

NPA-FCL 28 (JAR-FCL 3) - Medical

EXPLANATORY NOTE

INTRODUCTION

1. NPA-FCL 28 (JAR-FCL 3) - Medical will affect the content of JAR-FCL 3 (Medical) and the proposals concern Subparts A, B, C, Appendices to Subparts A, B & C, and Section 2 Material. The items contained in this NPA cover medical issues that needed review and updating, and amendments for clarification. As a result the Central JAA - Licensing Division considers it necessary to consult on the proposals to amend JAR-FCL 3 (Medical).
2. The following pages are in two parts:
 - (a) This Explanatory Note under which each of the proposals is separately identified with an explanation of the reasons for the intended amendment, and
 - (b) The proposed amendments. All proposals included in this NPA have been prepared by the Licensing Subsectorial Team (Medical) over the last two years and were accepted by the Licensing Sectorial Team for NPA.
3. It is advised that these proposals should be incorporated in JAR-FCL 3 (Medical) on 3Q 2006 at the latest.
4. For ease of reference, the proposals are shown in much the same format as they would appear in the JAR except that Section 1 material is not shown in columnar format but, like Section 2 material, reads across the page on order to reduce the volume of this NPA.
5. The proposed changes appear by a combination of ~~striketrough~~ for deletions and/or **bold italics** indicating the new wording or numbering which is intended. For convenience changes of passages which appear in bold already in the original text or are intended to appear bold are **marked by additional underlining**. Changes in medical forms may appear in **red fonts** as well.

GENERAL OVERVIEW

6. The table below shows a General Overview of affected JAR-FCL paragraphs due to NPA-FCL 28 (JAR-FCL 3) - Medical.

JAR-FCL Reference	New	Amendment
Section 1		
Subpart A		
General Requirements		
JAR-FCL 3.015		✓
JAR-FCL 3.035		✓
JAR-FCL 3.040		✓
JAR-FCL 3.045		✓
JAR-FCL 3.080		✓
JAR-FCL 3.090		✓
JAR-FCL 3.091	✓	
JAR-FCL 3.100		✓
JAR-FCL 3.105		✓
JAR-FCL 3.115		✓
JAR-FCL 3.125		✓
Appendix 1 to JAR-FCL 3.105		✓

Subpart B		
Class 1 Medical Requirements		
JAR-FCL 3.130		✓
JAR-FCL 3.135		✓
JAR-FCL 3.140		✓
JAR-FCL 3.150		✓
JAR-FCL 3.155		✓
JAR-FCL 3.160		✓
JAR-FCL 3.170		✓
JAR-FCL 3.180		✓
JAR-FCL 3.195		✓
JAR-FCL 3.210		✓
JAR-FCL 3.215		✓
JAR-FCL 3.220		✓
JAR-FCL 3.225		✓
JAR-FCL 3.230		✓
JAR-FCL 3.235		✓

Subpart C		
Class 2 Medical Requirements		
JAR-FCL 3.250		✓
JAR-FCL 3.255		✓
JAR-FCL 3.260		✓
JAR-FCL 3.270		✓
JAR-FCL 3.275		✓
JAR-FCL 3.280		✓
JAR-FCL 3.290		✓
JAR-FCL 3.300		✓
JAR-FCL 3.315		✓
JAR-FCL 3.335		✓
JAR-FCL 3.340		✓
JAR-FCL 3.345		✓
JAR-FCL 3.350		✓
JAR-FCL 3.355		✓
Appendices to Subparts B & C		
Appendix 1 to Subparts B and C		✓
Appendix 2 to Subparts B and C		✓
Appendix 3 to Subparts B and C		✓
Appendix 4 to Subparts B and C		✓
Appendix 5 to Subparts B and C		✓
Appendix 6 to Subparts B and C		✓
Appendix 7 to Subparts B and C		✓
Appendix 8 to Subparts B and C		✓
Appendix 9 to Subparts B and C		✓
Appendix 10 to Subparts B and C		✓
Appendix 11 to Subparts B and C		✓

Appendix 12 to Subparts B and C		✓
Appendix 13 to Subparts B and C		✓
Appendix 15 to Subparts B and C		✓
Appendix 16 to Subparts B and C		✓
Appendix 18 to Subparts B and C		✓
Appendix 19 to Subparts B and C		✓

JAR-FCL Reference	New	Amendment
Section 2		
<i>Acceptable Means of Compliance (AMC) / Interpretative and Explanatory Material</i>		
<i>AMC/IEM - General Requirements</i>		
IEM FCL 3.045		✓
IEM FCL 3.095 (a) & (b)		✓
IEM FCL 3.095 (c) (1)		✓
IEM FCL 3.095 (c) (2)		✓
IEM FCL 3.095 (c) (3)		✓
IEM FCL 3.095 (c) (4)		✓
IEM FCL 3.095 (c) (5)		✓
IEM FCL 3.095 (c) (6)		✓
IEM FCL 3.095 (c) (7)		✓
IEM FCL 3.100 (a)		✓
IEM FCL 3.100 (b)		✓
IEM FCL 3.100 (c)		✓
<i>IEM FCL 3, A, B, & C</i>		
<i>JAA Manual of Civil Aviation Medicine</i>		
whole Manual		deleted

JUSTIFICATIONS

NPA-FCL 28 (JAR-FCL 3) - Medical

General remarks

Some years after implementation of JAR-FCL 3 in several JAA member states a great amount of experience with the requirements was gained by AMSs, AMCs, AMEs and affected pilots. Several procedures needed to be optimised to the needs of pilots, industry and authorities. Progress in science and medicine required adaptations of the existing requirements as well. Furthermore, Amendment 166 of ICAO Annex 1 will be implemented in November 2005. These developments made several amendments to the requirements of JAR-FCL 3 necessary. Furthermore, the JAA Manual of Civil Aviation Medicine has been deleted from Section 2 of JAR-FCL 3 and has been published as a part of the Joint Implementation Procedures to allow for a quicker cycle of updating.

SECTION 1

Changes throughout the requirements

1. JAR-11 requires a clear, consistent and uncontentious wording within the requirements. This prevents different and contentious interpretation. In order to comply with JAR-11 it was agreed to replace two different terms, one with two different spellings, by the term "multi-pilot (Class 1 'OML') limitation". This change applies to various parts of the requirements (see JAR-FCL 3.035, Appendix 1, 2, 3, 4, 7, 8, 9, 10, 11, 13, 18, 19). The terms "comprehensive" and "extended" have been used as synonyms. This has been removed in favour of "comprehensive" (JAR-FCL 3.230, IEM 3.095 (a) & (b)).

