow up in the case of a fit assessment.

response *Noted*

Please see response to identical comment under No 743.

comment

1008

comment by: *European Society of Space and Aviation Medicine (ESAM)*

**Author: European Society of Space and Aviation Medicine (ESAM) - Cardiology Group -**

**Subpart B Requirements for medical certificates**

**Section: 1 Specific requirements for class 1 and class 2 medical certificates**

**Chapter A AMC for class 1 medical certificates**

**Page: 36**

**Relevant Text:**

*6. Complete right bundle branch block*

Applicants with complete right bundle branch block should require cardiological evaluation on first presentation and subsequently:

(i) For initial applicants under 40 years of age a fit assessment may be considered by the licensing authority. Initial applicants over 40 years should demonstrate a period of stability of approximately 12 months.

(ii) For revalidation a fit assessment may be considered if the applicant is under 40 years. A multipilot limitation should be applied for 12 months for those over 40 years of age.

*7. Complete left bundle branch block*

A fit assessment may be considered by the licensing authority.

(i) Initial applicants should demonstrate a 3 year period of stability.

(ii) For revalidation, after a 3 year period with a multipilot limitation applied, a fit assessment without a multipilot limitation may be considered.

(iii) Investigation of the coronary arteries is necessary for applicants over age 40.

**Comment:** An OML is not necessarily related to the age of 40 and might be necessary even below that age and in some cases will not be necessary above the age of 40.

The sentence for the necessity of the cardiological evaluation is missing in the section for left bundle branch block.

**Proposal:**

6. and (i) unchanged

(ii) For revalidation a fit assessment may be considered if the applicant is

response	<p>under 40 years. A multipilot limitation may be applied.  7. <i>Complete left bundle branch block</i>  Applicants with complete left bundle branch block should require cardiological evaluation on first Presentation. A fit assessment may be considered by the licensing authority.  (i), (ii), (iii) unchanged</p> <p><i>Noted</i></p> <p>Please see response to identical comment under No 744.</p>	
comment	1009	<p>comment by: <i>European Society of Space and Aviation Medicine (ESAM)</i></p> <p><b>Author: European Society of Space and Aviation Medicine (ESAM) - Cardiology Group -</b></p> <p><b>Subpart B Requirements for medical certificates</b>  <b>Section: 1 Specific requirements for class 1 and class 2 medical certificates</b>  <b>Chapter A AMC for class 1 medical certificates</b></p> <p><b>Page: 36</b></p> <p><b>Relevant Text:</b>  8. <i>Ventricular preexcitation</i>  A fit assessment may be considered by the licensing authority.  (i) Asymptomatic initial applicants with preexcitation may be assessed as fit by the licensing authority if an electrophysiological study, including adequate drug induced autonomic stimulation reveals no inducible reentry tachycardia and the existence of multiple pathways is excluded.  (ii) Asymptomatic applicants with preexcitation may be assessed as fit by the licensing authority at revalidation with a multipilot limitation.</p> <p><b>Comment:</b> the inducibility of a <u>sustained</u> reentry tachycardia is relevant; if the tachycardia blocks after a few beats, it is irrelevant.</p> <p><b>Proposal:</b>  (i) Asymptomatic initial applicants with preexcitation may be assessed as fit by the licensing authority if an electrophysiological study, including adequate drug induced autonomic stimulation reveals no inducible, sustained reentry tachycardia and the existence of multiple pathways is excluded.</p>
response	<p><i>Noted</i></p> <p>Please see response to identical comment under No 745.</p>	
comment	1010	<p>comment by: <i>European Society of Space and Aviation Medicine (ESAM)</i></p> <p><b>Author: European Society of Space and Aviation Medicine (ESAM) - Cardiology Group -</b></p> <p><b>Subpart B Requirements for medical certificates</b>  <b>Section: 1 Specific requirements for class 1 and class 2 medical certificates</b></p>

**Chapter A AMC for class 1 medical certificates****Page:** 36 - 37**Relevant Text:***9. Pacemaker*

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

- (i) no other disqualifying condition;
- (ii) a bipolar lead system;
- (iii) that the applicant is not pacemaker dependent;
- (iv) regular follow up including a pacemaker check;
- (v) a multipilot limitation.

9.2. Applicants with an antitachycardia pacemaker should be assessed as unfit.

**Comment:** new pacemaker devices have a lot of automatic mode changes and some will have an automatic change between bipolar and unipolar sensing and pacing, so it is useless to insist on bipolar electrodes, if they are programmed to unipolar mode in the end.

There seems to be a misunderstanding of antitachycardia pacemakers. Most pacemaker devices have some antitachycardia programme settings. Such a device is not the same as an AICD. The sentence 9.2. should be deleted, it is nonsense.

**Proposal:***9. Pacemaker*

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

- (i) no other disqualifying condition;
- (ii) a bipolar lead system programmed in bipolar mode without automatic mode change of the device;
- (iii) that the applicant is not pacemaker dependent;
- (iv) regular follow up including a pacemaker check;
- (v) a multipilot limitation.

9.2. deleted

response *Noted*

Please see response to identical comment under No 746.

comment 1011 comment by: *European Society of Space and Aviation Medicine (ESAM)*

**Author: European Society of Space and Aviation Medicine (ESAM) - Cardiology Group -**

**Subpart B Requirements for medical certificates**

**Section: 1 Specific requirements for class 1 and class 2 medical certificates**

**Chapter A AMC for class 1 medical certificates**

**Page:** 37

**Relevant Text:**

10. *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.

11. *Implantable Cardioverter Defibrillators*

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

**Comment:** 11. it is already mentioned on page 12 and it's unnecessary to repeat that here.

**Proposal:**

10. unchanged

11. deleted

response *Accepted*

Thank you for the comment. The text will be changed accordingly.

comment

1030

comment by: *Ilse Janicke Heart Center Duisburg*

Author: Janicke Ilse, Senior MD, AME I and II, Cardiologist and Angiologist at Heart Center Duisburg

Section: **Subpart B Requirements for Medical Certificates**

Section 1 Specific requirements for class 1 and class 2 medical certificates

**Chapter A AMC for class 1 medical certificates**

**AMC A to MED.B.005 Cardiovascular System - Class 1 medical certificates**

**Page:** 31/32 (NPA 2008-17c)

Relevant Text: **4. Aortic aneurysm**

4.2. Applicants may be assessed as fit by the licensing authority after surgery for an infra-renal aortic aneurysm with a multi-pilot limitation at revalidation if the blood pressure, exercise electrocardiographic response and cardiovascular assessment are satisfactory. Regular cardiological review should be required.

**Comment:**

why regular cardiological assessments and exercise ECG`s after surgery for infrarenal aneurysms?

**Proposal:**

4.2. Applicants may be assessed as fit by the licensing authority after surgery for an infra-renal aortic aneurysm with a multi-pilot limitation at revalidation if there is a good postoperative outcome, the blood pressure is normal or well treated with medication and cardiovascular assessment is satisfactory.

response *Noted*

Please see response to identical comment under No 626.

comment

1031

comment by: *Ilse Janicke Heart Center Duisburg*

Author: Janicke Ilse, Senior MD, AME I and II, Cardiologist and Angiologist at Heart Center Duisburg

Section: **Subpart B Requirements for Medical Certificates**

Section 1 Specific requirements for class 1 and class 2 medical certificates

**Chapter A AMC for class 1 medical certificates  
AMC A to MED.B.005 Cardiovascular System - Class 1 medical certificates**

**Page:** 32 (NPA 2008-17c)

**Relevant Text: 5. Cardiac Valvular Abnormalities**

**5.2.1 Aortic valve disease**

(iii) ....There should be no demonstrable abnormality of the ascending aorta on 2D Doppler echocardiography....

**5.2.2. Mitral Valve Disease**

(V) Applicants with evidence of volume overloading of the left ventricle demonstrated by increased left ventricular end-diastolic diameter should be assessed as unfit.

**Comment:**

Aortic valve disease: In 2D Doppler echocardiography often one can not assess well enough the ascending aorta. Other methods like MRA or CT will be suitable too.

MV-Disease: This is correct, but belongs to significant MI (even asymptomatic), is equal to or greater than Grade III, enlarged enddiastolic diameter (> 60 mm) and /or endsystolic diameter > 40 mm (indication for surgery) and/or TIA is disqualifying for all classes.

On the other hand secondary mitral insufficiency appears in all dilatative diseases of the left ventricle.

**Proposal:**

(iii) ....There should be no demonstrable abnormality like significant dilatation or dissection of the ascending aorta on 2D Doppler echocardiography or equivalent test (MRA,CT-scan)...

(v) Applicants with evidence of higher degrees of mitral regurgitation and/or volume overloading of the left ventricle demonstrated by increased left ventricular end-diastolic diameter should be assessed as unfit

response

*Not accepted*

The proposed NPA text is a transposition of the corresponding requirement from JAR FCL 3. Additional requirements in the implementing rule may be introduced only through a new rulemaking task.

The possibility to require additional medical examinations and investigations is proposed in MED.B.001(d).

comment

1032

comment by: *Ilse Janicke Heart Center Duisburg*

Author: Janicke Ilse, Senior MD, AME I and II, Cardiologist and Angiologist at Heart Center Duisburg

**Section: Subpart B Requirements for Medical Certificates**

Section 1 Specific requirements for class 1 and class 2 medical certificates

**Chapter A AMC for class 1 medical certificates**

**AMC A to MED.B.005 Cardiovascular System - Class 1 medical certificates**

**Page:** 33 (NPA 2008-17c)

**Relevant Text: 6. Valvular surgery**

6.3. Asymptomatic applicants with a tissue valve who, at least 6 months following surgery, are taking no cardioactive medication may be considered for

a fit assessment with a multi-pilot limitation by the licensing authority....  
 (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.....

**Comment:**

Cardioactive medication can be a  $\beta$ -blocker without problems for the fitness to fly.  
 More important is discontinouing systemic anticoagulation which takes place normally up to 3 months after tissue valve surgery or repair.  
 Very young patients are not checked for CAD before valve surgery.  
 Some biological valves or some repair are not leading to normal Doppler blood flow but there is no significant stenosis or insufficiency.

**Proposal:**

**6. Valvular surgery**

Applicants with cardiac valve replacement/repair should be assessed as unfit. A fit assessment may be considered by the licensing authority provided good postoperative cardiological results and no anticoagulants are necessary. An OML limitation may be applied.

(ii) a 2D Doppler echocardiogram showing no significant selective chamber enlargement, a tissue valve with minimal structural alteration and without significant changes in Doppler blood flow,.....

response *Noted*

See response to comment No 628.

comment

1033

comment by: *Ilse Janicke Heart Center Duisburg*

Author: Janicke Ilse, Senior MD, AME I and II, Cardiologist and Angiologist at Heart Center Duisburg

Section:

**Subpart B Requirements for Medical Certificates**

Section 1 Specific requirements for class 1 and class 2 medical certificates

**Chapter A AMC for class 1 medical certificates**

**AMC A to MED.B.005 Cardiovascular System - Class 1 medical certificates**

**Page:** 33 (NPA 2008-17c)

Relevant Text: **8. Other Cardiac disorders**

8.1 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 Dopplerechocardiography, exercise ECG and/or myocardial szintigraphy/stress echcardiography and 24-hour ambulatory ECG.....

**Comment:**

It is not necessary to mention all these examinations, if one will follow so cardiac MRI or equivalent test should be included.

**Proposal:**

8.1 ...A fit assessment may be considered by the licensing authority following complete resolution and satisfactory full assessment by a cardiologist.

response	<p data-bbox="352 203 440 232"><i>Noted</i></p> <p data-bbox="352 259 823 291">See response to comment No 629.</p>	
comment	1034	comment by: <i>Ilse Janicke Heart Center Duisburg</i>
<p data-bbox="352 416 1437 477">Author: Janicke Ilse, Senior MD, AME I and II, Cardiologist and Angiologist at Heart Center Duisburg</p> <p data-bbox="352 479 467 508">Section:</p> <p data-bbox="352 510 1082 542"><b>Subpart B Requirements for Medical Certificates</b></p> <p data-bbox="352 544 1362 573">Section 1 Specific requirements for class 1 and class 2 medical certificates</p> <p data-bbox="352 575 1046 607"><b>Chapter A AMC for class 1 medical certificates</b></p> <p data-bbox="352 609 1437 669"><b>AMC A to MED.B.005 Cardiovascular System - Class 1 medical certificates</b></p> <p data-bbox="352 672 766 703"><b>Page:</b> 33, 34 (NPA 2008-17c)</p> <p data-bbox="352 734 1050 766"><b>Relevant Text: 9. Recurrent Vasovagal Syncope</b></p> <p data-bbox="352 768 1437 828">9.1 (i)...If the exercise ECG is abnormal, myocardial scintigraphy/stress echocardiography should be required.</p> <p data-bbox="352 831 775 862"><b>(d) Coronary artery disease</b></p> <p data-bbox="352 864 1437 992">4.2 (iii) In cases of angioplasty/stenting, a myocardial perfusion scan or stress echocardiogram... should show no evidence of reversible myocardial ischaemia. If there is any doubt about myocardial perfusion in other cases...a perfusion scan should also be required.</p> <p data-bbox="352 1025 512 1057"><b>Comment:</b></p> <p data-bbox="352 1059 1437 1155">Since the last decade the stress cardiac MRI has developed in the assessment of the morphological and functional characteristics to diagnose cardiac illnesses and ischaemic disorders with good results. This test is missed.</p> <p data-bbox="352 1189 499 1220"><b>Proposal:</b></p> <p data-bbox="352 1223 1437 1283">9.1 (i)...If the exercise ECG is abnormal, myocardial scintigraphy/stress echocardiography or equivalent test should be required.</p> <p data-bbox="352 1285 1437 1413">4.2 (iii) In cases of angioplasty/stenting, a myocardial perfusion scan or stress echocardiogram or equivalent test should show no evidence of reversible myocardial ischaemia. If there is any doubt about myocardial perfusion in other cases...a perfusion scan or equivalent test should also be required.</p>		
response	<p data-bbox="352 1442 440 1471"><i>Noted</i></p>	
<p data-bbox="352 1496 1437 1556">The examination techniques will be reviewed in rulemaking task MED.001. The basis for this CRD /Opinion and Decision is JAR-FCL 3.</p>		
comment	1111	comment by: <i>Moldavian Society of Aviation Medicine</i>
<p data-bbox="352 1675 1193 1706">Chapter A AMC for class 1 medical certificates (b) 4.(4.1, 4.2)</p> <p data-bbox="352 1740 499 1771"><b>Comment:</b></p> <p data-bbox="352 1774 1437 1933">Ultra-sound investigation is not the best method for evaluation of aortic aneurysm, there are other modern methods of investigation available. Exercise ECG has nothing in assessment of the results after surgery for an infra renal aneurysm and cardiological reviews are not required for its assessment on a regular base.</p> <p data-bbox="352 1966 483 1998"><b>Proposal:</b></p>		

	<p>(b) General 4. Aortic Aneurysm 4.1. Applicants with an aneurysm of the infra-renal abdominal aorta may be assessed as fit for class 1 with a multi-pilot limitation by the licensing authority. Follow-up by ultra-sound scans or other imaging techniques should be determined by the licensing authority. 4.2. Applicants may be assessed as fit by the licensing authority after surgery for an infra-renal aortic aneurysm with a multi-pilot limitation at revalidation, if there is good postoperative outcome, the blood pressure is normal or well treated with medication and cardiovascular assessment is satisfactory.</p>	
response	<p><i>Noted</i></p> <p>See response to comment No 626.</p>	
comment	1125	comment by: <i>Moldavian Society of Aviation Medicine</i>
	<p>Subpart B Requirements for medical certificates Section: 1 Specific requirements for class 1 and class 2 medical certificates Chapter A AMC for class 1 medical certificates (b) 2. <i>Cardiovascular Assessment</i> 2.1. Reporting of resting and exercise electrocardiograms should be by the AME or other specialist.</p> <p>Comment: Reporting of ECG shall be made only by a specialist trained in ECG that could be a cardiologist if not AME.</p> <p>Proposal: (b) General 2. <i>Cardiovascular Assessment</i> 2.1. Reporting of resting and exercise electrocardiograms should be by the AME or cardiologist.</p>	
response	<p><i>Noted</i></p> <p>See response to comment No 467.</p>	
comment	1126	comment by: <i>Moldavian Society of Aviation Medicine</i>
	<p>Subpart B Requirements for medical certificates Section: 1 Specific requirements for class 1 and class 2 medical certificates Chapter A AMC for class 1 medical certificates (c) BLOOD PRESSURE</p> <p>Comment: In the (iii) the correct name of the group of medication is - angiotensin II AT1 blocking agents (the sartans); It should also be mentioned that the initiation of treatment require the temporary suspension of the medical certificate before the reassessment will be made.</p> <p>Proposal: ... (iii) angiotensin II blocking agents (sartans); ...</p>	

	<p>3. The initiation of medication for the control of blood pressure shall require a period of temporary suspension of the medical certificate. Applicants should be reassessed to verify that the treatment is compatible with the safe exercise of the privileges of the licence held.</p>		
response	<p><i>Partially accepted</i></p>		
	<p>Thank you for the comment. The name of the group of sartans will be changed accordingly.</p> <p>The issue of the temporary unfitness in the case of the medication is covered in MED.A.060(a)(3).</p>		
comment	<table border="1"> <tr> <td data-bbox="343 582 454 705">1245</td> <td data-bbox="454 582 1455 705">comment by: <i>Swedish Transport Agency, Civil Aviation Department (Transportstyrelsen, Luftfartsavdelningen)</i></td> </tr> </table>	1245	comment by: <i>Swedish Transport Agency, Civil Aviation Department (Transportstyrelsen, Luftfartsavdelningen)</i>
1245	comment by: <i>Swedish Transport Agency, Civil Aviation Department (Transportstyrelsen, Luftfartsavdelningen)</i>		
	<p><b>Comment:</b> In (b) 2.1. The wording "Other specialist" needs to be defined, otherwise any specialist may be used, e.g. an ophthalmologist, psychiatrist, or orthopaedic surgeon, which is not the intention.</p> <p><b>Proposal:</b> Amend AMC A to MED.B.005:</p> <p><i>2. Cardiovascular Assessment</i> 2.1. Reporting of resting and exercise electrocardiograms should be made by the AME or other specialist with relevant qualifications for assessing ECGs.</p>		
response	<p><i>Noted</i></p>		
	<p>See response to comment No 467.</p>		
comment	<table border="1"> <tr> <td data-bbox="343 1198 598 1299">1516</td> <td data-bbox="598 1198 1455 1299">comment by: <i>Dr Ian Perry</i></td> </tr> </table>	1516	comment by: <i>Dr Ian Perry</i>
1516	comment by: <i>Dr Ian Perry</i>		
	<p>AMC.4 to Med.B.005 (d).4.1 page 34.. All % figures given should be flexible, not rigid, as repeated or subsequent examinations may give different figures. It should be left at the discretion of the Consultant Cardiologist.</p>		
response	<p><i>Not accepted</i></p>		
	<p>The proposed NPA text is a transposition of the corresponding requirements from JAR-FCL 3; changes to the FCL text should only be done for compelling reasons at this stage. The 'downgrading' from rule (Appendix to JAR-FCL 3) to acceptable means of compliance in Part FCL is already a significant change the effect of which has to be evaluated once the rules and AMCs are implemented.</p> <p>The percentages given stem from JAR-FCL 3 and should not prevent the cardiologist from making his/her own judgement. It also ensures the baseline for assessments around Europe.</p>		
comment	<table border="1"> <tr> <td data-bbox="343 1780 518 1881">1684</td> <td data-bbox="518 1780 1455 1881">comment by: <i>UK CAA MEDICAL ADVISORY PANEL</i></td> </tr> </table>	1684	comment by: <i>UK CAA MEDICAL ADVISORY PANEL</i>
1684	comment by: <i>UK CAA MEDICAL ADVISORY PANEL</i>		
	<p><b>Paragraph MED.B.005(a) Cardiovascular system Examination</b> <b>Page 31</b></p> <p><b>Comment</b></p>		

	<p>The statement "...minimum of Bruce Stage IV or equivalent" needs clarification.  <b>Justification</b>  9 minutes of the Bruce protocol is the end of Stage III.  <b>Proposed Text</b>  Suggest insert "see guidance material".</p>		
response	Noted		
	<p>The Bruce Protocol should be understood in a harmonised way in all Member States. In case of doubt on Bruce Stage IV, please ask for clarification from the AMS as this is presently the protocol in use for conducting stress ECGs in compliance with JAR-FCL3.</p> <p>Guidance Material will be added to Part Medical after adoption of the Opinion and it will contain guidance on stress ECG.</p>		
comment	<table border="1"> <tr> <td data-bbox="343 683 539 779">1685</td> <td data-bbox="539 683 1445 779">comment by: UK CAA MEDICAL ADVISORY PANEL</td> </tr> </table>	1685	comment by: UK CAA MEDICAL ADVISORY PANEL
1685	comment by: UK CAA MEDICAL ADVISORY PANEL		
	<p><b>Paragraph MED.B.005(b)(5)5.2.1 (ii) Cardiac valvular abnormalities</b>  <b>Page 32</b></p> <p><b>Comment</b>  The text recommends mean pressure gradients. These are not used in the UK and are not in general use overall. They have to be calculated. The simplest measurement is with the peak Doppler velocity although some experienced departments will use the valve area.</p> <p><b>Justification</b></p> <p><b>Proposed Text</b>  "..those with a Doppler derived peak aortic velocity of 22.5m/s may be assessed as unfit in the absence of other abnormality. Those with a peak velocity of 2.5m/s – 3.5m/s may be assessed fit with a multipilot limitation provided there is no evidence of left ventricular hypertrophy or calcification in the valve. Cardiological follow-up ...Those with a Doppler velocity of &lt;3.5m/s should be denied certification".</p>		
response	Noted		
	See response to comment No 471.		
comment	<table border="1"> <tr> <td data-bbox="343 1462 539 1559">1686</td> <td data-bbox="539 1462 1445 1559">comment by: UK CAA MEDICAL ADVISORY PANEL</td> </tr> </table>	1686	comment by: UK CAA MEDICAL ADVISORY PANEL
1686	comment by: UK CAA MEDICAL ADVISORY PANEL		
	<p><b>Paragraph MED.B.005(b)(6)6.2. Valvular surgery</b>  <b>Page 33</b></p> <p><b>Comment</b>  This is a vague statement.</p> <p><b>Justification</b></p> <p><b>Proposed Text</b>  "...provided post-operative investigations reveal satisfactory left ventricular function without systolic or diastolic dilatation and no more than minor mitral regurgitation".</p>		
response	Accepted		

comment	1687	comment by: UK CAA MEDICAL ADVISORY PANEL
	<p><b>Paragraph MED.B.005(d)4. Coronary artery disease</b> <b>Page 34</b></p> <p><b>Comment</b> Evidence of exercise induced myocardial ischaemia should only be disqualifying, pending further investigation. False/positive exercise response is well recognised and not a reason, of its own, to deny fitness.</p> <p><b>Justification</b></p> <p><b>Proposed Text</b></p>	
response	<i>Noted</i>	
	<p>We understand you comment on (d) 3.</p> <p>The applicant may require examination results to be reviewed by the licensing authority and require further tests if he/she suspects false/positive exercise response that resulted in an unfit assessment.</p>	
comment	1688	comment by: UK CAA MEDICAL ADVISORY PANEL
	<p><b>Paragraph MED.B.005(d)4. 4.2(iii)</b> <b>Page 35</b></p> <p><b>Comment</b> The data are thin on the prognostic value of a pharmacological stress echocardiogram after coronary angioplasty/stenting. I would suggest this is deleted.</p> <p><b>Justification</b></p> <p><b>Proposed Text</b> The word "stress" should become "before myocardial perfusion" and the word "imaging" should follow it with "scan" being deleted.</p>	
response	<i>Not accepted</i>	
	<p>The proposed NPA text is a transposition of the corresponding requirement from JAR-FCL 3. Changes to the text are only done for compelling reasons at this stage. The assessment criteria and examination techniques will be reviewed in rulemaking task MED.001.</p>	
comment	1689	comment by: UK CAA MEDICAL ADVISORY PANEL
	<p><b>Paragraph MED.B.005(e)(4) 4.2(ii) Supraventricular arrhythmias</b> <b>Page 36</b></p> <p><b>Comment</b> Spelling error – "assessed".</p> <p><b>Justification</b></p> <p><b>Proposed Text</b> Spelling error – "assessed".</p>	

response	<i>Accepted</i>	
	Thank you for the comment.	
comment	1690	comment by: UK CAA MEDICAL ADVISORY PANEL
	<p><b>Paragraph MED.B.005(e)(10) QT Prolongation</b>  <b>Page 37</b></p> <p><b>Comment</b>  In view of the difficulties of predicting those who show intermittent and/or minor prolongation of the QT interval which is suggestive that a multipilot be required until pilots can be genotyped with less difficulty than at present.</p> <p><b>Justification</b></p> <p><b>Proposed Text</b>  "...evaluation for a fit assessment with a multipilot limitation".</p>	
response	<i>Partially accepted</i>	
	The licensing authority can impose an OML also in cases where it is not mentioned in the AMC. For clarification, the words 'a multi-pilot limitation may be required' were added.	
comment	1806	comment by: CAA Belgium
	<p>Relevant Text: AMC A to MED.B.005 (b) 1.2.  An accumulation of risks factors should require cardiovascular evaluation by the AMC or AME in conjunction with the licensing authority.  Comment: A cardiovascular evaluation should be carried out by a cardiologist  Proposal: An accumulation of risks factors should require cardiovascular evaluation by a cardiologist or the AMC in conjunction with the licensing authority.</p>	
response	<i>Not accepted</i>	
	The proposed NPA text is a transposition of the corresponding requirement from JAR-FCL 3 where a cardiologist was not specifically required in this context. This paragraph in JAR-FCL 3 has never been questioned and should, if at all, only be amended in a new rulemaking task.	
comment	1807	comment by: CAA Belgium
	<p>Relevant Text: AMC A to MED.B.005 (b) 2.1.  Reporting of resting and exercise electrocardiogram should be by the AME or other specialist.  Comment: The specialist should be a cardiologist who is accredited to perform exercise tests.  It should be useful that the ECGs be sent to the Licensing Authority, appended to the copy of the report. ( as in FAA requirements)  Proposal: Reporting of resting should be by a cardiologist or delegated to the AME and exercise electrocardiogram by a cardiologist.  The electrocardiograms should be submitted to the Licensing Authority, appended to the copy of the report.</p>	

response	<i>Noted</i>	
	Please see response to comment No 467.	
comment	1808	comment by: CAA Belgium
	<p>Relevant Text: AMC A to MED.B.005 (b) 5.2.1. (ii) A mean pressure gradient up to 50 mm Hg may be acceptable...</p> <p>Comment: a mean pressure gradient &gt; 50 mm Hg (or Doppler outflow velocity <math>\geq 4</math> m/s or valve area &lt; 1 cm<sup>2</sup>) is considered as severe aorta stenosis. " the onset of angina, dyspnea or syncope in asymptomatic patients with Doppler outflow velocities <math>\geq 4</math> m/s has been reported as high as 14 % after 1 year, 38 % after 2 years and 79 % after 3 years" ACC/AHA guidelines. A mean pressure gradient &gt; 40 Hg is not acceptable in pilots. Proposal: "A mean pressure gradient up to 50 mm Hg may be acceptable" should be deleted from the text.</p>	
response	<i>Not accepted</i>	
	<p>The proposed NPA text is a transposition of the corresponding requirement from JAR-FCL 3 where these values were not contested over the past years. They provide a baseline for assessments but a cardiologist who sees a pilot with clinical symptoms of aortic valve disease has to declare him/her unfit although they may be in the range given in Part Medical.</p>	
comment	1809	comment by: CAA Belgium
	<p>Relevant Text: AMC A to MED.B.005 (b) 5.2.2. (iv) ...and satisfactory myocardial function is confirmed by exercise electrocardiography.</p> <p>Comment: In mitral regurgitation, myocardial function is not evaluated by electrocardiogram but by exercise tolerance and the onset of symptoms. Proposal: ... and satisfactory myocardial function is confirmed by symptom-limited exercise testing.</p>	
response	<i>Not accepted</i>	
	<p>The proposed NPA text is a transposition of the corresponding requirement from JAR FCL 3. Additional requirements in the implementing rule may be introduced only through a new rulemaking task.</p> <p>The possibility to require additional medical examinations and investigations is proposed in MED.B.001(d).</p>	
comment	1810	comment by: CAA Belgium
	<p>Relevant text: AMC A to MED.B.005 (b) 9.1. A fit assessment may be considered by the licensing authority after 6 month period without recurrence provided cardiological evaluation is satisfactory.</p> <p>Comment: a 6 month period of observation may be too short in recurrent vasovagal syncope. The risk of recurrence must be minimal. Proposal: ... after a 1 year period without recurrence provided a satisfactory cardiovascular evaluation. A shorter period may be considered if the unlikelihood of a recurrence is proven.</p>	

response	<i>Not accepted</i>	
	The proposed NPA text is a transposition of the corresponding requirement from JAR-FCL 3 where a period of 6 months without recurrence of a syncope was not contested over the past years.	
comment	1811	comment by: CAA Belgium
	<p>Relevant Text: AMC A to MED.B.005 (b) 6.3. (i)</p> <ul style="list-style-type: none"> <li>- a satisfactory symptom-limited exercise ECG.</li> <li>- Myocardial scintigraphy/stress echocardiography should be required if exercise ECG is abnormal or any coronary artery disease has been demonstrated.</li> </ul> <p>Comment: - The myocardial function must be evaluated</p> <ul style="list-style-type: none"> <li>- this is out of place in this paragraph. If coronary disease is suspected, the examiner should refer to the chapter relating to this subject.</li> </ul> <p>Proposal: - A satisfactory symptom-limited exercise rest.</p> <ul style="list-style-type: none"> <li>- "Myocardial scintigraphy/stress echocardiography should be required if exercise ECG is abnormal or any coronary artery disease has been demonstrated." should be deleted in the text.</li> </ul>	
response	<i>Noted</i>	
	<p>AMC to MED.B.005(b)6.3(i) deals with the assessment after valve surgery and an exercise ECG is indicated in these cases.</p> <p>If the stress ECG is abnormal, Coronary Artery Disease has to be excluded. If Coronary Artery Disease can be excluded, the checks according to (b)3.(ii) have to be done. If there are signs for Coronary Artery Disease the AME has to go to the corresponding paragraph to continue the assessment.</p>	
comment	1812	comment by: CAA Belgium
	<p>Relevant text: AMC A to MED.B.005 (b) 7. Thromboembolic Disorders</p> <p>Comment: Requirements about stroke and TIA are missing</p> <p>Proposal: After a transient ischemic attack or a stroke, applicants should be assessed as unfit. A fit assessment may be considered, if the defined cause of a TIA is eliminated and after a neurological review. OML limitation may be required.</p>	
response	<i>Not accepted</i>	
	<p>The NPA text is a transposition of the corresponding requirement from JAR-FCL 3 which does not contain the proposed paragraph on stroke/TIA&lt;.</p> <p>Additional requirements/AMCs may be introduced through the new rulemaking task MED.001. This comment has been added to the list of topics to be evaluated/discussed/included.</p>	
comment	1813	comment by: CAA Belgium
	<p>Relevant Text: AMC A to MED.B.005 (d) 4.2. (iii)</p> <p>In case of angioplasty/stenting, a myocardial perfusion scan or stress echocardiogram which should show no evidence of reversible myocardial</p>	

	<p>ischemia. If there is any doubt about myocardial perfusion in other cases (infarction or by-pass grafting) a perfusion scan should also be required;  Comment: I think we must be sure of the absence of residual ischemia in all the cases including myocardial infarction and CABS. False negative exercise tests are not uncommon.  Proposal: a myocardial perfusion scan or stress echocardiogram should show no evidence of reversible myocardial ischemia.</p>	
response	<p><i>Noted</i></p> <p>The issue is covered in (d) 4.2. (iii).</p>	
comment	1814	comment by: CAA Belgium
	<p>Relevant Text: AMC A to MED.B.005 (e) 3.  For those in whom the long term outcome cannot be assured by invasive or non-invasive testing, an additional period with a multi-pilot limitation and/or observation may be necessary.  Comment: If the risk of arrhythmia persists, the multi-pilot limitation should be maintained.  Proposal: For those in whom the long term outcome cannot be assured by invasive or non-invasive testing, a multi-pilot limitation should be maintained.</p>	
response	<p><i>Not accepted</i></p> <p>Only the licensing authority can impose and remove the multi-pilot limitation. This will be done according to the assessment of the condition. An amendment of the paragraph (e)(3) therefore does not seem necessary.</p>	
comment	1815	comment by: CAA Belgium
	<p>Relevant Text: AMC A to MED.B.005 (e) 4.2. (ii)  For revalidation, applicants may be assessed as fit if cardiological evaluation is satisfactory.  Comment: AF/flutter are at risk of sudden incapacitation chiefly if the rhythm disturbance is paroxysmal.  Proposal: For revalidation, applicants may be assessed as fit, with an OML limitation, in cases of "lone", permanent AF if heart rate is controlled at rest and during exercise.</p>	
response	<p><i>Noted</i></p> <p>The licensing authority will decide on the limitation to be applied. There is no need for more specific requirements, because all of them are included in the requirement for 'satisfactory cardiological evaluation'. However, the comment has been taken up for the Guidance Material to be drafted after the adoption of the Part Medical Opinion.</p>	
comment	1816	comment by: CAA Belgium
	<p>Relevant Text: AMC A to MED.B.005 (e) 6.  Complete right bundle branch block  Comment: Bifascicular block (complete RBBB + left anterior or posterior hemiblock) entails a risk of progression to complete AV bloc which is difficult to predict, but which may be evaluated by an electrophysiological study  Proposal: (iii) Applicants with bifascicular block should be assessed as fit after</p>	

response	<p>a cardiological examination, with a multi-pilot limitation. A fit assessment without limitation may be considered if an electrophysiological study demonstrates no infra-His block.</p> <p><i>Noted</i></p> <p>The proposed NPA text is a transposition of the corresponding requirement from JAR FCL-3 where the bifascicular block was not mentioned in Subpart B or Appendix. Additional requirements/AMCs Medical may be introduced through the new rulemaking task MED.001. The comment has been added to the list of possible additions to either AMC or Guidance Material.</p>	
comment	1817	comment by: <i>CAA Belgium</i>
response	<p>Relevant Text: AMC A to MED.B.005 (e) 10.  QT prolongation  Comment: other diseases (as Brugada syndrome, short QT syndrome...) are at high risk of unexpected syncope and sudden death :  Proposal: QTprolongation and other primary electrophysiological diseases (Brugada syndrome, short QT syndrome...)</p> <p><i>Partially accepted</i></p> <p>Brugada syndrome will be added into a rule.</p>	
comment	1839	comment by: <i>European CMO Forum</i>
	<p><b>Paragraph: AMC A to MED.B.005 (b) ADD NEW 6.4</b>  <b>Page No: 33</b></p> <p><b>Comment:</b>  Authorities in many non-JAA member states (e.g. US-FAA, New Zealand, Australia, Transport Canada) allow anticoagulation therapy under special conditions. The European requirements should accept anticoagulation with special conditions according to the medical circumstances if the underlying disease demanding anticoagulation is acceptable and stable anticoagulation is demonstrated within the last 6 months (at least 5 INR values, of which 4 are within the INR target range).</p> <p><b>Justification:</b>  Self monitoring of INR is now available which enables individuals to maintain stable anticoagulant levels. Studies which showed an increase risk of major bleeding in the past have been superceded by studies that demonstrate this risk is much reduced in the pilot population age group and with maintenance of INR levels in the target range.  Mechanical valves are often the first choice in clinical practice and it is important that pilots are able to receive the type of valve that is recommended for them. Anticoagulation is now considered to be safe for use in pilots, with special conditions.</p> <p><b>Proposed Text:</b>  <b>(if applicable)</b>  NEW 6.4: In the case of anticoagulation after valvular surgery, a fit assessment with multi pilot limitation may be considered after review by the authority if the anticoagulation is stable (within the last 6 months at least 5 INR values, of which at least 4 are within the INR target range)</p>	

response	<i>Accepted</i>	
	Accepted with minimal text change.	
comment	1840	comment by: <i>European CMO Forum</i>
	<p><b>Paragraph: AMC A to MED.B.005 (b) (7)</b>  <b>Page No: 33</b></p> <p><b>Comment:</b>  The European requirements should accept anticoagulation with special conditions according to the medical circumstances.</p> <p><b>Justification:</b>  The medical condition requiring anticoagulation is very important to consider. Anticoagulation being used for treatment of a thrombosis is not acceptable. Anticoagulation being used for prophylaxis should be permitted.</p> <p><b>Proposed Text:  (if applicable)</b>  Replace proposed para <b>AMC A to MED.B.005 (b) (7)</b> with:</p> <p><b>AMC A to MED.B.005 (b) (7):</b> Arterial or venous thrombosis or pulmonary embolism are disqualifying whilst anticoagulation is being used as treatment rather than prophylaxis. After 6 months of stable anticoagulation (within the last 6 months at least 5 INR values, of which at least 4 are within the INR target range) a fit assessment with multi pilot limitation may be considered after review by the licensing authority. Pulmonary embolus should require full evaluation. Following cessation of anticoagulant therapy, for any indication, applicants should require review by the licensing authority.</p>	
response	<i>Accepted</i>	
	Accepted with minimal text change.	
	Amendments to revised text also consider comment 1839 above.	
comment	1886	comment by: <i>AECA(SPAIN)</i>
	<p>(b) 1. 1.1 and 1.2 ?...in conjunction with the licensing authority'.</p> <p>This procedure is not clear, need to be explained.  Whath is the role of AMS in this case?</p>	
response	<i>Noted</i>	
	The role of the licensing authority/medical assessor is described in NPA 2008-22b Authority Requirements paragraph AR.MED.025.	
comment	2157	comment by: <i>DGAC FRANCE</i>
	<p><b>AMC A to MED.B.005 (b) General, paragraph 6</b></p> <p><b>Comment :</b></p>	

Authorities in many non-JAA member states (e.g. US-FAA, New Zealand, Australia, Transport Canada) allow anticoagulation therapy under special conditions. The European requirements should accept anticoagulation with special conditions according to the medical circumstances if the underlying disease demanding anticoagulation is acceptable and stable anticoagulation is demonstrated within the last 6 months (at least 5 INR values, of which 4 are within the INR target range).

Self monitoring of INR is now available which enables individuals to maintain stable anticoagulant levels. Studies which showed an increase risk of major bleeding in the past have been superceded by studies that demonstrate this risk is much reduced in the pilot population age group and with maintenance of INR levels in the target range.

Mechanical valves are often the first choice in clinical practice and it is important that pilots are able to receive the type of valve that is recommended for them. Anticoagulation is now considered to be safe for use in pilots, with special conditions.

Modification :

Add a paragraph 6.4. in the paragraph 6 "*Valvular surgery*" of the chapter (b) General :

AMC A to MED.B.005

(b) General

6. *Valvular surgery*

**6.4 In the case of anticoagulation after valvular surgery, a fit assessment with multi pilot limitation may be considered after review by the authority if the anticoagulation is stable (within the last 6 months at least 5 INR values, of which at least 4 are within the INR target range)**

response *Accepted*

The NPA text will be changed accepting anticoagulation therapy under special conditions.

comment

2161

comment by: DGAC FRANCE

AMC A to MED.B.005 (b) General, **paragraph 7**

Comment :

The European requirements should accept anticoagulation with special conditions according to the medical circumstances.

The medical condition requiring anticoagulation is very important to consider. Anticoagulation being used for treatment of a thrombosis is not acceptable. Anticoagulation being used for prophylaxis should be permitted.

Modification :

Delete proposed paragraph 7. "*Thromboembolic Disorders*" in (b) and replace it by the following proposition :

	<p>AMC A to MED.B.005 (b) General</p> <p><b><u>(7) Arterial or venous thrombosis or pulmonary embolism are disqualifying whilst anticoagulation is being used as treatment rather than prophylaxis. After 6 months of stable anticoagulation (within the last 6 months at least 5 INR values, of which at least 4 are within the INR target range) a fit assessment with multi pilot limitation may be considered after review by the licensing authority. Pulmonary embolus should require full evaluation. Following cessation of anticoagulant therapy, for any indication, applicants should require review by the licensing authority.</u></b></p>
response	<p><i>Noted</i></p> <p>See response to comment No 2157.</p>

comment	<p>2405</p> <p>comment by: <i>Irish Aviation Authority</i></p> <p>(B) ADD NEW 6.4                  Authorities in many non-JAA member states (like. US-FAA, New Zealand, Australia, Transport Canada) allow anticoagulation therapy under special conditions. The European requirements should accept anticoagulation with special /clearconditions according to the medical circumstances if the underlying disease demanding anticoagulation is acceptable and stable anticoagulation is demonstrated within the last 6 months (at least 5 INR values, of which 4 are within the INR target range).</p> <p>Justification:                  Self monitoring of INR is available and enables individuals to maintain stable anticoagulant levels. Studies that showed an increase risk of major bleeding in the past have been superseded by studies that demonstrate this risk is reduced in the pilot population age group and with maintenance of INR levels in the target range.                  Mechanical valves are often the best choice in clinical practice and it is important that pilots are able to receive the type of valve that is best for them. Anticoagulation is now considered to be safe for use in pilots, under special conditions.</p> <p>Proposed text:                  NEW 6.4: In the case of anticoagulation after valvular surgery, a fit assessment with OML may be considered after review by the authority if the anticoagulation is stable (within the last 6 months at least 5 INR values, of which at least 4 are within the INR target range)</p>
response	<p><i>Noted</i></p> <p>See response to comment No 2157.</p>

comment	<p>2406</p> <p>comment by: <i>Irish Aviation Authority</i></p> <p>(b)(7)                  The European requirements should accept anticoagulation under special conditions according to the medical circumstances.</p> <p>Justification:</p>
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The medical condition requiring anticoagulation is important to consider. Anticoagulation being used for treatment of a thrombosis is not acceptable. Anticoagulation being used for prophylaxis should be permitted.

Proposed text:

Replace proposed para **AMC A to MED.B.005 (b) (7)** with:

**AMC A to MED.B.005 (b) (7):** Arterial or venous thrombosis or pulmonary embolism are disqualifying as anticoagulation is being used as treatment rather than prophylaxis. After 6 months of stable anticoagulation (within the last 6 months at least 5 INR values, of which at least 4 are within the INR target range) a fit assessment with OML may be considered after review by the licensing authority. Pulmonary embolus will require full evaluation. Following cessation of anticoagulant therapy, for any indication, applicants will require review by the licensing authority.

response *Noted*

See response to comment No 2157.

comment 2501 comment by: UK CAA MEDICAL ADVISORY PANEL

**Paragraph MED.B.005(b)(2)2.1 General Cardiovascular risk factor assessment**  
Page 31

**Comment**

Reporting of the resting and exercise electrocardiogram by an Authorised Medical Examiner would be quite unacceptable to the European Society of Cardiology, no doubt. Reporting by a specialist other than a cardiologist would likewise be unacceptable unless the specialist was dually accredited.

**Justification**

The AME has no particular skills in the interpretation of resting or exercise electrocardiograms.

**Proposed Text**

"Reporting of the resting electrocardiogram by computer is acceptable. If this is not available, resting recordings and all exercise electrocardiograms should be reported by an accredited cardiologist".

response *Not accepted*

Whether reporting of resting and exercise can be done by an AME or not it depends on the qualification of the AME. If the AME is an Internist or Occupational Health Specialist he/she is, at least in some Member States, perfectly qualified to evaluate ECGs.

Evaluation of ECG by computer has its downfalls. A computer result has to be checked by a person who is qualified to interpret ECGs and accept or reject the computer diagnosis as is appropriate.

comment 2502 comment by: UK CAA MEDICAL ADVISORY PANEL

**Paragraph MED.B.005(b)(3)(i)**  
Page 31

**Comment**

	<p>This is a vague statement. Symptomatic patients would in any event have been denied fitness. There is also overlap between (i) and (ii).</p> <p><b>Justification</b></p> <p><b>Proposed Text</b>          "All applicants should take measures directed towards secondary prevention, including smoking cessation".</p>	
response	<p><i>Noted</i></p> <p>Please see response to comment No 469.</p>	
comment	2503	comment by: UK CAA MEDICAL ADVISORY PANEL
	<p><b>Paragraph MED.B.005(b)(3)(iii)</b>  <b>Page 31</b></p> <p><b>Comment</b>          Elsewhere the requirements for exercise electrocardiography have been stated and should be restated here.</p> <p><b>Justification</b></p> <p><b>Proposed Text</b>          Suggest "Exercise electrocardiography to a minimum of Bruce Stage IV or equivalent (see guidance material) should be satisfactory. In the event of non-compliance with the exercise recording, further tests may be required....".</p>	
response	<p><i>Not accepted</i></p> <p>Please see AMC to MED.B.005 (a). This paragraph explains what is meant in cases where exercise ECG is required.</p>	
comment	2504	comment by: UK CAA MEDICAL ADVISORY PANEL
	<p><b>Paragraph MED.B.005(b)(4)4.2 Aortic Aneurysm</b>  <b>Page 31</b></p> <p><b>Comment</b>          It is not acceptable for the patient to continue to fly after the point at which surgical intervention is normally recommended – when the diameter exceeds 5.5cm.</p> <p><b>Justification</b></p> <p><b>Proposed Text</b>          "When the ultrasonic dimension of the vessel exceeds 5.5cm, the pilot should be assessed unfit".</p>	
response	<p><i>Not accepted</i></p> <p>Applicants with aneurysm of the infrarenal abdominal aorta shall be referred to the licensing authority for a decision and follow-up. It is difficult to believe that a licensing authority would allow continuing flying when surgical intervention is necessary.</p>	
comment	2505	comment by: UK CAA MEDICAL ADVISORY PANEL

**Paragraph MED.B.005(b)(5)5.2.2(v) Mitral valve disease**  
**Page 32**

**Comment**

It is anticipated that in the presence of volume overloading there will be an increase in the left ventricular end diastolic diameter. This is becoming significant when the end systolic dimension is increased.

**Justification**

**Proposed Text**

Suggest "systolic" be inserted for "diastolic".

response *Not accepted*

The proposed NPA text is a transposition of the corresponding requirement from JAR-FCL 3 where the left ventricular end-diastolic diameter is presently used as evidence for volume overloading. An amendment of this paragraph, if needed, can be postponed to a future rulemaking task.

comment

2506

comment by: UK CAA MEDICAL ADVISORY PANEL

**Paragraph MED.B.005(b)(6)6.3**  
**Page 33**

**Comment**

The valve needs to be specified. Tissue valves are rarely inserted in the mitral position now on account of poor performance and increased risk of thromboembolism.

**Justification**

**Proposed Text**

"...with a tissue valve in the aortic position who, ....".

response *Not accepted*

**OPEN**

comment

2507

comment by: UK CAA MEDICAL ADVISORY PANEL

**Paragraph MED.B.005(b)(6)6.3(i)**  
**Page 33**

**Comment**

The chosen form exercise electrocardiographic standard needs to be inserted (see above). Myocardial scintigraphy has been replaced in the nomenclature by stress myocardial perfusion imaging (MPI).

**Justification**

**Proposed Text**

Suggest "...satisfactory symptom limited exercise electrocardiogram (see guidance material). Stress Myocardial Perfusion Imaging (MPI)/ stress echocardiography ..".

response *Partially accepted*

Exercise electrocardiography: Please see response to comment No 2503. Myocardial scintigraphy is replaced by Myocardial perfusion imaging.

comment 2508 comment by: UK CAA MEDICAL ADVISORY PANEL

**Paragraph MED.B.005(b)(6)6.2(ii)**  
**Page 33**

**Comment**

Doppler measures velocities not blood flow which is derives.

**Justification**

**Proposed Text**

Delete "blood flow" and insert "velocities".

response *Noted*

The expression 'Doppler blood flow' has been taken from JAR-FCL 3 which is presently implemented. The expression never attracted comments and is used more than once in the rules. However, all the technical terms transposed from JAR-FCL 3 will be checked whether still appropriate prior to the publication of the Opinion and no change is made at this stage.

comment 2509 comment by: UK CAA MEDICAL ADVISORY PANEL

**Paragraph MED.B.005(b)(9) Vasovagal syncope**  
**Page 33**

**Comment**

Vasovagal syncope should be reviewed whether recurrent or not.

**Justification**

**Proposed Text**

Delete "recurrent".

response *Not accepted*

The NPA text is a transposition of the corresponding requirement from JAR-FCL 3 which was the basis for Part Medical. The heading of the paragraph is now 'Syncope' but the body text has not been changed to remain in line with JAR-FCL 3. Amendments to the text may be done, if necessary, in a future rulemaking task.

comment 2510 comment by: UK CAA MEDICAL ADVISORY PANEL

**Paragraph MED.B.005(b)(9)9.1(i)**  
**Page 33**

**Comment**

Satisfactory standard format needs to be used.

**Justification**

**Proposed Text**

Insert "(see guidance material)...If the exercise ECG is abnormal, Stress Myocardial Imaging (MPI)/stress...".

response	<i>Partially accepted</i>	
	'Myocardial scintigraphy' is replaced by 'myocardial perfusion imaging'.	
comment	2511	comment by: UK CAA MEDICAL ADVISORY PANEL
	<p><b>Paragraph MED.B.005(d)4.</b> <b>Page 34</b></p> <p><b>Comment</b> This is syntactically not well expressed.</p> <p><b>Justification</b></p> <p><b>Proposed Text</b> "....All applicants should adopt strategies of secondary prevention".</p>	
response	<i>Noted</i>	
	<p>The wording in the paragraph is to say that applicants should be on secondary prevention treatment (e.g. Aspirin, medication to control cholesterol).</p> <p>Strategies of secondary prevention (e.g. no smoking, weight control) may be in future guidance material.</p>	
comment	2512	comment by: UK CAA MEDICAL ADVISORY PANEL
	<p><b>Paragraph MED.B.005(d)4. 4.1(i)</b> <b>Page 34</b></p> <p><b>Comment</b> This is poorly expressed.</p> <p><b>Justification</b></p> <p><b>Proposed Text</b> Insert "...except in a vessel subtending a myocardial infarction". Delete "leading to an infarction".</p>	
response	<i>Accepted</i>	
	Thank you for the comment. The text will be amended.	
comment	2513	comment by: UK CAA MEDICAL ADVISORY PANEL
	<p><b>Paragraph MED.B.005(d)4. 4.5.</b> <b>Page 35</b></p> <p><b>Comment</b> Tests include myocardial i.e. not cardiac ischaemia.</p> <p><b>Justification</b></p> <p><b>Proposed Text</b></p>	
response	<i>Accepted</i>	
	Thank you for the comment. The text will be amended.	

comment	2514	comment by: UK CAA MEDICAL ADVISORY PANEL
	<p><b>Paragraph MED.B.005(e)(1)(i) Rhythm and Conduction disturbance</b>  <b>Page 35</b></p> <p><b>Comment</b>  Satisfactory exercise electrocardiogram (see guidance material) should be inserted. Withdrawal of cardioactive medication is normal practice unless the investigation is targeted at the protective effect with the medication being taken.</p> <p><b>Justification</b></p> <p><b>Proposed Text</b>  "...withdrawal of cardioactive medication should normally be required".</p>	
response	<p><i>Not accepted</i></p> <p>The proposed NPA text is a transposition of the corresponding requirement from JAR FCL 3.</p>	
comment	2515	comment by: UK CAA MEDICAL ADVISORY PANEL
	<p><b>Paragraph MED.B.005(e)(1)(iii)</b>  <b>Page 35</b></p> <p><b>Comment</b>  The most effective way of studying the ejection fraction using echocardiography is using Simpson's Rule.</p> <p><b>Justification</b></p> <p><b>Proposed Text</b>  "...ventricular ejection fraction, using Simpson's Rule".</p>	
response	<p><i>Accepted</i></p> <p>The NPA text was transposed from JAR-FCL 3; however, the comment is accepted for clarity of the paragraph.</p>	
comment	2516	comment by: UK CAA MEDICAL ADVISORY PANEL
	<p><b>Paragraph MED.B.005(e)(1)(iv)</b>  <b>Page 35</b></p> <p><b>Comment</b>  The syntax needs tidying.</p> <p><b>Justification</b></p> <p><b>Proposed Text</b>  "24 hour (Holter) electrocardiogram, repeated as necessary". Delete ECG recording.</p>	
response	<p><i>Partially accepted</i></p> <p>Text change to: 24-hour ECG recording, repeated as necessary.</p>	

comment	2517	comment by: UK CAA MEDICAL ADVISORY PANEL
	<p><b>Paragraph MED.B.005(e)(1)(vi)</b>  <b>Page 35</b></p> <p><b>Comment</b>  This line is inconsistent with what has gone before.</p> <p><b>Justification</b></p> <p><b>Proposed Text</b>  Insert "Stress Myocardial Perfusion Imaging" and delete "scanning".</p>	
response	<i>Partially accepted</i>	
	'scanning' replaced by 'imaging'.	
comment	2518	comment by: UK CAA MEDICAL ADVISORY PANEL
	<p><b>Paragraph MED.B.005(e)(1)(vii)</b>  <b>Page 35</b></p> <p><b>Comment</b>  Cardiac magnetic resonance imaging (MRI).</p> <p><b>Justification</b></p> <p><b>Proposed Text</b>  "Cardiac magnetic resonance imaging (MRI)".</p>	
response	<i>Accepted</i>	
	Thank you for the comment. The text will be amended.	
comment	2519	comment by: UK CAA MEDICAL ADVISORY PANEL
	<p><b>Paragraph MED.B.005(e)(3) Ablation</b>  <b>Page 35</b></p> <p><b>Comment</b>  Syntax.</p> <p><b>Justification</b></p> <p><b>Proposed Text</b>  Insert "Applicants who have undergone" delete "received".</p>	
response	<i>Accepted</i>	
	Thank you for the comment. The text will be amended.	
comment	2520	comment by: UK CAA MEDICAL ADVISORY PANEL
	<p><b>Paragraph MED.B.005(e)(5) Heart block</b>  <b>Page 36</b></p> <p><b>Comment</b>  Heart block is slang. Atrioventricular (AV block). Pilots with Mobitz Type 2 and 2:1 atrioventricular block are very unlikely to be assessed as fit.</p>	

	<b>Justification</b>	
	<b>Proposed Text</b> "Pilots with Mobitz Type 2 and 2:1 atrioventricular require full cardiological evaluation and are likely to be assessed as unfit".	
response	<i>Noted</i>	
	See response to comment No 478.	
	It is not possible to use 'are likely to be assessed as unfit' because of lack of clarity.	
comment	2521	comment by: UK CAA MEDICAL ADVISORY PANEL
	<b>Paragraph MED.B.005(e)(6)(i) Complete right bundle branch block</b> <b>Page 36</b>	
	<b>Comment</b> Following successful completion, initial applicants under age 40 years of age may be considered for a fit assessment. Initial applicants over 40 years should demonstrate no change 12 months later.	
	<b>Justification</b> <b>Proposed Text</b>	
response	<i>Noted</i>	
	Please see response to comment No 479.	
comment	2522	comment by: UK CAA MEDICAL ADVISORY PANEL
	<b>Paragraph MED.B.005(e)(7) Complete left bundle branch block</b> <b>Page 36</b>	
	<b>Comment</b> The default position for left bundle branch block is a multipilot limitation in view of the difficulties with being confident about the outcome even in the absence of coronary artery disease, muscle disorder or evidence of further conducting system abnormality.	
	<b>Justification</b> <b>Proposed Text</b> "A fit assessment with multipilot limitation may be considered by the licensing authorities".	
response	<i>Not accepted</i>	
	There is a multi-pilot limitation for 3 years (e)(7)(ii). This limitation will only be lifted if the licensing authority is confident that issuing a medical certificate without this limitation is safe.	
comment	2523	comment by: UK CAA MEDICAL ADVISORY PANEL
	<b>Paragraph MED.B.005(e)(7)(i)</b> <b>Page 36</b>	

**Comment**

For confidence in left bundle branch aberration there has to be no evidence of coronary artery disease, of a myocardial abnormality or of distal conducting tissue disease. A better way of expressing this paragraph is..

**Justification****Proposed Text**

"Initial applicants who demonstrate no change over a 3 year period may be considered for a fit assessment by the licensing authority".

response *Not accepted*

Thank you for the comment. For the time being the NPA text remains in place.

comment

2524

comment by: UK CAA MEDICAL ADVISORY PANEL

**Paragraph MED.B.005(e)(8)(i) Ventricular pre-excitation  
Page 36**

**Comment**

Additional paragraph.

**Justification****Proposed Text**

Insert "(iii) Symptomatic applicants shall be assessed as unfit" – this should be in the IR.

response *Not accepted*

The rule allows a fit assessment only for asymptomatic applicants.

**C. Draft Decision Part-MED - Subpart B: Requirements for Medical Certificates - Section 1: Specific requirements for class 1 and class 2 medical certificates - Chapter A: AMC for Class 1 medical certificates - AMC A to MED.B.010: Respiratory System** p. 37-38

comment

13

comment by: GEMA

3. Cinco mgr. de Metilprednisolona al dia no es compatible ni con limitaciones?

response

*Noted*

Cortisone was also not accepted in Appendix 2 to Subparts B & C in JAR-FCL 3 which was the basis of this document. This may be re-evaluated in the rulemaking task MED.001.

comment

14

comment by: GEMA

7.2 Se ha colado un AMS

response

*Accepted*

Thanks, corrected.

comment	142	comment by: <i>Civil Aviation Authority - The Netherlands</i>
	<p><b>AMC A to MED.B.010, onder 1.1. (Blz. 37 van 66)</b> De CAA-The Netherlands merkt op dat niet duidelijk is wat met "A low FEV/FVC" wordt bedoeld. De CAA-The Netherlands verzoekt aan EASA om aan te geven hoe laag nog is toegestaan.</p> <p><b>AMC A to MED.B.010, onder 2. (Blz. 37 van 66)</b> De CAA-The Netherlands merkt op dat niet duidelijk is wat met "minor impairment" wordt bedoeld. De CAA-The Netherlands verzoekt EASA om deze term met cijfers te verduidelijken.</p>	
response	<i>Partially accepted</i>	
	The value of 70%, that was in Appendix 2 to Subparts B & C of JAR-FCL 3, will be re-introduced in Part MED.	
comment	480	comment by: <i>UK CAA</i>
	<p><b>AMC A to MED.B.010 1.1</b> <b>Page: 37</b></p> <p><b>Comment:</b> Additional lung function tests may be more appropriate than additional clinical review.</p> <p><b>Justification:</b> Review by a specialist may not be necessary in all cases.</p> <p><b>Proposed Text:</b> Delete 'by a specialist in respiratory disease'. Amend to: '...should require <b>further</b> evaluation.'</p>	
response	<i>Not accepted</i>	
	Additional lung function tests still should be reviewed by a specialist in respiratory diseases. Also, the requirement of JAR-FCL 3 has been retained.	
comment	481	comment by: <i>UK CAA</i>
	<p><b>AMC A to MED.B.010 5.1</b> <b>Page: 37</b></p> <p><b>Comment:</b> The importance of investigating whether cardiac sarcoid is present should be emphasised.</p> <p><b>Justification:</b> Cardiac sarcoidosis is the greatest risk to flight safety from sarcoid.</p> <p><b>Proposed Text:</b></p>	

response	Amend to: `...possibility of systemic, <b>particularly cardiac</b> , involvement.' <i>Accepted</i>	
comment	482	comment by: <i>UK CAA</i>
	<p><b>AMC A to MED.B.010 6.1 (i)</b>  <b>Page: 37</b>  <b>Comment:</b>  It would be inappropriate to undertake single pilot flying using a Class 1 medical certificate within 1 year of a spontaneous pneumothorax.</p> <p><b>Justification:</b>  The greatest risk of recurrence of a pneumothorax is within a few months of the original episode.</p> <p><b>Proposed Text:</b>  Amend to: <b>'for an initial applicant</b>, one year following full recovery from...'</p>	
response	<i>Not accepted</i>	
	<p>The rule is applicable for all applicants, not only for initial ones.</p> <p>The proposed NPA text is a transposition of the corresponding requirement from JAR FCL 3. Additional requirements in the implementing rule may be introduced only through a new rulemaking task.</p>	
comment	506	comment by: <i>UK CAA</i>
	<p><b>AMC A to MED.B.010 6.1 (iii)</b></p> <p><b>Comment:</b>  Para (iii) relates to post-surgical aeromedical disposal.</p> <p><b>Justification:</b>  This requirement applies following surgical intervention, irrespective of whether the history is of a single or recurrent pneumothoraces.</p> <p><b>Proposed Text:</b>  Delete: 'in the case of a recurrent pneumothorax'.</p>	
response	<i>Not accepted</i>	
	<p>The proposed NPA text is a transposition of the corresponding requirement from JAR FCL 3.</p>	
comment	768	comment by: <i>European Society of Space and Aviation Medicine (ESAM)</i>
	<p><b>Author: European Society of Space and Aviation Medicine (ESAM) - Internal Medicine Group -</b></p> <p><b>Section: AMC to MED B.010 Respiratory System - class 1 medical certificates</b></p> <p><b>Page: 37 - 38</b></p>	

**Relevant Text:**

## 1. Examinations

## 1.1 Spirometry

Spirometric examination is required for initial examination. A low FEV1/FVC ratio at initial examination should require evaluation by a specialist in respiratory disease.

## 1.2 Chest radiography

Posterior/anterior chest radiography may be required at initial, revalidation or renewal examinations when indicated on clinical or epidemiological grounds.

## 2. Chronic obstructive airways disease

Applicants with chronic obstructive airways disease should be assessed as unfit. Applicants with only minor impairment of their pulmonary function may be assessed as fit.

## 3. Asthma

For applicants with asthma requiring medication or experiencing recurrent attacks of asthma, a fit assessment may be considered if the asthma is considered stable with satisfactory pulmonary function tests and medication is compatible with flight safety (systemic steroids are disqualifying).

## 4. 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.

## 5. Sarcoidosis

5.1. 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 if no medication is required, and the disease is investigated and shown to be limited to hilar lymphadenopathy and inactive.

5.2. Applicants with cardiac sarcoid should be assessed as unfit.

## 6. Pneumothorax

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

- (i) one year following full recovery from a single spontaneous pneumothorax;
- (ii) at revalidation, six weeks following full recovery from a single spontaneous pneumothorax, with a multipilot limitation;
- (iii) following surgical intervention in the case of a recurrent pneumothorax provided there is satisfactory recovery.

6.2. A recurrent spontaneous pneumothorax that has not been surgically treated is disqualifying.

6.3. 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.

## 7. Thoracic surgery

7.1. Applicants requiring major thoracic surgery should be assessed as unfit for a minimum of three 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).

7.2. A fit assessment following lesser chest surgery may be considered by the AMS after satisfactory recovery and full respiratory evaluation.

### Sleep apnoea syndrome

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

### **Comment:**

### **Proposal:**

#### 1. Examinations

##### 1.1 Spirometry

Spirometric examination is required for initial examination. A low FEV1/FVC ratio at initial examination should require evaluation by a specialist in respiratory disease.

##### 1.2 Chest radiography

Posterior/anterior chest radiography may be required at initial, revalidation or renewal examinations when indicated on clinical or epidemiological grounds.

#### 2. Chronic obstructive airways disease

Applicants with chronic obstructive airways disease should be assessed as unfit. Applicants with only minor impairment of their pulmonary function may be assessed as fit.

#### 3. Asthma

For applicants with asthma requiring medication or experiencing recurrent attacks of asthma, a fit assessment may be considered if the asthma is considered stable with satisfactory pulmonary function tests and medication is compatible with flight safety. Systemic steroids Therapy is disqualifying, if daily dose is higher than 7,5 mg Prednisolon or Equivalent.

#### 4. 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.

#### 5. Sarcoidosis

5.1. 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 if no medication is required, and the disease is investigated and shown to be limited to hilar lymphadenopathy and inactive.

5.2. Applicants with cardiac sarcoid should be assessed as unfit.

#### 6. Pneumothorax

6.1. Applicants with a spontaneous pneumothorax should be assessed as unfit. A fit assessment may be considered if respiratory evaluation is

satisfactory:

- (i) at revalidation, six weeks following full recovery demonstrated by a normal CT scan from a single spontaneous pneumothorax,
- (ii) following surgical intervention in the case of are current pneumothorax provided there is satisfactory recovery.

6.2. A recurrent spontaneous pneumothorax that has not been surgically treated is disqualifying.

6.3. 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.

7. Thoracic surgery

7.1. Applicants requiring major thoracic surgery should be assessed as unfit for a minimum of three 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).

7.2. A fit assessment following lesser chest surgery may be considered after satisfactory recovery and full respiratory evaluation.

Sleep apnoea syndrome

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

response

*Not accepted*

Comment is on 3.:  
Not accepted. The proposed addition could be added to future Guidance Material.

comment

1517	comment by: <i>Dr Ian Perry</i>
Page 37 6 Pneumothorax 6.1(1) This statement may limit those with a lesser type of the condition. The one year ban should be made more flexible, and left to the discretion of the Licensing Authority.	

response

*Noted*

The proposed NPA text is a transposition of the corresponding requirement from JAR-FCL 3. The one year of unfitness only applies to initial applicants. At revalidation, a period of 6 weeks can be accepted with a multi-pilot limitation (which is not possible for initial applicants).

comment

2525	comment by: <i>UK CAA MEDICAL ADVISORY PANEL</i>
<p><b>Paragraph</b>  <b>AMC A to MED.B.010 5 Respiratory system</b>  <b>AMC A to MED.B.010 5 Sarcoidosis</b></p> <p><b>Page 37</b></p>	

	<p><b>Comment</b> Possibly the most important part about sarcoidosis is the risk of sudden death from cardiac involvement.</p> <p><b>Justification</b> Cardiac involvement with sarcoidosis is associated with sudden death.</p> <p><b>Proposed Text</b></p>
response	<p><i>Noted</i></p> <p>Please see response to comment No 481.</p>

comment	2526	comment by: UK CAA MEDICAL ADVISORY PANEL
	<p><b>Paragraph AMC A to MED.B.010 5 5.1 Sarcoidosis</b> <b>Page 37</b></p> <p><b>Comment</b></p> <p><b>Justification</b></p> <p><b>Proposed Text</b> "..of systemic and particularly of cardiac involvement".</p>	
response	<p><i>Noted</i></p> <p>Please see response to comment No 481.</p>	

**C. Draft Decision Part-MED - Subpart B: Requirements for Medical Certificates - Section 1: Specific requirements for class 1 and class 2 medical certificates - Chapter A: AMC for Class 1 medical certificates - AMC A to MED.B.015: Digestive System**

p. 38

comment	15	comment by: GEMA
	6.1 Y 6.2 es practicamente lo mismo	
response	<p><i>Noted</i></p> <p>Not really. In 6.1 a fit assessment is possible earlier than 3 months. In 6.2 the period of unfitness is 3 months or longer.</p>	

comment	769	comment by: European Society of Space and Aviation Medicine (ESAM)
	<p><b>Author: European Society of Space and Aviation Medicine (ESAM) - Internal Medicine Group -</b></p> <p><b>Section: AMC to MED B.015</b> <b>Digestive System - class 1 medical certificates</b></p> <p><b>Page: 38</b></p> <p><b>Relevant Text:</b> 1. Oesophageal varices</p>	

Applicants with oesophageal varices should be assessed as unfit.

## 2. 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.

## 3. Gallstones

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

3.2. An applicant with asymptomatic multiple gallstones may be assessed as fit with a multipilot limitation.

## 4. 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 systemic steroids are not required for its control.

## 5. Peptic ulceration

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

## 6. Abdominal surgery

6.1. Abdominal surgery is disqualifying for a minimum of three 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.

6.2. 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 three 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).

### **Comment:**

### **Proposal:**

#### 1. Oesophageal varices

Applicants with oesophageal varices should be assessed as unfit.

#### 2. 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.

#### 3. Gallstones

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

3.2. An applicant with asymptomatic multiple gallstones may be assessed as fit with a multipilot limitation.

#### 4. 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 systemic steroids are not required for its control.

#### 5. Peptic ulceration

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

#### 6. Abdominal surgery

6.1. Abdominal surgery is disqualifying for a minimum of three months. An earlier minimum 4 weeks 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.

6.2. 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 three 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).

response *Noted*

The comment is on 6.1 only. It does not seem practical to include the additional limit of 4 weeks. If an earlier fit assessment is considered, it can only be done after careful investigation of the case and depending on the clinical situation. The proposed new minimum of 4 weeks before a fit assessment can be made is also not in JAR-FCL 3, which was the basis of this document.

**C. Draft Decision Part-MED - Subpart B: Requirements for Medical Certificates - Section 1: Specific requirements for class 1 and class 2 medical certificates - Chapter A: AMC for Class 1 medical certificates - AMC A to MED.B.020: Metabolic and Endocrine Systems**

p. 39

comment *16* comment by: *GEMA*

7. II ¿cuales?

response *Noted*

**Open.**

comment *143* comment by: *Civil Aviation Authority - The Netherlands*

**AMC A to MED.B.020, onder 7, onder ii (Blz. 39 van 66)**

De CAA-The Netherlands merkt op dat niet duidelijk is wat met 'certain antidiabetic medications', wordt bedoeld. De CAA-The Netherlands verzoekt EASA om duidelijk in het voorschrift aan te geven om welke medicijnen het gaat. In JAR-FCL staan de medicijnen duidelijk genoemd.

response *Partially accepted*

The words ... medications 'that are not likely to cause hypoglycaemia' ... will be added. More clarification can be given in future Guidance Material to be added under the rulemaking task MED.001.

comment	408	comment by: <i>European CMO Forum</i>
	<p>Comment:</p> <p>It needs to be clear that there should be a negligible risk of hypoglycaemia from treatment.</p> <p>Justification:</p> <p>Hypoglycaemia is a risk to flight safety.</p> <p>Proposed Text:</p> <p>Insert: `...medications <b>that are not likely to cause hypoglycaemia</b> may be acceptable...'</p>	
response	<i>Accepted</i>	
	Thank you for the comment. The text will be changed accordingly.	
comment	680	comment by: <i>Pekka Oksanen</i>
	<p>Hypoglycaemia is a risk to flight safety and must be taking into consideration when selecting a medication.</p> <p>Proposal: insert text to 7(ii) Diabetes mellitus:</p> <p>... medications <b>that are not likely to cause hypoglycaemia</b> may be acceptable ...</p>	
response	<i>Noted</i>	
	Please see response to comment No 408.	
comment	2101	comment by: <i>DGAC FRANCE</i>
	<p>AMC to MED.B.020, <b>paragraph 7</b></p> <p>Comment :</p> <p>It is necessary to incorporate developments in the medical treatment of diabetes into the EASA requirements.</p> <p>Alpha-glucosidase inhibitors delay the digestion and absorption of starch and glucose. They do not have the side effect of hypoglycaemia, and their use for pilots with unrestricted class 1 medication is currently supported by JAR-FCL 3, Manual – Endocrinology – 6.</p> <p>Thiazolidinediones reduce peripheral insulin resistance leading to a reduction in blood glucose concentration. There is no significant association between thiazolidinediones and the risk of non-severe hypoglycaemia.</p> <p>Medication that acts on the incretin pathway when used in combination with other medication is acceptable where studies have demonstrated that there is no significant increase in hypoglycaemic side effects compared with use of the other medication alone.</p>	

Modification :

Delete the proposed paragraph 7 and replace it by the following proposition :

**7. Diabetes mellitus**

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

**applicants with diabetes mellitus may be assessed as fit by the licensing authority subject to good blood sugar control on**

**(i) alpha-glucosidase inhibitors.**

**(ii) thiazolidinediones.**

**(iii) thiazolidinediones in combination with medication that acts on the incretin pathway, may be acceptable for a Class 1 fit assessment with multi – pilot Class 1 ‘OML’ limitation.**

**(iv) biguanides, and biguanides in combination with medication that acts on the incretin pathway, may be acceptable for a Class 1 fit assessment with multi – pilot Class 1 ‘OML’ limitation.**

response *Noted*

One product containing rosiglitazone (thiazolidinediones are also called glitazones) is presently under investigation by the FDA (Food and Drug Administration) to evaluate the outcome of the RECORD study that was designed to evaluate the cardiovascular safety risk. The result will be presented in July 2010. It may therefore not be appropriate to include thiazolidinediones in general in the AMC.

Alpha-glucosidase inhibitors and biguanides which were included in Appendix 4 in JAR-FCL 3 will be re-introduced in Part MED. Other medication can be added as Guidance Material to be drafted in the rulemaking task MED.001.

comment 2314

comment by: *DLR*

The BMI is no prognostic factor for a cardiovascular risk. Either an extended cardiovascular investigation at a BMI above 35 should follow to assess the blood pressure behaviour, the cardiopulmonary performance to judge other cardiovascular risk factors or the passage concerning the cardiovascular risk can be deleted.

In case the BMI has an influence on the safe performance of an aircraft, the AME is not the right person to assess that during the examination. The candidate should show a proof of a check flight or by a checker that there are no relevant safety issues concerning the operating and evacuation of the aircraft related to his/her body constitution.

Proposal:

2. In case of obesity the candidate shall proof in a check that there are no relevant safety issues concerning the operating and evacuation of the aircraft related to his/her body constitution.

response *Not accepted*

The proposed NPA text is a transposition of the corresponding requirement in JAR-FCL 3.175 (e). Amendments do not seem necessary at this stage.

comment	2407	comment by: <i>Irish Aviation Authority</i>
	<p>It has to be clear that there should be a negligible risk of hypoglycaemia from treatment.</p> <p>Justification: Hypoglycaemia is a risk for flight safety.</p> <p>Proposed text: Insert: '<b>...medication that is unlikely to cause hypoglycaemia may be acceptable...</b>'</p>	
response	Noted	
	See response to comment No 408.	

comment	2408	comment by: <i>Irish Aviation Authority</i>
	<p>para 7 Developments in the medical treatment of diabetes should be incorporated into the EASA requirements.</p> <p>Justification: Alpha-glucosidase inhibitors delay the digestion and absorption of starch and glucose. They have not the side effect of hypoglycaemia, and their use for pilots with unrestricted class 1 medication is currently supported by JAR-FCL 3, Manual – Endocrinology – 6. Thiazolidinediones reduce peripheral insulin resistance leading to reduction of blood glucose concentration. There is no significant association between thiazolidinediones and the risk of hypoglycaemia. Medication that acts on the incretin pathway when used in combination with other medication is acceptable as studies have demonstrated that there is no significant increase in hypoglycaemic side effects compared with use of the other medication alone.</p> <p>Proposed text: Replace proposed paragraph with: AMC A to MED.B.020 para 7 <i>Diabetes mellitus</i> Subject to good control of blood sugar with no hypoglycaemic episodes: applicants with diabetes mellitus may be assessed as fit subject to good blood sugar control on <b>i) alpha-glucosidase inhibitors</b> <b>(ii) thiazolidinediones</b></p> <p><b>(i) (ii) thiazolidinediones in combination with medication that acts on the incretin pathway, may be acceptable for a Class 1 fit assessment with for Class 1 'OML' limitation</b></p> <p><b>(ii) (i) biguanides, and biguanides in combination with medication that acts on the incretin pathway, may be acceptable for a Class 1 fit assessment with multi – pilot Class 1 'OML' limitation</b></p>	
response	Noted	

Please see response to comment No 2101.

**C. Draft Decision Part-MED - Subpart B: Requirements for Medical Certificates - Section 1: Specific requirements for class 1 and class 2 medical certificates - Chapter A: AMC for Class 1 medical certificates - AMC A to MED.B.025: Haematology** p. 39-40

comment	17	comment by: GEMA
	2.1 Si la Hemoglobina es lo que hay que mirar en cada reconocimiento, por qué la cifra de corte se da en hematocrito? Esto es algo arrastrado desde al menos la primera edición de JAR-FCL3	
response	Noted	
comment	18	comment by: GEMA
	¿Cuanta policitemia es necesaria para dar no apto?	
response	Noted	
	No fixed numbers. The condition must be stable and no associated pathology shall be demonstrated.	
comment	19	comment by: GEMA
	7.3. ¿Para siempre?	
response	Noted	
	Depends on the recovery.	
comment	483	comment by: UK CAA
	<p><b>AMC A to MED.B.025 5 and 6</b>  <b>Page: 40</b></p> <p><b>Comment:</b>  Paras 5 and 6 can be combined.</p> <p><b>Justification:</b>  There is no justification for only permitting Class 1 OML with a haemorrhagic disorder.</p> <p><b>Proposed Text:</b>  New para 5: 'Applicants with a coagulation or haemorrhagic disorder may be assessed as fit if there is no history of significant bleeding episodes.'</p> Delete para 6.	
response	Not accepted	
	The NPA text is a transposition of the corresponding requirement from JAR-FCL 3.180 (g) and (h). In the corresponding Appendix there is a requirement for an	

OML limitation for both conditions whereas in the NPA this limitation is only for haemorrhagic disorders. As there are no comments to re-introduce the OML for coagulation disorders, the text will remain unchanged for the time being.

comment 484 comment by: UK CAA

**AMC A to MED.B.025 7.2**

**Page: 40**

**Comment:**

The use of anti-coagulants for treatment and prophylaxis should be differentiated.

