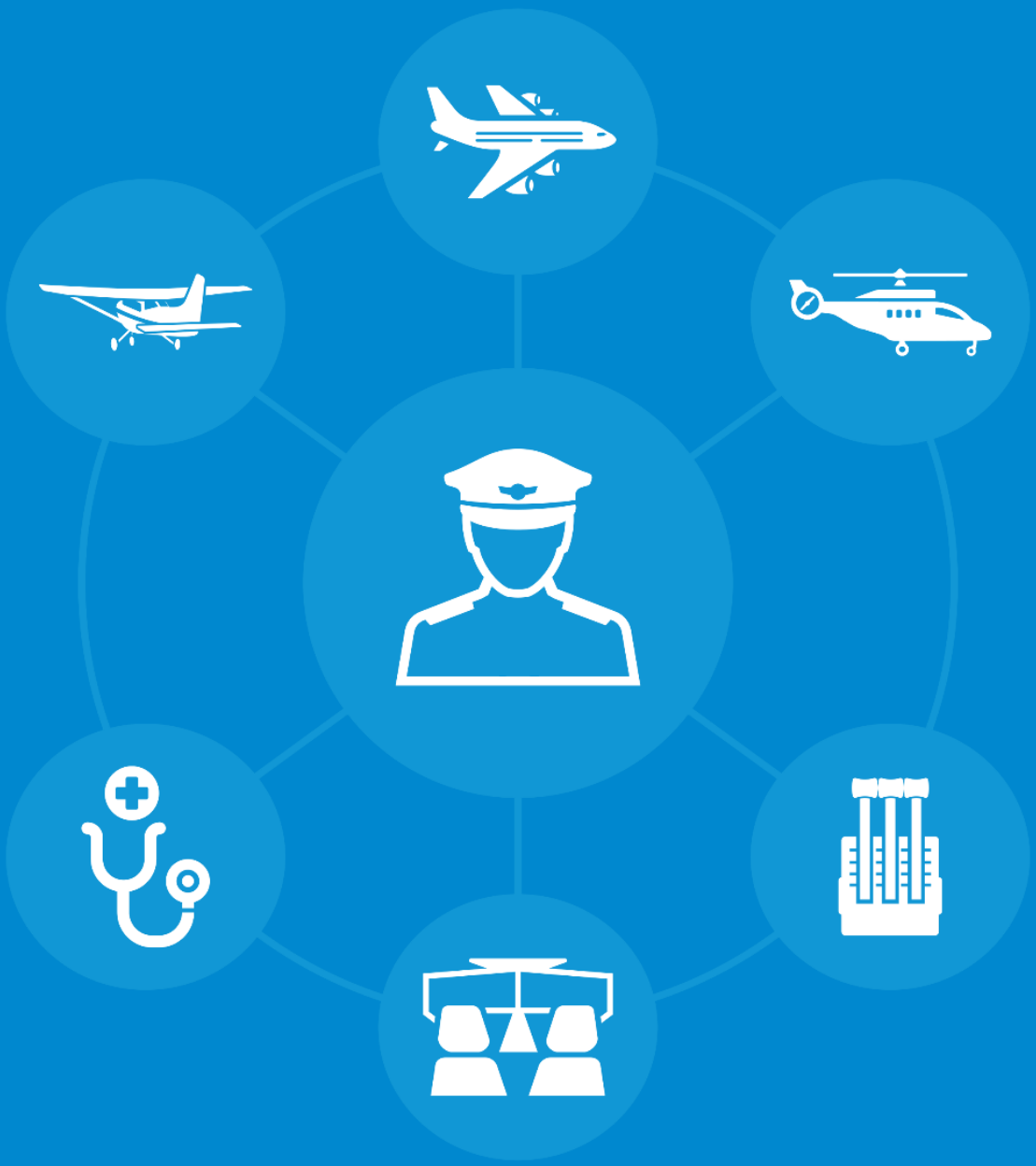
EASA
European Union Aviation Safety Agency



Medical rule book (IR + AMC/GM)

eRules

Easy Access Rules for Medical Requirements

EASA eRules: aviation rules for the 21st century

Rules and regulations are the core of the European Union civil aviation system. The aim of the **EASA eRules** project is to make them **accessible** in an efficient and reliable way to stakeholders.