2. Several mainly editorial changes are proposed. Some more contentious terms have been agreed to be deleted and replaced throughout the requirements (see JAR-FCL 3.135, 3.140, 3.170, 3.180, 3.220, 3.255, 3.260, 3.290, 3.300, 3.340, 3.355, Appendices 1, 2, 3, 4, 5, 6, 7, 8, 9, 10, 11, 12, 13, 15, 16, 18, 19). The term "certification" is used for fit assessments, in other parts of the JARs for the technical action of granting a certificate, the term "recertification" is used as a synonym for "revalidation", sometimes it summarises "revalidation" and "renewal". Moreover, it is used for fit assessments subsequent to a decrease of medical fitness. The terms "restriction" and "restricted" are used as synonyms for "limitation", but also in the sense of "restricting something". The terms "variation" and "condition" were used as synonyms for "limitation" (like "OML", "VDL" etc.). Because these terms have different meanings, which are used throughout the requirements as well ("variation" as a synonym for "review procedure", "condition" as a

synonym for a medical condition or a condition in a legal or grammatical sense), and could result in misinterpretation, it appeared appropriate to delete and replace them with the terms "limitation" and "review procedure" where appropriate (see also page 12 of this Explanatory note, JAR-FCL 3.100, change 1). The term "drug" is used as a synonym for "medication" as well as for "(illegal) substances" and so-called "recreational drugs". These terms have been replaced where appropriate. Different terms like "considered", "considered fit", "assessed as fit" have been used in interchangeable way. They have been replaced by "assessed as fit" throughout the requirements. Where paragraphs of Subparts B and C were intended to be identical, existing differences have been identified and the paragraphs been brought in line with each other. Furthermore, some typoids have been deleted. In some paragraphs a clearer wording is proposed.

3. An Ophthalmology Working Group was established and tasked to review the ophthalmological requirements in the light of experience following the implementation and use of JAR-FCL 3 for some time already. The requirements had to be assessed in terms of their paramount scope: safety. In addition the requirements had to be justified, taking into account the required level of safety and unintended impacts, for example possible unjustified denial of medical fit assessment, unjustified superfluous examinations and the associated costs involved. Ophthalmology is an important issue, because a relatively large number of initial applicants have been rejected in the past on grounds of ophthalmological requirements (mainly refractive error and colour vision).

The proposals comprise in various changes: streamlining the contents of ophthalmological examinations for Class 1 applicants (colour vision testing only at initial examination); reducing the frequency of specialist ophthalmology examinations, in that the periodicity does not depend on the same routine scheme for all those with refractive correction any more, but depending on the degree of refractive error; refractive error limits for Class 1 and Class 2 applicants (changed from +/- 3 to + 5 resp. - 6 for Class 1 and +/- 5 to + 5 resp. - 8 diopters for Class 2 applicants at initial examination; from a maximum limit of - 8 for Class 1 and Class 2 at revalidation or renewal to no "absolute" upper limit, but subjecting those exceeding -6 diopters for Class 1 and - 8 for Class 2 to a closer supervision and review by a vision care specialist, based on the fact that - according to leading specialists in European aviation ophthalmology - pathological hypermetropia starts from + 5 and pathological myopia starts from -6 dioptries); less stringent limits for esophoria at near distance (at near distance heterophoria the risk of diplopia is higher, however, esophoria can be compensated better); altering the frequency of review of applicants with keratoconus on discretion of AMS; bringing in line the requirements of those with a visual field defect to those with monocularly; bringing in line the requirements for those with refractive surgery to the new proposed refractive error limits; clarifying the requirements for retinal surgery. Furthermore, some editorial changes are proposed.

The substantive changes had to take into account that there were those specialists favouring no refractive error limits at all, thus applying ICAO standards. The latter have been used by the FAA for some years, the accident rate did not show any difference from that of JAA member states. On the other hand there were those favouring to keep stricter limits and arguing that pathology in an eye would start above + 5 diopters (risk of acute narrow angle glaucoma) and above - 6 diopters (risk of retinal detachment). Experience shows that only a small amount of applicants will exceed the proposed standards. The proposed changes are a sound compromise between keeping the level of safety and creating some degree of flexibility in favour of future applicants.

Subpart A – General Requirements

- **JAR–FCL 3.015**, *Acceptance of licence, ratings, authorisations, approvals or certificates.*

Some member states - e.g. the UK - issue a number of deviations to applicants who are outside the JAR-FCL 3 requirements but do not pose an unacceptable flight safety risk. These pilots are limited to aircraft registered in that state, unless another AMS permits them to fly on aircraft registered in its state. As JAR-FCL 3.015 requires a respective endorsement on the licence and no further guidance is given, it is proposed to add the relevant text.

- **JAR–FCL 3.035**, *Medical fitness.*

1. It was agreed that the term "condition" as a synonym for "limitation" could be relinquished (see page 12 of this Explanatory note, JAR-FCL 3.100, change 1 and page 7 Changes throughout the requirements, change 2). Here it appeared as a synonym for "medical condition" as well.

2. The limitation "OML 'Valid only as or with qualified co-pilot'" applies to pilots who do not meet the medical requirements for single crew operations, but are fit for multi-pilot operations. As this is applicable for Flight Engineers (FE) as well the above-mentioned terms had to be adapted for FE and another limitation with appropriate acronym to be created. Should the pilot with "OML" get incapacitated, the other pilot will take over command of the aircraft and should therefore not be subject to an "OML" himself. However, even though a FE is neither taking over the command of the aircraft if a pilot with "OML" should get incapacitated, nor would a pilot vice versa leave the controls and take over the position of a FE should the latter get incapacitated. It was agreed that at maximum one crew member on duty should be allowed with an "OML"- or "OFL"-limitation. Moreover, the text had to be in line with JAR-FCL 4. Therefore, the word "member" was changed to "members".

3. The present wording in subparagraph (d)(1) allows an ‘OML’ limitation to be applied only to holders of a commercial licence and not to applicants. The issue becomes relevant in the light of an upcoming MPL (Multi Pilot Licence). An OML limitation is given to those exceeding certain standards, mostly of Subpart B, but not posing an unacceptable risk to flight safety. Therefore it was proposed that an ‘OML’ limitation could be granted to initial applicants as well. As an unanimous position of the LST could not be found the stakeholders are asked for their opinion.

- JAR–FCL 3.040, *Decrease in medical fitness.*

After implementation of JAR-FCL 3 the workload of Authorities in general and AMSs in particular has increased significantly, because a lot of routine work has been transferred from AMEs to the AMS. At the same time financial resources and staff did not increase and even shrunk. This may result in overload of work and time delays. Furthermore, the AME or AMC are the major points of contact and know the pilot himself best. Therefore, it was agreed to delegate routine work as dealing with decrease in medical fitness to AMCs and AMEs. Furthermore, it was clarified in which instances the Authority and in which the AMS is meant, as both terms are used as synonyms and as specific terms as well.

- JAR–FCL 3.045, *Special circumstances.*

1. It was found that the term “variation” would be relinquishable and should be replaced by “review” (see page 12 of this Explanatory Note, JAR-FCL 3.100, change 1).

2. Medicine and science are rapidly developing and changing. This may have implications for aeromedical regulation allowing for the range of abnormality to be extended. Certain conditions may be safely accepted for licensing - after experience has shown that it is safe to do so. This will enable a larger number of pilots to take up or to continue flying despite those medical conditions. However, existing regulations prevent to gain experience with such conditions in the aviation environment as they are unacceptable according to them. This “catch 22” situation prevents progress towards more liberal requirements that would result in the same level of safety. A working group within the LSST(M) developed a controlled and strictly supervised protocol, involving cooperation between two or more member states, to assess conditions, technologies, therapies and medications currently not accepted within the cockpit, but well-known and proven in medical practice. A ReDWiG group (Research and Development Working Group) will develop individual protocols, which will be limited to aircraft registered within the participating states. Finally, the findings due to observation of the protocol may result in a proposal for a change of the current requirements. The idea of the general protocol is covered by ICAO Annex 1, 1.2.4.8. The particular procedure is described

within the JIP (Administrative and Guidance Material, Section V - Licensing, Joint Implementation Procedures, Chapter 6, 6.10.2). The proposal was agreed in the LST, there was only strong opposition of just one authority. The stakeholders are invited for specific comments on the issue.