**Justification:**

The use of anti-coagulants for prophylaxis in low risk cases is within acceptable flight safety parameters.

**Proposed Text:**

Change 'therapy' to 'treatment'.

response *Partially accepted*

The text of the proposed rule will be changed accepting anticoagulation under special circumstances.

comment 1842 comment by: European CMO Forum

**Paragraph: AMC A to MED. B.025 7.2**

**Page No: 40**

**Comment:**

This paragraph is now covered by **AMC A to MED.B.005 (b) (7)** and can be deleted.

**Justification:**

To prevent duplication

**Proposed Text:**

**(if applicable)**

Delete **AMC A to MED. B.025 7.2**

response *Accepted*

Thank you for the comment. The text will be changed accordingly.

comment 1847 comment by: European CMO Forum

**Paragraph: AMC A to MED.B.020 para 7**

**Page No: 39**

**Comment:**

**It is necessary to incorporate developments in the medical treatment of diabetes into the EASA requirements.**

**Justification:**

Alpha-glucosidase inhibitors delay the digestion and absorption of starch and glucose. They do not have the side effect of hypoglycaemia, and their use for pilots with unrestricted class 1 medication is currently supported by JAR-FCL 3, Manual – Endocrinology – 6.  
 Thiazolidinediones reduce peripheral insulin resistance leading to a reduction in blood glucose concentration. There is no significant association between thiazolidinediones and the risk of non-severe hypoglycaemia.  
 Medication that acts on the incretin pathway when used in combination with other medication is acceptable where studies have demonstrated that there is no significant increase in hypoglycaemic side effects compared with use of the other medication alone.

**Proposed Text:  
 (if applicable)**

Replace proposed paragraph with:

AMC A to MED.B.020 para 7 *Diabetes mellitus*

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

applicants with diabetes mellitus may be assessed as fit subject to good blood sugar control on

***i) alpha-glucosidase inhibitors (ii) thiazolidinediones***

***(i) thiazolidinediones in combination with medication that acts on the incretin pathway, may be acceptable for a Class 1 fit assessment with multi – pilot Class 1 ‘OML’ limitation***

***(ii) biguanides, and biguanides in combination with medication that acts on the incretin pathway, may be acceptable for a Class 1 fit assessment with multi – pilot Class 1 ‘OML’ limitation***

response *Noted*

Please see response to comment No 408 in the segment ‘Metabolic and Endocrine Disorders’.

comment

2164

comment by: DGAC FRANCE

AMC A to MED.B.025, **paragraph 7.2**

comment :

This paragraph is now covered by **AMC A to MED.B.005 (b) (7)** and can be deleted. To prevent duplication

Modification :

Delete AMC A to MED. B.025 § 7.2

~~7.2. Applicants with a deep vein thrombosis or pulmonary embolus shall be assessed as unfit. A fit assessment may be considered after anti-coagulation therapy is discontinued.~~

response *Noted*

Please see response to comment No 1842.

comment	2409	comment by: <i>Irish Aviation Authority</i>
	<p>7.2 This paragraph is covered by <b>AMC A to MED.B.005 (b) (7)</b> and can be deleted.</p> <p>Justification: To prevent duplication</p> <p>Proposed text: <del>AMC A to MED. B.025 7.2</del></p>	
response	<i>Noted</i>	
	Please see response to comment No 1842	

**C. Draft Decision Part-MED - Subpart B: Requirements for Medical Certificates - Section 1: Specific requirements for class 1 and class 2 medical certificates - Chapter A: AMC for Class 1 medical certificates - AMC A to MED.B.030: Genitourinary System** p. 40-41

comment	20	comment by: <i>GEMA</i>
	Hay cálculos renales que por su tamaño y/o localización NUNCA van a producir cólicos, ojo	
response	<i>Noted</i>	
comment	21	comment by: <i>GEMA</i>
	Hay calculos renales que por tamaño/localización nunca van a producir cólicos	
response	<i>Noted</i>	

**C. Draft Decision Part-MED - Subpart B: Requirements for Medical Certificates - Section 1: Specific requirements for class 1 and class 2 medical certificates - Chapter A: AMC for Class 1 medical certificates - AMC A to MED.B.035: Infectious Disease** p. 41-42

comment	22	comment by: <i>GEMA</i>
	4.2 Conceptos muy antiguos, que hay que revisar	
response	<i>Noted</i>	
comment	23	comment by: <i>GEMA</i>
	Hapatitis infecciosa, recuperación completa... ¿Y si es una hepatitis crónica por virus C?	
response	<i>Noted</i>	
comment	485	comment by: <i>UK CAA</i>

**AMC A to MED.B.035 4.2**

Page: 41

**Comment:**

Terminology inappropriate and it is only disease that presents an increased risk to flight safety that is relevant.

**Justification:**

Terminology is outdated and does not allow for complete recovery from an AIDs defining condition. Suggested text is compatible with the new proposed ICAO wording as per ICAO State Letter 08-33.

**Proposed Text:**

Amend to: '**Clinical disease that might give rise to incapacitating symptoms is disqualifying**'

Delete: 'The occurrence of AIDS or AIDS related complex is disqualifying'.

response *Not accepted*

This is a major change to JAR-FCL 3 that should not be introduced at this stage. If this proposal is taken up in rulemaking task MED.001, the question of an OML limitation in the case of clinical disease due to an HIV infection should also be considered.

**C. Draft Decision Part-MED - Subpart B: Requirements for Medical Certificates - Section 1: Specific requirements for class 1 and class 2 medical certificates - Chapter A: AMC for Class 1 medical certificates - AMC A to MED.B.040: Obstetrics and Gynaecology**

p. 42

comment 144 comment by: *Civil Aviation Authority - The Netherlands*

**AMC A to MED.B.040, onder 3.1. (Blz. 42 van 66)**

De CAA-The Netherlands merkt op dat niet duidelijk is wat met 'following review' wordt bedoeld. De CAA-The Netherlands verzoekt aan EASA om de eisen van het review op te sommen in het voorschrift.

response *Noted*

'following review' means 'after review'. A comma will be added to make the text clearer: 'A pregnant licence holder may be assessed as fit ... during the first 26 weeks of gestation, following review ... by the AeMC ...'.

comment 770 comment by: *European Society of Space and Aviation Medicine (ESAM)*

**Author: European Society of Space and Aviation Medicine (ESAM) - Internal Medicine Group -**

**Section: AMC to MED B.040  
Obstetrics and Gynaecology - class 1 medical certificate**

**Page: 42**

**Relevant Text:**

1. Gynaecological surgery

An applicant who has undergone a major gynaecological operation shall be assessed as unfit for a period of three 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 is completely asymptomatic and there is only a minimal risk of secondary complication or recurrence.

2. Severe menstrual disturbances

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

3. Pregnancy

3.1. A pregnant pilot may be assessed as fit with a multipilot limitation during the first 26 weeks of gestation following review of the obstetric evaluation by the AeMC or AME who shall inform the licensing authority.

3.2. The AeMC or AME shall provide written advice to the applicant and the supervising physician regarding potentially significant co

**Comment:**

**Proposal:**

1. Gynaecological surgery

An applicant who has undergone a major gynaecological operation shall be assessed as unfit for a period of three 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 is completely asymptomatic and there is only a minimal risk of secondary complication or recurrence minimum 4 weeks

2. Severe menstrual disturbances

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

3. Pregnancy

3.1. A pregnant pilot may be assessed as fit with a multipilot limitation during the first 26 weeks of gestation following review of the obstetric evaluation by the AeMC or AME who shall inform the licensing authority.

3.2. The AeMC or AME shall provide written advice to the applicant and the supervising physician regarding potentially significant co

response

*Not accepted*

The comment is under number 1.

The proposal to introduce second minimum period of being unfit after surgery is not accepted. A fit assessment, made earlier than 3 months after surgery, will be based on clinical findings.

**C. Draft Decision Part-MED - Subpart B: Requirements for Medical Certificates - Section 1: Specific requirements for class 1 and class 2 medical certificates - Chapter A: AMC for Class 1 medical certificates - AMC A to MED.B.045: Musculoskeletal System** p. 42

comment

24

comment by: GEMA

	¿UN paciente con artrosis, patología degenerativa, tiene que pasar un test de vuelo...siempre?	
response	<i>Noted</i>	
comment	1349	comment by: <i>European Disabled Aviators</i>
	Attachment <a href="#">#21</a>	
	<p>The replacement of the word "of" by the word "affecting" suggested for this article (first line) has to be paralleled with the amendment recommended below to AMC A to MED.B.060. Its purpose is to make sure that the whole article will not only apply to conditions strictly inherent to the bones, joints, muscles and tendons but also to all diseases, injuries and abnormalities that impact them - such as neurological conditions.</p> <p>1. An applicant with any significant sequela from disease, injury or congenital abnormality of <u>affecting</u> the bones, joints, muscles or tendons with or without surgery requires full evaluation prior to a fit assessment.</p> <p>2. In case of limb deficiency, [...]</p>	
response	<i>Accepted</i>	

<p><b>C. Draft Decision Part-MED - Subpart B: Requirements for Medical Certificates - Section 1: Specific requirements for class 1 and class 2 medical certificates - Chapter A: AMC for Class 1 medical certificates - AMC A to MED.B.050: Psychiatry</b></p>	p. 42-43
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comment	25	comment by: <i>GEMA</i>
	5.- ¿No se permite ningún fármaco, ni siquiera los inhibidores de la recaptación de la serotonina, con un OML por ejemplo? El tratamiento de la depresión es muy largo, al menos 6 meses, y el concepto de depresión vs tristeza es cada vez más laxo	
response	<i>Noted</i>	
comment	67	comment by: <i>Dr Graham Cresswell, chief medical officer, bmi</i>
	<p>AMC A to MED.B.050 (5)</p> <p>This will prohibit pilots from flying while taking SSRIs. Considerable progress has been made with this in Australia, Canada and Europe and it is widely accepted that it is safer to have pilots flying on SSRIs, under the control of psychiatrists or AMEs, than to have them flying with untreated depressive illness or flying while taking psychoactive substances unsupervised.</p> <p>See also ICAO letter AN 5/22-08/33 of 5 May 2008.</p> <p>Suggest...</p> <p>AMC A to MED.B.050 (5). Place a full stop after "gravity" and delete the remainder of the sentence.</p>	
response	<i>Partially accepted</i>	

The text has been re-worded to allow psychotropic medication.

comment

486

comment by: UK CAA

**AMC A to MED.B.050 3****Page: 43****Comment:**

The LSST/M agreed at meeting no.17 in June 2007 (WP 07/07) to support the certification of pilots on certain anti-depressants under strict protocols and oversight procedures. The LST endorsed this proposal in September 2007. It was only the dissolution of the JAA NPA process that has stopped this change from being adopted into JAR FCL 3.

This proposal is supported by the experience of States such as Australia and Canada that have, for some years, permitted antidepressant use by pilots.

This proposal is compatible with the changes to Medical Provisions proposed in ICAO State Letter 08-33.

**Justification:**

Some psychotropic substances are acceptable for certification with a multi pilot limitation. It is safer for pilots on antidepressants who are stable and being actively monitored to fly than for pilots not to declare they are depressed and either fly whilst taking undeclared medication or to not declare they are depressed and to continue flying whilst remaining untreated.

The World Health Organization has indicated that the incidence of depression is increasing and that treatment has improved greatly with the introduction of effective medications that have fewer side effects of aeromedical significance when compared to their predecessors.

**Proposed Text:**

Insert `...substances **likely to affect flight safety** is...'

response

*Noted*

See response to comment No 67.

comment

489

comment by: UK CAA

**AMC A to MED.B.050 5****Page: 43****Comment:**

Text amendment required to permit use of certain psychotropic substances. See comment against **AMC A to MED.B.050 3**

**Justification:**

Some psychotropic substances may be acceptable.

**Proposed Text:**

Delete: `and after all psychotropic medication has been stopped for an appropriate period.'

response

*Noted*

Please see response to comment No 67.

comment 662 comment by: ERA

AMC A to MED.B.050

PSYCHIATRY - class 1 medical certificates

5. Mood disorder

ERA suggest placing a full stop after the word "*gravity*" and deleting the remainder of the sentence.

response *Partially accepted*

The text has been re-worded to allow psychotropic medication.

comment 846 comment by: Swiss Association of Aviation Medicine

**Comment:**

Otherwise the risk of recurrence could be overlooked

**Proposal:**

1. *Psychotic disorder*

A history of, or the occurrence of, a functional psychotic disorder is disqualifying unless in certain rare cases a cause can be unequivocally identified as one which is transient, has ceased and will not recur. Psychiatric evaluation is mandatory

response *Partially accepted*

The text will be amended by: 'Psychiatric evaluation may be necessary'.

comment 847 comment by: Swiss Association of Aviation Medicine

**Proposal:**

4. *Schizophrenia, schizotypal or delusional disorder*

Applicants with an established schizophrenia, schizotypal or delusional disorder should only be considered for a fit assessment if the licensing authority concludes that the original diagnosis was inappropriate or inaccurate and if there is otherwise no risk of recurrence.

(or in the case of a single episode of delirium, provided that the applicant has suffered no permanent impairment.) (delete)

response *Not accepted*

The proposed NPA text is a transposition of the corresponding requirement from JAR-FCL 3 where it did not cause any difficulties.

comment 848 comment by: Swiss Association of Aviation Medicine

**Comment:**

Especially Australian and to some degree Canadian experiences have proven that under specific control there is no risk for aviation safety.

Ross J., K. Griffiths, K. Dear, et al. 'Anti-depressant Use and Safety in Civil

Aviation; A Case-Control Study of 10 Years of Australian Data'. Aviation, Space and Environmental Medicine. 78, 749-755, 2007.

**Proposal:**

An established mood disorder is disqualifying. A fit assessment may be considered after full consideration of an individual case, depending on the mood disorder characteristics and gravity, after full recovery and after regular follow up, all psychotropic medication has been stopped for an appropriate period.

The following sentence should be added:

In case by case decisions some SSRI and SRNI may be accepted under close psychiatric review.

response *Noted*

Please see response to comment No 67.

comment 849 comment by: *Swiss Association of Aviation Medicine*

**Proposal:**

6. *Neurotic, stress-related or somatoform disorder*

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

response *Not accepted*

The possibility to require additional medical examinations and investigations is proposed in MED.B.001 (d).

comment 850 comment by: *Swiss Association of Aviation Medicine*

**Proposal:**

9. *Deliberate self-harm*

A single self destructive action or repeated acts of deliberate self-harm are disqualifying. A fit assessment may be considered after full consideration of an individual case and may require psychiatric and/or psychological review. Neuropsychological assessment may (delete) also be required.

response *Not accepted*

The licensing authority will decide whether additional investigations are necessary.

comment 856 comment by: *Swiss Association of Aviation Medicine*

**Comment:**

These diagnostic groups bare a high risk to endanger others or violate rules, i.e. flying in controlled air space.

Draeger J., J. Kriebel (Eds). Praktische Flugmedizin. Ecomed Verlag 2002.

C. Curdt - Christiansen, J. Dreager, J. Kriebel (Eds). Practical Aviation Medicine. World Scientific Press. Singapore. Impress.

**Proposal:**

1. Psychotic disorder

*Schizophrenia, schizotypal or delusional disorder*

Applicants with an established schizophrenia, schizotypal or delusional disorder should only be considered for a fit assessment if the licensing authority concludes that the original diagnosis was inappropriate or inaccurate and otherwise no risk of recurrence.

## 2. Mood disorder

An established mood disorder is disqualifying. A fit assessment may be considered after full consideration of an individual case, depending on the mood disorder characteristics and gravity, after full recovery and after regular follow up, as well as all psychotropic medication has been stopped for an appropriate period.

In case by case decisions some SSRI and SRNI may be accepted under close psychiatric review.

## 3. Psychotropic substances

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

## 4. Personality or behavioural disorder

After medical evaluation where there is suspicion or established evidence that an applicant has a psychological disorder (delete) deficiency (insert) , the applicant should be referred for psychiatric and/or psychological opinion and advice.

response

*Noted*

1. See response to comment No 847.

2. See response to comment No 848.

3. **Open.**

4. 'Psychological deficiency' is not in an ICD-10 terminology.

comment

896

comment by: *European Society of Space and Aviation Medicine (ESAM)*

**Author: European Society of Space and Aviation Medicine (ESAM) - Group Neurology Psychiatry-**

**Section: 1****Subpart B****Requirements for medical certificates****Specific requirements for class 1 and class 2 medical certificates****Chapter A****AMC for class 1 medical certificates****AMC.A. to Med.B.050 - PSYCHIATRY - class 1 medical certificates****Page: 42****Relevant Text:**1. *Psychotic disorder*

A history of, or the occurrence of, a functional psychotic disorder is disqualifying unless in certain rare cases a cause can be unequivocally identified as one which is transient, has ceased and will not recur.

	<p><b>Comment:</b> Otherwise the risk of recurrence could be overlooked</p> <p><b>Proposal:</b> 1. <i>Psychotic disorder</i> A history of, or the occurrence of, a functional psychotic disorder is disqualifying unless in certain rare cases a cause can be unequivocally identified as one which is transient, has ceased and will not recur. Psychiatric evaluation is mandatory</p>	
response	<p><i>Noted</i></p> <p>See response to comment No 846.</p>	
comment	899	<p>comment by: <i>European Society of Space and Aviation Medicine (ESAM)</i></p> <p><b>Author: European Society of Space and Aviation Medicine (ESAM)- Group Neurology Psychiatry-</b></p> <p><b>Section: 1</b> <b>Subpart B</b> <b>Requirements for medical certificates</b> <b>Specific requirements for class 1 and class 2 medical certificates</b> <b>Chapter A</b> <b>AMC for class 1 medical certificates</b></p> <p><b>AMC.A. to Med.B.050 - PSYCHIATRY - class 1 medical certificates</b></p> <p><b>Page: 43</b></p> <p><b>Relevant Text:</b> 4. <i>Schizophrenia, schizotypal or delusional disorder</i> Applicants with an established schizophrenia, schizotypal or delusional disorder should only be considered for a fit assessment if the licensing authority concludes that the original diagnosis was inappropriate or inaccurate or in the case of a single episode of delirium, provided that the applicant has suffered no permanent impairment.</p> <p><b>Comment:</b></p> <p><b>Proposal:</b> 4. <i>Schizophrenia, schizotypal or delusional disorder</i> Applicants with an established schizophrenia, schizotypal or delusional disorder should only be considered for a fit assessment if the licensing authority concludes that the original diagnosis was inappropriate or inaccurate and if there is otherwise no risk of recurrence. (or in the case of a single episode of delirium, provided that the applicant has suffered no permanent impairment.) (delete)</p>
response	<p><i>Noted</i></p> <p>See response to comment No 847.</p>	
comment	900	<p>comment by: <i>European Society of Space and Aviation Medicine (ESAM)</i></p>

**Author: European Society of Space and Aviation Medicine (ESAM)-  
Group Neurology Psychiatry-**

**Section: 1**

**Subpart B**

**Requirements for medical certificates**

**Specific requirements for class 1 and class 2 medical certificates**

**Chapter A**

**AMC for class 1 medical certificates**

**AMC.A. to Med.B.050 - PSYCHIATRY - class 1 medical certificates**

**Page:** 43

**Relevant Text:**

*5. Mood disorder*

An established mood disorder is disqualifying. A fit assessment may be considered after full consideration of an individual case, depending on the mood disorder characteristics and gravity and after all psychotropic medication has been stopped for an appropriate period.

**Comment:**

Especially Australian and to some degree Canadian experiences have proven that under specific control there is no risk for aviation safety.

Ross J., K. Griffiths, K. Dear, et al. 'Anti-depressant Use and Safety in Civil Aviation; A Case-Control Study of 10 Years of Australian Data'. *Aviation, Space and Environmental Medicine*. 78, 749-755, 2007.

**Proposal:**

An established mood disorder is disqualifying. A fit assessment may be considered after full consideration of an individual case, depending on the mood disorder characteristics and gravity, after full recovery and after regular follow up, all psychotropic medication has been stopped for an appropriate period.

The following sentence should be added:

In case by case decisions some SSRI and SRNI may be accepted under close psychiatric review.

response

*Noted*

See response to comment No 848.

comment

903

comment by: *European Society of Space and Aviation Medicine (ESAM)*

**Author: European Society of Space and Aviation Medicine (ESAM) -  
Group Neurology Psychiatry-**

**Section: 1**

**Subpart B**

**Requirements for medical certificates**

**Specific requirements for class 1 and class 2 medical certificates**

**Chapter A**

**AMC for class 1 medical certificates**

**AMC.A. to Med.B.050 - PSYCHIATRY - class 1 medical certificates**

**Page:** 43

**Relevant Text:**

6. *Neurotic, stress-related or somatoform disorder*

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

**Comment:**

**Proposal:**

6. *Neurotic, stress-related or somatoform disorder*

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

response *Noted*

See response to comment No 849.

comment

906

comment by: *European Society of Space and Aviation Medicine (ESAM)*

**Author: European Society of Space and Aviation Medicine (ESAM) - Group Neurology Psychiatry-**

**Section: 1**

**Subpart B**

**Requirements for medical certificates**

**Specific requirements for class 1 and class 2 medical certificates**

**Chapter A**

**AMC for class 1 medical certificates**

**AMC.A. to Med.B.050 - PSYCHIATRY - class 1 medical certificates**

**Page:** 43

**Relevant Text:**

9. *Deliberate self-harm*

A single self destruction action or repeat acts of deliberate self-harm are disqualifying. A fit assessment may be considering after full consideration of an individual case and may require psychiatric or psychological review. Neuropsychological assessment may also be required.

**Comment:**

**Proposal:**

9. *Deliberate self-harm*

A single self destructive action or repeated acts of deliberate self-harm are disqualifying. A fit assessment may be considered after full consideration of an individual case and may require psychiatric and/or psychological review. Neuropsychological assessment may (delete) also be required.

response *Noted*

See response to comment No 849.

comment	1843	comment by: CAA Belgium
	<p>Relevant Text::</p> <p>4 Schizophrenia, schizotypal or delusional disorder:  Applicants with an established schizophrenia, schizotypal or delusional disorder should only be considered for a fit assessment if the licensing authority concludes that the original diagnosis was inappropriate or inaccurate or, in the case of a single episode of delirium, provided that the applicant has suffered no permanent impairment.</p> <p>9. Deliberate self-harm:  A single self destructive action or repeated acts of deliberate self-harm are disqualifying. A fit assessment may be considered after full consideration of an individual case and may require psychiatric or psychological review. Neuropsychological assessment may also be required.</p> <p>Comment:  9. The formulation:  'or' psychological review could lead to misdiagnosing or the overlook of psychotic causal factors – and first evaluation by a psychiatrist is therefore mandatory.</p> <p>Proposal:  4. Applicants with an established schizophrenia, schizotypal or delusional disorder should only be considered for a fit assessment if the licensing authority concludes that the original diagnosis was inappropriate or inaccurate.  Delete the remaining part of the sentence.</p> <p>9. No recommended change in the first sentence.  A fit assessment may be considered after full psychiatric consideration of an individual case and may require additional psychological review. Neuropsychological assessment may also be required.</p>	
response	Noted	
	<p>4. Please see Appendix 10 (1) in JAR-FCL 3 and response to comment No 847.</p> <p>9. Please see response to comment No 850.</p>	
comment	2410	comment by: Irish Aviation Authority
	<p>3  Current wording does not cover all possible scenarios.</p> <p>Justification:  To clarify</p> <p>Proposed text:  Insert '...substances <b>likely to affect flight safety</b> is...'</p> <p>NB These substances should be specified in the Guidance Material.</p>	
response	Accepted	
	The text will be changed accordingly.	

**MED.B.055: Psychology**

comment	181	comment by: <i>Oliver Dzvonik</i>
	<p>a) Psychological evaluation shall be required by AMS as independent special examination and may indicate further medical examinations (e.g. neurological, psychiatric examinations)</p> <p>b) When appropriate, a psychological examination may be also required as part of, or complementary to, a specialist psychiatric or neurological examination.</p> <p>c) Psychological evaluation has to be carried out by aviation psychologist. The requirements have to be defined by the authority and to be published in an adequate way. The authority has to run a list of such psychologists and to publish that list in an adequate way.</p> <p>d) Aviation psychologist shall submit to the AMS a written report detailing his opinion and recommendation.</p> <p>e) Authority receives verifiable information from an identifiable source which evokes doubts concerning 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 or knowledge relevant to the safe exercise of the privileges of the applicable licences.</p>	
response	<i>Noted</i>	
	<p>a) Psychological evaluation is a special examination if considered necessary by the AME. Like all other specialist examinations (cardiology, ophthalmology, psychiatry), it is an examination within the overall assessment of fitness to fly.</p> <p>b) This is what is written in the implementing rules (MED.B.055 (b)).</p> <p>c) Aviation psychologists could be the first choice in cases where a specialist examination is required but an accredited psychologist can do it as well. ICAO provides standards for the AME but not for other specialists. The licensing authority cannot restrict access to certain psychologists (and not to other specialists) and there is basically a free choice of doctors/psychologists for a pilot – except that the AME must have an AME certificate.</p> <p>d) The report must go to the AME, AeMC or to the licensing authority, depending on who asked for an evaluation. In these cases an assessment of fitness to fly cannot be made without the report.</p> <p>e) Correct.</p>	
comment	183	comment by: <i>Oliver Dzvonik</i>
	<p>a) Psychological evaluation shall be required by AMS as independent special examination and may indicate further medical examinations (e.g. neurological, psychiatric examinations)</p> <p>b) When appropriate, a psychological examination may be also required as part of, or complementary to, a specialist psychiatric or neurological examination.</p>	

	<p>c) Psychological evaluation has to be carried out by aviation psychologist. The requirements have to be defined by the authority and to be published in an adequate way. The authority has to run a list of such psychologists and to publish that list in an adequate way.</p> <p>d) Aviation psychologist shall submit to the AMS a written report detailing his opinion and recommendation.</p> <p>e) Authority receives verifiable information from an identifiable source which evokes doubts concerning 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 or knowledge relevant to the safe exercise of the privileges of the applicable licences.</p>
response	<p><i>Noted</i></p> <p>Please see response to identical comment No 181.</p>

comment	<p>347</p> <p style="text-align: right;">comment by: <i>Rosa Lopez-Martinez</i></p> <p>NPA 200817c                  AMC A to MED.B.055                  Psychology</p> <p>(a) Applicants shall have no established psychological deficiencies, (operational aptitudes, memory, attention,...), any relevant personality, behavioural, neurotic or stress-related disorder which are likely to interfere with the safe exercise of the privileges of the applicable licence(s). Where there is doubt or established evidence the applicant should be referred for psychological evaluation.</p> <p>(b) Mental or behavioural disorders due to alcohol or other substance use, with or without dependency, are disqualifying. A fit assessment may be considered after a period of two years documented sobriety or freedom of substance use and should include a neuropsychological assessment of cognitive function.</p> <p>(c) An established mood disorder is disqualifying. A fit assessment should include a neuropsychological assessment.</p> <p>(d) A single self destructive action or repeated acts of deliberate self-harm are disqualifying. A fit assessment may be considered after full consideration of an individual case and may require psychological evaluation which includes a neuropsychological assessment.</p> <p>(e) When the authority receives verifiable information from an identifiable source which evokes doubts concerning the mental fitness, behaviour or personality of a particular individual a psychological evaluation may be required. Sources for this information can be accidents or incidents, problems in training or proficiency checks, delinquency or knowledge relevant to the safe exercise of the privileges of the applicable licences.</p> <p>(f) When a psychological evaluation is indicated, it has to be done by a psychologist who is entitled to do such evaluation through applicable European law or, in the absence of European law, the national law of such state where the authority (represented by the AMS, the AMC or the AME) requiring the evaluation is located. Such psychologist must have demonstrated sufficient knowledge in Aviation and Clinical Psychology to the relevant authority which</p>
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defines such knowledge and publishes it in an adequate way. The relevant authority has to run a list of such psychologists and to publish it in an adequate way.

(g) The psychologist shall submit to the relevant authority a written report detailing assessment results, diagnostic and recommendations.

II Draft Decision AMC and GM for Part Medical

AMC A to MED.B.055 (AMC or Class 1 medical certificates)

AMC B to MED.B.055 (AMC for Class 2 medical certificates)

#### PSYCHOLOGY

a) A psychological evaluation shall be required by AMS where it is indicated independently of other examinations.

b) When appropriate, a psychological or neuropsychological examination may be required as part of, or complementary to a psychiatric or neurological evaluation.

c) Psychological evaluation must be done by an Aviation Psychologist.

d) The Psychologist shall submit to the relevant authority a written report detailing assessment results, diagnostic and recommendations.

#### MED.B.055 Psychology

The psychological evaluation may include a collection of biographical data, the administration of aptitudinal, personality and neuropsychological tests as well as a psychological interview.

In case of an accident, psychological reasons for that accident should be evaluated also according to the human-factors criteria published by the ICAO - Human Factors Digest No. 7, ICAO-Circular 240-AN/144.

response *Noted*

a) Paragraph a) in MED.055 covers these conditions.

b), c), d) are covered in the chapter on Psychiatry.

e) This could be Guidance Material at a later stage.

f) Each Member State has its laws for the curriculum of the studies of psychology and the acceptance/accreditation of psychologists to practice. For the purpose of this Part, an accredited psychologist (State Diploma and the right to practice) can be entrusted to examine the applicant and to provide his/her opinion on the specific questions of an AME. The licensing authority should not restrict access of specialists to these examinations.

g) Noted.

#### PSYCHOLOGY

a) Not accepted: The AME or the AeMC will be the first to require a psychological examination. It is not independent but part of the overall aeromedical assessment.

b) Covered in MED.B.055 (b).

c) Not accepted. Psychological evaluation can be done by a psychologist.

d) Report to be sent to the physician (AME, AeMC, medical assessor) who requested the examination/evaluation.

MED.B.055 Psychology

The paragraphs could be included in future Guidance Material.

comment 601 comment by: *Lufthansa German Airlines*

Author: Prof. Dr. Jürgen Kriebel

Section: 2

Subpart B

Specific requirements for class 1 and class 2

AMC A to MED.B.055

PSYCHOLOGY - medical certificates class 1

**Page:**

Relevant Text::

Where there is suspicion or established evidence that an applicant has a psychological disorder the applicant should be referred for psychological opinion and advice.

**Comment:**

See comment Section 2, MED.B.055 - Psychology

**Proposal:**

If after medical evaluation there is suspicion or established evidence that an applicant has a psychological disorder the applicant should be referred for psychological opinion and advice.

response *Not accepted*

Suspicion of a psychological disorder could be voiced independently of the aeromedical examination, e.g. during training or behaviour on the airfield.

comment 851 comment by: *Swiss Association of Aviation Medicine*

**Proposal:**

After medical evaluation where there is suspicion or established evidence that an applicant has a psychological disorder (delete) deficiency (insert) , the applicant should be referred for psychiatric and/or psychological opinion and advice.

response *Noted*

Please see response to comment No 601.

comment 909 comment by: *European Society of Space and Aviation Medicine (ESAM)*

**Author: European Society of Space and Aviation Medicine (ESAM) - Group Neurology Psychiatry-**

**Section:**

AMC A to MED.B.055

PSYCHOLOGICAL - class 1 medical certificates

**Page:** 43

**Relevant Text:**

*7. Personality or behavioural disorder*

Where there is suspicion or established evidence that an applicant has a psychological disorder, the applicant should be referred for psychological opinion and advice.

**Comment:**

**Proposal:**

After medical evaluation where there is suspicion or established evidence that an applicant has a psychological disorder (delete) deficiency (insert) , the applicant should be referred for psychiatric and/or psychological opinion and advice.

response

*Noted*

Please see response to comment No 601.

comment

1141

comment by: *Austrian Professional Association of Psychologists (BÖP)*

We recommend the following AMC A to MED.B.055

The psychological evaluation may include a collection of biographical data, the administration of aptitudes as well as personality tests and a psychological interview.

In case of an accident, psychological reasons for that accident should be evaluated also according to the human-factors criteria published by the ICAO - Human Factors Digest No. 7, ICAO-Circular 240-AN/144.

response

*Noted*

Please see response to the last 2 paragraphs of comment No 347.

comment

1292

comment by: *European Association for Aviation Psychology EAAP*

Attachment [#22](#)

The European Association for Aviation Psychology (EAAP) is commenting on a) the lack of certification requirements for psychologists, b) the limited reasons for initiating a psychological evaluation as compared to the old JAR, c) the apparent underdevelopment of sections with respect to psychological criteria and requirements.

It recommends the development of an APE (Aviation Psychological Examiner) or Aviation Psychologist (AP) certification and to develop a list of events, observations, recommendations etc. that can be used to initiate a psychological evaluation.

It is widely accepted (see Basic regulation) that people change over time in medical fitness. Medical fitness has a physical component that is checked

regularly for the whole lifecycle of a flight crew. Medical fitness also has a mental fitness component for the same flightcrew, but this is never re-checked on a regular basis. Human performance issues play a role in 75% of the accidents and incidents. It should be considered to develop a psychological check-up on a regular basis.

Psychological checkups will be(come) needed to maintain safety during forthcoming changes in aviation such as those initiated by ACARE, SESAR, marketdevelopments and demographic changes.

Examples are:

- single pilot operations en-route, two crew during TO and landing
- single piloting of small jets
- single piloting of personal airtransports
- self separation assurance by flight crew
- aging pilot community
- reduced availability of applicants
- aging of flight crew
- reduced stress tolerance by aging and psychological trauma
- etc.

response *Noted*

Please see responses to comments No 181 and 347.

comment

1518

comment by: *Dr Ian Perry*

AMC A to Med.B.055 This entire section should be deleted as being totally unnecessary Psychological reports are an adjunct to the treating psychiatrists assessment.

response

*Not accepted*

This section provides the possibility for the treating psychiatrist to require additional psychological evaluation.

comment

1938

comment by: *Deutsches Zentrum für Luft- und Raumfahrt, Abteilung Luft- und Raumfahrtpsychologie, Hamburg*

<![endif]-->

- The psychological evaluation is only indicated "as part of" a medical examination. There can be many other safety related indications for a psychological evaluation or treatment such as training and proficiency problems, insufficient coping with stresses of work, changes in operational risk taking behavior, recurring incidents, operational performance deviations and not at least findings in accident investigations etc. (See JAR-FCL 3 Appendix 17 to JAR-FCL 3.240 and 3.360). Such safety related indications would remain undetected because they go beyond of what a medical or specialized neurological or psychiatric examination would be able to reveal.

A clinical evaluation, as part of the medical evaluation differs in many aspects from a psychological performance or function evaluation of a pilot or pilot candidate. While a clinical evaluation leads to a diagnose of "healthy" or "not healthy", the psychological performance evaluation is based on the assessment of the person's cognitive functions, mental abilities, motivational factors and other personal factors in relation to

the operational job requirements of a pilot. For example a completely "healthy" person can have a deficient ability for spatial orientation or short-term memory, which would disqualify the person from safely operating aircraft.

DLR supports the proposal of the European Association for Aviation Psychology (EAAP) with respect to a revision of AMCs A and B to MED.B.055 (Class 1 and 2, and Leisure Pilot License). The recommended new phrasing based on JAR is as follows:

<![endif]-->

**AMC A to MED.B.055 PSYCHOLOGY (AMC for class 1 medical certificates)**

**AMC B to MED.B.055 (AMC for class 2 medical certificates)**

**Specific requirements for LPL medical certificates**

The psychological evaluation may include a collection of biographical data, the administration of aptitudes as well as personality tests and a psychological interview.

In case of an accident, psychological reasons for that accident should be evaluated also according to the human-factors criteria published by the ICAO - Human Factors Digest No. 7, ICAO-Circular 240-AN/144.

response *Noted*

Please see responses to comments No 181 and 347.

comment

2452 ❖

comment by: *AEPA, Asociación Española de Psicología de la Aviación Civil*

Comments in regard to the Psychological Part of the 2008-17 c NPA (MED.B.055 Psychology (including AMC A to MED.B.055 PSYCHOLOGY (AMC class 1 medical certificates), AMC B to MED.B.055 (AMC for Class 2 medical certificates and Psychological and the "Specific requirements for LPL medical certificates - Psychology) draft

- The psychology sections are underdeveloped, lack detail and are therefore open to misinterpretation and misuse.

- The wording used is inconsistent, the terminology psychological "disorders" and/or "deficiencies" are both used but lack any definition or specification.

- The psychological evaluation is only indicated "as part of" a medical examination. There can be many other safety related indications for a psychological evaluation or treatment such as training and proficiency problems, insufficient coping with stresses of work, changes in operational risk taking behaviour, recurring incidents, operational performance deviations and not at least findings in accident investigations etc. (See JAR-FCL 3 Appendix 17 to JAR-FCL 3.240 and 3.360)

- A clinical evaluation as part of the medical evaluation differs in many aspects from a psychological performance evaluation of a pilot or pilot candidate. While a clinical evaluation leads to a diagnose of "pathology" or "not pathology", the psychological performance evaluation is based on the assessment of the person's cognitive functions, mental abilities, motivational factors and other personal factors in relation to the operational job requirements of a pilot.

- It is not specified or recommended who should perform the psychological evaluation, nor any specification of the required certification. This is in conflict with the high level safety objectives of the commission with FCL that a.o. includes: *"to require organizations, flight synthetic training devices and persons involved in the training, testing, checking and medical assessments to be certified on the basis of common rules.*

- With all respect for the medical science and the good collaboration in the clinical fields, psychology was and is an independent science focusing on the abilities and mental capacity in a specified operational, technical, organizational and cultural context. To understand the complexity and professionally assess such as psychological performance factors is of utmost relevance for safety in aviation. Not at least do the incident and accident rates provide the evidence.

- Oversight over a psychological evaluation is not within the competence of an AME who is untrained in Aviation psychology.

- It is therefore recommended that any psychological evaluation should only be performed by psychologists specialized and trained in "Aviation Psychology". Their training will allow the timely detection and mediation of potential deviations in performance capabilities and protects the pilot community against unrealistic assessments that do not address the specific aviation working context.

- Psychological evaluation is today not always under the head of Aviation Medicine. This position has been and is supported by national authorities (example Austria) who already maintain a list of certified aviation psychologists for psychological evaluations next to a list of AeroMedical Examiners (AME).

- In order to assure a "level playing field", the Commission is proposing that examiners are no longer acting on a delegation from the authority, but exercising the privileges that are given to them by the certificate they hold. Also, for approval "instructors providing flight training and flight simulation training, as well as examiners and aeromedical examiners, shall hold a certificate attesting their compliance with the essential requirements and relating implementing rules".

- Consistent rulemaking would benefit from developing a certificate for an "Aero Psychological Examiner" or accept and approve the authorization in Spain set by AEPA, the Spanish professional organization in the field.

- An "Aero Psychological Examiner" or Aviation Psychologist certificate is recommended as an alternative to delegation by national authorities only and/or detailing many specific psychological requirements in the rule text and/or AMC. A certification as an Aero Psychological Examiner or as Aviation Psychologist would assure at least a standardization of criteria and methods.

- Our association, AEPA, could assist either in providing adequate training for an "Aero Psychological Examiner" or in advising the Authorities in these issues.

response *Noted*

Please see responses to comments No 181 and 347.

comment	2454	comment by: <i>AEPA, Asociación Española de Psicología de la Aviación Civil</i>
	<p><b>AMC A to MED.B.055 PSYCHOLOGY (AMC for class 1 medical certificates)</b>  <b>AMC B to MED.B.055 (AMC for class 2 medical certificates)</b></p> <p><i>Specific requirements for LPL medical certificates</i></p> <p>The psychological evaluation may include any psychological technical or professional tool such as the collection of biographical data, the administration of aptitudes, attitudes and personality tests as well as psychological interview. In case of an accident, psychological reasons for that accident must be evaluated also according to the human-factors criteria published by the ICAO – Human Factors Digest No 7, ICAO-Circular 240-AN/144</p>	
response	<i>Noted</i>	
	Please see responses to comments No 181 and 347.	

**C. Draft Decision Part-MED - Subpart B: Requirements for Medical Certificates - Section 1: Specific requirements for class 1 and class 2 medical certificates - Chapter A: AMC for Class 1 medical certificates - AMC A to MED.B.060: Neurology** p. 43-44

comment	26	comment by: <i>GEMA</i>
	La epilepsia rolándica es patología del adolescente y su pronóstico es excelente	
response	<i>Noted</i>	
comment	27	comment by: <i>GEMA</i>
	2.- Un ejemplo de patología con alta propensión para disfunción cerebral, por favor	
response	<i>Noted</i>	
	Examples could be inserted in the Guidance Material that will be added in rulemaking task MED.001	
comment	145	comment by: <i>Civil Aviation Authority - The Netherlands</i>
	<b>AMC A to MED.B.060. (Blz. 43 van 66)</b>	
	Onder het hoofdstuk 'neurology' missen een aantal medische condities waaronder met name hersenbloedingen, beroertes en TIA's. Daarmee is niet duidelijk wat is toegestaan ten aanzien van deze aandoeningen. De CAA-The Netherlands verzoekt aan EASA om in ieder geval deze twee medische condities in de voorschriften te behandelen.	
response	<i>Noted</i>	
	We agree with your proposal to add TIA and intracerebral haemorrhage to the neurological requirements. However, as these conditions were not mentioned	

in JAR-FCL 3 (which was the basis of this NPA), we prefer to include them in the rulemaking task MED.001.

comment 490 comment by: UK CAA

**AMC A to MED.B.060 1.2**

**Page:44**

**Comment:**

Inappropriate use of the word 'epilepsy'.

**Justification:**

The word 'seizure' is preferable.

**Proposed Text:**

Amend: 'epilepsy' to '**seizure**'.

response *Not accepted*

The proposed NPA text is a transposition of the corresponding requirement from JAR-FCL 3.

While the term 'epilepsy' as used in JAR-FCL 3 and in this NPA is perfectly clear, we agree that 'seizure' includes a range of conditions and epilepsy is a specific case. However, there are many different types of seizures and simply replacing 'epilepsy' by 'seizure' may not be the best option. This comment has been noted for consideration in MED.001.

comment 602 ❖ comment by: Lufthansa German Airlines

Author: Prof. Dr. Jürgen Kriebel

Section: 2

AMC A to MED.B.060

NEUROLOGY - class 1 medical certificates

3.2

**Page:**

Relevant Text::

3.2. Clinical EEG abnormalities:

Epileptiform paroxymal EEG abnormalities and focal slow waves should be disqualifying.

**Comment:**

Sometimes focal slow waves are not clinically relevant residuals e.g after head injuries or successfully treated ischemic or infectious disorders.

**Proposal:**

Epileptiform paroxymal EEG abnormalities should be disqualifying. Focal slow waves, especially if not over temporal leads need further specialist evaluation.

response *Partially accepted*

The wording will be adapted to match the original JAR-FCL 3 wording to read: 'Epileptiform paroxysmal EEG abnormalities and focal slow waves normally are disqualifying'.

comment 854 comment by: Swiss Association of Aviation Medicine

	<p><b>Comment:</b> 'Explainable' disturbances of consciousness have rather often had recurrences.</p> <p><b>Proposal:</b> <i>5. Episode of disturbance of consciousness</i> In the case of a single episode of disturbance of consciousness, which can be satisfactorily explained, a fit assessment may be considered, if the risk of relapse is sufficiently low.</p>	
response	<p><i>Not accepted</i></p> <p>The wording 'a fit assessment can be considered' means that in cases where a risk of a relapse of an 'explainable disturbance of consciousness' is high, the outcome of the 'consideration' may be an unfit assessment.</p>	
comment	855	comment by: <i>Swiss Association of Aviation Medicine</i>
	<p><b>Proposal:</b> <i>7. Spinal or peripheral nerve injury, myopathies</i> An applicant with a history or diagnosis of spinal or peripheral nerve injury or myopathy should be assessed as unfit. A fit assessment may be considered if neurological review and musculoskeletal assessments are satisfactory.</p>	
response	<p><i>Accepted</i></p> <p>The addition 'or myopathy' will be included in the text.</p>	
comment	858	comment by: <i>Swiss Association of Aviation Medicine</i>
	<p><b>Proposal:</b> <i>3. Neurological disease</i> Any stationary or progressive disease of the nervous system or history of disturbance of consciousness which has caused or is likely to cause a significant disability is disqualifying. In case of minor functional loss associated with stationary disease a fit assessment may be considered after full evaluation.</p>	
response	<p><i>Not accepted</i></p> <p>The addition of 'history of disturbance of consciousness' is not necessary as it is included under number 7 in AMC 1 to MED.060.</p>	
comment	859	comment by: <i>Swiss Association of Aviation Medicine</i>
	<p><b>Proposal:</b> <i>5. Spinal or peripheral nerve injury, myopathies</i> An applicant with a history or diagnosis of spinal or peripheral nerve injury or myopathy should be assessed as unfit. A fit assessment may be considered if neurological review and musculoskeletal assessments are satisfactory.</p>	
response	<p><i>Noted</i></p> <p>Duplication of comment No 855.</p>	
comment	911	comment by: <i>European Society of Space and Aviation Medicine (ESAM)</i>

**Author: European Society of Space and Aviation Medicine (ESAM) - Group Neurology Psychiatry-****Section:**

AMC A to MED.B.060

Neurology - class 1 medical certificates

**Page:** 43 / 44**Relevant Text:**1. *Epilepsy*

1.1 A diagnosis of epilepsy is disqualifying, 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 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.

**Comment:**

Aeromedical neurological experience confirms too many recurrences.

**Proposal:**1. *Epilepsy*

1.1 A diagnosis of epilepsy is disqualifying, 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 disqualifying. In the case of an acute symptomatic seizure, which is considered to have a very low risk of recurrence and after adequate neurological review, a fit assessment may be considered.

**• 1 Comment****Author: European Society of Space and Aviation Medicine (ESAM) - Group Neurology Psychiatry-****Section:**

AMC A to MED.B.060

Neurology - class 1 medical certificates

**Page:****Relevant Text:**3. *Clinical EEG abnormalities*

3.2 Epileptiform paroxysmal EEG abnormalities and focal slow waves should be disqualifying.

**Comment:**

Focal slow waves e.g. after head trauma or successfully treated diseases are in some cases waivable

**Proposal:**

Epileptiform paroxysmal EEG abnormalities and focal slow waves (delete) should be disqualifying. Focal slow waves should undergo neurological evaluation.

response	<i>Partially accepted</i>	
	<p>Epilepsy: addition of 'after neurological review' is accepted.</p> <p>EEG abnormalities: 'should be disqualifying' will be replaced by 'normally are disqualifying'.</p>	
comment	912	comment by: <i>European Society of Space and Aviation Medicine (ESAM)</i>
	<p><b>Author: European Society of Space and Aviation Medicine (ESAM) - Group Neurology Psychiatry-</b></p> <p><b>Section:</b> AMC A to MED.B.060 Neurology - class 1 medical certificates</p> <p><b>Page: 44</b></p> <p><b>Relevant Text:</b> <i>5. Episode of disturbance of consciousness</i> In the case of a single episode of disturbance of consciousness, which can be satisfactorily explained, a fit assessment may be considered.</p> <p><b>Comment:</b> 'Explainable' disturbances of consciousness have rather often had recurrences.</p> <p><b>Proposal:</b> <i>5. Episode of disturbance of consciousness</i> In the case of a single episode of disturbance of consciousness, which can be satisfactorily explained, a fit assessment may be considered, if the risk of relapse is sufficiently low.</p>	
response	<i>Noted</i>	
	Please see response to identical comment No 854.	
comment	915	comment by: <i>European Society of Space and Aviation Medicine (ESAM)</i>
	<p><b>Author: European Society of Space and Aviation Medicine (ESAM) - Group Neurology Psychiatry-</b></p> <p><b>Section:</b> AMC A to MED.B.060 Neurology - class 1 medical certificates</p> <p><b>Page: 44</b></p> <p><b>Relevant Text:</b> <i>7. Spinal or peripheral nerve injury</i> An applicant with a history or diagnosis of spinal or peripheral nerve injury should be assessed as unfit. A fit assessment may be considered if neurological review and musculoskeletal assessments are satisfactory.</p> <p><b>Comment:</b></p>	

	<p><b>Proposal:</b>  <i>7. Spinal or peripheral nerve injury, myopathies</i>  An applicant with a history or diagnosis of spinal or peripheral nerve injury or myopathy should be assessed as unfit. A fit assessment may be considered if neurological review and musculoskeletal assessments are satisfactory.</p>	
response	<p><i>Noted</i></p> <p>Please see response to identical comment No 855.</p>	
comment	918	comment by: <i>European Society of Space and Aviation Medicine (ESAM)</i>
	<p><b>Author: European Society of Space and Aviation Medicine (ESAM) - Group Neurology Psychiatry-</b></p> <p><b>Section:</b>  AMC A to MED.B.060  Neurology - class 1 medical certificates</p> <p><b>Page: 44</b></p> <p><b>Relevant Text:</b>  <i>3. Clinical EEG abnormalities</i>  3.2 Epileptiform paroxysmal EEG abnormalities and focal slow waves should be disqualifying.</p> <p><b>Comment:</b>  Focal slow waves e.g. after head trauma or successfully treated diseases are in some cases waivable</p> <p><b>Proposal:</b>  Epileptiform paroxysmal EEG abnormalities and focal slow waves (delete) should be disqualifying. Focal slow waves should undergo neurological evaluation.</p>	
response	<p><i>Noted</i></p> <p>Please see response to identical comment No 602.</p>	
comment	1350	comment by: <i>European Disabled Aviators</i>
	<p>Attachment <a href="#">#23</a></p> <p>The last paragraph 7, if left unchanged, may bar access to class1 medical certificate for paraplegic pilots. In order to avoid any restricted interpretation of "... neurological review and musculoskeletal assessment are satisfactory", it is suggested that such assessment be linked with stipulations of (modified) AMC A to MED.B.045:  <i>7. Spinal or peripheral nerve injury</i></p> <p>An applicant with a history or diagnosis of spinal or peripheral nerve injury should be assessed as unfit.  A fit assessment may be considered if neurological review <u>is satisfactory</u> and/or musculoskeletal assessments <u>are satisfactory</u> <u>complies with above AMC A to MED.B.045</u></p>	
response	<p><i>Not accepted</i></p>	

'satisfactory assessment' has to be seen in context with MED.A.045 (a); the proposed addition is not necessary.

comment 1390 comment by: *ophthalmologie aerospace medecin*

**Comment:**  
 There are numerous class 1 pilots, who show to have hypermetropia exceeding + 5 diopters, when they show up for a renewal application exam. By law hypermetropia exceeding + 5,0 diopters makes them unfit for a class 1 license. To avoid this problem, it is of utmost importance to determine objective and subjective refraction in cycloplegia at the intial ophthalmological exam class 1. Therefore it is not enough to ask for cycloplegia in initial applicants under the age of 25. An applicant of 28 years may be +2 diopters in miosis and + 6,5 diopters in cycloplegia!!! This pilot will lose his license at the age of 50, if his hypermetropia is not detected at the initial exam. To avoid these problems in the future, cycloplegia at the initial exam should be applied, when clinically indicated and not only according to age.

**Proposal:**  
 Hyperopic initial applicants with 1.5 diopters or more under the age of 25, or if indicated, shall undergo objective refraction in cycloplegia.

response *Noted*  
 Please see comments in segment AMC A to MED.B.065

comment 1944 comment by: *International Air Transport Association (IATA)*

Page 45 AMC A to MED.B.065 4.1 and 4.2  
 This is inconsistent with the ICAO standard and seems unnecessarily restrictive. ICAO does not have a refractive error limitation as long as optimal correction is achieved and no significant pathology is demonstrated.

response *Noted*  
 Ophthalmology: Please see comments in segment AMC A to MED.065.  
 General response: Part MED is based on JAR-FCL 3 where refractive error limits exist. Further changes must go through a new rulemaking process.

comment 2349 comment by: *DLR*

There are numerous class 1 pilots, who show to have hypermetropia exceeding + 5 diopters, when they show up for a renewal application exam. By law hypermetropia exceeding + 5,0 diopters makes them unfit for a class 1 license. To avoid this problem, it is of utmost importance to determine objective and subjective refraction in cycloplegia at the intial ophthalmological exam class 1. Therefore it is not enough to ask for cycloplegia in initial applicants under the age of 25. An applicant of 28 years may be +2 diopters in miosis and + 6,5 diopters in cycloplegia!!! This pilot will lose his license at the age of 50, if his hypermetropia is not detected at the initial exam. To avoid these problems in the future, cycloplegia at the initial exam should be applied, when clinically indicated and not only according to age.

**Proposal:**

	Hyperopic initial applicants with 1.5 diopters or more under the age of 25, or if indicated, shall undergo objective refraction in cycloplegia.
response	<i>Noted</i>
	Copy of comment No 1390 above; please see comments in segment AMC A to MED.065.

**C. Draft Decision Part-MED - Subpart B: Requirements for Medical Certificates - Section 1: Specific requirements for class 1 and class 2 medical certificates - Chapter A: AMC for Class 1 medical certificates - AMC A to MED.B.065: Visual System** p. 44-47

comment 35 comment by: *Thomas WOLFF*

AMC A to MED.B.065

Item 4.1 (iv) should read:

anisometropia exceeding 2.0 dioptrés (contact lenses should be worn);

Item 4.2 (iv) should read:

anisometropia exceeding 3.0 dioptrés (contact lenses should be worn);

Reasoning:

While the Class 2 and LPL Medical requirements in regard to all items of refractive error (including anisometropia), as well as myopia/hypermetropia for Class 1 have been eased, which is highly appreciated, acknowledging the international best-practice, ICAO and FAA standards that this is not reducing safety of flight with optimum correction, the same should be done for the anisometropia requirements in Class 1.

It is not logical that the single point of Class 1 anisometropia remains so stringent, while all other items of refractive error are correctly eased to reflect accepted international standards (e.g. ICAO, FAA).

Given the coming shortage of professional pilots, this should not be unduely stringent if it does not affect safety of flight.

The reasoning that anisometropia is only acceptable with existing flight experience should not automatically lead to a more stringent requirement for initial examinations. If someone has hundreds of hours on a PPL with a Class 2 modical, and he decides to become professional, his Class 1 medical would be seen as an initial examination, even though because of his flight experience he should be assessed according to item 4.2 (iv).

response *Partially accepted*

A new subparagraph 4.2 will be added for the licensing authority to consider applicants who do not meet 4.1 (ii), (iii) and (iv).

comment 104 comment by: *KlaasDEGROOT*

Why is there a refractive limit of -6.0 dioptrés (for myopia). When you have -

response	<p>5.5 dioptrres you can also only see things that are very close. What is the reason for this limit, with contacts or glasses the required 6/6 vision is easily acquired. And if I read correctly after you have passed the initial examination, there is no more diopter limit (for myopia).</p>	
	<p><i>Noted</i></p>	
	<p>Please see response to comment No 35.</p>	
comment	105	comment by: <i>Daniel Noll</i>
	<p>In my opinion, the refractive error should not be limited for both revalidation and initial examination, because I see no reason for setting such entry limits. Why should a person with -6 be medical able to start flying and a person with -6.5 not? Where should be these limits? A young pilot with refractive error -8 is medical able to fly just as well a pilot who already fly for several years, no metter how experienced he is because experience doesn't influence the visual acuity.</p>	
response	<p><i>Noted</i></p>	
	<p>Please see response to comment No 35.</p>	
comment	109	comment by: <i>Thomas BLODER</i>
	<p>Dear Ladies and Gentlemen,</p> <p>A comment to Point 4 "Refractive Error":</p> <p>I (and many others in our club - Flugsportzentrum Tirol - ) cannot see the point in regulating the refractive error, if my visual acuity is satisfactory (corrected to 6/6, or 6/9 in one eye) and I carry reserve spectacles/lenses with me. Especially if 1 year after the initial examination my refractive error may climb to 10+ dioptrres and I would still be assessed as fit if I was below 5 or 6 dioptrres at the time of my initial examination.</p> <p>So I would suggest to limit the (initial) visual examination to the points described in MED.B.065, pages 15 and 16 and/or to remove the paragraph 4.1 to 4.4, page 45 of this document, and cancel the limit in dioptrres. Or maybe you could add a paragraph "flexibility" like the New Zealandish CAA does: If the pilot´s over the limit for the initial examination but there´s no safety risk for the plane, its crew and the passengers while the pilot´s doing his job he may be assessed as fit. (For example: Pilot has myopia, -7 dioptrres, but is otherwise fit -&gt; AMC can decide to issue the class I medical).</p> <p>Yours, Thomas Bloder</p>	
response	<p><i>Noted</i></p>	
	<p>Please see response to comment No 35.</p>	
comment	146	comment by: <i>Civil Aviation Authority - The Netherlands</i>
	<p><b>4.3 en 4.4. (Blz. 45 van 66)</b></p> <p>De CAA-The Netherlands merkt op dat niet duidelijk is wat met 'eye specialist'</p>	

	<p>wordt bedoeld. De CAA-The Netherlands verzoekt EASA om duidelijk in de voorschriften aan te geven om met deze specialist een oogarts of optometrist wordt bedoeld.</p>
response	<p><i>Noted</i></p>
	<p>Professional training for eye specialists other than ophthalmologists differs among the Member States. The term 'ophthalmologist' is used in cases where the examination of the eyes has to be done by the physician specialised in ophthalmology. The term 'eye specialist' is used for cases where a special eye examination is needed, but not necessarily by an ophthalmologist. The NAA will decide where the training for their eye specilists is sufficient for the task or where the ophthalmologist has to perform the examination.</p>
comment	<p>170 <span style="float: right;">comment by: <i>Joanne Debono</i></span></p>
	<p>My question is regarding refractive eye surgery. I have had Lasik done over 5 years ago and my eye sight then exceeded slightly the -6 limit. Today, I have stable vision with no complications and can pass Class 1 Medical unless there is this restriciton. The only factor stopping me from getting a JAR class 1 is that the requirements state that pre-surgery the eye sight cannot exceed +5 to -6 diopters. Currently and as I understood even the proposal state in Clause 9 Page 46 of NPA No 200817C that:</p> <p>9. <i>Eye surgery</i>  9.1. After refractive surgery, a fit assessment may be considered provided that:</p> <p style="padding-left: 40px;">(i) preoperative refraction was no greater than +5 or -6 dioptres;</p> <p>which means there are no changes unless I understood differently as in Page 15 MED.B.065, it states nothing about limits but only:</p> <p>(f) Applicants who have undergone refractive surgery may be assessed as fit subject to satisfactory ophthalmic evaluation.</p> <p>Considering the above may I ask:</p> <ol style="list-style-type: none"> <li>1. Why is the intial medical test requirement for Class 1 limited to -6 prior to refractive surgery?</li> <li>2. If my eye sight is good and I have no complications post surgery, why should I be neglected from studying for an airline pilot?</li> <li>3 If during renewal, pilots who exceed the -6 diopters are considered anyhow, why should I be discriminated through the initial test?</li> </ol> <p>Whilst hoping that regulations change, I thank you in advance for your reply.</p>
response	<p><i>Noted</i></p>
	<ol style="list-style-type: none"> <li>1. Pre-operative refractive error limit in the case of myopia will be removed.</li> <li>2. MED.B 065(f) opens the possiblity for a fit assessment after eye surgery (including refractive surgery) in general. AMC 1 to MED.B.065 explains the details.</li> <li>3. See point 1.</li> </ol>

comment	228	comment by: Erik Vloothuis
Attachment <a href="#">#24</a>		
<p>AMC A to MED.B.065 Visual system (pages 44 to 47)- Class 1 medical certificates</p> <p>There cannot be a substantial basis for the additional specific criteria as stated in Paragraph 9.1(i) due to the following points:</p> <ol style="list-style-type: none"> <li>1) In Paragraph 9.1(i), there is a limit to the allowed refractive error to be maximum -6.0 Dioptre for the pre-operative condition of the patient. However, it is clear from Paragraph 4.4 that a refractive error greater than -6.0 Dioptres is acceptable for class 1 with the additional requirement of a 2 yearly examination.</li> <li>2) The statement in Paragraph 9.1(i) is therefore contradicted by the statements in Paragraphs 4.1 and 4.2 and 4.3 and 4.4. Specifically that myopic condition greater than -6.0 Diopetre is still fit for fclass 1 in Paragraph 4.2 yet is not fit for class 1 in Paragraph 9.1(i)</li> <li>3)As in AMC B to MED.B065 (page 57)Paragraph 5.1 the pre-operative refractive error is not specified. Instead stating "After refractive surgery, a fit assesment may be considered provided that there is stability of the refraction, thaere are no post-operative complications and no increase in glare sensitivity".</li> <li>4)Is there a definitive base for the Pre operative Refrative error limitation of -6.0 Dioptre? Refractive correction surgery can assume many varying procedures including PRK, Lasik, Corneal Rings, ALK, lens insertion etc... How can a single "pre-operative" condition be a consistant exclusionary factor for all possible refractive correction surgery possibilities, each tailored to suit varying conditions suchs as difference in corneal thickness etc..?</li> <li>5)As a further informational refererance to other national authorities. Such as in the USA FAA regulation and Australian CASA regulation, it is clear the use of refractive surgery is not disallowed. The focus of assesment is the Post-Operative condition of the patient. A document is added from the Australian CASA documenting Refractive Surgery (Paragraph 2.1.4.</li> </ol> <p>Suggestions</p> <ol style="list-style-type: none"> <li>1) Deletion of Paragraph 9.1(i)</li> <li>2) Maintain Paragraphs 9.1 (ii) up to and including (vi)</li> <li>3) Add wording to Paragraph 9.1 to harmonise class 1 visual requirements in Paragraph 4.2. i.e "..., a review shall be undertaken 2 yearly by an eye specialist.</li> </ol>		
response	<i>Noted</i>	
<ol style="list-style-type: none"> <li>1. Please see response to comment No 170.</li> <li>2. No contradiction: paragraph 4.1–4.4 deals with refractive errors (no surgery); paragraph 9 deals with refractive errors before surgery. However, both paragraphs have been amended.</li> <li>3. See comments to AMC B to MED.065 for class 2.</li> </ol>		

4. The pre-operative refractive error limit for applicants with myopia has been deleted.

5. Noted.

Proposals:

- 1) Deletion of para 9.1(i): not accepted, except for pre-operative dioptre limits for applicants with myopia.
- 2) Noted.
- 3) Not accepted; these are two different issues.

comment	229	comment by: Erik Vloothuis
	<p>AMC A to MD.B.065 Visual System - Class 1 medical certificates</p> <p>There is no significant medical basis to show reason to maintain separate Paragraphs 4.1 and 4.2. More specifically the allowance of a revalidation application with results outside of initial licence assessment (e.g Paragraph 4.2.(ii) "<i>Myopia exceeding -6.0 Dioptres</i>") , but no allowance of an initial examination having the same results.</p> <p>It is clear that the specifications of an assesment made under Paragraph 4.2 deems the license holder as fit to fly . This could have the potential "unfairly" exclude and predjudice persons in medical application process. Therefore Inital examinations should also be added to Paragraph 4.2.</p> <p>Suggested rewording (added words):</p> <p>"Paragraph 4.2 At <b>initial examination or</b> revalidation an applicaiton may be assessed as fit with: ....<i>cont</i>"</p> <p>or similar to the effect of equalising the initial and revalidation examination medical requirements.</p>	
response	<p><i>Noted</i></p> <p>Please see response to comment No 35.</p>	

comment	230	comment by: R. Don
	<p>Regarding the refractive errors; three comments:</p> <p>A.) The initial and revalidation norms differ, while one is being assessed for the same job, for the same type of work. It would seem more appropriate to consider the ability to meet the required visual standards as a requirement, as opposed to placing restrictions on applicants who require high levels of correction. Therefore I would suggest removing the refractive limits for the initial application.</p> <p>B) Internationally speaking, it would make the requirements more uniform if the refractive limits on initial examinations would be removed. Among others, the FAA (U.S.) and CASA (Australia) consider the ability to meet the standard all that is required, with or without correction. Therefore I suggest the refractive limits for initial application are lifted in an attempt towards a more uniform, global standard.</p>	

C) Unreferenced sources suggest that the number of accidents due to high refractive errors in both U.S. and Australia are zero to none. That also speaks for a removal of the refractive limits on applicants for a Class 1 medical.

One more point about high refractive errors:  
To prevent unacceptable peripheral distortion, it would be justified to require the applicant to wear contact lenses for myopes requiring more than 5 dioptries of correction.

response

*Noted*

Please see response to comment No 35.

Contact lenses are required in anisometropia of more than 3 dioptries and could be imposed as a limitation for refractive errors if considered necessary by an ophthalmologist or eye specialist.

comment

291

comment by: *Lufthansa German Airlines*

**Author:** Dr. Esther Stahl-Buhl, AMC Frankfurt

**Section:** 1

Subpart B

1) AMC A to MED.B.065 - 9.1

2) AMC to MED.B.065 - (i)(iv)(v)

**Page:** 46

**Relevant Text:**

1) After refractive surgery, a fit assessment may be considered provided that:

2) (i) Pre-operative refraction was not greater than +5 or -6 dioptries.....

(iv) Glare sensitivity is within normal standards

(v) Mesopic contrast sensitivity is not impaired.

**Comment:**

3 months after surgery, a fit assessment may be considered provided that:

Pre-operative refraction was not greater than +5 or -6 dioptries. Corneal

thickness postoperatively shall not be thinner than 420 µm excluding the flap!

Corneal thickness shall be measured by ( we need to discuss this )? .....

Post-operative stability of refraction has been achieved ( less than 0.75 dioptries variation diurnally )

Glare sensitivity is within normal standards

Mesopic contrast sensitivity is not impaired. .

Examination of the eye shows no postoperative complications .

Do we all have the same standards concerning what is "normal Standard " of glare sensitivity or should we suggest a number, same for contrast sensitivity?

The same applies for "stable postoperative refraction", how should this be measured,

How often, when, objectively, subjectively?

response

*Noted*

Thank you for the comment. There is no proposal.

comment

292

comment by: *Lufthansa German Airlines*

	<p><b>Author:</b> Dr. Esther Stahl-Buhl, AMC Frankfurt  <b>Section:</b> 1  Subpart B  AMC A to MED.B.065  viii (2)  <b>Page:</b> 44-45</p> <p>Relevant Text:  A comprehensive eye examination should include among others:  (viii) tonometry on clinical indication</p> <p><b>Comment:</b>  I would make tonometry obligatory for an initial and comprehensive eye examination. I have seen too many cases of ocular hypertension with thin corneas running into problems or glaucomas detected too late.</p>
response	<p><i>Not accepted</i></p> <p>The proposed text allows flexibility and provides with the possibility for the AeMC to decide on each individual case.</p>

comment	293	comment by: <i>Lufthansa German Airlines</i>
	<p><b>Author:</b> Dr. Esther Stahl-Buhl, AMC Frankfurt  <b>Section:</b> 1  AMC A to MED.B.065  2  <b>Page:</b> 44</p> <p><b>Relevant Text:</b>  A comprehensive eye examination should include among others:</p> <p><b>Comment:</b></p> <p><b>Proposal:</b>  The test of glare sensitivity and mesopic contrast sensitivity is not included. This should be included especially for applicants. It is required post refractive surgery, so why not for an applicant. They should be as fit as someone having undergone refractive surgery.</p>	
response	<p><i>Not accepted</i></p> <p>Glare sensitivity and mesopic contrast sensitivity may be impaired after refractive surgery and a test is therefore necessary. It can otherwise be required on clinical indication.</p>	

comment	294	comment by: <i>Lufthansa German Airlines</i>
	<p><b>Author:</b> Dr. Esther Stahl-Buhl, AMC Frankfurt  <b>Section:</b> 1  AMC A to MED.B.065  9.2  <b>Page:</b> 46</p> <p>Relevant Text:  Cataract surgery entails unfitness. A fit assessment may be considered after 3 months.</p>	

	<p><b>Comment:</b></p> <p><b>Proposal:</b></p> <ul style="list-style-type: none"> <li>• a) Glare sensitivity and mesopic contrast sensitivity should be included in an assessment post surgery.</li> <li>• b) It should be specified that only monofocal intraocular lenses for pseudophakia are accepted.</li> </ul>
response	<p><i>Noted</i></p> <p>The basis for Part Medical is JAR-FCL 3. Some amendments were introduced but higher standards for examinations or tests were avoided.</p> <p>a) This test was not required under JAR-FCL 3 requirements after cataract surgery.</p> <p>b) There was no specification of intraocular lenses in JAR-FCL 3. This specification could be requested for task MED.001.</p>

comment	295	comment by: <i>Lufthansa German Airlines</i>
	<p><b>Author:</b> Dr. Esther Stahl-Buhl, AMC Frankfurt  Section: 1  AMC A to MED.B. 065  1.1.2  <b>Page:</b> 44</p> <p><b>Relevant Text:</b>  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.</p> <p><b>Comment:</b></p> <p><b>Proposal:</b>  I would suggest: Conditions which indicate ophthalmological examination include.... Tensio above 20 mm Hg in tonometry, a substantial decrease in the uncorrected visual acuity, ...</p>	
response	<p><i>Not accepted</i></p> <p>Your proposal is included in the wording 'abnormal and doubtful cases'.</p>	

comment	296	comment by: <i>Lufthansa German Airlines</i>
	<p><b>Author:</b> Dr. Esther Stahl-Buhl, AMC Frankfurt  <b>Section:</b> 1  AMC A to MED.B.65  4.3  <b>Page:</b> 45  Relevant Text:  If the refractive error is +3.0 to +5.0 or -3.0 to -6.0 dioptries a review shall be undertaken 5 yearly by an eye specialist.</p>	

<p><b>Comment:</b></p> <p><b>Proposal:</b>                  I would write: IF the refractive error is +3.0 - +5.0 dioptrres or -3.0 to -6.0 a comprehensive eye examination shall be undertaken 2 yearly! By an ophthalmologist.                  Reason: Hyperopia: 5 years are too long in regards to complication by high values of optic correction, narrow anterior chambers and potential hypertension. Myopia: 5 years are way to long to supervise the retina and resulting potential problems.</p>
<p>response <i>Not accepted</i></p>
<p>The proposed NPA text is a transposition of the corresponding requirement from JAR-FCL 3.</p> <p>The definition 'eye specialist' is used due to the fact that Member States have different medical systems and ophthamologists may not be easily accessible in some Member States. However, there are eye specialists, trained to recognise pathologies. In the case of a pathology, an ophthalmologist will see the case.</p>

<p>comment 323 <span style="float: right;">comment by: Patrick DE KRUIF</span></p>
<p>Part 4: Refractive error</p> <p>In my opinion this section <i>could</i> and <u>should</u> be scrapped. Compare this to FAA rules; There is no such requirement (class 1 or others).</p> <p>JAA rules already widened these requirements to such extend (-6 to +5, same as in the draft here) that it effectively renders it useless for the purpose of flight safety. while a person with +5 can compensate to a large degree, a person with -6 is pretty much blind without corrective lenses.</p> <p>Ruling like this keeps otherwise good candidates out of the cockpit, and worse, sends trained pilots looking for other jobs.</p> <p>If EASA really needs to be the best boy in class, rather require a minimum vision without corrective lenses.</p>
<p>response <i>Noted</i></p>
<p>Please see response to comment No 35.</p>

<p>comment 324 <span style="float: right;">comment by: Patrick DE KRUIF</span></p>
<p>Part 9.1.i:</p> <p>What's important is what the eye condition is at present, and foreseeable in the near future (at least between certifications). Why bother with the past? It has no bearing on the present condition. The only argument for this requirement is to keep applicants from passing initial certification through refractive surgery. Any such decision should be the sole responsibility of the applicant, not EASA!</p>
<p>response <i>Noted</i></p>

See response to comment No 170.

comment 340 comment by: FOCA Switzerland

AMC A to MED.B 065 Objective refraction in cycloplegia should be only mandatory in applicants under age 25 with hyperopia of more than 2 Dpt

Proposed text:

**(ix) refraction. Initial applicants under the age of 25 with hyperopia of more than +2 Diopters should undergo objective refraction in cycloplegia.**

response Accepted

The NPA text is a transposition of the corresponding requirement from JAR-FCL 3. However, the requirements on refractive errors have been discussed for a long time. The outcome was that some of them could be relaxed.

comment 341 comment by: FOCA Switzerland

AMC A to MED.B065 A different limit concerning astigmatism between initial exam and renewal should be avoided. (Why should a pilot at the initial exam be unfit with -2.5 D of astigmatism, whereas a pilot, who had -2 D one year before and now 2.5 is considered to be fit?) (In JAR astigmatism with 3 D was negative at initial, but positive at renewal, which is inconsistent.)

Proposed text:

**4.1. (iii) astigmatism exceeding 2 D subject to an examination of an ophthalmologist.**

response Accepted

comment 491 comment by: UK CAA

**AMC A to MED.B.065 2 (ix)**

Page: 44

**Comment:**

There is no justification for this requirement. Hyperopia is not defined. Cycloplegia is not without risk and should only be performed when clinically indicated.

**Justification:**

This requirement cannot be justified and presents a risk of severe potential complications.

It is not reasonable to disqualify initial applicants on the basis of a problem that they may develop in the future, especially given that such a problem develops slowly and can be examined for at routine eye examinations.

Cycloplegia can precipitate acute glaucoma.

Cycloplegic refraction should only be performed where there is clinical suspicion that the applicant's refraction is outside the acceptable limits. The following are the main clinical indications:-

(1) Spectacle prescription or other measurement of refraction indicates a likely

result in cycloplegia of +5.00 or greater.  
 (2) Below average accommodation for age.  
 (3) Esophoria with correction.  
 (4) History of patching in childhood with no squint (anisometropic amblyopia).

**Proposed Text:**

Amend (ix) to:

ix) **'refraction. Initial applicants should undergo objective refraction in cycloplegia if clinically indicated.'**

response *Partially accepted*

The NPA text is a transposition of the corresponding requirement from JAR-FCL 3. However, the requirements on refractive errors have been discussed for a long time. The outcome was that some of them could be relaxed. In this case it has been accepted that objective refraction in cycloplegia should be required in applicants who are younger than age 25 and present with a hyperopia of more than +2 dioptries.

comment

492

comment by: UK CAA

**AMC A to MED.B.065 4.1 and 4.2 and 4.4**

**Page: 45**

**Comment:**

No need to differentiate between initial and revalidation requirements. There is no rational basis for a difference.

**Justification:**

The important points underpinning these requirements are that the requirements state that the correction is optimal and no significant pathology is present.

**Proposed Text:**

Amend 4.1 to: **'At initial examination an applicant with**

- **(i) hypermetropia exceeding +3 dioptries**
- **(ii) myopia exceeding -3 dioptries**
- **(iii) astigmatism exceeding 2 dioptries**
- **(iv) anisometropia exceeding 2 dioptries (contact lenses should be worn if the anisometropia exceeds 3 dioptries)**

**should be assessed by an eye specialist and may be assessed as fit provided that optimal correction has been considered and no significant pathology is demonstrated.'**

Delete 4.2.

Amend 4.4 to: **'If the refractive error is more than -6 or +5 dioptries, there...'**

response *Noted*

Please see response to comment No 35.

comment

932

comment by: *European Society of Space and Aviation Medicine (ESAM)*

**Author: European Society of Space and Aviation Medicine (ESAM)-**

**Group Ophthalmology -****Section: 2****Class 1**

- 1) Subpart B - Requirements for medical certificates  
MED.B.065  
c (2)
- 2) AMC A to MED.B.065  
6.1

**Page:** 16 and 46

**Relevant Text:**

1) An applicant with substandard vision in one eye may be assessed as fit subject to satisfactory ophthalmic assessment

2) Applicants with reduced central vision in one eye may be assessed as fit if the binocular visual field is normal and the underlying pathology is acceptable according to ophthalmic assessment.

II: The better eye achieves distant visual acuity of 6/6 ( 1.0) corrected or uncorrected

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 pilot is assessed as unfit.

**Comment:**

Substandard Vision in one eye can mean monocularly, or functional monocularly or severe amblyopia.

The reduced vision has a major impact on visual functions as the binocular vision is a summation of visual functions of both eyes.

Nearly all thresholds of monocular visual function are with normal binocular vision better than monocular.

The absolute threshold for light is 1,5-1,8 times better

The contrast recognition is 1,5-1,7 times better

The resolution is 1,1 times better

The recognition of moving stimulus is 1,9 times better.

The visual field is reduced.

The blind spot can mostly not be compensated.

Dille and Booze published in 1979 (1974-1976) the "Accident experience of civilian pilots with static physical defects", FAA Office of Aviation Medicine Report No. AM-79-19, 77-20, 76-7. They showed that pilots with blindness or absence of one eye had significantly higher accident observed-to-expected ratios and higher rates per 100.000 hours. Airmen with deficient distant vision had significantly higher observed-to-expected ratios and higher rates per 100.000 hours (0,001).