EASA eRules will be a comprehensive, single system for the drafting, sharing and storing of rules. It will be the single source for all aviation safety rules applicable to European airspace users. It will offer easy (online) access to all rules and regulations as well as new and innovative applications such as rulemaking process automation, stakeholder consultation, cross-referencing, and comparison with ICAO and third countries' standards.

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The **EASA eRules** system is developed and implemented in close cooperation with Member States and aviation industry to ensure that all its capabilities are relevant and effective.

Published March 2019[1]

[1] The published date represents the date when the consolidated version of the document was generated.

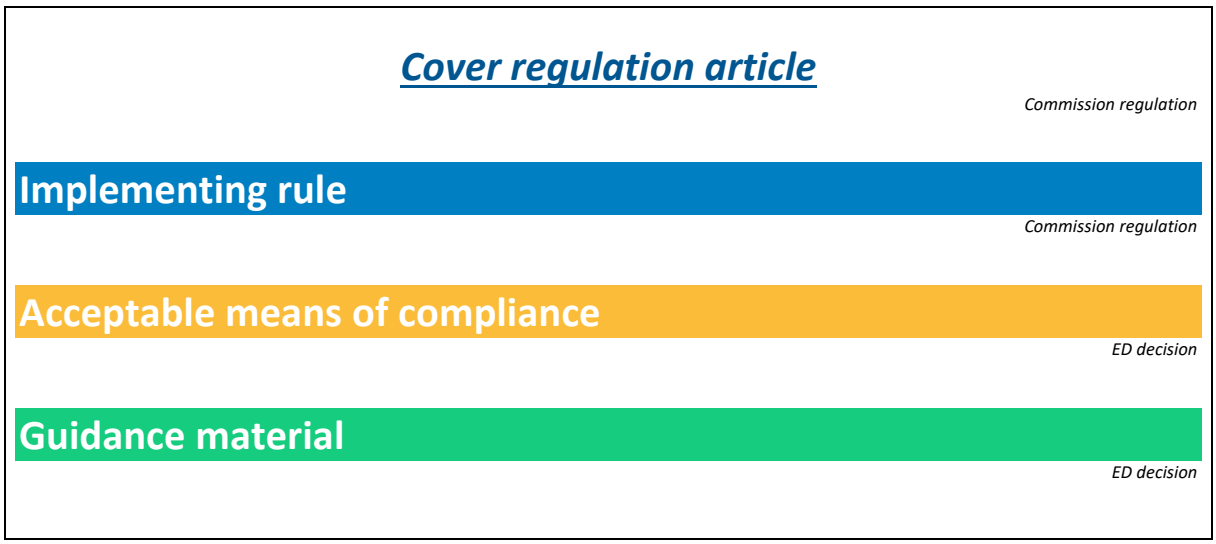
DISCLAIMER

This version is issued by the European Union Aviation Safety Agency (EASA) in order to provide its stakeholders with an updated and easy-to-read publication. It has been prepared by putting together the officially published regulations with the related acceptable means of compliance and guidance material (including the amendments) adopted so far. However, this is not an official publication and EASA accepts no liability for damage of any kind resulting from the risks inherent in the use of this document.

NOTE FROM THE EDITOR

The content of this document is arranged as follows: the cover regulation (recitals and articles) with the implementing rule (IR) points appear first, followed by the related acceptable means of compliance (AMC) and guidance material (GM) paragraph(s).

All elements (i.e. cover regulation, IRs, AMC, and GM) are colour-coded and can be identified according to the illustration below. The Commission regulation or EASA Executive Director (ED) decision through which the point or paragraph was introduced or last amended is indicated below the point or paragraph title(s) *in italics*.



This document will be updated regularly to incorporate further amendments.

The format of this document has been adjusted to make it user-friendly and for reference purposes. Any comments should be sent to erules@easa.europa.eu.