- JAR–FCL 3.080, Aeromedical Section (AMS).

The proposal clarifies the availability of confidential medical information only for the completion of a medical assessment.

- JAR–FCL 3.090, Authorised Medical Examiners (AMEs).

1. In the present version of the paragraph the terms "approval" resp. "approve" and "authorise" are used, which indicate different legal actions within the requirements of JAR-FCL. As there is no specified legal action or procedure for approval of training courses in place, neither by CJAA nor by individual AMSs, the acceptance of training courses is absolutely in the individual AMS's gift, which authorises an AME. The training courses, which are precondition for that authorisation, have to be accepted by that AMS on three different occasions: either by accepting courses in that country, accepting courses attended abroad or by accepting courses abroad attended by AMEs from third countries that apply for authorisation in the AMS's country. This had to be clarified by the proposed changes.

2. When a new paragraph (f) was introduced in the context of NPA 21 (JAR-FCL 3) the old paragraph (f) got lost inadvertently. As erratum the paragraph had to be reintroduced. However, the paragraph had to be adapted since the date given was no more appropriate. The paragraph will be applied to AMEs of countries that are going to implement JAR-FCL 3. Therefore the date was replaced by the term "implementation of JAR-FCL 3".

- JAR–FCL 3.091, Aeromedical examination and assessment - General

Scope of JAA was to adopt and use common codes throughout the JAA member states and apply them in a standardised way in order to reach harmonisation and to create a level playing field. Medical examinations and assessments have to comply with the requirements of JAR-FCL 3, Subparts A, B and C and the Appendices to Subparts B and C. The JAA Manual of Civil Aviation Medicine was not only created as a textbook for Aviation Medicine, but predominantly to give guidance how the requirements have to be applied and which aeromedical procedures and examination techniques of good aeromedical practice are to be used in aeromedical examinations and assessments. Therefore it contributes to

create a level playing field and to ensure harmonised application of the requirements. As the exact role of the JAA Manual of Civil Aviation Medicine and the hierarchy of requirements and guidance material is not outlined in JAR-FCL 3 so far, a new paragraph should be inserted to catch up for the need of clarification, thus complying with JAR 11 which requires clear, uncontentious and self-contained requirements with reference to the associated procedures. It was agreed to introduce a new paragraph to Subpart A outlining the references for aeromedical assessment in JAR-FCL 3 and the JAA Manual of Civil Aviation Medicine.

- JAR–FCL 3.100, *Medical certificates.*

1. JAR-11 requires a clear, consistent and uncontentious wording within the requirements. The nomenclature for the review process has been contentious. The term "derogation" has a different meaning in different languages. The term "variation" was used for "limitation" as well and can be confused with the term "national variant" or the general meaning of the term, which appears in Section 2. The term "condition" is used as a synonym for "limitation" as well and appears in different meanings (synonym for stipulation, a precondition, a state of being, as a certain medical state or as a pathological medical "condition") within the requirements and in general use. Therefore it was found that the terms "variation" and "condition" could be relinquished and that the term "review procedure" should be used.

2. Medical Certificates can be issued by AMEs at initial Class 2 and at Class 1 and 2 revalidation and renewal examinations, by AMC at Class 1 revalidation and renewal and all types of Class 2 examinations and by AMS at all examinations and subsequent to review procedures. This has to be reflected in JAR-FCL 3.100, listing the contents of Medical Certificates.

3. Amendment 4 changed the content of the medical certificates (IEM 3.100 (c)). The changes had to be reflected in the paragraph describing the contents required for the medical certificate as well ("Date and place of initial medical examination", which could not be remembered by the majority of applicants anyway, had been replaced by expiry dates of current and previous medical certificate).

4. The changes in the validity period for Class 1 medical certificates had to be reflected in the medical certificate as well (see page 13 of this NPA, JAR-FCL 3.105, change 1). This resulted in a different validity period depending on the type of operation.

5. As the term "extended examination" is not applicable any more after the changes proposed by this NPA (the former "extended" or "comprehensive" ophthalmological and otorhinolaryngological

examinations are performed at the initial examination or on clinical indication resp. depending on the refractive error) and these “extended” examinations had not necessarily be performed on the same date, the term “extended examination” for an aeromedical examination was misleading. It was agreed to be deleted. Furthermore, it was agreed that the date of the previous medical examination might be useful for AME and Authority. The term “general” examination related to the actual medical examination, was misleading and therefore renounceable.

- JAR–FCL 3.105, *Period of validity of medical certificates.*

1. The requirement for an increase in frequency for Class 1 medical examinations over the age of 40 was established with the rationale that the risk for developing medical problems and an increasing risk of incapacitation was developing with age. However, it was found that the threshold of 40 years was chosen arbitrarily. Effective from November 2005 on ICAO changed its standards (Amendment 166). Multi-pilot operation is 1000 times less likely to result in a fatal accident than single pilot operations (only 10 % of the flight time is critical and a unsuccessful takeover from an incapacitated pilot to the other pilot can be expected only in less than 1%). In multi-pilot operations only 1 case of medical incapacitation was found as contributory to an accident in the last 20 years worldwide. Furthermore, it was argued that a medical examination would be poorly predictive of future incapacitation and would have a low detection rate of unrecognised illness. ICAO addressed the fact that medical scrutiny should be concentrated on those operations that - in case of incapacitation - would most likely result in a fatal accident. It was agreed to adopt the ICAO requirement to keep the reduction of validity to six months only for those over 60 years of age and for those on single pilot commercial operations carrying passengers. If an AMS would hold it for appropriate for clinical reasons the validity period may be reduced.

2. In ICAO Amendment 6 the standards for validity periods of medical certificates Class 2 have been changed as well, in that it will be 60 months for those until age 40. It was agreed to adopt the ICAO standards for Class 2 applicants as well in that the validity period of 60 months extends to those until age 40 and not only to those until age 30 as currently.

3. JAR-FCL 3.105 (b) states how the date of expiry of the next medical certificate is to be calculated. As it was not clear from the JAR whether a medical certificate issued prior to the expiry of the current certificate (the usual situation) should immediately become the valid certificate, in effect superseding the ‘old’ certificate. Otherwise, the pilot would have two medical certificates, one of which is valid until its expiry date and the other is not valid until this one has expired. It was clarified that - when a pilot holds two valid medical certificates (which could differ from each other e.g. with respect to any limitations in place) the “old one” becomes invalid.