In 1984 Dille and Booze published "The 1980 and 1981 Accident Experience of Civil Airmen with Selected Visual Pathology", Aviat. Space Environ. Med. 1984: 55:966-9

In the years 1980 and 1981 monocular and amblyopic airmen had higher accident rates than the total airmen population.

Mayer and Lane published in 1973 "Monocular Pilots - a Follow-up Study",

Aerosp. Med. 44: 1070-1074. The number of monocular pilots who applied for a student pilot license after having obtained a waiver was proportionately less (84%) than the number of controls who applied (91%). More monocular pilots than control pilots became endorsed on more than one aircraft. There is a suspicion, that monocular pilots were involved in somewhat more hazardous events than control pilots.

The decision of the monocular working group of the JAA was that monocularity in a class 1 applicant or the pilot is not acceptable. Therefore it is essential to implement the sentence "Monocularity is not acceptable for a class 1 applicant" into the "Implementing Rules".

**Proposal:**

Monocularity is not acceptable for a class 1 applicant.

Initial applicants for class 1 medical certificate with reduced central vision should be assessed as unfit.

At revalidation applicants for a class 1 medical certificate with a substandard vision of 0.5 (6/12) or better in one eye can be assessed as fit. In this case the visual acuity of the better eye should be at least 1.0 uncorrected or corrected. However a comprehensive eye examination and evaluation have to be performed for a fit assessment.

response

*Noted*

The comment is covered in Part Medical:

Initial certification is not possible for an applicant with substandard vision in one eye because this condition requires a multi-pilot limitation (6.1) and a student pilot with a multi-pilot limitation cannot do solo flights — which is required to obtain a licence.

A pilot with substandard vision in one eye needs to have a visual acuity of 6/6 in the better eye (6.2).

A comprehensive eye examination is required (6.1).

comment

939

comment by: *European Society of Space and Aviation Medicine (ESAM)*

**Author: European Society of Space and Aviation Medicine (ESAM)- Group Ophthalmology -**

**Section: 1**

**Subpart B**

- 1) MED.B.065  
g (3)
- 2) AMC to MED.B.065  
7

**Page:** 16 and 46 and page 57

**Relevant Text:**

- 1) Applicants for class 1 medical certificate with a clinical diagnosis of keratoconus may be assessed as fit subject to a satisfactory examination by an ophthalmologist.
- 2) *Keratoconus:*

Applicants with keratoconus may be considered for a fit assessment, if the visual requirements are met with the use of corrective lenses and periodic review is undertaken by an ophthalmologist.

3) No text concerning keratoconus in class 2 was found on page 57.

**Comment:**

If applicants for class 1 and 2 can be assessed as fit with the clinical diagnosis of keratoconus, we will "produce" a considerable amount of pilots, who will for sure later on have to be assessed as unfit, as even with contact lenses their visual requirements will not be sufficient any longer. Many eyes with keratoconus in young patients will end in keratoplasty which also makes unfit.

**Proposal:**

Applicants class 1 and class 2! with the diagnosis of keratoconus are assessed as unfit. At revalidation examination applicants for a class 1 and class 2 medical certificate with a clinical diagnosis of keratoconus may be assessed as fit subject to a satisfactory examination by an ophthalmologist.

•1) *Keratoconus:*

At renewal examinations applicants with keratoconus may be considered for a fit assessment, if the visual requirements are met with the use of corrective lenses and at least a yearly examination is undertaken by an ophthalmologist.

response *Not accepted*

An applicant with keratoconus can be assessed as fit as long as he/she can meet the visual requirements with corrective lenses. The risk of losing the licence because the visual requirements are no longer met rests with the pilot. The AME should inform him/her about this risk.

comment

942

comment by: *European Society of Space and Aviation Medicine (ESAM)*

**Author: European Society of Space and Aviation Medicine (ESAM) - Group Ophthalmology-**

**Section: 1**

Subpart B

- 1) MED.B.065

g (3)

- 2) AMC to MED.B.065

7

**Page: 16 and 46**

**Relevant Text:**

- 1) Applicants for class 1 medical certificate with a clinical diagnosis of keratoconus may be assessed as fit subject to a satisfactory examination by an ophthalmologist.
- 2) *Keratoconus:*

Applicants with keratoconus may be considered for a fit assessment, if the visual requirements are met with the use of corrective lenses and periodic review is undertaken by an ophthalmologist.

**Comment:**

If applicants for class 1 can be assessed as fit with the clinical diagnosis of keratoconus, we will "produce" a considerable amount of pilots, who will for sure later on have to be assessed as unfit, as even with contact lenses their visual requirements will not be sufficient any longer. Should we discuss this? Most eyes with keratoconus in young patients will end in keratoplasty which also makes unfit.

**Proposal:**

- 1) Applicants class 1 and class 2! with the diagnosis of keratoconus are assessed as unfit. At revalidation examination applicants for a class 1 and class 2 medical certificate with a clinical diagnosis of keratoconus may be assessed as fit subject to a satisfactory examination by an ophthalmologist.
- 2) *Keratoconus:*

Applicants with keratoconus may be considered for a fit assessment, if the visual requirements are met with the use of corrective lenses and at least a yearly examination is undertaken by an ophthalmologist.

response

*Noted*

See response to comment No 939.

comment

945

comment by: *European Society of Space and Aviation Medicine (ESAM)*

**Author: European Society of Space and Aviation Medicine (ESAM)- Group Ophthalmology -**

**Section: 1  
Subpart B  
AMC A to MED.B.065**

**Page: 45**

**Relevant Text:**

Refractive error 4.2

At revalidation an applicant may be assessed as fit with:  
myopia exceeding - 6,0 diopters

**Comment:**

Very thorough examinations are needed to really assure flight safety in myopia exceeding 6 diopters. Retinal problems and optical problems due to high correcting glasses are more frequent in high myopia.

**Proposal:**

At revalidation an applicant may be assessed as fit with:  
myopia exceeding - 6,0 diopters . The applicant may be assessed as fit if the comprehensive ophthalmological examination shows no elevated intraocular pressure, no myopic degenerations, no optical problems and no any other pathological conditions.

response

*Noted*

A licence holder with a myopia exceeding -6 dioptrres will undergo a 2-yearly review by an eye specialist (4.7) and the report should be forwarded to the licensing authority. The eye specialist should refer the licence holder to an ophthalmologist in case of pathological findings. This should cover the

consequences of eventual optical problems with regard to the licence.

comment

946

comment by: *European Society of Space and Aviation Medicine (ESAM)*

**Author: European Society of Space and Aviation Medicine (ESAM) - Group Ophthalmology-**

**Section: 1**  
MED.B.065 - Visual System

**Page: 44**

**Relevant Text:**

Eye examination

1.2 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.

**Comment:**

If eye drops are needed to be taken for a longer period of time, a major ophthalmological disease is usually the cause. Especially for inflammations or neurological diseases steroids are very often used. Steroids can have many side effects which often occur as high intraocular pressure (steroidresponder) with corneal edema and reduced visual acuity. Also the oral or iv. medication of steroids can have side effects such as diabetes mellitus and or seizures.

If eye drops or oral medication are used to treat a glaucoma it is important to know whether there are visual field defects or an elevation of the pressure that cause visual problems (reduced visual acuity, halos ...) or even headache and/or gastrointestinal problems.

The routine ophthalmological examinations every second year has been dropped by the medical subcommittee of the JAA, as not to burden the pilots who always see well and do not have any diseases or complications. But therefore the idea was to send people to the ophthalmologist if problems occur. Medication for a longer period of time describes exactly the kind of problem which requires an comprehensive ophthalmological exam.

**Proposal:**

If an applicant for a class 1 medical certificate needs oral or iv. medication for his eyes or affecting his eyes or if any of these pilots needs eye drops, he or she shall report this to his/her AME. If the eye medication is prescribed for more than two weeks, or the eye medication has changed, a comprehensive eye examination has to be performed.

response

*Noted*

The issue is covered in MED.A.025.

comment

948

comment by: *European Society of Space and Aviation Medicine (ESAM)*

**Author: European Society of Space and Aviation Medicine (ESAM) - Group Ophthalmology -**

**Section: 1**  
**AMC A to MED.B.065**  
**2**

**Page: 45**

**Relevant Text:**

4.2 Refractive error:

At revalidation an applicant may be assessed as fit with:  
 Hypermetropia not exceeding + 5,0 diopters

**Comment:**

There are class 1 pilots at age of 45 and more, who show up for a renewal examination and it is discovered at the time of that renewal exam, that their hypermetropia exceeds 5 diopters. At the moment there is no legal way to have them keep their license, even if there are no other pathological findings in their eyes except exceeding hypermetropia. If there are really no any other pathological findings in these eyes, we need a legal way to have them keep their license. Therefore we suggest the following text:

**Proposal:**

Hyperopia exceeding + 5 diopters makes an applicant unfit!

If however at a renewal exam a pilot at age 45 or more ( not younger than 45 years) shows a hyperopia of + 5 diopters or more but not more than +6 diopters, he may be by exception be assessed as fit by an extensive ophthalmological evaluation! , not only an ophthalmological comprehensive exam, if the following guidelines are respected and an AMC assesses fitness together with the evaluating ophthalmologist.

Visual acuity in both eyes with correction shall be 1.0 or more. No ophthalmological pathological findings, no obvious signs of a risk of developing a acute narrow angle glaucoma, no signs of a narrow anterior chamber angle, no visual field problems, no ring scotoma, no prismatic deviation problems from high correcting glasses, no optical or any other problems from wearing contact lenses, no elevated intraocular pressure or any other pathological findings may be present. At least yearly ophthalmological comprehensive exams are required to keep medical fitness.

response

*Noted*

This is covered by new paragraph 4.4:

Applicants with hypermetropia exceeding + 5 dioptrres should be referred to the licensing authority. A fit assessment may be considered if the examination by an ophthalmologist confirms that there is no accommodative asthenopia and no narrow anterior chamber.

comment

949

comment by: *European Society of Space and Aviation Medicine (ESAM)*

**Author: European Society of Space and Aviation Medicine (ESAM) - Group Ophthalmology -**

**Section: 1**  
**AMC A to MED.B.65**  
**4.3**

**Page: 45**

**Relevant Text:**

If the refractive error is +3.0 to +5.0 or -3.0 to -6.0 dioptres a review shall be undertaken 5 yearly by an eye specialist.

**Comment:**

Hyperopia: 5 years are too long in regards to complication by high values of optic correction, narrow anterior chambers and potential hypertension. Myopia: 5 years are way to long to supervise the retina and resulting potential problems.

**Proposal:**

If the refractive error is +3.0 - +5.0 dioptres or -3.0 to -6.0 a comprehensive eye examination shall be undertaken 2 yearly after the age of 40 by an ophthalmologist.

response *Noted*

See response to comment No 296.

comment

950

comment by: *European Society of Space and Aviation Medicine (ESAM)*

**Author: European Society of Space and Aviation Medicine (ESAM)-  
Group Ophthalmology -**

**Section: 1****Subpart B****Chapter A**

**AMC A to MED.B.065 - Visual System, class 1 medical certificates**

**9.1 - Eye surgery**

**Page: 46/47**

**Relevant Text:**

After refractive surgery, a fit assessment may be considered provided that:

- (i) pre-operative refraction was no greater than + 5 or -6 dipotres
- (ii) post-operative stability of refraction has been achieved (less than 0.75dioptres variation diurnally);
- (iii) examination of the eye shows no postoperative complications;
- (iv) glare sensitivity is within normal standards;
- (v) mesopic contrast sensitivity is not impaired;
- (vi) review is undertaken by an eye specialist.

**Comment:**

After refractive surgery a period of 6 months is needed for recovery of the visual function of the eye. Corneal scarring, flap problems, refraction, postoperative destability, sicca problems most often occur during the first months post surgery. Visual stability cannot be achieved before a period of 6 months. Corneal thickness postoperatively should not be thinner than 420 µm!

**Proposal:**

Keep the text as it is and add the following text:

In refractive surgery a fit assessment may be granted earliest 6 months post surgery.

.....and add:

response	<p>(vii) In ophthalmological evaluation, postoperative corneal thickness should be taken into account.</p> <p><i>Not accepted</i></p> <p>The AMC provides flexibility with regard to the minimal period of unfitness after refractive surgery and a fit assessment can be made in cases where the requirements are met. The possibility to require additional medical examinations and investigations is in MED.B.001 (d).</p>	
comment	951	<p>comment by: <i>European Society of Space and Aviation Medicine (ESAM)</i></p> <p><b>Author: European Society of Space and Aviation Medicine (ESAM)-Group Ophthalmology -</b></p> <p><b>Section: 1</b> <b>Subpart B</b> <b>Chapter A</b> <b>AMC A to MED.B.065 - Visual System, class 1 medical certificates</b> <b>9.1 - Eye surgery</b></p> <p><b>Page: 46/47</b></p> <p><b>Relevant Text:</b> 9.2. Cataract surgery entails unfitness. A fit assessment may be considered after 3 months.</p> <p><b>Comment:</b> Tinted lenses impair flight safety by excluding (!) perception of visual objects at a certain range of nanometers.</p> <p><b>Proposal:</b> Cataract surgery: Only monofocal, non tinted intraocular lenses are allowed. If however a tinted intraocular lens has been implanted, the blue-yellow colour vision axis has to be evaluated and has to be normal.</p> <p><i>Not accepted</i></p> <p>Please see response to comment No 294.</p>
response	<p><i>Not accepted</i></p> <p>Please see response to comment No 294.</p>	
comment	952	<p>comment by: <i>European Society of Space and Aviation Medicine (ESAM)</i></p> <p><b>Author: European Society of Space and Aviation Medicine (ESAM)-Group Ophthalmology -</b></p> <p><b>Section: 1</b> MED.B.065</p> <p><b>Page: 45</b></p> <p><b>Relevant Text:</b> 2. (viii) tonometry on clinical indication; and</p> <p><b>Comment:</b></p>

An acute glaucoma attack can be very problematic in-flight. An increase of intraocular pressure in an eye with a narrow anterior chamber angle can give important information to hinder that incidence. Open Angle- Glaucoma is still one of the most frequent cause of blindness in the western world and can lead to visual field defects and reduced visual acuity. Therefore it is very important to know the intraocular pressure. In some countries the examination of intraocular pressure is performed by the optician or optometrist. They cannot perform an ophthalmological examination, evaluation and, if necessary, start a treatment. Therefore an ophthalmological examination is necessary.

**Proposal:**

Tonometry every 24 months or if indicated. In the case of an intraocular pressure of 21 mm Hg or above an eye examination by an ophthalmologist should be performed.

response *Noted*

See response to comment No 292.

comment

953

comment by: *European Society of Space and Aviation Medicine (ESAM)*

**Author: European Society of Space and Aviation Medicine (ESAM)- Group Ophthalmology -**

**Section: 1**

AMC A to MED.B. 065

1.1.2

**Page: 44**

**Relevant Text:**

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.

**Comment:**

Acute glaucoma can create among others symptoms of an acute abdomen which can be very problematic in-flight. An increase of intraocular pressure in an eye with a narrow anterior chamber angle can give important information to hinder that incidence. Glaucoma is still one of the most frequent cause of blindness in the western world and can lead to visual field defects and reduced visual acuity. Therefore it is very important to know the intraocular pressure.

**Proposal:**

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 and intraocular tension of 21 mm Hg in tonometry or above.

response *Not accepted*

NPA text covers all issues, including intraocular tension.

comment	954	comment by: <i>European Society of Space and Aviation Medicine (ESAM)</i>
<p><b>Author: European Society of Space and Aviation Medicine (ESAM)-Group Ophthalmology -</b></p> <p><b>Section: 1</b> AMC A to MED.B.65 4.3</p> <p><b>Page: 45</b></p> <p><b>Relevant Text:</b> If the refractive error is +3.0 to +5.0 or -3.0 to -6.0 dioptries a review shall be undertaken 5 yearly by an eye specialist.</p> <p><b>Comment:</b> Hyperopia: 5 years are too long in regards to complication by high values of optic correction, narrow anterior chambers and potential hypertension. Myopia: 5 years are way to long to supervise the retina and resulting potential problems.</p> <p><b>Proposal:</b> If the refractive error is +3.0 - +5.0 dioptries or -3.0 to -6.0 a comprehensive eye examination shall be undertaken <u>2 yearly</u> after the age of 40 by an ophthalmologist.</p>		
response	<i>Noted</i>	
See response to comment No 296.		
comment	964	comment by: <i>European Society of Space and Aviation Medicine (ESAM)</i>
<p><b>Author: European Society of Space and Aviation Medicine (ESAM)-Group Ophthalmology -</b></p> <p><b>Section: 1</b> MED.B.065</p> <p><b>Page: 44</b></p> <p><b>Relevant Text:</b> 2. Comprehensive eye examination (ix) refraction. Hyperopic initial applicants under the age of 25 should undergo objective refraction in cycloplegia.</p> <p><b>Comment:</b> There are numerous class 1 pilots, who show to have hypermetropia exceeding + 5 diopters, when they show up for a renewal application exam. By law hypermetropia exceeding + 5,0 diopters makes them unfit for a class 1 license. To avoid this problem, it is of utmost importance to determine objective and subjective refraction in cycloplegia at the intial ophthalmological exam class 1. Therefore it is not enough to ask for cycloplegia in initial applicants under the age of 25. An applicant of 28 years may be +2 diopters in miosis and + 6,5 diopters in cycloplegia!!! This pilot will lose his license at the age of 50, if his</p>		

hypermetropia is not detected at the initial exam. To avoid these problems in the future, cycloplegia at the initial exam should be applied, when clinically indicated and not only according to age.

**Proposal:**

Hyperopic initial applicants with 1.5 diopters or more under the age of 25, or if indicated, shall undergo objective refraction in cycloplegia.

response *Noted*

Please see response to comment No 340.

comment

1076

comment by: *Aviation Ophthalmology Sweden*

Relevant Text:

**9. Eye Surgery**

9.1. After refractive surgery, a fit assessment may be considered provided that 9.1.(ii) post-operative stability of refraction has been achieved (less than 0.75 diopters variation diurnally).

**Comment:**

A considered diurnal variation of +- 0.75 dpt is too large !. A variation as considered tolerable ie +- 0.75 dpt **could lead to sudden and, even worse , unnoticed incapacitation of the pilot in flight** when minimum visual acuity is no longer maintained. As this possibility would be a contradiction to the visual requirements on visual acuity , a change of this chapter is urgently recommended. Also, which such a variation it will be impossible to meet the visual requirements constantly; hence it is a contradiction to point 10. corrective lenses.

**Proposal:**

**9. Eye Surgery**

9.1. After refractive surgery, a fit assessment may be considered provided that 9.1.(ii) post-operative stability of refraction has been achieved (less than **0.5 diopters** variation diurnally and **constantly meets the visual requirements**). The visual acuity must be stable at least three different measurements three weeks apart.

response *Noted*

The stability of refraction of 0.75 dioptres diurnally has been transposed from JAR-FCL 3. On a general basis the rules and AMCs on the visual system are rather relaxed than tightened and going back to 0.5 dioptres of stability does not seem appropriate under these circumstances.

However, the comment on 3 measurements 3 weeks apart has been noted for Guidance Material to be drafted in rulemaking task MED.001.

comment

1077

comment by: *Aviation Ophthalmology Sweden*

Relevant Text:

**10. Correcting lenses**

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

**Comment:**

	Is insufficient
	<p><b>Proposal:</b> Correcting lenses should permit the license holder to meet the visual requirements at all distances <b>at all times</b>.</p>
response	<i>Not accepted</i>
	The addition would not add clarity.
comment	<p>1078 <span style="float: right;">comment by: Aviation Ophthalmology Sweden</span></p> <p>Relevant Text: <b>8 Heterophoria</b> ... And 33cms 1.0 prism dioptre in hyperphoria</p> <p><b>Comment:</b> Determination of distance of heterophoria measurement to exactly 33 cm doesn't make sense as it is very difficult to maintain this distance during the investigation. No clinician is either used to measure the distance to exact 33 cm or possibly could see any advantage in a rule requiring this exact distance. As the question is heterophoria in the area of 50 to 30 cm this distance should also be defined as such. This distance is practical and useful, and will lead to equally comparable results.</p> <p><b>Proposal:</b> <b>8 Heterophoria</b> .... And At 30-50 cms 1.0 prism dioptre in hyperphoria...</p>
response	<i>Not accepted</i>
	The proposed NPA text is a transposition of the corresponding requirement from JAR-FCL 3 where obviously did not cause any problems over the years. If there is a compelling reason to change the text, a rulemaking task could be requested.
comment	<p>1079 <span style="float: right;">comment by: Aviation Ophthalmology Sweden</span></p> <p>Relevant Text: <b>9. Eye surgery</b> 9.2. Cataract surgery entails unfitness. A fit assessment may be considered after 3 months ..... 9.5. For 9.2., 9.2.. and 9.4. above, a fit assessment may be considered earlier if recovery is complete.</p> <p><b>Comment:</b> The time for visual recovery and stabilization after a normal cataract surgery with implantation of an intraocular lens has been shown to be about four to six weeks ; thereafter the refraction has stabilized. The rapid visual recovery has been shown and proven extensively. In a very recent study the visual acuity improved in all patients one day after surgery with 60 % (27) of the patients achieving a BCVA of 0.9 or better <b>one day</b> postoperatively von Jagow B,</p>

Wirbelauer C, Häberle H, Pham DT. **Klin Monatsbl Augenheilkd. 2007 Jul;224(7):585-9)**

There is no definition of **complete recovery**. Amongst the operations cited does cataract surgery have a separate place. It is the **only** operation that might significantly improve and restore visual acuity and function. In contrast to this, both glaucoma and retinal surgery aim to preserve the visual function at the present stage and to prevent further deterioration.

**Proposal:**

**9. Eye surgery**

9.2. Cataract surgery entails unfitness. A fit assessment may be considered after **6 weeks**

.....  
9.5. For 9.2., 9.2.. and 9.4. above, a fit assessment may be considered earlier **as soon as the visual acuity and function has stabilized** .

response *Noted*

See response to comment No 950.

comment

1326

comment by: *Jan VLASTUIN*

Comment on 9.1 (i)

In march 2008 I was issued a FAA Class 1 medical certificate by the Aerospace Medical Certification Division, 6 weeks after refractive surgery. My pre-operative refraction was -8,25 and -8,5, however, it was successfully corrected to 0.0 and +0.25, with 20/20 vision in both eyes. I passed all the relevant tests concerning glare, haze, halo's and nightvision.

As a currently licensed pilot in the United States, I find it hard to explain why the European rules refer to a pre-operative situation, and deny licensing of otherwise safe and competent pilots based on a condition that no longer has relevance since it was successfully resolved by surgery.

response *Noted*

See response to comment No 170.

comment

1342

comment by: *Veijo Virtanen*

Visual system - class 1 medical certificates

9. Eye Surgery

9.1(i) should be removed. There is no reason, why pre-operative refraction should be between +5 and -6 dioptries. If applicant meets all other requirements, pre-operative refraction cannot reject the applicant. Situation before refractive surgery do not affect to flight safety.

There is not this kind of requirement in ICAO Annex 1. The Federal Aviation Administration (FAA) or many other ICAO contracting states do not have this kind of requirement.

response *Noted*

See response to comment No 170.

comment	1358	comment by: <i>ophtalmologie aerospace medecin</i>
<p><b>Comment:</b> If applicants for class 1 and 2 can be assessed as fit with the clinical diagnosis of keratoconus, we will "produce" a considerable amount of pilots, who will for sure later on have to be assessed as unfit, as even with contact lenses their visual requirements will not be sufficient any longer. Many eyes with keratoconus in young patients will end in keratoplasty which also makes unfit.</p> <p><b>Proposal:</b> Applicants class 1 and class 2! with the diagnosis of keratoconus are assessed as unfit. At revalidation examination applicants for a class 1 and class 2 medical certificate with a clinical diagnosis of keratoconus may be assessed as fit subject to a satisfactory examination by an ophthalmologist.</p> <p>1) <i>Keratoconus:</i> At renewal examinations applicants with keratoconus may be considered for a fit assessment, if the visual requirements are met with the use of corrective lenses and at least a yearly examination is undertaken by an ophthalmologist.</p>		
response	Noted	
<p>The comment is absolutely correct — but the requirements for fitness of pilots are not intended to cover the risk of losing the licence at a later stage. Please see response to comment No 939.</p>		
comment	1359	comment by: <i>ophtalmologie aerospace medecin</i>
<p><b>Comment:</b> If applicants for class 1 can be assessed as fit with the clinical diagnosis of keratoconus, we will "produce" a considerable amount of pilots, who will for sure later on have to be assessed as unfit, as even with contact lenses their visual requirements will not be sufficient any longer. Should we discuss this? Most eyes with keratoconus in young patients will end in keratoplasty which also makes unfit.</p> <p><b>Proposal:</b> 1) Applicants class 1 and class 2! with the diagnosis of keratoconus are assessed as unfit. At revalidation examination applicants for a class 1 and class 2 medical certificate with a clinical diagnosis of keratoconus may be assessed as fit subject to a satisfactory examination by an ophthalmologist. 2) <i>Keratoconus:</i> Applicants with keratoconus may be considered for a fit assessment, if the visual requirements are met with the use of corrective lenses and at least a yearly examination is undertaken by an ophthalmologist.</p>		
response	Noted	
<p>Please see response to identical comment No 1358 and to comment No 939.</p>		
comment	1362	comment by: <i>ophtalmologie aerospace medecin</i>
<p><b>Comment:</b> A lot of problems we run into later on, could be prevented, if the initial</p>		

examination was a comprehensive one. General practitioners are in no way trained to perform a thorough eye exam. They cannot detect diseases or risk factors that could cause in-flight problems later. They also cannot see, which **ophthalmological** condition needs additional restrictions or additional eye examinations.

**Proposal:**

For a class 2 medical certificate a comprehensive eye examination shall form part of the initial examination and if required.

response *Not accepted*

Medical requirements are to ensure the safe exercise of the privileges of a licence during the period of validity of the medical certificate. Any risk of losing the licence because of (foreseeable) medical problems is to be taken by the pilot. The AME should inform the pilot of that risk when the AME sees a condition that may deteriorate in a way that may lead to an unfit assessment.

comment

1363

comment by: *ophthalmologie aerospace medecin*

**Comment:**

A lot of problems we run into later on, could be prevented, if the initial examination was a comprehensive one. General practitioners are in no way trained to perform a thorough eye exam. They cannot detect diseases or risk factors that could cause in-flight problems later. They also cannot see, which **ophthalmological** condition needs additional restrictions or additional eye examinations.

**Proposal:**

For a class 2 medical certificate a comprehensive eye examination shall form part of the initial examination and if required.

response *Noted*

Please see response to comment No 1362.

comment

1365

comment by: *ophthalmologie aerospace medecin*

**Comment:**

A lot of problems we run into later on, could be prevented, if the initial examination was a comprehensive one. General practitioners are in no way trained to perform a thorough eye exam. They cannot detect diseases or risk factors that could cause in-flight problems later. They also cannot see, which **ophthalmological** condition needs additional restrictions or additional eye examinations.

**Proposal:**

For a class 2 medical certificate a comprehensive eye examination shall form part of the initial examination and if required.

response *Noted*

Please see response to comment No 1362.

comment

1366

comment by: *ophthalmologie aerospace medecin*

**Comment:**

There are class 1 pilots at age of 45 and more, who show up for a renewal examination and it is discovered at the time of that renewal exam, that their hypermetropia exceeds 5 diopters. At the moment there is no legal way to have them keep their license, even if there are no other pathological findings in their eyes except exceeding hypermetropia. If there are really no any other pathological findings in these eyes, we need a legal way to have them keep their license. Therefore we suggest the following text:

**Proposal:**

Hyperopia exceeding + 5 diopters makes an applicant unfit!

If however at a renewal exam a pilot at age 45 or more ( not younger than 45 years) shows a hyperopia of + 5 diopters or more but not more than +6 diopters, he may be by exception be assessed as fit by an extensive ophthalmological evaluation! , not only an ophthalmological comprehensive exam, if the following guidelines are respected and an AMC assesses fitness together with the evaluating ophthalmologist.

Visual acuity in both eyes with correction shall be 1.0 or more. No ophthalmological pathological findings, no obvious signs of a risk of developing a acute narrow angle glaucoma, no signs of a narrow anterior chamber angle, no visual field problems, no ring scotoma, no prismatic deviation problems from high correcting glasses, no optical or any other problems from wearing contact lenses, no elevated intraocular pressure or any other pathological findings may be present. At least yearly ophthalmological comprehensive exams are required to keep medical fitness.

response *Noted*

See response to comment No 948.

comment

1369

comment by: *ophtalmologie aerospace medecin*

**Relevant Text:**

If the refractive error is +3.0 to +5.0 or -3.0 to -6.0 dioptries a review shall be undertaken 5 yearly by an eye specialist.

**Comment:**

Hyperopia: 5 years are too long in regards to complication by high values of optic correction, narrow anterior chambers and potential hypertension. Myopia: 5 years are way to long to supervise the retina and resulting potential problems.

**Proposal:**

If the refractive error is +3.0 - +5.0 dioptries or -3.0 to -6.0 a comprehensive eye examination shall be undertaken **2 yearly** after the age of 40 by an ophthalmologist.

response *Noted*

See response to comment No 296.

comment

1370

comment by: *ophtalmologie aerospace medecin*

**Comment:**

After refractive surgery a period of 6 months is needed for recovery of the visual function of the eye. Corneal scarring, flap problems, refraction,

postoperative instability, sicca problems most often occur during the first months post surgery. Visual stability cannot be achieved before a period of 6 months. Corneal thickness postoperatively should not be thinner than 420 µm!

**Proposal:**

Keep the text as it is and add the following text:

In refractive surgery a fit assessment may be granted earliest 6 months post surgery.

.....and add:

(vii) In ophthalmological evaluation, postoperative corneal thickness should be taken into account.

response *Noted*

See response to comment No 950.

comment

1371

comment by: *ophthalmologie aerospace medecin*

**Comment:**

Tinted lenses severely impair flight safety by excluding (!) perception of visual objects at a certain range of nanometers.

**Proposal:**

Cataract surgery: Only monofocal, non tinted intraocular lenses are allowed.

If however a tinted intraocular lens has been implanted, the blue-yellow colour vision axis has to be evaluated and has to be normal.

response

*Noted*

See response to comment No 951.

comment

1372

comment by: *ophthalmologie aerospace medecin*

**Comment:**

Very thorough examinations are needed to really assure flight safety in myopia exceeding 6 diopters. Retinal problems and optical problems due to high correcting glasses are more frequent in high myopia.

**Proposal:**

At revalidation an applicant may be assessed as fit with:

myopia exceeding - 6,0 diopters . The applicant may be assessed as fit if the comprehensive ophthalmological examination shows no elevated intraocular pressure, no myopic degenerations, no optical problems and no any other pathological conditions.

response

*Noted*

Please see response to identical comment No 945.

comment

1373

comment by: *ophthalmologie aerospace medecin*

**Comment:**

If eye drops are needed to be taken for a longer period of time, a major ophthalmological disease is usually the cause. Especially for inflammations or neurological diseases steroids are very often used. Steroids can have many side effects which often occur as high intraocular pressure (steroidresponder)

with corneal edema and reduced visual acuity. Also the oral or iv. medication of steroids can have side effects such as diabetes mellitus and or seizures. If eye drops or oral medication are used to treat a glaucoma it is important to know whether there are visual field defects or an elevation of the pressure that cause visual problems (reduced visual acuity, halos ...) or even headache and/or gastrointestinal problems. The routine ophthalmological examinations every second year has been dropped by the medical subcommittee of the JAA, as not to burden the pilots who always see well and do not have any diseases or complications. But therefore the idea was to send people to the ophthalmologist if problems occur. Medication for a longer period of time describes exactly the kind of problem which requires an comprehensive ophthalmological exam.

**Proposal:**

If an applicant for a class 1 medical certificate needs oral or iv. medication for his eyes or affecting his eyes or if any of these pilots needs eye drops, he or she shall report this to his/her AME. If the eye medication is prescribed for more than two weeks, or the eye medication has changed, a comprehensive eye examination has to be performed.

response *Noted*

The issue is covered in MED.A.025.  
(Identical comment under No 946)

comment

1375

comment by: *ophthalmologie aerospace medecin*

**Comment:**

There are class 1 pilots at age of 45 and more, who show up for a renewal examination and it is discovered at the time of that renewal exam, that their hypermetropia exceeds 5 diopters. At the moment there is no legal way to have them keep their license, even if there are no other pathological findings in their eyes except exceeding hypermetropia. If there are really no any other pathological findings in these eyes, we need a legal way to have them keep their license. Therefore we suggest the following text:

**Proposal:**

Hyperopia exceeding + 5 diopters makes an applicant unfit!

If however at a renewal exam a pilot at age 45 or more ( not younger than 45 years) shows a hyperopia of + 5 diopters or more but not more than +6 diopters, he may be by exception be assessed as fit by an extensive ophthalmological evaluation! , not only an ophthalmological comprehensive exam, if the following guidelines are respected and an AMC assesses fitness together with the evaluating ophthalmologist.

Visual acuity in both eyes with correction shall be 1.0 or more. No ophthalmological pathological findings, no obvious signs of a risk of developing a acute narrow angle glaucoma, no signs of a narrow anterior chamber angle, no visual field problems, no ring scotoma, no prismatic deviation problems from high correcting glasses, no optical or any other problems from wearing contact lenses, no elevated intraocular pressure or any other pathological findings may be present. At least yearly ophthalmological comprehensive exams are required to keep medical fitness.

response *Noted*

Please see response to identical comment No 948.

comment	1376	comment by: <i>ophtalmologie aerospace medecin</i>
	<p><b>Comment:</b> Hyperopia: 5 years are too long in regards to complication by high values of optic correction, narrow anterior chambers and potential hypertension. Myopia: 5 years are way to long to supervise the retina and resulting potential problems.</p> <p><b>Proposal:</b> If the refractive error is +3.0 - +5.0 dioptrés or -3.0 to -6.0 a comprehensive eye examination shall be undertaken <b>2 yearly</b> after the age of 40 by an ophthalmologist.</p>	
response	Noted	
	See response to comment No 296.	
comment	1378	comment by: <i>ophtalmologie aerospace medecin</i>
	<p><b>Comment:</b> Tinted lenses <b>severely</b> impair flight safety by excluding (!) perception of visual objects at a certain range of nanometers.</p> <p><b>Proposal:</b> Cataract surgery: Only monofocal, non tinted intraocular lenses are allowed. If however a tinted intraocular lens has been implanted, the blue-yellow colour vision axis has to be evaluated and has to be normal.</p>	
response	Noted	
	Please see response to comment No 294.	
comment	1379	comment by: <i>ophtalmologie aerospace medecin</i>
	<p><b>Comment:</b> An acute glaucoma attack can be very problematic in-flight. An increase of intraocular pressure in an eye with a narrow anterior chamber angle can give important information to hinder that incidence. Open Angle- Glaucoma is still one of the most frequent cause of blindness in the western world and can lead to visual field defects and reduced visual acuity. Therefore it is very important to know the intraocular pressure. In some countries the examination of intraocular pressure is performed by the optician or optometrist. They cannot perform an ophthalmological examination, evaluation and, if necessary, start a treatment. Therefore an ophthalmological examination is necessary.</p> <p><b>Proposal:</b> Tonometry every 24 months or if indicated. In the case of an intraocular pressure of 21 mm Hg or above an eye examination by an ophthalmologist should be performed.</p>	
response	Noted	
	See response to comment No 292.	
comment	1380	comment by: <i>ophtalmologie aerospace medecin</i>

response	<p><b>Comment:</b> Acute glaucoma can create among others symptoms of an acute abdomen which can be very problematic in-flight. An increase of intraocular pressure in an eye with a narrow anterior chamber angle can give important information to hinder that incidence. Glaucoma is still one of the most frequent cause of blindness in the western world and can lead to visual field defects and reduced visual acuity. Therefore it is very important to know the intraocular pressure.</p> <p><b>Proposal:</b> 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 and intraocular tension of 21 mm Hg in tonometry or above.</p> <p><i>Noted</i></p> <p>See response to comment No 292.</p>						
comment	<table border="1"> <tr> <td data-bbox="343 817 518 873">1381</td> <td data-bbox="518 817 1449 873">comment by: <i>ophthalmologie aerospace medecin</i></td> </tr> <tr> <td colspan="2" data-bbox="343 873 1449 1220"> <p><b>Comment:</b> Hyperopia: 5 years are too long in regards to complication by high values of optic correction, narrow anterior chambers and potential hypertension. Myopia: 5 years are way to long to supervise the retina and resulting potential problems.</p> <p><b>Proposal:</b> If the refractive error is +3.0 - +5.0 dioptries or -3.0 to -6.0 a comprehensive eye examination shall be undertaken <u>2 yearly</u> after the age of 40 by an ophthalmologist.</p> </td> </tr> <tr> <td colspan="2" data-bbox="343 1220 1449 1332"> <p><i>Noted</i></p> <p>See response to comment No 296.</p> </td> </tr> </table>	1381	comment by: <i>ophthalmologie aerospace medecin</i>	<p><b>Comment:</b> Hyperopia: 5 years are too long in regards to complication by high values of optic correction, narrow anterior chambers and potential hypertension. Myopia: 5 years are way to long to supervise the retina and resulting potential problems.</p> <p><b>Proposal:</b> If the refractive error is +3.0 - +5.0 dioptries or -3.0 to -6.0 a comprehensive eye examination shall be undertaken <u>2 yearly</u> after the age of 40 by an ophthalmologist.</p>		<p><i>Noted</i></p> <p>See response to comment No 296.</p>	
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comment	<table border="1"> <tr> <td data-bbox="343 1370 566 1426">1480</td> <td data-bbox="566 1370 1449 1426">comment by: <i>Prüfinstitut Hoch</i></td> </tr> <tr> <td colspan="2" data-bbox="343 1426 1449 1832"> <p>As I have to travel longer distances in Europe now and then I thought about doing this with an Ultra-Light-Plane.</p> <p>This had meant an entrance into the flight business but the first step was so high, that I left it:</p> <p>The eyes may only have a weakness of +- 5 dioptries. With my 10 dioptries I do not have any problem in life, but the first step into flying a plane is impossible.</p> <p>So my plea is to adapt the regulation to the one in England: You have to wear glasses that compensate your weakness in the eye sight and you do have to have a second pair of glasses on board!</p> </td> </tr> <tr> <td colspan="2" data-bbox="343 1832 1449 1944"> <p><i>Noted</i></p> <p>See response to comment No 105.</p> </td> </tr> </table>	1480	comment by: <i>Prüfinstitut Hoch</i>	<p>As I have to travel longer distances in Europe now and then I thought about doing this with an Ultra-Light-Plane.</p> <p>This had meant an entrance into the flight business but the first step was so high, that I left it:</p> <p>The eyes may only have a weakness of +- 5 dioptries. With my 10 dioptries I do not have any problem in life, but the first step into flying a plane is impossible.</p> <p>So my plea is to adapt the regulation to the one in England: You have to wear glasses that compensate your weakness in the eye sight and you do have to have a second pair of glasses on board!</p>		<p><i>Noted</i></p> <p>See response to comment No 105.</p>	
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1500	comment by: <i>Austrian Medical Chamber</i>						

On page 44, in point 1.2. and point 2, as well as on page 45, in point 4, in the last paragraph, it is stipulated that all abnormal and doubtful cases should be referred to an ophthalmologist. This implies e contrario that all other cases could be examined by a less qualified optometrist.

As outlined above with regard to the definition of "eye specialist" after the title MED.A.010 on page 3, we have serious concerns of legal as well as medical nature against any obligation for the Member States to allow medical eye examinations of pilots to be undertaken by professionals other than highly qualified ophthalmologists.

In referring to our comprehensive justification with regard to the definition of "eye specialist", the Austrian Medical Chamber proposes amendment of the wording on page 44 et sqq., 1.2., 2. and 4., into: ***„Where national legislation allows the visual examination and review to be undertaken by eye specialists other than ophthalmologists, at least all abnormal and doubtful cases should be referred to an ophthalmologist“***.

response *Noted*

See response to comment No 296.

The aim of the new regulations is to avoid national differences in the rules. This is why the wording 'acceptable to the authority', that was used in JARs on a regular basis, has been taken out. The ophthalmological examinations shall be done by professionals who are trained to recognise pathologies (see MED.A.010 Definitions). This may not be the case for optometrists trained in Austria which is something that the Agency cannot judge. But if there is insufficient training the optometrist cannot do the examinations.

comment

1502

comment by: PPL/IR Europe

In reference to para 4, Refractive Error

Historically, JAR-FCL medicals have been denied to applicants able to fulfill corrected vision requirements, but whose uncorrected refractive error exceed certain limits. In our view, this limitation on uncorrected error was a needless restriction with no meaningful safety benefit and no precedent in ICAO.

We welcome the fact that the Implementing Rules in this Part only refer to corrected vision standards. However, we are somewhat confused, as layperson readers, over the wording of the AMC in para 4. Does this AMC provide for a candidate who exceeds the Refractive error in 4.1 and 4.2, to still be awarded a Class 1 or 2 Medical on the basis of 4.3 and 4.4? If not, we believe it should do.

In reference to para 9.1.(i) Eye Surgery and pre-operative refractive error, the statement that a fit assessment may be considered provided that *"pre-operative refraction was no greater than +5 or -6 dioptres"* should be deleted on the grounds above. We believe the conditions in 9.1.(ii) to (vi) suffice.

response *Noted*

See responses to comments No 105 and 228.

comment

1519

comment by: Dr Ian Perry

	4.1/4.2/4.3/4.6 etc ICAO standards should be used as all these figures are too prescriptive. Experience has shown that there have been no problems/accidents or incidents using the recommended ICAO standards. They are used in the US/Canada/Australia/New Zealand/HongKong etc.	
response	<i>Noted</i>	
	See response to comment No 105.	
comment	1520	comment by: <i>Dr Ian Perry</i>
	9.2 A fit assessment could be considered after 2-3 weeks, as modern cataract eye surgery only takes minutes. In the opinion of most eye surgeons 3 months is far too long a period for reassessment.	
response	<i>Noted</i>	
	The issue is covered in 9.5.	
comment	1614	comment by: <i>Dr Lilla Ungváry</i>
	<p><b>Relevant Text:</b> 2. (viii) tonometry on clinical indication; and</p> <p><b>Comment:</b> An acute glaucoma attack can be very problematic in-flight. An increase of intraocular pressure in an eye with a narrow anterior chamber angle can give important information to hinder that incidence. Open Angle- Glaucoma is still one of the most frequent cause of blindness in the western world and can lead to visual field defects and reduced visual acuity. Therefore it is very important to know the intraocular pressure. In some countries the examination of intraocular pressure is performed by the optician or optometrist. They cannot perform an ophthalmological examination, evaluation and, if necessary, start a treatment. Therefore an ophthalmological examination is necessary.</p> <p><b>Proposal:</b> Tonometry every 24 months or if indicated. In the case of an intraocular pressure of 21 mm Hg or above an eye examination by an ophthalmologist should be performed.</p>	
response	<i>Noted</i>	
	See response to comment No 292.	
comment	1722	comment by: <i>Österr. Ophthalmologische Gesellschaft</i>
	Attachment <a href="#">#25</a>	
	Amendment of the wording 1.2 , 2. and 4. into: "Where national legislation allows the visual examination and review to be undertaken by eye specialists other than ophthalmologists, at least all abnormal and doubtful cases should be referred to an ophthalmologist."	
response	<i>Noted</i>	
	See response to comment No 1500.	

comment	1830	comment by: <i>European CMO Forum</i>
<p><b>Paragraph:</b> AMC A to Med.B.065 4.1  <b>Page No:</b> 45</p> <p><b>Comment:</b>  New requirements for refractive error limits for initial Class 1 applicants should be adopted as soon as possible.</p> <p><b>Justification:</b>  Years of cumulative experience from the European aviation authorities have demonstrated that high levels of myopia, astigmatism and anisometropia are associated with an extremely low risk of sudden incapacitation and that, provided there is good optical correction and these pilots are subject to regular ophthalmological follow up, the refractive error limits should be amended.</p> <p><b>Proposed Text:  (if applicable)  Delete proposed paragraph 4.1 and replace with:</b></p> <p>4.1 <i>Refractive error</i>  (i) At initial examination an applicant may be assessed as fit with hypermetropia not exceeding +5.0 dioptres;  (ii) In cases of myopia exceeding 6.0 dioptres, astigmatism exceeding 2.0 dioptres or anisometropia exceeding 2.0 dioptres the authority may assess the applicant as fit provided that optimal correction has been considered and no significant pathology is demonstrated on ophthalmological examination.  (iii) In cases of myopia, astigmatism or anisometropia optimal correction should have been considered and no significant pathology demonstrated.  (iv) In the case of anisometropia exceeding 3.0 dioptres contact lenses should be worn.</p>		
response	<i>Partially accepted</i>	
<p>Paragraph 4.1 remains unchanged. New paragraph 4.2 has been introduced to allow the licensing authority to issue a medical certificate in cases where the refractive error is beyond the limits specified in 4.1 (ii), (iii) and (iv).</p>		
comment	1831	comment by: <i>European CMO Forum</i>
<p><b>Paragraph:</b> AMC A to Med.B.065 4.2  <b>Page No:</b> 45</p> <p><b>Comment:</b>  New requirements for refractive error limits for revalidation Class 1 applicants should be adopted to align with the proposals for initial class 1 (see CMOs' Forum's comments on para 4.1).</p> <p><b>Justification:</b>  Detailed examination of the eye now makes it possible to be much more confident about the likely risks associated with hypermetropia, in particular precise measurement of the anterior chamber angle is now possible.</p> <p><b>Proposed Text:  (if applicable)  Delete proposed paragraph 4.2 and replace with:</b></p>		

response	<p>4.2 At revalidation an applicant may be assessed as fit by the authority with hypermetropia exceeding + 5 dioptries if there is no accommodative asthenopia and no narrow anterior chamber after a full ophthalmological examination.</p> <p><i>Partially accepted</i></p> <p>One sub-paragraph 4.4 added to enable the authority to make a fit assessment in applicants with hypermetropia that exceeds +5 dioptries.</p>	
comment	1832	<p>comment by: <i>European CMO Forum</i></p> <p>AMC A to Med.B.065 4.4 45</p> <p>New refractive error limits should be reflected in the requirement for specialist follow up.</p> <p>Pilots with high levels of refractive error should be reviewed more frequently than those with low limits.</p> <p><b>Delete proposed paragraph 4.4 and replace with:</b></p> <p>4.4 If the refractive error is greater than -6 dioptries or greater than +5 dioptries a review should be undertaken 2 yearly by an eye specialist.</p>
response	<p><i>Accepted</i></p>	
comment	1834	<p>comment by: <i>European CMO Forum</i></p> <p><b>Paragraph:</b> AMC A to Med.B.065 9.1 <b>Page No:</b> 46</p> <p><b>Comment:</b> The pre-operative refractive error limit should be removed for high levels of myopia.</p> <p><b>Justification:</b> Long term studies and wide experience of refractive surgery demonstrate that high levels of myopia may be surgically treated with a favourable outcome in terms of lack of side-effects and good refractive result. It is no longer justifiable to exclude such pilots from applying for Class 1 certification.</p> <p><b>Proposed Text: (if applicable)</b> Delete 'or - 6' in (i) such that it reads: (i) pre-operative refraction was no greater than +5 dioptries;</p>
response	<p><i>Noted</i></p> <p>Please see response to comment No 170.</p>	
comment	1910	<p>comment by: <i>Österr. Ophthalmologische Gesellschaft</i></p> <p>It has to be taken into consideration, however, that some of the limits are more liberally defined than those for drivers on the streets of EU member states</p>

response	<p>Therefore demand</p> <p>(x) mesopic vision and a glare sensitivity test should be added</p> <p>This is of great importance in the case of cataract and cornea surgery, in other postoperative states and the like.</p> <p><i>Noted</i></p> <p>See response to comment No 293.</p>	
comment	1981	<p>comment by: <i>MOT Austria</i></p> <p><b>Comment:</b></p> <p>Austria opposes, that 'optometrists' should be involved in eye examination of flying personnel. Extended eye examinations shall be performed by ophthalmologists only.</p> <p><b>Justification:</b></p> <p>Optometrists in Austria are no 'eye specialists' because they have no clinical training and are unable to recognize pathological eye conditions. By Austrian law (Gewerbeordnung 1994) 'optometrists' are just opticians, who are only allowed to sell and to adapt eyeglasses and contact lenses.</p> <p><b>Proposed Text:</b></p> <p>Change the text in:</p> <p>2. Comprehensive eye examination A comprehensive visual examination by an <b>ophthalmologist</b> is required at the initial examination. All abnormal and doubtful cases should be referred to an ophthalmologist.</p> <p>4.3. If the refractive error is +3.0 to +5.0 or 3.0 to 6.0 dioptres a review shall be undertaken 5 yearly by an <b>ophthalmologist</b>.</p> <p>4.4. 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 shall be undertaken 2 yearly by an <b>ophthalmologist</b>.</p> <p>In cases 4.3. and 4.4. above the applicant should supply the ophthalmologist 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 <b>ophthalmologist</b>.</p> <p>9. <i>Eye surgery</i> 9.1. After refractive surgery, a fit assessment may be considered provided that: (vi) review is undertaken by an <b>ophthalmologist</b>.</p> <p><i>Noted</i></p> <p>See response to comment No 1500.</p>
response	<p><i>Noted</i></p> <p>See response to comment No 1500.</p>	

comment	2003	comment by: Aki Kylamaa
	<p>AMC A to MED.B.065</p> <p>4. Refractive error (class 1)</p> <p>Vision have to be 6/9 or better in each eye separately and 6/6 with both eyes. There is no need for hypermetropia or myopia limits. Most of ICAO contracting states do not have any limits for refractive error. If corrected or uncorrected vision is 6/9 or better in each eyes separately and 6/6 with both eyes, it should be good enough. There is not any limits for uncorrected vision in paragraph 5 (uncorrected visual acuity), so paragraph 4 (refractive error) could be removed or at least hypermetropia and myopia limits should be removed.</p> <p>9. Eye surgery (class 1)</p> <p>9.1 (i) should be removed. There is not any reason for this kind of requirement. Refractive surgeries have been done over 20 years and nowadays pre-operative refraction do not affect to vision after surgery.</p> <p>If applicants vision is 6/9 or better in each eye separately and 6/6 with both eyes, it is good enough. Most of ICAO contracting states do not have any limits for pre-operative refraction.</p>	
response	<p><i>Noted</i></p> <p>Please see response to comment No 170.</p>	
comment	2020	comment by: Dr. med. Hans Brandl
	<p>In section 2 (viii) tonometry on clinical indication; and please delete the words "...on clinical indication; and"</p> <p>The new text should read as follows: (viii) tonometry;</p> <p>Rational: Tonometry is necessary in any case and not only on clinical indication.</p>	
response	<p><i>Noted</i></p> <p>See response to comment No 292.</p>	
comment	2021	comment by: Dr. med. Hans Brandl
	<p>In section 2 (ix) refraction. Hyperopic initial applicants under the age of 25 should undergo objective refraction in cycloplegia. please delete at the end of the sentence the full stop sign and add the word "and" after the word "cycloplegia-"</p> <p>The new text part in section 2 (ix) should read as follows: (ix) refraction. Hyperopic initial applicants under the age of 25 should undergo objective refraction in cycloplegia and</p>	
response	<p><i>Not accepted</i></p> <p>The NPA text is a transposition of JAR-FCL 3, where mesopic contrast</p>	

sensitiviy/glare sensitivity (see comment No 2024 below) was not required as a routine examination. The 'and' is therefore not needed.

comment 2024 comment by: *Dr. med. Hans Brandl*

After text of section 2 (ix) please add the following text as separate new section 2 (x):  
(x) mesoptict contrast sensitivity / glare sensitivity.

Rational: Both examinations are necessary in any case

response *Noted*

See response to comment No 293.

comment 2025 comment by: *Dr. med. Hans Brandl*

In section 3 (iv) further examination on clinical indication.  
please delete at the end of the sentence the full stop sign and add the word "and" after the word "indication"

The new text part in section 3 (iv) should read as follows:  
3 (iv) further examination on clinical indication and

response *Not accepted*

The wording 'and' is connecting the next requirement with the previous one. In this case it is not possible, because 3(iv) ends the paragraph 3.

comment 2026 comment by: *Dr. med. Hans Brandl*

After text of section 3 (iv) please add the following text as separate new section 3 (v):  
(v) tonometry (in 24-months intervals).

response *Noted*

See response to comment No 292.

comment 2027 comment by: *Dr. med. Hans Brandl*

In section 4.2 (iv) anisometropia exceeding 2.0 dioptres (contact lenses should be worn if the anisometropia exceeds 3.0 dioptres;  
please delete the following text part  
(contact lenses should be worn if the anisometropia exceeds 3.0 dioptres

The new text part in section 4.2 (iv) should read as follows:  
4.2 (iv) anisometropia exceeding 2.0 dioptres;

Rational:

Please see page 16 of 66  
MED.B.065 Visual System

(j)

(3) the correction shall provide optimal visual function, be well-tolerated and suitable for aviation purposes

response	<i>Accepted</i>	
comment	2028	comment by: <i>Dr. med. Hans Brandl</i>
	<p>In section 8. <i>Heterophoria</i>  please delete the following text parts completely:  and  At 33cms 1.0 prism dioptre in hyperphoria,  8.0 prism dioptres in esophoria,  12.0 prism dioptres in exophoria</p> <p>Rational:  This text concerning nearphoria (33 cms) should be deleted as it <u>has absolutely no flight ophthalmological relevance</u> for class 1 applicants.</p> <p>The new text part in section 8 <i>Heterophoria</i> should read as follows:</p> <p>8. <i>Heterophoria</i>  Applicants with a heterophoria (imbalance of the ocular muscles) exceeding:  At 6 metres 2.0 prism dioptres in hyperphoria,  10.0 prism dioptres in esophoria,  8.0 prism dioptres in exophoria;  should be assessed as unfit. 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.</p>	
response	<i>Not accepted</i>	
	The NPA text is a transposition of the corresponding requirement from JAR-FCL 3. An amendment/change in this case could be done in a new NPA.	
comment	2029	comment by: <i>Dr. med. Hans Brandl</i>
	<p>In section 9. <i>Eye surgery</i>  please delete the following text part in subsection 9.1 (ii) completely:  (ii) postoperative stability of refraction has been achieved (less than 0.75 dioptres variation diurnally);</p> <p>Rational:  Minor refraction deficits (e.g. ca 4 dioptres at the age of 40-45) can be compensated by accommodation.  In this specific case, mydriasis induced by medication is not appropriate and target-orientated. Examination by automatic refractometer does not make any sense due to physical reasons.</p>	
response	<i>Not accepted</i>	
	The NPA text is a transposition of the corresponding requirement from JAR-FCL 3. An amendment/change in this case could be done in a new NPA.	
comment	2030	comment by: <i>Dr. med. Hans Brandl</i>
	<p>In section 9. <i>Eye surgery</i>  please delete the following text part in subsection 9.1 (v) completely:</p>	

(v) mesopic contrast sensitivity is not impaired;

and add the following new text in subsection 9.1 (v):  
 (v) mesopic contrast sensitivity with following defined accurate threshold values:

- mesopic contrast sensitivity value up to 1:2.7  
 ----> applicant to be assessed as fit;
- mesopic contrast sensitivity value up to 1:5  
 ----> class 1 applicant to be assessed as "OML" mandatory;
- mesopic contrast sensitivity value up to 1:23:  
 ----> applicant to be assessed as absolutely unfit;

response *Noted*

The NPA text is a transposition of the corresponding requirement from JAR-FCL 3. The additions proposed in this comment could be discussed when drafting Guidance Material.

comment

2032

comment by: *Dr. med. Hans Brandl*

In section 9.3 Retinal surgery entails unfitness. A fit assessment may be considered 6 months after successful surgery. A fit assessment may be acceptable earlier after retinal laser therapy. Follow up may be required.

Please add the following new text after the word "laser therapy." :

A fit assessment may be considered provided if  
 (i) glare sensitivity is within normal standards  
 (ii) mesopic contrast sensitivity with following defined accurate threshold values:

- mesopic contrast sensitivity value up to 1:2.7  
 ----> applicant to be assessed as fit;
- mesopic contrast sensitivity value up to 1:5  
 ----> class 1 applicant to be assessed as "OML" mandatory;
- mesopic contrast sensitivity value up to 1:23:  
 ----> applicant to be assessed as absolutely unfit.

These ophthalmological examinations have to be performed at initial and at revalidation examinations.

Rational:

Due to surgery an opacity of lens can develop which may have negative effects on the individual glare sensitivity as well as on the mesopic contrast sensitivity.

response *Noted*

Please see response to comment No 2030.

comment

2036

comment by: *Dr. med. Hans Brandl*

In section 9.4 Glaucoma surgery entails unfitness. A fit assessment may be considered 6 months after successful surgery. Followup may be required.

Please add the following new text after the word "surgery." :  
 A fit assessment may be considered provided if

(i) glare sensitivity is within normal standards  
 (ii) mesopic contrast sensitivity with following defined accurate threshold values:  
 - mesopic contrast sensitivity value up to 1:2.7  
     ---->applicant to be assessed as fit;  
 - mesopic contrast sensitivity value up to 1:5  
     ----> class 1 applicant to be assessed as "OML" mandatory;  
 - mesopic contrast sensitivity value up to 1:23:  
     ---->applicant to be assessed as absolutely unfit.  
 These ophthalmological examinations have to be performed at initial and at revalidation examinations.

**Rational:**  
 Due to surgery an opacity of lens can develop which may have negative effects on the individual glare sensitivity as well as on the mesopic contrast sensitivity.

response *Not accepted*

Please see response to comment No 2030.

comment 2040

comment by: *Tomasz Gorzenski*

Any reference to refractive error, especially regarding myopia should have been eliminated from the regulation.

What's the reason for such limits in the proposed regulation? Aesthetic? While the probability of significant eye pathology increases with refractive error, it is possible to have much higher refractive errors than those proposed and yet have no significant eye pathology, which could adversely affect flight safety, as well as normal fields of vision and 6/6 distant visual acuity. On the other hand it is possible, although less likely, to have no refraction error and have developed significant eye pathology or illnesses. The only important things are: appropriate distant, intermediate and near visual acuity with whatever correction, if required, normal fields of vision and no significant pathologies. This is requested that the EASA go forward with the rest of the world (at least with the ICAO and the FAA) and not leaves us in the middle ages of aviation medicine science. The refractive error criteria proposed by EASA are based rather on myths, prejudice and long, although biased tradition supported previously by the JAA - and not modern aviation medicine science. The JAA was inherently unable to create better aviation regulations due to the principle of unanimity. The EASA can.

This is worthy to note, that while present EASA proposal regarding refractive error continues with the wrong, old european tradition (although at least increasing the limit), how happened that the EU authorities have been accepting the situation, when lives of millions of EU citizens have been in jeopardy, because they use non-EU airlines, most notably U.S. airlines, and some of their pilots do not meet present JAA Class 2 medical certificate visual requirement, because even though they are required by the FAA to have 6/6 distant visual acuity in each eye separately, some of them may have higher refraction error that that for JAA class 2 medical? If nothing could be done, EU citizens deserve at least a warning that their life is endangered while travelling onboard of a U.S. airliner. I believe that EU authorities are aware that there is no danger - but then - why to continue with the discrimination of own, EU citizens in pursuit of their career or passion goals? Actually, this is easy to note, that flying with U.S. airlines is safer than with EU airlines - because U.S.

airline transport pilots are required to have 1.5 times better distant visual acuity than their EU colleagues (6/6 in each eye separately vs. 6/9, and 6/6 for both eyes, but having 6/6 in each eye separately usually means better acuity using both eyes - typically 1.5 times better). And such a distant visual acuity is hard to achieve, if at all possible, with any eye pathology, which, according to the JAA and EASA, seems to be inherently associated with higher than proposed refraction errors.

If the proposed refractive error limits are not withdrawn, the subject will be finally brought to the attention of the Euroombudsman and, eventually, the European Court of Justice - such unjust and unfair that proposal is, in the light of present international vision standards for pilots and modern aviation medicine.

In any case, a refractive error limits during initial examinations should not apply to applicants with previous aeronautical experience. This would be ridiculous to assess an experienced ICAO ATPL-holder during initial examination (due to validation or conversion of his/her ICAO non-EASA pilot license, or due to need of medical certificate renewal) as unfit, because his refractive error is 10, 20 or 30% more than the limit, despite having normal fields of vision, no eye pathology, 6/6 distant visual acuity in each eye separately (1.5 times better than present and proposed European regulations, as required by FARs for professional pilots) and several thousand hours of safe flying.

response *Noted*

comment *2042* comment by: *Tomasz Gorzenski*

Please remove the requirement for pre-operative refraction error to be less than +5 or -6 diopters. For explanation - please see my previous comment regarding refraction errors.

response *Noted*

See response to comment No 170.

comment *2044* comment by: *Tomasz Gorzenski*

Point 10 - Corrective lenses should permit the license holder to meet the visual requirements at all distances.

If I understand it correctly, it doesn't make sense, in case of highly myopic old pilot wearing contact lenses, who may need reading glasses when he becomes older. The general requirement in your proposal says that "only one pair of spectacles can be used" - that's fine, because contact lenses are different from spectacles. But Point 10? If it is just a general statement, not limiting the amount of corrective lenses (which can be either spectacles or contact lenses), that is OK, but if you mean just one pair of corrective lenses - it doesn't make sense.

response *Noted*

comment *2087* comment by: *DGAC FRANCE*

AMC A to MED.B.065, **paragraph 4.1.**

comment :

New requirements for refractive error limits for initial Class 1 applicants should be adopted as soon as possible.

Years of cumulative experience from the European aviation authorities have demonstrated that high levels of myopia, astigmatism and anisometropia are associated with an extremely low risk of sudden incapacitation and that, provided there is good optical correction and these pilots are subject to regular ophthalmological follow up, the refractive error limits should be amended.

Modification :

Delete proposed paragraph 4.1 and replace it by the following proposition :

**4.1**

**(i) At initial examination an applicant may be assessed as fit with hypermetropia not exceeding +5.0 dioptries ;**

**(ii) In cases of myopia exceeding 6.0 dioptries, astigmatism exceeding 2.0 dioptries or anisometropia exceeding 2.0 dioptries the authority may assess the applicant as fit provided that optimal correction has been considered and no significant pathology is demonstrated on ophthalmological examination.**

**(iii) In cases of myopia, astigmatism or anisometropia optimal correction should have been considered and no significant pathology demonstrated.**

**(iv) In the case of anisometropia exceeding 3.0 dioptries contact lenses should be worn.**

response *Noted*

Please see response to comment No 35.

comment

2091

comment by: *DGAC FRANCE*

AMC A to MED.B.065, **paragraph 4.2.**

comment :

New requirements for refractive error limits for revalidation Class 1 applicants should be adopted to align with the proposals for initial class 1 (see comments on paragraph 4.1).

Detailed examination of the eye now makes it possible to be much more confident about the likely risks associated with hypermetropia, in particular precise measurement of the anterior chamber angle is now possible.

Modification :

Delete proposed paragraph 4.2 and replace it by the following proposition :

**4.2 At revalidation an applicant may be assessed as fit by the authority with hypermetropia exceeding + 5 dioptries if there is no**

	<b><u>accommodative asthenopia and no narrow anterior chamber after a full ophthalmological examination.</u></b>	
response	<i>Partially accepted</i>	
	Please see response to comment No 35; examination criteria have been added.	
comment	2093	comment by: DGAC FRANCE
	<p>AMC A to MED.B.065, <b>paragraph 4.4.</b></p> <p>comment :</p> <p>New refractive error limits should be reflected in the requirement for specialist follow up.</p> <p>Pilots with high levels of refractive error should be reviewed more frequently than those with low limits.</p> <p>Modification :</p> <p>Delete proposed paragraph 4.4 and replace it by the following proposition :</p> <p><b><u>4.4</u></b></p> <p><b><u>If the refractive error is greater than –6 dioptries or greater than +5 dioptries a review should be undertaken 2 yearly by an eye specialist.</u></b></p>	
response	<i>Partially accepted</i>	
	The proposal to include applicants with +5 dioptries or more is accepted. The deletion of those who present with astigmatism or anisometropia of more than 3 dioptries is not.	
comment	2096	comment by: DGAC FRANCE
	<p>AMC A to MED.B.065, <b>paragraph 9.1.</b></p> <p>comment :</p> <p>The pre-operative refractive error limit should be removed for high levels of myopia.</p> <p>Long term studies and wide experience of refractive surgery demonstrate that high levels of myopia may be surgically treated with a favourable outcome in terms of lack of side-effects and good refractive result. It is no longer justifiable to exclude such pilots from applying for Class 1 certification.</p> <p>Modification : <b>Delete "or – 6 dioptries" in (i) as followed :</b></p> <p>9.1. <i>After refractive surgery, a fit assessment may be considered provided that</i> :</p> <p>(i) pre-operative refraction was no greater than + 5 dioptries <del>or – 6 dioptries</del> ;</p>	

response	<i>Noted</i>	
	Please see response to comment No 170.	
comment	2231	comment by: <i>Ulrich Ablassmeier</i>
	Of course a pilot has to have a good vision. But it does not matter how he achieves that. If a refractive error can be compensated by glasses or correcting lenses it is ok. It is not sensible to limit the dioptries of the glasses if the pilot gets sufficient vision with them.	
response	<i>Noted</i>	
	Please see response to comment No 35.	
comment	2297	comment by: <i>DLR</i>
	<p>Substandard Vision in one eye can mean monocularity, or functional monocularity or severe amblyopia.</p> <p>The reduced vision has a major impact on visual functions as the binocular vision is a summation of visual functions of both eyes.</p> <p>Nearly all thresholds of monocular visual function are with normal binocular vision better than monocular.</p> <p>The absolute threshold for light is 1,5-1,8 times better  The contrast recognition is 1,5-1,7 times better  The resolution is 1,1 times better  The recognition of moving stimulus is 1,9 times better.</p> <p>The visual field is reduced.  The blind spot can mostly not be compensated.</p> <p>Dille and Booze published in 1979 (1974-1976) the "Accident experience of civilian pilots with static physical defects", FAA Office of Aviation Medicine Report No. AM-79-19, 77-20, 76-7. They showed that pilots with blindness or absence of one eye had significantly higher accident observed-to-expected ratios and higher rates per 100.000 hours. Airmen with deficient distant vision had significantly higher observed-to-expected ratios and higher rates per 100.000 hours (0,001).</p> <p>In 1984 Dille and Booze published "The 1980 and 1981 Accident Experience of Civil Airmen with Selected Visual Pathology", Aviat. Space Environ. Med. 1984: 55:966-9  In the years 1980 and 1981 monocular and amblyopic airmen had higher accident rates than the total airmen population.</p> <p>Mayer and Lane published in 1973 "Monocular Pilots – a Follow-up Study", Aersp. Med. 44: 1070-1074. The number of monocular pilots who applied for a student pilot license after having obtained a waiver was proportionately less (84%) than the number of controls who applied (91%). More monocular pilots than control pilots became endorsed on more than one aircraft. There is a suspicion, that monocular pilots were involved in somewhat more hazardous events than control pilots.</p> <p>The decision of the monocularity working group of the JAA was that monocularity in a class 1 applicant or the pilot is not acceptable. Therefore it is essential to implement the sentence " Monocularity is not acceptable for a class</p>	

	<p>1 applicant" into the "Implementing Rules".</p> <p>Proposal:                  Monocularity is not acceptable for a class 1 applicant.                  Initial applicants for class 1 medical certificate with reduced central vision should be assessed as unfit.                  At revalidation applicants for a class 1 medical certificate with a substandard vision of 0.5 (6/12) or better in one eye can be assessed as fit. In this case the visual acuity of the better eye should be at least 1.0 uncorrected or corrected. However a comprehensive eye examination and evaluation have to be performed for a fit assessment.</p>
response	<p>Noted</p> <p>See response to comment No 932.</p>

comment	<p>2305</p> <p style="text-align: right;">comment by: DLR</p> <p><b><u>If applicants for class 1 and 2 can be assessed as fit with the clinical diagnosis of keratoconus, we will "produce" a considerable amount of pilots, who will for sure later on have to be assessed as unfit, as even with contact lenses their visual requirements will not be sufficient any longer. Many eyes with keratoconus in young patients will end in keratoplasty which also makes unfit.</u></b></p> <p><b><u>Proposal:</u></b>  <u>Applicants class 1 and class 2! with the diagnosis of keratoconus are assessed as unfit. At revalidation examination applicants for a class 1 and class 2 medical certificate with a clinical diagnosis of keratoconus may be assessed as fit subject to a satisfactory examination by an ophthalmologist.</u></p> <p>1) <u>Keratoconus:</u>  <b>At renewal examinations applicants with keratoconus may be considered for a fit assessment, if the visual requirements are met with the use of corrective lenses and at least a yearly examination is undertaken by an ophthalmologist.</b></p>
response	<p>Noted</p> <p>See response to comment No 939.</p>

comment	<p>2309</p> <p style="text-align: right;">comment by: DLR</p> <p>If applicants for class 1 can be assessed as fit with the clinical diagnosis of keratoconus, we will "produce" a considerable amount of pilots, who will for sure later on have to be assessed as unfit, as even with contact lenses their visual requirements will not be sufficient any longer. Should we discuss this?                  Most eyes with keratoconus in young patients will end in keratoplasty which also makes unfit.</p> <p><b>Proposal:</b></p> <p>1) Applicants <u>class 1 and class 2! with the diagnosis of keratoconus are assessed as unfit. At revalidation examination applicants for a class 1 and class 2</u> medical certificate with a clinical diagnosis of keratoconus may be assessed as fit subject to a satisfactory examination by an ophthalmologist.</p> <p>2) <u>Keratoconus:</u>                  Applicants with keratoconus may be considered for a fit assessment, if the</p>
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	visual requirements are met with the use of corrective lenses and at least a yearly examination is undertaken by an ophthalmologist.	
response	<i>Noted</i>	
	See response to comment No 939.	
comment	2316	comment by: <i>DLR</i>
	<p>Very thorough examinations are needed to really assure flight safety in myopia exceeding 6 diopters. Retinal problems and optical problems due to high correcting glasses (scotoma) are more frequent in high myopia. There are other ophthalmological diseases that are associated with high myopia e.g. glaucoma, macula scars.</p> <p><b>Proposal:</b>  At revalidation an applicant may be assessed as fit with:  myopia exceeding – 6,0 diopters . The applicant may be assessed as fit if the comprehensive ophthalmological examination shows no elevated intraocular pressure, no myopic degenerations, no optical problems and no any other pathological conditions.</p>	
response	<i>Noted</i>	
	See response to comment No 945.	
comment	2321	comment by: <i>DLR</i>
	<p>If eye drops are needed to be taken for a longer period of time, a major ophthalmological disease is usually the cause. Especially for inflammations or neurological diseases steroids are very often used. Steroids can have many side effects which often occur as high intraocular pressure (steroidresponder) with corneal edema and reduced visual acuity. Also the oral or iv. medication of steroids can have side effects such as diabetes mellitus and or seizures.</p> <p>If eye drops or oral medication are used to treat a glaucoma it is important to know whether there are visual field defects or an elevation of the pressure that cause visual problems (reduced visual acuity, halos ...) or even headache and/or gastrointestinal problems.</p> <p>The routine ophthalmological examinations every second year has been dropped by the medical subcommittee of the JAA, as not to burden the pilots who always see well and do not have any diseases or complications. But therefore the idea was to send people to the ophthalmologist if problems occur. Medication for a longer period of time describes exactly the kind of problem which requires a comprehensive ophthalmological exam.</p> <p><b>Proposal:</b>  If an applicant for a class 1 medical certificate needs oral or iv. medication for his eyes or affecting his eyes or if any of these pilots need eye drops, he or she shall report this to his/her AME. If the eye medication is prescribed for more than two weeks, or the eye medication has changed, a comprehensive eye examination has to be performed</p>	
response	<i>Noted</i>	
	The issue is covered in MED.A.025.	
comment	2325	comment by: <i>DLR</i>

There are class 1 pilots at age of 45 and more, who show up for a renewal examination and it is discovered at the time of that renewal exam, that their hypermetropia exceeds 5 diopters. At the moment there is no legal way to have them keep their license, even if there are no other pathological findings in their eyes except exceeding hypermetropia. If there are really no any other pathological findings in these eyes, we need a legal way to have them keep their license. Therefore we suggest the following text:

**Proposal:**

Hyperopia exceeding + 5 diopters makes an applicant unfit!

If however at a renewal exam a pilot at age 45 or more ( not younger than 45 years) shows a hyperopia of + 5 diopters or more but not more than +6 diopters, he may be by exception be assessed as fit by an extensive ophthalmological evaluation! , not only an ophthalmological comprehensive exam, if the following guidelines are respected and an AMC assesses fitness together with the evaluating ophthalmologist.

Visual acuity in both eyes with correction shall be 1.0 or more. No ophthalmological pathological findings, no obvious signs of a risk of developing a acute narrow angle glaucoma, no signs of a narrow anterior chamber angle, no visual field problems, no ring scotoma, no prismatic deviation problems from high correcting glasses, no optical or any other problems from wearing contact lenses, no elevated intraocular pressure or any other pathological findings may be present. At least yearly ophthalmological comprehensive exams are required to keep medical fitness.

response

*Noted*

See response to comment No 948.

comment

2326

comment by: *DLR*

Hyperopia: 5 years are too long in regards to complication by high values of optic correction, narrow anterior chambers and potential hypertension. Myopia: 5 years are way to long to supervise the retina and resulting potential problems.

**Proposal:**

If the refractive error is +3.0 - +5.0 dioptres or -3.0 to -6.0 a comprehensive eye examination shall be undertaken 2 yearly after the age of 40 by an ophthalmologist.

response

*Noted*

See response to comment No 296.

comment

2327

comment by: *DLR*

After refractive surgery a period of 6 months is needed for recovery of the visual function of the eye. Corneal scarring, flap problems, refraction, postoperative instability, sicca problems most often occur during the first months post surgery. Visual stability cannot be achieved before a period of 6 months. Corneal thickness postoperatively should not be thinner than 420 µm!

**Proposal:**

Keep the text as it is and add the following text:

In refractive surgery a fit assessment may be granted earliest 6 months post surgery.

.....and add:

(vii) In ophthalmological evaluation, postoperative corneal thickness should be

	taken into account.	
response	<i>Noted</i>	
	See response to comment No 950.	
comment	2329	comment by: <i>DLR</i>
	<p>Tinted lenses impair flight safety by excluding (!) perception of visual objects at a certain range of nanometers.</p> <p><b>Proposal:</b>  <u>Cataract surgery: Only monofocal, non tinted intraocular lenses are allowed.</u>  <u>If however a tinted intraocular lens has been implanted, the blue-yellow colour vision axis has to be evaluated and has to be normal.</u></p>	
response	<i>Noted</i>	
	See response to comment No 951.	
comment	2331	comment by: <i>DLR</i>
	<p>An acute glaucoma attack can be very problematic in-flight. An increase of intraocular pressure in an eye with a narrow anterior chamber angle can give important information to hinder that incidence. Open Angle- Glaucoma is still one of the most frequent cause of blindness in the western world and can lead to visual field defects and reduced visual acuity. Therefore it is very important to know the intraocular pressure. In some countries the examination of intraocular pressure is performed by the optician or optometrist. They cannot perform an ophthalmological examination, evaluation and, if necessary, start a treatment. Therefore an ophthalmological examination is necessary.</p> <p><b>Proposal:</b>  Tonometry every 24 months or if indicated. In the case of an intraocular pressure of 21 mm Hg or above an eye examination by an ophthalmologist should be performed.</p>	
response	<i>Noted</i>	
	See response to comment No 292.	
comment	2333	comment by: <i>DLR</i>
	<p>Acute glaucoma can create among others symptoms of an acute abdomen which can be very problematic in-flight. An increase of intraocular pressure in an eye with a narrow anterior chamber angle can give important information to hinder that incidence. Glaucoma is still one of the most frequent cause of blindness in the western world and can lead to visual field defects and reduced visual acuity. Therefore it is very important to know the intraocular pressure.</p> <p><b>Proposal:</b>  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 and intraocular tension of 21 mm Hg in tonometry or above.</p>	
response	<i>Noted</i>	

See response to comment No 953.

comment 2411 comment by: *Irish Aviation Authority*

4.1

New requirements for refractive error limits for initial Class 1 applicants should be adopted as soon as possible.

Justification:

Years of experience from the European aviation authorities have demonstrated that high levels of myopia, astigmatism and anisometropia are not associated with risk of sudden incapacitation and that, provided there is good optical correction and these pilots are subject to regular ophthalmologic review, the refractive error limits could be amended.