- JAR–FCL 3.125, *Variation and review policy*

1. The same proposal as for JAR-FCL 3.100 applies (see page 12 of this Explanatory note, JAR-FCL 3.100, change 1).

2. With implementation of JAR-FCL 3 the assessment of pilots with slight abnormal values or medical conditions has shifted from AME to AMS. As this applies to routine problems as well a lot of additional workload has arisen for the AMS. Limited manpower has resulted in delayed decision making and additional cost for industry (more than 10 million Euro for single airlines), pilots and AMS. The provisions of JAR-FCL 3 ensure a high quality of AMEs and AMCs, who are required to be well-trained and experienced. As harmonisation is safeguarded by compliance to the Appendices it is proposed to delegate assessment of conditions not requiring any kind of extensive judging and difficult decision-making to AMCs or AMEs on discretion of the AMS. According to ICAO Annex 1, Chapter 6, Preliminary Note many decisions have to be left to the judgement and discretion of the AME. The proposal is in line with the European principle of subsidiarity and in JAR-FCL 3.080 (a) such proposal is already outlined with the expression "duly empowered to act on behalf of the Authority".

- Appendix 1 to JAR-FCL 3.105, *Validity period of medical certificates.*

It was agreed to delete the EEG requirement for initial Class 1 applicants. Therefore, a sentence using the example of an EEG for an initial Class 1 applicant had to be deleted.

Subpart B - Class 1 Medical Requirements

- JAR-FCL 3.130, *Cardiovascular system - Examination*

1. Subsequent to the changes proposed due to adoption of the ICAO standards concerning validity periods of Class 1 medical certificates - as per Amendment 166 (see page 13 of this Explanatory Note, JAR-FCL 3.105, change 1) - the periodicity of Class 1 resting ECG examinations had to be adapted as well.

2. AMEs and AMCs are highly-trained specialists. As recording and reporting of resting and exercise ECG is a basic medical skill and as in some countries AMEs have to be trained in Internal Medicine and therefore cardiology it was agreed that reporting of both resting and exercise ECG should be by AMEs or other specialists acceptable to the AMS.

- JAR-FCL 3.135, *Cardiovascular system - Blood pressure*

The paragraphs outlines the requirements for technique, limits, treatment with reference to the appropriate Appendix 1. It is commonly understood that blood pressure as a part of a routine medical examination is assessed at each examination and noted in the Medical Examination Report Form. However, even though a whole paragraph is dedicated to blood pressure, the latter is not mentioned, which is not consistent with JAR 11. Therefore, it was agreed to specifically mention that blood pressure has to be determined at each examination.

- JAR-FCL 3.155, Respiratory system - General

1. The requirement for chest radiography for initial Class 1 applicants is in excess of ICAO standards. In accordance to the recommendations of the International Commission on Radiological Protection (ICRP) chest X-ray has to be justified and should not be used just for routine screening. The benefit of chest radiography to flight safety is very small (it was stated that relevant conditions are more likely to be revealed by the history of the applicant) and on the other hand a - even though small - harm by the radiological exposure may result. Therefore it was agreed that the requirement should be abolished.

2. Peak flow testing is not a very sophisticated and sensitive test method, it is used for self-assessment for the efficiency of an anti-obstructive therapy (used for self-observation of patients). The variability of flow, which is typical for asthma, is missing in patients with chronic obstructive pulmonary disease. There is no validation for prognostic assessment with peak flow as a screening test. Therefore, the prognostic value of the test is doubtful, it is no proper test for the pulmonary function. It was agreed that these tests should not be required any more. Furthermore, it was agreed that pulmonary function tests are required at initial Class 1 examination and on clinical indication, which was self-evident, but not mentioned before.

- JAR-FCL 3.160, Respiratory system - Disorders

1. The term "chronic obstructive airway disease" encompasses different clinical entities like COPD (chronic obstructive pulmonary disease), emphysema and asthma and may appear with different severity. The ability to cope with and to function in a hypobaric environment may be severely impaired in applicants with significant impairment of their respiratory function. Therefore, they are unfit for flying. However, those with only minor impairment of their pulmonary function have no restriction in their abilities to cope and to perform within a hypobaric environment. Therefore, it was agreed to propose that the latter may be assessed as fit.

2. JAR-11 requires a clear, consistent and uncontentious wording within the requirements. In order to prevent misinterpretations or different interpretations it was agreed to use the same term "asthma" where

"reactive airway disease", "bronchial asthma" and "asthma" were used before.

- JAR-FCL 3.170, Digestive system - Disorders

Some editorial changes were introduced for a more concise and clear wording.

- JAR-FCL 3.180, Haematology

1. Apart from some editorial changes a more concise and clear wording concerning the required procedures for applicants with abnormal haemoglobin is proposed.

2. The term "leukaemia" describes a variety of heterogeneous conditions with different natural history, clinical behaviour and prognosis. Intensive treatment modalities like bone marrow transplantation are used now and result in cure rates up to 50 %. Therefore, it was agreed that it would be appropriate to assess applicants on an individual basis taking into account diagnosis, subtype and stage of disease, treatment and prognosis.

- JAR-FCL 3.195, Gynaecology and obstetrics

1. In case of pregnancy female pilots may be assessed as fit in case of a completely normal pregnancy. It had been agreed that dealing with "decrease of medical fitness" could be delegated to AMC and AME as well as they would deal with the pilot directly. In case of pregnancy in Class 1 applicants all three of them could impose and - after termination of the pregnancy - remove the required 'OML' limitation (see page 10 of this Explanatory Note, JAR-FCL 3.040) and assess the applicant as fit. This would remove a lot of workload from the AMS and at the same time delegate the work to those, who know the applicants best.

2. So far applicants had to be assessed as unfit for at least three months after major gynaecological operations. As the definition of this entity might be used in a wider or more narrow sense it was found that there are such operations - such as Caesarian section - where a shorter time of disqualification would be sufficient. Therefore, an applicant might be assessed as fit individually on safety based criteria (if the effects of the operation are not likely to interfere with safe flying).

- JAR-FCL 3.210, Neurological requirements

Recording and reporting of electroencephalography was found not to be standardised throughout the JAA member states. Therefore, findings and results may be interpreted differently. Furthermore, it was found that the low risk of in-flight incapacitation, which might be prevented by EEG tests,

is only reduced by 50 %. It was common understanding that this does not to justify an EEG test for all initial Class 1 applicants.

- JAR-FCL 3.215, *Ophthalmological requirements*

1. Routine ophthalmological examinations are performed by AMEs, however, this was not explicitly stated before in Subparts B and C, which are relevant for AMEs and AMCs.
2. Several changes are proposed as a result of reviewing the existing requirements in the light of experience of a couple of years after implementation and ICAO standards (see page 8 of this Explanatory note, Section 1, Changes throughout the requirements, Change 3).

- JAR-FCL 3.220, *Visual requirements*

1. ICAO Annex 1, Chapter 6, 6.3.3.2.2 requires applicants with large refractive errors to use contact lenses or high-index spectacle lenses. This has to be reflected in the corresponding paragraph of JAR-FCL 3 - JAR-FCL 3.220 (b) - as well, because ICAO contracting states are required to follow the ICAO standards.
2. ICAO Annex 1, Chapter 6, 6.3.3.2.1 requires applicants using contact lenses to meet the visual requirements have to use mono-focal, non-tinted and well-tolerated lenses. This has to be reflected in the corresponding paragraph of JAR-FCL 3 - JAR-FCL 3.220 (g) - as well.
3. The proposal is meant for clarification. Different types of contact lenses are used more and more, having possible impact on flight safety. This relates to bifocal (one contact lens for distant and near vision - probably resulting in visual blurring), monovision (one lens for distant in one and another for near vision in the other eye - probably interfering in 3-dimensional vision) and orthokeratologic lenses (lenses worn in the night and - by changing the surface of the eye, the cornea - improving vision for a limited time, enabling fraudulent applicants to pass an eye examination, even if their natural vision is not sufficient - probably resulting in pilots with insufficient eyesight). Monovision and bifocal contact lenses interfere with binocular vision. Even though some opticians advertise the use of orthokeratologic lenses as a way to pass initial examinations, these lenses preclude a stable refraction.
4. Several changes are proposed as a result of reviewing the existing requirements in the light of experience of a couple of years after implementation and ICAO standards (see page 8 of this Explanatory note, Section 1, Changes throughout the requirements, Change 3).