Proposed text:

**Delete proposed paragraph 4.1 and replace with:**

*Refractive error*

(i) At initial examination an applicant may be assessed as fit with a hypermetropia not exceeding +5.0 dioptres;

(ii) In cases of myopia exceeding -6.0 dioptres, astigmatism exceeding 2.0 dioptres or anisometropia exceeding 2.0 dioptres the authority may assess the applicant as fit provided optimal correction has been considered and no significant pathology is found at extensive ophthalmological examination.

(iii) In cases of myopia, astigmatism or anisometropia optimal correction should have been considered and no significant pathology found.

(iv) In the case of anisometropia exceeding 3.0 dioptres contact lenses should be worn.

response *Accepted*

Please see response to comment No 35.

comment 2412 comment by: *Irish Aviation Authority*

4.2

New requirements for refractive error limits for revalidation Class 1 applicants should be adopted to be in line with the proposals for initial class 1 (see comments on para 4.1).

Justification:

Detailed modern examination of the eye now makes it possible to be more confident about the likely risks associated with hypermetropia

Proposed text:

**Delete proposed paragraph 4.2 and replace with:**

4.2 At revalidation an applicant with hypermetropia exceeding + 5 dioptres may be assessed as fit by the authority if there is no accommodative asthenopia and no narrow anterior chamber after a full ophthalmological examination.

response *Noted*

Please see response to comment No 35.

comment	2413	comment by: <i>Irish Aviation Authority</i>
	<p>4.4 New refractive error limits should be reflected in the requirement for specialist review</p> <p>Justification: Pilots with high refractive errors should be reviewed more frequently than those with low refractive errors.</p> <p>Proposed text: <b>Delete proposed paragraph 4.4 and replace with:</b> 4.3 If the refractive error is &gt; -6 dioptres or &gt; +5 dioptres a review should be undertaken 2 yearly by an eye specialist. 4.4</p>	
response	<i>Noted</i>	
	The proposal to include applicants with +5 dioptres or more is accepted. The deletion of the text with regard to those who present with astigmatism or anisometropia of more than 3 dioptres is not.	
comment	2414	comment by: <i>Irish Aviation Authority</i>
	<p>9.1 The pre-operative refractive error limits should be removed for high levels of myopia.</p> <p>Justification: Long term studies and wide experience of refractive surgery demonstrate that high levels of myopia may be surgically treated with a good outcome in terms of side-effects and good refractive result. It is not justifiable anymore to exclude such pilots from applying for Class 1 certification.</p> <p>Proposed text: <del>'or -6' in (i) such that it reads:</del> <del>(i) pre-operative refraction was no greater than +5 dioptres;</del></p>	
response	<i>Accepted</i>	
	Please see response to comment No 170	
comment	2575	comment by: <i>Heinz Fricke-Bohl and Kirsten Bohl</i>
	AMC A to MED.B.065: Keine Festlegung auf +5 bis -6 Dioptrin. Wir wissen doch noch gar nicht welche Fortschritte auf diesem Gebiet sein werden und was in Zukunft noch besser gehen wird.	
response	<i>Noted</i>	

comment	297	comment by: <i>Lufthansa German Airlines</i>
<p><b>Author:</b> Dr. Esther Stahl-Buhl, AMC Frankfurt  <b>Section:</b> 1  AMC A to MED.B.70  2  <b>Page:</b> 47</p> <p><b>Relevant Text:</b>  The Ishihara test (24 plates version) is considered passed if the first 15 plates, presented in a random order, are identified without error.</p> <p><b>Comment:</b></p> <p><b>Proposal:</b>  This must be a mistake, it should say, the first 17 plates, plate number 16 and 17 are important plates for colour distinction.</p>		
response	<i>Not accepted</i>	
<p>The proposed NPA text is a transposition of the corresponding requirement from JAR-FCL 3, where the first 15 plates were required to be identified correctly.</p>		
comment	298	comment by: <i>Lufthansa German Airlines</i>
<p><b>Author:</b> Dr. Esther Stahl-Buhl, AMC Frankfurt  <b>Section:</b> 1  AMC A to MED.B.70  3  <b>Page:</b> 47</p> <p><b>Relevant Text:</b>  Those failing the Ishihara test should be examined either by:  Anomaloscopy ( Nagel or equivalent). This test is considered passed if the colour match is trichromatic and the matching range is 4 scales units or less, or by Lantern testing.</p> <p><b>Comment:</b></p> <p><b>Proposal:</b>  I would put the wording: This test is considered passed if the colour match is a normal trichromatic ( AQ range from 0.65 - 1.4) and the matching range is 4 scale units or less. An ophthalmologist shall have conducted this test.  Reason: In the suggested version of the EASA an highly abnormal protanomalous pilot with an AQ of 0.3 might be considered as colour safe, and that protanomalous pilot would never be able to distinguish yellow and red in case of bad light conditions , small colour fields and low colour saturations. ( See airplane crash of FedEx machine in the US due to colour deficiency). In Germany any public bus driver transporting more than 8 passengers is considered unfit, if his AQ is below 0.5.</p>		
response	<i>Not accepted</i>	
<p>The NPA text is a transposition of the corresponding requirement from JAR-FCL 3. In this case it is a pure copy because this was the compromise made in the past years and the debate should not be re-openend.</p>		

comment	410	comment by: <i>European CMO Forum</i>
	<p><b>AMC A to MED.B.070 3 (ii)</b></p> <p>Comment: Lanterns should be specified.</p> <p>Justification: To ensure standardisation.</p> <p>Proposed Text: Amend to: '...a test with a Spectrolux, Beynes or Holmes-Wright lantern.'</p>	
response	<i>Accepted</i>	
comment	681	comment by: <i>Pekka Oksanen</i>
	<p>3 (ii) Color lanterns must be specified to ensure standardisation.</p> <p>Proposal change text: ... without error a test with <del>accepted lanterns</del> a <b>Spectrolux, Beynes or Holmes-Wright lantern</b></p>	
response	<i>Noted</i>	
	See comment No 410 above.	
comment	828	comment by: <i>Thomas Cook Airlines UK</i>
	<p><b>Commentator: The UK Association of Aviation Medical Examiners</b></p> <p><b>Paragraph:</b> AMC A to MED B. 070 Colour vision - Class I medical certificates</p> <p><b>Page Number:</b> 47</p> <p><b>Comment:</b> Specify which lantern tests are acceptable for candidates who fail the Ishihara plates. The use of the new City University tests should be permitted.</p> <p><b>Justification:</b> New colour tests have been shown to be more accurate than some of the lantern tests.</p> <p><b>Proposed text:</b> AMC A to MED B.070 3. (iii) Acceptable lantern tests include the Holmes Wright. Colour Assessment by the UK City University colour vision test is also permitted.</p>	
response	<i>Noted</i>	
	Please see response to comment No 410.	
comment	838	comment by: <i>Thomas Cook Airlines UK</i>
	<p><b>Commentator: The UK Association of Aviation Medical Examiners</b></p> <p><b>Paragraph:</b> AMC A to MED B.070 Colour vision Class I medical certificate</p>	

**Page Numbers:** 47

**Comment:** AMC A to MED B.070 Para 3 (i) there is a spelling mistake the word should be "colour" not "clour"

**Justification:** correct spelling mistake

**Proposed text:** 3. (i) 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 by.....

response *Accepted*

comment

955

comment by: *European Society of Space and Aviation Medicine (ESAM)*

**Author: European Society of Space and Aviation Medicine (ESAM)-  
Group Ophthalmology -**

**Section: 1**

Chapter A

AMC A to MED.B.070

Chapter 3

3

**Page: 47 and 58**

**Relevant Text:**

Those failing the Ishihara test should be examined either by:

Anomaloscopy (Nagel or equivalent). This test is considered passed if the colour match is trichromatic and the matching range is 4 scales units or less, or by Lantern testing.

**Comment:**

Colour coded information occur in different areas of aviation. Scientific publications show that a normal trichromatic observer notices information faster and more effectively if it is based on colour differences. This reduces the rate of errors and of reaction time. Colour displays all imply that they are focused by a biologically "normal" eye with the possibility of discrimination of the entire colour spectrum. The correct perception and reading of a display is necessary, even more if difficult environmental conditions like glare, high light intensity in the cockpit and on the displays occur.

Electronic flight information displays present several colours at the same time in order to code information thus being identified and resolved faster. Humans with colour vision deficiencies are only able to identify two to three colours if another comparable colour is missing. People with colour vision deficiencies make even more errors at display work if only white signals with different illumination are presented. Already in 1965 Gramberg-Danielsen showed, that protanomals or protanopes have a higher number of rear-end collisions while driving. In 1975 Christ showed that colour coding on displays shows a 200% advantage over size and form coding. The perception time and the error rate can be reduced (Cole, MacDonald). The probability of a person with a colour vision deficiency to perform as good as a colour normal in the identification of colour information decrease by the increase of the degree of severity of the colour vision deficiency and is about 0 in the protanopes. In 1980 Robert Dille published that pilots with a waiver for colour vision deficiency are significant

more often involved in aviation accidents than it is expectable by the statistics. In 2000 Ivan declared that people with colour vision deficiencies are usually not aware of the whole limited performance but think that they can identify colours and work satisfactorily in their operative environment. But the colour discrimination of these persons is not based on biological colour discrimination but on different aids as differences in illumination or learning by trial and error. Only normal trichromates should be considered to be colour safe. 4% of the Deuteranomals pass the Ishihara plates anyhow. Applicants could otherwise be protanomalous, trichromatic and have a matching range of 4 scale units. But they are not normal trichromatic and do see red lights much darker or even as grey or yellow, compared to normal trichromatic. This can be very dangerous.

**Proposal:**

Those failing the Ishihara test should be examined by the following two tests: Anomaloscopy (Nagel or equivalent). This test is considered passed if the colour match is the one of a **normal** trichromatic (0.7-1.4) and the matching range is 4 scales units or less, and by Lantern testing. The Lantern test is considered passed if the applicant passes without error a test with accepted lanterns (Holmes Wright B, Beynes or Spectrolux). Applicants need to pass both tests (Anomaloscopy and Lantern) in order to be assessed as colour safe.

response

*Noted*

See response to comment No 410.

The basis of this document was JAR-FCL 3, where the Lantern Test was only required if the Ishihara test and Anomaloscopy failed.

Adding the Lantern test to Anomaloscopy on a routine basis for those who do not pass the Ishihara test is too stringent and does not help the applicant either.

comment

1382

comment by: *ophthalmologie aerospace medecin*

**Comment:**

Colour coded information occur in different areas of aviation. Scientific publications show that a normal trichromatic observer notices information faster and more effectively if it is based on colour differences. This reduces the rate of errors and of reaction time. Colour displays all imply that they are focused by a biologically "normal" eye with the possibility of discrimination of the entire colour spectrum. The correct perception and reading of a display is necessary, even more if difficult environmental conditions like glare, high light intensity in the cockpit and on the displays occur.

Electronic flight information displays present several colours at the same time in order to code information thus being identified and resolved faster. Humans with colour vision deficiencies are only able to identify two to three colours if another comparable colour is missing. People with colour vision deficiencies make even more errors at display work if only white signals with different illumination are presented. Already in 1965 Gramberg-Danielsen showed, that protanomalous or protanopes have a higher number of rear-end collisions while driving. In 1975 Christ showed that colour coding on displays shows a 200% advantage over size and form coding. The perception time and the error rate can be reduced (Cole, MacDonald). The probability of a person with a colour vision deficiency to perform as good as a colour normal in the identification of colour information decrease by the increase of the degree of severity of the

colour vision deficiency and is about 0 in the protanopes. In 1980 Robert Dille published that pilots with a waiver for colour vision deficiency are significant more often involved in aviation accidents than it is expectable by the statistics. In 2000 Ivan declared that people with colour vision deficiencies are usually not aware of the whole limited performance but think that they can identify colours and work satisfactorily in their operative environment. But the colour discrimination of these persons is not based on biological colour discrimination but on different aids as differences in illumination or learning by trial and error. Only normal trichromates should be considered to be colour safe. 4% of the Deuteranomals pass the Ishihara plates anyhow. Applicants could otherwise be protanomalous, trichromatic and have a matching range of 4 scale units. But they are not normal trichromatic and do see red lights much darker or even as grey or yellow, compared to normal trichromatic. This can be very dangerous.

**Proposal:**

Those failing the Ishihara test should be examined by the following two tests: Anomaloscopy (Nagel or equivalent). This test is considered passed if the colour match is the one of a **normal** trichromatic (0.7-1.4) and the matching range is 4 scale units or less, and by Lantern testing. The Lantern test is considered passed if the applicant passes without error a test with accepted lanterns (Holmes Wright B, Beynes or Spectrolux). Applicants need to pass both tests (Anomaloscopy and Lantern) in order to be assessed as colour safe.

response

*Noted*

Please see response to comment No 955.

comment

2037

comment by: *Dr. med. Hans Brandl*

As alternative, Dr. med. Hans Brandl proposes a complete new text for chapter "Colour Vision - class 1 medical certificates:

**Proposed new wording:**

1. Reading/identification of ISHIIHARA plates (24 plates version) without error provides evidence of colour safety of the applicant.

2. If ISHIIHARA plates were not read/identified without error, applicants shall undergo further colour perception testing to establish whether they are colour safe.

As appropriate alternative to verify sufficient colour discrimination the Nagel-anomaloscope (or equivalent method) should be used resulting in the following findings:

0.5 £ AQ £ 6

Maximum allowable value: Protanomalie 0.5

**Rational:**

According to European Directive requirements for bus and taxi driver licences.

**Please note:**

Lantern tests are demonstrably inappropriate / unqualified to be used as method to confirm/verify proof of colour safety.

response

*Not accepted*

The NPA text is a transposition of the corresponding requirements from JAR FCL 3. Additional requirements in the implementing rule may be introduced only through a new rulemaking task.

comment	2046	comment by: <i>Tomasz Gorzenski</i>
	<p>What kind of lantern testing? It seems like the EASA defines color safe as color normal. The tolerance for error is too tight, in my opinion. And this is not exactly the same what ICAO and FAA consider color safe.</p> <p>In addition, there are quite a few commercial pilot activities (particularly in helicopters and small airplanes) which can be safely and proficiently performed in daylight conditions by commercial pilots who are not color normal and even not color safe. Actually, some of those activities can be performed only during daylight and in VMC, as VFR/day-only operations. Assessing those pilots as unfit is an unnecessary discrimination - their flying privileges could have been limited to daytime only, as in case of proposed EASA class 2 medical certificate. This is how it works in the USA, and how it should have worked in the EU, too.</p> <p>Please follow other authorities, most notably the FAA and allow commercial pilot privileges for non-color safe pilot with daytime only limitation. There is enough evidence from the USA to pacify any safety concerns.</p>	
response	<i>Noted</i>	
	<p>See response to comment No 410.</p> <p>Applicants who fail all tests (last would be the Lantern test) may, nevertheless, get a licence, restricted to daytime only. Please note that without privileges to fly at night there is no possibility to get an instrument rating.</p>	
comment	2335	comment by: <i>DLR</i>
	<p>Colour coded information occur in different areas of aviation. Scientific publications show that a normal trichromatic observer notices information faster and more effectively if it is based on colour differences. This reduces the rate of errors and of reaction time. Colour displays all imply that they are focused by a biologically "normal" eye with the possibility of discrimination of the entire colour spectrum. The correct perception and reading of a display is necessary, even more if difficult environmental conditions like glare, high light intensity in the cockpit and on the displays occur.</p> <p>Electronic flight information displays present several colours at the same time in order to code information thus being identified and resolved faster. Humans with colour vision deficiencies are only able to identify two to three colours if another comparable colour is missing. People with colour vision deficiencies make even more errors at display work if only white signals with different illumination are presented. Already in 1965 Gramberg-Danielsen showed, that protanomals or protanopes have a higher number of rear-end collisions while driving. In 1975 Christ showed that colour coding on displays shows a 200% advantage over size and form coding. The perception time and the error rate can be reduced (Cole, MacDonald). The probability of a person with a colour vision deficiency to perform as good as a colour normal in the identification of colour information decrease by the increase of the degree of severity of the colour vision deficiency and is about 0 in the protanopes. In 1980 Robert Dille published that pilots with a waiver for colour vision deficiency are significant more often involved in aviation accidents than it is expectable by the statistics. In 2000 Ivan declared that people with colour vision deficiencies are usually not aware of the whole limited performance but think that they can identify</p>	

colours and work satisfactorily in their operative environment. But the colour discrimination of these persons is not based on biological colour discrimination but on different aids as differences in illumination or learning by trial and error. Only normal trichromates should be considered to be colour safe. 4% of the Deuteranomals pass the Ishihara plates anyhow. Applicants could otherwise be protanomalous, trichromatic and have a matching range of 4 scale units. But they are not normal trichromatic and do see red lights much darker or even as grey or yellow, compared to normal trichromatic. This can be very dangerous.

**Proposal:**

Those failing the Ishihara test should be examined by the following two tests: Anomaloscopy (Nagel or equivalent). This test is considered passed if the colour match is the one of a **normal** trichromatic (0.7-1.4) and the matching range is 4 scale units or less, and by Lantern testing. The Lantern test is considered passed if the applicant passes without error a test with accepted lanterns (Holmes Wright B, Beynes or Spectrolux). Applicants need to pass both tests (Anomaloscopy and Lantern) in order to be assessed as colour safe.

response *Noted*

Please see response to identical comment No 955.

comment

2415

comment by: *Irish Aviation Authority*

3(ii)  
Lanterns should be specified.

Justification:  
for standardisation.

Proposed text:  
Amend to: '...testing with a Spectrolux, Beynes or Holmes-Wright lantern.'

response *Noted*

Please see response to comment No 410.

**C. Draft Decision Part-MED - Subpart B: Requirements for Medical Certificates - Section 1: Specific requirements for class 1 and class 2 medical certificates - Chapter A: AMC for Class 1 medical certificates - AMC A to MED.B.075: Otorhino-laryngology** p. 47-48

comment

274

comment by: *Lufthansa German Airlines*

**Author:** Dr. Ulrike Springer AMC Frankfurt  
**Section: 2**  
AMC A to MED.B.075  
1.11 - hearing - Chapter A  
AMC for Class 1 Medical Certificates  
**Page: 47**

**Relevant Text:**

The applicant should understand correctly conversational speech when tested with each ear at a distance of 2 m from and with the applicant's back turned towards the AME.

response	<p><b>Comment:</b> Pure-tone audiometry assures precise and reproducible measurements.</p> <p><b>Proposal:</b> The applicant shall correctly understand conversational speech. This is to be determined by pure-tone audiometric testing of each ear.</p> <p><i>Noted</i></p>				
	<p>Pure tone audiometry is required for class 1 and for class 2 for instrument rating holders: at initial examination, every 5 years until the age of 40 and every 2 years thereafter.</p> <p>This is the same periodicity as in JAR-FCL 3.</p> <p>Conversational speech test is required at each examination.</p>				
comment	<table border="1"> <tr> <td data-bbox="341 813 512 875">275</td> <td data-bbox="512 813 1449 875">comment by: <i>Lufthansa German Airlines</i></td> </tr> <tr> <td colspan="2" data-bbox="341 875 1449 1570"> <p><b>Author:</b> Dr. Ulrike Springer AMC Frankfurt <b>Section: 2</b> AMC A to MED.B.075 4 - vestibular disturbance <b>Page:</b> 48</p> <p><b>Relevant Text:</b> An applicant 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. Significant abnormal caloric or rotational vestibular responses are disqualifying. Abnormal vestibular responses shall be assessed in their clinical context.</p> <p><b>Comment:</b> This type of nystagmus indicates incomplete compensation following acute vestibular dysfunction.</p> <p><b>Proposal:</b> In addition, examination of nystagmus enhanced by head movement is recommended.</p> </td> </tr> </table>	275	comment by: <i>Lufthansa German Airlines</i>	<p><b>Author:</b> Dr. Ulrike Springer AMC Frankfurt <b>Section: 2</b> AMC A to MED.B.075 4 - vestibular disturbance <b>Page:</b> 48</p> <p><b>Relevant Text:</b> An applicant 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. Significant abnormal caloric or rotational vestibular responses are disqualifying. Abnormal vestibular responses shall be assessed in their clinical context.</p> <p><b>Comment:</b> This type of nystagmus indicates incomplete compensation following acute vestibular dysfunction.</p> <p><b>Proposal:</b> In addition, examination of nystagmus enhanced by head movement is recommended.</p>	
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response	<p><i>Noted</i></p> <p>A clinical assessment of the vestibular function is required under AMC A to MED.B.075. This can well include the examination of nystagmus by head movement.</p>				
comment	<table border="1"> <tr> <td data-bbox="341 1749 512 1845">278</td> <td data-bbox="512 1749 1449 1845">comment by: <i>Lufthansa German Airlines</i></td> </tr> <tr> <td colspan="2" data-bbox="341 1845 1449 2020"> <p><b>Author:</b> Dr. Ulrike Springer AMC Frankfurt <b>Section: 2</b> Subpart A AMC to MED.B.075 1.1.3 - hearing - Validity, Revalidation, and Renewal of Medical Certificates</p> </td> </tr> </table>	278	comment by: <i>Lufthansa German Airlines</i>	<p><b>Author:</b> Dr. Ulrike Springer AMC Frankfurt <b>Section: 2</b> Subpart A AMC to MED.B.075 1.1.3 - hearing - Validity, Revalidation, and Renewal of Medical Certificates</p>	
278	comment by: <i>Lufthansa German Airlines</i>				
<p><b>Author:</b> Dr. Ulrike Springer AMC Frankfurt <b>Section: 2</b> Subpart A AMC to MED.B.075 1.1.3 - hearing - Validity, Revalidation, and Renewal of Medical Certificates</p>					

	<p>Class 1 Medical Certificates  <b>Page:</b> 47</p> <p><b>Relevant Text:</b>                  An applicant with hypoacusis should be referred to the licensing authority. A fitness assessment can be made if a speech discrimination test or functional flight deck hearing test demonstrates satisfactory hearing ability.</p> <p><b>Comment:</b></p> <p><b>Proposal:</b>                  Following additions are recommended:                  An applicant with hypoacusis should be referred to the licensing authority. A fitness assessment can be made if hearing and <b>vestibular function</b> are satisfactory for the safe exercise of the privileges of the applicable licence(s)</p>
response	<p><i>Partially accepted</i></p> <p>The Agency appreciates that Lufthansa in this case accepts the referral of an applicant to the licensing authority.</p> <p>One sentence has been added to AMC 1 to MED.075 1.3.: 'A vestibular function test may be appropriate'.</p>

comment	613	comment by: <i>Lufthansa German Airlines</i>
	<p><b>Author:</b> Dr. Ulrike Springer AMC Frankfurt  <b>Section: 2</b>                  AMC A to MED.B.075                  4 - vestibular disturbance  <b>Page:</b> 48</p> <p><b>Relevant Text:</b>                  An applicant 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. Significant abnormal caloric or rotational vestibular responses are disqualifying. Abnormal vestibular responses shall be assessed in their clinical context.</p> <p><b>Comment:</b>                  This type of nystagmus indicates incomplete compensation following acute vestibular dysfunction.</p> <p><b>Proposal:</b>                  In addition, examination of nystagmus enhanced by head movement is recommended.</p>	
response	<p><i>Noted</i></p> <p>Please see response to your identical comment No 275.</p>	

comment	758	comment by: <i>Swiss Association of Aviation Medecine</i>
	<p><b>Comment:</b>                  There are more different types of nystagmus, that can indicate severe diseases</p>	

of the vestibular system, which have to be regarded.

**Proposal:**

An applicant with disturbance of vestibular function should be assessed as unfit. A fit assessment may be considered after full recovery. The presence of spontaneous, positional, or any other type of nystagmus requires complete vestibular evaluation by an ENT specialist accepted by the authority. Significant abnormal caloric vestibular responses are disqualifying. Abnormal vestibular responses shall be assessed in their clinical context.

response *Noted*

We agree that more detailed AMCs regarding nystagmus are possible. However, this NPA is based on JAR-FCL 3 which is also not very specific on nystagmus. The comment will be used as input for Guidance Material to be drafted for the rulemaking task MED.001

comment

844

comment by: *European Society of Space and Aviation Medicine (ESAM)*

**Author: European Society of Space and Aviation Medicine (ESAM) - Group ENT -**

**Section:**

**2 AMC A to MED .B.075**

4- Vestibular disturbance

**Page: 48**

**Relevant Text:** An applicant 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. Significant abnormal caloric or rotational vestibular responses are disqualifying. Abnormal vestibular responses shall be assessed in their clinical context.

**Comment:**

There are more different types of nystagmus, that can indicate severe diseases of the vestibular system, which have to be regarded.

**Proposal:**

An applicant with disturbance of vestibular function should be assessed as unfit. A fit assessment may be considered after full recovery. The presence of spontaneous, positional, or any other type of nystagmus requires complete vestibular evaluation by an ENT specialist accepted by the authority. Significant abnormal caloric vestibular responses are disqualifying. Abnormal vestibular responses shall be assessed in their clinical context.

response *Noted*

Please see response to identical comment No 758.

comment

1057

comment by: *Dr Michel Kossowski AeMC Clamart*

same comment than for the page 17

response *Noted*

Same answer as to the comment on page 17.

comment 1058 comment by: *Dr Michel Kossowski AeMC Clamart*

vestibular balance : I think that the head shaking test must be done to evaluate vestibular balance because if the candidate has an history of vertigo and if there no symptom, this test can reveal a nystagmus and so induced a complete vestibular evaluation

response *Noted*

Please see response to comment No 275.

comment 1452 comment by: *Michel KOSSOWSKI*

4 vestibular balance : I thik that the head shaking test must be done because if the candidat has an history of vertigo and if there is no symptom, this test can reveal a nystagmus and so induce a complete vestibular evaluation.

response *Noted*

Identical comment under No 1058.

Please see response to comment No 275.

comment 1529 comment by: *Andrew CAMPBELL*

AMC A to MED.B.075 makes no mention of whether the applicant is permitted to wear hearing aids or similar devices when undertaking the audiogram. If it is permissible, and I submit that it should be, then this should be expressly stated to remove ambiguity.

response *Partially accepted*

Subparagraph 1.4 has been added to clarify the ENT AMCs with regard to hearing aids: 'If the hearing requirements can only be met with the use of hearing aids, ...'.

comment 1991 comment by: *CAA Belgium*

Relevant Text:

1. Hearing

1.1. The applicant 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.

1.2. The pure tone audiogram shall cover the 500Hz, 1000Hz, 2000Hz and 3000Hz frequency thresholds.

1.3. An applicant with hypoacusis should be referred to the licensing authority. A fit assessment can be made if a speech discrimination test or functional flight deck hearing test demonstrates satisfactory hearing ability.

Comment:

This text is subject to misunderstanding: If the applicant satisfied to 1.1, when it is necessary to perform a hearing test? A applicant must to be able to understand correctly a conversational speech AND perform a tonal hearing test

with pure-tone. Hearing is important factor for safety in aviation and can be affected by different factors during the life.

Proposal:

1.1. At each examination, the applicant 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.

1.2. At the initial examination and every five years up to age of 40 and thereafter every two years, an examination of hearing by pure-tone audiogram is required. The pure tone audiogram shall cover the 500Hz, 1000Hz, 2000Hz and 3000Hz frequency thresholds.

1.3. An applicant with hypoacusis should be referred to the licensing authority for further evaluation and assessment. A fit assessment can be made if a speech discrimination test or functional flight deck hearing test demonstrates satisfactory hearing ability.

response *Noted*

1.1. The issue is covered in MED.B.075 (c)(1) and AMC to MED.B.075 1.1.

1.2. The issue is covered in MED.B.075 (c)(1)(i).

1.3. The issue is covered in MED.B.075 (c)(1)(iii) and AMC to MED.B.075 1.3.

comment

1992

comment by: CAA Belgium

2. Comprehensive otorhinolaryngological examination

Relevant Text:

A comprehensive otorhinolaryngological examination should include:

(i) history;

(ii) clinical examination including otoscopy, rhinoscopy, and examination of the mouth and throat;

(iii) tympanometry or equivalent;

(iv) clinical assessment of the vestibular system.

Comment:

(ii) For otoscopy, the use of microscope is essential for detailed view of the entire eardrum.

(iii): Eustachian function is essential for flying.

Proposal:

A comprehensive otorhinolaryngological examination should include:

(i) history;

(ii) clinical examination including otoscopy with microscope, rhinoscopy and examination of the mouth and throat;

(iii) tympanometry or equivalent and Eustachian tube function.

(iv) clinical assessment of the vestibular system.

response *Noted*

The inclusion of 'with microscope' under (ii) and 'and Eustachian tube function' under (iii) would be new when compared to JAR-FCL 3 which was the basis of this NPA. However, the comment is taken as input for Guidance Material to be drafted for the rulemaking task MED.001

**Certificates - Section 1: Specific requirements for class 1 and class 2 medical certificates - Chapter A: AMC for Class 1 medical certificates - AMC A to MED.B.080: Dermatology**

comment	2012	comment by: <i>chris huck</i>
	<p><b>I feel that</b> recognising that;</p> <p>a. Sailplane pilots holding a pilot qualification that is identified as ICAO equivalent by the national authorities should be automatically recognised as qualified for the SPL and the LPL(S).</p> <p>b. Sailplane pilots holding a pilot qualification that is identified as sub-ICAO by the national authorities should be automatically recognised as qualified for the LPL(S).</p> <p>c. The right to exercise the privileges of an SPL or LAPL(S) is dependent on the medical held, it`s not rocket science!</p>	
response	Noted	

**C. Draft Decision Part-MED - Subpart B: Requirements for Medical Certificates - Section 1: Specific requirements for class 1 and class 2 medical certificates - Chapter A: AMC for Class 1 medical certificates - AMC A to MED.B.085: Oncology**

p. 48

comment	147	comment by: <i>Civil Aviation Authority - The Netherlands</i>
	<p><b>AMC A to MED.B.085. (Blz. 48 van 66)</b></p> <p>In dit voorschrift wordt aangegeven wanneer deze personen medisch geschikt zijn. Echter in het voorschrift wordt niet aangegeven dat de kandidaten onder voorwaarden geschikt worden bevonden. De CAA-The Netherlands geeft aan dat het noodzakelijk kan zijn om een medische verklaring af te geven onder voorwaarden. De CAA-The Netherlands verzoekt aan EASA om veiligheidsredenen dat (in lijn met blz. 49 van 66, 5.2) voorwaarden door de autoriteit kunnen worden gesteld.</p>	
response	<p><i>Partially accepted</i></p> <p>The first sentence under 1 will be amended to include referral to the licensing authority.</p>	
comment	148	comment by: <i>Civil Aviation Authority - The Netherlands</i>
response	<p>Noted</p> <p>There is no comment.</p>	

**C. Draft Decision Part-MED - Subpart B: Requirements for Medical Certificates - Section 1: Specific requirements for class 1 and class 2 medical certificates - Chapter B: AMC for Class 2 medical certificates**

p. 49

comment	560	comment by: <i>British Microlight Aircraft Association</i>
	Medical requirements shall be equal to and not greater than those published as ICAO minimum requirements.	
response	<i>Noted</i>	
comment	1818	comment by: <i>CAA Belgium</i>
	<p>Relevant text:  Comment: General considerations : The licensing authorities will have no control on the application of the requirements by the AMEs and the specialists (most of the latter are unaware of these requirements). The result of this will be a great disparity between the decisions and a worsening in the safety.  Proposal: Submission of the cases to the licensing authority as for class 1.</p>	
response	<i>Not accepted</i>	
	<p>Ther control of the AMEs is ensured by the provision of Authority requirements proposed in NPA 2008-22b Subpart MED Section 2 'Aeromedical examiners'.</p> <p>Records of all aeromedical examinations will be submitted to the licensing authority, decision on fitness in borderline cases will be taken by the AME in consultation with the licensing authority.</p>	
comment	1844	comment by: <i>European CMO Forum</i>
	<p><b>Paragraph: AMC B to MED. B.005 (b) (6)</b>  <b>Page No: 49</b></p> <p><b>Comment:</b>  Anticoagulation should be permitted in private pilots after valvular surgery in certain circumstances.</p> <p><b>Justification:</b>  Mechanical valves are often the first choice in clinical practice and it is important that pilots are able to receive the type of valve that is recommended for them. Anticoagulation is now considered to be safe for use in pilots, with special conditions.</p> <p><b>Proposed Text: (if applicable)</b>  Delete proposed paragraph <b>AMC B to MED. B.005 (b) (6)</b> and replace with:  <b>AMC B to MED. B.005 (b) (6):</b> Applicants who have undergone cardiac valve replacement or repair should be assessed as fit if post-operative cardiac function and investigations are satisfactory and no anticoagulation is needed. Applicants needing continuous anticoagulation should be assessed as fit with OSL or OPL restriction if postoperative cardiac function and investigations are satisfactory and the anticoagulation is demonstrated to be stable (within the last 6 months at least 5 INR values, of which 4 are within the INR target range).</p>	
response	<i>Partially accepted</i>	
	The text of the proposed rules will be changed accepting anticoagulation under special circumstances.	

<p><b>C. Draft Decision Part-MED - Subpart B: Requirements for Medical Certificates - Section 1: Specific requirements for class 1 and class 2 medical certificates - Chapter B: AMC for Class 2 medical certificates - AMC B to MED.B.005: Cardiovascular System</b></p>	p. 49-51
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comment	149	comment by: <i>Civil Aviation Authority - The Netherlands</i>
	<p><b>AMC B to MED.B.005, onder 5.2. (Blz. 49 van 66)</b></p> <p>De CAA-The Netherlands merkt op dat niet duidelijk is wat met 'minor' wordt bedoeld. De CAA-The Netherlands verzoekt aan EASA om 'minor' met cijfers te verduidelijken.</p> <p><b>AMC B to MED.B.005, onder 8. (Blz. 49 van 66)</b></p> <p>De CAA-The Netherlands acht het om veiligheidsredenen noodzakelijk dat de autoriteit kan eisen dat medische geschiktheid wordt bevonden onder de voorwaarde dat de kandidaat met een 'safety-pilot' vliegt.</p>	
response	<p><i>Noted</i></p> <p>'Minor' means 'functionally unimportant'. Further explanation could be provided with the future Guidance Material.</p>	
comment	493	comment by: <i>UK CAA</i>
	<p><b>AMC B to MED.B.005 (b) 2</b> Page: 49</p> <p><b>Comment:</b> Exercise electrocardiograms should be reported by a cardiologist.</p> <p>Separate the reporting of electrocardiograms and exercise electrocardiograms into two requirements.</p> <p><b>Justification:</b> AMEs (unless accredited in cardiology) do not have the expertise to report exercise electrocardiograms.</p> <p>The reporting of resting and exercise electrocardiograms requires different competencies.</p> <p><b>Proposed Text:</b> Delete: 'and exercise' so (b) 2 (i) reads: 'Reporting of resting electrocardiograms should be by the AME or other specialist.'</p> <p>Insert as (b) 2 (ii) <b>Reporting of exercise electrocardiograms should be by a cardiologist.'</b></p>	
response	<p><i>Noted</i></p> <p>'other spcialist' will be replaced by 'accredited specialist'. See also response to comment No 467 in segment AMC A to MED.B.005.</p>	

comment	630	comment by: <i>Lufthansa German Airlines</i>
<p>Author: Dr. Christine Huber, Cardiologist, AMC Frankfurt  Section: 2 Specific requirements for class 1 and class 2 medical certificates  Chapter A AMC for Class 1 medical certificate  Draft Version 3.0  <b>Page: 51</b></p> <p>Relevant Text:  <b>(e) RHYTHM and CONDUCTION DISTURBANCES</b>  1. Any significant rhythm or conduction disturbance should require evaluation by a cardiologist and appropriate follow-up in the case of a fit assessment. 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, nor evidence of myocardial ischaemia should be demonstrated. Withdrawal of cardioactive medication prior to the test should be considered.  (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) Repeated 24-hour ECG recording;  (v) Electrophysiological study;  (vi) Myocardial perfusion scanning;  (vii) Cardiac MRI;  (viii) Coronary angiogram.  2. Applicants with frequent or complex forms of supra ventricular or ventricular ectopic complexes require full cardiological evaluation.</p> <p><b>Comment:</b> Why do they mention all these examinations once more instead of simply relating to a cardiological evaluation?</p> <p><b>Proposal: (e) RHYTHM and CONDUCTION DISTURBANCES</b>  1. Any significant rhythm or conduction disturbance should require evaluation by a cardiologist and appropriate follow-up in the case of a fit assessment.  2. Applicants with frequent or complex forms of supra ventricular or ventricular ectopic complexes require full cardiological evaluation.</p>		
response	<i>Noted</i>	
<p>We do not find the text that is quoted in the comment under 'relevant text'. Draft Version 3.0 is probably different from the NPA that was published.</p>		
comment	632	comment by: <i>Lufthansa German Airlines</i>
<p>Author: Dr. Christine Huber, Cardiologist, AMC Frankfurt  Section: 2 Specific requirements for class 1 and class 2 medical certificates  Chapter B AMC for Class 2 medical certificate  Draft Version 3.0  <b>Page: 49</b></p> <p>Relevant Text: 2. Cardiovascular Assessment  Reporting of resting and exercise electrocardiograms should be by the AME or other specialist.</p>		

6. Valvular surgery  
 Applicants who have undergone cardiac valve replacement or repair should be assessed as fit if post-operative cardiac function and investigations are satisfactory.

8. Recurrent Vasovagal Syncope  
 Applicants with a history of recurrent vasovagal syncope should be assessed as fit after a 6 month period without recurrence provided cardiological evaluation is satisfactory. Neurological review may be indicated.

**Comment:** 2. What is meant by other specialist here?  
 6. What about artificial valve replacement and anticoagulants?  
 8. A 6 month interval is not reasonable in recurrent syncope! A neurological review is indicated.

**Proposal:** 2. Cardiovascular Assessment  
 Reporting of resting and exercise electrocardiograms should be by the AME or cardiologist.

6. Valvular surgery  
 Applicants who have undergone cardiac valve replacement or repair should be assessed as fit if post-operative cardiac function and investigations are satisfactory and no anticoagulation is necessary.

8. Recurrent Vasovagal Syncope  
 Applicants with a history of recurrent vasovagal syncope are assessed unfit. Neurological review is indicated.

response

*Noted*

2. 'other specialist' has been replaced by 'accredited specialist'.

6. Anticoagulation will be acceptable; the paragraph has been amended accordingly.

8. The wording provides the flexibility needed for the few cases where neurological review may not be indicated.

comment

633	comment by: <i>Lufthansa German Airlines</i>
Author: Dr. Christine Huber, Cardiologist, AMC Frankfurt Section: 2 Specific requirements for class 1 and class 2 medical certificates Chapter B AMC for Class 2 medical certificate Draft Version 3.0 <b>Page:</b> 50  Relevant Text: (d) CORONARY ARTERY DISEASE  <b>Comment:</b> Why do they mention all these examinations once more instead of simply relating to a cardiological evaluation?  <b>Proposal:</b> remove 3.2	

response

*Not accepted*

A 'cardiological evaluation' is not necessarily done by a cardiologist and does not necessarily include examinations. In the case of ischaemic events examinations should be done and this is why they are mentioned.

comment	634	comment by: <i>Lufthansa German Airlines</i>
<p>Author: Dr. Christine Huber, Cardiologist, AMC Frankfurt  Section: 2 Specific requirements for class 1 and class 2 medical certificates  Chapter B AMC for Class 2 medical certificate  Draft Version 3.0  <b>Page:</b> 51</p> <p>Relevant Text: (e) RHYTHM and CONDUCTION DISTURBANCES  1. Ablation  A fit assessment may be considered following successful catheter ablation subject to satisfactory cardiological review undertaken at a minimum of two months after the ablation.  7. Pacemaker</p> <p><b>Comment:</b> (e)1.) no matter what ablation - all at a minimum interval of 2 months?  7. see remark in comment 18</p> <p><b>Proposal:</b> (e)1.) discussion of this topic  7. see pacemaker proposal in comment 18</p>		
response	<i>Noted</i>	
<p>1. Yes.  7. There is no comment 18 in this segment.</p>		
comment	748	comment by: <i>Swiss Association of Aviation Medicine</i>
<p><b>Comment:</b> other specialist should be substituted by cardiologist.</p> <p><b>Proposal:</b>  <b>(b) GENERAL</b>  2. Cardiovascular Assessment  Reporting of resting and exercise electrocardiograms should be by the AME or cardiologist.</p>		
response	<i>Noted</i>	
Please see response to comment No 493.		
comment	751	comment by: <i>Swiss Association of Aviation Medicine</i>
<p><b>Comment:</b> the sentence 1. is missing here, it should be adapted to Class 1 - like in comment 14.  In electrophysiology it is called intermittent or <u>permanent</u>, not established!</p> <p><b>Proposal:</b>  <b>(e) RHYTHM AND CONDUCTION DISTURBANCES</b>  Any significant rhythm or conduction disturbance should require evaluation by a cardiologist and appropriate follow up in the case of a fit assessment.  2. <i>Supraventricular Arrhythmias</i>  2.1. Applicants with significant disturbance of supraventricular rhythm, including sinoatrial dysfunction, whether intermittent or permanent, may be assessed as fit if cardiological evaluation is satisfactory.</p>		

response	<i>Partially accepted</i>	
	<p>There is no comment 14 in this segment.</p> <p>The word 'estalished' is used in JAR-FCL 3; it did not cause any problems and will be retained for the time being.</p> <p>The sentence proposed as an introduction to to section (e) is partially accepted.</p>	
comment	752	comment by: <i>Swiss Association of Aviation Medecine</i>
	<p><b>Comment:</b> see comment 17; new pacemaker devices have a lot of automatic mode changes and some will have an automatic change between bipolar and unipolar sensing and pacing, so it is useless to insist on bipolar electrodes, if they are programmed to unipolar mode in the end.</p> <p>There seems to be a misunderstanding of antitachycardia pacemakers. Most pacemaker decives have some antitachycardia programme settings. Such a device is not the same as an AICD. The sentence 9.2. should be deleted, it is nonsense.</p> <p><b>Proposal:</b>  <i>7. Pacemaker</i>  7.1. Applicants with a subendocardial pacemaker may be assessed as fit no sooner than three months after insertion provided:  (i) there is no other disqualifying condition;  (ii) a bipolar lead system programmed in bipolar mode without automatic mode change of the device is used;  (iii) the applicant is not pacemaker dependent;  (iv) the applicant has regular follow up including a pacemaker check;  7.2. deleted</p>	
response	<i>Partially accepted</i>	
	<p>There is no comment 17 in this segment.</p> <p>The proposed addition under (ii) is accepted (second part of the sentence, starting with 'programmed in a bipolar mode ...').</p> <p>7.2 is deleted because anti tachycardia pacemaker is covered in the IRs.</p>	
comment	1012	comment by: <i>European Society of Space and Aviation Medicine (ESAM)</i>
	<p><b>Author: European Society of Space and Aviation Medicine (ESAM) - Cardiology Group -</b></p> <p><b>Chapter B AMC for class 2 medical certificates</b>  <b>AMC B to MED.B.005</b>  <b>Cardiovasuclar System - class 2 medical certificates</b></p> <p><b>Page: 49</b></p> <p><b>Relevant Text:</b>  <b>(b) GENERAL</b>  2. Cardiovascular Assessment  Reporting of resting and exercise electrocardiograms should be by the AME or</p>	

other specialist.

**Comment:** other specialist should be substituted by cardiologist.

**Proposal:**

**(b) GENERAL**

2. Cardiovascular Assessment

Reporting of resting and exercise electrocardiograms should be by the AME or cardiologist.

response *Noted*

Please see response to comment No 149.

comment

1013

comment by: *European Society of Space and Aviation Medicine (ESAM)*

**Author: European Society of Space and Aviation Medicine (ESAM) - Cardiology Group -**

**Chapter B AMC for class 2 medical certificates**

**AMC B to MED.B.005**

**Cardiovascular System - class 2 medical certificates**

**Page: 49**

**Relevant Text:**

5. *Cardiac Valvular Abnormalities*

5.2. Applicants with minor cardiac valvular abnormalities may be assessed as fit.

6. *Valvular surgery*

Applicants who have undergone cardiac valve replacement or repair should be assessed as fit if postoperative cardiac function and investigations are satisfactory.

8. *Recurrent Vasovagal Syncope*

Applicants with a history of recurrent vasovagal syncope should be assessed as fit after a 6 month period without recurrence provided cardiological evaluation is satisfactory. Neurological review may be indicated.

**Comment:** Better graduation than minor is insignificant in 5.2. In cases of valvular surgery it is very relevant to mention the anticoagulation probability. See also comment 11 for the issue 8. syncope.

**Proposal:**

5.2. Applicants with insignificant cardiac valvular abnormalities may be assessed as fit.

6. *Valvular surgery*

Applicants who have undergone cardiac valve replacement or repair should be assessed as fit if postoperative cardiac function and investigations are satisfactory and no anticoagulants are necessary.

8. *Syncope*

Applicants with a history of syncope should be assessed as fit provided

response	<p>cardiological evaluation is satisfactory. Neurological review may be indicated.</p> <p><i>Not accepted</i></p>				
	<p>5.2 'minor' is used for class 1 as well — should therefore be acceptable for class 2.</p> <p>6. Anticoagulation is accepted for class 1 — therefore also for class 2. A paragraph has been added to clarify this situation.</p> <p>8. The text is the same as for class 1, the heading has been changed ('Recurrent Vasovagal' deleted).</p>				
comment	<table border="1"> <tr> <td data-bbox="343 582 502 705">1014</td> <td data-bbox="502 582 1455 705">comment by: <i>European Society of Space and Aviation Medicine (ESAM)</i></td> </tr> <tr> <td colspan="2" data-bbox="343 705 1455 2018"> <p><b>Author: European Society of Space and Aviation Medicine (ESAM) - Cardiology Group -</b></p> <p><b>Chapter B AMC for class 2 medical certificates</b>  <b>AMC B to MED.B.005</b>  <b>Cardiovasuclar System - class 2 medical certificates</b></p> <p><b>Page: 50</b></p> <p><b>Relevant Text:</b>  <b>(d) CORONARY ARTERY DISEASE</b></p> <p>1. Chest pain of uncertain cause requires full investigation.</p> <p>2. In suspected asymptomatic coronary artery disease cardiological evaluation should show no evidence of myocardial ischemia or significant coronary artery stenosis.</p> <p>3. After an ischemic cardiac event, or revascularisation, applicants without symptoms should have reduced any vascular risk factors to an appropriate level. Medication, when used to control cardiac symptoms, is not acceptable. All applicants should be on acceptable secondary prevention treatment.</p> <p>3.1. A coronary angiogram obtained around the time of, or during, the ischemic cardiac event and a complete, detailed clinical report of the ischemic event, the angiogram and any operative procedures should be available.</p> <p>(i) 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 leading to an infarct. More than two stenoses between 30% and 50% within the vascular tree should not be acceptable.</p> <p>3.2. At least 6 months from the ischemic cardiac event, including revascularisation, the following investigations should be completed (equivalent tests may be substituted):</p> <p>(iii) in cases of angioplasty/stenting, a myocardial perfusion scan or stress echocardiogram which shall 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 will also be required;</p> <p>3.4. After coronary artery vein 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 a safety pilot limitation.</p> <p>3.6. Successful completion of the six month or subsequent review will allow a fit assessment. Applicants may fly with a safety pilot limitation having successfully completed only an exercise ECG.</p> </td> </tr> </table>	1014	comment by: <i>European Society of Space and Aviation Medicine (ESAM)</i>	<p><b>Author: European Society of Space and Aviation Medicine (ESAM) - Cardiology Group -</b></p> <p><b>Chapter B AMC for class 2 medical certificates</b>  <b>AMC B to MED.B.005</b>  <b>Cardiovasuclar System - class 2 medical certificates</b></p> <p><b>Page: 50</b></p> <p><b>Relevant Text:</b>  <b>(d) CORONARY ARTERY DISEASE</b></p> <p>1. Chest pain of uncertain cause requires full investigation.</p> <p>2. In suspected asymptomatic coronary artery disease cardiological evaluation should show no evidence of myocardial ischemia or significant coronary artery stenosis.</p> <p>3. After an ischemic cardiac event, or revascularisation, applicants without symptoms should have reduced any vascular risk factors to an appropriate level. 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1014	comment by: <i>European Society of Space and Aviation Medicine (ESAM)</i>				
<p><b>Author: European Society of Space and Aviation Medicine (ESAM) - Cardiology Group -</b></p> <p><b>Chapter B AMC for class 2 medical certificates</b>  <b>AMC B to MED.B.005</b>  <b>Cardiovasuclar System - class 2 medical certificates</b></p> <p><b>Page: 50</b></p> <p><b>Relevant Text:</b>  <b>(d) CORONARY ARTERY DISEASE</b></p> <p>1. Chest pain of uncertain cause requires full investigation.</p> <p>2. In suspected asymptomatic coronary artery disease cardiological evaluation should show no evidence of myocardial ischemia or significant coronary artery stenosis.</p> <p>3. After an ischemic cardiac event, or revascularisation, applicants without symptoms should have reduced any vascular risk factors to an appropriate level. Medication, when used to control cardiac symptoms, is not acceptable. All applicants should be on acceptable secondary prevention treatment.</p> <p>3.1. A coronary angiogram obtained around the time of, or during, the ischemic cardiac event and a complete, detailed clinical report of the ischemic event, the angiogram and any operative procedures should be available.</p> <p>(i) 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 leading to an infarct. More than two stenoses between 30% and 50% within the vascular tree should not be acceptable.</p> <p>3.2. At least 6 months from the ischemic cardiac event, including revascularisation, the following investigations should be completed (equivalent tests may be substituted):</p> <p>(iii) in cases of angioplasty/stenting, a myocardial perfusion scan or stress echocardiogram which shall 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 will also be required;</p> <p>3.4. After coronary artery vein 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 a safety pilot limitation.</p> <p>3.6. Successful completion of the six month or subsequent review will allow a fit assessment. Applicants may fly with a safety pilot limitation having successfully completed only an exercise ECG.</p>					

4. Angina pectoris is disqualifying, whether or not it is abolished by medication.

**Comment:** "ischemia" not ischaemia! 1. cardiological investigation is more precise than "full" investigation. Second sentence has to be adapted to class 1 - see comment 13. We object to the sentence "Medication, when used to control cardiac symptoms, is not acceptable." as  $\beta$ -blockers are used in secondary prevention and of course affect cardiac symptoms as well. So this sentence should be removed.

For changes in 3.1. (i) and 3.2. (iii) see comment 13.

3.4 the "vein" should be deleted form the "coronary artery vein bypass grafting", as there are not only vein grafts available.

4. This sentence should be deleted, as it is already mentioned in sentence 1.

**Proposal:**

**(d) CORONARY ARTERY DISEASE**

1. Chest pain of uncertain cause requires cardiological investigation.

2. In suspected coronary artery disease, a cardiological evaluation is required.

3. After an ischemic cardiac event, or revascularisation, applicants without symptoms should have reduced any vascular risk factors to an appropriate level. All applicants should be on acceptable secondary prevention treatment.

3.1. (i) 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 leading to an infarct. More than two stenoses between 30% and 50% within major coronary vessels should not be acceptable.

3.2. (iii) in cases of angioplasty/stenting, a myocardial perfusion scan or equivalent test, which shall show no evidence of reversible myocardial ischemia. If there is any doubt about myocardial perfusion in other cases (infarction or bypass grafting) a perfusion scan or equivalent test will also be required;

3.4. 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 a safety pilot limitation.

3.6. Successful completion of the six month or subsequent review will allow a fit assessment. Applicants for revalidation or renewal may fly with a safety pilot limitation having successfully completed only an exercise ECG.

4. deleted

response

*Not accepted*

'Ischemia': For the time being the ICD 10 spelling is used: 'I20-I25 Ischaemic heart diseases'.

'Full' is used to let the cardiologist decide what kind of evaluation has to be done in an individual case, and to do other investigations in cases where chest pain is of another origin (e.g. oesophagus).

Comment on medication is noted. However, for example angina pectoris (cardiac symptom) under control by medication is not acceptable.

'vein' is deleted.

4. is not deleted — the context differs from number 1.

comment

1015

comment by: *European Society of Space and Aviation Medicine*

	(ESAM)
	<p><b>Author: European Society of Space and Aviation Medicine (ESAM) - Cardiology Group -</b></p> <p><b>Chapter B AMC for class 2 medical certificates AMC B to MED.B.005 Cardiovasuclar System - class 2 medical certificates</b></p> <p><b>Page: 51</b></p> <p><b>Relevant Text:</b> <b>(e) RHYTHM AND CONDUCTION DISTURBANCES</b> <i>2. Supraventricular Arrhythmias</i> 2.1. Applicants with significant disturbance of supraventricular rhythm, including sinoatrial dysfunction, whether intermittent or established, may be assessed as fit if cardiological evaluation is satisfactory.</p> <p><b>Comment:</b> the sentence 1. is missing here, it should be adapted to Class 1 - like in comment 14. In electrophysiology it is called intermittennd or <u>permanent</u>, not established!</p> <p><b>Proposal:</b> <b>(e) RHYTHM AND CONDUCTION DISTURBANCES</b> Any significant rhythm or conduction disturbance should require evaluation by a cardiologist and appropriate follow up in the case of a fit assessment. <i>2. Supraventricular Arrhythmias</i> 2.1. Applicants with significant disturbance of supraventricular rhythm, including sinoatrial dysfunction, whether intermittent or permanent, may be assessed as fit if cardiological evaluation is satisfactory.</p>
response	<p><i>Noted</i></p> <p>There is no comment 14 in this segment. 'Established', as in JAR-FCL 3, is kept for the time being.</p>
comment	<p>1016</p> <p style="text-align: right;">comment by: <i>European Society of Space and Aviation Medicine (ESAM)</i></p> <p><b>Author: European Society of Space and Aviation Medicine (ESAM) - Cardiology Group -</b></p> <p><b>Chapter B AMC for class 2 medical certificates AMC B to MED.B.005 Cardiovasuclar System - class 2 medical certificates</b></p> <p><b>Page:51</b></p> <p><b>Relevant Text:</b> <b>(e) RHYTHM AND CONDUCTION DISTURBANCES</b> <i>7. Pacemaker</i> 7.1. Applicants with a subendocardial pacemaker may be assessed as fit no sooner than three months after insertion provided: (i) there is no other disqualifying condition; (ii) a bipolar lead system is used; (iii) the applicant is not pacemaker dependent;</p>

(iv) the applicant has regular follow up including a pacemaker check;  
 7.2. Applicants with an antitachycardia pacemaker should be assessed as unfit.

**Comment:** see comment 17; new pacemaker devices have a lot of automatic mode changes and some will have an automatic change between bipolar and unipolar sensing and pacing, so it is useless to insist on bipolar electrodes, if they are programmed to unipolar mode in the end.  
 There seems to be a misunderstanding of antitachycardia pacemakers. Most pacemaker decives have some antitachycardia programme settings. Such a device is not the same as an AICD. The sentence 9.2. should be deleted, it is nonsense.

**Proposal:**

*7. Pacemaker*

7.1. Applicants with a subendocardial pacemaker may be assessed as fit no sooner than three months after insertion provided:

- (i) there is no other disqualifying condition;
  - (ii) a bipolar lead system programmed in bipolar mode without automatic mode change of the device is used;
  - (iii) the applicant is not pacemaker dependent;
  - (iv) the applicant has regular follow up including a pacemaker check;
- 7.2. deleted

response

*Noted*

Please see response to comment No 752.

comment

1035

comment by: *Ilse Janicke Heart Center Duisburg*

Author: Janicke Ilse, Senior MD, AME I and II, Cardiologist and Angiologist at Heart Center Duisburg

Section: **Chapter B AMC for Class 2 medical certificates**

**AMC B to MED.B.005 Cardiovascular System - class 2 medical certificates**

**(b) General**

(9) Missing

**Page:** 49 (NPA 2008-17c)

**Relevant Text: Heart and heart/lung transplantation**

**Comment:** It is new that persons after heart or lung transplantation could get a medical. There is an interest study, which was decided from the FAA.

1) *McGiffin DC et al. The case of selective re-issuance of medical certificates to allow pilots who have received a heart transplant to resume flying. J Heart Lung Transplant 2005 Mar; 24(3): 259-69*

The study was undertaken to determine the risk of death and sudden cardiac death during 12 month after annual evaluation. 4978 patients survived for 1 year and forme the basis of the study. There is a group of heart transplant recipients which could be defined with a 12 month risk of death of any cause of 1 % and of sudden cardiac death of 0,3 %. This group has nor risk factors such as allograft vasculopathy, left ventricular systolic dysfunction, history of rejection, malignancy, infection and pretransplant IDDM.

2) *McGiffin DC et al: Risk of death or incapacitation aftre heart transplantation, with particular reference to pilots. J Heart Lung Transplant. 1998 May; 17(5): 497-504.*

In 3676 survived patients the rapid onset on death during the second posttransplantation year was 1,4% and the third year 1,6 %, presumed the coronary angiogram is normal and there was no rejection in the first year.

**Proposal: Heart and heart/lung transplantation**

(9) A fit assessment may be made not sooner than 1 year after transplantation for applicants who have had a satisfactory cardiological evaluation to include symptom limited exercise test, have a left ventricular ejection fraction of  $\geq 0,5$ , no rejection in the first year post transplant, a normal coronarangiogram and no significant arrhythmias. Intensified cardiological follow ups are necessary. An OSL may be applied. A combined heart and lung transplantation should be assessed as unfit.

response *Noted*

Thank you for this comment including very good reasoning supporting the possibility of a fit assessment for private pilots after heart transplantation. However, the change to the requirements as compared to JAR-FCL 3 is too significant for inclusion of the proposal in Part-MED at this stage of the NPA. The Agency will consult on this proposal in the next rulemaking task MED.001.

comment

1036

comment by: *Ilse Janicke Heart Center Duisburg*

Author: Janicke Ilse, Senior MD, AME I and II, Cardiologist and Angiologist at Heart Center Duisburg

Section: **Chapter B AMC for Class 2 medical certificates**

**AMC B to MED.B.005 Cardiovascular System - class 2 medical certificates**

(b) General

(10) Missing

**Page:** 49 (NPA 2008-17c)

Relevant Text:

Missing

**Comment:** The spontaneously bleeding rate within normal INR range 2,0 - 3,0 extends up to 2 % per year. Any underlying disorder needing anticoagulant therapy will probably enhance the risk of sudden incapacitation especially thromboembolic disorders like pulmonary embolism with pulmonary arterial hypertension. All together this is likely to jeopardize flight safety. This is very important in class 2 medical holders because pilots are flying solo with guests or as instructeur and this is not a redundant system!

**Proposal:**

**10. Thromboembolic disorders and systemic anticoagulant therapy**

Arterial or venous thrombosis or pulmonary embolism is disqualifying until anticoagulation has been discontinued. Pulmonary embolus should require full evaluation. Systemic anticoagulant therapy is disqualifying. Following cessation of anticoagulant therapy, for any indication, applicants should require review by the licensing authority.

response *Partially accepted*

A subparagraph on Thromboembolic Disorders has been added.

comment

1037

comment by: *Ilse Janicke Heart Center Duisburg*

Author: Janicke Ilse, Senior MD, AME I and II, Cardiologist and Angiologist at Heart Center Duisburg  
 Section: **Chapter B AMC for Class 2 medical certificates**  
**AMC B to MED.B.005 Cardiovascular System - class 2 medical certificates**  
**(d) Coronary artery disease**  
 Page: 50 (NPA 2008-17c)

**Relevant Text:**

(3) After an ischaemic cardiac event, or revascularisation, applicants without symptoms should have reduced any vascular risk factors to an appropriate level. Medication, when used to control cardiac symptoms, is not acceptable...  
 3.1 A coronary angiogram obtained around the time of, or during, the ischaemic cardiac event....should be available.  
 (i) ...More then two stenosis between 30% and 50% within the vascular tree should not be acceptable.

**Comment:**

Ad (3) Due to better prognostic value in CAD patients β-blocker is the gold standard to prevent sudden cardiac events. The most β-blockers especially the hydrophile substances are compatible with flying duties.  
 Ad 3.1(i) more then two stenosis in the vascular tree restrict the decision for recertification of the pilot. Prognostic relevant are stenosis in the major vessels.

**Proposal:**

(3) After an ischaemic cardiac event, or revascularisation, applicants without symptoms should have reduced any vascular risk factors to an appropriate level. Medication, when used to control angina pectoris, is not acceptable...  
 3.1 (i) More then two stenosis between 30% and 50% within the major coronary vessels should not be acceptable.

response

*Noted*

Medication 'when used to control angina pectoris': accepted.

Changes proposed for the medical assessment are not accepted, but have been noted for rulemaking task MED.001.

comment

1038

comment by: *Ilse Janicke Heart Center Duisburg*

Author: Janicke Ilse, Senior MD, AME I and II, Cardiologist and Angiologist at Heart Center Duisburg  
 Section: **Chapter B AMC for Class 2 medical certificates**  
**AMC B to MED.B.005 Cardiovascular System - class 2 medical certificates**  
**(e) RHYTHM AND CONDUCTION DISTURBANCES**  
 Page: 51 (NPA 2008-17c)

**Relevant Text:**

7. Pacemaker  
 7.3 missing

**Comment:** Patients with an automatic implantable cardioverter defibrillator system have this therapy due to progressive heart disease with low ejection fraction or survived sudden cardiac death or malignant rhythm disorders.

		Mostly these persons is forbidden to drive a car. As pilot they are dangerous for peoples.  <b>Proposal:</b> supply 7.3 Applicants with AICD should be asessed as unfit.
response	1246	<i>Noted</i>
		Unfitness after implantation of AICD is in the Implementing Rules (MED.B.005 (e)(5).
comment	1246	comment by: <i>Swedish Transport Agency, Civil Aviation Department (Transportstyrelsen, Luftfartsavdelningen)</i>
		<b>Comment:</b> In (b) 2. the wording "Other specialist" needs to be defined, otherwise any specialist may be used, e.g. an ophthalmologist, psychiatrist, or orthopaedic surgeon, which is not the intention (same comment as for AMC A to MED.B.005).  <b>Proposal:</b> Amend AMC B to MED.B.005: 2. <i>Cardiovascular Assessment</i> 2.1. Reporting of resting and exercise electrocardiograms should be made by the AME or other specialist with relevant qualifications for assessing ECGs.
response		<i>Noted</i>
		Please see response to comment No 493.
comment	1247	comment by: <i>Swedish Transport Agency, Civil Aviation Department (Transportstyrelsen, Luftfartsavdelningen)</i>
		<b>Comment:</b> For class 1, a reassessment of the effects of the medication is required before returning to flying duties (AMC A to MED.B.005), which is most appropriate for all classes of medical certificates. This should be added also for class 2.  <b>Proposal:</b> Amend AMC to MED.B.005: 5. Following initiation of medication for the control of blood pressure, applicants should be reassessed to verify that the treatment is compatible with the safe exercise of the privileges of the licence held.
response		<i>Accepted</i>
comment	1693	comment by: <i>UK CAA MEDICAL ADVISORY PANEL</i>
		<b>Paragraph</b> AMC B to MED.B.005 CARDIOVASCULAR SYSTEM class 2 medical certificates (a) <b>Page</b> 49  <b>Comment</b> Bruce stage IV insert time <b>Justification</b> clarification

	<b>Proposed Text</b> .....(9 – 12 minutes),
response	<i>Not accepted</i>
	Determining that the exercise ECG should be completed to a minimum of Bruce stage IV or equivalent should give the examining specialist sufficient information on the way to do the examination.

comment	1694	comment by: UK CAA MEDICAL ADVISORY PANEL
	<b>Paragraph</b> AMC B to MED.B.005 (d) 3 <b>Page</b> 50	
	<b>Comment</b> Delete <i>cardiac</i>	
	<b>Justification</b> slang	
	<b>Proposed Text</b> Insert ..... <i>myocardial</i>	
response	<i>Accepted</i>	

comment	1819	comment by: CAA Belgium
	Relevant text: AMC B to MED.B.005 (b) 2. Reporting of resting and exercise electrocardiogram should be by the AME or other specialist. Comment: The specialist should be a cardiologist who is accredited to perform exercise tests. It should be useful that the ECGs be sent to the Licensing Authority, appended to the copy of the report. ( as in FAA requirements)	
	Proposal: Reporting of resting electrocardiograms should be by a cardiologist or delegated to the AME and exercise electrocardiogram should be performed by a cardiologist. The electrocardiograms should be submitted to the Licensing Authority, appended to the copy of the report.	
response	<i>Noted</i>	
	Please see response to comment No 493.	

comment	1820	comment by: CAA Belgium
	Relevant Text: AMC B to MED.B.005 (b) 4. Applicant with an aneurysm of the thoracic or abdominal aorta may be assessed as fit, subject to satisfactory cardiological evaluation and regular follow up. Applicants may be assessed as fit after surgery for a thoracic or abdominal aortic aneurysm subject to satisfactory cardiological evaluation Comment: In young patients, thoracic aortic aneurysm often result from a congenital abnormality of the aortic wall, as cystic medial degeneration ; it is associated with Marfan syndrome, bicuspid aortic valve or familial thoracic aortic aneurysm syndrome The complications are rupture and dissection whose rate reaches 2 % for a < 5 cm diameter and adverse events up to 14 %	

	(rupture + dissection + death) for $\geq 6$ cm Proposal: Same requirements as for class 1	
response	<i>Noted</i>	
	No maximum acceptable diameter of an aneurysm is provided in class 1 or class 2. The assessment will depend on possible complications as the ones mentioned in the comment and the condition of the individual pilot.	
comment	1821	comment by: CAA Belgium
	Relevant Text: AMC B to MED.B.005 (b) 5. Cardiac Valvular Abnormalities Comment: concerning aortic and mitral valve disease, the same comments as for Class 1 medical certificates, would be useful for class 2 as well. Proposal: 5.2.1. Aortic valve Disease ... 5.2.2. Mitral valve disease ...	
response	<i>Noted</i>	
	The text in the AMC for class 2 has been shortened to be more in line with ICAO Annex 1 where this would be covered under 6.4.2.5.1.	
comment	1822	comment by: CAA Belgium
	Relevant Text: AMC B to MED.B.005 (b) 6. ... and investigations are satisfactory. Comment: Anticoagulant therapy Proposal: ... and investigations are satisfactory, provided that no anticoagulant therapy is required	
response	<i>Not accepted</i>	
	One of the few changes in Part-MED against JAR-FCL 3 is that anticoagulation is now accepted under certain conditions.	
comment	1823	comment by: CAA Belgium
	Relevant Text: AMC B to MED.B.005 (b) 7.2. Applicants with a congenital abnormality of the heart, including those who have undergone surgical correction, may be assessed as fit subject to satisfactory assessment. Comment Arrhythmias is a late risk of congenital heart disease, even after correction. The evaluation must be careful. Proposal: Applicants with congenital heart disease, including those who have undergone surgical correction, should be assessed as unfit. Applicants with minor abnormalities may be assessed as fit following cardiological evaluation.	
response	<i>Noted</i>	
	We agree that cardiological assessment and aeromedical evaluation must be made with care for applicants with congenital abnormalities of the heart. In spite of this the amendment proposed in the comment, it is not accepted because the intention was to have class 2 provisions at the level of ICAO Annex 1. Many paragraphs therefore provide maximum flexibility. However, a	

sentence on follow-up has been added to 7.2 (renumbered to 8.2).

comment 1824 comment by: CAA Belgium

Relevant Text: AMC B to MED.B.005 (d) 3.2. (ii)

...satisfactory left ventricular ejection fraction.

Comment: poor left ventricular function is a strong predictor of cardiac events, arrhythmias and sudden death

Proposal: ...satisfactory left ventricular ejection fraction, not less than 50 %.

response Accepted

This was in the Appendix of JAR-FCL 3, valid for class 1 and class 2.

In Part MED, an echocardiogram is also requested after an ischaemic myocardial event and no additional test to determine the left ventricular ejection fraction would have to be introduced. It seems sensible to assess a left ventricular ejection fraction of less than 50% as not satisfactory without mentioning it. Nevertheless, in this case the JAR-FCL 3 limit has been taken back.

comment 1825 comment by: CAA Belgium

Relevant Text: AMC B to MED.B.005 (d) 3.2. (iii)

In case of angioplasty/stenting, a myocardial perfusion scan or stress echocardiogram which should show no evidence of reversible myocardial ischemia. If there is any doubt about myocardial perfusion in other cases (infarction or by-pass grafting) a perfusion scan should also be required;

Comment: - The myocardial function must be evaluated

- this is out of place in this paragraph. If coronary disease is suspected, the examiner should refer to the chapter relating to this subject.

Proposal: a myocardial perfusion scan or stress echocardiogram should show no evidence of reversible myocardial ischemia.

response Not accepted

comment 1826 comment by: CAA Belgium

Relevant Text: AMC B to MED.B.005 (e) 1.

Ablation

Comment: in case of the persistence of a risk of arrhythmia a safety pilot limitation is indicated.

Proposal: For those in whom the long term outcome cannot be assured by invasive or non-invasive testing, a safety pilot limitation may be required.

response Not accepted

MED.A.045 states that applicants who do not fully meet the requirements should be assessed to establish whether they can perform their duties safely when complying with one or more limitations. Therefore, the OML or OSL (or any other limitation) should always be considered, depending on the condition of the individual pilot. Therefore, AMC 2 to Subpart 2 hardly gives any specific indication on limitations except for compelling reasons (e.g. anticoagulation).

comment 1827 comment by: CAA Belgium

response	<p>Relevant Text: AMC B to MED.B.005 (e) 6.  Applicant with ventricular pre-excitation...  Comment: only asymptomatic applicants may be concerned  Proposal: asymptomatic applicants with ventricular pre-excitation...</p> <p><i>Accepted</i></p>	
comment	1849	comment by: UK CAA MEDICAL ADVISORY PANEL
	<p><b>Paragraph</b> AMC B to MED.B.005 (d) 3.2. (iii)  <b>Page</b> 50</p> <p><b>Comment</b>  Poor syntax</p> <p><b>Justification</b></p> <p><b>Proposed Text</b>  <i>.....in cases of angioplasty/stenting, a myocardial perfusion scan or stress echocardiogram shall show no evidence of reversible myocardial ischaemia. If there is doubt about revascularisation in myocardial infarction or bypass grafting, a perfusion scan will also be required;</i></p>	
response	<p><i>Accepted</i></p>	
comment	2165	comment by: DGAC FRANCE
	<p>AMC B to MED.B.005, (b) GENERAL, <b>paragraph 6</b></p> <p>comment :</p> <p>Anticoagulation should be permitted in private pilots after valvular surgery in certain circumstances.</p> <p>Mechanical valves are often the first choice in clinical practice and it is important that pilots are able to receive the type of valve that is recommended for them. Anticoagulation is now considered to be safe for use in pilots, with special conditions.</p> <p>Modification :</p> <p>Delete proposed paragraph 6. "Valvular surgery" and replace it by the following proposition :</p> <p>AMC B to MED. B.005  (b) General</p> <p><b><u>(6) Applicants who have undergone cardiac valve replacement or repair should be assessed as fit if post-operative cardiac function and investigations are satisfactory and no anticoagulation is needed. Applicants needing continuous anticoagulation should be assessed as fit by the licensing authority with OSL or OPL restriction if postoperative cardiac function and investigations are satisfactory and the anticoagulation is demonstrated to be stable (within the last 6 months at least 5 INR values, of which 4 are within the INR target range).</u></b></p>	

response	<i>Partially accepted</i>	
	The addition concerning anticoagulation after valvular surgery is accepted. MED.B.005 (b)(3) specifies that a class 2 applicant should be assessed in consultation with the licensing authority after cardiac valvular surgery. The referral to the licensing authority was therefore not included in the text as posposed in the comment.	
comment	2416	comment by: <i>Irish Aviation Authority</i>
	<p>(b)(6) Anticoagulation should be permitted in private pilots after valvular surgery under certain circumstances.</p> <p>Justification: Mechanical valves are often the best choice in clinical practice and it is important that pilots are able to receive the type of valve that is best for them. Anticoagulation is now considered to be safe for use in pilots, underspecial conditions.</p> <p>Proposed text: <del>AMC B to MED. B.005 (b) (6)</del> and replace with: <b>AMC B to MED. B.005 (b) (6)</b>: Applicants who have undergone cardiac valve replacement or repair should be assessed fit if post-operative cardiac function and investigations are satisfactory and no anticoagulation is needed. Applicants needing continuous anticoagulation should be assessed as fit with OSL or OPL restriction if postoperative cardiac function and investigations are favourable and the anticoagulation is demonstrated to have been stable (within the last 6 months at least 5 INR values, of which 4 are within the INR target range).</p>	
response	<i>Noted</i>	
	Please see response to comment No 2165.	
comment	2527	comment by: <i>UK CAA MEDICAL ADVISORY PANEL</i>
	<p><b>Paragraph</b> AMC B to MED.B.005 (b) 1 <b>Page</b> 49</p> <p><b>Comment</b> CVS risk assessment insert age</p> <p><b>Justification</b> Age is the most potent cvs risk</p> <p><b>Proposed Text</b> .....including age</p>	
response	<i>Not accepted</i>	
	If age was added, gender should be added too.	
comment	2528	comment by: <i>UK CAA MEDICAL ADVISORY PANEL</i>
	<p><b>Paragraph</b> AMC B to MED.B.005 (b) 2 <b>Page</b> 49</p> <p><b>Comment</b></p>	

	Reporting should be by a specialist <b>Justification</b> An AME is untrained in cardiology <b>Proposed Text</b> <i>.....computer and if abnormal by an accredited specialist in cardiology.</i>	
response	<i>Noted</i>	
	Please see response to comment No 493.	
comment	2529	comment by: UK CAA MEDICAL ADVISORY PANEL
	<b>Paragraph</b> AMC B to MED.B.005 (b) 3 <b>Page</b> 49  <b>Comment</b> On is slang <b>Justification</b>  <b>Proposed Text</b> Insert <i>receiving</i> instead of on	
response	<i>Accepted</i>	
comment	2530	comment by: UK CAA MEDICAL ADVISORY PANEL
	<b>Paragraph</b> AMC B to MED.B.005 (b) 4.1 <b>Page</b> 49  <b>Comment</b> This is a dangerous statement without immediate qualification <b>Justification</b> 5.5cm diameter is the normal surgical intervention point <b>Proposed Text</b> Insert <i>provided the diameter of the vessel does not exceed 5.5 cm.</i>	
response	<i>Noted</i>	
	The text in 4.1 is: 4.1. Applicants with an aneurysm of the thoracic or abdominal aorta may be assessed as fit, subject to satisfactory cardiological evaluation and regular follow-up.	
comment	2531	comment by: UK CAA MEDICAL ADVISORY PANEL
	<b>Paragraph</b> AMC B to MED.B.005 (b) 4.2 <b>Page</b> 49  <b>Comment</b> The reason for cvs examination needs qualification <b>Justification</b> To guide the investigation <b>Proposed Text</b> <i>.....to exclude the presence of coronary artery disease.</i>	
response	<i>Accepted</i>	

comment	2532	comment by: UK CAA MEDICAL ADVISORY PANEL
	<p><b>Paragraph</b> AMC B to MED.B.005 (b) 5.1  <b>Page</b> 49</p> <p><b>Comment</b>  The review must be by a properly qualified person</p> <p><b>Justification</b>  Needs to be stated</p> <p><b>Proposed Text</b>  .....by an accredited cardiologist.</p>	
response	Partially accepted	
	The text has been amended to say that there should be cardiological review.	
comment	2533	comment by: UK CAA MEDICAL ADVISORY PANEL
	<p><b>Paragraph</b> AMC B to MED.B.005 (b) 5.2  <b>Page</b> 49</p> <p><b>Comment</b>  Mitral stenosis is unacceptable if the applicant is in atrial fibrillation</p> <p><b>Justification</b>  Needs to be stated</p> <p><b>Proposed Text</b>  .....provided the applicant is in sinus rhythm..</p>	
response	Noted	
	Mitral stenosis is not specifically mentioned in the AMC for class 2 medical requirements. The fit (or unfit) assessment will be done depending on the outcome of a cardiological review.	
comment	2534	comment by: UK CAA MEDICAL ADVISORY PANEL
	<p><b>Paragraph</b> AMC B to MED.B.005 (b) 6  <b>Page</b> 49</p> <p><b>Comment</b>  Mechanical valves are not currently accepted</p> <p><b>Justification</b>  Needs to be stated</p> <p><b>Proposed Text</b>  ....replacement with a tissue valve, or a repair should be assessed as fit if postoperative cardiac function and investigations are satisfactory. If warfarin is indicated clinically, the applicant shall be unfit.</p>	
response	Not accepted	
	Anticoagulation will be accepted under certain conditions (please see new paras (b) 6.2 and 7.).	
comment	2535	comment by: UK CAA MEDICAL ADVISORY PANEL

	<p><b>Paragraph</b> AMC B to MED.B.005 (b)7.1  <b>Page</b> 49</p> <p><b>Comment</b>  Terms should be stated</p> <p><b>Justification</b>  Too loose</p> <p><b>Proposed Text</b>  .....in terms of structure, function and rhythm.</p>	
response	<p><i>Noted</i></p> <p>Text has been added to say that cardiological follow-up may be necessary. It is then up to the specialist to give advice on the fitness of the applicant.</p>	
comment	2536	comment by: UK CAA MEDICAL ADVISORY PANEL
	<p><b>Paragraph</b> AMC B to MED.B.005 (b)7.2  <b>Page</b> 49</p> <p><b>Comment</b>  Terms should be stated</p> <p><b>Justification</b>  Too loose</p> <p><b>Proposed Text</b>  .....in terms of structure, function and rhythm.</p>	
response	<p><i>Noted</i></p> <p>See response to comment No 2535; the addition is for the full paragraph.</p>	
comment	2537	comment by: UK CAA MEDICAL ADVISORY PANEL
	<p><b>Paragraph</b> AMC B to MED.B.005 (d) 3.1  <b>Page</b> 50</p> <p><b>Comment</b>  Delete <i>cardiac</i></p> <p><b>Justification</b>  slang</p> <p><b>Proposed Text</b>  Insert .....<i>myocardial</i></p>	
response	<p><i>Noted</i></p> <p>'cardiac' was replaced by 'angina perctoris' following comment No 1037.</p>	
comment	2538	comment by: UK CAA MEDICAL ADVISORY PANEL
	<p><b>Paragraph</b> AMC B to MED.B.005 (d) 3. 1. (i)  <b>Page</b> 50</p> <p><b>Comment</b>  Delete <i>leading to</i></p> <p><b>Justification</b>  Poor usage</p>	

	<b>Proposed Text</b> Insert ..... <i>subtending</i>	
response	<i>Accepted</i>	
comment	2539	comment by: UK CAA MEDICAL ADVISORY PANEL
	<b>Paragraph</b> AMC B to MED.B.005 (d) 3.2. <b>Page</b> 50	
	<b>Comment</b> Delete <i>cardiac</i>	
	<b>Justification</b> slang	
	<b>Proposed Text</b> Insert ..... <i>myocardial</i>	
response	<i>Accepted</i>	
comment	2540	comment by: UK CAA MEDICAL ADVISORY PANEL
	<b>Paragraph</b> AMC B to MED.B.005 (d) 3.2. (iii) <b>Page</b> 50	
	<b>Comment</b> Poor syntax	
	<b>Justification</b>	
	<b>Proposed Text</b> <i>.....in cases of angioplasty/stenting, a myocardial perfusion scan or stress echocardiogram shall show no evidence of reversible myocardial ischaemia. If there is doubt about revascularisation in myocardial infarction or bypass grafting, a perfusion scan will also be required;</i>	
response	<i>Accepted</i>	
comment	2541	comment by: UK CAA MEDICAL ADVISORY PANEL
	<b>Paragraph</b> AMC B to MED.B.005 (d) 3.5 <b>Page</b> 50	
	<b>Comment</b> Delete <i>cardiac</i>	
	<b>Justification</b> slang	
	<b>Proposed Text</b> Insert ..... <i>myocardial</i>	
response	<i>Accepted</i>	
comment	2542	comment by: UK CAA MEDICAL ADVISORY PANEL
	<b>Paragraph</b> AMC B to MED.B.005 (d) 3.5 <b>Page</b> 50	

	<p><b>Comment</b> Delete <i>cardiac</i></p> <p><b>Justification</b> slang</p> <p><b>Proposed Text</b> Insert .....<i>myocardial</i></p>
response	<i>Noted</i>
	See your comment No 2541.