- JAR-FCL 3.225, *Colour perception*

Colour vision normally does not change during life-time. Abnormal colour vision is mostly congenital. Only rarely clinical conditions like retinitis, intoxication, certain medication or recreational drugs may result in secondary colour abnormality. However, this results in blue-yellow deficiencies, whereas the colour vision tests required for aviation aeromedical assessment by JAR-FCL 3 test for the red-green deficiencies typical for congenital colour vision abnormalities. Therefore, it is prudent to use these tests for initial applicants only and no more at revalidation / renewal on a recurrent basis.

- JAR-FCL 3.230, *Otorhinolaryngological requirements*

1. Introduction of the specialist comprehensive ENT examinations with JAR-FCL 3 has created problems for pilots (to have the examinations performed in time) and created additional cost. These examinations reveal hardly any previously unknown problem within the ENT region. As these examinations have been performed by AMEs before, it was agreed that comprehensive ENT examinations should be required only at initial examinations and subsequently on clinical indication and not routinely any more and could be carried out by AMEs as well. Abnormal and doubtful cases within the ORL region have to be referred to a specialist anyway (Appendix 15).

2. A sentence was added, requiring all abnormal and doubtful cases to be referred to an ORL specialist.

3. So far the contents of a comprehensive ORL examination are described in the JAA Manual of Civil Aviation Medicine only. It was agreed to clarify the extent of such an examination in the requirements of Section 1 as well.

- JAR-FCL 3.235, *Hearing requirements*

1. Deterioration in hearing practically never poses a problem, especially not in terms of safety. Therefore, it was agreed to lower the requirement for the initial Class 1 hearing standards and adopt the ICAO standards. The difference between initial and revalidation / renewal standards was removed and the revalidation / renewal standards are proposed to be used for initial applicants as well. A lot of countries and regulation systems use these standards (e.g. FAA) or have used it before implementation of JAR-FCL 3 (e.g. Germany) and the rate of accidents and incidents shows no significant difference to the one in JAA member states after implementation of JAR-FCL 3 standards.

2. Furthermore, the requirement for annual pure tone audiometry for those with a hearing loss of more than 30 resp. 45 dB in pure tone audiometry was removed, because it was regarded as superfluous. Young pilots with hearing loss are 'socially deaf' pilots (hearing loss caused by

recreational noise exposure by walkmen, MP3 players, discotheques etc.). Experience shows that this group does not have any operational problems communicating on the flight deck with the other crew members or ATC. Those with hearing loss due to occupational exposure over a long period of time are older and therefore subject to biannual audiometry anyway. Significant deterioration within a shorter period seems unlikely.

Subpart C - Class 2 Medical Requirements

- JAR-FCL 3.250, Cardiovascular system - Examination

1. The same proposal as for Class 1 applies (see page 15 of this Explanatory Note, JAR-FCL 3.130, change 1).

2. The paragraph outlines the requirements for the necessity of lipid and cholesterol examination for Class 2 applicants in case of accumulation of cardiovascular risk factors at initial examination and at the first examination after age 40. It was agreed that the examinations should be required on clinical indication as well (as it is self-evident anyway).

- JAR-FCL 3.255, Cardiovascular system - Blood pressure

The same proposal as for Class 1 applies (see page 15 of this Explanatory Note, JAR-FCL 3.135).

- JAR-FCL 3.275, Respiratory system - General

1. As peak flow testing is only a very rough test method for the efficiency of an anti-obstructive therapy (used for self-observation of patients) and not a proper test for the pulmonary function anyway, it was agreed that this test should not be required any more.

2. In line with other requirements of JAR-FCL 3 pulmonary function tests for Class 2 are required only on clinical indication. Although this might appear prudent even if not explicitly mentioned, the structure of the JARs require an explicit statement, particularly after there is no peak flow testing on a recurrent basis any more (see paragraph 1 above), bringing the paragraph in line with the equivalent one for Class 1.

- JAR-FCL 3.280, Respiratory system - Disorders

The same proposal as for Class 1 applies (see page 16 of this Explanatory Note, JAR-FCL 3.160).

- JAR-FCL 3.290, Digestive system - Disorders

Some editorial changes were introduced for a more concise and clear wording. Furthermore, the text was brought in line with JAR-FCL 3.170, the corresponding text in Subpart B, where appropriate.

- JAR-FCL 3.300, Haematology

1. Apart from some editorial changes a more concise and clear wording concerning the required procedures for applicants with abnormal haemoglobin is proposed, similar to JAR-FCL 3.180 - the corresponding paragraph in Subpart B - where appropriate.

2. The term “leukaemia” describes a variety of heterogeneous conditions with different natural history, clinical behaviour and prognosis. Intensive treatment modalities like bone marrow transplantation are used now and result in cure rates up to 50 %. Therefore it was agreed that it would be appropriate to assess applicants on an individual basis taking into account diagnosis, subtype and stage of disease, treatment and prognosis.

- JAR-FCL 3.315, Gynaecology and obstetrics

1. The same proposal as for Class 1 applies (see page 17 of this Explanatory Note, JAR-FCL 3.195, change 1).

2. The same proposal as for Class 1 applies (see page 17 of this Explanatory Note, JAR-FCL 3.195, change 2).

- JAR-FCL 3.335, Ophthalmological requirements

1. The same proposal as for Class 1 applies (see page 17 of this Explanatory note, JAR-FCL 3.215 (c), change 1).

2. Several changes are proposed as a result of reviewing the existing requirements in the light of experience of a couple of years after implementation and ICAO standards (see page 8 of this Explanatory note, Section 1, Changes throughout the requirements, Change 3).

- JAR-FCL 3.340, Visual requirements

1. ICAO Annex 1, Chapter 6, 6.4.3.2.2 requires applicants with large refractive errors to use contact lenses or high-index spectacle lenses. This has to be reflected in the corresponding paragraph of JAR-FCL 3 - JAR-FCL 3.340 (b) - as well, because ICAO contracting states are required to follow the ICAO standards.

2. ICAO Annex 1, Chapter 6, 6.3.3.2.1 requires applicants using contact lenses to meet the visual requirements have to use mono-focal, non-tinted and well-tolerated lenses. This has to be reflected in the corresponding paragraph of JAR-FCL 3 - JAR-FCL 3.340 (f) - as well.

3. Different from what was intended (more flexibility and clarification), amendment 3 resulted in stricter requirements for applicants with amblyopia. It was agreed to allow for a fit assessment of those with an acceptable refractive error and an otherwise healthy "good eye". Furthermore, a typoid was corrected (instead of "0,32" equalling "6/18" the current text is a number "0/32").