**C. Draft Decision Part-MED - Subpart B: Requirements for Medical Certificates - Section 1: Specific requirements for class 1 and class 2 medical certificates - Chapter B: AMC for Class 2 medical certificates - AMC B to MED.B.010: Respiratory System** p. 51-52

comment	150	comment by: <i>Civil Aviation Authority - The Netherlands</i>
	<p><b>AMC B to MED.B.010, onder 2. (Blz. 51 van 66)</b></p> <p>De CAA-The Netherlands merkt op dat niet duidelijk is wat met 'minor impairment' wordt bedoeld. De CAA-The Netherlands verzoekt aan EASA om 'minor' met cijfers te verduidelijken.</p>	
response	<i>Noted</i>	
	<p>Class 2 medical requirements proposed in the Part Medical were aligned with ICAO class 2 requirements laid down in Annex I. In this case, the wording 'minor impairment' corresponds to the wording 'condition found unlikely to interfere with the safe exercise of their licence and rating privileges'.</p>	
comment	262	comment by: <i>Lufthansa German Airlines</i>
	<p>Author: Gabel A MD, AME/Cardiologist Aeromedical Center Frankfurt/M, Germany Section: AMC to MED.B.010 <b>Page: 51</b></p> <p>Relevant Text: Chronic obstructive airways disease Applicants with only minor impairment of pulmonary function may be assessed as fit.</p> <p><b>Comment:</b> "Minor" impairment must be defined, if not - there is no limit at all. Because Chronic obstructive lung disease (COPD) bears the risk of hypoxic incapacitation (impaired colour vision at low altitudes - esp. in smokers) the affected patients should be excluded from performance of flight duties. The measurement of SO2 is a cheap and readily available method to demonstrate sufficient capacity of oxygenation.</p> <p><b>Proposal:</b> Chronic obstructive airways disease (a) Applicants with only minor impairment of pulmonary function may be assessed as fit. <u>Minimum values for FEV1/FVC of 70 % and FVC of 80 % must be demonstrated. In the presence of chronic obstructive lung disease a</u></p>	

	<p><u>satisfactory level of blood oxygenation (SO<sub>2</sub> &gt; 95 % at room air on the ground) has to be demonstrated.</u></p>	
response	<p><i>Noted</i></p>	
	<p><b>Open</b></p> <p>See response to comment No. 150.</p> <p>Following the principle of medical standards laid down in ICAO Annex I, numerical values and some methods in medical investigation may be proposed as a Guidance Material during the next rulemaking task..</p>	
comment	771	<p>comment by: <i>European Society of Space and Aviation Medicine (ESAM)</i></p>
	<p><b>Author: European Society of Space and Aviation Medicine (ESAM) - Internal Medicine Group -</b></p> <p><b>Chapter B AMC for class 2 medical certificate</b>  <b>Section: AMC B to MED B.010</b>  <b>Respiratory System - class 2 medical certificate</b></p> <p><b>Page: 51</b></p> <p>Relevant Text:</p> <p>1. Chest radiography  Posterior/anterior chest radiography may be required if indicated on clinical grounds.</p> <p>2. Chronic obstructive airways disease  Applicants with only minor impairment of pulmonary function may be assessed as fit.</p> <p>3. 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 (systemic steroids are disqualifying).</p> <p>4. Inflammatory disease  Applicants with active inflammatory disease of the respiratory system should be assessed as unfit pending resolution of the condition.</p> <p>5. Sarcoidosis</p> <p>5.1 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.</p> <p>5.2 Applicants with cardiac sarcoid should be assessed as unfit.</p> <p>6. Pneumothorax</p> <p>6.1. Applicants with spontaneous pneumothorax should be assessed as unfit. A fit assessment may be considered if respiratory evaluation is satisfactory six weeks following full recovery from a single spontaneous pneumothorax or following recovery from surgical intervention in the case of treatment for a recurrent pneumothorax.</p>	

6.2. 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.

7. 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).

Sleep apnoea syndrome

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

**Comment:**

**Proposal:**

1. Examinations

1.1 Spirometry

Spirometric examination is required for initial examination. A low FEV1/FVC ratio at initial examination should require evaluation by a specialist in respiratory disease.

1.2 Chest radiography

Posterior/anterior chest radiography may be required if indicated on clinical grounds.

response

*Not accepted*

Spirometric examination for initial class 2 applicants is neither required by ICAO Annex I nor by JAR FCL 3 Amendment 5. Introduction of this examination would be unnecessarily burdensome for private pilots. It may be required if there would be a clinical indication.

comment

821

comment by: *Swiss Association of Aviation Medicine*

**Proposal:**

1. Spirometry

Spirometric examination may be required if indicated on clinical grounds.

**Comment:**

Without spirometry the diagnosis of a chronic obstructive airways disease (3.) cannot be established.

2. Chest radiography

Posterior/anterior chest radiography may be required if indicated on clinical grounds.

3. Chronic obstructive.....

response

*Noted*

See response to comment No 771.

comment	1850	comment by: UK CAA MEDICAL ADVISORY PANEL
	<p><b>Paragraph</b> AMC B to MED.B.005 (e) 1  <b>Page</b> 51</p> <p><b>Comment</b>  What is being ablated - ?RV outflow tract ? atrial flutter circuit</p> <p><b>Justification</b>  <b>incomplete</b></p> <p><b>Proposed Text</b>  <i>....following successful catheter ablation of an atrial flutter circuit subject to satisfactory  Cardiological review</i></p>	
response	Noted	
	Please, see responses in the section 'Cardiology'.	
comment	2543	comment by: UK CAA MEDICAL ADVISORY PANEL
	<p><b>Paragraph</b> AMC B to MED.B.005 (e) 2.1  <b>Page</b> 51</p> <p><b>Comment</b>  It seems self evident that if the rhythm disturbance is significant, cardiological evaluation will not be satisfactory</p> <p><b>Justification</b></p> <p><b>Proposed Text</b>  Insert and the patient is completely asymptomatic.</p>	
response	Noted	
	Please, see responses in the section 'Cardiology'.	
comment	2544	comment by: UK CAA MEDICAL ADVISORY PANEL
	<p><b>Paragraph</b> AMC B to MED.B.005 (e) 2.2  <b>Page</b> 51</p> <p><b>Comment</b>  Atrial flutter is not acceptable before conversion to sinus rhythm / AF</p> <p><b>Justification</b>  <b>Possibility of 1:1 conduction</b></p> <p><b>Proposed Text</b>  Persisting atria flutter is not acceptable. Applicants with atrial fibrillation may be assessed as fit if cardiological evaluation including echocardiography, Holter monitoring and exercise ECG is satisfactory</p>	
response	Noted	
	Please, see responses in the section 'Cardiology'.	
comment	2545	comment by: UK CAA MEDICAL ADVISORY PANEL

	<p><b>Paragraph</b> AMC B to MED.B.005 (e) 3  <b>Page</b> 51  <b>Comment</b>  “Heart block” is incomplete.  <b>Justification</b>  <b>Not used alone by cardiologists</b>  <b>Proposed Text</b>  Inset atrio-ventricular block</p>
response	<p><i>Noted</i></p> <p>Please, see responses in the section ‘Cardiology’.</p>

comment	<p>2546</p> <p>comment by: UK CAA MEDICAL ADVISORY PANEL</p> <p><b>Paragraph</b> AMC B to MED.B.005 (e) 3.1  <b>Page</b> 51  <b>Comment</b>  Mobitz type 1 AV block should not occur during the day  <b>Justification</b>  <b>Associated with higher degrees of AV block</b>  <b>Proposed Text</b>  Insert ....Mobitz 1 AV block during the night</p>
response	<p><i>Noted</i></p> <p>Please, see responses in the section ‘Cardiology’.</p>

comment	<p>2547</p> <p>comment by: UK CAA MEDICAL ADVISORY PANEL</p> <p><b>Paragraph</b> AMC B to MED.B.005 (e) 3.2  <b>Page</b> 51  <b>Comment</b>  No. Mobitz type 2 AV block is associated with a significant risk of progression  <b>Justification</b>    <b>Proposed Text</b>  delete</p>
response	<p><i>Noted</i></p> <p>Please, see responses in the section ‘Cardiology’.</p>

**C. Draft Decision Part-MED - Subpart B: Requirements for Medical Certificates - Section 1: Specific requirements for class 1 and class 2 medical certificates - Chapter B: AMC for Class 2 medical certificates - AMC B to MED.B.015: Digestive System** p. 52-53

comment	<p>151</p> <p>comment by: Civil Aviation Authority - The Netherlands</p> <p><b>AMC B to MED.B.015, onder 3.1 en 3.2. (Blz. 52 van 66)</b></p> <p>De CAA-The Netherlands acht de aanwezigheid van een enkele galsteen een</p>
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response	<p>gevaar. Elke individuele galsteen levert een gelijkwaardig potentieel veiligheidsrisico op.</p> <p><i>Noted</i></p> <p>The potential safety risk of a single gallstone or multiple gallstones shall be assessed by an AME/AeMC in consultation with the licensing authority taking into account the conclusion of the medical investigations.</p>	
comment	263	comment by: <i>Lufthansa German Airlines</i>
response	<p>Author: Gabel A MD, AME/Cardiologist Aeromedical Center Frankfurt/M, Germany Section: AMC B to MED.B.015 <b>Page: 53</b></p> <p>Relevant Text: 6. Abdominal Surgery 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.</p> <p><b>Comment:</b> To avoid unforeseen complications from pain due to gas expansion in higher altitudes a minimum time of 6 weeks should be prescribed to give the wound enough time for recovery.</p> <p><b>Proposal:</b> 6. Abdominal Surgery 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, <u>and a minimum time of 6 weeks has elapsed since the operation.</u></p> <p><i>Not accepted</i></p> <p>Fixed minimal periods of unfitness after a surgery are considered to inflexible in cases where full recovery is reached at an early stage. Satisfactory gastroenterological evaluation seems to be a better criterion to assess fitness to fly.</p> <p>If a minimum period on unfitness is stated, some applicants may also insist on a fit assessment purely because this period elapsed although the post-operative situation may not allow this.</p>	
comment	1848	comment by: <i>European CMO Forum</i>
	<p><b>Paragraph:</b> AMC B to MED.B.020 paragraph 7 <b>Page No:</b> 53</p> <p><b>Comment:</b> <b>It is necessary to incorporate developments in the medical treatment of diabetes into the EASA requirements.</b></p> <p><b>Justification:</b> Alpha-glucosidase inhibitors delay the digestion and absorption of starch and glucose. They do not have the side effect of hypoglycaemia, and their use for pilots with unrestricted class 1 medication is currently supported by JAR-FCL 3,</p>	

Manual – Endocrinology – 6.

Thiazolidinediones reduce peripheral insulin resistance leading to a reduction in blood glucose concentration. There is no significant association between thiazolidinediones and the risk of non-severe hypoglycaemia.

Medication that acts on the incretin pathway when used in combination with other medication is acceptable where studies have demonstrated that there is no significant increase in hypoglycaemic side effects compared with use of the other medication alone.

**Proposed Text:  
(if applicable)**

Replace proposed paragraph with:

AMC B to MED.B.020 paragraph 7 *Diabetes mellitus*

Subject to good control of blood sugar with no hypoglycaemic episodes: applicants with diabetes mellitus may be assessed as fit subject to good blood sugar control on

- (i) alpha-glucosidase inhibitors
- (ii) thiazolidinediones
- (iii) thiazolidinediones in combination with medication that acts on the incretin pathway
- (iv) biguanides, and biguanides in combination with medication that acts on the incretin pathway
- (v) sulphonylureas, and sulphonylureas in combination with medication that acts on the incretin pathway, may be acceptable for a Class 2 fit assessment with a safety pilot limitation

response *Not accepted*

The current text in AMC 2 to MED.B.020 paragraph 7 *Diabetes mellitus* provides the sufficient flexibility for the use of various medications. The Agency is of the opinion that the AMC should contain a general requirement and details such as the names of medicaments will be better placed in Guidance Material. Development of the Guidance Material is planned for the next rulemaking task MED.001.

**C. Draft Decision Part-MED - Subpart B: Requirements for Medical Certificates - Section 1: Specific requirements for class 1 and class 2 medical certificates - Chapter B: AMC for Class 2 medical certificates - AMC B to MED.B.020: Metabolic and Endocrine Systems**

p. 53

comment 152 comment by: *Civil Aviation Authority - The Netherlands*

**AMC B to MED.B.020, onder 7 (Blz. 53 van 66)**

Welke medicijnen bedoelt EASA met 'certain'? De CAA-The Netherlands verzoekt aan EASA om de toegestane medicijnen limitatief in de voorschriften op te sommen.

response *Not accepted*

The Agency avoided referring to specific medication in the AMCs; however, Guidance Material (GM) will be developed to include medication. The AeMC/AME should, in consultation with the licensing authority, assess the risk of the applicant's condition including the treatment to decide on the fitness to fly.

comment	598	comment by: <i>Lufthansa German Airlines</i>
<p>Author: Gabel A MD, AME/Cardiologist Aeromedical Center Frankfurt/M, Germany  Section: AMC B to MED.B.020  <b>Page:</b> 53</p> <p>Relevant Text:  7 Diabetes mellitus  Applicants with diabetes mellitus may be assessed as fit. The use of certain antidiabetic medications may be acceptable.</p> <p><b>Comment:</b> Besides insulin several different drugs can induce severe hypoglycaemia with loss of consciousness, as demonstrated in numerous lethal traffic accidents on the roads. So the use of antidiabetics should be limited to those which are not at risk to cause hypoglycaemic situations.  The rules should not be limited to class 1 but be applicable to all classes, because they even apply as minimum criteria for driving licences on the roads.</p> <p><b>Proposal:</b>  7 Diabetes mellitus  (1) Applicants with diabetes requiring insulin or antidiabetics which might induce hypoglycaemia 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 with absence of hypoglycaemic events or excess blood levels of more than 180 mg/dl.</p>		
response	<i>Not accepted</i>	
<p>The proposal contained in the comment is sufficiently covered in the IR and should not be repeated in the AMC.</p>		
comment	2104	comment by: <i>DGAC FRANCE</i>
<p>AMC B to MED.B.020, <b>paragraph 7</b></p> <p>comment :</p> <p>It is necessary to incorporate developments in the medical treatment of diabetes into the EASA requirements.</p> <p>Alpha-glucosidase inhibitors delay the digestion and absorption of starch and glucose. They do not have the side effect of hypoglycaemia, and their use for pilots with unrestricted class 1 medication is currently supported by JAR-FCL 3, Manual – Endocrinology – 6.</p> <p>Thiazolidinediones reduce peripheral insulin resistance leading to a reduction in blood glucose concentration. There is no significant association between thiazolidinediones and the risk of non-severe hypoglycaemia.</p> <p>Medication that acts on the incretin pathway when used in combination with other medication is acceptable where studies have demonstrated that there is no significant increase in hypoglycaemic side effects compared with use of the other medication alone.</p> <p>Modification :</p>		

Delete the proposed paragraph 7 and replace it by the following proposition :

**7. Diabetes mellitus**

**Subject to good control of blood sugar with no hypoglycaemic episodes:  
applicants with diabetes mellitus may be assessed as fit by the licensing authority subject to good blood sugar control on**

**(i) alpha-glucosidase inhibitors.**

**(ii) thiazolidinediones.**

**(iii) thiazolidinediones in combination with medication that acts on the incretin pathway.**

**(iv) biguanides, and biguanides in combination with medication that acts on the incretin pathway.**

**(v) sulphonylureas, and sulphonylureas in combination with medication that acts on the incretin pathway, may be acceptable for a Class 2 fit assessment with a safety pilot limitation.**

response *Not accepted*

The currently proposed text in AMC B to MED.B.020 paragraph 7 *Diabetes mellitus* provides sufficient flexibility for the use of various medications. The Agency is of the opinion that the rule should contain a general requirement, and details such as the names of medicaments would be better to be provided in the Guidance Material. This would allow to incorporate easier into a rule new developments in the medical treatment. Development of the Guidance Material is planned for the future rulemaking task.

comment

2417

comment by: *Irish Aviation Authority*

paragraph 7

Developments in the medical treatment of diabetes shall be incorporated into the EASA requirements

Justification:

Alpha-glucosidase inhibitors delay the digestion and absorption of starch and glucose. They do not have the side effect of hypoglycaemia, and their use for pilots is currently supported by JAR-FCL 3, Manual – Endocrinology – 6.

Thiazolidinediones reduce peripheral insulin resistance leading to a reduction in blood glucose concentration. There is no significant association between thiazolidinediones and the risk hypoglycaemia.

Medication that acts on the incretin pathway when used in combination with other medication is acceptable where studies have demonstrated that there is no significant increase in hypoglycaemic side effects compared with use of the other medication alone.

Proposed text:

Replace proposed paragraph with:

AMC B to MED.B.020 paragraph 7 *Diabetes mellitus*

Subject to good control of blood sugar with no hypoglycaemic episodes: applicants with diabetes mellitus may be assessed as fit subject to good blood sugar control on

- (i) alpha-glucosidase inhibitors
- (ii) thiazolidinediones

(iii) thiazolidinediones in combination with medication that acts on the incretin pathway

(iv) biguanides, and biguanides in combination with medication that acts on the incretin pathway

(v) sulphonylureas, and sulphonylureas in combination with medication that acts on the incretin pathway, may be acceptable for a Class 2 fit assessment with OSL limitation

response *Noted*

See response to comment No 2104.

comment

2576

comment by: *Heinz Fricke-Bohl and Kirsten Bohl*

AMC B to MED.B.020: (7) Piloten versuchen grundsätzlich bekannte Diab.-Erkrankungen zu schönen. Mindestens der HBA1C-Wert (Langzeitzuckerwert) ist erforderlich und erheblich besser als der veraltete Glucosebelastungstest.

response *Noted*

Thank you for this information.

**C. Draft Decision Part-MED - Subpart B: Requirements for Medical Certificates - Section 1: Specific requirements for class 1 and class 2 medical certificates - Chapter B: AMC for Class 2 medical certificates - AMC B to MED.B.025: Haematology** p. 53-54

comment

264

comment by: *Lufthansa German Airlines*

Author: Gabel A MD, AME/Cardiologist Aeromedical Center Frankfurt/M, Germany

Section: AMC B to MED.B.025

**Page:** 53

Relevant Text: 1 Abnormal haemoglobin

Haemoglobin should be tested when clinically indicated

**Comment:** Haemoglobin level plays an essential role in preventing hypoxia due to the physical laws, that apply to all airmen regardless of the desired class of med. Certificate. Haemoglobin (today only available: cell count) should be determined at every aeromedical examination.

**Proposal:** Cell count should be tested at every aeromedical examination.

response *Not accepted*

Class 2 medical requirements are aligned with ICAO Annex I class 2 assessments which do not require haemoglobin testing. JAR-FCL 3 Amendment 5 requires testing haemoglobin only on clinical indication.

comment	494	comment by: UK CAA
	<p><b>AMC B to MED.B.025 6.2</b> Page: 54</p> <p><b>Comment:</b> The use of anti-coagulants for treatment and prophylaxis should be differentiated</p> <p><b>Justification:</b> The use of anti-coagulants for prophylaxis in low risk cases is within acceptable flight safety parameters.</p> <p><b>Proposed Text:</b> Change 'therapy' to '<b>treatment</b>'.</p>	
response	Noted	
	Paragraph 7.2 has been deleted and is covered under Cardiology (b) 5.	
comment	495	comment by: UK CAA
	<p><b>AMC B to MED.B.025 8.1 and 8.2</b> Page: 54</p> <p><b>Comment:</b> Text change to clarify that medical certification 'may' be possible. 'Should' implies that certification is straightforward which is incorrect.</p> <p><b>Justification:</b> Leukaemias are a heterogeneous group of conditions and treatments and outcomes are changing very rapidly with advances in medicine.</p> <p>Extensive guidance material will be required on haematological malignancies because of the many different disorders covered by the terms 'leukaemia' and lymphoma and will need to be regularly updated.</p> <p><b>Proposed Text:</b> Change 'should' to '<b>may</b>'.</p>	
response	Accepted	
	Thank you for the comment. The text will be changed accordingly.	
comment	1846	comment by: European CMO Forum
	<p><b>Paragraph: AMC B to MED.B.025 6.2</b> Page No: 54</p> <p><b>Comment:</b> The European requirements should accept anticoagulation with special conditions according to the medical circumstances.</p> <p><b>Justification:</b> The medical condition requiring anticoagulation is very important to consider.</p>	

Anticoagulation being used for treatment of a thrombosis is not acceptable. Anticoagulation being used for prophylaxis should be permitted.

**Proposed Text:  
(if applicable)**

**AMC B to MED.B.025 6.2:** Applicants with deep vein thrombosis or pulmonary embolus should be assessed as fit after anticoagulation therapy is discontinued or in case of continuous anticoagulation the anticoagulation is proven to be stable (within the last 6 months at least 5 INR values, of which 4 are within the INR target range).

response *Noted*

See response to comment No 494.

comment

2167

comment by: *DGAC FRANCE*

**AMC B to MED.B.025, paragraph 6.2.**

comment :

The European requirements should accept anticoagulation with special conditions according to the medical circumstances.

The medical condition requiring anticoagulation is very important to consider. Anticoagulation being used for treatment of a thrombosis is not acceptable. Anticoagulation being used for prophylaxis should be permitted.

Modification :

AMC B to MED.B.025

6. Thrombo-embolic disorders

**6.2.** Applicants with deep vein thrombosis or pulmonary embolus should be assessed as fit **by the licensing authority** after anticoagulation therapy is discontinued **or in case of continuous anticoagulation the anticoagulation is proven to be stable (within the last 6 months at least 5 INR values, of which 4 are within the INR target range).**

response *Noted*

See response to comment No 494.

comment

2418

comment by: *Irish Aviation Authority*

6.2

The European requirements should accept anticoagulation with underconditions according to the medical circumstances.

Justification:

The medical condition requiring anticoagulation is important to consider. Anticoagulation being used for treatment of a thrombosis is not acceptable. Anticoagulation being used as prophylaxis should be permitted.

Proposed text:

**AMC B to MED.B.025 6.2:** Applicants with deep vein thrombosis or

pulmonary embolus should be assessed as fit after anticoagulation therapy is discontinued or in case of continuous anticoagulation the anticoagulation is proven to have been stable (within the last 6 months at least 5 INR values, of which 4 are within the INR target range).

response *Noted*

See response to comment No 494.

**C. Draft Decision Part-MED - Subpart B: Requirements for Medical Certificates - Section 1: Specific requirements for class 1 and class 2 medical certificates - Chapter B: AMC for Class 2 medical certificates - AMC B to MED.B.030: Genitourinary System** p. 54-55

comment 153 comment by: *Civil Aviation Authority - The Netherlands*

**AMC B to MED.B.030, onder 2.3 (Blz. 54 van 66)**

Tijdens wachten op beoordeling of behandeling kan de kandidaat medisch geschikt worden verklaard met de beperking te moeten vliegen met een 'safety pilot'.

De CAA-The Netherlands merkt op dat uit dit artikel volgt dat bij nierstenen medische geschiktheid kan worden beperkt door het verplichten te vliegen met een 'safety pilot'. Wanneer de constructie met een 'safety pilot' is toegestaan bij nierstenen, waarom dan niet bij galstenen? In voorschrift AMC B to MED.B.015, onder 3.3 zou volgens de CAA-The Netherlands omwille van de rechtsgelijkheid het voorschrift moeten worden opgenomen als bedoeld in AMC B to MED.B.030, onder 2.3.

response *Not accepted*

The paragraphs are different and in the case of gallstones the pilot can be assessed as fit without safety pilot if asymptomatic.

comment 496 comment by: *UK CAA*

**AMC B to MED.B.030**

Page: 54

**Comment:**

Clarification of text.

**Justification:**

Clarity.

**Proposed Text:**

Amend: 'Applicants presenting with **symptoms from** one or more...'

response *Not accepted*

The proposed text changes significantly the meaning of the original text and introduces a disorder in the sequence of AME/AeMC actions required in 2.2.-2.4.

comment 2274 comment by: *R. Szwagrzak*

	<p>1. "2.1 Applicants presenting with one or more urinary calculi should be assessed as unfit." contradicts the general statement in MED.B.30 (d): "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/urological evaluation."</p> <p>2. Considering the above, an absolute ban based on the existence of urinary calculi alone, not taking into account any other medical factors, is not risk-based and therefore illogical.</p> <p>3. It is discriminatory to declare unfit pilots who present with urinary calculi but who are demonstrably asymptomatic. For such pilots the existence of urinary calculi presents a risk factor no greater than the common cold.</p>
response	<i>Noted</i>
	<p>1. Please read the full text of the AMC B to MED.B.030 2. <i>Urinary calculi</i>. The possibility of the fit assessment is provided in 2.2.-2.4. There is no contradiction with the Implementing Rule.</p> <p>2. See 1.</p> <p>3. See 1.</p>

<p><b>C. Draft Decision Part-MED - Subpart B: Requirements for Medical Certificates - Section 1: Specific requirements for class 1 and class 2 medical certificates - Chapter B: AMC for Class 2 medical certificates - AMC B to MED.B.035: Infectious Disease</b></p>	<p>p. 55</p>
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	<p>497</p>	<p>comment by: UK CAA</p>
	<p><b>AMC B to MED.B.035 2</b> Page: 55</p> <p><b>Comment:</b> Terminology inappropriate and it is only disease that presents an increased risk to flight safety that is relevant in this context.</p> <p><b>Justification:</b> Terminology is outdated and does not allow for complete recovery from an AIDs defining condition. Suggested text is compatible with the new proposed ICAO wording as per ICAO State Letter 08-33.</p> <p><b>Proposed Text:</b> Amend to: '...clinical disease <b>that might give rise to incapacitating symptoms subject to...</b>' Delete: 'The occurrence of AIDS or AIDS related complex is disqualifying'.</p>	
response	<p><i>Partially accepted</i></p> <p>The deletion is accepted; the full wording from ICAO SL 08/33 is used for this paragraph.</p>	

**C. Draft Decision Part-MED - Subpart B: Requirements for Medical Certificates - Section 1: Specific requirements for class 1 and class 2 medical certificates - Chapter B: AMC for Class 2 medical certificates - AMC B to MED.B.040: Obstetrics and Gynaecology**

p. 55

comment	772	comment by: <i>European Society of Space and Aviation Medicine (ESAM)</i>
		<p><b>Author: European Society of Space and Aviation Medicine (ESAM) - Internal Medicine Group -</b></p> <p><b>Section: AMC B to MED B.040 Obstetrics and Gynaecology - class 2 medical certificates</b></p> <p><b>Page: 55</b></p> <p><b>Relevant Text:</b></p> <p>1. Gynaecological surgery An applicant who has 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).</p> <p>2. Pregnancy</p> <p>2.1. A pregnant pilot may be assessed as fit during the first 26 weeks of gestation following satisfactory obstetric evaluation.</p> <p>2.2. Licence privileges may be resumed upon satisfactory confirmation of full recovery following confinement or termination of pregnancy.</p> <p><b>Comment:</b></p> <p><b>Proposal:</b></p> <p>1. Gynaecological surgery An Applicant who has 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), minimum 4 weeks.</p> <p>2. Pregnancy</p> <p>2.1. A pregnant pilot may be assessed as fit during the first 26 weeks of gestation following satisfactory obstetric evaluation.</p> <p>2.2. Licence privileges may be resumed upon satisfactory confirmation of full recovery following confinement or termination of pregnancy.</p>
response		<p><i>Not accepted</i></p> <p>Following the principle of the ICAO Annex I standards, periods of unfitness after surgery were not included into the text of NAP allowing flexibility and giving the opportunity for assessment on individual basis.</p>

**C. Draft Decision Part-MED - Subpart B: Requirements for Medical Certificates - Section 1: Specific requirements for class 1 and class 2 medical certificates - Chapter B: AMC for Class 2 medical certificates - AMC B to MED.B.045: Musculoskeletal System**

p. 55-56

comment	498	comment by: UK CAA
	<p><b>AMC B to MED.B.045 3 and 4</b>  <b>Page: 55</b></p> <p><b>Comment:</b>  Inappropriate to include the possibility that a limitation could be required in the circumstances mentioned in this paragraph.</p> <p><b>Justification:</b>  One or more limitation(s) may be required in many circumstances.</p> <p><b>Proposed Text:</b>  Delete: 'A limitation to specified aircraft type(s) may be required'.</p>	
response	<p><i>Not accepted</i></p> <p>The possibility for the limitation in the circumstances mentioned in AMC B to MED.B.045 3 and 4 was included in accordance with the requirement laid down in the BR Annex III Paragraph 4.a.2 stating 'Where medical fitness cannot be fully demonstrated, mitigation measures that provide equivalent flight safety may be implemented'.</p>	
comment	1351	comment by: European Disabled Aviators
	<p>Attachment <a href="#">#26</a></p> <p>The purpose of below proposed amendment – replacement of the word “of” by the word “affecting” in paragraph 1 - is to make sure that the whole article will not only apply to conditions strictly inherent to the bones, joints, muscles and tendons but also to all diseases, injuries and abnormalities that impact them - such as neurological conditions.</p> <p>1. An applicant with any significant sequela from disease, injury or congenital abnormality of <u>affecting</u> the bones, joints, muscles or tendons with or without surgery should require full evaluation prior to fit assessment.</p> <p>2. In cases of limb deficiency, [...]</p>	
response	<p><i>Accepted</i></p>	

**C. Draft Decision Part-MED - Subpart B: Requirements for Medical Certificates - Section 1: Specific requirements for class 1 and class 2 medical certificates - Chapter B: AMC for Class 2 medical certificates - AMC B to MED.B.050: Psychiatry**

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comment	273	comment by: Lufthansa German Airlines
	<p>Section: 2  AMC B to MED B.050  PSYCHIARTY - class 2 medical certificate  <b>Page:</b></p> <p>Relevant Text: :  4. Alcohol or other substance abuse/dependency may only be considered fit after useful treatment and psychiatric evaluation.</p>	

	<p><b>Comment:</b> 1 - 3 - no recommended change</p> <p><b>Proposal:</b> see class 1</p>
response	Accepted
comment	<p>600 <span style="float: right;">comment by: <i>Lufthansa German Airlines</i></span></p>
	<p>Author: Prof. Dr. Jürgen Kriebel Section: 2 Subpart B Specific requirements for class 1 and class 2 AMC.A. to MED.B.050 PSYCHIARTY - class 1 medical certificates 4, 5, 9 <b>Page:</b></p> <p>Relevant Text:: 4 Schizophrenia, schizotypal or delusional disorder: Applicants with an established schizophrenia, schizotypal or delusional disorder should only be considered for a fit assessment if the licensing authority concludes that the original diagnosis was inappropriate or inaccurate or, in the case of a single episode of delirium, provided that the applicant has suffered no permanent impairment.</p> <p>5. Mood disorder: An established mood disorder is disqualifying. A fit assessment may be considered after full consideration of an individual case, depending on the mood disorder characteristics and gravity and after all psychotropic medication has been stopped for an appropriate period.</p> <p>9. Deliberate self-harm: A single self destructive action or repeated acts of deliberate self-harm are disqualifying. A fit assessment may be considered after full consideration of an individual case and may require psychiatric or psychological review. Neuropsychological assessment may also be required.</p> <p><b>Comment:</b> 9. The formulation: 'or' psychological review could lead to misdiagnosing or the overlook of psychotic causal factors - and first evaluation by a psychiatrist is therefore mandatory.</p> <p><b>Proposal:</b> 4. Applicants with an established schizophrenia, schizotypal or delusional disorder should only be considered for a fit assessment if the licensing authority concludes that the original diagnosis was inappropriate or inaccurate. Delete the remaining part of the sentence.</p> <p>5. An established mood disorder is disqualifying. A fit assessment may be considered after full consideration of an individual case, depending on the mood disorder characteristics and gravity, after full recovery including anti-depressive medication like SSRI and SNRI without side effects under regular follow ups.</p>

	<p>9. No recommended change in the first sentence. A fit assessment may be considered after full psychiatric consideration of an individual case and may require additional psychological review. Neuropsychological assessment may also be required.</p>
response	Noted
	<p>4. Not accepted. The text was carried over from JAR-FCL 3 (Appendix 10(1)) which was the basis for this document.</p> <p>5. Partly accepted. The text will be changed allowing some psychotropic medication.</p> <p>9. Not accepted. The involvement of specialists is subject to the decision of AME/AeMC/licensing authority. This is also a copy of JAR-FCL 3 Appendix 10 (3)</p>

comment	919 comment by: <i>European Society of Space and Aviation Medicine (ESAM)</i>
	<p><b>Author: European Society of Space and Aviation Medicine (ESAM) - Group Neurology Psychiatry-</b></p> <p><b>Section:</b> AMC B to MED.B.050 PYSCHIARTY - class 2 medical certificates</p> <p><b>Page:</b> 56</p> <p><b>Relevant Text:</b> (all text)</p> <p><b>Comment:</b> These diagnostic groups bare a high risk to endanger others or violate rules, i.e. flying in controlled air space. Draeger J., J. Kriebel (Eds). <i>Praktische Flugmedizin</i>. Ecomed Verlag 2002. C. Curdt - Christiansen, J. Dreager, J. Kriebel (Eds). <i>Practical Aviation Medicine</i>. World Scientific Press. Singapore. Impress.</p> <p><b>Proposal:</b></p> <p>1. Psychotic disorder <i>Schizophrenia, schizotypal or delusional disorder</i> Applicants with an established schizophrenia, schizotypal or delusional disorder should only be considered for a fit assessment if the licensing authority concludes that the original diagnosis was inappropriate or inaccurate and otherwise no risk of recurrence.</p> <p>2. Mood disorder An established mood disorder is disqualifying. A fit assessment may be considered after full consideration of an individual case, depending on the mood disorder characteristics and gravity, after full recovery and after regular follow up, as well as all psychotropic medication has been stopped for an appropriate period. In case by case decisions some SSRI and SRNI may be accepted under close psychiatric review.</p> <p>3. Psychotropic substances</p>

	Use or abuse of psychotropic substances likely to affect flight safety is disqualifying.	
	4. Personality or behavioural disorder After medical evaluation where there is suspicion or established evidence that an applicant has a psychological disorder (delete) deficiency (insert) , the applicant should be referred for psychiatric and/or psychological opinion and advice.	
response	<i>Noted</i>	
	1, 2 and 3: See response to comment No 600.	
	4: Please see response to comment No 273.	
comment	1835	comment by: CAA Belgium
	<p>Relevant Text:</p> <ol style="list-style-type: none"> <li>1. Psychotic disorder...</li> <li>2. Psychotropic substances...</li> <li>3. Schizophrenia, schizotipal or delusional disorder...</li> </ol> <p>Comment: It's very important also for class 2 to specify all the psychiatric conditions like class 1.</p> <p>Proposal:</p> <p>1-2 no change</p> <p>Add to these the following:</p> <ol style="list-style-type: none"> <li>4. Schizophrenia, schizotipal or delusional disorder</li> </ol> <p>An applicant with a history of schizophrenia, schizotipal or delusional disorder may only be considered fit if the original diagnosis was inappropriate or inaccurate as confirmed by psychiatric evaluation. Delete the remaining part of the sentence.</p> <ol style="list-style-type: none"> <li>5. Organic mental disorder...</li> <li>6. Mood disorder...</li> <li>7. Neurotic, stress related or somatoform disorder...</li> <li>8. Personality or behavioural disorder...</li> <li>9. Disorders due to alcohol or other substance use...</li> <li>10. Deliberate self-harm</li> </ol> <p>A single self destructive action or repeated acts of deliberate self –harm are disqualifying. A fit assessment may be considered after full consideration of an individual case and may require psychiatric and psychological review.</p>	
response	<i>Not accepted</i>	
	4.: please see response to comment No 600.	
	5.-8.: The disorders mentioned under these paragraphs should be covered sufficiently in the implementing rules for class 2 where, under MED.B.050, a psychiatric evaluation is required.	
	9. Comment is accepted (see response to comment No 273).	
comment	1845	comment by: CAA Belgium
	Relevant Text: :	

4. Alcohol or other substance abuse/dependency may only be considered fit after useful treatment and psychiatric evaluation.

Comment:

1 – 3 – no recommended change

Proposal:

see class 1 Pag 43 8.1 & 8.2

response *Noted*

See response to comment No 273.

**C. Draft Decision Part-MED - Subpart B: Requirements for Medical Certificates - Section 1: Specific requirements for class 1 and class 2 medical certificates - Chapter B: AMC for Class 2 medical certificates - AMC B to MED.B.055: Psychology**

p. 56

comment 920 comment by: *European Society of Space and Aviation Medicine (ESAM)*

**Author: European Society of Space and Aviation Medicine (ESAM) - Group Neurology Psychiatry-**

**Section:**

AMC B to MED.B.055

PSYCHOLOGY - class 2 medical certificates

**Page:** 56

**Relevant Text:**

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

**Comment:**

**Proposal:**

Applicants with a psychological deficiency, likely to interfere with aviation safety should be referred for psychological or psychiatric or neurological opinion and advice.

Disorders may need to be referred for psychological or neuropsychiatric opinion and advice. (delete sentence)

response *Not accepted*

The AME or AeMC will determine whom an applicant is referred to. If the AME/AeMC is of the opinion that they need psychological advice due to a psychological deficiency that might interfere with flight safety, the applicant should be referred to a specialist in psychology.

Cases where an applicant is referred to a Psychiatrist or Neurologist are covered in the respective paragraphs.

comment 1142 comment by: *Austrian Professional Association of Psychologists (BÖP)*

We recommend the following AMC B to MED.B.055

	<p>The psychological evaluation may include a collection of biographical data, the administration of aptitudes as well as personality tests and a psychological interview.</p> <p>In case of an accident, psychological reasons for that accident should be evaluated also according to the human-factors criteria published by the ICAO - Human Factors Digest No. 7, ICAO-Circular 240-AN/144.</p>	
response	<i>Not accepted</i>	
	<p>The text in the first paragraph of this comment is from JAR-FCL 3, Appendix 17 (2). This has been added to the AMC for class 1 medical certificates. However, for class 2 medical certificates it does not seem necessary to go beyond saying that psychological opinion and advice is sought. This provides the psychologist with more flexibility concerning data and tests.</p> <p>Paragraph 2 of the comment is a reference to ICAO provisions. The Agency is of the opinion that giving references to other rules in IRs or AMCs should be avoided to prevent the necessity to change the provisions should the documents mentioned in the text be re-named, re-numbered or withdrawn.</p>	
comment	1490	comment by: <i>President of AEPA</i>
	Attachments <a href="#">#27</a> <a href="#">#28</a>	
	Comments from the Spanish Association for Aviation Psychology	
response	<i>Noted</i>	
	See response to comment No 920.	
comment	1521	comment by: <i>Dr Ian Perry</i>
	This section should be deleted. Anyone with a psychological disorder should be referred to a consultant psychiatrist in the first instant. The psychiatrist may require a psychological opinion as part of the psychiatric assessment.	
response	<i>Noted</i>	
	See response to comment No. 920.	
comment	1837	comment by: <i>CAA Belgium</i>
	<p>Relevant Text:  Applicants with a psychological disorder may need to be referred for psychological or neuropsychiatric opinion and advice.  Comment:  Proposal:  Applicants with a psychological disorder may need to be referred for psychological, neurological or / and psychiatric opinion and advice.</p>	
response	<i>Noted</i>	
	See response to comment No 920.	
comment	1940	comment by: <i>Deutsches Zentrum für Luft- und Raumfahrt, Abteilung</i>

	<i>Luft- und Raumfahrtpsychologie, Hamburg</i>
	<p>&lt;![endif]--&gt;</p> <ul style="list-style-type: none"> <li>- The psychological evaluation is only indicated "as part of" a medical examination. There can be many other safety related indications for a psychological evaluation or treatment such as training and proficiency problems, insufficient coping with stresses of work, changes in operational risk taking behavior, recurring incidents, operational performance deviations and not at least findings in accident investigations etc. (See JAR-FCL 3 Appendix 17 to JAR-FCL 3.240 and 3.360). Such safety related indications would remain undetected because they go beyond of what a medical or specialized neurological or psychiatric examination would be able to reveal. &lt;![endif]--&gt;</li> <li>- A clinical evaluation, as part of the medical evaluation differs in many aspects from a psychological performance or function evaluation of a pilot or pilot candidate. While a clinical evaluation leads to a diagnose of "healthy" or "not healthy", the psychological performance evaluation is based on the assessment of the person's cognitive functions, mental abilities, motivational factors and other personal factors in relation to the operational job requirements of a pilot. For example a completely "healthy" person can have a deficient ability for spatial orientation or short-term memory, which would disqualify the person from safely operating aircraft.</li> </ul> <p>DLR supports the proposal of the European Association for Aviation Psychology (EAAP) with respect to a revision of AMCs A and B to MED.B.055 (Class 1 and 2, and Leisure Pilot License). The recommended new phrasing based on JAR is as follows:</p> <p>&lt;![endif]--&gt;</p> <p><b>AMC A to MED.B.055 PSYCHOLOGY (AMC for class 1 medical certificates)</b></p> <p><b>AMC B to MED.B.055 (AMC for class 2 medical certificates)</b></p> <p><b>Specific requirements for LPL medical certificates</b></p> <p>The psychological evaluation may include a collection of biographical data, the administration of aptitudes as well as personality tests and a psychological interview.</p> <p>In case of an accident, psychological reasons for that accident should be evaluated also according to the human-factors criteria published by the ICAO - Human Factors Digest No. 7, ICAO-Circular 240-AN/144.</p>
response	<p><i>Noted</i></p> <p>See response to comment No 1142.</p>

comment	<p>2452 ❖</p> <p style="text-align: right;">comment by: <i>AEPA, Asociación Española de Psicología de la Aviación Civil</i></p>
	<p>Comments in regard to the Psychological Part of the 2008-17 c NPA (MED.B.055 Psychology (including AMC A to MED.B.055 PSYCHOLOGY (AMC class 1 medical certificates), AMC B to MED.B.055 (AMC for Class 2 medical certificates and Psychological and the "Specific requirements for LPL medical certificates - Psychology) draft</p> <ul style="list-style-type: none"> <li>- The psychology sections are underdeveloped, lack detail and are therefore</li> </ul>

open to misinterpretation and misuse.

- The wording used is inconsistent, the terminology psychological "disorders" and/or "deficiencies" are both used but lack any definition or specification.

- The psychological evaluation is only indicated "as part of" a medical examination. There can be many other safety related indications for a psychological evaluation or treatment such as training and proficiency problems, insufficient coping with stresses of work, changes in operational risk taking behaviour, recurring incidents, operational performance deviations and not at least findings in accident investigations etc. (See JAR-FCL 3 Appendix 17 to JAR-FCL 3.240 and 3.360)

- A clinical evaluation as part of the medical evaluation differs in many aspects from a psychological performance evaluation of a pilot or pilot candidate. While a clinical evaluation leads to a diagnose of "pathology" or "not pathology", the psychological performance evaluation is based on the assessment of the person's cognitive functions, mental abilities, motivational factors and other personal factors in relation to the operational job requirements of a pilot.

- It is not specified or recommended who should perform the psychological evaluation, nor any specification of the required certification. This is in conflict with the high level safety objectives of the commission with FCL that a.o. includes: *"to require organizations, flight synthetic training devices and persons involved in the training, testing, checking and medical assessments to be certified on the basis of common rules.*

- With all respect for the medical science and the good collaboration in the clinical fields, psychology was and is an independent science focusing on the abilities and mental capacity in a specified operational, technical, organizational and cultural context. To understand the complexity and professionally assess such as psychological performance factors is of utmost relevance for safety in aviation. Not at least do the incident and accident rates provide the evidence.

- Oversight over a psychological evaluation is not within the competence of an AME who is untrained in Aviation psychology.

- It is therefore recommended that any psychological evaluation should only be performed by psychologists specialized and trained in "Aviation Psychology". Their training will allow the timely detection and mediation of potential deviations in performance capabilities and protects the pilot community against unrealistic assessments that do not address the specific aviation working context.

- Psychological evaluation is today not always under the head of Aviation Medicine. This position has been and is supported by national authorities (example Austria) who already maintain a list of certified aviation psychologists for psychological evaluations next to a list of AeroMedical Examiners (AME).

- In order to assure a "level playing field", the Commission is proposing that examiners are no longer acting on a delegation from the authority, but exercising the privileges that are given to them by the certificate they hold. Also, for approval "instructors providing flight training and flight simulation training, as well as examiners and aeromedical examiners, shall hold a certificate attesting their compliance with the essential requirements and

relating implementing rules”.

- Consistent rulemaking would benefit from developing a certificate for an “Aero Psychological Examiner” or accept and approve the authorization in Spain set by AEPA, the Spanish professional organization in the field.

- An “Aero Psychological Examiner” or Aviation Psychologist certificate is recommended as an alternative to delegation by national authorities only and/or detailing many specific psychological requirements in the rule text and/or AMC. A certification as an Aero Psychological Examiner or as Aviation Psychologist would assure at least a standardization of criteria and methods.

- Our association, AEPA, could assist either in providing adequate training for an “Aero Psychological Examiner” or in advising the Authorities in these issues.

response *Noted*

See response to comment No 920.

comment

2454 ❖

comment by: *AEPA, Asociación Española de Psicología de la Aviación Civil*

**AMC A to MED.B.055 PSYCHOLOGY (AMC for class 1 medical certificates)**

**AMC B to MED.B.055 (AMC for class 2 medical certificates)**

***Specific requirements for LPL medical certificates***

The psychological evaluation may include any psychological technical or professional tool such as the collection of biographical data, the administration of aptitudes, attitudes and personality tests as well as psychological interview. In case of an accident, psychological reasons for that accident must be evaluated also according to the human-factors criteria published by the ICAO – Human Factors Digest No 7, ICAO-Circular 240-AN/144

response *Noted*

See response to comment No 1142.

**C. Draft Decision Part-MED - Subpart B: Requirements for Medical Certificates - Section 1: Specific requirements for class 1 and class 2 medical certificates - Chapter B: AMC for Class 2 medical certificates - AMC B to MED.B.060: Neurology**

p. 56

comment

499

comment by: *UK CAA*

**AMC B to MED.B.060**

**Page: 56**

**Comment:**

Minor changes to text for clarity.

**Justification:**

Clarity.

response	<p><b>Proposed Text:</b>  Insert (i)....;or  (ii) ....;and  Also change (iii) 'epilepsy' to '<b>seizure</b>'.</p> <p><i>Noted</i></p> <p>The proposed NPA text is a transposition of the corresponding requirement from JAR-FCL 3.  While the term 'epilepsy' as used in JAR-FCL 3 and in this NPA is perfectly clear, we agree that 'seizure' includes a range of conditions and epilepsy is a specific case. However, there are many different types of seizures and simply replacing 'epilepsy' by 'seizure' may not be the best option. This comment has been noted for consideration in MED.001.</p>	
comment	921	<p>comment by: <i>European Society of Space and Aviation Medicine (ESAM)</i></p> <p><b>Author: European Society of Space and Aviation Medicine (ESAM) - Group Neurology Psychiatry-</b></p> <p><b>Section:</b>  AMC B to MED.B.060  NEUROLOGY - class 2 medical certificates</p> <p><b>Page:</b> 56</p> <p><b>Relevant Text:</b>  3. <i>Neurological disease</i>  Any stationary or progressive disease of the nervous system which has caused or is likely to cause a significant disability is disqualifying. In case of minor functional loss associated with stationary disease a fit assessment may be considered after full evaluation.</p> <p><b>Comment:</b></p> <p><b>Proposal:</b>  3. <i>Neurological disease</i>  Any stationary or progressive disease of the nervous system or history of disturbance of consciousness which has caused or is likely to cause a significant disability is disqualifying. In case of minor functional loss associated with stationary disease a fit assessment may be considered after full evaluation.</p>
response	<p><i>Noted</i></p> <p>The proposed addition of 'history of disturbance of consciousness' is not needed because it is covered by 'which has caused ...'.</p>	
comment	922	<p>comment by: <i>European Society of Space and Aviation Medicine (ESAM)</i></p> <p><b>Author: European Society of Space and Aviation Medicine (ESAM) - Group Neurology Psychiatry-</b></p> <p><b>Section:</b>  AMC B to MED.B.060</p>

	<p>NEUROLOGY - class 2 medical certificates</p> <p><b>Page:</b> 56</p> <p><b>Relevant Text:</b> New relevant text.</p> <p><b>Comment:</b></p> <p><b>Proposal:</b> 5. <i>Spinal or peripheral nerve injury, myopathies</i> An applicant with a history or diagnosis of spinal or peripheral nerve injury or myopathy should be assessed as unfit. A fit assessment may be considered if neurological review and musculoskeletal assessments are satisfactory.</p>
response	<p><i>Not accepted</i></p> <p>This paragraph has been omitted with the intention to align Part MED for class 2 to ICAO Annex 1. The diagnosis of spinal or peripheral nerve injury and myopathies is considered to be covered in MED.B.060 (c)(7) with the flexibility of an assessment for the AME, in consultation with the licensing authority.</p>

comment	<p>1838</p> <p>comment by: CAA Belgium</p>
	<p>Relevant Text: 1. Epylepsy.... – 4. Head injury</p> <p>Comment:</p> <p>Proposal:</p> <p>1-4 no change</p> <p>Add to these the following:</p> <p>5. 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 .</p> <p>6. Spinal or peripheral nerve injury An applicant with Spinal or peripheral nerve injury may be considered fit if neurological review and musculoskeletal assessments are satisfactory.</p>
response	<p><i>Not accepted</i></p> <p>These paragraphs from JAR-FCL 3, Appendix 11, have been omitted with the intention to align Part MED for class 2 to ICAO Annex 1. The conditions mentioned in the comment are considered to be covered in MED.B.060 with the flexibility of an assessment for the AME, in consultation with the licensing authority.</p>

<p><b>C. Draft Decision Part-MED - Subpart B: Requirements for Medical Certificates - Section 1: Specific requirements for class 1 and class 2 medical certificates - Chapter B: AMC for Class 2 medical certificates - AMC B to MED.B.065: Visual System</b></p>	<p>p. 57</p>
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comment	<p>107</p> <p>comment by: Daniel Noll</p>
	<p>This point is well regulated, no limits for refractive error for private pilots anymore, because it really doesn't metter whether a pilot has -8 or -6 or -7 if his visual acuity is at least 6/9 - 70%. There is no logical reason for a refractive error limitations and so this point must be adopted as it is now into</p>

	the final regulation.	
response	<i>Noted</i>	
comment	300	comment by: <i>Lufthansa German Airlines</i>
	<p><b>Author:</b> Dr. Esther Stahl-Buhl, AMC Frankfurt  <b>Section:</b> Chapter B  AMC B to MED.B.065  1.1.2  <b>Page:</b> 57</p> <p><b>Relevant Text:</b>  At the initial assessment the examination should include ocular motility, binocular vision, colour vision and visual fields.</p> <p><b>Comment:</b></p> <p><b>Proposal:</b>  See above, the initial exam should be a comprehensive exam.  In worst case: The initial exam has to include on top of what is mentioned: Examination of the external eye, anatomy, media and funduscopy, binocular status.</p>	
response	<i>Partially accepted</i>	
	The items of the routine eye examination are part of the initial eye examination. This was obviously not clear and they are now repeated for the initial examination.	
comment	301	comment by: <i>Lufthansa German Airlines</i>
	<p><b>Author:</b> Dr. Esther Stahl-Buhl, AMC Frankfurt  <b>Section:</b> Chapter B  AMC B to MED.B.065  4.4.2  <b>Page:</b> 57</p> <p><b>Relevant Text:</b>  (i) If the better eye achieves distant visual acuity of 6/6 ( 1.0), corrected or uncorrected (iii) has no significant pathology</p> <p><b>Comment:</b></p> <p><b>Proposal:</b>  (i) Same as in 4)  (iii) This should include: no history of refractive surgery</p>	
response	<i>Not accepted</i>	
	Class 2 requirements have been aligned with ICAO class 2 standards. The focus in ICAO Annex 1 is on visual acuity only. Applicants after refractive surgery have to be assessed — but not in the context of this paragraph.	
comment	606	comment by: <i>Lufthansa German Airlines</i>

	<p><b>Author:</b> Dr. Esther Stahl-Buhl, AMC Frankfurt  <b>Section:</b> Chapter B                  AMC B to MED.B.065                  3  <b>Page:</b> 57</p> <p><b>Relevant Text:</b>  <i>Visual Acuity:</i>                  If an applicant with amblyopia, the visual acuity of the amblyopic eye shall 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 an be demonstrated</p> <p><b>Comment:</b></p> <p><b>Proposal:</b>                  As for class 1 I suggest, the visual acuity for the better eye should be 6/6 without correction or if with correction, visual acuity without correction on the better eye should at least be 0.5 ( 6/12 ). ( see my comment for class 1 above.)</p> <p>The same applies for substandard vision:</p>
response	<p><i>Not accepted</i></p> <p>The focus is on visual acuity with correction also for applicant with amblyopia.</p>

comment	607	comment by: <i>Lufthansa German Airlines</i>
	<p><b>Author:</b> Dr. Esther Stahl-Buhl, AMC Frankfurt  <b>Section:</b> Chapter B                  AMC B to MED. B. 065                  5  <b>Page:</b> 57</p> <p><b>Relevant Text:</b>                  Eye surgery</p> <p><b>Comment:</b></p> <p><b>Proposal:</b>                  Standards or criteria for evaluation of post -surgery status; refractive surgery, cataract- glaucoma or retinal-surgery should be the <b>same</b> as in class 1. ( See above)</p>	
response	<p><i>Noted</i></p> <p>The criteria for a class 1 assessment after eye surgery are not accepted for class 2. However, a paragraph has been added to state that an examination by an ophthalmologist is needed for the assessment.</p>	

comment	608	comment by: <i>Lufthansa German Airlines</i>
	<p><b>Author:</b> Dr. Esther Stahl-Buhl, AMC Frankfurt</p>	

**Section:**

There are no limits for refractive errors for Class 2

**Page:****Relevant Text:****Comment:**

I suggest to reimplement the "old" limits of class2.

Meaning: An applicant can be assessed as fit with a refractive error of +5 /-8 dioptres and anisometropia and astigmatism not above 3 dioptres.

If at renewal exam myopia exceeds 8 dioptres and anisometropia or astigmatism exceed 3dioptres, an ophthalmological comprehensive eye exam and evaluation of the case is required to obtain medical fitness. A AMC or AME may then attest medical fitness.

The reason, why I would suggest a limit of + 5 diopters, is a significant ring scotoma due to high correcting glasses, especially in the + area, increasing prismatic deviation due to high correcting glasses and an increasingly narrow anterior chamber angle. The same applies to high values of myopia, not talking about retinal complications.

response *Not accepted*

Class 2 requirements have been aligned with ICAO Annex 1 where only the corrected visual acuity is mentioned for a fit assessment.

comment

609

comment by: *Lufthansa German Airlines*

**Author:** Dr. Esther Stahl-Buhl, AMC Frankfurt

**Section:**

There are also no comments concerning keratoconus.

**Page:****Relevant Text:**

If the diagnosis of keratoconus is established, a comprehensive ophthalmological exam is required and an AMC or AME may attest medical fitness.

response *Noted*

Please see response to comment No 608.

comment

655

comment by: *Royal Danish Aeroclub*

**AMC B TO MED.B.065(4)(4.1)**

The text say: " Reduced stereopsis, abnormal.....".

It is not a demand to have stereopsis for Class1 or Class 2 medical.

**Suggestion:**

To replace the words "Reduced stereopsis" with "Substandard binocular function".

response *Not accepted*

We do not think that this change is necessary at this moment.

comment

934

comment by: *European Society of Space and Aviation Medicine (ESAM)*

**Author: European Society of Space and Aviation Medicine (ESAM)-  
Group Ophthalmology -**

**Section: 2**

**Class 2**

- 1) Subpart B - Requirements for medical certificates  
MED.B.065  
c (2)
- 2) AMC A to MED.B.065  
6.1

**Page:** 16 and 57

**Relevant Text:**

(c) (2) In the case of class 2 medical certificates, 6/12 or better in each eye separately and visual acuity with both eyes shall be 6/9 or better. An applicant with substandard vision in one eye may be assessed as fit subject to a satisfactory ophthalmic assessment.

4. Substandard Vision

4.1 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.

**Comment:**

Substandard Vision in one eye can mean monocularly, or functional monocularly, or severe amblyopia.

The reduced vision is a major impact on visual functions as the binocular vision is a summation of visual functions of both eyes.

Nearly all thresholds of monocular visual function are with normal binocular vision better than monocular

The absolute threshold for light is 1,5-1,8 times better

The contrast recognition is 1,5-1,7 times better

The resolution is 1,1 times better

The recognition of moving stimulus is 1,9 times better.

The visual field is reduced.

The blind spot can mostly not be compensated.

Dille and Booze published in 1979 (1974-1976) the "Accident experience of civilian pilots with static physical defects", FAA Office of Aviation Medicine Report No. AM-79-19, 77-20, 76-7. They showed that pilots with blindness or absence of one eye had significantly higher accident observed-to-expected ratios and higher rates per 100.000 hours. Airmen with deficient distant vision had significantly higher observed-to-expected ratios and higher rates per 100.000 hours (0,001).

In 1984 Dille and Booze published "The 1980 and 1981 Accident Experience of Civil Airmen with Selected Visual Pathology", Aviat. Space Environ. Med. 1984: 55:966-9

In the years 1980 and 1981 monocular and amblyopic airmen had higher accident rates than did the total airmen population.

Mayer and Lane published in 1973 "Monocular Pilots - a Follow-up Study", *Aerosp. Med.* 44: 1070-1074. The number of monocular pilots who applied for a student pilot license after having obtained a waiver was proportionately less (84%) than the number of controls who applied (91%). More monocular pilots than control pilots became endorsed on more than one aircraft. There is a suspicion, that monocular pilots were involved in somewhat more hazardous events than control pilots.

The proposal is slightly above the requirements for car drivers who move in just two dimensions with additional clues that are usually not available in the air. A visual acuity of 0.3 is substandard vision or amblyopia.

**Proposal:**

Monocularity is not acceptable for an initial class 2 applicant certification.

In the case of a substandard vision in a class 2 applicant, one eye should have a visual acuity of at least 0.5 (6/12) with or without correction and the better other eye at least 0.5 (6/12) uncorrected or corrected. Visual acuity with both eyes shall be 1.0 (6/6)!! or better uncorrected or corrected. Ocular misalignment where the fusional reserves are sufficient to prevent asthenopia and diplopia may be acceptable. Binocular vision shall be normal.

response *Not accepted*

The text of the rules and AMC for class 2 was drafted to reflect ICAO class 1 standards. The Agency is of the opinion that this has been achieved and that additions may conflict with the intention to match ICAO rules.

comment

936

comment by: *European Society of Space and Aviation Medicine (ESAM)*

**Author: European Society of Space and Aviation Medicine (ESAM)-  
Group Ophthalmology -**

**Section: 1**

Subpart B

**Class 2**

MED.B.065

2

**Page: 57**

**Relevant Text:**

*3. Visual acuity*

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

4.2 An applicant with substandard vision in 1 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.

**Comment:**

The proposal is slightly above the requirements for car drivers who move in just two dimensions with additional clues that are usually not available in the air. A visual acuity of 0.3 is substandard vision or amblyopia.

4.1 Describes a possible potential functional monocularly through strabism (ocular misalignment where the fusional reserves are sufficient to prevent asthenopia and diplopia may be acceptable). If one eye is excluded, there is no diplopia and no asthenopia. Therefore the binocular vision, which means the vision with both eyes at the same time, must be normal.

**Proposal:**

Delete 4.2 and keep 4.1 in a changed version and 4.3

4. Substandard Vision

4.1 Monocularly is not acceptable for an initial class 2 applicant certification.

In the case of a substandard vision in a class 2 applicant, one eye shall have a visual acuity of at least 0.3 with or without correction and the better other eye at least 1.0 (6/6) uncorrected or corrected. Visual acuity with both eyes shall be 1.0 (6/6)!! or better uncorrected or corrected. Ocular misalignment where the fusional reserves are sufficient to prevent asthenopia and diplopia may be acceptable. Binocular vision shall be normal. An opthalmological exam and evaluation shall be required in order to obtain medical fitness.

response *Noted*

Please see response to comment No 934.

comment

940

comment by: *European Society of Space and Aviation Medicine (ESAM)*

**Author: European Society of Space and Aviation Medicine (ESAM)-Group Ophthalmology -**

**Section: 1**

**Subpart B**

- 1) MED.B.065  
g (3)
- 2) AMC to MED.B.065  
7

**Page: 16 and 46 and page 57**

**Relevant Text:**

•1) Applicants for class 1 medical certificate with a clinical diagnosis of keratoconus may be assessed as fit subject to a satisfactory examination by an ophthalmologist.

•2) *Keratoconus:*

Applicants with keratoconus may be considered for a fit assessment, if the visual requirements are met with the use of corrective lenses and periodic review is undertaken by an ophthalmologist.

3) No text concerning keratoconus in class 2 was found on page 57.

**Comment:**

If applicants for class 1 and 2 can be assessed as fit with the clinical diagnosis of keratoconus, we will "produce" a considerable amount of pilots, who will for sure later on have to be assessed as unfit, as even with contact lenses their visual requirements will not be sufficient any longer. Many eyes with

keratoconus in young patients will end in keratoplasty which also makes unfit.

**Proposal:**

Applicants class 1 and class 2! with the diagnosis of keratoconus are assessed as unfit. At revalidation examination applicants for a class 1 and class 2 medical certificate with a clinical diagnosis of keratoconus may be assessed as fit subject to a satisfactory examination by an ophthalmologist.

•1) *Keratoconus:*

At renewal examinations applicants with keratoconus may be considered for a fit assessment, if the visual requirements are met with the use of corrective lenses and at least a yearly examination is undertaken by an ophthalmologist.

response *Noted*

Please see response to comment No 936.

comment

947

comment by: *European Society of Space and Aviation Medicine (ESAM)*

**Author: European Society of Space and Aviation Medicine (ESAM) - Group Ophthalmology**

**Section: 1**

MED.B.065 - Visual System - class 2 medical certificates

**Page: 57**

**Relevant Text:**

Eye examination

1.1 At each aeromedical revalidation examination an assessment of the visual fitness of the license 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.

**Comment:**

If eye drops are needed to be taken for a longer period of time, a major ophthalmological disease is usually the cause. Especially for inflammations or neurological diseases steroids are very often used. Steroids can have many side effects which often occur as high intraocular pressure (steroidresponder) with corneal edema and reduced visual acuity. Also the oral or iv. medication of steroids can have side effects such as diabetes mellitus and or seizures.

If eye drops or oral medication are used to treat a glaucoma it is important to know whether there are visual field defects or an elevation of the pressure that cause visual problems (reduced visual acuity, halos ...) or even headache and/or gastrointestinal problems.

The routine ophthalmological examinations every second year has been dropped by the medical subcommittee of the JAA, to not put burden on the pilots who always see well and do not have any diseases or complications. But therefore the idea was to send people to the ophthalmologist if problems occur. Medication for a longer period of time is this kind of problem which were meant and which have to be closer looked at.

response	<p><b>Proposal:</b> If an applicant for a class 2 medical certificate needs oral or iv. medication for his/her eyes or affecting his/her eyes or if any of these pilots needs eye drops, he or she should report this to his/her AME. If the eye medication is prescribed for more than two weeks, or the eye medication has changed a comprehensive eye examination has to be performed.</p> <p><i>Noted</i></p> <p>Medication is covered under MED.A.025 (b).</p>	
comment	958	<p>comment by: <i>European Society of Space and Aviation Medicine (ESAM)</i></p> <p><b>Author: European Society of Space and Aviation Medicine (ESAM)- Group Ophthalmology -</b></p> <p><b>Section:</b> Chapter B AMC B to MED.B.065 1.1.2</p> <p><b>Page:</b> 57</p> <p><b>Relevant Text:</b> At the initial assessment the examination should include ocular motility, binocular vision, colour vision and visual fields.</p> <p><b>Comment:</b> The initial examination should be a comprehensive eye examination performed by an ophthalmologist. Reason: A lot of problems we usually run into later during two examinations can be prevented by checking properly at the first exam. E.g. strabism, decompensated heterophoria, diplopia, glaucoma, monocularity... Besides in the U.K. no general practitioners are trained to do an eye examination. Especially at the initial examination diseases or risk factors that could cause in-flight problems could be seen and additional restrictions or examinations can become necessary.</p> <p><b>Proposal:</b> A comprehensive eye examination shall be performed by an ophthalmologist and shall be part of the initial examination. A comprehensive eye exam shall be performed later, if indicated by the AME or ophthalmologist.</p> <p><i>Noted</i></p> <p>Please see response to comment No 300.</p>
comment	959	<p>comment by: <i>European Society of Space and Aviation Medicine (ESAM)</i></p> <p><b>Author: European Society of Space and Aviation Medicine (ESAM) - Group Ophthalmology-</b></p> <p><b>Section:</b> Chapter B AMC B to MED.B.065</p>

3

**Page:** 57**Relevant Text:***Visual Acuity:*

If an applicant with amblyopia, the visual acuity of the amblyopic eye shall 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

**Comment:**

Substandard Vision in one eye can mean monocularly, or functional monocularly, or severe amblyopia.

The reduced vision is a major impact on visual functions as the binocular vision is a summation of visual functions of both eyes.

Nearly all thresholds of monocular visual function are with normal binocular vision better as monocular

The absolute threshold for light is 1,5-1,8 times better

The contrast recognition is 1,5-1,7 times better

The resolution is 1,1 times better

The recognition of moving stimulus is 1,9 times better.

The visual field is reduced.

The blind spot can mostly not be compensated.

Dille and Booze published in 1979 (1974-1976) the "Accident experience of civilian pilots with static physical defects", FAA Office of Aviation Medicine Report No. AM-79-19, 77-20, 76-7. They showed that pilots with blindness or absence of one eye had significantly higher accident observed-to-expected ratios and higher rates per 100.000 hours. Airmen with deficient distant vision had significantly higher observed-to-expected ratios and higher rates per 100.000 hours (0,001).

One monocular pilot, performing agricultural operation, taxied into another aircraft.

The FAA accident investigator noted the medical defect in his report of the accident, advised the Regional Flight Surgeon, a recommended re-evaluation of the pilot through medical flight test procedure.

In 1984 Dille and Booze published "The 1980 and 1981 Accident Experience of Civil Airmen with Selected Visual Pathology", *Aviat. Space Environ. Med.* 1984: 55:966-9

In the years 1980 and 1981 monocular and amblyopic airmen had higher accident rates than did the total airmen population.

Mayer and Lane published in 1973 "Monocular Pilots - a Follow-up Study", *Aerosp. Med.* 44: 1070-1074. The number of monocular pilots who applied for a student pilot license after having obtained a waiver was proportionately less (84%) than the number of controls who applied (91%). More monocular pilots than control pilots became endorsed on more than one aircraft. There is a suspicion, that monocular pilots were involved in somewhat more hazardous events than control pilots.

**Proposal:**

In the case of amblyopia in a class 2 applicant, the better other eye shall have

response	<p>a visual acuity of at least 0.5 uncorrected or corrected. Visual acuity with both eyes shall be 1.0 or better uncorrected or corrected.</p> <p><i>Noted</i></p> <p>Please see response to comment No 934.</p>				
comment	<table border="1"> <tr> <td data-bbox="343 392 470 515">960</td> <td data-bbox="470 392 1455 515">comment by: <i>European Society of Space and Aviation Medicine (ESAM)</i></td> </tr> <tr> <td colspan="2" data-bbox="343 515 1455 2018"> <p><b>Author: European Society of Space and Aviation Medicine (ESAM)- Group Ophthalmology -</b></p> <p><b>Section:</b> There are no limits for refractive errors for Class 2</p> <p><b>Page:</b></p> <p><b>Relevant Text:</b></p> <p><b>Comment:</b> The refractive limits of the amendment 5 should be reimplemented. If a high refraction error exist a significant ring scotoma due to high correcting glasses, especially in the + area, increasing prismatic deviation due to high correcting glasses and an increasingly narrow anterior chamber angle can exist. The same applies to high values of myopia, not talking about retinal complications. The higher the myopia the higher the probability of developing retinal scars (also in the area of macula and peripheral degenerations with following retinal detachments. Especially the narrow angle of the eye with the high hyperopia which is much too short can result in an acute glaucoma with blurred vision, severe headaches and symptoms of an acute abdomen. If astigmatism of more than 2 diopters is corrected by glasses an anamorphic image with compression and stretching of the perceived objectives results. This can lead amongst other things to problems by the estimation of distances and height. Also kinetosis can occur under these circumstances. If an anisometropia of more than 2 diopters exists there will result a different prismatic deviation in the outer periphery of the glasses depending on the different viewing directions. The pair of eyes must conduct different motions of vergence depending on the correction of the glasses and the viewing direction. An anisometropia can cause aniseikonia. Aniseikonia exists if the subjectively with both eyes perceived retinal image sizes are disparate. The glass correction to correct myopia leads to a reduction in image size. If there is a difference in the power of the glass correction the perceived retinal images are also different. As a result the fusion of the two retinal images can be complicated or even impossible. This can lead to diplopia or suppression of the image of one eye.</p> <p><b>Proposal:</b> An applicant can be assessed as fit with a refractive error of +5 /-8 dioptrres and anisometropia and astigmatism not above 3 dioptrres. Refraction exceeding -8.0 diopters of myopia and 3 diopters of astigmatism and anisometropia makes the applicant unfit for class 2. In case of astigmatism or anisometropia above 3 diopters, the applicant may be assessed as fit if the comprehensive ophthalmological examination of the revalidation examination shows no elevated intraocular pressure, no myopic degenerations , no asthenopia, nor any other pathological conditions. Contact lenses should be considered.</p> </td> </tr> </table>	960	comment by: <i>European Society of Space and Aviation Medicine (ESAM)</i>	<p><b>Author: European Society of Space and Aviation Medicine (ESAM)- Group Ophthalmology -</b></p> <p><b>Section:</b> There are no limits for refractive errors for Class 2</p> <p><b>Page:</b></p> <p><b>Relevant Text:</b></p> <p><b>Comment:</b> The refractive limits of the amendment 5 should be reimplemented. If a high refraction error exist a significant ring scotoma due to high correcting glasses, especially in the + area, increasing prismatic deviation due to high correcting glasses and an increasingly narrow anterior chamber angle can exist. 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<p><b>Author: European Society of Space and Aviation Medicine (ESAM)- Group Ophthalmology -</b></p> <p><b>Section:</b> There are no limits for refractive errors for Class 2</p> <p><b>Page:</b></p> <p><b>Relevant Text:</b></p> <p><b>Comment:</b> The refractive limits of the amendment 5 should be reimplemented. If a high refraction error exist a significant ring scotoma due to high correcting glasses, especially in the + area, increasing prismatic deviation due to high correcting glasses and an increasingly narrow anterior chamber angle can exist. The same applies to high values of myopia, not talking about retinal complications. The higher the myopia the higher the probability of developing retinal scars (also in the area of macula and peripheral degenerations with following retinal detachments. Especially the narrow angle of the eye with the high hyperopia which is much too short can result in an acute glaucoma with blurred vision, severe headaches and symptoms of an acute abdomen. If astigmatism of more than 2 diopters is corrected by glasses an anamorphic image with compression and stretching of the perceived objectives results. This can lead amongst other things to problems by the estimation of distances and height. Also kinetosis can occur under these circumstances. If an anisometropia of more than 2 diopters exists there will result a different prismatic deviation in the outer periphery of the glasses depending on the different viewing directions. The pair of eyes must conduct different motions of vergence depending on the correction of the glasses and the viewing direction. An anisometropia can cause aniseikonia. Aniseikonia exists if the subjectively with both eyes perceived retinal image sizes are disparate. The glass correction to correct myopia leads to a reduction in image size. If there is a difference in the power of the glass correction the perceived retinal images are also different. As a result the fusion of the two retinal images can be complicated or even impossible. This can lead to diplopia or suppression of the image of one eye.</p> <p><b>Proposal:</b> An applicant can be assessed as fit with a refractive error of +5 /-8 dioptrres and anisometropia and astigmatism not above 3 dioptrres. Refraction exceeding -8.0 diopters of myopia and 3 diopters of astigmatism and anisometropia makes the applicant unfit for class 2. In case of astigmatism or anisometropia above 3 diopters, the applicant may be assessed as fit if the comprehensive ophthalmological examination of the revalidation examination shows no elevated intraocular pressure, no myopic degenerations , no asthenopia, nor any other pathological conditions. Contact lenses should be considered.</p>					

response	<i>Noted</i>	
	The statement is correct. Class 2 requirements were aligned with ICAO class 2 standards where no limit for refractive errors is set, provided that the visual acuity rules are complied with.	
comment	961	comment by: <i>European Society of Space and Aviation Medicine (ESAM)</i>
	<p><b>Author: European Society of Space and Aviation Medicine (ESAM)-Group Ophthalmology -</b></p> <p><b>Section: 1</b>  <b>Chapter B</b>  <b>AMC B to MED.B.065</b>  <b>Class 2 medical certificates</b>  <b>5 - Eye surgery</b></p> <p><b>Page: 57</b></p> <p><b>Relevant Text:</b>  5.1 - after refractive surgery, a fit assessment may be considered provided that there is stability of refraction, there are no postoperative complications and no increase in glare sensitivity.</p> <p>Comment:  Standards or criteria for evaluation of post- surgery status; refractive surgery, cataract- glaucoma or retinal-surgery should be the same as in class 1. After refractive surgery a period of 6 months is needed for recovery of the visual function of the eye. Corneal scarring, flap problems, refraction postoperative instability , sicca problems most often occur during the first months post surgery. Visual stability cannot be achieved before a period of 6 months. Corneal thickness postoperatively should not be thinner than 420 µm!</p> <p>Proposal:  Replace the above text by the text for class 1 and add the following text:  After refractive surgery a fit assessment may be granted earliest 6 months post surgery.  After refractive surgery, a fit assessment may be considered provided that:  Preoperative refraction was no greater than + 5 or - 8 diopters.  (vii) Postoperative corneal thickness should be taken into account. .</p>	
response	<i>Noted</i>	
	Ophthalmological examination will be done after refractive surgery (1.1) and fitness to fly will depend on the outcome of this examination.	
comment	962	comment by: <i>European Society of Space and Aviation Medicine (ESAM)</i>
	<p><b>Author: European Society of Space and Aviation Medicine (ESAM)-Group Ophthalmology-</b></p> <p><b>Section: 1</b>  <b>Chapter B</b>  <b>AMC B to MED.B.065</b></p>	

**Class 2 medical certificates**  
**5 - Eye surgery**

**Page: 57**

**Text: 5.2 After cataract, retinal or glaucoma surgery a fit assessment may be considered once recovery is complete.**

**Comment:**

Standards or criteria for evaluation of post- surgery status; refractive surgery, cataract- glaucoma or retinal-surgery should be the same as in class 1  
 Recovery time after cataract surgery usually amounts to three months, after retinal and glaucoma surgery amounts to 6 months. Tinted lenses impair flight safety by excluding (!) perception of visual objects at a certain range of nanometers.

**Proposal:**

A fit assessment after cataract surgery may be granted 3 months post surgery, a fit assessment after glaucoma or retinal surgery may be granted 6 months post surgery by ophthalmological evaluation.

Cataract surgery: Only monofocal, non tinted intraocular lenses are allowed.

If however a tinted intraocular lens has been implanted, the blue-yellow colour vision axis has to be evaluated and has to be normal.

response

*Noted*

Please see response to comment No 961.

comment

1080

comment by: *Aviation Ophthalmology Sweden*

**Relevant Text:**

**5.Eye Surgery**

**5.2.** After cataract, retinal or glaucoma surgery a fit assignment may be considered once recovery is complete.

**Comment:**

There is no definition of **complete recovery**. Amongst the operations cited does cataract surgery have a separate place. It is the **only** operation that might significantly improve and restore visual acuity and function. In contrast to this, both glaucoma and retinal surgery aim to preserve the visual function at the present stage and to prevent further deterioration.

**Proposal:**

**5.2.** After cataract, retinal or glaucoma surgery a fit assignment may be considered **as soon the visual requirements are fulfilled and the visual acuity and function has stabilized** .

response

*Noted*

The visual requirements must be met for a fit assessment. An ophthalmological examination will be performed after eye surgery the outcome of which will be decisive for a fit/unfit assessment.

comment

1364

comment by: *ophthalmologie aerospace medecin*

**Comment:**

A lot of problems we run into later on, could be prevented, if the initial

	<p>examination was a comprehensive one. General practitioners are in no way trained to perform a thorough eye exam. They cannot detect diseases or risk factors that could cause in-flight problems later. They also cannot see, which <b>ophthalmological</b> condition needs additional restrictions or additional eye examinations.</p> <p><b>Proposal:</b> For a class 2 medical certificate a comprehensive eye examination shall form part of the initial examination and if required.</p>
response	<p><i>Noted</i></p> <p>The requirements were aligned with ICAO class 2 standards. The examination criteria in this AMC have been amended for more clarity.</p>

comment	<p>1374</p> <p>comment by: <i>ophthalmologie aerospace medecin</i></p> <p><b>Comment:</b> If eye drops are needed to be taken for a longer period of time, a major ophthalmological disease is usually the cause. Especially for inflammations or neurological diseases steroids are very often used. Steroids can have many side effects which often occur as high intraocular pressure (steroidresponder) with corneal edema and reduced visual acuity. Also the oral or iv. medication of steroids can have side effects such as diabetes mellitus and or seizures.</p> <p>If eye drops or oral medication are used to treat a glaucoma it is important to know whether there are visual field defects or an elevation of the pressure that cause visual problems (reduced visual acuity, halos ...) or even headache and/or gastrointestinal problems.</p> <p>The routine ophthalmological examinations every second year has been dropped by the medical subcommittee of the JAA, to not put burden on the pilots who always see well and do not have any diseases or complications. But therefore the idea was to send people to the ophthalmologist if problems occur. Medication for a longer period of time is this kind of problem which were meant and which have to be closer looked at.</p> <p><b>Proposal:</b> If an applicant for a class 2 medical certificate needs oral or iv. medication for his/her eyes or affecting his/her eyes or if any of these pilots needs eye drops, he or she should report this to his/her AME. If the eye medication is prescribed for more than two weeks, or the eye medication has changed a comprehensive eye examination has to be performed.</p>
response	<p><i>Noted</i></p> <p>Please see response to comment No 947.</p>

comment	<p>1384</p> <p>comment by: <i>ophthalmologie aerospace medecin</i></p> <p><b>Comment:</b> The initial examination should be a comprehensive eye examination performed by an ophthalmologist. Reason: A lot of problems we usually run into later during two examinations can be prevented by checking properly at the first exam. E.g. strabism, decompensated heterophoria, diplopia, glaucoma, monocularity... Besides in the U.K. no general practitioners are trained to do an eye</p>
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examination. Especially at the initial examination diseases or risk factors that could cause in-flight problems could be seen and additional restrictions or examinations can become necessary.

**Proposal:**

A comprehensive eye examination shall be performed by an ophthalmologist and shall be part of the initial examination. A comprehensive eye exam shall be performed later, if indicated by the AME or ophthalmologist.

response

*Noted*

Please see response to comment No 958.

comment

1385

comment by: *ophthalmologie aerospace medecin*

**Comment:**

Substandard Vision in one eye can mean monocularly, or functional monocularly, or severe amblyopia.

The reduced vision is a major impact on visual functions as the binocular vision is a summation of visual functions of both eyes.

Nearly all thresholds of monocular visual function are with normal binocular vision better as monocular

The absolute threshold for light is 1,5-1,8 times better

The contrast recognition is 1,5-1,7 times better

The resolution is 1,1 times better

The recognition of moving stimulus is 1,9 times better.

The visual field is reduced.

The blind spot can mostly not be compensated.

Dille and Booze published in 1979 (1974-1976) the "Accident experience of civilian pilots with static physical defects", FAA Office of Aviation Medicine Report No. AM-79-19, 77-20, 76-7. They showed that pilots with blindness or absence of one eye had significantly higher accident observed-to-expected ratios and higher rates per 100.000 hours. Airmen with deficient distant vision had significantly higher observed-to-expected ratios and higher rates per 100.000 hours (0,001).

One monocular pilot, performing agricultural operation, taxied into another aircraft.

The FAA accident investigator noted the medical defect in his report of the accident, advised the Regional Flight Surgeon, a recommended re-evaluation of the pilot through medical flight test procedure.

In 1984 Dille and Booze published "The 1980 and 1981 Accident Experience of Civil Airmen with Selected Visual Pathology", Aviat. Space Environ. Med. 1984: 55:966-9

In the years 1980 and 1981 monocular and amblyopic airmen had higher accident rates than did the total airmen population.

Mayer and Lane published in 1973 "Monocular Pilots - a Follow-up Study", Aerosp. Med. 44: 1070-1074. The number of monocular pilots who applied for a student pilot license after having obtained a waiver was proportionately less (84%) than the number of controls who applied (91%). More monocular pilots than control pilots became endorsed on more than one aircraft. There is a suspicion, that monocular pilots were involved in somewhat more hazardous events than control pilots.

	<p><b>Proposal:</b> In the case of amblyopia in a class 2 applicant, the better other eye shall have a visual acuity of at least 0.5 uncorrected or corrected. Visual acuity with both eyes shall be 1.0 or better uncorrected or corrected.</p>
response	<p><i>Noted</i></p>
	<p>Please see response to comment No 934.</p>

comment	1386	comment by: <i>ophthalmologie aerospace medecin</i>
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**Comment:**  
The refractive limits of the amendment 5 should be reimplemented. If a high refraction error exist a significant ring scotoma due to high correcting glasses, especially in the + area, increasing prismatic deviation due to high correcting glasses and an increasingly narrow anterior chamber angle can exist. The same applies to high values of myopia, not talking about retinal complications. The higher the myopia the higher the probability of developing retinal scars (also in the area of macula and peripheral degenerations with following retinal detachments. Especially the narrow angle of the eye with the high hyperopia which is much too short can result in an acute glaucoma with blurred vision, severe headaches and symptoms of an acute abdomen.  
If astigmatism of more than 2 diopters is corrected by glasses an anamorphic image with compression and stretching of the perceived objectives results. This can lead amongst other things to problems by the estimation of distances and height. Also kinetosis can occur under these circumstances.  
If an anisometropia of more than 2 diopters exists there will result a different prismatic deviation in the outer periphery of the glasses depending on the different viewing directions. The pair of eyes must conduct different motions of vergence depending on the correction of the glasses and the viewing direction. An anisometropia can cause aniseikonia. Aniseikonia exists if the subjectively with both eyes perceived retinal image sizes are disparate. The glass correction to correct myopia leads to a reduction in image size. If there is a difference in the power of the glass correction the perceived retinal images are also different. As a result the fusion of the two retinal images can be complicated or even impossible. This can lead to diplopia or suppression of the image of one eye.

**Proposal:**  
An applicant can be assessed as fit with a refractive error of +5 /-8 dioptrés and anisometropia and astigmatism not above 3 dioptrés. Refraction exceeding -8.0 diopters of myopia and 3 diopters of astigmatism and anisometropia makes the applicant unfit for class 2. The applicant may be assessed as fit if the comprehensive ophthalmological examination of the revalidation examination shows no elevated intraocular pressure, no myopic degenerations and no any other pathological conditions.

response	<p><i>Noted</i></p>
	<p>Please see response to comment No 960.</p>

comment	1387	comment by: <i>ophthalmologie aerospace medecin</i>
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**Comment:**  
Standards or criteria for evaluation of post- surgery status; refractive surgery,

cataract- glaucoma or retinal-surgery should be the same as in class 1.  
After refractive surgery a period of 6 months is needed for recovery of the visual function of the eye. Corneal scarring, flap problems, refraction postoperative instability , sicca problems most often occur during the first months post surgery. Visual stability cannot be achieved before a period of 6 months. Corneal thickness postoperatively should not be thinner than 420 µm!

**Proposal:**

Replace the above text by the text for class 1 and add the following text:  
After refractive surgery a fit assessment may be granted earliest 6 months post surgery.

After refractive surgery, a fit assessment may be considered provided that:

Preoperative refraction was no greater than + 5 or – 8 diopters.

(vii) Postoperative corneal thickness should be taken into account. .

response *Noted*

Please see response to comment No 962.

comment

1388

comment by: *ophthalmologie aerospace medecin*

**Comment:**

Standards or criteria for evaluation of post- surgery status; refractive surgery, cataract- glaucoma or retinal-surgery should be the same as in class 1

Recovery time after cataract surgery usually amounts to three months, after retinal and glaucoma surgery amounts to 6 months. Tinted lenses **severely** impair flight safety by excluding (!) perception of visual objects at a certain range of nanometers.

**Proposal:**

A fit **assessEment** after cataract surgery may be granted 3 months post surgery, a fit assessment after glaucoma or retinal surgery may be granted 6 months post surgery by ophthalmological evaluation.

Cataract surgery: Only monofocal, non tinted intraocular lenses are allowed.

If however a tinted intraocular lens has been implanted, the blue-yellow colour vision axis has to be evaluated and has to be normal.

response *Noted*

Please see response to comment No 607.

comment

1911

comment by: *Österr. Ophthalmologische Gesellschaft*

Here the perimetry is missing

Demand: Inserting the visual field in class 2, since it is also required for LPL medical certificates

response *Noted*

Paragraph 1.1 has been amended for clarity.

comment

2038

comment by: *Dr. med. Hans Brandl*

**In section 1.2** At the initial assessment the examination should include ocular motility, binocular vision, colour vision and visual fields.

response	<p>please delete the word "and" before "visual fields" and add after the term "visual fields" the following new words: tonometry, glare sensitivity and mesopic contrast sensitivity.</p> <p>The new complete text in section 1.2 should read as follows: 1.2 At the initial assessment the examination should include ocular motility, binocular vision, colour vision, visual fields, tonometry, glare sensitivity and mesopic contrast sensitivity.</p>	
	<p><i>Not accepted</i></p>	
	<p>The class 2 requirements/AMC have been aligned with ICAO class 2 standards.</p>	
comment	2041	comment by: <i>Dr. med. Hans Brandl</i>
	<p>After section 2 (iv) further examination on clinical indication please add the following text parts as separate new sections 2 (v); 2 (vi) and 2 (vii):</p> <p>(v) tonometry (at initial and at revalidation in 24-months intervals); (vi) glare sensitivity is within normal standards (at initial and at revalidation in 24-months intervals); (vii) mesopic contrast sensitivity with following defined accurate threshold values:</p> <ul style="list-style-type: none"> <li>- mesopic contrast sensitivity value up to 1:2.7 ----&gt;applicant to be assessed as fit;</li> <li>- mesopic contrast sensitivity value up to 1:5 ----&gt; for class 2 applicants a mesopic contrast sensitivity value of 1:5 is requested as absolute compulsory precondition in order to pass the test and to be assessed as fit. This applies for initial examination as well as for revalidation examination. A revalidation in 24-months interval is required.</li> <li>- mesopic contrast sensitivity value up to 1:23 ----&gt;applicant to be assessed as absolutely unfit;</li> </ul>	
response	<p><i>Not accepted</i></p>	
	<p>The class 2 requirements/AMC have been aligned with ICAO class 2 standards.</p>	
comment	2043	comment by: <i>Dr. med. Hans Brandl</i>
	<p>In section 5.1 After refractive surgery, a fit assessment may be considered provided that there is stability of refraction, there are no postoperative complications and no increase in glare sensitivity. please add after the term "glare sensitivity." the following new sentence: Mesopic contrast sensitivity value up to 1:5: A revalidation in 24-months interval is required.</p> <p>Rational: Mesopic contrast sensitivity value of 1 : 5 is requested as absolute compulsory precondition in order to pass the test and to be assessed as fit. This applies for initial examination as well as for revalidation examination.</p> <p>The new complete text in section 5.1 should read as follows: 5.1 After refractive surgery, a fit assessment may be considered provided that there is stability of refraction, there are no postoperative complications and no increase in glare sensitivity. Mesopic contrast sensitivity value up to 1:5: A</p>	

response	<p>revalidation in 24-months interval is required.</p> <p><i>Not accepted</i></p> <p>The class 2 requirements/AMC have been aligned with ICAO class 2 standards.</p>	
comment	2045	<p>comment by: <i>Dr. med. Hans Brandl</i></p> <p>In section 5.2 After cataract, retinal or glaucoma surgery a fit assessment may be considered once recovery is complete.  please add after the term "is complete." the following new text:  A fit assessment may be considered provided if  (i) glare sensitivity is within normal standards  (ii) mesopic contrast sensitivity value up to 1:5  These ophthalmological examinations have to be performed at initial and at revalidation examinations.</p> <p>Rational:  Due to surgery an opacity of lens can develop which may have negative effects on the individual glare sensitivity as well as on the mesopic contrast sensitivity.</p> <p>The new complete text in section 5.2 should read as follows:  5.2 After cataract, retinal or glaucoma surgery a fit assessment may be considered once recovery is complete. A fit assessment may be considered provided if  (i) glare sensitivity is within normal standards  (ii) mesopic contrast sensitivity value up to 1:5  These ophthalmological examinations have to be performed at initial and at revalidation examinations.</p>
response	<p><i>Not accepted</i></p> <p>The class 2 requirements/AMC have been aligned with ICAO class 2 standards.</p>	
comment	2180	<p>comment by: <i>Prof. Dr. Helmut Wilhelm, Centre of Ophthalmology, Tübingen</i></p> <p>There should be a hint on the definition of Refraction: <b>Refraction is the correction which allows the best visual acuity. The gold standard of refraction is subjective refraction, not objective refraction by autorefractometer.</b> Measurement by autorefractometer is never exact. A definition of refraction should be added.</p> <p>AMC A to MED.B.065  4.1 (iii) astigmatism. It is not necessary to define such a low limit for astigmatism. Many people with 3.5 D astigmatism have excellent vision. Corrected astigmatism is not a problem. If it is a problem the applicant will have reduced visual acuity. It must definitely be excluded that this paragraph urges an applicant to undergo refractive surgery. A pilot with 3 D Astigmatism and perfect contrast vision is much better than the one with zero astigmatism but haze after refractive surgery. <b>No applicant must be urged to worsen his eyes in order to be licensed as a pilot.</b> Suggestion: In case of astigmatism exceeding 2 D contrast vision must be tested as normal.</p> <p>4.1.(iv) A limit for anisometropia is not necessary. If the applicant corrects his/her anisometropia by refractive surgery he will considerably worsen his/her</p>

binocular vision and possibly not be able anymore to enjoy comfortable viewing. This point is definitely dangerous. If anisometropia can be corrected in way that the applicant has binocular (stereoscopic vision) it is not a problem. Anisometropia caused by different eye lengths by physical reasons can usually only be corrected with contact lenses, within this group of young people contact lenses will only work if there is no binocular vision.

Suggestion: In case of anisometropia there should be sufficient binocular vision.

**4.2 (iv) This is definitely wrong and it has to be considered as malpractice if the typical anisometropia of young people with binocular vision is corrected with contact lenses! This must under all circumstances be cancelled. It forces the doctor to worsen the pilot's vision.**

response

*Noted*

The definition of 'refractive error' is in MED.A.010.

AMC A to MED.065: The comments are noted and will be discussed in a future rulemaking task. For the time being the provisions for class 1 from JAR-FCL 3 will be kept.

comment

2300

comment by: *DLR*

The proposal is slightly above the requirements for car drivers who move in just two dimensions with additional clues that are usually not available in the air. A visual acuity of 0.3 is substandard vision or amblyopia.

4.1 Describes a possible potential functional monocularly through strabism (ocular misalignment where the fusional reserves are sufficient to prevent asthenopia and diplopia may be acceptable). If one eye is excluded, there is no diplopia and no asthenopia. Therefore the binocular vision, which means the vision with both eyes at the same time, must be normal.

Proposal:

Delete 4.2 and keep 4.1 in a changed version and 4.3

4. Substandard Vision

4.1 Monocularly is not acceptable for an initial class 2 applicant certification.

In the case of a substandard vision in a class 2 applicant, one eye shall have a visual acuity of at least 0.3 with or without correction and the better other eye at least 1.0 (6/6) uncorrected or corrected. Visual acuity with both eyes shall be 1.0 (6/6)!! or better uncorrected or corrected. Ocular misalignment where the fusional reserves are sufficient to prevent asthenopia and diplopia may be acceptable. Binocular vision shall be normal. An ophtalmological exam and evaluation shall be required in order to obtain medical fitness.

response

*Noted*

The class 2 requirements/AMC have been aligned with ICAO class 2 standards.

comment

2307

comment by: *DLR*

If applicants for class 1 and 2 can be assessed as fit with the clinical diagnosis of keratoconus, we will "produce" a considerable amount of pilots, who will for sure later on have to be assessed as unfit, as even with contact lenses their

visual requirements will not be sufficient any longer. Many eyes with keratoconus in young patients will end in keratoplasty which also makes unfit.

**Proposal:**

Applicants class 1 and class 2! with the diagnosis of keratoconus are assessed as unfit. At revalidation examination applicants for a class 1 and class 2 medical certificate with a clinical diagnosis of keratoconus may be assessed as fit subject to a satisfactory examination by an ophthalmologist.

1) Keratoconus:

**At renewal examinations applicants with keratoconus may be considered for a fit assessment, if the visual requirements are met with the use of corrective lenses and at least a yearly examination is undertaken by an ophthalmologist.**

response

Noted

The responsibility for future unfitness rests with the pilot, not with the AME who should, nevertheless, explain that future fitness may not be possible.

The class 2 requirements/AMC have been aligned with ICAO class 2 standards where yearly ophthalmological examinations are not required. However, in cases of pathological conditions that need close follow-up, an AME can (and has to) put a time limitation on the medical certificate.

comment

2323

comment by: DLR

If eye drops are needed to be taken for a longer period of time, a major ophthalmological disease is usually the cause. Especially for inflammations or neurological diseases steroids are very often used. Steroids can have many side effects which often occur as high intraocular pressure (steroidresponder) with corneal edema and reduced visual acuity. Also the oral or iv. medication of steroids can have side effects such as diabetes mellitus and or seizures.

If eye drops or oral medication are used to treat a glaucoma it is important to know whether there are visual field defects or an elevation of the pressure that cause visual problems (reduced visual acuity, halos ...) or even headache and/or gastrointestinal problems.

The routine ophthalmological examinations every second year has been dropped by the medical subcommittee of the JAA, to not put burden on the pilots who always see well and do not have any diseases or complications. But therefore the idea was to send people to the ophthalmologist if problems occur. Medication for a longer period of time is this kind of problem which were meant and which have to be closer looked at.

**Proposal:**

If an applicant for a class 2 medical certificate needs oral or iv. medication for his/her eyes or affecting his/her eyes or if any of these pilots needs eye drops, he or she should report this to his/her AME. If the eye medication is prescribed for more than two weeks, or the eye medication has changed a comprehensive eye examination has to be performed.

response

Noted

This is covered under MED.A.025 (b).

comment

2340

comment by: DLR

The initial examination should be a comprehensive eye examination performed by an ophthalmologist. Reason: A lot of problems we usually run into later during two examinations can be prevented by checking properly at the first exam. E.g. strabism, decompensated heterophoria, diplopia, glaucoma, monocularity...

Besides in the U.K. no general practitioners are trained to do an eye examination. Especially at the initial examination diseases or risk factors that could cause in-flight problems could be seen and additional restrictions or examinations can become necessary.

**Proposal:**  
A comprehensive eye examination shall be performed by an ophthalmologist and shall be part of the initial examination. A comprehensive eye exam shall be performed later, if indicated by the AME or ophthalmologist.

response

*Noted*

The paragraph on the initial examination has been amended for clarity purposes.

comment

2341	comment by: DLR
<p>Substandard Vision in one eye can mean monocularity, or functional monocularity, or severe amblyopia. The reduced vision is a major impact on visual functions as the binocular vision is a summation of visual functions of both eyes. Nearly all thresholds of monocular visual function are with normal binocular vision better as monocular The absolute threshold for light is 1,5-1,8 times better The contrast recognition is 1,5-1,7 times better The resolution is 1,1 times better The recognition of moving stimulus is 1,9 times better.</p> <p>The visual field is reduced. The blind spot can mostly not be compensated.</p> <p>Dille and Booze published in 1979 (1974-1976) the "Accident experience of civilian pilots with static physical defects", FAA Office of Aviation Medicine Report No. AM-79-19, 77-20, 76-7. They showed that pilots with blindness or absence of one eye had significantly higher accident observed-to-expected ratios and higher rates per 100.000 hours. Airmen with deficient distant vision had significantly higher observed-to-expected ratios and higher rates per 100.000 hours (0,001). One monocular pilot, performing agricultural operation, taxied into another aircraft. The FAA accident investigator noted the medical defect in his report of the accident, advised the Regional Flight Surgeon, a recommended re-evaluation of the pilot through medical flight test procedure. In 1984 Dille and Booze published "The 1980 and 1981 Accident Experience of Civil Airmen with Selected Visual Pathology", Aviat. Space Environ. Med. 1984: 55:966-9 In the years 1980 and 1981 monocular and amblyopic airmen had higher accident rates than did the total airmen population.</p> <p>Mayer and Lane published in 1973 "Monocular Pilots - a Follow-up Study", Aerosp. Med. 44: 1070-1074. The number of monocular pilots who applied for a student pilot license after having obtained a waiver was proportionately less</p>	

	<p>(84%) than the number of controls who applied (91%). More monocular pilots than control pilots became endorsed on more than one aircraft. There is a suspicion, that monocular pilots were involved in somewhat more hazardous events than control pilots.</p> <p><b>Proposal:</b> In the case of amblyopia in a class 2 applicant, the better other eye shall have a visual acuity of at least 0.5 uncorrected or corrected. Visual acuity with both eyes shall be 1.0 or better uncorrected or corrected.</p>
response	<p><i>Noted</i></p> <p>Please see response to comment No 934.</p>

comment	<p>2342</p> <p style="text-align: right;">comment by: <i>DLR</i></p> <p>The refractive limits of the amendment 5 should be reimplemented. If a high refraction error exist a significant ring scotoma due to high correcting glasses, especially in the + area, increasing prismatic deviation due to high correcting glasses and an increasingly narrow anterior chamber angle can exist. The same applies to high values of myopia, not talking about retinal complications. The higher the myopia the higher the probability of developing retinal scars (also in the area of macula and peripheral degenerations with following retinal detachments. Especially the narrow angle of the eye with the high hyperopia which is much too short can result in an acute glaucoma with blurred vision, severe headaches and symptoms of an acute abdomen.</p> <p>If astigmatism of more than 2 diopters is corrected by glasses an anamorphic image with compression and stretching of the perceived objectives results. This can lead amongst other things to problems by the estimation of distances and height. Also kinetosis can occur under these circumstances.</p> <p>If an anisometropia of more than 2 diopters exists there will result a different prismatic deviation in the outer periphery of the glasses depending on the different viewing directions. The pair of eyes must conduct different motions of vergence depending on the correction of the glasses and the viewing direction. An anisometropia can cause aniseikonia. Aniseikonia exists if the subjectively with both eyes perceived retinal image sizes are disparate. The glass correction to correct myopia leads to a reduction in image size. If there is a difference in the power of the glass correction the perceived retinal images are also different. As a result the fusion of the two retinal images can be complicated or even impossible. This can lead to diplopia or suppression of the image of one eye.</p> <p><b>Proposal:</b> An applicant can be assessed as fit with a refractive error of +5 /-8 dioptrres and anisometropia and astigmatism not above 3 dioptrres. Refraction exceeding -8.0 diopters of myopia and 3 diopters of astigmatism and anisometropia makes the applicant unfit for class 2. In case of astigmatism or anisometropia above 3 diopters, the applicant may be assessed as fit if the comprehensive ophthalmological examination of the revalidation examination shows no elevated intraocular pressure, no myopic degenerations , no asthenopia, nor any other pathological conditions. Contact lenses should be considered.</p>
response	<p><i>Noted</i></p> <p>The class 2 provisions for a class 2 medical certificate were aligned with ICAO class 2 standards where no refractive error limits apply. Please see response to comments No 608 and 960 as well.</p>

comment	2345	comment by: DLR
	<p>Standards or criteria for evaluation of post- surgery status; refractive surgery, cataract- glaucoma or retinal-surgery should be the same as in class 1.          After refractive surgery a period of 6 months is needed for recovery of the visual function of the eye. Corneal scarring, flap problems, refraction postoperative destability , sicca problems most often occur during the first months post surgery. Visual stability cannot be achieved before a period of 6 months. Corneal thickness postoperatively should not be thinner than 420 µm!  <b>Proposal:</b>          Replace the above text by the text for class 1 and add the following text:          After refractive surgery a fit assessment may be granted earliest 6 months post surgery.          After refractive surgery, a fit assessment may be considered provided that:          Preoperative refraction was no greater than + 5 or – 8 diopters.          (vii) Postoperative corneal thickness should be taken into account. .</p>	
response	Noted	
	Please see response to comment No 607.	

comment	2346	comment by: DLR
	<p>Standards or criteria for evaluation of post- surgery status; refractive surgery, cataract- glaucoma or retinal-surgery should be the same as in class 1          Recovery time after cataract surgery usually amounts to three months, after retinal and glaucoma surgery amounts to 6 months. Tinted lenses impair flight safety by excluding (!) perception of visual objects at a certain range of nanometers.  <b>Proposal:</b>          A fit assessment after cataract surgery may be granted 3 months post surgery, a fit assessment after glaucoma or retinal surgery may be granted 6 months post surgery by ophthalmological evaluation.          Cataract surgery: Only monofocal, non tinted intraocular lenses are allowed.          If however a tinted intraocular lens has been implanted, the blue-yellow colour vision axis has to be evaluated and has to be normal.</p>	
response	Noted	
	Please see response to comment No 607.	

**C. Draft Decision Part-MED - Subpart B: Requirements for Medical Certificates - Section 1: Specific requirements for class 1 and class 2 medical certificates - Chapter B: AMC for Class 2 medical certificates - AMC B to MED.B.070: Colour vision**

p. 58

comment	302	comment by: Lufthansa German Airlines
	<p><b>Author:</b> Dr. Esther Stahl-Buhl, AMC Frankfurt  <b>Section:</b> Chapter B          AMC B to MED B. 070          2  <b>Page:</b> 58  <b>Relevant Text:</b></p>	

The Ishihara test (24 plate version) is considered passed if the first 15 plates, presented in a random order, are identified without error.  
 My comment: See above class 1. This must be a mistake, it should say, the first 17 plates, plate number 16 and 17 are important plates for colour distinction.

**Comment:**

**Proposal:**

If an applicant for class 2 does not pass the Ishihara test without mistakes, he should be evaluated for colour safety with Nagel Anomaloscopy or Lantern Test as described above for class 1. If the applicant is assessed as not colour safe, likewise not being fit to operate during night time (VCL) ( MED . A. 045 ( c ) 3 VIII ) he should not be fit to operate only according to instruments. An ophthalmologist shall have conducted this test.

response *Partially accepted*

The requirement to identify the first 15 plates is taken over from JAR-FCL 3 and there is no intention to tighten the requirements.

The possibility for lantern testing and anomaloscopy has been added.

comment

650

comment by: *Royal Danish Aeroclub*

**Page 58, AMC B to MED B.070**

There is no need for colour perception test.

See Cmt# 647.

response

*Noted*

There is no need for colour perception tests if flights are VFR and by day only.

comment

956

comment by: *European Society of Space and Aviation Medicine (ESAM)*

**Author: European Society of Space and Aviation Medicine (ESAM)- Group Ophthalmology -**

**Section: 1**

Chapter A  
 AMC A to MED.B.070  
 Chapter 3  
 3

**Page: 47 and 58**

**Relevant Text:**

Those failing the Ishihara test should be examined either by: Anomaloscopy (Nagel or equivalent). This test is considered passed if the colour match is trichromatic and the matching range is 4 scales units or less, or by Lantern testing.

**Comment:**

Colour coded information occur in different areas of aviation. Scientific publications show that a normal trichromatic observer notices information faster and more effectively if it is based on colour differences. This reduces the rate of errors and of reaction time. Colour displays all imply that they are focused by a biologically "normal" eye with the possibility of discrimination of the entire colour spectrum. The correct perception and reading of a display is necessary, even more if difficult environmental conditions like glare, high light intensity in the cockpit and on the displays occur.

Electronic flight information displays present several colours at the same time in order to code information thus being identified and resolved faster. Humans with colour vision deficiencies are only able to identify two to three colours if another comparable colour is missing. People with colour vision deficiencies make even more errors at display work if only white signals with different illumination are presented. Already in 1965 Gramberg-Danielsen showed, that protanomals or protanopes have a higher number of rear-end collisions while driving. In 1975 Christ showed that colour coding on displays shows a 200% advantage over size and form coding. The perception time and the error rate can be reduced (Cole, MacDonald). The probability of a person with a colour vision deficiency to perform as good as a colour normal in the identification of colour information decrease by the increase of the degree of severity of the colour vision deficiency and is about 0 in the protanopes. In 1980 Robert Dille published that pilots with a waiver for colour vision deficiency are significant more often involved in aviation accidents than it is expectable by the statistics. In 2000 Ivan declared that people with colour vision deficiencies are usually not aware of the whole limited performance but think that they can identify colours and work satisfactorily in their operative environment. But the colour discrimination of these persons is not based on biological colour discrimination but on different aids as differences in illumination or learning by trial and error. Only normal trichromates should be considered to be colour safe. 4% of the Deuteranomals pass the Ishihara plates anyhow. Applicants could otherwise be protanomalous, trichromatic and have a matching range of 4 scale units. But they are no normal trichromatic and do see red lights much darker or even as grey or yellow, compared to normal trichromatic. This can be very dangerous.

**Proposal:**

Those failing the Ishihara test should be examined by the following two tests: Anomaloscopy (Nagel or equivalent). This test is considered passed if the colour match is the one of a **normal** trichromatic (0.7-1.4) and the matching range is 4 scales units or less, and by Lantern testing. The Lantern test is considered passed if the applicant passes without error a test with accepted lanterns (Holmes Wright B, Beynes or Spectrolux). Applicants need to pass both tests (Anomaloscopy and Lantern) in order to be assessed as colour safe.

response

*Noted*

Please see response to comment No 302.

comment

963

comment by: *European Society of Space and Aviation Medicine (ESAM)*

**Author: European Society of Space and Aviation Medicine (ESAM)-  
Group Ophthalmology -**

**Section: 1**

Chapter B  
AMC B to MED B. 070  
2

**Page:** 58

**Relevant Text:**

The Ishihara test (24 plate version) is considered passed if the first 15 plates, presented in a random order, are identified without error.  
It should say, the first 17 plates, plate number 16 and 17 are important plates for colour distinction.

**Comment:**

No reason for taking only 15 plates exists, plate 16 and 17 are very important plates. The wrong identification of these plates may also give a hint of what kind of anomaly or anomaly is involved. The total of correct identified numbers is not of any quantitative value of the colour vision. The Ishihara test is only a screening test. The results depend very much on the correct lightning. As the results of Ishihara plates are available on the internet and it is very easy to buy Ishihara plates, it is of vital importance that all plates are correctly identified. 4% of the deuteranomals pass the Ishihara plates anyhow.

**Proposal:**

If an applicant for class 2 does not pass the Ishihara test without any error and hesitation, he/she should be evaluated for colour safety with Nagel Anomaloscopy and Lantern Test. This test is considered passed if the colour match is the one of a normal trichromatic (0.7-1.4) and the matching range is 4 scales units or less, and by Lantern testing. The Lantern test is considered passed if the applicant passes without error a test with accepted lanterns (Holmes Wright B, Beynes or Spectrolux). Applicants need to pass both tests (Anomaloscopy and Lantern) in order to be assessed as colour safe. If the applicant is assessed as not colour safe, he or she shall be restricted to fly VFR day only and VFR (VCL).

response *Noted*

The reason for testing 15 plates is JAR-FCL 3.

comment

1081

comment by: *Aviation Ophthalmology Sweden*

**Relevant Text:**

**COLOUR VISION**

- 1. **At revalidation colour vision should be tested on clinical indication**
- 2. **the The Ishihara test (24 plate version) is considered passed if the first 15 plates, presented in a random order, are identified without error**

**Comment:**

Colour testing should be elementary part of every renewal because many diseases of the eye that could be a threat to aviation safety in means of colour discrimination have no other clinical symptom or anatomical correlate. That means with the new regulation as proposed the authority is willing to take the risk to leave these pilots go undetected and expose them, their passengers and third parties to an unknown risk. Some disease such as diseases of the optic nerve and glaucoma may lead early to altered colour vision, long before they

cause major damage to the visual system.  
 The Ishihara test (24 plate version) is already an abbreviated form of colour vision test. To shorten it more will undermine its clinical relevance, is contradictory to the rules of its use according to Professor Ishihara's instructions and severely impairs the value of this test.

**Proposal:**

**COLOUR VISION**

- 1. At any revalidation colour vision should be tested,
- 2. the Ishihara test (24 plate version) is considered passed if presented in a random order, are identified without error.

response

*Noted*

Class 2 requirements have been aligned with ICAO class 2 standards. For colour vision testing, ICAO Annex 1 neither specifies the test nor the number of plates to be tested. Therefore JAR-FCL 3 requirements in Appendix 14 were used for Part MED. 15 plates are required to be identified by the applicant according to the currently implemented JAR-FCL 3.

Repetition of colour vision testing does not seem necessary as most conditions that lead to colour vision deficiencies are hereditary.

comment

1389

comment by: *ophthalmologie aerospace medecin*

**Comment:**

No reason for taking only 15 plates exists, plate 16 and 17 are very important plates. The wrong identification of these plates may also give a hint of what kind of anomaly or anomaly is involved. The total of correct identified numbers is not of any quantitative value of the colour vision. The Ishihara test is only a screening test. The results depend very much on the correct lightning. As the results of Ishihara plates are available on the internet and it is very easy to buy Ishihara plates, it is of vital importance that all plates are correctly identified. 4% of the deuteranomals pass the Ishihara plates anyhow.

**Proposal:**

If an applicant for class 2 does not pass the Ishihara test without any error and hesitation, he/she should be evaluated for colour safety with Nagel Anomaloscopy and Lantern Test. This test is considered passed if the colour match is the one of a normal trichromatic (0.7-1.4) and the matching range is 4 scales units or less, and by Lantern testing. The Lantern test is considered passed if the applicant passes without error a test with accepted lanterns (Holmes Wright B, Beynes or Spectrolux). Applicants need to pass both tests (Anomaloscopy and Lantern) in order to be assessed as colour safe. If the applicant is assessed as not colour safe, he or she shall be restricted to fly VFR day only and VFR (VCL).

response

*Noted*

Please see responses to comments No 302 and 1081.

comment

2047

comment by: *Dr. med. Hans Brandl*

**After section 2.** The Ishihara test (24 plate version) is considered passed if the first 15 plates, presented in a random order, are identified without error.  
**please add the following text parts as separate new section 3** (see also text

listed in AMC A to MED B.070 page 47 of 66):

3. Those failing the Ishihara test should be examined either by:
- (i) 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 by
  - (ii) Lantern testing. This test is considered passed if the applicant passes without error a test with accepted lanterns.
  - (iii) In the case of class 2 applicant who does not have satisfactory perception of colours, a medical certificate with condition "VCL" can be granted, where flying privileges shall be limited to daytime only.

response *Noted*

Please see response to comment No 302.

comment

2048

comment by: *Dr. med. Hans Brandl*

As alternative to current text, Dr. med. Hans Brandl strongly recommends a complete new text for chapter "Colour Vision - class 2 medical certificates:

Proposed new wording:

1. Reading/identification of ISHIHARA plates (24 plates version) without error provides evidence of colour safety of the applicant.

2. If ISHIHARA plates were not read/identified without error, applicants shall undergo further colour perception testing to establish whether they are colour safe.

As appropriate alternative to verify sufficient colour discrimination the Nagel-anomaloscope (or equivalent method) should be used resulting in the following findings:

0.5 £ AQ £ 6

Maximum allowable value: Protanomalie 0.5

Rational:

According to European Directive requirements for bus and taxi driver licences.

Please note:

Lantern tests are demonstrably inappropriate / unqualified to be used as method to confirm/verify proof of colour safety.

In the case of class 2 applicant who does not have satisfactory perception of colours, a medical certificate with condition "VCL" can be granted, where flying privileges shall be limited to daytime only.

response *Noted*

For the time being Lantern Testing and anomaloscopy have been added as was the case in JAR-FCL 3. New methods of colour testing may be added when valid tests will appear.

comment

2337

comment by: *DLR*

Colour coded information occur in different areas of aviation. Scientific publications show that a normal trichromatic observer notices information faster and more effectively if it is based on colour differences. This reduces the rate of errors and of reaction time. Colour displays all imply that they are

focused by a biologically "normal" eye with the possibility of discrimination of the entire colour spectrum. The correct perception and reading of a display is necessary, even more if difficult environmental conditions like glare, high light intensity in the cockpit and on the displays occur.

Electronic flight information displays present several colours at the same time in order to code information thus being identified and resolved faster. Humans with colour vision deficiencies are only able to identify two to three colours if another comparable colour is missing. People with colour vision deficiencies make even more errors at display work if only white signals with different illumination are presented. Already in 1965 Gramberg-Danielsen showed, that protanomals or protanopes have a higher number of rear-end collisions while driving. In 1975 Christ showed that colour coding on displays shows a 200% advantage over size and form coding. The perception time and the error rate can be reduced (Cole, MacDonald). The probability of a person with a colour vision deficiency to perform as good as a colour normal in the identification of colour information decrease by the increase of the degree of severity of the colour vision deficiency and is about 0 in the protanopes. In 1980 Robert Dille published that pilots with a waiver for colour vision deficiency are significant more often involved in aviation accidents than it is expectable by the statistics. In 2000 Ivan declared that people with colour vision deficiencies are usually not aware of the whole limited performance but think that they can identify colours and work satisfactorily in their operative environment. But the colour discrimination of these persons is not based on biological colour discrimination but on different aids as differences in illumination or learning by trial and error. Only normal trichromates should be considered to be colour safe. 4% of the Deuteranomals pass the Ishihara plates anyhow. Applicants could otherwise be protanomalous, trichromatic and have a matching range of 4 scale units. But they are not normal trichromatic and do see red lights much darker or even as grey or yellow, compared to normal trichromatic. This can be very dangerous.

**Proposal:**

Those failing the Ishihara test should be examined by the following two tests: Anomaloscopy (Nagel or equivalent). This test is considered passed if the colour match is the one of a **normal** trichromatic (0.7-1.4) and the matching range is 4 scale units or less, and by Lantern testing. The Lantern test is considered passed if the applicant passes without error a test with accepted lanterns (Holmes Wright B, Beynes or Spectrolux). Applicants need to pass both tests (Anomaloscopy and Lantern) in order to be assessed as colour safe.

response

*Noted*

Please see response to comment No 302.

comment

2348

comment by: *DLR*

No reason for taking only 15 plates exists, plate 16 and 17 are very important plates. The wrong identification of these plates may also give a hint of what kind of anomaly or anomaly is involved. The total of correct identified numbers is not of any quantitative value of the colour vision. The Ishihara test is only a screening test. The results depend very much on the correct lightning. As the results of Ishihara plates are available on the internet and it is very easy to buy Ishihara plates, it is of vital importance that all plates are correctly identified. 4% of the deuteranomals pass the Ishihara plates anyhow.

**Proposal:**

If an applicant for class 2 does not pass the Ishihara test without any error and hesitation, he/she should be evaluated for colour safety with Nagel

Anomaloscopy and Lantern Test. This test is considered passed if the colour match is the one of a normal trichromatic [\(0.7-1.4\)](#) and the matching range is 4 scales units or less, and by Lantern testing. The Lantern test is considered passed if the applicant passes without error a test with accepted lanterns (Holmes Wright B, Beynes or Spectrolux). Applicants need to pass both tests (Anomaloscopy and Lantern) in order to be assessed as colour safe. If the applicant is assessed as not colour safe, he or she shall be restricted to fly VFR day only and VFR (VCL).

response *Noted*

Please see response to comment No 302.

**C. Draft Decision Part-MED - Subpart B: Requirements for Medical Certificates - Section 1: Specific requirements for class 1 and class 2 medical certificates - Chapter B: AMC for Class 2 medical certificates - AMC B to MED.B.075: Otorhino-laryngology**

p. 58

comment 154 comment by: *Civil Aviation Authority - The Netherlands*

**AMC B to MED.B.075, onder 7. (Blz. 58 van 66)**

De CAA-The Netherlands acht dit voorschrift te restrictief. Het voorschrift zou alleen moeten gelden in omstandigheden waar Air Traffic Management (ATM) een rol speelt. Immers het uitvoeren van een VFR vlucht, waarbij start en landing plaatsvinden op een ongecontroleerd veld, vereist het gebruik van een radio niet.

response *Partially accepted*

Provisions for applicants with hearing disabilities have been added.

comment 284 comment by: *Lufthansa German Airlines*

Section: 2  
AMC B to MED.B.075  
Chapter B  
1.1.1 - Hearing - AMC for Class 2 medical certificates  
**Page: 58**

**Relevant Text:**

The applicant should understand correctly conversational speech when tested with each ear at a distance of 2 m from and with the applicant's back turned towards the AME.

**Comment:**

The pure-tone audiometry is precise and reproducible.

**Proposal:**

A pure-tone audiometry test is preferable

response *Noted*

Pure tone audiometry is required for class 2 medical certificates if an instrument rating is added to the licence. Applicants who do not have an instrument rating they do not have to undergo pure tone audiometry, also not

under the presently implemented standards in JAR-FCL 3.

Part-MED is in line with ICAO standards for class 2.

comment 845 comment by: *European Society of Space and Aviation Medicine (ESAM)*

**Author: European Society of Space and Aviation Medicine (ESAM) - Group ENT -**

**Section:**  
**2 AMC B to MED.B.075**  
**2. - 8. Examination**

**Page:** 58

**Relevant Text:**

2. An ENT examination should form part of all revalidation and renewal examinations.

**Comment:**

An AME normally may not be competent enough to perform the ENT examination.

The examination of the tubal function is essential to prevent barotraumas which can cause severe sudden in flight incapacitation.

**Proposal:**

An ear nose and throat examination should form part of all examinations. All abnormal and doubtful cases should be referred to a specialist in Aviation ENT acceptable to the authority.

Add 9.:Tubal dysfunction

An applicant with tubal dysfunction should be assessed as fit if ENT examination is satisfactory.

response *Partially accepted*

Paragraph 2 on examinations has been amended to include initial examinations.

comment 1059 comment by: *Dr Michel Kossowski AeMC Clamart*

1.2define the a satisfactory hearing ability  
 4. head shaking test

response 1. See response to the comment Nr 1453.

2. Any test may be performed by an ENT specialist if there is a clinical indication.

comment 1453 comment by: *Michel KOSSOWSKI*

AMC B to MED.B.075 1.2 : define a satisfactory hearing ability.

response *Noted*

a) The ability to understand correctly conversational speech ... (see paragraph 1.1) for pilots without instrument rating.

b) The ability to pass pure tone audiometer test as required for class 1 medical certificates MED.B.075 (c) (1).

c) Hypoacusis: Either pass the tests with hearing aid or pass a flight test for a medical certificate with limitation with regard to airspace.

comment 1530 comment by: Andrew CAMPBELL

AMC B to MED.B.075 makes no mention of whether a hearing aid or similar device may be worn during the examination. This ambiguity should be removed and reference included to this being possible, per my comments regarding AMC A to MED.B.075.

response Partially accepted

Paragraph 1.3 has been added to indicate that the tests can be done with hearing aids.

comment 1993 comment by: CAA Belgium

Relevant Text:

1. Hearing

1.1 The applicant should understand correctly conversational speech when tested with each ear at a distance of 2 meters from and with the applicant's back turned towards the AME.

1.2. An applicant with hypoacusis should be assessed as fit if a speech discrimination test or functional cockpit hearing test demonstrates satisfactory hearing ability.

Comment:

Cfr comment 1988. For a class 2, radio communication is mandatory. A good hearing function is absolutely necessary to understand ATC in control area and thus for flight safety. Only a pure tone audiogram can precise the hearing function.

Proposal:

1.1 The applicant should understand correctly conversational speech when tested with each ear at a distance of 2 meters from and with the applicant's back turned towards the AME.

1.2 At the initial examination and every five years up to age of 40 and thereafter every two years, an examination of hearing by pure-tone audiogram is required. The pure tone audiogram shall cover the 500Hz, 1000Hz, 2000Hz and 3000Hz frequency thresholds.

1.3. For renewal and revalidation, applicant with hypoacusis should be assessed as fit if a functional cockpit hearing test demonstrates satisfactory hearing ability.

response Not accepted

1.1: no change proposed.

1.2: not accepted. No pure tone audiogram is required for a class 2 medical certificate except in cases where an instrument rating is added to the licence. In this case class 1 requirements apply (MED.B.075 (c)(1)(i)). The reason for not introducing pure tone audiometry for class 2 medical certificates is that it is not required neither in JAR-FCL 3 nor in ICAO Annex 1.

1.3: There will be no difference in initial and revalidation requirements for class 2. Additional tests can be done to evaluate whether the applicant is able to perform the duties safely (MED.A.045 and AMC to MED.A.045).

comment 1994 comment by: CAA Belgium

Relevant Text:  
 2. Examination  
 An ear, nose and throat (ENT) examination should form part of all revalidation and renewal examination.

Comment:  
 For a AME, complete ENT examination can be not easy to carry out. And for initial???? Not defined.

Proposal:  
 2. Examination  
 A comprehensive ear, nose and throat examination shall be undertaken for the initial issue of a class 2 medical certificate and periodically thereafter when clinically indicated. For renewal or revalidation, all abnormal and doubtful cases shall be referent to a specialist in aviation ENT acceptable to the authority.

response Noted

Paragraph 2 on examinations has been amended to include initial examinations.

Class 2 rules/AMCs have been aligned with ICAO Annex 1 standards. The AME is expected to be able to do the ENT examinations. If he/she is not trained to do so they will have to refer the pilot to an ENT specialist.

comment 1995 comment by: CAA Belgium

Relevant Text:  
 8. Air passage restrictions  
 An applicant with significant restriction of the nasal air passage on either side or significant malformation of the oral cavity or upper respiratory tract should be assessed as fit if ENT evaluation is satisfactory.

9. ....

Comment:  
 Eustachian function is essential for flying.

Proposal:  
 9. Eustachian tube function  
 A applicant with tubal dysfunction should be assessed as fit if ENT evaluation is satisfactory.

response Partially accepted

Paragraph 9 dealing with Eustachian tube disfunction has been added.

comment	265	comment by: <i>Lufthansa German Airlines</i>
	<p>Author: Gabel A MD, AME/Cardiologist Aeromedical Center Frankfurt/M, Germany  Section: _AMC B to MED.B.085  <b>Page:</b> 59</p> <p><b>Relevant Text:</b>  Applicants may be assessed as fit after treatment for malignant disease if:  (i) there is no evidence of residual malignant disease after treatment,  (ii) time appropriate to the type of tumour has elapsed since the end of treatment  (iii) the risk of in-flight incapacitation from a recurrence or metastasis is sufficiently low;  (iv) there is no evidence of short or long-term sequelae from treatment that may adversely affect flight safety.</p> <p><b>Comment:</b> The Likelihood to interfere with the safe exercise of the privileges must be defined to achieve uniform safety-levels. The "one-percent-rule" should be applicable as well in malignant disease, esp. for incapacitating events like unforeseen seizures from brain metastasis, severe haemorrhage, pathologic bone ore vertebra fracture etc. The essential safety level should be applicable for all kind of medical classes. A minimum recovery time of three months after diagnosis or treatment of cancer deems essential to overcome the debilitating effects of the disease itself or chemotherapy or radiation as well as the secondary psychic affections (secondary depression etc.). Following chemotherapy or radiation patients are at risk to develop progressive cardiomyopathy even years after treatment. Regular cardiologic follow-up should be guaranteed.</p> <p><b>Proposal:</b></p> <p>Applicants may be assessed as fit after treatment for malignant disease if:  (i) there is no evidence of residual malignant disease after treatment and criteria of full remission are met,  (ii) time appropriate to the type of tumour (at least 3 months) has elapsed since the end of treatment,  (iii) the risk of in-flight incapacitation from a recurrence or metastasis is considered to be less than 2 % per year;  (iv) there is no evidence of short or long-term sequelae from treatment that may adversely affect flight safety.</p> <p>Regular oncologic follow-up examinations are obligatory at intervals of 6 months for the first three years, at intervals of 12 months hereafter until the fifth year after successful treatment is completed. Following systemic chemotherapy or radiotherapy involving the thorax an annual cardiologic examination including ECG and Echocardiography is necessary.</p>	
response	<p><i>Noted</i></p> <p>(i): Not accepted. The addition would go beyond JAR-RCL 3 but the regulatory provisions for class 2 medical certificates were aligned with ICAO standards that are less restrictive.  (ii): Not accepted. The time that has to elapse before a fit assessment can be made may be very different. The clinical parameters in relation to the privileges of the licence should be used for an assessment.</p>	

(iii) Noted. The risk assessment criteria of JAR-FCL 3 date back to the 1990s and need to be revised together with specialists in statistics in medicine. This will be done in the rulemaking tak MED.001 and will be added to Part MED as Guidance Material as presently in JAR-FCL 3.

Follow-up: One paragraph on oncological follow-up from JAR-FCL 3 has been re-introduced.

Chemotherapy: One paragraph on anthracycline from JAR-FCL 3 has been re-introduced.

**C. Draft Decision Part-MED - Subpart B: Requirements for Medical Certificates - Section 2: Specific requirements for LPL medical certificates** p. 60

comment

102

comment by: *British Gliding Association*

Page 60/66

**Specific requirements for LPL medical certificates**

*It is not understood why these specific requirements for the LPL exist. There are two differences between the LPL and other levels of medical fitness certification. Firstly the methods employed to validate fitness should be simple and cheap, secondly and because of the lower risk exposure, a greater risk of incapacity can be accepted especially when mitigating limitations are applied.*

**BGA Proposal:**

**That the need for these to apply to the LPL be reconsidered by EASA**

response

*Noted*

Medical requirements below ICAO Annex 1 standards are presently highly uncommon in Europe. This NPA, containing sub-ICAO medical rules and Acceptable Means of Compliance for the LAPL, attracted a total of ca 2300 comments around half of which were addressing the LAPL requirements and the GMP issuing the medical certificates.

Many comments were very supportive but others also extremely controversial to all areas: The examination form with embedded requirements, this AMC with medical provisions for the LAPL and, last but not least, the General Medical Practitioner to issue medical certificates.

All comments have been carefully reviewed and the result was to reconsider all provisions regarding the LAPL: The Implementing Rules in MED.B.090, the AMCs to MED.A.040 (examination form LAPL) and MED.090 (medical provisions), and Subpart D concerning the GMP.

**NOTE on responses to comments on AMC MED.B.090:**

**There are no individual responses to the comments to this AMC MED.B.090 because the AMC was reconsidered in its entirety. The reason why and how this was done is explained in depth in the Explanatory Note/Memorandum.**

comment

31

comment by: *Horst Metzsig*

I apply with the EASA, if the sail flight pilot is planing only to fly solo with no

passengers, to release from the obligation of a flight-medical investigation at GMP, AME or AeMC.

Ich beantrage bei der EASA, das Segelflugpilotinnen/Piloten von der Verpflichtung befreit werden, sich fliegerärztlich untersuchen zu lassen, wenn diese Personengruppe ausschliesslich alleine fliegen will, also keine Passagiere mitnehmen möchte.

Ich begründe meinen Antrag mit der Tatsache, das in zahlreichen Auflistungen der EASA in Section 2 ( specific requirements for LPL medical certificates ) ohnehin bei nicht erreichen der geforderten gesundheitlichen Limite eine Ausnahme mit der Beschränkung auf Alleinflug getroffen wurde.

Das würde für den gewollten alleinfliegenden Segelflugpiloten/Pilotin eine deutliche Kostenreduktion mit sich bringen.

Mein Vorschlag ist eigentlich die logische Folgerung aus dieser Tatsache.

Ich beantrage weiter, das diese Fliegerarztbefreiung auch auf allein fliegende Piloten mit dem Tourenmotorsegelflugzeug erfolgen sollte.

Noch deutlicher kommt eine AOPA Studie zu der Fragestellung:

#### **MEDICAL CERTIFICATION: DOES IT PREVENT ACCIDENTS?**

A just-completed AOPA Air Safety Foundation analysis of U. S. accidents caused by medical problems shows no meaningful correlation between FAA medical certificate requirements and GA accident rates.

ASF researchers analyzed 37,946 general aviation accidents that occurred from 1983 - 2000, involving fixed wing aircraft under 12,500 pounds gross weight and operated under FAR Part 91 general flight and operating rules. All such aircraft require a valid FAA medical certificate for the pilot in command. Of that total, they found 137 accidents caused by medical incapacitation, for a rate of just 0.36%, slightly over one-third of one percent (heart attacks were the most common accident cause.)

A similar study conducted by the FAA of accidents in gliders and balloons (whose pilots are *not* required to have a valid medical certificate), found only two medically-induced accidents in the ten-year period from 1990 - 2000. With a total of 609 glider and balloon accidents shown in the ASF database for that period, the no-medical-certificate required rate works out to 0.33%, slightly *lower* than that for pilots requiring an FAA medical certificate.

Ich berufe mich hier auf die AOPA Studie und bitte, für alleinfliegende Segelflugpiloten, auch mit Motorantrieb, die flugmedizinische Untersuchung nicht weiter vorzuschreiben.

Horst Metzsig

response *Noted*

See response to comment No 102 in this segment.

comment 569

comment by: *British Microlight Aircraft Association*

General comment.

The basis for the requirements should be equal to, and not greater than, used to authorise road vehicle driving licenses.

response *Noted*

See response to comment No 102 in this segment.

comment

580

comment by: *Florian Söhn*

Tested standards are either below ICAO standards (eg vision)

or

even in contradiction to current medical knowledge (eg pacemakers need at least 12 weeks to fully heal into the heart muscle and have an reliable function after - 6 weeks seems to me hazardous from the cardiologic viewpoint)

This easiest and in my opinion cleanest solution would be to merge LPL with Class 2 use Class 2 standards for LPL-medical and therefore adhering to ICAO worldwide medical standards.

response *Noted*

See response to comment No 102 in this segment.

comment

593

comment by: *dr roland vermeiren eurocontrol*

**Comments on NPA No 2008-17c Part-Medical**

About the medical criteria for LPL

**Author:**

Dr Roland Vermeiren , head medical service Eurocontrol

**Section :** Draft opinion annex II subpart B, section 3 page 18

Draft decision AMC/GM - subpart A, section 2 page 22

- subpart B, section 2 page 60

**Comment :**

- 1) the medical follow-up for the LPL will entail a higher risk for the flight safety. One of the main reasons is the immense increase of the intervals between medical contacts , during which a wide spectrum of medical conditions even not clear for the applicant , may have a negative impact on his/her performance .
- 2) separate medical criteria for LPL and class 2 are not needed and can be confusing for examiners . The flying environment is similar, the airplanes can be very similar and the risks in case of sudden incapacitation for pilot, passenger(s) and population or other aviation activities are similar . This creates 2 different kinds of private pilots flying under similar circumstances - many applicants with known medical problems will shift to the LPL having higher risks but less medical supervision. This shift seems also have happened in the USA.

For optimal clarity both for applicants, medical examiners ( and the general population ) and simplicity ( which is an important factor for safety ) we need in the future only 3 sets of medical criteria : professional flying, private flying and air traffic control duties.

- 3) The different sets of medical criteria for class 2 and LPL do not show any consistency or logic between them , sometimes LPL criteria are less specified / lower and sometimes better specified / higher without any obvious scientific reason , which gives the impression that there was no common risk/safety assessment approach between the different working groups who made them. The medical evidence for these completely new LPL criteria, different from class 2 criteria in aviation, are not clear.
- 4) The medical criteria for LPL are only AMC's and thus not at all binding , and the GMP's going to use are not obliged to know them - this will lead to very inconsistent application and loss of harmonisation through Europe, even when these applicants will be entitled to use their license in all EASA countries.
- 5) The medical criteria for private flying should by principle not be below ICAO criteria. This creates again confusion for examiners and pilots , and diminishes the trust in the medical safety aspects for passengers and the general population. It will also have a negative impact on the usability of the certificate outside the EU which will cause more costs for some pilots.

It is also contradictory to the paragraph(3) of the introductory text of the Basic Regulation about application of ICAO standards by EASA.

**Proposal :**

To delete the separate medical criteria for LPL and to replace them by the medical assessment criteria of ICAO for Class 2 pilots.

Brussels, 04/09/08

response

*Noted*  
See response to comment No 102 in this segment.

comment

599	comment by: <i>Lufthansa German Airlines</i>
Author: Gabel A MD, AME/Cardiologist Aeromedical Center Frankfurt/M, Germany Section: 2; Specific requirements for LPL medical certificates Page: 60-65	
Relevant Text:	
<p><b>Comment:</b> Since the privilege of a LPL is to carry up to 3 passengers and to fly an aircraft up to 2000 kg, the same minima as for class 2 should apply. The conditions described on page 60-65 are not acceptable at all in terms of medical flight safety. For all classes of certificates the same physical laws apply, so minima protecting from hypoxia and sudden incapacitation should be the same. The majority of accidents occur with light aircraft, the more lenient failures (no oxygen supply when flying in high altitudes, no sufficient fuel</p>	

supply or abolished pre-flight-checks etc.) are committed by "light" aircraft pilots. In the experience of an Aeromedical Center, especially light aircraft pilots are very ambitious towards their sport, tend to dissimulate, neglect or deny abnormal medical conditions, they are "blind" for their own state of impairment and naturally want to avoid any professional medical control. For that reason more precise control of abnormal medical conditions is necessary to ensure flight safety for carried passengers, that naturally would rely in adequate medical checks of "their" pilot - which is not the fact with the actual proposals for AMC to LPL.

**Proposal:**

Apply the same criteria for LPL as for class 2 medical, which are the absolute base-line for a minimum of medical flight safety.

response

*Noted*

See response to comment No 102 in this segment.

comment

930

comment by: *European Society of Space and Aviation Medicine (ESAM)*

**Author: European Society of Space and Aviation Medicine (ESAM) - Group Ophthalmology -**

**Section: 1**

Subpart A

MED A.055

**(a) 4 an AMC to MED B. 090****Page: 7 and 60****Relevant Text:**

LPL medical certificates shall be valid:

- (i) until the age of 45

Specific requirements for LPL medical certificates

**Comment:**

LPL pilots and class 2 pilots use the same airspace and can fly nearly the same type of aircrafts (in class 2 only heavier and with a higher cruising range) and they have the same privileges. Therefore it does not make sense to have, from a safety perspective, different requirements for these two kinds of licenses. LPL pilots may even have glass cockpits with a lot of colour information. Safety issues should not be decided upon by politicians, but by specialist. It looks like the LPL is introduced only as a result of enormous pressure of the leisure pilot associations. The requirements are lower than the ones for sailing a boat on a lake. If a plane with the weight of two tons crashes in a public building it can cause fatal accidents and death to people in this area.

**Proposal:**

LPL requirements should be the same as class 2 including a comprehensive ophthalmological eye examination by an ophthalmologist at initial examination or if indicated.

response

*Noted*

See response to comment No 102 in this segment.

comment

1248

comment by: *Swedish Transport Agency, Civil Aviation Department (Transportstyrelsen, Luftfartsavdelningen)*

**Comment:**

Generally, in the AMC to MED.B.090 Specific requirements for LPL medical certificates, the requirements are written in a different way compared to the requirements for class 1 and class 2. In the class 1 and 2 requirements, each paragraph usually begins with a definition of a generally disqualifying condition, followed by the specific provisions for a fit assessment of the same condition after a comprehensive evaluation. For LPL, on the contrary, the AMC generally only describes provisions for a fit assessment without defining a condition as basically disqualifying if the provisions are not met. This will create confusion and problems with interpretation, both for the examining GMPs and AMEs and for the licensing authorities.

As the proposed text does not contain any legally valid text prescribing an unfit assessment if the applicant does not fulfil the provisions, or if the provisions do not cover all possible conditions, the result would be that the licensing authority could never claim any applicant to be unfit.

**Proposal:**

If the LPL should have any specific medical requirements, the paragraphs should have the same structure as for class 1 and class 2 in MED.B and the AMCs to MED.B.

response

*Noted*

See response to comment No 102 in this segment.

comment

1268

comment by: *Swedish Transport Agency, Civil Aviation Department (Transportstyrelsen, Luftfartsavdelningen)*

## Relevant Text:

**X. MUSCULOSKELETAL SYSTEM**

## Comment:

The binding Implementing Rule MED.B.090 requires an examination of the musculoskeletal system to be performed; however, there is no corresponding requirement in the AMC to MED.B.090.

**Proposal:**

AMC to MED.B.090 should be amended to elaborate the requirements for the musculoskeletal system.

response

*Noted*

See response to comment No 102 in this segment.

comment

1472

comment by: *Trevor Wilcock*

p60 Specific requirements for LPL medical certificates. Further to my

comments against p23 et seq, again the level of complexity seems inappropriate to the level of risk exposure associated with LPL operations and the intention to have a "simple" LPL licence and procedure. This section should be reconsidered.

response *Noted*

See response to comment No 102 in this segment.

comment

1498

comment by: *Dr. Med. Wolfgang SCHAUM*

My comments to the conditions for LAPL planed by the EASA.  
I am sure- as now planed- we will loose human life caused by human factors in sudden incapacity to conduct an airplane.  
There is no difference between small or big airplanes!  
My experiance from more then 20 jears says that we can prohibit accidents by finding deseases as following.

1. Haert deseases- arrythmia (fe.WPW) coronary, heart deseaes, myocard infarktion.
2. circulation desease (hypertention)
3. Diabetes mellitus- controlled or uncontrolled
4. Psychiatric deseases f.e. abuse from THC, Heroin or C2H5OH.
5. All kinds of maligne deseases, f.e leukemia, embolic complications...
6. Eye deseases (now to important)
7. Handling the situation after med. treatmant and surg. operations.
8. Neurological failures, cerebral infartion, epilepsie, MS...

Every points are not under control and will cause accidents by human failure.

Please pay attention to these remarks.

response *Noted*

See response to comment No 102 in this segment.

comment

1524

comment by: *Karlheinz Hurraß*

Ich möchte den Vorschlag zur Einführung eines medizinischen Standards unterhalb der ICAO Klasse 2 unterstützen. Die Untersuchung sollte durch einen Hausarzt möglich sein.

Begründung:

Während meiner 50jährigen fliegerischen Tätigkeit ist mir kein einziger Unfall bekanntgeworden, der sich eindeutig auf körperliche Defizite zurückführen ließ. Deshalb glaube ich nicht an eine Verschlechterung der Flugsicherheit. Außerdem können die Kosten erheblich gesenkt werden. Das erleichtert auch Jüngeren den Einstieg in den Luftsport.

response *Noted*

See response to comment No 102 in this segment.

comment	1569	comment by: <i>Helicopter Club of Great Britain</i>
	<p>C. Draft Opinion and Decision Part Medical - Annex II to Implementing Regulation.</p> <p>We support the LPL and in particular the medical standards within the LPL proposal. These standards will ensure that few if any people, who should be allowed to fly, will be denied the right to do so. This is fundamental to the <b>rights</b> of the European citizen.</p> <p>Further, the ability for a GMP to conduct the medical certification within those member states whose national law allow that (vide: Basic Regulation 216) is a welcome removal of unnecessary restrictions created by the JAA system which limited most countries to having to use an AME.</p> <p>The LPL will be a welcome recognition of the need for an entry level set of qualifications to private civil aviation, so long dominated in many states by the thinking borne out of commercial and military aviation where someone else (the passenger or the military establishment) is paying the costs!</p>	
response	<p><i>Noted</i></p> <p>See response to comment No 102 in this segment.</p>	
comment	1600	comment by: <i>William Harford</i>
	<p>As a PPL(H) I support the medical requirements for the LPL(H) as proposed.</p>	
response	<p><i>Noted</i></p> <p>See response to comment No 102 in this segment.</p>	
comment	1787	comment by: <i>Norwegian Association of Aviation Medicine</i>
	<p>We will recommend that this requirements are cancelled and the requirement for class 2 also has to apply for the LPL-pilot. There are very few differences between the physical strain on the PPL and LPL pilot and it is essential to keep the high, medical requirement to both this. See also earlier arguments.</p>	
response	<p><i>Noted</i></p> <p>See response to comment No 102 in this segment.</p>	
comment	1828	comment by: <i>CAA Belgium</i>
	<p>Relevant text: Specific requirements for LPL medical certificates  Comment: The requirements for LPL medical certificates are unacceptable. Their level is so low that it leads to a marked decrease in aviation safety. There is a contradiction between these requirements and the Regulation (EC) No 216/670/EEC of the European Parliament and of the Council (5) : ..."However, proportionate measures should be taken to increase generally the level of safety of recreational aviation"...; (31) : "It is a general objective that the transfer of functions and tasks from the Member States, including those</p>	

resulting from their cooperation through the Joint Aviation Authorities, to the Agency should be effected efficiently, without any reduction in the high levels of safety, and without any negative impact on certification schedules".  
 Proposal: The medical requirement for LPL must be the same as those of class 2.

response *Noted*

See response to comment No 102 in this segment.

comment 1851 comment by: UK CAA MEDICAL ADVISORY PANEL

**Paragraph AMC to MED.B.090 1.2. (i)**  
**Page 60**

**Comment**

No

**Justification**

The risk of event is too high

**Proposed Text**

Insert ... is known to be less than 0.4;

response *Noted*

See response to comment No 102 in this segment.

comment 1852 comment by: UK CAA MEDICAL ADVISORY PANEL

**Paragraph AMC to MED.B.090 1.6)**  
**Page 60**

**Comment**

Should be myocardial ischaemia

This not well stated.

**Justification**

Usage.

It pre-empts fitness

**Proposed Text**

insert ....myocardial

.....Applicants with suspected myocardial ischemia should be fully investigated before a fit assessment can be made

response *Noted*

See response to comment No 102 in this segment.

comment 2017 comment by: Lars Tjensvoll

I will suggest to cancel this section, as argued earlier.

response	<i>Noted</i>	
	See response to comment No 102 in this segment.	
comment	2113	comment by: <i>Light Aircraft Association UK</i>
	This extensive list does not seem to be compatible with the principles of a cheap and simple system, nor with the fact that a greater exposure to risk of incapacitation is acceptable due to the lower exposure to risk of third parties.	
response	<i>Noted</i>	
	See response to comment No 102 in this segment.	
comment	2133	comment by: <i>Croft Brown</i>
	<p>Page 60/66</p> <p>Specific requirements for LPL medical certificates</p> <p>It is not understood why these specific requirements for the LPL exist. There are two differences between the LPL and other levels of medical fitness certification. Firstly the methods employed to validate fitness should be simple and cheap, secondly and because of the lower risk exposure, a greater risk of incapacity can be accepted especially when mitigating limitations are applied. Croft Brown endorses the BGA Proposal: That the need for these to apply to the LPL be reconsidered by EASA</p>	
response	<i>Noted</i>	
	See response to comment No 102 in this segment.	
comment	2156	comment by: <i>AMS Denmark</i>
	Specific requirements for LPL medical certificates should be identical with ICAO class 2.	
response	<i>Noted</i>	
	See response to comment No 102 in this segment.	
comment	2209	comment by: <i>Royal Netherlands Aeronautical Association</i>
	<p>In section 2, there are a lot of specific requirements that also should be applicable for the LPL medical certificate, e.g. MED.B.010 (a), or MED.B.025 (a) and many others.</p> <p>KNVvL PROPOSAL:</p> <p>-For the LPL there should be a complete overall picture of the requirements</p>	
response	<i>Noted</i>	
	See response to comment No 102 in this segment.	

comment	2222	comment by: <i>Royal Netherlands Aeronautical Association</i>
	<p>Comments of the KNVvL medical committee:</p> <p>In this section no attention is paid on the respiratory system. AMC B to MED.B.010 is also appropriate for LPL.</p> <p>The definitions of "minor impairment" and "satisfactory pulmonary function" need to be clarified.</p>	
response	<i>Noted</i>	
	See response to comment No 102 in this segment.	
comment	2224	comment by: <i>Swiss Association of Aviation Medicine</i>
	<p>LPL-Questionnaire</p> <p>Like we stated above we prefer a questionnaire that can be filled in by the pilot himself. We propose to cancel it completely. Some questions/decisions are not ethically. They would allow pilots to fly with diseases that normally would be treated in the normal population because there is evidence that mortality and morbidity will be reduced.</p>	
response	<i>Noted</i>	
	See response to comment No 102 in this segment.	
comment	2257	comment by: <i>Martyn Johnson</i>
	<p>Page 60/66 Specific requirements for LPL medical certificates</p> <p>I do not understand why these specific requirements for the LPL exist. There are two differences between the LPL and other levels of medical fitness certification. Firstly the methods employed to validate fitness should be simple and cheap, secondly and because of the lower risk exposure, a greater risk of incapacity can be accepted especially when mitigating limitations are applied.</p> <p>The need for these to apply to the LPL should be reconsidered by EASA.</p>	
response	<i>Noted</i>	
	See response to comment No 102 in this segment.	
comment	2448	comment by: <i>SANMA Swedish Aeronautical Association</i>
	<p>Förslagen talar bara om piloten och ev passagerare men ej om säkerheten för personer på marken. Med nuvarande förslag löper dessa risk att skadas vid olycka.</p>	
response	<i>Noted</i>	

See response to comment No 102 in this segment.

comment 2466 comment by: Paul Mc G

This list is huge. How does this fit with the principles of a cheap and simple system?

Specific requirements for LPL medical certificates

Why do these specific requirements for the LPL exist? There are two differences between the LPL and other medical fitness certifications. The methods employed to validate fitness should be simple and cheap. Can the LPL medical certification rules be reconsidered by EASA?

response Noted

See response to comment No 102 in this segment.

comment 2548 comment by: UK CAA MEDICAL ADVISORY PANEL

Paragraph AMC to MED.B.090 1.2. (iv)

**Page 60**

**Comment**

aneurism is unqualified. >5.5 cm the risk of rupture is too high for any flying privileges

**Justification**

**Proposed Text**

Insert thoracic and / or abdominal aortic...

Delete ...to 6.5cm

response Noted

See response to comment No 102 in this segment.

comment 2549 comment by: UK CAA MEDICAL ADVISORY PANEL

**Paragraph AMC to MED.B.090 1.3. (I)**

**Page 60**

**Comment**

This needs qualification

**Justification**

The meaning of significant is unstated

**Proposed Text**

....Preexcitation associated

with atrial fibrillation or atrio-ventricular re-entrant or other sustained tachycardia tachardia

response Noted

See response to comment No 102 in this segment.

comment	2550	comment by: UK CAA MEDICAL ADVISORY PANEL
<p><b>Paragraph AMC to MED.B.090 1.3. (ii)</b>  <b>Page 60</b></p> <p><b>Comment</b>  Is this not covered in iv, above?</p> <p><b>Justification</b></p> <p><b>Proposed Text</b>  delete</p>		

response	<i>Noted</i>
See response to comment No 102 in this segment.	

comment	2551	comment by: UK CAA MEDICAL ADVISORY PANEL
<p><b>Paragraph AMC to MED.B.090 1.3. (iii)</b>  <b>Page 60</b></p> <p><b>Comment</b>  This is too minimal</p> <p><b>Justification</b>  Interventricular septal diameter &gt; 2.5 cm and ventricular tachycardia also predict poorer outcome as does a family history of sudden cardiac death</p> <p><b>Proposed Text</b>  Insert .... And if the interventricular septal diameter &gt; 3.0 cm and / or ventricular tachycardia has been recorded and / or there is a family history of sudden cardiac death</p>		

response	<i>Noted</i>
See response to comment No 102 in this segment.	

comment	2552	comment by: UK CAA MEDICAL ADVISORY PANEL
<p><b>Paragraph AMC to MED.B.090 1.7)</b>  <b>Page 60</b></p> <p><b>Comment</b>  No way.</p> <p><b>Justification</b>  An applicant with new angina with a negative exercise ecg is not fit to fly</p> <p><b>Proposed Text</b>  Applicants,with or without treatment, who have suffered angina shall be assessed as unfit. Following a full and satisfactory cardiological evaluation.to include an exercise ECG, or equivalent, may be assessed as fit provided there is no coronary artery stenosis &gt;50% in any ungrafted / angioplastied vessel (&lt;30% for left main and left anterior descending coronary arteries.</p>		

response	<i>Noted</i>
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See response to comment No 102 in this segment.

comment 2553 comment by: UK CAA MEDICAL ADVISORY PANEL

**Paragraph AMC to MED.B.090 1.8)**  
**Page 60**

**Comment**

No way.

**Justification**

Ellective angioplasty often does not bring about full revascularisation and the event rate in the first year may be 4 – 8%. Passengers should not be carried so soon

**Proposed Text**

Applicants should not have had an elective angioplasty within the preceding 4 months. Thereafter, applicants who have had a satisfactory and full cardiological evaluation to include an exercise ECG or equivalent may be assessed as fit provided there is no coronary artery stenosis >50% in any ungrafted / angioplastied vessel (<30% for left main and left anterior descending coronary arteries).

response *Noted*

See response to comment No 102 in this segment.

comment 2554 comment by: UK CAA MEDICAL ADVISORY PANEL

**Paragraph AMC to MED.B.090 1.9)**  
**Page 60**

**Comment**

3 months is too soon

**Justification**

Sternal fastness and rehabilitaion

**Proposed Text**

Insert 4+ months

response *Noted*

See response to comment No 102 in this segment.

comment 2555 comment by: UK CAA MEDICAL ADVISORY PANEL

**Paragraph AMC to MED.B.090 1.10)**  
**Page 60**

**Comment**

Too vague

**Justification**

Heart attack is vernacular

**Proposed Text**

Myocardial infaction. Applicants folowing a myocardial infarctio should be assessed as unfit. Applicants who have undergone a satisfactory full

cardiological evaluation to include an exercise ECG, or equivalent, may be assessed as fit fit provided there is no coronary artery stenosis >50% in any ungrafted / angioplastied vessel (<30% for left main and left anterior descending coronary arteries).

response *Noted*

See response to comment No 102 in this segment.

comment 2556 comment by: UK CAA MEDICAL ADVISORY PANEL

**Paragraph AMC to MED.B.090 1.12**  
**Page 60**

**Comment**

no

**Justification**

3 months of stability does offer adequate warranty

**Proposed Text**

A fit assessment may be made when the arrhythmia has been fully managed by a cardiologist and the LV ejection fraction is >0.5. Atrial flutter is disqualifying

response *Noted*

See response to comment No 102 in this segment.