4. The same proposal as for Class 1 applies (see page 18 of this Explanatory note, JAR-FCL 3.220, change 3).

5. Several changes are proposed as a result of reviewing the existing requirements in the light of experience of a couple of years after implementation and ICAO standards (see page 8 of this Explanatory note, Section 1, Changes throughout the requirements, Change 3).

- JAR-FCL 3.345, *Colour perception*

1. The same proposal as for Class 1 applies (see page 18 of this Explanatory note, JAR-FCL 3.225).

2. Another proposed change brings the paragraph in line with JAR-FCL 3.225 - the corresponding paragraph in Subpart B, thus removing a moment of different interpretation of colour vision requirements.

3. Presently colour unsafe Class 2 applicants who want to be assessed as fit to fly by day only have to undergo a review by the AMS. A considerable number of applicants do not want to fly by night anyway from the beginning of their flying career and intend to perform recreational flying by day only. For these applicants it would seem appropriate if the AME or AMC could assess them as fit to fly by day only and to impose the appropriate limitation "VCL - valid by day only".

- JAR-FCL 3.350, *Otorhinolaryngological requirements*

1. A comprehensive otorhinolaryngological examination at initial Class 2 examination was regarded as superfluous as abnormal and doubtful cases within the ORL region have to be referred to a specialist anyway (Appendix 15).

2. After removal of the comprehensive ORL examination for initial Class 2 applicants it was regarded as prudent to require a routine ORL examination instead.

- JAR-FCL 3.355, Hearing requirements

1. According to ICAO Annex 1, Chapter 6, 6.3.4 applicants with an Instrument Rating (IR) are required to fulfill Class 1 hearing requirements. The hearing requirements for initial Class 1 applicants in JAR-FCL 3 are much stricter than those of ICAO, which are equal to Class 1 revalidation standards of JAR-FCL 3. It was agreed that the latter should be used instead, thus being compliant with the ICAO SARPS. The stricter standards did not result in any difference in accident or incident rates in comparison with other states' regulations (e.g. FAA). On the other hand a lot of pilots had been denied to acquire an Instrument Rating, even though they had had a FAA IR before. It was taken into account that those applying for an IR would be experienced pilots anyway.

2. Furthermore, it was agreed that those IR applicants with a hearing loss of more than 30 resp. 45 dB in pure tone audiometry should not be required to undergo an annual audiogram any more (see page of this Explanatory Note, JAR-FCL 3.235, change 2).

Appendices to Subparts B and C

**- Appendix 1 to Subparts B & C, Cardiovascular system.
- Paragraphs 8, 9**

The proposal consists in

1. an amendment of paragraph 2 (a) and (b)
1. an amendment of paragraphs 8 and 9 (b) and (c)
2. an amendment of paragraph 9 (b)(2)

1. The paragraph outlines the requirements for the necessity of lipid and cholesterol examination for Class 2 applicants in case of accumulation of cardiovascular risk factors. The assessment of those with abnormal lipid findings or with an accumulation of risk factors is currently assigned to the AMS. However, as AME and AMC deal with the applicant directly it was agreed that the required evaluations should be performed by AMC or AME in conjunction with the AMS.

2. It was found that fixed and inflexible mandatory periods of follow-up would be inappropriate. Reassessment was regarded as necessary only in cases of severe changes or in cases determined by their clinical presentation. Therefore, it is proposed to give the AMS discretion in determining the appropriate periodicity.

3. It was felt that the current requirements for applicants with an aortic stenosis would be too strict and needed to be less restrictive. Furthermore, new limits were proposed to allow for a more specific approach relating to the state of the individual pilot and the new limits

related to the mean pressure gradient (in contrast to the Doppler flow rate) - in accordance with the international literature.

- Appendix 2 to Subparts B & C, Respiratory system.
- Paragraph 1,

Pulmonary function testing is required for initial Class 1 applicants, peak flow testing was required for initial Class 2 applicants and in certain intervals at revalidation / renewal for Class 1 and Class 2. According to the current requirements a FEV1/FVC ratio less than 70 % requires further evaluation and a peak flow of less than 80 % of the norm. As peak flow testing is only a very rough test method for the efficiency of an anti-obstructive therapy (used for self-observation of patients), not a proper test for assessing the pulmonary function and does not reveal anything that is not revealed already by clinical examination, it is proposed to delete the requirement for peak flow testing.

- Appendix 3 to Subparts B & C, Digestive system.
- Paragraphs 1, 2, 3

1. In the current text radiologic or endoscopic examinations are required as internal examinations - inter alia - in case of recurrent dyspepsia. As radiologic examination is not state of the art any more and medical science may change, present examination techniques be abandoned and new examination techniques be introduced, it was agreed to require investigation and not a specific technique. Furthermore, some editorial changes were introduced for a more concise and clear wording and an identical nomenclature in the appendix and the corresponding paragraphs of Subpart B and C.

2. The finding of multiple gallstones in a pilot is not necessarily a significant flight safety hazard. As the same medical standard for a commercial pilot as for a private pilot is not appropriate it is suggested that some alleviation of the requirement is reasonable for private pilots, allowing for a fit assessment at initial examinations as well.

3. It was agreed that the requirements for applicants with inflammatory bowel disease could be summarised in a more concise and clear way, safeguarding that the applicants are in established remission and do not use systemic steroids, which are the issues of relevance for flight safety.

- Appendix 5 to Subparts B & C, Haematology.
- Paragraph 2 and 3

The proposal consists in

1. an amendment of paragraph 3
2. an amendment of paragraph 3
3. an amendment of paragraphs 2 and 3

1. With regard to JAR-11, requiring a clear, consistent and un-contentious wording within the requirements, it was agreed to improve the clarity of the wording of the paragraph focusing on leukaemia and elucidate what is intended.

2. The term “leukaemia” describes a variety of heterogeneous conditions with different natural history, clinical behaviour and prognosis. Intensive treatment modalities like bone marrow transplantation are used now and result in cure rates up to 50 %. Therefore it was agreed that it would be appropriate to assess applicants on an individual basis taking into account diagnosis, subtype and stage of disease, treatment and prognosis.

3. The requirements for applicants who have received anthracycline chemotherapy are described in Appendix 5 and Appendix 19. To avoid redundancy it is proposed to remove this particular requirement from Appendix 5.

**- Appendix 8 to Subparts B & C, Gynaecology and obstetrics.
- Paragraphs 1, 2, 3**

1. Before implementation of JAR-FCL 3 the AME, who usually knows the pilot herself well, was the major point of contact in case of pregnancies. Therefore, it was agreed to delegate discretion for fit assessment of pregnant aircrew during the first 26 weeks of gestation to AMEs and AMCs (see also page 10 of this Explanatory note, JAR-FCL 3.040).

2. In case of pregnancy in Class 1 applicants it was agreed that AMS as well as AMC and AME could impose and - after termination of the pregnancy - remove the required ‘OML’ limitation (see page 17 of this Explanatory Note, JAR-FCL 3.195, change 1) and assess the applicant as fit.