**C. Draft Decision Part-MED - Subpart B: Requirements for Medical Certificates - Section 2: Specific requirements for LPL medical certificates - p. 60-61 AMC to MED.B.090 - 1. Cardiovascular System**

comment 110 comment by: Roger Dyke

The new LPL Medical Requirement in it's present form will take the General Practitioner considerably more time to process than the existing UK NPPL one. This could be a lot more expensive to the applicant and possibly could compare with the cost of the current JAR PPL Class 2. This goes against the criteria of trying to make the Leisure Licence (LPA) cheaper for all.

Also the specifics within the medical check list could rule-out an existing UK NPPL(SSEA) holder, who has to convert his/her licence to an LPL(A), hence he/she will no longer be able to use their licence. I would like to think that we were encouraging people to take up flying, not putting them off by making it more difficult.

response *Noted*

See response to comment No 102.

comment 155 comment by: Civil Aviation Authority - The Netherlands

**AMC to MED.B.090, onder 1.2, onder i. (Blz. 60 van 66)**

De CAA-The Netherlands acht de grens van 0.4 veel te laag. Kandidaten met een dergelijke aandoening vormen een apert gevaar voor de luchtvaartveiligheid. Een kandidaat met een 'left ventricular ejection fraction' van 0,4 is zeer ernstig ziek en behoeft een medische ingreep. De CAA-The Netherlands verzoekt aan EASA om de toegestane ondergrens in samenspraak met cardiologen opnieuw vast te stellen en deze in het voorschrift op te nemen.

**AMC to MED.B.090, onder 1.2, onder iv. (Blz. 60 van 66)**

De CAA-The Netherlands acht dit voorschrift te soepel. Een kandidaat met een 'aortic aneurysm van 5,5 tot 6,5 cm' dient onmiddellijk geopereerd te worden. Een kandidaat goedkeuren met een dergelijke aandoening vormen een apert gevaar voor de luchtvaartveiligheid. De CAA-The Netherlands verzoekt aan EASA om de toegestane ondergrens in samenspraak met cardiologen opnieuw vast te stellen en deze in het voorschrift op te nemen.

**AMC to MED.B.090, onder 1.4. (Blz. 60 van 66)**

De CAA-The Netherlands stelt vast dat het lichamenlijk onderzoek bij het medisch LPL vereist geen hart en longonderzoek. De CAA-The Netherlands vraagt aan EASA hoe het mogelijk is om vast te stellen of sprake is van 'cardiac murmer'. Ingevolge dit voorschrift verzoekt De CAA-The Netherlands om de eisen van lichamenlijk onderzoek aan te passen.

**AMC to MED.B.090, onder 1.7. (Blz. 60 van 66)**

De CAA-The Netherlands acht de genoemde termijn van 6 weken veel te kort. Deze termijn moet gelijk zijn aan de termijn die vereist is in de zelfde situatie voor het medisch klasse 2 certificaat. De CAA-The Netherlands verzoekt aan EASA om de termijn in dit artikel te wijzigen in 6 maanden. Daarnaast acht de CAA-The Netherlands het onmogelijk dat een kandidaat met een dergelijke aandoening een inspanningstest kan maken zonder pijn.

**AMC to MED.B.090, onder 1.8. (Blz. 60 van 66)**

De CAA-The Netherlands acht de genoemde termijn van 6 weken veel te kort. Deze termijn moet gelijk zijn aan de termijn die vereist is in de zelfde situatie voor het medisch klasse 2 certificaat. De CAA-The Netherlands verzoekt aan EASA om de termijn in dit voorschrift te wijzigen in 6 maanden.

response

*Noted*

See response to comment No 102.

comment

156

comment by: *Civil Aviation Authority - The Netherlands***AMC to MED.B.090, onder 1.17, onder ii. (Blz. 61 van 66)**

De CAA-The Netherlands acht de gestelde toegestane ondergrens, zoals EASA die heeft vastgesteld in MED.B.090, onder 1.17, onder ii, veel te soepel. De CAA-The Netherlands acht een kandidaat met een lichamenlijk aandoening zoals omschreven in voorschrift MED.B.090, onder 1.17, onder ii medisch

ongeschikt. Vast staat dat een persoon met een zieke hartspeer zeer ernstig ziek is. Een kandidaat met een dergelijke aandoening medisch geschikt verklaren veroorzaakt een apert gevaar voor de luchtvaartveiligheid.

De CAA-The Netherlands verzoekt aan EASA om voorschrift AMC to MED.B.090, onder 1.17, onder ii, op een dusdanige manier aan te passen dat het niet mogelijk is om met een, zoals in het bovengenoemde voorschrift medische aandoening, medisch geschikt verklaard te worden.

**AMC to MED.B.090, onder 1.18. (Blz. 61 van 66)**

De CAA-The Netherlands acht de gestelde toegestane ondergrens van 0,4, zoals EASA die heeft vastgesteld in MED.B.090, onder 1.18, veel te soepel. De CAA-The Netherlands acht een kandidaat met een lichamelijk aandoening zoals omschreven in voorschrift MED.B.090, onder 1.18 medisch ongeschikt. Een kandidaat met een dergelijke aandoening medisch geschikt verklaren veroorzaakt een apert gevaar voor de luchtvaartveiligheid.

De CAA-The Netherlands verzoekt aan EASA om voorschrift AMC to MED.B.090, onder 1.18 op een dusdanige manier aan te passen dat het niet mogelijk is om na een hart- of longtransplantatie medisch geschikt verklaard te worden.

**AMC to MED.B.090, onder 2.1. (Blz. 61 van 66)**

De CAA-The Netherlands acht een kandidaat die insuline gebruikt medisch ongeschikt. Dit volgt tevens uit de voorschriften zoals die golden onder JAR-FCL 3.

De CAA-The Netherlands verzoekt aan EASA om voorschrift AMC to MED.B.090, onder 2.1 op een dusdanige manier aan te passen dat het niet mogelijk is om bij gebruik van insuline medisch geschikt verklaard te worden.

response

*Noted*

See response to comment No 102.

comment

318

comment by: *Aero-Club of Switzerland*

The medical specialist of the Aero-Club of Switzerland are of the opinion that the proposed requirements are unacceptable and ask for a completely new draft.

Justification: The requirements are not concise, many parts are contradictory, some requirements are far away from medical practice or from evidence-based medicine, like the LPL questionnaire. Some parts must even be declared as unethical. The whole text proves that it is not an easy task to set up a new list of requirements.

It is therefore much wiser to use an established system like the class 2 requirements or the ICAO class 2 requirements.

If these will be used, then there should be an additional text which states, that in special cases exceptions are possible. In order to know, however, what exception is possible, the acceptable risk for the LPL medical certificate must be defined (e.g. annual risk of 2 %).

This is not the case for the whole of the NPA 2008-17 c. We also could not find

a text about the acceptable annual risk for class 1 or class 2 medical certificates.

response *Noted*

See response to comment No 102.

comment

500

comment by: *UK CAA*

**AMC to MED.B.090 1.2 (iii)**

**Page: 60**

**Comment:**

Changes to text for clarity. The current text implies that they should have an exercise test which is not the intention.

**Justification:**

Clarity.

**Proposed Text:**

Change (iii) to "if they have had an exercise test that is unsatisfactory".

response *Noted*

See response to comment No 102.

comment

501

comment by: *UK CAA*

**AMC to MED.B.090 1.13**

**Page: 61**

**Comment:**

Pacemaker should be fitted with bipolar lead.

**Justification:**

To avoid interference to the pacemaker from the aircraft radio system.

**Proposed Text:**

Add: '**Only a pacemaker with a bipolar lead is acceptable as the pacemaker should be resistant to electrical interference**'.

response *Noted*

See response to comment No 102.

comment

561

comment by: *British Microlight Aircraft Association*

This section is helpful because it generally gives clear cut-off values in relation to fitness to hold and LPL. There are a few areas that are a bit vague. For example 1.2 (ii) A definition of "consistent" raised blood pressure would be helpful. The working definition often used is three separate sequential recordings. Similarly more specific guidance would be useful for 1.3 (iii) would

be useful as to what constitutes a satisfactory exercise test.

response *Noted*

See response to comment No 102.

comment

621

comment by: *Lufthansa German Airlines*

Author: Dr. Christine Huber, Cardiologist, AMC Frankfurt

Section: Subpart B Requirements for medical certificate - Section 1 - General - requirements for medical certificates for the LAPL

AMC to MED.B.090

Draft Version 3.0

### 1. Cardiovascular System

Page: 60

Relevant Text: 1.1. The Applicants pulse and blood pressure should be examined.

1.2. Applicants with any of the following conditions should have their privileges limited to operations without carrying passengers:

(i) if their LV ejection fraction is known to be less than 0.4;

(ii) when the blood pressure with or without treatment, at examination consistently exceeds 180 mmHg systolic and/or 100 mmHg diastolic

(iii) when they do have a satisfactory exercise test;

(iv) when they have an aneurysm in the range of 5.5 to 6.5 cm

1.3 Applicants that have

(i) preexcitation associated with a significant arrhythmia

(ii) aneurysms of greater than 6.5 cm

(iii) symptomatic hypertrophic cardiomyopathy

**Comment:** 1.2.(i) EF less than 40% is too low as a limit, high risk for ventricular arrhythmia

(ii) BP consistently exceeding 180 mmHg/100mmHg with or without treatment means the blood pressure is not sufficiently treated and should not be cleared

(iii) definition of satisfactory exercise test?

(iv) aneurysm above 5.5 cm should be treated surgically, and cannot be cleared

1.3 (i) aneurysm diameter limit is set too high

(i) why symptomatic hypertrophic CMP without mentioning dilated CMP which has the higher incidence?

**Proposal:** 1.2 applicant restriction to operations without carrying passengers: when they do not have an adequate age-related exercise test

1.3 Unfitness

(i) preexcitation with significant arrhythmias

(i) with an aortic aneurysm above 5.5 cm

(i) in symptomatic cardiomyopathy

(iv) if the LV ejection fraction is less than 50%.

(v) when the blood pressure with or without treatment, at examination consistently exceeds 160 mmHg

systolic and/or 90 mmHg diastolic, until adequate treatment exists

response *Noted*

See response to comment No 102.
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comment

622

comment by: *Lufthansa German Airlines*

Author: Dr. Christine Huber, Cardiologist, AMC Frankfurt

Section: Subpart B Requirements for medical certificate - Section 1 - General - requirements for medical certificates for the LAPL

AMC to MED.B.090

Draft Version 3.0

1. Cardiovascular System

**Page:** 60

Relevant Text: 1.4 General

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

1.5 Blood Pressure

The initiation of medication to control blood pressure requires a period of at least 2 weeks temporary suspension of the medical certificate to establish the absence of side effects.

1.7 Angina

Applicants with or without treatment, who have been free from angina for 6 weeks and who have had a satisfactory cardiological evaluation to include an exercise test, or equivalent test, that is negative for ischemia, may be assessed as fit.

1.10 Heart Attack

Applicants should not have had a heart attack within the last six weeks. Thereafter, applicants who have had a satisfactory cardiological evaluation to include an exercise test, or equivalent test that is negative for ischemia may be assessed as fit.

**Comment:** 1.4) how is the murmur assessed as being of no pathological significance?

1.5.) 2 weeks is a short interval for new medications to check on their side effects and the check of its efficiency is not mentioned at all

1.7) why is an interval of 6 weeks defined - the interval is not the relevant point. There could have been a myocardial infarction and pain stopped and still there could be relevant CAD.

1.10) why is an interval of 6 weeks defined - the interval is not the relevant point.

**Proposal:** 1.4 General

Applicants with a cardiac murmur may be assessed as fit if the murmur is assessed as being of no hemodynamical significance after echocardiogram.

1.5 Blood Pressure

The initiation of medication to control blood pressure requires a period of at least 2 weeks temporary suspension of the medical certificate to establish the absence of side effects. An efficiency check of the therapy has to be performed before certification.

1.7 Angina

Applicants with or without treatment, who are free of symptoms and a cardiological evaluation excluded myocardial ischemia during rest and exercise using an exercise test, or equivalent test, may be assessed as fit.

1.10 Heart Attack

Applicants should not have had a heart attack. Thereafter, applicants who have had a satisfactory cardiological evaluation to include an exercise test, or equivalent test that is negative for ischemia may be assessed as fit.

response	<i>Noted</i>
	See response to comment No 102.

comment	623	comment by: <i>Lufthansa German Airlines</i>
<p>Author: Dr. Christine Huber, Cardiologist, AMC Frankfurt  Section: Subpart B Requirements for medical certificate - Section 1 - General - requirements for medical certificates for the LAPL  AMC to MED.B.090  Draft Version 3.0  1. Cardiovascular System  <b>Page: 61</b></p> <p>Relevant Text:  1.11. Rhythm and conduction disturbances  Applicants with a significant disturbance of cardiac rhythm should be assessed as unfit unless the rhythm disturbance is assessed by a specialist as not likely to interfere with the safe exercise of the privilege of the LAPL.  1.12. Sinoatrial disease, atrio-ventricular conduction defects, atrial flutter/fibrillation, narrow or broad complex tachycardia  A fit assessment may be made when the arrhythmia has been controlled for 3 months and the LV ejection fraction is &gt; 0.4.  1.13. Pacemaker implantation  A fit assessment may be made 6 weeks after the pacemaker implantation.  1.14. Successful catheter ablation  A fit assessment may be made 6 weeks after successful catheter ablation.</p> <p><b>Comment:</b> 1.12 atrial flutter/fibrillation mentioned without relating to risk of embolism, anticoagulants - mentioned together with broad complex tachycardia "controlled" after 3 months is not useful. How is it controlled: by a defibrillator or amiodaron? Both variants are relevant for fitness to fly! The treatment itself is not mentioned at all! LV ejection fraction of 40% is too low as a limit.  1.13 pacemaker lead stabilisation takes longer than 6 weeks!  1.14 the necessary interval depends on the kind of ablation therapy.</p> <p><b>Proposal:</b> 1.11. Rhythm and conduction disturbances  Applicants with a significant disturbance of cardiac rhythm should be assessed as unfit unless the rhythm disturbance is assessed by a specialist as not likely to interfere with the safe exercise of the privilege of the LAPL.  1.12 Sinoatrial disease or atrioventricular conduction defects  A fit assessment may be made after a thorough cardiological evaluation.  1.13 Atrial flutter/fibrillation  Requires a cardiological evaluation and a fit assessment may be made after treatment or ablation therapy  1.14 Narrow or broad complex tachycardia  Require a cardiological evaluation and a fit assessment may be made after treatment or ablation therapy.  1.15 Pacemaker implantation  A fit assessment may be made 3 months after the pacemaker implantation.  1.16 Successful catheter ablation  A fit assessment may be made no sooner than 8 weeks after the successful catheter ablation.</p>		

comment	624	comment by: <i>Lufthansa German Airlines</i>
<p>Author: Dr. Christine Huber, Cardiologist, AMC Frankfurt  Section: Subpart B Requirements for medical certificate - Section 1 - General - requirements for medical certificates for the LAPL  AMC to MED.B.090  Draft Version 3.0  1. Cardiovascular System  <b>Page:</b> 61</p> <p>RelevantText: 1.15. Left bundle branch Block  A fit assessment can be made in applicants who have had a satisfactory cardiological evaluation to include an exercise test, or equivalent test. Applicants who do not meet the exercise test requirement may be assessed as fit for the OPL limitation.  1.16. Pre-excitation  Unless associated with an arrhythmia, applicants may be assessed as fit.</p> <p><b>Comment:</b> "A satisfactory cardiological evaluation" is not defined. An exercise test is insufficient in LBBB as it cannot rule out myocardial ischemia. What are "the exercise test requirements"? OPL limitation is not suitable in this issue. Preexcitation can be treated very well with catheter ablation in case it is associated with tachycardia - not "arrhythmias". How would it be checked, if the preexcitation is associated with an arrhythmia?</p> <p><b>Proposal:</b>  1.17 Preexcitation  May be assessed as fit after ablation therapy (see 1.16) or if it is not associated with tachycardias.  1.18 LBBB  A fit assessment may be made after thorough cardiological evaluation. An OSL limitation may be applied.</p>		
response	<i>Noted</i>	
See response to comment No 102.		
comment	625	comment by: <i>Lufthansa German Airlines</i>
<p>Author: Dr. Christine Huber, Cardiologist, AMC Frankfurt  Section: Subpart B Requirements for medical certificate - Section 1 - General - requirements for medical certificates for the LAPL  AMC to MED.B.090  Draft Version 3.0  <b>Page:</b> 61</p> <p>Relevant Text: 1.17. Arterial Disease  (i) Ascending/descending thoracic and abdominal aortic aneurysm.  Aneurysms of &lt;5.5 cm diameter may be assessed as fit in applicants who have had a satisfactory cardiological evaluation including an exercise test, or equivalent test.  (ii) Hypertrophic Cardiomyopathy  Hypertrophic cardiomyopathy is disqualifying if symptomatic. If asymptomatic a fit assessment can be made if 3 of the following criteria can be met: 1) There is no family history of sudden death in a first degree relative from presumed</p>		

hypertrophic cardiomyopathy. 2) A cardiologist can confirm that the hypertrophic cardiomyopathy is not severe and that the wall thickness does not exceed 3 cm. 3) No significant abnormality of heart rhythm has been demonstrated. 4) There is at least 25 mmHg increase in blood pressure during exercise testing.

1.18 Heart or lung transplant

A fit assessment may be made for applicants who have had a satisfactory cardiologist evaluation to include an exercise test, or equivalent test and have a left ventricular ejection fraction of >0.4.

**Comment:** (i) Exercise tests are not a useful tool to check on aortic aneurysms, transoesophageal echocardiography, MRI or CT scans are more relevant. The limit for the diameter has to be discussed.

1.17)(ii) the risk for arrhythmias is not discussed, it exists even if it has not been documented yet - wall thickness of 3 cm is way too high as a limit, the increase of 25 mmHg during exercise is not a suitable parameter and level to check on fitness in patients with hypertrophic cardiomyopathy.

What about the other cardiomyopathies?

1.18) no risk assessment is mentioned, nor medications and their side effects.

**Proposal:** (i) Ascending/descending thoracic and abdominal aortic aneurysm. Aneurysms of <5.0 cm diameter may be assessed as fit in applicants who have had a thorough cardiologist evaluation including transoesophageal echocardiography or MRI.

(ii) Hypertrophic Cardiomyopathy

Hypertrophic cardiomyopathy is disqualifying if symptomatic. If asymptomatic a fit assessment can be made after thorough cardiologist evaluation in the absence of arrhythmias and mild degree of wall hypertrophy.

1.18 Heart or lung transplant

A fit assessment may be made for applicants who have had a good cardiologist outcome, no side effects from medication interfering with flight fitness, good exercise capacity, normal left ventricular ejection fraction and no arrhythmias. Intensified cardiologist follow ups are necessary. An OSL may be applied.

response

*Noted*  
See response to comment No 102.

comment

695 comment by: *Robert Cronk*

The specific requirements for the LPL medical certification as proposed are far in excess of those applicable to drivers of commercial vehicles, which is a standard used for the UK NPPL and for UK glider pilot medical certification, without producing medical related accidents or incidents materially over the level found in Class 2 certified PPLs. Further, due to the lower level of risk exposure, a greater risk of incapacity should be acceptable for the LPL than would be the case for the full PPL

The methods employed to certify medical fitness need to be simple and cheap for the LPL.

response

*Noted*

See response to comment No 102.
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comment

754

comment by: *Swiss Association of Aviation Medecine*

**The Swiss Society of Aviation Medicine supports the following comment and proposal.**

**Comment:**

The working group of European Cardiologists in Aviation Medicine reached consensus, that the LPL requirements are medically - cardiologically critical for human safety for the pilot himself and for aviation safety. Furthermore multiple international study results prove the danger and risks of the requirements and limits set up in the LPL requirements (like for instance a left ventricular ejection fraction below 50%). It would be dangerous as well as stupid to assess cardiological and aeromedical "fitness" under such regulations. It would rather be an assessment and documentation of "sickness" than of fitness, ready for use against consultants by any lawyer or judge in the European Union.

Therefore the working group of cardiologists will refuse to check LPL pilots under these regulations.

**Proposal:**

Private Pilots should be checked for their fitness to fly according to AMC class 2 medical regulations.

LPL requirements should be deleted.

response

*Noted*

See response to comment No 102.
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comment

773

comment by: *European Society of Space and Aviation Medicine (ESAM)*

**Author: European Society of Space and Aviation Medicine (ESAM) - Internal Medicine Group -**

**Section: AMC to MED B.090**

**Page: 60**

**Relevant Text:**

(all of it)

**Comment:**

Requirements for LAPL totally lack a reasonable medical basis and controverse in most parts aeromedical and traffic medicine experience and good-practice. Going into details is not possible with the present structure of requirements and the remaining time of session, new structure should be built up in consultancy with an experienced Aeromedical examiner.

**Proposal:**

Set Class 2 standards and certification procedure as a minimum standard for any aeromedical certification.

response	<i>Noted</i>	
	See response to comment No 102.	
comment	823	comment by: <i>Swiss Association of Aviation Medicine</i>
	<p><b>Comment:</b> Requirements for LAPL totally lack a reasonable medical basis and controverse in most parts aeromedical and traffic medicine experience and good-practice. Going into details is not possible with the present structure of requirements and the remaining time of session, new structure should be built up in consultance with an experienced Aeromedical examiner.</p> <p><b>Proposal:</b> Set Class 2 standards and certification procedure as a minimum standard for any aeromedical certification.</p>	
response	<i>Noted</i>	
	See response to comment No 102.	
comment	1018	comment by: <i>European Society of Space and Aviation Medicine (ESAM)</i>
	<p><b>Author: European Society of Space and Aviation Medicine (ESAM) - Cardiology Group -</b></p> <p><b>Comment LPL</b></p> <p><b>Page: 23 - 26 and 60 - 61</b></p> <p><b>Comment:</b> The working group of European Cardiologists in Aviation Medicine reached consensus, that the LPL requirements are medically - cardiologically critical for human safety for the pilot himself and for aviation safety. Furthermore multiple international study results prove the danger and risks of the requirements and limits set up in the LPL requirements (like for instance a left ventricular ejection fraction below 50%). It would be dangerous as well as stupid to assess cardiologicial and aeromedical "fitness" under such regulations. It would rather be an assessment and documentation of "sickness" than of fitness, ready for use against consultants by any lawyer or judge in the European Union. Therefore the working group of cardiologists will refuse to check LPL pilots under these regulations.</p> <p><b>Proposal:</b> Private Pilots should be checked for their fitness to fly according to AMC class 2 medical regulations. LPL requirements should be deleted</p>	
response	<i>Noted</i>	
	See response to comment No 102.	

comment	1039	comment by: <i>Ilse Janicke Heart Center Duisburg</i>
<p>Author: Janicke Ilse, Senior MD, AME I and II, Cardiologist and Angiologist at Heart Center Duisburg  Section: <b>2 Specific requirements for LPL medical certificates AMC to MED.B.090</b>  <b>1. CARDIOVASCULAR SYSTEM</b>  Page: 60 (NPA 2008-17c)</p> <p>Relevant Text:  1.2. Applicants with any of the following conditions should have their privileges limited to operations without carrying passengers:  (i) if their LV ejection fraction is known to be less than 0.4;  (iii) when they do have a satisfactory exercise test;  (iv) when they have an aneurysm in the range of 5.5 to 6.5 cm  1.3 Applicants that have  (i) preexcitation associated with a significant arrhythmia  (ii) aneurysms of greater than 6.5 cm  (iii) symptomatic hypertrophic cardiomyopathy</p> <p><b>Comment:</b>  1.2.  (i) EF less than 40% is too low as a limit, high risk for ventricular arrhythmia and sudden cardiac death. An ejection fraction below 50 % without and especially with CHD is likely to jeopardize flight safety.  (iii) definition of satisfactory exercise test? The exercise ECG has little sensitivity and specificity for detecting CHD, this can be increased to 60-70 % sensitivity and 95 % specificity if symptom limited.  (iv) aneurysm above 5.5 cm should be treated surgically, and cannot be cleared. In the last 3 years the prevalence of abdominal aneurysm is consistently increasing, at the age &gt; 55 the prevalence is &gt; 5 %.Increasing age, atherosclerosis, hypertension and familial factors are involved in the pathogenesis. The risk of rupture and subsequently sudden incapacitation exerts 22% per year at aneurysm size &gt; 5,5 cm. The survival rate will be influenced further through coexisting CHD. This is likely to jeopardize flight safety.  1.3  (ii) aneurysm diameter limit is set too high  (i) why symptomatic hypertrophic CMP without mentioning dilated CMP which has the higher incidence?</p> <p><b>Proposal:</b>  Applicants with any of the following conditions should have their privileges limited to operations without carrying passengers:  (iii) when they do have a satisfactory age-related symptom-limited exercise test;  (iv) when they have an aneurysm in the range above 5.0 cm  1.3 Applicants that have  (i) LV ejection fraction is known to be less than 0.5;  (i) preexcitation with a significant arrhythmia  (ii) aneurysms of greater than 5.5 cm  (iii) symptomatic cardiomyopathy  should be assessed as unfit</p>		
response	<i>Noted</i>	

See response to comment No 102.

comment

1040

comment by: *Ilse Janicke Heart Center Duisburg*

Author: Janicke Ilse, Senior MD, AME I and II, Cardiologist and Angiologist at Heart Center Duisburg

Section:

**2 Specific requirements for LPL medical certificates**

**AMC to MED.B.090**

**1. CARDIOVASCULAR SYSTEM**

**Page:** 60 (NPA 2008-17c)

Relevant Text:

1.7 Angina

Applicants with or without treatment, who have been free from angina for 6 weeks and who have had a satisfactory cardiological evaluation to include an exercise test, or equivalent test, that is negative for ischemia, may be assessed as fit.

1.8 Elective Angioplasty

Applicants....who have been free from angina for 6 weeks, and ....to include an exercise test, or equivalent test, ...may be assessed as fit.

1.10 Heart Attack

Applicants should not have had a heart attack within the last six weeks. Thereafter, applicants who have had a satisfactory cardiological evaluation to include an exercise test, or equivalent test that is negative for ischemia may be assessed as fit.

**Comment:**

1.7) and 1.8) and 1.10: why is an interval of 6 weeks defined - the interval is not the relevant point. There could have been a myocardial infarction and pain stopped and still there could be relevant CAD. And 6 weeks are over and the pilot would not tell this to the doctor.

The exercise ECG has little sensitivity and specificity for detecting CAD, this can be increased to 60-70 % sensitivity and 95 % specificity if symptom limited.

**Proposal:**

1.7 Angina

Applicants with or without treatment, who are free of symptoms and a cardiological evaluation excluded myocardial ischemia during rest and symptom limited exercise test, or equivalent test, may be assessed as fit.

1.8 Elective Angioplasty

Applicants....who have been free of symptoms, and a cardiological evaluation excluded myocardial ischemia during rest and symptom limited exercise test, or equivalent test, ...may be assessed as fit

1.10 Heart Attack

Applicants should not have had a heart attack. Thereafter, applicants who have had a satisfactory cardiological evaluation to include a symptom limited exercise test, or equivalent test that is negative for ischemia may be assessed as fit.

response

*Noted*

See response to comment No 102.

comment	1041	comment by: <i>Ilse Janicke Heart Center Duisburg</i>
<p>Author: Janicke Ilse, Senior MD, AME I and II, Cardiologist and Angiologist at Heart Center Duisburg  Section:  <b>2 Specific requirements for LPL medical certificates</b>  <b>AMC to MED.B.090</b>  <b>1. CARDIOVASCULAR SYSTEM</b>  Page: 61 (NPA 2008-17c)</p> <p>Relevant Text:  1.12. Sinoatrial disease, atrio-ventricular conduction defects, atrial flutter/fibrillation, narrow or broad complex tachycardia  A fit assessment may be made when the arrhythmia has been controlled for 3 months and the LV ejection fraction is &gt; 0.4.  1.13. Pacemaker implantat  A fit assessment may be made 6 weeks after the pacemaker implantation.  1.14. Successful catheter ablation  A fit assessment may be made 6 weeks after successful catheter ablation.</p> <p><b>Comment:</b>  1.12 atrial flutter/fibrillation mentioned without relating to risk of embolism, anticoagulants - mentioned together with broad complex tachycardia "controlled" after 3 months is not useful. How is it controlled: by a defibrillator or amiodaron? Both variants are relevant for fitness to fly! The treatment itself is not mentioned at all! LV ejection fraction of 40% is too low as a limit.  1.13 pacemaker lead stabilisation takes longer than 6 weeks! An implanted pacemaker needs 3 month time two correct grow in the heart muscle. Then one can detect impedance and safely working of the pacemaker. In the first weeks the rate for dislocation of the sonden will be higher than after 3 months. That is why the first control after surgery will be 3 month after implantation. This is general agreement.  1.14 the necessary interval depends on the kind of ablation therapy.</p> <p><b>Proposal:</b>  1.12 A fit assessment may be made when the arrhythmia has been investigated and evaluated in accordance with best medical practice and is assessed not likely to jeopardize flight safety. A structural or organic heart disease should be ruled out, the ejection fraction is <math>\geq 0,5</math>.  1.12 Sinoatrial disease or atrioventricular conduction defects  A fit assessment may be made after a thorough cardiological evaluation.  Atrial flutter/fibrillation  Requires a cardiological evaluation and a fit assessment may be made after treatment or ablation therapy  Narrow or broad complex tachycardia  Require a cardiological evaluation and a fit assessment may be made after treatment or ablation therapy.  1.13 Pacemaker implantation  A fit assessment may be made 3 months after the pacemaker implantation.  1.14 Successful catheter ablation  A fit assessment may be made no sooner than 8 weeks after the successful catheter</p>		
response	Noted	
See response to comment No 102.		

comment	1042	comment by: <i>Ilse Janicke Heart Center Duisburg</i>
<p>Author: Janicke Ilse, Senior MD, AME I and II, Cardiologist and Angiologist at Heart Center Duisburg  Section:  <b>2 Specific requirements for LPL medical certificates</b>  <b>AMC to MED.B.090</b>  <b>1. CARDIOVASCULAR SYSTEM</b>  Page: 61 (NPA 2008-17c)</p> <p>Relevant Text:  1.15. Left bundle branch Block  A fit assessment can be made in applicants who have had a satisfactory cardiological evaluation to include an exercise test, or equivalent test. Applicants who do not meet the exercise test requirement may be assessed as fit for the OPL limitation.  1.16. Pre-excitation  Unless associated with an arrhythmia, applicants may be assessed as fit subject to satisfactory cardiological evaluation.</p> <p><b>Comment:</b>  "A satisfactory cardiological evaluation" is not defined. An exercise test is insufficient in LBBB as it cannot rule out myocardial ischemia. What are "the exercise test requirements"? OPL limitation is not suitable in this issue. Preexcitation can be treated very well with catheter ablation in case it is associated with tachycardia - not "arrhythmias". How would it be checked, if the preexcitation is associated with an arrhythmia?</p> <p><b>Proposal:</b>  1.15 LBBB  A fit assessment may be made after thorough cardiological evaluation. An OSL limitation may be applied.  1.17 Preexcitation  Applicants may be assessed as fit after ablation therapy (see 1.14) or if it is not associated with tachycardias.</p>		

response

*Noted*

See response to comment No 102.

comment

1044

comment by: *Ilse Janicke Heart Center Duisburg*

Author: Janicke Ilse, Senior MD, AME I and II, Cardiologist and Angiologist at Heart Center Duisburg  
Section:  
**2 Specific requirements for LPL medical certificates**  
**AMC to MED.B.090**  
**1. CARDIOVASCULAR SYSTEM**  
Page: 61 (NPA 2008-17c)

Relevant Text:  
Relevant Text: **1.17. Arterial Disease**  
(i) Ascending/descending thoracic and abdominal aortic aneurysm.  
Aneurysms of < 5.5 cm diameter may be assessed as fit in applicants who

have had a satisfactory cardiological evaluation including an exercise test, or equivalent test.

(ii) Hypertrophic Cardiomyopathy

Hypertrophic cardiomyopathy is disqualifying if symptomatic. If asymptomatic a fit assessment can be made if 3 of the following criteria can be met: 1) There is no family history of sudden death in a first degree relative from presumed hypertrophic cardiomyopathy. 2) A cardiologist can confirm that the hypertrophic cardiomyopathy is not severe and that the wall thickness does not exceed 3 cm. 3) No significant abnormality of heart rhythm has been demonstrated. 4) There is at least 25 mmHg increase in blood pressure during exercise testing.

**Comment: 1.17 Arterial Disease**

(i) Exercise tests are not a useful tool to check on aortic aneurysms, transoesophageal echocardiography, MRI or CT scans are more relevant. The limit for the diameter has to be discussed. The risk for rupture in ascending aorta increases above 5,0 cm. In some heart centers it will be operated above 5,0 cm and in others above 5,5 cm.

(ii) The hypertrophic cardiomyopathy is not an arterial disease but is a distinct disease. The risk for arrhythmias is not discussed, it exists even if it has not been documented yet - wall thickness of 3 cm is way too high as a limit, the increase of 25 mmHg during exercise is not a suitable parameter and level to check on fitness in patients with hypertrophic cardiomyopathy.

What about the other cardiomyopathies?

**Proposal:**

1.17 Arterial Disease

(i) Ascending/descending thoracic and abdominal aortic aneurysm.

Aneurysms of <5.0 cm diameter may be assessed as fit in applicants who have had a thorough cardiological evaluation including transoesophageal echocardiography or MRI.

1.19 Cardiomyopathies

Hypertrophic cardiomyopathy and significant cardiomyopathy of other origin (primary or secondary) is disqualifying if symptomatic. If asymptomatic a fit assessment can be made after thorough cardiological evaluation in the absence of arrhythmias, mild degree of wall hypertrophy, without history of sudden cardiac death in a first degree relative and without history of syncope.

response

*Noted*

See response to comment No 102.

comment

1045

comment by: *Ilse Janicke Heart Center Duisburg*

Author: Janicke Ilse, Senior MD, AME I and II, Cardiologist and Angiologist at Heart Center Duisburg

Section:

**2 Specific requirements for LPL medical certificates**

**AMC to MED.B.090**

**1. CARDIOVASCULAR SYSTEM**

Page: 61 (NPA 2008-17c)

Relevant Text:

**1.18 Heart or lung transplant**

A fit assessment may be made for applicants who have had a satisfactory cardiological evaluation to include an exercise test, or equivalent test and have

a left ventricular ejection fraction of >0.4.

**Comment:**

It is new that persons after heart or lung transplantation could get a medical. There is an interest study, which was decided from the FAA.

1) McGiffin DC et al. *The case of selective re-issuance of medical certificates to allow pilots who have received a heart transplant to resume flying. J Heart Lung Transplant 2005 Mar; 24(3): 259-69*

He study was undertaken to determine the risk of death and sudden cardiac death during 12 month after annual evaluation. 4978 patients survived for 1 year and formde the basis of the study. There is a group of heart transplant recipients which could be defined with a 12 month risk of death of any cause of 1 % and of sudden cardiac death of 0,3 %. This group has nor risk factors such as allograft vasculopathy, left ventricular systolic dysfunction, history of rejection, malignancy, infection and pretransplant IDDM.

2) McGiffin DC et al: *Risk of death or incapacitation aftre heart transplantation, with particular reference to pilots. J Heart Lung Transplant. 1998 May; 17(5): 497-504.*

In 3676 survived patients the rapid onset on death during the second posttransplantation year was 1,4% and the third year 1,6 %, presumed the coronary angiogram is normal and there was no rejction in the first year.

**Proposal:**

1.18 Heart or lung transplantation

A fit assessment may be made not sooner than 1 year after transplantation for applicants who have had a satisfactory cardiological evaluation to include symptom limited exercise test, have a left ventricular ejection fraction of ≥ 0,5, no rejection in the first year post transplant, a normal coronarangiogram and no significant arrhythmias. Intensified cardiological follow ups are necesesary. An OSL may be applied. A combined heart and lung transplantation should be assessed as unfit.

response

*Noted*

See response to comment No 102.

comment

1088

comment by: *Robert Corbin*

This section should be for the guidance of a General Medical Practioner and not a requirement.

response

*Noted*

See response to comment No 102.

comment

1249

comment by: *Swedish Transport Agency, Civil Aviation Department (Transportstyrelsen, Luftfartsavdelningen)*

**Comment:**

In 1.2, a number of cardiovascular conditions are mentioned, which should result in an unfit assessment or a fit assessment without carrying passengers. The AME taking the decision thus will have two different options for exactly the same condition, which may result in a completely random decision. This is against the principles of equity and should not appear in a regulatory text.

With the very low proposed standard for a LPL medical certificate no operational limitations at all should be accepted for a LPL medical certificate.

**Proposal:**

If the LPL should have medical requirements below ICAO class 2 standards, this paragraph should be amended:

1.2. Applicants with any of the following conditions should be assessed as unfit:

response

*Noted*

See response to comment No 102.

comment

1250

comment by: *Swedish Transport Agency, Civil Aviation Department (Transportstyrelsen, Luftfartsavdelningen)*

**Comment:**

In 1.2 (i), the limit of 0,5 for LVEF universally accepted by European cardiologists has been lowered to 0,4 without any scientific basis. With a LVEF less than 0,4 (and with NO lower limit mentioned!) the applicant is suffering from serious cardiac failure which may lead to acute in-flight incapacitation. By using the expression "is known to be", the text also implies that if a GMP or AME does not ask for this specific test, which only can be performed by a specialist in cardiology, the applicant should be assessed as fit!

The proposed limit for LVEF for LPL will neither ensure that the level of safety is maintained, which is required in Article 7 of the Basic Regulation, nor fulfil the requirement for an appropriate assessment based on aero-medical best practice as laid down in Annex III to the Basic regulation.

**Proposal:**

If the LPL should have medical requirements below ICAO class 2 standards, this paragraph should be amended:

(i) if their left ventricular ejection fraction is less than 0.5.

response

*Noted*

See response to comment No 102.

comment

1251

comment by: *Swedish Transport Agency, Civil Aviation Department (Transportstyrelsen, Luftfartsavdelningen)*

**Comment:**

In 1.2 (iii), there is no definition or interpretation of the wording "not have a satisfactory exercise test". There are a number of different conditions which may lead to this conclusion, with totally different risks for a sudden incapacitation during flight.

Using the expression "when they do not have" also implies that every applicant for a LPL medical certificate has to pass an exercise test, which is not even required for class 1, except when specified in the requirements. The need for an exercise test as a part of a cardiological assessment should be detailed as in AMC B to MED.B.005.

The proposed text for LPL in 1.2 does not fulfil the requirement for an appropriate assessment based on aero-medical best practice as laid down in Annex III to the Basic regulation.

**Proposal:**

If the LPL should have medical requirements below ICAO class 2 standards, this paragraph should be amended in accordance with the requirements for a cardiological assessment as outlined in AMC B to MED.B.005.

response

*Noted*

See response to comment No 102.

comment

1252

comment by: *Swedish Transport Agency, Civil Aviation Department (Transportstyrelsen, Luftfartsavdelningen)*

**Comment:**

In 1.2 (iv), a limit of 6.5 cm for an aortic aneurysm is introduced without giving any scientific basis for choosing this size. Neither class 1 nor class 2 has any size limits for aortic aneurysms. Moreover, there is an enormous difference between infrarenal and suprarenal aortic aneurysms, the latter also including aneurysms of the ascending aorta. Any aortic aneurysm will need a regular follow-up. The proposed text does not take these aspects into account at all, as it has been done for class 2 medical requirements in AMC B to MED.B.005, which requires an assessment by a cardiologist.

The proposed text for LPL will neither ensure that the level of safety is maintained, which is required in Article 7 of the Basic Regulation, nor fulfil the requirement for an appropriate assessment based on aero-medical best practice as laid down in Annex III to the Basic regulation.

**Proposal:**

If the LPL should have specific medical requirements, this paragraph should be amended in accordance with the requirements for a cardiological assessment as outlined in AMC B to MED.B.005.

response

*Noted*

See response to comment No 102.

comment

1253

comment by: *Swedish Transport Agency, Civil Aviation Department (Transportstyrelsen, Luftfartsavdelningen)*

1.5. *Blood Pressure*

**Comment:**

A suspension of a medical certificate can only be imposed and lifted by the licensing authority (MED.A.065), which implies that every LPL holder starting antihypertensive medication should contact the licensing authority. This suspension is neither required for class 2 nor for class 1. However, for class 1, a reassessment of the effects of the medication is required before returning to flying duties (AMC A to MED.B.005), which is most appropriate for all classes of medical certificates.

Suspension of exercise of the privileges only, and not of the certificate, is

regulated in MED.A.060 (a), however this paragraph does not cover the LPL.

**Proposal:**

Amend AMC to MED.B.090 1.5. *Blood Pressure* in order to be in line with AMC A to MED.B.005:

Following initiation of medication for the control of blood pressure, applicants should be reassessed to verify that the treatment is compatible with the safe exercise of the privileges of the licence held.

response *Noted*

See response to comment No 102.

comment

1254

comment by: *Swedish Transport Agency, Civil Aviation Department (Transportstyrelsen, Luftfartsavdelningen)*

*1.7. Angina*

**Comment:**

Angina is not a clearly defined entity which might hide symptoms emanating from other organs than the heart, and should be avoided in a regulation. An applicant with a history of true symptomatic angina pectoris invariably has an ischaemic heart disease and will not pass a cardiological evaluation that is negative for ischaemia, unless being treated with coronary angioplasty which is covered in 1.7 and 1.8., or if the diagnosis was totally wrong. Medication only will not eliminate or even reduce the risk for future incapacitation during flight. Also, there is no scientific basis to stipulate that a symptom-free period of 6 weeks will make any difference in the risk for future incapacitation during flight. It is not enough only to exclude ischaemia during the evaluation, but also significant coronary artery stenosis which has a high risk for sudden incapacitation during flight.

The class 2 requirements does not even mention angina, but uses instead a more appropriate entity, 'suspected asymptomatic coronary artery disease'. For class 2, the cardiological evaluation required for this entity should show no evidence of myocardial ischaemia or significant coronary artery stenosis, which is most appropriate also for LPL.

The proposed text for LPL will neither ensure that the level of safety is maintained, which is required in Article 7 of the Basic Regulation, nor fulfil the requirement for an appropriate assessment based on aero-medical best practice as laid down in Annex III to the Basic regulation.

If the LPL should have separate medical requirements, this paragraph should be amended in order to be in line with the requirements for a cardiological assessment as outlined in AMC B to MED.B.005.

**Proposal:**

Amend AMC to MED.B.090 1.7. *Angina* to be in line with AMC B to MED.B.005: *1.7. Suspected asymptomatic coronary artery disease*

In suspected asymptomatic coronary artery disease cardiological evaluation should show no evidence of myocardial ischaemia or significant coronary artery stenosis.

response *Noted*

See response to comment No 102.

comment	1255	comment by: <i>Swedish Transport Agency, Civil Aviation Department (Transportstyrelsen, Luftfartsavdelningen)</i>
<p><b>1.8. Elective Angioplasty</b></p> <p><b>Comment:</b> In 1.8, the time frame of 6 months after an angioplasty universally accepted by European cardiologists has been reduced to 6 weeks without any scientific basis. The risk for early restenosis of a treated coronary artery resulting in a possible sudden in-flight incapacitation remains far longer than the proposed 6 weeks. It is not enough only to exclude ischaemia during the evaluation, but also significant coronary artery stenosis, which has a high risk for sudden incapacitation during flight.</p> <p>If the LPL should have separate medical requirements, this paragraph should be amended in order to be in line with the requirements for a cardiological assessment as outlined in AMC B to MED.B.005.</p> <p><b>Proposal:</b> Amend AMC to MED.B.090 1.8. <i>Elective Angioplasty</i> to be in line with AMC B to MED.B.005.</p>		

response *Noted*

See response to comment No 102.

comment	1256	comment by: <i>Swedish Transport Agency, Civil Aviation Department (Transportstyrelsen, Luftfartsavdelningen)</i>
<p><b>1.9. Coronary Artery ByPass Grafting</b></p> <p><b>Comment:</b> In 1.9, the time frame of 6 months after coronary artery by-pass grafting universally accepted by European cardiologists has been reduced to 3 months without any scientific basis. Also for a coronary by-pass graft the risk for early restenosis of the graft resulting in a possible sudden in-flight incapacitation remains longer than the proposed 3 months. It is not enough only to exclude ischaemia during the evaluation, but also significant coronary artery stenosis, which has a high risk for sudden in-flight incapacitation.</p> <p>If the LPL should have separate medical requirements, this paragraph should be amended in order to be in line with the requirements for a cardiological assessment as outlined in AMC B to MED.B.005.</p> <p><b>Proposal:</b> Amend AMC to MED.B.090 1.9. <i>Coronary Artery ByPass Grafting</i> in order to be in line with AMC B to MED.B.005.</p>		

response *Noted*

See response to comment No 102.

comment	1257	comment by: <i>Swedish Transport Agency, Civil Aviation Department</i>
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	<i>(Transportstyrelsen, Luftfartsavdelningen)</i>
	<p><i>1.10. Heart Attack</i></p> <p><b>Comment:</b>  A heart attack is a layman's term and not a scientifically defined entity and should thus not be used in a regulation. In 1.10, the time frame of 6 months after a myocardial infarction universally accepted by European cardiologists has been reduced to 6 weeks without any scientific basis. The remaining risk for a sudden in-flight incapacitation is not only depending on the result of an exercise test but also on the proneness for rhythm disturbances and reduced pumping ability when part of the heart muscle has been destroyed. The recovery from some of the damage to the heart will take far longer time than the proposed 6 weeks. Also, it is not enough only to exclude ischaemia during the evaluation, but also significant coronary artery stenosis which has a high risk for sudden incapacitation during flight. Also, there is no requirement to reduce any risk factors for heart disease, which should be mandatory to reduce the risk for additional heart trouble.</p> <p>The proposed text for LPL will neither ensure that the level of safety is maintained, which is required in Article 7 of the Basic Regulation, nor fulfil the requirement for an appropriate assessment based on aero-medical best practice as laid down in Annex III to the Basic regulation.</p> <p>If the LPL should have separate medical requirements, this paragraph should be amended in order to be in line with the requirements for a cardiological assessment as outlined in AMC B to MED.B.005.</p> <p><b>Proposal:</b>  Amend AMC to MED.B.090 <i>1.10. Heart Attack</i> in order to be in line with AMC B to MED.B.005.</p>

response

*Noted*

See response to comment No 102.

comment

1258

comment by: *Swedish Transport Agency, Civil Aviation Department  
(Transportstyrelsen, Luftfartsavdelningen)**1.12. Sinoatrial disease, atrioventricular conduction defects, atrial flutter/fibrillation, narrow or broad complex tachycardia***Comment:**

The text contains a mixture of different conduction defects and arrhythmias with totally different causes and prognosis. They are sometimes difficult to diagnose and will need an assessment by a cardiologist. To include a requirement for an acceptable left ventricular function is inexplicable because that has no relation to the described conditions.

If the LPL should have separate medical requirements, this paragraph should be amended in order to be in line with the requirements for a cardiological assessment as outlined in AMC B to MED.B.005.

**Proposal:**

Amend AMC to MED.B.090 *1.12. Sinoatrial disease, atrioventricular conduction defects, atrial flutter/fibrillation, narrow or broad complex tachycardia* in order to be in line with AMC B to MED.B.005.

response	<i>Noted</i>
	See response to comment No 102.

comment	1259	comment by: <i>Swedish Transport Agency, Civil Aviation Department (Transportstyrelsen, Luftfartsavdelningen)</i>
<p><i>1.13. Pacemaker implant</i></p> <p><b>Comment:</b> Pacemakers and pacemaker implants cannot be treated as a single entity. Both the underlying condition and the type of pacemaker system will influence the risk for in-flight incapacitation. No scientific evidence is presented to justify the proposed shortening of the generally accepted 3 month 'quarantine' to 6 weeks.</p> <p>If the LPL should have separate medical requirements, this paragraph should be amended in order to be in line with the requirements for a cardiological assessment as outlined in AMC B to MED.B.005.</p> <p><b>Proposal:</b> Amend AMC to MED.B.090 <i>1.13. Pacemaker implant</i> in order to be in line with AMC B to MED.B.005.</p>		

comment	1260	comment by: <i>Swedish Transport Agency, Civil Aviation Department (Transportstyrelsen, Luftfartsavdelningen)</i>
<p><i>1.14. Successful Catheter Ablation</i></p> <p><b>Comment:</b> Catheter ablation cannot be treated as a single entity. There are a number of different underlying conditions and different modes of treatment with different risk recurrence and in-flight incapacitation. About 5% of the most common arrhythmias treated with ablation will recur within 6 months. For atrial fibrillation treated with ablation there is a recommendation to continue medication with Warfarin for 6 months after the ablation, during which time the pilot is unfit for flying. A cardiological evaluation is always needed before a fit assessment can be made after a catheter ablation.</p> <p>If the LPL should have separate medical requirements, this paragraph should be amended in order to be in line with the requirements for a cardiological assessment as outlined in AMC B to MED.B.005.</p> <p><b>Proposal:</b> Amend AMC to MED.B.090 <i>1.14. Successful Catheter Ablation</i> in order to be in line with AMC B to MED.B.005.</p>		

response	<i>Noted</i>
	See response to comment No 102.

comment	1261	comment by: <i>Swedish Transport Agency, Civil Aviation Department (Transportstyrelsen, Luftfartsavdelningen)</i>
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*1.15. Left bundle branch block***Comment:**

The proposed text is impossible to understand. There is no definition of exercise test requirement[JM1]. An applicant who does not meet the requirement could, at random, be assessed as fit with an OPL limitation, regardless of the test results, which is against the principle of equity.

The proposed text for LPL will neither ensure that the level of safety is maintained, which is required in Article 7 of the Basic Regulation, nor fulfil the requirement for an appropriate assessment based on aero-medical best practice as laid down in Annex III to the Basic regulation.

If the LPL should have separate medical requirements, this paragraph should be amended in order to be in line with the requirements for a cardiological assessment as outlined in AMC B to MED.B.005.

**Proposal:**

Amend AMC to MED.B.090 *1.15. Left bundle branch block* in order to be in line with AMC B to MED.B.005.

[JM1]Se upp med detta; ibland smyger det sig in ett mellanslag mellan bokstav och skiljetecken!

response

*Noted*

See response to comment No 102.

comment

1262

comment by: *Swedish Transport Agency, Civil Aviation Department (Transportstyrelsen, Luftfartsavdelningen)**1.17. Arterial Disease***Comment:**

No similar size limit is described for class 2, which only requires a cardiological evaluation and regular follow-up which gives far more flexibility than the proposed requirements for LPL which are considered disproportionate.

**Proposal:**

Use the requirements for 'aortic aneurysm' as described for class 2 in AMC B to MED.B.005.

response

*Noted*

See response to comment No 102.

comment

1263

comment by: *Swedish Transport Agency, Civil Aviation Department (Transportstyrelsen, Luftfartsavdelningen)**1.17. Arterial Disease***Comment:**

No similar detailed requirement is described for class 2, not even for class 1. HCMF would fall into the category 'other cardiac disorders', which only requires a cardiological evaluation which gives far more flexibility than the proposed requirements for LPL which are considered disproportionate.

**Proposal:**

Use the requirements for 'other cardiac disorders' as described for class 1 in AMC A to MED.B.005.

response *Noted*

See response to comment No 102.

comment

1264

comment by: *Swedish Transport Agency, Civil Aviation Department (Transportstyrelsen, Luftfartsavdelningen)*

*1.18 Heart or lung transplant*

**Comment:**

The described tests are insufficient to make a fit assessment after a heart or heart/lung transplantation. Moreover, the immunosuppressive medication necessary after a transplantation must be compatible with flying.

The proposed requirement for LPL would also include solitary lung transplantation, which is not included for class 2 and should be considered as a different condition.

A better approach is to use the requirements for class 2, which only requires a cardiological evaluation which gives far more flexibility than the proposed requirements for LPL which are considered disproportionate.

**Proposal:**

Use the requirements for heart or heart/lung transplantation described for class 2 in MED.B.005 (b)

response *Noted*

See response to comment No 102.

comment

1391

comment by: *Andy Austin*

Generally I agree that disciplined controls should be in place for aviation sport. The current system of local GPS performing medicals to HGV standards works very well. How many accidents have there been with balloons that were caused by poor quality medicals ?

Having to use a specialist doctor for medicals will add to the cost of the sport and will help to destroy the industry that supports this growing sport. Pilots will start to leave this sport because it is too difficult to maintain.

The current controls work. What have I missed ?

response *Noted*

See response to comment No 102.

comment

1588

comment by: *DAvid Monks*

I believe it is essential this section is included in its entirety as it is pivotal to the success of the LPL.

response	<i>Noted</i>	
	See response to comment No 102.	
comment	1739	comment by: <i>DCA Malta</i>
	<p>AMC to MED.B.090</p> <p>Delete LPL pilots should meet class 2 medical requirements. These pilots could fly in the same airspace as commercial aircraft and over densely populated areas.</p>	
response	<i>Noted</i>	
	See response to comment No 102.	
comment	1853	comment by: <i>UK CAA MEDICAL ADVISORY PANEL</i>
	<p><b>Paragraph</b> AMC to MED.B.090 <b>1.13</b> <b>Page</b> 60</p> <p><b>Comment</b> Incomplete.</p> <p><b>Justification</b> The applicant should not be P/M dependent</p> <p><b>Proposed Text</b> insert... a bipolar lead system should be used and the applicant not be pacemaker dependent</p>	
response	<i>Noted</i>	
	See response to comment No 102.	
comment	1864	comment by: <i>Dr Stephen Gibson</i>
	<p>re page 60, 1.2(iii)</p> <p>I suggest add the words " if one has been performed" or change the wording to read " if applicants have had an unsatisfactory exercise test"</p> <p>reason: as it is drafted at present it might exclude ALL applicants who have never had an exercise test or satisfactory test</p> <p>1.5</p> <p>I suggest temporary suspension "of flying" in place of "the medical certificate" to reduce unnecessary administration.</p> <p>1.7 I suggest insert "who have had angina" after "Applicants," or else the current wording might seem to mean ALL applicants must have had a cardiological evaluation</p>	

1.12 I suggest insert " Applicants who have sino-atrial etc" or else the current wording might seem to mean ALL applicants must have had a LV fraction evaluation

1.15 I suggest insert "LBB and" after "Applicants, who have" or else the current wording might seem to mean ALL applicants must have had a cardiological evaluation

1.16 I suggest insert "with pre-excitation" after "Applicants" or else the current wording might seem to mean ALL applicants must have had a cardiological evaluation.

2.1 Diabetes managed by insulin. I suggest insert "any long" between "during" and "flight", or else this standard might appear to be demanding an in flight sugar measurement during a simple 10 minute circuit. This latter would not be compatible with safety.

6.9 I suggest define WHICH grading system or substitute the words of 6.10 instead into 6.9

7.2 I suggest add words " equal to or better than"

response

*Noted*

See response to comment No 102.

comment

1985

comment by: *EFLEVA*

EFLEVA considers that this is not in keeping with the principle of a low cost and simple system.

response

*Noted*

See response to comment No 102.

comment

2090

comment by: *Royal Swedish Aeroclub*

The proposed requirements are too stringent and detailed to be considered simple.

response

*Noted*

See response to comment No 102.

comment

2158

comment by: *AMS Denmark*

Cardiovascular requirements for LPL medical certificates should be identical with ICAO class 2.

response

*Noted*

See response to comment No 102.

comment	2295	comment by: <i>DLR</i>
<p>LPL pilots and class 2 pilots use the same airspace and can fly nearly the same type of aircrafts (in class 2 only heavier and with a higher cruising range) and they have the same privileges. Therefore it does not make sense to have, from a safety perspective, different requirements for these two kinds of licenses. LPL pilots may even have glass cockpits with a lot of colour information. Safety issues should not be decided upon by politicians, but by specialist. It looks like the LPL is introduced only as a result of enormous pressure of the leisure pilot associations. The requirements are lower than the ones for sailing a boat on a lake. If a plane with the weight of two tons crashes in a public building it can cause fatal accidents and death to people in this area.</p> <p>Proposal: LPL requirements should be the same as class 2 including a comprehensive ophthalmological eye examination by an ophthalmologist at initial examination or if indicated.</p>		
response	<i>Noted</i>	
See response to comment No 102.		
response	<i>Noted</i>	
See response to comment No 102.		
comment	2343	comment by: <i>Tim FREEGARDE</i>
<p>AMC to MEDB090 The specific requirements proposed for LPL medical certificates are inconsistent with the excellent proposal that general practitioners should be able to issue a certificate on the basis of the pilot's medical history. For example, 1.2(iii) requires that an exercise test have been administered, 3.1 requires the pilot to have undergone a urine test, and 7 requires a test of visual acuity.</p>		
response	<i>Noted</i>	
See response to comment No 102.		
comment	2367	comment by: <i>Mike Armstrong</i>
<p>Page 60 AMC to MED.B.090</p> <p>The basic premise of the LPL was that it should be a simple licence with simple requirements and limited entitlements. However the LPL medical requirements in this section are only a little less onerous than those for Class 2 medical.</p> <p>There are several sailplane pilots in the UK who fly sailplanes very successfully with absolutely no hearing capability and limited speech that would not meet the EASA standards. They have been trained using customised techniques and, while perhaps unable to fly in controlled airspace due to lack of radio operation capability, they can still enjoy most of the freedoms of a sailplane pilot. There appear to be no dispensations for these and other such disabilities.</p>		

In the UK the majority of sailplane pilots and many light aircraft leisure pilots use either self certification or medical declaration countersigned by the GMP of the pilot based on an examination of the pilot's medical records. Only in the event of an area of doubt is physical examination required. To my knowledge, this has not led to any significant reduction in safety or increase in risk.

If this was permitted then it should mean that the majority of medicals could be issued with nominal charge from the GMP, AME or AeMC. This would be appropriate for a sporting licence.

response *Noted*

See response to comment No 102.

comment 2557 comment by: UK CAA MEDICAL ADVISORY PANEL

**Paragraph** AMC to MED.B.090 1.14  
**Page** 60

**Comment**

Of what?

**Justification**

Needs to state a lot of things can be catheter ablated

**Proposed Text**

Applicants following successful ablation of an atrial flutter circuit ... Following AVNRT / AVRT / RVOFT ablation specialist advice is needed

response *Noted*

See response to comment No 102.

comment 2558 comment by: UK CAA MEDICAL ADVISORY PANEL

**Paragraph** AMC to MED.B.090 1.15  
**Page** 60

**Comment**

Too loose

**Justification**

**Proposed Text**

... full cardiological ... exercise ECG

response *Noted*

See response to comment No 102.

comment 2559 comment by: UK CAA MEDICAL ADVISORY PANEL

**Paragraph** AMC to MED.B.090 1.18  
**Page** 60

**Comment**  
 EF too low  
**Justification**  
 The applicant will be on immuno-suppressive treatment  
**Proposed Text**  
 ... ejection fraction > 0.5

response

*Noted*  
 See response to comment No 102.

**C. Draft Decision Part-MED - Subpart B: Requirements for Medical Certificates - Section 2: Specific requirements for LPL medical certificates - p. 61  
 AMC to MED.B.090 - 2. Metabolic and Endocrine Systems**

comment

502	comment by: UK CAA
<p><b>AMC to MED.B.090 2.2</b>  <b>Page: 61</b></p> <p><b>Comment:</b>                  Measurement of blood sugar before and during flight should be demonstrated as part of the skills test.</p> <p><b>Justification:</b>                  This rule should be applicable to both fixed wing and rotary operations as the potential effects on aircraft control and flight monitoring are the same.</p> <p>New devices are available that continuously and/or intermittently monitor tissue glucose levels without the need for performing finger prick estimations. There are also alarm functions if levels fall outside an acceptable range.</p> <p>The availability of 'free hands' and suitable equipment is little different to use of radio / navigation equipment/reference material.</p> <p><b>Proposed Text:</b>                  Delete 2.2 and replace with:  <b>'Applicants with diabetes mellitus managed by insulin should demonstrate their knowledge and ability to safely manage their condition in flight.'</b></p>	

response

*Noted*  
 See response to comment No 102.

comment

562	comment by: British Microlight Aircraft Association
<p>This seems generally sound. We was a little surprised that there was not a provision for stable insulin dependant diabetics to be considered for an LPL after a number of years demonstrated good control, particularly with the advent of insulin pumps and so called "artificial pancreas"</p>	

response	Noted	
	See response to comment No 102.	
comment	1265	comment by: <i>Swedish Transport Agency, Civil Aviation Department (Transportstyrelsen, Luftfartsavdelningen)</i>
	<p><b>Comment:</b> The reason for the proposal that flying with aeroplanes/sailplanes/balloons would be allowed when at the same time it is proposed to be forbidden for helicopter flying is unclear. It would be easier to perform a quick emergency landing outside an airfield with a helicopter than with an aeroplane. The same unfit assessment should apply also to at least motor-powered aeroplanes.</p> <p>If a fit assessment would be considered, it should be restricted to the less hypoglycaemia-prone diabetes type 2.</p> <p>The legal implication of the text is also unclear, because the limitation of privileges refers only to those who have good recognition of the warning symptoms - others would be allowed to fly without any limitations.</p> <p><b>Proposal:</b> Amend 2.1: Applicants with diabetes mellitus type 2 managed by insulin should have their privileges limited to [...]</p> <p>Amend 2.2: Applicants with diabetes mellitus managed by insulin should not have the privilege to fly motor-powered aeroplanes or helicopters.</p>	
response	Noted	
	See response to comment No 102.	
comment	2049	comment by: <i>ELFNER</i>
	Attachments <a href="#">#29</a> <a href="#">#30</a> <a href="#">#31</a> <a href="#">#32</a> <a href="#">#33</a> <a href="#">#34</a>	
	<p><b>Abstract</b></p> <p>The possibility within the LPL License to fly with insulin by following certain rules and fulfilling physical preconditions goes in the right direction – such smart regulations for private pilots suffering by Insulin Dependent Diabetes Mellitus (IDDM) exist in the United States of America since 1996 reporting big success and no incidents.</p> <p>However, the planned restriction to prohibit carrying passengers tends to be contradicting – the worst case incident might be a slight and temporary (several minutes) hypoglycaemia where a passenger is able to save the pilot's life if one is on board.</p> <p>This document will make a proposal to define rules where the adherence is as easy and simple as rules to be followed e.g. concerning alcoholic beverages.</p> <p>No alcohol within 24 hours before piloting. No rapid-acting insulin within 3 hours before piloting.</p>	
response	Noted	

See response to comment No 102.

comment	2159	comment by: <i>AMS Denmark</i>
	Metabolic and endocrine systems requirements for LPL medical certificates should be identical with ICAO class 2.	

response	<i>Noted</i>
	See response to comment No 102.

comment	2212	comment by: <i>Royal Netherlands Aeronautical Association</i>
	<p>Metabolic and endocrine systems.</p> <p>Patients with diabetes mellitus using insulin should be assessed as unfit. They can be assessed as fit, with their privileges limited operation without carrying passengers, when:</p> <ol style="list-style-type: none"> <li>1. they have a stable blood sugar for at least three months,</li> <li>2. they have proven that they can measure their blood sugar level themselves.</li> <li>3. they have proven to regulate their blood sugar themselves</li> </ol>	

response	<i>Noted</i>
	See response to comment No 102.

comment	2213	comment by: <i>Royal Netherlands Aeronautical Association</i>
	<p>It has no sense to examine glucose in the urine as long as applicants with diabetes mellitus are allowed to fly.</p> <p>State of the art medical examination gives enough information to suspect an applicant for undiscovered diabetes mellitus.</p>	

response	<i>Noted</i>
	See response to comment No 102.

**C. Draft Decision Part-MED - Subpart B: Requirements for Medical Certificates - Section 2: Specific requirements for LPL medical certificates - AMC to MED.B.090 - 3. Genitourinary System** p. 62

comment	563	comment by: <i>British Microlight Aircraft Association</i>
	Accepted	

response	<i>Noted</i>
	See response to comment No 102.

comment	1161	comment by: <i>Keith WHITE</i>
	For SPL and LPL[S], <b>Delete this requirement.</b> There is o indication from the UK BGA records that this would improve safety for glider pilots.	
response	<i>Noted</i>	
	See response to comment No 102.	
comment	1266	comment by: <i>Swedish Transport Agency, Civil Aviation Department (Transportstyrelsen, Luftfartsavdelningen)</i>
	<p><b>Comment:</b> According to the general layout of an AMC, the word 'should' is used throughout the requirements in the AMCs. In 3.1 'should' has been replaced by 'is', and in 3.3 'should be' has been replaced by 'are'. Unless this requirement is moved to the IRs to be binding, the word 'should' has to be used.</p> <p><b>Proposal:</b> Amend 3. GENITOURINARY SYSTEM: 3.1. The urine should be examined for glucose at every examination. 3.2. Glycosuria should be investigated. A fit assessment may only be made if the glycosuria is not of pathological significance. 3.3. Applicants with urinary calculi likely to cause renal colic should be assessed as unfit.</p>	
response	<i>Noted</i>	
	See response to comment No 102.	

<p><b>C. Draft Decision Part-MED - Subpart B: Requirements for Medical Certificates - Section 2: Specific requirements for LPL medical certificates - AMC to MED.B.090 - 4. Obstetrics and Gynaecology</b></p>	p. 62
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comment	564	comment by: <i>British Microlight Aircraft Association</i>
	Accepted	
response	<i>Noted</i>	
	See response to comment No 102.	
comment	1267	comment by: <i>Swedish Transport Agency, Civil Aviation Department (Transportstyrelsen, Luftfartsavdelningen)</i>
	<p><b>Comment:</b> In this context the word 'applicant' should be replaced by 'pregnant pilot' in line with the requirements for class 1 and class 2, because the paragraph refers to a licence holder and not to an applicant.</p> <p>Unless this requirement is moved to the IRs to be binding, the word 'can' has to be replaced with 'should'.</p>	

The expression 'until the 26<sup>th</sup> week' includes an ambiguity that should be corrected, as it might be interpreted both as 'until, but not including' and 'until, and including' the 26<sup>th</sup> week. A better approach is the clear requirement for class 2: 'a pregnant pilot may be assessed as fit during the first 26 weeks of gestation following satisfactory obstetric evaluation.

**Proposal:**

Use the requirement for pregnant pilots as described for class 2 in AMC B to MED.B.040.

response

*Noted*

See response to comment No 102.

comment

2375

comment by: *Ingo Wiebelitz*

Was sagen denn die Frauen zu diesem Thema?

What are women thinking about this theme?

response

*Noted*

See response to comment No 102.

**C. Draft Decision Part-MED - Subpart B: Requirements for Medical Certificates - Section 2: Specific requirements for LPL medical certificates - AMC to MED.B.090 - 5. Psychiatry and Psychology** p. 62

comment

56

comment by: *Horst Metzig*

Psychiatrie und Psychologie sollten getrennt betrachtet werden.

Auch hier möchte ich auf die AOPA Studie verweisen, die folgende Frage aufwirft:

**MEDICAL CERTIFICATION: DOES IT PREVENT ACCIDENTS?**

A just-completed AOPA Air Safety Foundation analysis of U. S. accidents caused by medical problems shows no meaningful correlation between FAA medical certificate requirements and GA accident rates.

ASF researchers analyzed 37,946 general aviation accidents that occurred from 1983 - 2000, involving fixed wing aircraft under 12,500 pounds gross weight and operated under FAR Part 91 general flight and operating rules. All such aircraft require a valid FAA medical certificate for the pilot in command. Of that total, they found 137 accidents caused by medical incapacitation, for a rate of just 0.36%, slightly over one-third of one percent (heart attacks were the most common accident cause.)

A similar study conducted by the FAA of accidents in gliders and balloons (whose pilots are *not* required to have a valid medical certificate), found only two medically-induced accidents in the ten-year period from 1990 - 2000. With

a total of 609 glider and balloon accidents shown in the ASF database for that period, the no-medical-certificate required rate works out to 0.33%, slightly *lower* than that for pilots requiring an FAA medical certificate.

Ich bin der Überzeugung, dass alle Unfälle ausnahmslos zuvor im Kopf vorbereitet werden, ohne es zu wollen.

Aus diesen Grund halte ich nicht viel von reinen körperlichen Tauglichkeitsuntersuchungen.

Ich schlage vor, bei Privatpiloten und Segelflugpiloten auf freiwilliger Basis eine eingangspsychologische Untersuchung nach dem Wiener Testsystem durchzuführen. Als Grundlage dient das Expert System Aviation test battery based on JAR-FCL3, welches von der Firma Schuhfried ausgearbeitet wurde. Es bleibt nur die Frage, was wären angemessene Untersuchungen, die die Flugsicherheit im privaten Bereich erhöhen könnten. Hier bin ich bereits tätig geworden, und stehe in Verbindung mit einem erfahrenen Leistungspsychologen, welcher auch in der Militärluftfahrt gewisse Erfahrungen vorweisen kann. Wir werden eine geeignete Testbatterie ausarbeiten, die auf freiwilliger Basis in die individuelle Flugausbildung integriert werden soll. Die Ergebnisse dieser psychologischen Untersuchungen sollen dafür dienen, dass der Fluglehrer sich ein besseres Bild über den Kandidaten machen kann.

Flugunfälle werden durch unbewusste Handlungssteuerungen im Kopf produziert. Es soll ein Test ausgearbeitet werden, um diese Handicaps möglichst frühzeitig, also vor Beginn einer Privatpilotausbildung, zu erkennen. Dann soll die spätere Flugausbildung auf Erkenntnissen des Test aufgebaut werden.

Diesen Weg halte ich für wesentlich geeigneter, als die jetzige überzogene alleinige körperliche Tauglichkeitsuntersuchung. Das alles setzt aber voraus, dass die Qualitäten der Privatpilotausbildung, also der Fluglehrer, angepasst werden müssen.

Im Gegensatz zu der Berufsluftfahrt wird dem Privatpiloten auf der Forschungsebene zu wenig Aufmerksamkeit geschenkt. Wir brauchen in Europa eine Universität, welche sich leistungspsychologisch den Anforderungsprofil des Segelflugsport widmet.

Viel besser als jeder Fliegerarzt, auch wenn dieser in der Funktion als psychiatrischer/psychologischer Sachverständiger ein Gutachten zur Beurteilung der Fliegertauglichkeit anfertigen muss, halte ich die Beobachtungen des Fluglehrers. Meine Erklärung ist in den nachfolgenden englischen Text zu finden.:

#### **Psychiatric conditions:**

These can prove difficult to manage and provide the commonest reason why a gliding club may require a member to seek medical advice. Communication from the gliding club to the doctor can be helpful in making a diagnosis. Medical advice can help the gliding club to take proper action in supervising or limiting flying by the individual, with the avoidance of inappropriate disciplinary action. A history of neurotic illness is not a bar to gliding, and such individuals are often helped by the cooperative activity of a club. Suicide by aircraft is not unknown, but is rare. A previous suicide attempt need not be a bar to flying gliders. In psychiatric conditions, it is essential that the supervising instructors understand the nature of the illness, and for reasons of medical confidentiality this implies restriction to one club. Therefore it is recommended

that membership is authorised at one named club where the officials have been informed in confidence of the nature of the illness; subsequent flying being at their discretion.

Ich möchte auch darauf hinweisen, das speziell bei psychiatrischen Erkrankungen eine Diagnose schwierig, und manchmal Jahrzehnte dauert. Es fehlt auch an geeigneten erfahrenen Psychiatern, die Fliegererfahrung haben. Aus diesen Grund will ich vorschlagen, das bei anfallenden psychiatrisch bedingte Krankheiten, bei der Beurteilung der Fliegertauglichkeit auf jeden Fall die Aussage des Fluglehrers berücksichtigt werden soll.

Wegen der Komplexität und oft Seltenheit bestimmter psychiatrischer Erkrankungen, als Beispiel ADHS, Asperger Syndrom, können einzelne kleinere Staaten bei der Beurteilung überfordert werden, und ungerecht urteilen. Daher ist es auf jeden Fall besser, anstelle die Beurteilung den nationalen AeMC zu überlassen, alle psychiatrischen Entscheidungen bezüglich Fliegertauglichkeit bei LPL Piloten einem überregionalen europäischen Team und Beratungsgremium, bestehend aus Psychiatern, Psychologen, Juristen und Fluglehrern, zu übertragen. So soll auch der bisherige Flugtauglichkeitstourismus zukünftig nicht mehr sinnvoll werden.

Dem Fluglehrer kommt bei der Beurteilung von Fähigkeiten mehr Bedeutung zu als dem Fliegerarzt, weil der Fluglehrer den Kandidaten in seiner fliegerischen Tätigkeit und den Lernfortschritten weitaus besser beurteilen kann, als die beste und teuerste psychologisch sowie psychiatrische Anamnese.

Allerdings setzt das voraus, das der Fluglehrer qualifiziert und neutral genug ist, eine geeignete Stellungnahme abzugeben.

Horst Metzig

response

*Noted*

See response to comment No 102.

comment

271

comment by: *Lufthansa German Airlines*

Author: Prof. Dr. Jürgen Kriebel  
 Section: 1  
 Subpart B  
 General - requirements for medical certificate for LAPL  
 AMC to MED.B.001  
 5

**Page:**

Relevant Text::

5. PSYCHIARTY and PSYCHOLOGY

5.1 applicants should be assessed as unfit:

- (i) if they are taking anti-psychotic medication;
- (ii) following an alcohol related seizure

5.4 History of Psychosis:

Applicants should be well and stable for 3 years. They should have functional recovery with an insight into their illness. Their risk of relapse should be assessed as low.

**Comment:**

5. delete psychology because the following examples are primarily psychiatric ones  
 5.1 (i) replace anti-psychotic medication because one could for example miss tranquiliser abuse  
 5.2 no change recommended  
 5.3 no change recommended

**Proposal:**

5. PSYCHIARTY

5.1 (i) if they are taking psychotropic medication;

(ii) following seizures including alcohol related seizures,

5.4 History of psychosis. Applicants should be well and stable for 3 years. They should have functional recovery with an insight into their illness. Their risk of relapse should be assessed as low, after psychiatric evaluation.

response *Noted*

See response to comment No 102.

comment

351

comment by: *Dr. Barbara Weinmeier*

Zu medizinische Voraussetzungen 5.4, History of Psychosis: Die Forderung, Bewerber sollten frei von antipsychotischer Medikation sein, ist aus psychiatrischer Sicht bedenklich: Anhaltende psychische Stabilität nach einer durchgemachten Psychose ist nur durch die langfristige- meist.lebenslange-Einnahme eines Neuroloptikums gewährleistet. Die inzwischen verfügbaren Medikamente wirken nicht nur stabilisierend, sondern positiv auch auf die kognitive Leistungsfähigkeit. Ihre Einnahme ist stellt daher keine Kontraindikation für die Flugerlaubnis dar, sondern sollte eher Voraussetzung sein.

response *Noted*

See response to comment No 102.

comment

503

comment by: *UK CAA***AMC to MED.B.090 5.1****Page: 62****Comment:**

Incorrect term.

**Justification:**

This paragraph relates specifically to alcohol use.

**Proposed Text:**Replace 'substance' by '**alcohol**'.response *Noted*

See response to comment No 102.

comment	504	comment by: UK CAA
	<p><b>AMC to MED.B.090 5.2</b>  <b>Page: 62</b></p> <p><b>Comment:</b>  The requirement for abstinence from alcohol is repeated.</p> <p><b>Justification:</b>  Reduce repetition.</p> <p><b>Proposed Text:</b>  Delete: 'or until such time that freedom from substance use is established and can be demonstrated'.</p>	
response	Noted	
	See response to comment No 102.	
comment	565	comment by: British Microlight Aircraft Association
	Accepted	
response	Noted	
	See response to comment No 102.	
comment	923	comment by: European Society of Space and Aviation Medicine (ESAM)
	<p><b>Author: European Society of Space and Aviation Medicine (ESAM) - Group Neurology Psychiatry-</b></p> <p><b>Section:2</b>  <b>Specific requirements for LAPL medical certificates</b></p> <p><b>Page: 62</b></p> <p><b>Relevant Text:</b>  5. PSYCHIARTY AND PSYCHOLOGY  (all text)</p> <p><b>Comment:</b></p> <p><b>Proposal:</b>  Delete entire text.</p> <p><b>Insert:</b>  5. From clinical and aeromedical experience the total paragraph number 5 is unacceptable. It does not exclude safely psychiatric pilots with high risk for aviation safety.  We recommend instead the regulations for class 2.</p>	
response	Noted	

See response to comment No 102.

comment

1269

comment by: *Swedish Transport Agency, Civil Aviation Department  
(Transportstyrelsen, Luftfartsavdelningen)*

## 5. PSYCHIATRY AND PSYCHOLOGY

### 5.1.

#### **Comment:**

No similar requirement is proposed for class 2 medical certificate, which instead requires an individual psychiatric and/or neurological assessment, based on aero-medical best practice.