**- Appendix 12 to Subparts B & C, Ophthalmological requirements.
- Paragraph 1**

The proposal brings the text of this paragraph concerning Class 2 applicants, in line with paragraph 1, concerning Class 1 applicants. It is intended that applicants with abnormal and doubtful findings should be referred to an ophthalmologist, if the initial examination by a vision care specialist would reveal such findings.

**- Appendix 13 to Subparts B & C, Visual requirements.
- Paragraphs 4, 7**

The proposal consists in

1. an amendment of paragraph 2

2. an amendment of paragraph 4
3. an amendment of paragraph 7
4. an amendment of paragraphs 2, 3, 4, 5, 6, 7

1. Relating to a comment concerning NPA-FCL 3-21 it was agreed that a 5 yearly specialist ophthalmological review for those Class 2 applicants with a refractive error within the range -5/-8 dioptries would not be required.

2. ICAO Annex 1, Chapter 6 requires good vision in both eyes, but accepts that contracting states may wish to certify monocular pilots under the flexibility standard 1.2.4.8 and it provides guidance on the assessment of monocular private pilot applicants in its Manual of Civil Aviation Medicine. Under the current JAR-FCL 3 pilots who already hold a class 2 certificate and who subsequently become monocular may be assessed as fit at revalidation / renewal. The proposal allows a fit assessment of those pilots with a sufficient "good eye", who got monocular after age of five years (therefore got a spatial imagination due to brain development until this critical age) and pass a medical flight test.

3. The same proposal as for Appendix 1 applies (see page 23 of this Explanatory note, Appendix 1, change 1).

4. Several changes are proposed as a result of reviewing the existing requirements in the light of experience of a couple of years after implementation and ICAO standards (see page 8 of this Explanatory note, Section 1, Changes throughout the requirements, Change 3).

- Appendix 15 to Subparts B & C, Otorhinolaryngological requirements.

- Paragraphs 1, 2

1. Comprehensive otorhinolaryngological examinations were required at initial examination and subsequently every five years (JAR-FCL 3.230 (a)), under guidance and supervision of a specialist in aviation otorhinolaryngology. The contents of that examinations are outlined in the JAA Manual of Civil Aviation Medicine. Except Impedance Tympanometry, which is only required at initial examination, none of the examinations - except those required on clinical indication - require any special equipment or knowledge of an ORL specialist. Therefore, it was agreed that the comprehensive ORL examination should be carried out by the AME. Furthermore, it was agreed that comprehensive examinations in routine intervals should not be required any more.

2. A reference to the JAA Manual of Civil Aviation Medicine was added, giving guidance - inter alia - concerning comprehensive ORL examinations.

- Appendix 16 to Subparts B & C, Hearing requirements.

- Paragraph 2

Experience shows that 'socially deaf' pilots (hearing loss caused by recreational noise exposure by walkmen, MP3 players, discotheques etc.) do not have any operational problems communicating on the flight deck with the other crew members or ATC. Currently applicants passing the practical hearing test in the cockpit may be assessed as fit by the AMS. It was agreed that the fit assessment might be done by the AME as well, as these tests are performed mostly by AMEs anyway.

- Appendix 19 to Subparts B & C, *Oncology Requirements.*

- Paragraph 1

According to a study conducted by the CAA UK from 1998 - 2000 with all professional pilots who had received anthracycline chemotherapy as part of a treatment for malignant disease, this group had a potentially increased risk of incapacitation from long term side effects of that treatment. This included left ventricular dysfunction and arrhythmias. Whereas a cardiological review appeared to be appropriate for Class 1 pilots this does not apply to Class 2 pilots. The proposed change requires special attention to those mentioned above and leaves the follow-up to the discretion of the AMS.

Section 2

Subpart A – AMC/IEM General Requirements

- **IEM FCL 3.045**, *Procedures for medical certification exemptions / variations.*

The diagram was outdated, moreover it had to be amended according to the proposals for change of JAR-FCL 3.100.

- **IEM FCL 3.095 (a) & (b)**, *Summary of minimum requirements.*

Several changes in the ophthalmological and other requirements were proposed as a result of reviewing the existing requirements in the light of experience of a couple of years after implementation and the changing ICAO standards (see - inter alia - page 8 of this Explanatory note, Section 1, Changes throughout the requirements, Change 3). The proposed changes have to be reflected in the table.

- **IEM FCL 3.095 (c)**, *Medical Forms, guidelines for examination and instructions to complete the forms.*

IEM 3.095 (c) contains application forms, examination report forms, guidelines for examination and instructions how to complete the forms. As the provisions of JAR-FCL 3 as well as the instructions to complete application forms and reports should be unequivocal, user-friendly and self-explaining, some editorial changes are proposed to delete some common misunderstandings and errors. Furthermore, some changes of nomenclature and requirements had to be reflected in these publications as well. As different units for Haemoglobin are used throughout the different member states the unit used has to be stated. The forms "Ophthalmology" and "Otorhinolaryngology Examination Report" and the "Instructions for Completion" of these forms had to be changed according to the proposed changes of the requirements as well. For ease of reference and in order not to confuse the reader the changes within tables and where appropriate otherwise are not marked by strikethroughs and bold font but by **red font and / or by underlining** where appropriate.

- **IEM FCL 3.100 (a) & (b)**, *Medical certificate Class 1/2 and Medical certificate Class 2.*

1. The table "Minimum Periodic Requirements" within the medical certificates had to be amended according to the changes agreed for the original table and for the validity of medical certificates (see page 28 of this Explanatory note, Section 2, IEM 3.095 (a) & (b)). Some editorial changes applied as well.

2. Further changes of the medical certificates resulted from the proposed changes of the validity periods of medical certificates as well as from other proposed changes (deletion of peak flow).

- **IEM FCL 3.100 (c)**, *Limitations, conditions and variations*.

1. Table and title have been amended according to the proposals for change of JAR-FCL 3.100 (see page 12 of this Explanatory note, JAR-FCL 3.100, changes 1 to 6).

2. For a clear and un-contentious wording throughout JAR-FCL 3 the term 'Valid only as or with qualified co-pilot' was agreed (see page 7 of this Explanatory note, Section 1, Changes throughout JAR-FCL3, Change 1).

3. A new limitation was introduced (table and explanations). The limitation "OML 'Valid only as or with qualified co-pilot'" applies to pilots who do not meet the medical requirements for single crew operations, but are fit for multi-pilot operations. As this is applicable for Flight Engineers (FE) as well the above-mentioned terms had to be adapted for FE and another limitation with appropriate acronym to be created.

4. A new limitation resp. annotation was introduced (table and explanations) to indicate a previous review procedure (e.g. if an operational limitation like "OML" has not been imposed). Furthermore, it was proposed to allow AMEs and AMCs to impose and remove an "OML"-limitation in case of a pregnancy, reflected by an asterisk and a remark. Some adjustments to the explanations of "SIC"- and "AMS"-limitation clarify the intended procedures and allow for a more specific approach to the individual pilot.

5. A new limitation was introduced (table and explanations). Since implementation of Amendment 4 the validity of the medical certificate for Flight Engineers (FE) over 40 is not reduced from 12 to 6 months as for pilots. As only one medical certificate is held, it had to be clarified that for those FE over age 40 years, who hold a FE and a commercial licence, the validity for pilot's duties is reduced to 6 months and only for FE duties remains 12 months.