An evaluation of alcohol abuse or dependency and its possible treatment and follow-up is as important as to only require a certain time free of seizure. For class 2 there is no time limit, which allows for a more flexible and individual approach which is more appropriate. The proposed requirement for LPL seems to be disproportionate.

#### **Proposal:**

Use the requirements for psychiatric and neurological conditions as described for class 2 in MED.B.050, MED.B.060, AMC B to MED.B.050, and AMC B to MED.B.060.

response

*Noted*

See response to comment No 102.

comment

1270

comment by: *Swedish Transport Agency, Civil Aviation Department  
(Transportstyrelsen, Luftfartsavdelningen)*

## 5. PSYCHIATRY AND PSYCHOLOGY

### 5.2.

#### **Comment:**

No similar requirement is proposed for class 2 medical certificate, which instead requires an individual psychiatric assessment, based on aero-medical best practice. The paragraph only covers alcohol dependency, not alcohol abuse, drug abuse or use of illicit substances, which must be included.

This paragraph is not in line with 5.1 which uses the correct provision '... and until such time...'. The word 'or' in this context would have the implication that the limitation could be lifted earlier than after 2 years sobriety or freedom from 'substance use'.

However, a more appropriate approach would be to use the class 2 requirements with no specified time limit, which allows for a more flexible and individual approach. The proposed requirement for LPL then seems to be disproportionate.

#### **Proposal:**

Use the requirements for psychiatric conditions as described for class 2 in MED.B.050 and AMC B to MED.B.050.

response	<i>Noted</i>
	See response to comment No 102.

comment	1271	comment by: <i>Swedish Transport Agency, Civil Aviation Department (Transportstyrelsen, Luftfartsavdelningen)</i>
<p><b>5. PSYCHIATRY AND PSYCHOLOGY</b> 5.3.</p> <p><b>Comment:</b> The word 'must' is not to be used in an AMC. Unless the requirements are moved to IRs, 'must not' has to be replaced by 'should not'.</p> <p>This paragraph is related to severe anxiety or depressive states. No definitions of these entities are given, but a severe depressive state is often defined as requiring hospitalisation and may have a psychotic character. A severe depressive state has a recurrence rate of more than 50% within a year and is associated with a high suicide risk. These conditions will definitely need individual psychiatric expert assessment and continuous follow-up to be assessed as fit for any kind of licence.</p> <p>The requirements for class 1 and 2 laid down in MED.B.050 and AMC B to MED.B.050 are appropriate and proportionate also for LPL.</p> <p>The proposed acceptance of these conditions for LPL will neither ensure that the level of safety is maintained, which is required in Article 7 of the Basic Regulation, nor fulfil the requirement for an appropriate assessment based on aero-medical best practice as laid down in Annex III to the Basic regulation.</p> <p><b>Proposal:</b> Use the requirements for psychiatric conditions as described for class 2 in MED.B.050 and AMC B to MED.B.050.</p>		

response	<i>Noted</i>
	See response to comment No 102.

comment	1272	comment by: <i>Swedish Transport Agency, Civil Aviation Department (Transportstyrelsen, Luftfartsavdelningen)</i>
<p><b>5. PSYCHIATRY AND PSYCHOLOGY</b> 5.4.</p> <p><b>Comment:</b> The headline is only focusing on previous history of psychosis and not on the present state or risk for recurrence. Psychosis is a generic term including a number of different psychiatric conditions with substantially different aeromedical risk. These conditions will definitely need individual psychiatric expert assessment and continuous follow-up to be assessed as fit for any kind of licence. The requirements for class 1 and 2 laid down in MED.B.050 and AMC B to MED.B.050 are definitely appropriate also for LPL, and will also give a higher level of proportionate flexibility than the proposal in 5.4.</p>		

**Proposal:**

Use the requirements for psychiatric conditions as described for class 2 in MED.B.050 and AMC B to MED.B.050.

response *Noted*

See response to comment No 102.

comment

1559

comment by: *Swiss Association of Aviation Medicine*

**Proposal:**

Delete entire text.

**Insert:**

5. From clinical and aeromedical experience the total paragraph number 5 is unacceptable. It does not exclude safely psychiatric pilots with high risk for aviation safety.

We recommend instead the regulations for class 2.

response

*Noted*

See response to comment No 102.

comment

2214

comment by: *Royal Netherlands Aeronautical Association*

(5.2) Party drugs, cocaine and cannabis are more and more used.  
An applicant using these drugs is unfit to fly.

response

*Noted*

See response to comment No 102.

**C. Draft Decision Part-MED - Subpart B: Requirements for Medical Certificates - Section 2: Specific requirements for LPL medical certificates - p. 62-64 AMC to MED.B.090 - 6. Neurology**

comment

157

comment by: *Civil Aviation Authority - The Netherlands*

**AMC to MED.B.090, onder 6.2 (Blz. 62 van 66)**

De CAA-The Netherlands acht de genoemde termijn van 1 maand veel te kort. Deze termijn moet gelijk zijn aan de termijn die vereist is in de zelfde situatie voor het medisch klasse 2 certificaat. De CAA-The Netherlands verzoekt aan EASA om de termijn in dit voorschrift te wijzigen in 6 maanden.

Ook de termijn van 11 maanden acht de CAA-The Netherlands te kort.

Daarnaast acht de CAA-The Netherlands het medisch niet verantwoord dat een kandidaat die een 'stroke' heeft gehad daarna nog vliegt. De ervaring leert dat na een eerste stroke altijd een tweede volgt.

Een kandidaat met een dergelijke aandoening medisch geschikt verklaren veroorzaakt een apert gevaar voor de luchtvaartveiligheid.

De CAA-The Netherlands verzoekt aan EASA om voorschrift AMC to

MED.B.090, onder 6.2 op een dusdanige manier aan te passen dat het niet mogelijk is om na 'stroke' medisch geschikt verklaard te worden.

response *Noted*

See response to comment No 102.

comment

158

comment by: *Civil Aviation Authority - The Netherlands*

**AMC to MED.B.090, onder 6.9. (Blz. 63 van 66)**

De CAA-The Netherlands acht hetgeen gesteld in AMC to MED.B.090, onder 6.9. veel te soepel. Onder JAR-FCL 3 werd een kandidaat met een dergelijke lichamelijke aandoening medisch ongeschikt verklaard. Dit door onder andere het risico van 'epileptische aanvallen', waarmee rekening dient te worden gehouden, als bijkomstigheid bij een dergelijk ziektebeeld.

De CAA-The Netherlands verzoekt aan EASA om voorschrift AMC to MED.B.090, onder 6.9 op een dusdanige manier aan te passen dat het niet mogelijk is om kandidaten met een dergelijk ziektebeeld medisch geschikt te verklaren.

**AMC to MED.B.090, onder 6.10 en 6.11. (Blz. 63 van 66)**

De CAA-The Netherlands acht hetgeen gesteld in AMC to MED.B.090, onder 6.10 en 6.11 veel te soepel. Onder JAR-FCL 3 gold een risico van 1%. De CAA-The Netherlands kent geen medische onderbouwing voor de genoemde 2%, en ziet geen reden om af te wijken van de voorheen geldende 1%.

De CAA-The Netherlands verzoekt aan EASA om de genoemde 2% in het voorschrift AMC to MED.B.090, onder 6.10 en 6.11 te wijzigen in 1%.

response *Noted*

See response to comment No 102.

comment

272

comment by: *Lufthansa German Airlines*

Author: Prof. Dr. Jürgen Kriebel  
 Section: 1  
 Subpart B  
 General - requirements for medical certificate for LAPL  
 AMC to MED.B.001  
 6 - NEUROLOGY  
**Page:**

Relevant Text::

- **1.1 no change recommended**
- **1.2 Cerebrovascular Disease:**

Following a stroke or transit ischemic attack applicants should be assessed as unfit for a **minimum** period of 1 month. After this date...

6.3.3. Applicants may be assessed as fit but with their privileges limited to operating without carrying passengers;

**Comment:**

The outcome after a stroke needs in most cases cardio-neurologic, sometimes neuropsychologic revalidation.

**Proposal:**

• **1.2 Following a stroke or transit ischemic attack applicants should be assessed as unfit for a minimum period of 1 month. After this date and neurological evaluation...and no change recommended for the rest of the clause.**

6.3.3 After specialist review applicants may be assessed...

response *Noted*

See response to comment No 102.

comment

310

comment by: *David Irwin*

Attachment [#35](#)

The UK CAA National Pilots licence (NPPL) allows pilots such as myself with less disabling neurological conditions, such as sleep epilepsy, to fly albeit with restrictions ie solo and no passenger carrying. The proposed EASA requirements do not allow for epileptic pilots with well controlled and proven fit free periods to continue flying on a LPL. Suggest UK CAA NPPL limitations are adopted which allows pilots to fly after a period of 1 year on medication and no further episodes, with suitable limitations applied ie solo flying or with safety pilot only. See attached file.

response *Noted*

See response to comment No 102.

comment

505

comment by: *UK CAA*

**AMC to MED.B.090 6.16 (i)**  
**Page: 64**

**Comment:**

Need to include other treatment modalities.

**Justification:**

Subarachnoid haemorrhage may be treated by means other than surgery eg interventional radiology.

**Proposed Text:**

Delete: 'surgically'.

response *Noted*

See response to comment No 102.

comment

566

comment by: *British Microlight Aircraft Association*

	Accepted
response	<p><i>Noted</i></p> <p>See response to comment No 102.</p>
comment	<p>651 <span style="float: right;">comment by: <i>Royal Danish Aeroclub</i></span></p> <p><b>6.13 (first line) Chronic subdural treated surgically</b></p> <p>The word "haematoma" is missing in the text..</p> <p>The text should say: "Chronic subdural haematoma treated surgically."</p>
response	<p><i>Noted</i></p> <p>See response to comment No 102.</p>
comment	<p>861 <span style="float: right;">comment by: <i>Swiss Association of Aviation Medecine</i></span></p> <p><b>Proposal:</b>  <b>6.2 Cerebovascular Disease</b>          Following a stroke or transient ischemic attack applicants should be assessed as unit for a minimum period of 1 month. After this date, if there has been a full function recovery applicants may be assessed as fit with their privileges limited to operations without carrying passengers for a minimum period of 11 months. A satisfactory neurological and cardiological investigation including exercise ECG is required to remove the limitation.</p>
response	<p><i>Noted</i></p> <p>See response to comment No 102.</p>
comment	<p>862 <span style="float: right;">comment by: <i>Swiss Association of Aviation Medecine</i></span></p> <p><b>Comment:</b>          The text is contradictory because it would allow pilots to fly with seizures, if their last 'episode' i.e. more episodes, occurred one year ago. Aeromedical and neurological experience show that there is a further risk of recurrence.</p> <p><b>Proposal:</b>          Delete all text.</p> <p><b>6.5. Chronic neurologic disorder</b> (e.g. Parkinson's disease, Multiple Sclerosis)          Applicants may be assessed as fit if they are stable with adequate functional ability under neurological control.</p> <p><b>6.6 Liability to sudden giddiness (delete) instability/vertigo (insert)</b> (e.g. Meniere's disease)</p> <p><b>6.7</b> If cured and seizure free, applicants may be considered for operations without carrying passengers after one year. If cured and seizure free the</p>

limitation can be lifted after a further 4 years. Exceptions may be assessed in case by case decisions under neurological control.

6.14

Delete the whole paragraph (iv)

Insert:

The problem is already covered by part (i).

6.15. *Incidental finding of intracranial aneurysm*

(ii) If treated by surgery the applicant may be considered for operations without carrying passengers when full clinical recovered (delete) recovery is confirmed. The limitation may be lifted after 1 year.

response

*Noted*

See response to comment No 102.

comment

863

comment by: *Swiss Association of Aviation Medicine*

**Comment:**

Univocal comment from the international group representing neurology, psychiatry and psychology:

From a medical point of view, especially the branch related LPL is unacceptable. The requirements are below ICAO standard. Many of neurological and psychiatric aeromedical diseases emerge in the time span between the first examination and age of 45 e.g. MS, seizures, subarachnoid hemorrhages (SAH), schizophrenic and manic psychosis, psychotic depression with suicidality etc. Some of these diseases present with low self criticism and lack of insight. This risk for aviation safety cannot be covered with requirements below ICAO standards and such large time intervals.

Further more a general practitioner without experience in neurology and psychiatry and without aeromedical education is not able to fulfill reliable examinations/evaluations.

In the worst case, if LPL were to be implemented, the question rises why do we need the explanations in section 2 specific requirements LPL medical certificates if a grey box in the questionnaire is ticked. The medical report should be referred to an AME or AeMC for further assessment. AME or AeMC have the knowledge and experience and don't need the information AMC to MED.B.090 etc.

response

*Noted*

See response to comment No 102.

comment

924

comment by: *European Society of Space and Aviation Medicine (ESAM)*

**Author: European Society of Space and Aviation Medicine (ESAM) - Group Neurology Psychiatry-**

**Section:**

**Specific requirements for LAPL medical certificates**

**Page: 62**

**Relevant Text:***6.2 Cerebrovascular Disease*

Following a stroke or transient ischemic attack applicants should be assessed as unfit for a minimum period of 1 month. After this date, if there has been a full function recovery applicants may be assessed as fit with their privileges limited to operations without carrying passengers for a minimum period of 11 months. A satisfactory exercise ECG is required to remove the limitation.

**Comment:****Proposal:***6.2 Cerebrovascular Disease*

Following a stroke or transient ischemic attack applicants should be assessed as unfit for a minimum period of 1 month. After this date, if there has been a full function recovery applicants may be assessed as fit with their privileges limited to operations without carrying passengers for a minimum period of 11 months. A satisfactory neurological and cardiological investigation including exercise ECG is required to remove the limitation.

response

*Noted*

See response to comment No 102.

comment

925

comment by: *European Society of Space and Aviation Medicine (ESAM)*

**Author: European Society of Space and Aviation Medicine (ESAM) - Group Neurology Psychiatry-**

**Section:****Specific requirements for LAPL medical certificates****Page: 62****Relevant Text:**

6.3. Epilepsy  
(iii) (all text)

6.5. *Chronic neurologic disorder* (e.g. Parkinson's disease, Multiple Sclerosis)  
Applicants may be assessed as fit if they are stable with adequate functional ability.

6.6 *Liability to sudden giddiness* (e.g. Meniere's disease)

6.7. *Benign supratentorial tumour treated by craniotomy*

If cured and seizure free, applicants may be considered for operations without carrying passengers after one year. If cured and seizure free the limitation can be lifted after a further 4 years.

6.14. *Acute intracerebral haemorrhage*  
(iv) (all text)

6.15. *Incidental finding of intracranial aneurysm*

(ii) If treated by surgery the applicant may be considered for operations

without carrying passengers when clinically recovered. The limitation may be lifted after 1 year.

**Comment:**

The text is contradictory because it would allow pilots to fly with seizures, if their last 'episode' i.e. more episodes, occurred one year ago. Aeromedical and neurological experience show that there is a further risk of recurrence.

**Proposal:**

Delete all text.

6.5. *Chronic neurologic disorder* (e.g. Parkinson's disease, Multiple Sclerosis)  
Applicants may be assessed as fit if they are stable with adequate functional ability under neurological control.

6.6 *Liability to sudden giddiness (delete) instability/vertigo (insert)* (e.g. Meniere's disease)

6.7 If cured and seizure free, applicants may be considered for operations without carrying passengers after one year. If cured and seizure free the limitation can be lifted after a further 4 years. Exceptions may be assessed in case by case decisions under neurological control.

6.14

Delete the whole paragraph (iv)

**Insert:**

The problem is already covered by part (i).

6.15. *Incidental finding of intracranial aneurysm*

(ii) If treated by surgery the applicant may be considered for operations without carrying passengers when full clinical recovered (delete) recovery is confirmed. The limitation may be lifted after 1 year.

response

*Noted*  
See response to comment No 102.

comment

1046	comment by: <i>Ilse Janicke Heart Center Duisburg</i>
Author: Janicke Ilse, Senior MD, AME I and II, Cardiologist and Angiologist at Heart Center Duisburg Section: <b>2 Specific requirements for LPL medical certificates                  AMC to MED.B.090                  6. NEUROLOGY                  Page: 62 (NPA 2008-17c)</b>	
Relevant Text: <b>6.2 Cerebrovascular Disease</b> Following a stroke or TIA applicants should be assessed...for..1 month. After this date, if there has been a full function recovery applicants may be assessed as fit with their privileges limited to operations without carrying passengers for...11 month. A satisfactory exercise ECG is required to remove limitation.	

**Comment:**

STROKE or TIA will be often cardioembolic of origin (due to arrhythmias, PFO, left ventricular thrombus, aortic atherosclerosis etc). The frequency is up to 15%. This is not likely to jeopardize flight safety. So a satisfactory full cardiological evaluation is necessary. An exercise ECG is of very limited value in this disorder.

**Proposal:** 6.2 Cerebrovascular disease

Following a stroke or TIA applicants should be assessed as unfit for a minimum period of 1 month. After this date, if there has been a full function recovery applicants may be assessed as fit with their privileges limited to operations without carrying passengers for...11 month presumed a satisfactory full cardiological evaluation and risk assessment is required. If no recurrence of stroke or TIA is seen after this period the limitation may be removed.

response

*Noted*

See response to comment No 102.

comment

1047

comment by: *Ilse Janicke Heart Center Duisburg*

Author: Janicke Ilse, Senior MD, AME I and II, Cardiologist and Angiologist at Heart Center Duisburg

Section:

**2 Specific requirements for LPL medical certificates****AMC to MED.B.090****6. NEUROLOGY****Page:** 62 (NPA 2008-17c)

Relevant Text:

## 6.3 Epilepsy

(ii) Applicants with a history of presumed loss of consciousness or altered awareness with seizure markers(...) may be assessed as fit if they have had no further episodes for at least 5 years.

(iii) applicants may be assessed as fit but with their privileges limited to operating without carrying passengers if their last episode of loss of consciousness or altered awareness with seizure markers occurred more than one year ago and they have had no further episodes off all treatment during this period.

**Comment:**

Syncope may be defined as transient loss of consciousness with or without seizure markers. And so the theme belongs to cardiologic chapter too. The origin of syncope could be neurocardiogenic (24%), orthostatic (8%), structural heart disease and cardiac (4%) arrhythmias (14%), neurologic disorders and others (15%) and unknown 35 %. In case of detecting the origin of loss of consciousness or altered awareness with seizure markers and adequate treatment of this cause a fit assessment can be made.

**Proposal:**

Applicants with a history of presumed loss of consciousness or altered awareness with seizure markers(...) may be assessed as fit if they have had no further episodes for at least 5 years provided cardiological evaluation is satisfactory.

(iii) applicants may be assessed as fit but with their privileges limited to

operating without carrying passengers if there last episode of loss of consciousness or altered awareness with seizure markers occurred more than one year ago and they have had no further episodes off all treatment during this period provided cardiological evaluation is satisfactory. In case of detecting andadequate treating the origin of loss of consciousness or altered awareness with seizure markers a fit assessment without limitation can be made.

response *Noted*

See response to comment No 102.

comment

1273

comment by: *Swedish Transport Agency, Civil Aviation Department (Transportstyrelsen, Luftfartsavdelningen)*

## **6. NEUROLOGY**

### *6.2. Cerebrovascular Disease*

#### **Comment:**

No similar requirement is proposed for class 2 medical certificate, which instead requires an individual neurological assessment, based on aero-medical best practice.

The risk for recurrence after a stroke or a transient ischemic attack is about 5% per year, and also the risk for sudden death is about 5% per year. The future risk for recurrence is highly depending on the cause of the attack and possible treatment of this cause, but the proposal neither requires any investigation of the cause for the cerebrovascular event, nor any treatment or preventive measures.

The proposed text for LPL will neither ensure that the level of safety is maintained, which is required in Article 7 of the Basic Regulation, nor fulfil the requirement for an appropriate assessment based on aero-medical best practice as laid down in Annex III to the Basic regulation.

#### **Proposal:**

Use the corresponding requirements as for a class 2 medical certificate.

response *Noted*

See response to comment No 102.

comment

1274

comment by: *Swedish Transport Agency, Civil Aviation Department (Transportstyrelsen, Luftfartsavdelningen)*

## **NEUROLOGY**

### *6.3. Epilepsy*

#### **Comment:**

No similar requirement is proposed for a class 2 medical certificate, based on aero-medical best practice, which instead requires an individual neurological assessment, focusing on the cause of loss of consciousness which is crucial information in the assessment.

(ii) contains a number of detailed symptoms which may be associated with an epileptiform seizure but also with other conditions. This should not be included

in a regulation.

Concerning medication, the text is inconsistent: (i) contains 'without anticonvulsant medication', while (ii) does not mention medication at all, and (iii) contains 'off all treatment'. A consistent approach using a uniform expression should be used in all subparagraphs.

(ii) should be limited to one single episode only, with recurrent episodes the condition would be diagnosed as epilepsy and (i) will be applicable

(iii) specifically mentions 'their last episode', with the implication that recurrent episodes, which then would be diagnosed as epilepsy where (i) is applicable, are acceptable for flying after one year. This is completely unacceptable and also incompatible with (i) and (ii).

The proposed text for LPL will neither ensure that the level of safety is maintained, which is required in Article 7 of the Basic Regulation, nor fulfil the requirement for an appropriate assessment based on aero-medical best practice as laid down in Annex III to the Basic regulation.

**Proposal:**

Use the corresponding requirements for a class 2 medical certificate.

response

*Noted*

See response to comment No 102.

comment

1275

comment by: *Swedish Transport Agency, Civil Aviation Department (Transportstyrelsen, Luftfartsavdelningen)*

**6. NEUROLOGY**

**6.4. Simple faint**

**Comment:**

No similar requirement is proposed for a class 2 medical certificate, which instead requires an individual neurological assessment, based on aero-medical best practice.

'Simple faint' is a layman's term and there is no scientific background or definition of this expression in a healthy person, thus the expression should not be used in a regulation. Any faint must be evaluated and explained to avoid overlooking potentially incapacitating conditions like cardiac arrhythmia. Even 'simple' vasovagal or orthostatic loss of consciousness may occur during flight and be potentially incapacitating.

The proposed text for LPL will neither ensure that the level of safety is maintained, which is required in Article 7 of the Basic Regulation, nor fulfil the requirement for an appropriate assessment based on aero-medical best practice as laid down in Annex III to the Basic regulation.

**Proposal:**

Use the corresponding requirements for a class 2 medical certificate.

response

*Noted*

See response to comment No 102.

comment	1276	comment by: <i>Swedish Transport Agency, Civil Aviation Department (Transportstyrelsen, Luftfartsavdelningen)</i>
<p><b>6. NEUROLOGY</b> 6.7. <i>Benign supratentorial tumour treated by craniotomy</i></p> <p><b>Comment:</b> Since there is a significant risk for epilepsy after operation of a benign supratentorial tumour, an observation period of at least two years is recommended.</p> <p><b>Proposal:</b> Amend 6.7. Benign supratentorial tumour treated by craniotomy If cured and seizure free, applicants may be considered for flying without carrying passengers after two years. If cured and seizure free the limitation can be lifted after a further 4 years.</p>		
response	<i>Noted</i>	
See response to comment No 102.		
comment	1277	comment by: <i>Swedish Transport Agency, Civil Aviation Department (Transportstyrelsen, Luftfartsavdelningen)</i>
<p><b>6. NEUROLOGY</b> 6.10. <i>Serious head injury</i></p> <p><b>Comment:</b> If the expression 'Serious head injury' is used, it has to be defined. A better, and even more proportionate, approach is to keep the corresponding requirements for class 2, based on aero-medical best practice, requiring an individual neurological assessment whenever there has been a loss of consciousness after head injury or a penetrating brain injury.</p> <p><b>Proposal:</b> Use the corresponding requirements for a class 2 medical certificate.</p>		
response	<i>Noted</i>	
See response to comment No 102.		
comment	1278	comment by: <i>Swedish Transport Agency, Civil Aviation Department (Transportstyrelsen, Luftfartsavdelningen)</i>
<p><b>6. NEUROLOGY</b> 6.11. <i>Intracranial haematoma</i></p> <p><b>Comment:</b> If the expression 'Intracranial haematoma' is used, it has to be defined. If the expression in this context is meant not to include intracerebral and subdural haematomas, only traumatic epidural haematomas are left, which is not clearly understood from the text. For traumatic epidural haematomas, when treated early before brain damage has occurred, the proposed rule is acceptable.</p>		

No similar requirement is proposed for a class 2 medical certificate, which instead requires an individual neurological assessment, based on aero-medical best practice.

A better, and more proportionate, approach is to use the corresponding requirements for class 2.

**Proposal:**

Use the corresponding requirements for a class 2 medical certificate.

response

*Noted*

See response to comment No 102.

comment

1279

comment by: *Swedish Transport Agency, Civil Aviation Department (Transportstyrelsen, Luftfartsavdelningen)*

**6. NEUROLOGY**

6.12. *Acute subdural haematoma*

**Comment:**

Acute subdural haematomas are always associated with brain damage due to contusion and the risk for posttraumatic epilepsy exceeds 2% per year, which makes the whole section obsolete.

No similarly detailed requirement is proposed for a class 2 medical certificate, which instead requires an individual neurological assessment, based on aero-medical best practice. A better, and more proportionate, approach is to use the corresponding requirements for class 2.

The proposed text for LPL will neither ensure that the level of safety is maintained, which is required in Article 7 of the Basic Regulation, nor fulfil the requirement for an appropriate assessment based on aero-medical best practice as laid down in Annex III to the Basic regulation.

**Proposal:**

Use the corresponding requirements for a class 2 medical certificate.

response

*Noted*

See response to comment No 102.

comment

1280

comment by: *Swedish Transport Agency, Civil Aviation Department (Transportstyrelsen, Luftfartsavdelningen)*

**6. NEUROLOGY**

6.13. *Chronic subdural treated surgically*

**Comment:**

The heading of 6.13 is incomplete and should read 'Chronic subdural haematoma treated surgically'.

**Proposal:**

Amend the heading of 6.13:

*Chronic subdural haematoma treated surgically*

response	<i>Noted</i>
	See response to comment No 102.

comment	1281	comment by: <i>Swedish Transport Agency, Civil Aviation Department (Transportstyrelsen, Luftfartsavdelningen)</i>
<p><b>6. NEUROLOGY</b> 6.14. <i>Acute intracerebral haemorrhage</i></p> <p><b>Comment:</b> The sections 6.14., 6.15., and 6.16. are completely confused and also suggest new complicated rules without any supporting scientific evidence. This should not appear in a regulatory text.</p> <p>In 6.14 (i), the haemorrhage should be specified as perimesencephalic, which is the only condition with a really good prognosis. However, an observation period of one year instead of 6 months is more adequate.</p> <p>A serious error is contained in 6.14 (iv), because a subarachnoid haemorrhage which has not been treated has a very high risk for re-bleeding which would immediately incapacitate a pilot during flight.</p> <p>No similarly detailed requirements are proposed for a class 2 medical certificate, which instead requires an individual neurological assessment, based on aero-medical best practice. A better, and also more proportionate, approach is to use the corresponding requirements for class 2.</p> <p>The proposed text for LPL will neither ensure that the level of safety is maintained, which is required in Article 7 of the Basic Regulation, nor fulfil the requirement for an appropriate assessment based on aero-medical best practice as laid down in Annex III to the Basic regulation.</p> <p><b>Proposal:</b> Use the corresponding requirements for a class 2 medical certificate.</p>		

response	<i>Noted</i>
	See response to comment No 102.

comment	1282	comment by: <i>Swedish Transport Agency, Civil Aviation Department (Transportstyrelsen, Luftfartsavdelningen)</i>
<p><b>6. NEUROLOGY</b> 6.15. <i>Incidental finding of intracranial aneurysm</i></p> <p><b>Comment:</b> The sections 6.14., 6.15., and 6.16. are completely confused and also suggest new complicated rules without any supporting scientific evidence. This should not appear in a regulatory text.</p> <p>No similarly detailed requirements are proposed for a class 2 medical certificate, which instead requires an individual neurological assessment, based</p>		

on aero-medical best practice. A better, and also more proportionate, approach is to use the corresponding requirements for class 2.

The proposed text for LPL will neither ensure that the level of safety is maintained, which is required in Article 7 of the Basic Regulation, nor fulfil the requirement for an appropriate assessment based on aero-medical best practice as laid down in Annex III to the Basic regulation.

**Proposal:**

Use the corresponding requirements for a class 2 medical certificate.

response

*Noted*

See response to comment No 102.

comment

1283

comment by: *Swedish Transport Agency, Civil Aviation Department (Transportstyrelsen, Luftfartsavdelningen)*

**6. NEUROLOGY**

6.16. *Subarachnoid haemorrhage due to intracranial arteriovenous malformation*

**Comment:**

The sections 6.14., 6.15., and 6.16. are completely confused and also suggest new complicated rules without any supporting scientific evidence. This should not appear in a regulatory text.

No similarly detailed requirements are proposed for a class 2 medical certificate, which instead requires an individual neurological assessment, based on aero-medical best practice. A better, and more appropriate, approach is to use the corresponding requirements for class 2.

The proposed text for LPL will neither ensure that the level of safety is maintained, which is required in Article 7 of the Basic Regulation, nor fulfil the requirement for an appropriate assessment based on aero-medical best practice as laid down in Annex III to the Basic regulation.

**Proposal:**

Use the corresponding requirements for a class 2 medical certificate.

response

*Noted*

See response to comment No 102.

comment

1300

comment by: *David Chapman*

*Epilepsy*

(i) Applicants with a history of epilepsy may be assessed as fit if they have been free from epileptic attacks for at least 10 years without anticonvulsant medication in that time.

**HARSH but clear**

(ii) Applicants with a history of presumed loss of consciousness or altered awareness with seizure markers (unconsciousness for more than 5 minutes,

amnesia greater than 5 minutes, injury, tongue biting, incontinence, remain conscious but with confused behaviour, headache post attack) may be assessed as fit if they have had no further episodes for at least 5 years.

**HARSH but clear**

(iii) Applicants may be assessed as fit but with their privileges limited to operating without carrying passengers if their last episode of loss of consciousness or altered awareness with seizure markers occurred more than one year ago and they have had no further episodes off all treatment during this period.

**Does not make sense,.... intended to say, ...????**

(iii) Applicants may be assessed as fit but with their privileges limited to operating without carrying passengers if their last episode of loss of consciousness, or altered awareness with seizure markers, occurred more than one year ago and they have had no further episodes while undergoing a uniform corrective treatment for a period of at least one year.

response *Noted*

See response to comment No 102.

comment *1997*

comment by: *Michael Willis*

I fly under the UK NPPL Epilepsy protocol, rated as fit for a DVLA Group 1 Drivers Licence. This requires an assessment as fit after a period of 1 year incident-free.

I believe the equivalent para is 6.3 (iii), but this has the qualification "off all treatment" that is not present in the DVLA At A Glance guidelines. My understanding is that the risk of reoccurrence is *always* lower if treatment continues. I understand also that in the UK it is standard practice to continue taking medication as long as a drivers licence is required providing there are no side effects.

It would appear that if you have seizure markers re 6.3.(ii) then you are better off than if you have more minor incidents.

I should add that the two incidents that led me to the original diagnosis and label were minor (otherwise I would not even consider continuing to fly) but unfortunately there are no "degrees" of diagnosis of this condition!

With the current draft wording it would appear to exclude me from continuing to hold a licence and owning a light aircraft.

response *Noted*

See response to comment No 102.

comment *2160*

comment by: *AMS Denmark*

Neurological requirements for LPL medical certificates should be identical with ICAO class 2.

response	<i>Noted</i>	
	See response to comment No 102.	
comment	2215	comment by: <i>Royal Netherlands Aeronautical Association</i>
	Neurology. The KNVvL prefers for the LPL the same requirements as for class 2 (see pag 56 of 66).	
response	<i>Noted</i>	
	See response to comment No 102.	
comment	2216	comment by: <i>Royal Netherlands Aeronautical Association</i>
	for 6.2 the KNVvL proposes: Following a first stroke or transient ischemic attack applicants should be assessed as unfit for a minimum period of 6 months. After this date, if there has been a full recovery proven by a full neurologic examination, brain scan included, applicants may be assessed as fit with their privileges limited to operations without carrying Passengers. After a second stroke a applicant is assessed as unfit. We don't see the reason for an exercise ECG. A brain scan with contrast is more appropriate.	
response	<i>Noted</i>	
	See response to comment No 102.	
comment	2217	comment by: <i>Royal Netherlands Aeronautical Association</i>
	The KNVvL proposes 6.3 (iii) to be deleted.	
response	<i>Noted</i>	
	See response to comment No 102.	
comment	2218	comment by: <i>Royal Netherlands Aeronautical Association</i>
	6.9 Applicants with a brain tumor are unfit to fly. They should be assessed as unfit.	
response	<i>Noted</i>	
	See response to comment No 102.	
comment	2220	comment by: <i>Royal Netherlands Aeronautical Association</i>
	6.10 and 6.11 The risk of 2% per annum is to much. The KNVvL medical	

committee proposes 1%.
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response	<i>Noted</i>
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See response to comment No 102.
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comment	2221	comment by: <i>Royal Netherlands Aeronautical Association</i>
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Regarding 6.12 - 6.16 The KNVvL medical committee comments:

It is not necessary to describe all these neurologic vascular diseases separately.

They all should absolutely be assessed as unfit.

Especially keeping in mind that during flying the pilot can be under influence of severe variations in G-forces, these diseases can lead to sudden death.

One year after treatment and full recovery proved by neurologic examination including brain scan, a fit assessment can be considered. The risk of seizures should be lower than 1%.

response	<i>Noted</i>
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See response to comment No 102.
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<b>C. Draft Decision Part-MED - Subpart B: Requirements for Medical Certificates - Section 2: Specific requirements for LPL medical certificates - AMC to MED.B.090 - 7. Visual System</b>	p. 64
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comment	159	comment by: <i>Civil Aviation Authority - The Netherlands</i>
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**AMC to MED.B.090, onder 7.2. (Blz. 64 van 66)**

De CAA-The Netherlands acht 6/9 een te lichte eis. Om veiligheidsredenen kan volgens de CAA-The Netherlands niet minder worden geëist dan een "visual acuity" van 6/6 (1.0) met twee ogen. De CAA-The Netherlands verzoekt aan EASA om 6/9 in onderdeel 7.2. te wijzigen in 6/6 (1.0).

**AMC to MED.B.090, onder 7.5. (Blz. 64 van 66)**

De CAA-The Netherlands acht 9 van de 15 platen een te lichte eis. Om veiligheidsredenen kan volgens de CAA-The Netherlands dit voorschrift niet worden ingevoerd. De CAA-The Netherlands beoordeelt een kandidaat die 9 van de 15 platen kan zien als kleurdeficiënt. De CAA-The Netherlands verzoekt aan EASA om het voorschrift aan te wijzigen in de eisen, zoals die gelden voor het medisch klasse 2 certificaat.

response	<i>Noted</i>
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See response to comment No 102.
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comment	307	comment by: <i>Lufthansa German Airlines</i>
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**Author:** Dr. Esther Stahl-Buhl, AMC Frankfurt

**Section:** 2

AMC to MED. B. 090

7.2

**Page:** 64

**Relevant Text:**

*7.2 Acuity*

The applicants visual acuity with or without corrective lenses should be 6/9 binocularly and 6/12 in each eye.

**Comment:**

**Proposal:**

The applicants visual acuity with or without corrective lenses should be 6/6! binocularly and 6/12 in each eye.

response

*Noted*

See response to comment No 102.

comment

308

comment by: *Lufthansa German Airlines*

**Author:** Dr. Esther Stahl-Buhl, AMC Frankfurt

**Section:** 2

AMC to MED. B. 090

7.3

**Page:** 64

**Relevant Text:**

Amblyopia and Monocularity:

An applicant with amblyopia or monocularity maybe assessed as fit, subject to a satisfactory flight test, if the visual acuity in the unaffected eye is with or without correction 6/ 6 or better.

**Comment:**

**Proposal:**

As for class 2 I suggest the following:

An applicant with amblyopia or monocularity maybe assessed as fit, subject to a satisfactory flight test, if the visual acuity in the unaffected eye is without ! correction 6/ 6 or better and that eye does not have a history of refractive surgery.

response

*Noted*

See response to comment No 102.

comment

309

comment by: *Lufthansa German Airlines*

**Author:** Dr. Esther Stahl-Buhl, AMC Frankfurt

**Section:** 2

AMC to MED. B. 090

7.4

**Page:** 64

**Relevant Text:**

Colour vision:

For the grant of a night rating applicants should have correctly identified 9 of the first 15 plates of the 24 - plate edition of Ishiharas pseudoisochromatic plates. A vision care specialist or a doctor may have conducted this test.

**Comment:**

This means, that any colour deficient LPL pilot may fly at night!

**Proposal:**

I suggest the same text as for class 2: Text: The Ishihara test ( 24 plate version) is considered passed if the first 15 plates, presented in a random order, are identified without error.

My comment: See above , class 1. This must be a mistake, it should say, the first 17 plates, plate number 16 and 17 are important plates for colour distinction.

If an applicant for LPL does not pass the Ishihara test without mistakes, he should be evaluated for colour safety with Nagel Anomaloscopy or Lantern Test as described above for class 1 and class 2. If the applicant is assessed as not colour safe, likewise not being fit to operate during night time ( VCL ) ( MED . A. 045 ( c ) 3 VIII ) he should not be fit to operate only according to instruments. An ophthalmologist shall have conducted this test.

response

*Noted*

See response to comment No 102.

comment

567

comment by: *British Microlight Aircraft Association*

Accepted

response

*Noted*

See response to comment No 102.

comment

610

comment by: *Lufthansa German Airlines*

**Author:** Dr. Esther Stahl-Buhl, AMC Frankfurt

**Section:**

Eye surgery:

There are no comments regarding eye surgery for LPL

**Page:**

**Relevant Text:**

There are no comments regarding eye surgery for LPL.

My comment: Standards or criteria for evaluation of post -surgery status; refractive surgery, cataract- glaucoma or retinal-surgery should be the same!! as in class 2. ( See above)

**Comment:**

There are no comments regarding eye surgery for LPL.

My comment: Standards or criteria for evaluation of post -surgery status;

refractive surgery, cataract- glaucoma or retinal-surgery should be the same!! as in class 2. ( See above)

response *Noted*

See response to comment No 102.

comment

611

comment by: *Lufthansa German Airlines*

**Author:** Dr. Esther Stahl-Buhl, AMC Frankfurt

**Section:**

There are no limits for refractive errors for LPL

**Page:**

**Relevant Text:**

**Comment:**

I suggest to implement the "old" limits of class 2 for LPL.

Meaning: An applicant can be assessed as fit with a refractive error of +5 /-8 dioptres and anisometropia and astigmatism not above 3 dioptres.

If at renewal exam myopia exceeds 8 dioptres and anisometropia or astigmatism exceed 3dioptres, an ophthalmological comprehensive eye exam and evaluation of the case is required to obtain medical fitness. An AMC or AME may then attest medical fitness.

The reason, why I would suggest a limit of + 5 diopters, is a significant ring scotoma due to high correcting glasses, especially in the + area, increasing prismatic deviation due to high correcting glasses and an increasingly narrow anterior chamber angle. The same applies to high values of myopia, not talking about retinal complications.

response *Noted*

See response to comment No 102.

comment

612

comment by: *Lufthansa German Airlines*

**Author:** Dr. Esther Stahl-Buhl, AMC Frankfurt

**Section:**

There are also no comments concerning keratoconus

**Page:**

**Relevant Text:**

**Comment:**

If the diagnosis of keratoconus is established, an comprehensive ophthalmological exam is required and an AMC or AME may attest medical fitness

response *Noted*

See response to comment No 102.

comment	653	comment by: <i>Royal Danish Aeroclub</i>
<p><b>Page 64, 7.3</b></p> <p>we suggest 6/9 as sufficient visual acuity in persons suffering from one eye amblyopia.</p> <p><b>Page 64, 7.5 Colour vision</b></p> <p>There is no need for colour perception test. See Cmt# 647.</p>		
response	<i>Noted</i>	
See response to comment No 102.		
comment	654	comment by: <i>Royal Danish Aeroclub</i>
<p><b>Page 64, 7.5 Colour Vision</b></p> <p>There is no need for colour perception test. See remarks above.</p> <p>We suggest to add the following: "Alternatively a practical medical flight test could be used to demonstrate the ability to see during flight."</p>		
response	<i>Noted</i>	
See response to comment No 102.		
comment	1082	comment by: <i>Aviation Ophthalmology Sweden</i>
<p>Relevant Text:</p> <p>7. VISUAL SYSTEM</p> <p><b>7.5. Colour vision</b></p> <p><b>For the grant of a night rating applicants should have correctly identified 9 of the first 15 plates of the 24 - plate Ishihara pseudoisochromaic plates. A vision care specialist or a doctor may have conducted this test</b></p> <p><b>Comment:</b></p> <p>Night flying imposes a high demand on colour discrimination , especially in today's aviation with glass panel. Colour testing should must be elementary part of every initial and any renewal because many diseases of the eye that could be a threat to aviation safety in means of colour discrimination have no other clinical symptom or anatomical correlate. That means with the new regulation as proposed the authority is willing to take the risk to leave these pilots go undetected and expose them, their passengers and third parties to an unknown risk. Some disease such as diseases of the optic nerve and glaucoma may lead early to altered colour vision, long before they cause major damage to the visual system.</p> <p><b>The Ishihara test (24 plate version)is already an abbreviated form of colour vision test. To shorten it more will undermine its clinical relevance, is contradictory to the rules of its use according to</b></p>		

**Professor Ishiharas instructions; a proposed shortening to the first 9 of 24 plates will make this test practically useless.**

**Proposal:**

7. VISUAL SYSTEM

**7.5. Colour vision**

**a night rating may only be granted if the applicant does identify all 24 plates of the 24 plate version of the Ishihara test without error , if presented in a random order.**

response *Noted*

See response to comment No 102.

comment 1165 comment by: *Dr. Ludger Beyerle*

With regard to the safety of the IFR - air traffic in mixed traffic areas and areas in the vicinity of airports, holders of LAPL should undergo examinations of the visual system and hearing at least every 5 years.

response *Noted*

See response to comment No 102.

comment 1284 comment by: *Swedish Transport Agency, Civil Aviation Department (Transportstyrelsen, Luftfartsavdelningen)*

**Comment:**

In 7.1, the word 'are' is erroneously used in an AMC. Unless this requirement is moved to the IRs to be binding, the word 'are' has to be replaced with 'should'.

The requirements for visual acuity are the same as for class 2, but the sentence is written differently for LPL, which is confusing. A better approach is to use the same wording as for class 2.

**Proposal:**

Amend 7. VISUAL SYSTEM:

7.1. The applicant's visual acuity and visual fields should be examined.

*7.2. Visual Acuity*

The applicant's visual acuity with or without corrective lenses should be 6/12 or better in each eye separately and visual acuity with both eyes shall be 6/9 or better.

response *Noted*

See response to comment No 102.

comment 1285 comment by: *Swedish Transport Agency, Civil Aviation Department (Transportstyrelsen, Luftfartsavdelningen)*

**7. VISUAL SYSTEM**

*7.3. Amblyopia or Monocularity*

**Comment:**

For LPL, in contrast to class 2, amblyopia and monocular vision have been merged to have identical requirements, with the implication that an amblyopic applicant for LPL is required to pass a satisfactory flight test, which for class 2 is only required when the applicant suffers monocular vision. This is disproportionate for LPL.

A far more appropriate and proportionate approach is to use the corresponding requirements for class 2.

**Proposal:****Amend 7. VISUAL SYSTEM:****7.3.1. Amblyopia**

In an applicant with amblyopia, the visual acuity of the amblyopic eye shall 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.

**7.3.2. Monocular vision**

An applicant with substandard vision in 1 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.

response

*Noted*

See response to comment No 102.

comment

1286

comment by: *Swedish Transport Agency, Civil Aviation Department (Transportstyrelsen, Luftfartsavdelningen)***7. VISUAL SYSTEM****7.5. Colour Vision****Comment:**

The procedure for the Ishihara colour vision test describes in detail how the test shall be performed, including that every plate must be correctly identified in order for the test to be considered passed. It is totally unacceptable that any 6 of the plates, also at random, need not to be identified, because every single plate of the Ishihara test has a specific meaning that has to be considered. If an applicant would not be required to pass all 15 plates, it is absolutely necessary to identify which plates must always be passed (e.g. No 2, 3, 5, 9, 12, and 16). However, this introduces a test level without scientific support and which has not been used, not been validated, and which deviates from the published procedure used worldwide.

The only acceptable approach is to use the corresponding requirements for class 2, which also gives a proportionate possibility of flexibility if the applicant is able to pass additional tests.

The proposed text for LPL will neither ensure that the level of safety is maintained, which is required in Article 7 of the Basic Regulation, nor fulfil the requirement for an appropriate assessment based on aero-medical best

practice as laid down in Annex III to the Basic regulation.

**Proposal:**

Amend 7.5. *Colour Vision:*

Applicants shall pass the Ishihara test for the initial issue of a medical certificate. When an applicant does not have satisfactory perception of colours, his/her flying privileges shall be limited to daytime only. The Ishihara test (24 plate version) is considered passed if the first 15 plates, presented in a random order, are identified without error.

response *Noted*

See response to comment No 102.

comment 1909 comment by: *Österr. Ophthalmologische Gesellschaft*

There is no definition of the method to test the visual field

Demands:

1) standardised threshold perimetry

2) Description of requirements:

minimum requirement 120 degrees in the horizontal

in addition: 20 degrees above and below horizontal a scotoma should not be permitted

response *Noted*

See response to comment No 102.

**C. Draft Decision Part-MED - Subpart B: Requirements for Medical Certificates - Section 2: Specific requirements for LPL medical certificates - p. 65  
AMC to MED.B.090 - 8. Otorhino-laryngology**

comment 279 comment by: *Lufthansa German Airlines*

**Author:** Dr. Ulrike Springer AMC Frankfurt

**Section:** 2

Subpart A

AMC to MED.B.001 - Requirements for Medical Certificates for the LAPL

8

**Page:** 65

**Relevant Text:**

The applicant should be able to hear a whispered voice in a quiet room.

**Comment:**

The draft version 3.0 is too nonspecific. Remarks: Hearing at a distance of 2 m indicates a medium level of hearing loss.

Precise reproducible results of hearing tests can only be obtained by electroacoustical measurements with calibrated audiometers.

Balance problems are not listed in draft version 3.0.

Eustachian tube function and normal middle ear pressure are basic requirements.  
Otoscopy is required for complete ear examination.

**Proposal:**

8.1 The applicant shall be able to hear whispered and conversational speech from a distance of 2 m with each ear, with the other ear covered and with his back turned towards to the examiner. The examination has to be performed using numbers containing four syllables.

8.2 In case the distance is less than 2 m for whispered and conversational speech an examination of hearing by pure-tone audiometry is required. The results of pure-tone audiometry are to be plotted in an audiogram.

8.3 Applicants with balance problems shall undergo a thorough examination of the vestibular system cerebellar system, cranial nerves, posture and gait. A number of specific factors should be evaluated: Nystagmus, fistula sign, positional tests, electronystagmography, caloric tests, rotatory chair test.

8.4 The assessment of Eustachian tube function, and therefore of middle ear pressure, is an important part of ear examination especially if a conductive type of hearing loss is present. The Valsalva inflation method and the much more accurate tympanometry are appropriate for examining the Eustachian tube.

8.5 Further detailed examination of the entire eardrum shall include microscopic assessment to rule out perforation of the drum, and acute or chronic pathological conditions.

response

*Noted*

See response to comment No 102.

comment

568

comment by: *British Microlight Aircraft Association*

Accepted

response

*Noted*

See response to comment No 102.

comment

603

comment by: *Lufthansa German Airlines*

**Author:** Dr. Ulrike Springer AMC Frankfurt

**Section:** 2

Subpart A

AMC to MED.B.001 - Requirements for Medical Certificates for the LAPL

8

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8.4 The assessment of Eustachian tube function, and therefore of middle ear pressure, is an important part of ear examination especially if a conductive type of hearing loss is present. The Valsalva inflation method and the much more accurate tympanometry are appropriate for examining the Eustachian tube.

8.5 Further detailed examination of the entire eardrum shall include microscopic assessment to rule out perforation of the drum, and acute or chronic pathological conditions.

response

*Noted*

See response to comment No 102.

comment

1060

comment by: *Dr Michel Kossowski AeMC Clamart*

define the whispered voice acoumetry

response

*Noted*

See response to comment No 102.

comment

1287

comment by: *Swedish Transport Agency, Civil Aviation Department (Transportstyrelsen, Luftfartsavdelningen)*

**Comment:**

The proposed requirement is disproportionate for LPL, requiring an ability to hear a whispered voice which is more strict than the class 2 requirement to understand correctly conversational speech at a distance of 2 metres. Moreover, the requirement for class 2 is focused on functional ability instead of

the unreal test situation for LPL. The class 2 requirement also contains provisions for a fit assessment when the hearing ability is reduced, which is not included in the LPL requirement.

A far more appropriate and proportionate approach is to use the requirement for class 2.

**Proposal:**

**Amend 8. OTORHINOLARYNGOLOGY :**

8.1 The applicant 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 examiner.

8.2. An applicant with hypoacusis should be assessed as fit if a speech discrimination test or functional cockpit hearing test demonstrates satisfactory hearing ability.

response

*Noted*

See response to comment No 102.

comment

1454

comment by: *Michel KOSSOWSKI*

define the whisperd voice acoumetry.

General remarks : why performing whispered voice test for leisure pilot and testing hear function for class 2 with a conversationnal speech? I thik, the more discriminant test is the whispered voice, for each ear. One ear is tested while we do a maskage on the other ear with repeted pression on the tragus. If thios tst is abnormal, thus an audiometry must be performed. eustachian tube function is not enaough individualized.

response

*Noted*

See response to comment No 102.

comment

1531

comment by: *Andrew CAMPBELL*

If this hearing standard is permissible to secure safe cockpit operation of an aircraft then why are more stringent requirements necessary for Class 2 medical certificates (or indeed Class 1)? Surely what is relevant is that the applicant can conduct a conversation using the apparatus in the cockpit under a practical cockpit test by the rating examiner? If the applicant is able to hear R/T communications properly by turning up the intercom or using a different headset then why is that not the appropriate standard - the standard listed bears no logical relationship with the environment in which the applicant is due to operate. What is the logical quantitative or qualitative relationship between hearing a whisper in a quiet room and being able to hear the engine and R/T communications in an operating aircraft?

response

*Noted*

See response to comment No 102.

comment	1996	comment by: CAA Belgium
<p>Relevant Text: 8. OTORHINOLARYNGOLOGY The applicant should be able to hear a whispered voice in a quiet room.</p> <p>Comment: That's all !!! The privileges of class 2 and LPL are exactly the same except a "payment for flying instruction ". All population of LPL (...more than 98% of current PPL !! ) will fly without else than this phrase in all European countries where the use of radio is mandatory and absolutely necessary, with no control on voice function, Eustachian function, sinus, vestibular, etc, etc... This is inadmissible and a future cause of accidents.</p> <p>Proposal: The same class 2 ENT requirements must be applied for LPL. This phrase must be applied only for Basic LPL requirements.</p>		

response	Noted
See response to comment No 102.	

comment	2162	comment by: AMS Denmark
<p>ORL requirement for LPL medical certificates should be identical with ICAO class 2.</p>		

response	Noted
See response to comment No 102.	

<b>C. Draft Decision Part-MED - Subpart D: General Medical Practitioners (GMPs)</b>	p. 66
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comment	1020	comment by: <i>European Society of Space and Aviation Medicine (ESAM)</i>
<p><b>Comment: Availability of complete medical files by GPs in different European countries</b> <b>European Society of Space and Aviation Medicine (ESAM) - Wiesbaden August 23<sup>rd</sup> - 24<sup>th</sup> 2008</b></p> <p><b>Medical file (complete) available from the GP</b></p> <p><b><u>Czech Republic -Dr. M. Rada-</u></b></p> <p>1) Normal GPs are not allowed to issue any certificates if not familiar with/certified AvnMed.</p> <p>2) On the other hand, there has been existing a group of approx. 100 GPs, who took a basic course in AvnMed at our Institute. Since that time they are 'designated' to perform an exam and issue a medical certificate but only for class 2, moreover only prolongation, not initial one. It must be issued only in our Institute of Aviation Medicine Prague.</p>		

3) In terms of documentation, an access to a complete medical file, the situation in the Czech Republic look like in Germany.

**Scotland -Dr. D Doyle-**

Most people register with a General Practitioner and attend that doctor or a group of doctors for all medical matters. If there is a need for specialist treatment, the General Practitioner usually arranges that and keeps a file of the reports that come back from the specialists. The General practitioner's records will have all of the person's medical attendances and will carry all details from birth. If a person moves to another part of the country, they will register with a GP there and the records from the last GP will be sent in through a central medical records exchange.

Everyone in this country has a National Health Service Number, known as the Community

Health Index Number (CHI Number) but not everyone knows their number or has kept the document with the number on it.

This number should allow the medical records of individuals to be traced, if it is known. The CHI Number can be obtained from National Health Service offices but you will appreciate that this could take time and effort, which a busy doctor may not be willing or able to give.

This sounds good and it is for most people but there are many who do not register with GPs when they move to a new location. Their childhood records may remain with a doctor where they lived or may be sent to the central medical records exchange if it is known that they have moved away. These people are difficult to deal with in respect of the accuracy of the available information. They could turn up at any GPs premise looking for a LPL licence medical and there would be no easy way of finding out about their medical history. This problem makes the present arrangements for LPL or NPPL medical certification difficult to support. It is easy, if the doctor is not able to know the history, for a person to obtain a medical certificate for the LPL or NPPL if they know they have a medical problem they wish to conceal.

**Croatia - Dr. Z. Lolic -**

Like in Britain and the Netherlands, Croatia has a national health system that every adult person has his/her own GP. The GP has a complete medical file.

Specialist of occupation medicine is qualified and licensed for the practice of aviation medicine, like AME, in accordance with applicable Croatian national health system.

**Bulgaria - Prof. Dr.Li Alexiev-**

The system for health insurance and medical servicing of the population using general practicing in Bulgaria is relatively new and therefore subject to development and corrections. The informational system with medical profiles of the patients is not yet complete and effective, wherefore we think that at this stage the medical certifying of LPL is better to be done by aviomedical examiners. In future the certification could be done by GP medical staff if they pass suitable preparation courses and licensing and this activity is included in GP duties by contract with the National Health Insurance Fund.

**Bulgaria - Z. Kernacs -**

We have 5130 GPs. They do not have access to complete medical files because the patient can see the specialist directly.

**Romania - Dr. Baloescu -**

In Romania isn't a national health system and a national health register. The

patients are free to select their GPs. They can visit specialists directly. In this case a GP never has access to ones whole medical file. Till now Romanian GPs didn't authorized to issue any aeromedical certificate. We think that ESM should oppose that GPs should be authorized to issue certificates on aeromedical fitness.

**Slovenia -Dr. T. Kozelj -**

Medical file on request from AME to obtained from GP.

**Spain - Dr. Alomar -**

In the Spanish medical system the GP have a lot of work and they don't want to do any medical certificate, so they cannot guaranty the safety purpose, so we think ESAM should oppose that GPs should be able to do aeromedical certificates.

**Norway - Dr. Wagstaff -**

The Norwegian GP is a system where each patient has his/her nominated GP until the patient wants to change another. Therefore many GPs have a lot of historical data on the patient. However there are also private GPs without government support that have higher prices and often are more accessible on short notice. In other words nothing prevents a pilot applicant to go to another GP than his/her usual one to get a medical certificate. Many AMEs are also GPs therefore this point also applies to AMEs.

ESAM should oppose that GMPS should be able to issue certificates or opinions on Aeromedical fitness without any requirement for Aeromedical knowledge as there is very little flight safety effect in this. In addition it may cause a false sense of security in the pilot.

**Netherlands - Dr. Ries Simons -**

In the Netherlands each citizen has his/her own GP, who -in principle - holds all medical information on his patient. However, each citizen is also free to go to another GP (who has no information at all) in order to have a medical examination (also for licensing purposes). For medical licensing concerning road driving, it is even mandatory to consult another GP than your own. This rule is meant to prevent GP's doing a favour for an unfit patient, who needs to have his license and with whom the GP has cordial contacts (they don't like to harm their patients).

**Hungary - Dr. H. Gabor -**

Every insured Hungarian person should have a GP, however there is a free of choice and unlimited changes situation. In the case visiting a specialist on hi9s own, there are no obligatory reporting system to the GP. Upon this the actual GP does not necessarily have all the medical data from the certain person.

**Hungary - Z. Kernacs -**

We have 5130 GPs. They do not have access to complete medical files because the patient can see the specialist directly.

**Spain - Dr. E. Alomar -**

In Spain we cannot control all the Gpm because we have multiple medical systems and they cannot connect in his medical histories, our opinion is that we cannot give to the Gpm's the capacity to make LPL examinations.

We have approximately between 200.000 and 400.000 general practitioners

response *Noted*

Thank you for the information.

comment	1788	comment by: Norwegian Association of Aviation Medicine
	Cancel	
response	Not accepted	
	GMPs acting as AMEs for the issuance of LPL medical certificates are envisaged in the Basic Regulation (EC) No 216/2008.	

comment	1897	comment by: Belgian Gliding Federation
	<p>AMC to MED.D.001  <i>Requirements for general medical practitioners</i>  <i>A speciality relevant to aeromedical practice in the sense of MED.D.001(a) should be considered as any speciality that gives competence to perform medical assessments in any of the systems described in Subpart B.</i></p> <p>Comment:  The intent of this paragraph is not obvious. If, as proposed, the qualification of a GMP is to have access to prior records, then in a few cases it might also be appropriate for other specialists with access to clinical records to provide certification.</p> <p><b>Proposal:</b>  <b>An in depth briefing about the air sport concerned shall make the GMP ready to perform medical examinations.</b></p>	
response	Noted	
	<p>The text of the implementing rule was amended to provide more clarity and the wording 'speciality relevant to aeromedical practice' was deleted. Following this, the AMC to MED.D.001 with the explanation of this wording was deleted too.</p> <p>GMPs may perform aeromedical examinations if permitted under national law. The text of the implementing rule was revised and GMPs wishing to act as AMEs are required to either acquire knowledge in aviation medicine or to hold, or have held, a pilot licence for any kind of aircraft.</p>	

comment	2018	comment by: Lars Tjensvoll
	Should be canceled	
response	Noted	
	See comment No 1788.	

**C. Draft Decision Part-MED - Subpart D: General Medical Practitioners (GMPs) - AMC to MED.D.001: Requirements for general medical practitioners**

p. 66

comment	103	comment by: British Gliding Association
	Page 66 of 66 <b>Subpart D</b>	

**GENERAL MEDICAL PRACTITIONERS (GMPS)**

**AMC to MED.D.001**

**Requirements for general medical practitioners**

A speciality relevant to aeromedical practice in the sense of MED.D.001(a) should be considered as any speciality that gives competence to perform medical assessments in any of the systems described in Subpart B.

*Comment: The intent of this paragraph is not obvious. If, as proposed, the qualification of a GMP is to have access to prior records, then in a few cases it might also be appropriate for other specialists with access to clinical records to provide certification.*

**APPEALS**

*Comment: Although the basic law in 216/2008 introduces mechanisms for appeal in other areas of certification, this does not apply to medical decisions. To establish an EASA medical appeal board would reduce the possibility of discontented individuals going to law and the probability of diverse judgments setting unwelcome precedents.*

**Proposal: That EASA establish an independent medical appeal board and that this be available initially through national escalation process.**

response *Not accepted*

The Basic Regulation establishes a mechanism to appeal against decisions of the Agency. This procedure is not applicable in the case of the appeal against the decision on medical fitness because this is a decision of a GMP/AME/AeMC or NAA. For this reason the process of the medical appeals is left for a national regulation. Requirements with regard to this procedure are proposed in the NPA 2008-22b Authority Requirements Subpart MED Section 3.

comment 406 comment by: *European CMO Forum*

Comment:

See comments against **MED.B.090**.

response *Noted*

comment 570 comment by: *British Microlight Aircraft Association*

Accepted

At first reading we found this a bit confusing. We thought it was indicating that Doctors had to have additional experience other than General practice. The language could perhaps be more straightforward. Specific requirements and processes must be published for "declare activity to appropriate authority".

response *Noted*

The text of the implementing rule was changed to provide more clarity and the wording 'speciality relevant to aeromedical practice' was deleted. Following this, AMC to MED.D.001 with the explanation of this wording was deleted too. The process of the GMP declaration will be in the Authority Requirements.

comment 839 comment by: *Thomas Cook Airlines UK*

**Commentator: The UK Association of Aviation Medical Examiners**

**Paragraph:** AMC to MED.D.001

**Page Numbers:** 66

**Comment:** GMPs should have evidence of knowledge of basic aviation medicine. They should also be aware of these guidelines and have ready access to them as well as knowledge of where to find an AME or an AeMC.

**Justification:** The accurate medical assessment of private pilots is not possible without at least some basic knowledge of aviation medicine. Without this some GMPs will be insecure and not wish to risk accusations of medical negligence. There will be a risk that GMPs will either refuse to see private pilots for medical certification or refer too frequently to AMEs or the AeMC. The busy GMP will see very few private pilots and may not feel confident to make the necessary judgement decisions.

**Proposed text:** AMC to MED.D.001 Requirements for general medical practitioners

A speciality relevant to aeromedical practice in the sense of MED.D.0.001 (a) should be considered as any speciality that gives competence to perform medical assessments in any of the systems described in Subpart B and that speciality should include the opportunity to acquire knowledge of basic aviation medicine.

response *Noted*

See response to comment No 570.

comment

973

comment by: *European Society of Space and Aviation Medicine (ESAM)*

**Author:**

**Group General Requirements - European Society of Space and Aviation Medicine (ESAM) - Wiesbaden August 23<sup>rd</sup>- 24<sup>th</sup> 2008**

**Section:** all paragraphs where GPs are recommended

**Page:** all paragraphs where GPs are recommended

**Relevant Text:**

**Comment:**

**GENERAL MEDICAL PRACTITIONERS (GMPS)  
MED.D.001 Requirements for general medical practitioners**

1. The use of GMP is below ICAO standard.

1.2.4.4 Contracting States shall designate medical examiners, qualified and licensed in the practice of medicine, to conduct medical examinations of fitness of applicants for the issue or renewal of the licences or ratings specified in Chapters 2 and 3, and of the appropriate licences specified in Chapter 4.

1.2.4.4.1 Medical examiners shall have received training in aviation medicine

and shall receive refresher training at regular intervals. Before designation, medical examiners shall demonstrate adequate competency in aviation medicine.

1.2.4.4.2 Medical examiners shall have practical knowledge and experience of the conditions in which the holders of licences and ratings carry out their duties.

2. According to ICAO Annex 1, 1.2.4.7.1 The medical examiner shall be required to submit sufficient medical information to the Licensing Authority to enable the Authority to audit Medical Assessments

Note.- The purpose of such auditing is to ensure that medical examiners meet applicable standards for good practice.

3. The practice of GMPs is not universal across the EU. There are marked variations in the ability to access medical records and data. In many European countries a therapeutic physician will not, according to national medical legislation, be to act in the role of assessor.

4. The proposed introduction of the GMPs does not include medical audit. The existing use of AME's includes recertification based on the activity of the AME and the requirement to avail of continuing medical education in the area of Aviation Medicine.

An example follows: In Germany 150 000 GPs are working in their own office. On the basic level of the requirements for general practitioners ( see **MED.D.001 Subpart D Page 21**) this number will increase to 175 000. If all 70 000 PPL license holders in Germany will decide to give up their PPL and fly only with an LPL license, there is only a small chance for a GP to perform **1.25 LPL medical /10 years**. Between the age of 16 up to the age of 80 years a LPL pilot has to perform 20 medicals. 70 000 license holders X 20 medicals = 1 400 000 Medicals in Germany in 64 years, which are 21 875 LPL Medicals /year. Statistically there is a chance of 1.25 LPL Medical in 10 years for one GP in Germany. This is not enough for getting experience to make safety relevant medical decisions for LPL.

5. Holistic medical examiners are required to carry out a comprehensive medical assessment. Any GMP planning to carry out an assessment must be a practitioner in holistic medicine

6. The introduction of the GMP assessment will result in the loss of harmonization of the medical assessment that already exists across the EU in the practice of the AMEs for more than eight years. The situation of mutual recognition results in harmonization. GMPs may practice in the absence of Aeromedical training

7. The absence of requirements for GMP as medical assessors of LPL, along with the lack of communication between the GMP and the Authority, will increase the risk to flight safety. We perceive a risk of medical tourism with the introduction of the GMP examination. This practice could enhance the loss of significant medical information Any pilot could travel to any GMP in any country (including countries outside the EU) for the granting of a medical certificate, without any proper control.

8. If the examiner status of GMP is introduced, the pilot should be examined by the GMP in the country of issue of the flying licence.

No state has responded to showing there is a system in place that can be used in any member state to harmonise standards across the EU.

**Proposal:** Delete GMP and use AME

response	<i>Not accepted</i>	
	The possibility for GMPs to issue LPL medical certificates is envisaged by the the Basic Regulation (EC) No 216/2008.	
comment	1164	comment by: <i>Pekka Oksanen</i>
	See comments against MED.B.090 Proposal: <b>Delete paragraph.</b>	
response	<i>Noted</i>	
	See comment No 973.	
comment	1288	comment by: <i>Swedish Transport Agency, Civil Aviation Department (Transportstyrelsen, Luftfartsavdelningen)</i>
	<p><b>Comment:</b> The proposed text is difficult to interpret and does not clarify the meaning of MED.D.001(a).</p> <p>The description of a GMP in the EU Directive 2005/36 EC includes all medical specialities, not only General Practice covering the whole spectrum of family medicine. Specialists in e.g. ophthalmology or psychiatry are covered by the definition of a GMP, and also by the proposed definition of 'a speciality relevant to aeromedical practice' in AMC to MED.D.001. However, they will probably have very limited competence to perform medical assessments outside their own speciality area.</p> <p>It is also unclear what is meant with 'the systems described in Subpart B'. Subpart B is divided into two sections, where only Section 2 relates to LPL, which is the only category that might be examined by a GMP. Section 2, however, does not describe all body systems included in Section 1.</p> <p>If the definition of speciality should refer only to the systems described in Section 2, then specialists in respiratory medicine, digestive systems, haematology, infectious diseases, orthopaedics, dermatology and oncology will be excluded.</p> <p>If the definition of speciality should refer to <u>all</u> systems described in Subpart B (including Section 1), it will in reality be a 'non-definition', because the systems described in Subpart B are covering every clinical speciality (possibly only excluding paediatrics) and also non-clinical specialities like laboratory medicine (haematology).</p> <p>The postgraduate training required in MED.D.001 does not always describe the actual field of practice, e.g. an orthopaedic surgeon with a specialist diploma in orthopaedic surgery may also act as a GMP for family medicine.</p> <p><b>Proposal:</b> AMC to MED.D.001 should either be deleted or be considerably more limited to include only active clinical practitioners with competence to perform medical assessments in <u>ALL</u> of the systems described in Subpart B.</p>	
response	<i>Noted</i>	

See response to comment No 570.

comment

1301

comment by: *David Chapman*

**possible Ambiguous statement , ...  
Med.D.001 (a) is, .....**

(a) have completed postgraduate training in general medical practice or any speciality relevant to aeromedical practice ; or

**has two parts**

**(i) post graduate training in GMP**

**(ii) any speciality relevant to aeromedical practice**

**So here when we see, ...**

A speciality relevant to aeromedical practice in the sense of MED.D.001(a) should be considered as any speciality that gives competence to perform medical assessments in any of the systems described in Subpart B.

**Suggestion - reword Med.D.001**

MED.D.001 Requirements for general medical practitioners

In order to issue LPL medical certificates, general medical practitioners (GMP) shall be fully qualified and licensed for the practice of medicine in accordance with applicable national rules, and

(a) have completed postgraduate training in general medical practice; or

(b) have completed post graduate training in a speciality relevant to aeromedical practice ; or

(c) have completed a training course in aviation medicine and have either:

(1) 1 year fulltime, or parttime equivalent, experience in practicing a medical speciality relevant to aeromedical practice; or

(2) hold, or have held, a pilot's licence for any kind of light aircraft.

I is not clear what intention is being sought with the final part "**declare their activity to the competent authority.**" Is this linked only to the aviation medicine specialist making declaration to the general medical competent authority? or what?

response

*Noted*

See response to comment No 570.

comment

1523

comment by: *Dr Ian Perry*

All appointed GMP's should have a basic qualification in aviation medicine.

I have run the UK's NPPL(engines) license since its inception. I am now rung up some 3-4 times a day by GP's with questions about medical licensing. How will this be dealt with across Europe where the medical care systems themselves differ from State to State? I receive a small fee for my services from the Licensing Group(UK).

How will this new system work out? The medical playing field is not a level one across EASA.

response	<i>Noted</i>	
	Thank you for the comment. GMPs may perform aeromedical examinations if it is permitted under national law. The text of the implementing rule was revised and GMPs wishing to act as AMEs are required to either acquire knowledge in aviation medicine or to hold, or have held, a pilot licence for any kind of aircraft.	
comment	1667	comment by: <i>Deutscher Aero Club (DAeC)</i>
	<p>Comment: The intent of this paragraph is not obvious. If, as proposed, the qualification of a GMP is to have access to prior records, then in a few cases it might also be appropriate for other specialists with access to clinical records to provide certification.</p> <p>DAeC Proposal: An in depth briefing about the air sport concerned shall make the GMP ready to perform medical examinations.</p>	
response	<i>Noted</i>	
	<p>A GMP, just as an AME, should be aware of the applicant's medical history before assessing fitness to fly. The system of using GMPs to issue medical certificates is based on the UK system where this is presently possible for national licences. For this medical certificate, the pilot has to see his/her GMP who, in the UK health system, holds the full medical file of all patients treated by him/her, including the pilot to whom the medical certificate is issued.</p> <p>In many other Member States a person can choose a different GMP each time he/she needs one, and the patient does not have to release the full medical history to the treating GMP.</p> <p>For this reason, the implementing rule contains a provision that GMPs can only issue medical certificates if they have access to the full medical history of the applicant.</p> <p>Briefing of the GMP: Please see response to comment No 1523.</p>	
comment	1712	comment by: <i>European Gliding Union (EGU)</i>
	<p>AMC to MED.D.001 Requirements for general medical practitioners A speciality relevant to aeromedical practice in the sense of MED.D.001(a) should be considered as any speciality that gives competence to perform medical assessments in any of the systems described in Subpart B.</p> <p>Comment: The intent of this paragraph is not obvious. If, as proposed, the qualification of a GMP is to have access to prior records, then in a few cases it might also be appropriate for other specialists with access to clinical records to provide certification.</p> <p>EGU Proposal: An in depth briefing about the air sport concerned shall make the GMP ready to perform medical examinations.</p>	

response	<i>Noted</i>	
	Please see response to comment No 1667.	
comment	1789	comment by: <i>Norwegian Association of Aviation Medicine</i>
	Cancel	
response	<i>Noted</i>	
comment	1976	comment by: <i>Richard WARRINER</i>
	<p>I disagree with the requirement for GMPs to have specific aviation training for the issuance of self certification declarations (ref MED.D.001)  Knowledge of a patient's medical history is more valuable than a single examination.</p> <p>If GMPs are required to undertake additional training in aviation medicine, they will be likely to refuse to have anything to do with the system and a proven route for medical oversight will be lost. Many medically fit pilots who to date have been using the system will in all likelihood either abandon flying or ignore the medical requirement and hence other legislation.</p> <p>In the UK we have managed to get most GMPs to accept the self declaration form, as long as they are assured that it is purely about health and that they don't need to know anything about aviation. This form can not be signed by anyone other than the pilot's personal GMP, so there is no possibility to take it to another GMP. The only option left is a JAR Class 2 medical, which adds layers of complication that they system was supposed to simplify.</p>	
response	<i>Noted</i>	
	See response to comment No 1523.	
comment	2134	comment by: <i>Croft Brown</i>
	<p>Page 66 of 66  Subpart D  GENERAL MEDICAL PRACTITIONERS (GMPS)  AMC to MED.D.001  Requirements for general medical practitioners  A speciality relevant to aeromedical practice in the sense of MED.D.001(a) should be considered as any speciality that gives competence to perform medical assessments in any of the systems described in Subpart B.  Comment: The intent of this paragraph is not obvious. If, as proposed, the qualification of a GMP is to have access to prior records, then in a few cases it might also be appropriate for other specialists with access to clinical records to provide certification.</p> <p>APPEALS  Comment: Although the basic law in 216/2008 introduces mechanisms for appeal in other areas of certification, this does not apply to medical decisions. To establish an EASA medical appeal board would reduce the possibility of discontented individuals going to law and the probability of diverse judgments setting unwelcome precedents.  Proposal: That EASA establish an independent medical appeal board and that</p>	

	this be available initially through national escalation process	
response	<i>Noted</i>	
	See response to comment No 103.	
comment	2258	comment by: <i>Martyn Johnson</i>
	<p>The intent of this paragraph is not obvious. If, as proposed, the qualification of a GMP is to have access to prior records, then in a few cases it might also be appropriate for other specialists with access to clinical records to provide certification.</p> <p>Although the basic law in 216/2008 introduces mechanisms for appeal in other areas of certification, this does not apply to medical decisions. To establish an EASA medical appeal board would reduce the possibility of discontented individuals going to law and the probability of diverse judgments setting unwelcome precedents.</p>	
response	<i>Noted</i>	
	See response to comment No 1667.	
comment	2440	comment by: <i>SANMA Swedish Aeronautical Association</i>
	Allmän läkare har ej heller någon kunskap om vilka medicinska krav som ställs för att flyga eller erfarenhet av flygmedicin.	
response	<i>Noted</i>	
	According to the Basic Regulation, GMPs are sufficiently qualified to perform LAPL medical examinations and issue LAPL medical certificates.	
comment	2467	comment by: <i>Paul Mc G</i>
	<p>Requirements for general medical practitioners  A speciality relevant to aeromedical practice in the sense of MED.D.001(a) should be considered as any speciality that gives competence to perform medical assessments in any of the systems described in Subpart B.  Is it proposed, that the qualification of a GMP allows access to prior records, then in a few cases it might also be appropriate for other specialists with access to clinical records to provide certification.</p> <p><b><u>APPEALS</u></b>  Comment: Although the basic law in 216/2008 introduces mechanisms for appeal in other areas of certification, this does not apply to medical decisions. This breeches HR legislation and has to be reconsidered.  An EASA medical appeal board would reduce the possibility of individuals going to law and the probability of diverse judgments. This could be established through national legal escalation processes, although this could be very costly.</p>	
response	<i>Noted</i>	
	See response to comment No 103.	



**Appendix A - Attachments**

 [Table - Standard Alcohol Units Worldwide.pdf](#)

Attachment #2 to comment [#1181](#)

 [Comments attachment.pdf](#)

Attachment #3 to comment [#1349](#)

 [EAAP-CRTok2 to EASA2003.pdf](#)

Attachment #4 to comment [#1292](#)

 [Comments attachment.pdf](#)

Attachment #5 to comment [#1350](#)

 [080r0201.pdf](#)

Attachment #6 to comment [#228](#)

 [ÖÄK comments A EASA draft pilot licensing Feb09 en.pdf](#)

Attachment #7 to comment [#1722](#)

 [Comments attachment.pdf](#)

Attachment #8 to comment [#1351](#)

 [carta adjuntando propuesta para EASA.pdf](#)

Attachment #9 to comment [#1490](#)

 [Propuesta de AEPA para JAR-EASA.pdf](#)

Attachment #10 to comment [#1490](#)

 [Attachment #5 - Request For Comments ITDM Pilots & Thrid-Class ITDM Pilots.pdf](#)

Attachment #1 to comment [#2049](#)

 [Attachment #1 - Diabetes Mellitus Type 2 in Aviators.pdf](#)

Attachment #2 to comment [#2049](#)

 [Attachment #4 - Flying With Insulin In Military Aviators.pdf](#)

Attachment #3 to comment [#2049](#)

 [Attachment #3 - An Analysis Of In-Flight Impairment And Incapacitation & Review of General Aviation Fatal Accidents.pdf](#)

Attachment #4 to comment [#2049](#)

 [Attachment #2 - FAA Medical Certification Guidelines.pdf](#)

Attachment #5 to comment [#2049](#)

 [Comment on NPA 200817c Section 2 Subsection 2.1 .pdf](#)

Attachment #6 to comment [#2049](#)

 [SRG\\_Med-NPPL\\_epilepsy.pdf](#)  
Attachment #7 to comment [#310](#)