6. Subsequent to the change proposed to JAR-FCL 3.345 (d) (see page 22 of this Explanatory note, JAR-FCL 3.345 (d), Change 3) the proposed change has to be reflected in the table as well.

IEM FCL 3, A, B, & C – JAA Manual of Civil Aviation Medicine

It was found that the Manual has proven to be a very valuable tool for all those involved in aviation medicine. Some parts of the Manual - e.g. the Chapter Medication and Flying - have to be up-dated on a quicker cycle as aviation medicine is progressing at a fast pace. The "JAA Manual of Civil Aviation Medicine" is proposed to be deleted from JAR-FCL 3. As the text

is guidance material, the Manual will therefore be published as a stand-alone document as hard copy and in electronic format as well. It is not re-printed as a strike-through version in this NPA because of the volume.

NPA – FCL 28 (JAR-FCL 3) - Medical

REGULATORY IMPACT ASSESSMENT

NPA – FCL 28 (JAR-FCL 3) - Medical consists of 79 working papers in total. Compliant with JAR-11 each working paper was accompanied by a Regulatory Impact Assessment where appropriate. This text only mentions the most important changes proposed in relation to the kind of potential impact.

The changes proposed by NPA-FCL 28 (JAR-FCL 3) - Medical consist predominantly of editorial changes. These changes and therefore the majority of changes will have no adverse impacts at all.

Impacts

I. Sectors Affected

The proposed changes to JAR-FCL 3 will affect almost all sectors of aviation medicine and those dealing with it, especially AMS, AMC, AME, pilots (commercial and private) and their organisations in terms of streamlining and clarifying and improving procedures

II. All impacts Identified

The safety impact and all the other possible impacts that may result from implementing the NPA, addressing, but not limited to, the following considerations:

A. Safety

The changes proposed remove inconsistencies and clarify the meaning of the requirements, thus enhancing safety. Other changes are adapting the requirements to the development of medical science and aviation, and pay respect to experience gained after implementation of JAR-FCL 3 and thus with a whole set of new aviation medical requirements. Some years after implementation of JAR-FCL 3 in various JAA member states a need for some changes and improvements to provisions, procedures, associated procedures and relevant forms was raised to keep pace with increased demands on safety. The provisions and associated publications have been tightened and clarified in their wording, the idea of self-contained provisions with clear referrals to a set of chapters has been strengthened. Other provisions have been adapted to the development of the relevant medical specialties. The procedures and associated procedures have been

streamlined and adapted to the needs of daily work and practical application of the requirements. Some inconsistency and anomaly has been removed and some facilitations been enacted (possibility for the AMS to delegate issue of initial Class 1 medical certificates to the AMC conducting the examination; routine decisions (decrease in medical fitness, routine review procedures of applicants beyond the limits as stated in Subparts B and C but within the limits as stated in the Appendices) may be delegated to AMC or AME on discretion of the AMS.

A protocol to assess conditions, technologies, therapies and medications currently not acceptable within the cockpit - whether they would be safe for the future - was proposed. This procedure will be in line with Annex 1 to the ICAO convention, 1.2.4.8, the so-called "flexibility paragraph". The procedure will allow for gaining scientific evidence whether it might be safe to accept such conditions, technologies, therapies and medications. This may prevent a significant number of experienced individuals to continue their career, to reveal upcoming deterioration of their health to their AME. Thus investment in training will not be lost and therefore cost for industry and applicants saved. Furthermore, safety will be promoted as certain conditions will be controlled by strict protocols, whereas they might be hidden and not be controlled at all under the current provisions, because those affected might fear to lose medical fitness and thus their occupation, if they would disclose their disposition.

All changes, especially those reducing cost, have been assessed concerning possible impacts on safety. It was found that safety will be enhanced by the proposed changes and not be affected in a negative way.

B. Economic

Removing inconsistencies and streamlining procedures will decrease the workload of AMS, AMC and AME significantly, will reduce time for processing a review and thus decrease cost and time for all those involved, especially pilots and industry.

Reduction in the frequency of aeromedical examinations and the validity period of medical certificates will result in less cost and time burden on AMS, pilots and industry.

Changes in the Ophthalmology specialty have been mandated by the experience in various member states and of experts in the field of ophthalmology. Less applicants, who had to go through a review procedure by the AMS before a fit assessment, will have to do so. Furthermore, the frequency of ophthalmological examinations by specialists has been reduced significantly. This will reduce cost for applicants and industry significantly. The changes in the ophthalmological requirements in total will result in less cost and time burden on AMS, pilots and industry.

The latter applies to otorhinolaryngological examinations as well. Applicants will have to be referred to a specialist in aviation otorhinolaryngology only in case of abnormal and doubtful findings. This will reduce cost for applicants and industry significantly.

Both in ophthalmology and otorhinolaryngology, in routine examinations work has been relocated to the AME, the one person knowing the applicant and having a confidential relationship with each other. Deleting the routine referral to specialists will significantly accelerate procedures and reduce cost.

The Peak Flow examination as a part of the examination of the respiratory system has been deleted. Being of no clinical value it was found to be renounceable. Pulmonary function tests will be required for Class 1 applicants at initial examination and on clinical indication for all applicants. These changes will reduce cost for industry and applicants.

Mandatory chest Xray and EEG for initial Class 1 applicants have been removed, these examinations have to be conducted on clinical indication. It was agreed that these examinations would not be justified in terms of safety. Furthermore, the former one would not be justified with respect to the relevant radiation protection directive. In addition a considerable amount of cost for the initial Class 1 examination will be saved.

C. Harmonisation

Clarifying the requirements and removing inconsistencies will remove contentious interpretation of the requirements in the different member states. This applies especially to the proposed changes within the ophthalmological requirements and clarifying the nomenclature used throughout JAR-FCL 3.

D. Environmental

Not applicable

E. Social

By removing some of the different standards for initial applicants versus revalidation / renewal applicants more applicants will have the chance to enter a career in civil aviation. The proposed changes concerning decrease in medical fitness will result in the AME or AMC having the opportunity to counsel the pilot and to facilitate and accelerate him to resume flying. This will result in improved trust between aeromedical expert and pilot.

A new protocol allowing strict supervision of applicants with certain medical conditions will allow for gaining experience with those conditions and gaining evidence for potential effects on safety. By allowing for a stringent protocol to be applied to a highly selected group of applicants under meticulous supervision such conditions that might have been passing an examination unnoticed will be more prone to be disclosed by affected applicants, thus enhancing safety.

F. Other aviation requirements outside the JAA scope, such as security, ATM, airports, etc.

No change will create a difference to the relevant provisions of Annex 1 to the ICAO Convention. Furthermore, changes in Annex 1 of the ICAO Convention (Amendment 166) had to be reflected in the ophthalmological requirements of JAR-FCL 3 as well. The standards will be less strict than before.

The period of validity of medical certificates - as laid down in Annex 1 to the ICAO convention - has been extended in Amendment 166 end of 2005. This change of ICAO SARPS has been reflected by the relevant changes of JAR-FCL 3.

The age limit for AMEs has been lifted, thus complying with anti-discrimination legislation.

Most of the changes proposed will reduce the significantly stricter requirements of JAR-FCL 3 in comparison with those of ICAO Annex 1 and e.g. FAA. Comments proposing to do so have been received from the FAA previously.