INCORPORATED AMENDMENTS

IMPLEMENTING RULES (IRS) (COMMISSION REGULATIONS)

Incorporated Commission Regulation	Affected Part	Regulation amendment	Applicability date[1]
Regulation (EU) No 1178/2011	Annex IV (Part-MED)	Initial issue	8/4/2012*
Regulation (EU) No 290/2012	Annex VI (Part-ARA) Annex VII (Part-ORA)	Amendment 1	8/4/2012*
Regulation (EU) No 70/2014	Annex VII (Part-ORA)	Amendment 2	17/2/2014
Regulation (EU) No 245/2014	Annex VI (Part-ARA)	Amendment 3	3/4/2014
Regulation (EU) 2015/445	Annex VI (Part-ARA) Annex VII (Part-ORA)	Amendment 4	8/4/2015*
Regulation (EU) 2016/539	Annex VII (Part-ORA)	Amendment 5	8/4/2016*
Regulation (EU) 2018/1065	Annex VI (Part-ARA)	Amendment 6	19/8/2018
Regulation (EU) 2018/1119	Annex VI (Part-ARA) Annex VII (Part-ORA)	Amendment 7	2/9/2018
Regulation (EU) 2018/1974	N/A	Amendment 8	20/12/2019*
Regulation (EU) 2019/27	Annex IV (Part-MED) Annex VI (Part-ARA)	Amendment 9	30/1/2019

** Refer to Article 12 of the cover regulation*

[1] *This is the earliest date of application (i.e. the date from which an act or a provision in an act produces its full legal effects) as defined in the relevant cover regulation article. Some provisions of the regulations though may be applicable at a later date (deferred applicability). Besides, there may be some opt-outs (derogations from certain provisions) notified by the Member States.*

AMC/GM TO IRs (ED DECISIONS)

Incorporated ED Decision	AMC/GM Issue No, Amendment No	Applicability date
ED Decision 2011/015/R	Initial issue to Annex IV (Part-MED)	22/12/2011
ED Decision 2012/006/R	Initial issue to Annex VI (Part-ARA)	20/4/2012
ED Decision 2012/007/R	Initial issue to Annex VII (Part-ORA)	20/4/2012
ED Decision 2013/006/R	Amendment 1 to Annex VI (Part-ARA)	23/4/2013
ED Decision 2013/008/R	Amendment 1 to Annex VII (Part-ORA)	23/4/2013
ED Decision 2013/016/R	Amendment 1 to Annex IV (Part-MED)	10/8/2013
ED Decision 2014/020/R	Amendment 2 to Annex VI (Part-ARA)	3/4/2014
ED Decision 2014/021/R	Amendment 2 to Annex VII (Part-ORA)	3/4/2014
ED Decision 2015/011/R	Amendment 3 to Annex VII (Part-ORA)	16/4/2015
ED Decision 2016/008/R	Amendment 3 to Annex VI (Part-ARA)	3/5/2016
ED Decision 2017/022/R	Amendment 4 to Annex VI (Part-ARA) Amendment 4 to Annex VII (Part-ORA)	12/12/2017
ED Decision 2018/001/R	Amendment 5 to Annex VII (Part-ORA)	31/1/2022
ED Decision 2018/009/R	Amendment 5 to Annex VI (Part-ARA)	15/9/2018
ED Decision 2018/011/R	Amendment 6 to Annex VI (Part-ARA)	7/11/2018[1]
ED Decision 2019/002/R	Amendment 7 to Annex VI (Part-ARA) Amendment 2 to Annex IV (Part-MED)	30/1/2019
ED Decision 2019/005/R	Amendment 6 to Annex VI (Part-ORA)	20/12/2019

Note: To access the official versions, please click on the hyperlinks provided above.

[1] Derogation of the applicability date in some amended points.

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COVER REGULATION

Commission Regulation (EU) No 1178/2011 of 3 November 2011

laying down technical requirements and administrative procedures related to civil aviation aircrew pursuant to Regulation (EC) No 216/2008 of the European Parliament and of the Council

Regulation (EU) No 1178/2011

THE EUROPEAN COMMISSION,

Having regard to the Treaty on the Functioning of the European Union,

Having regard to Regulation (EC) No 216/2008 of the European Parliament and of the Council of 20 February 2008 on common rules in the field of civil aviation and establishing a European Aviation Safety Agency, and repealing Council Directive 91/670/EEC, Regulation (EC) No 1592/2002 and Directive 2004/36/EC[1], and in particular Articles 7(6), 8(5) and 10(5) thereof,

Whereas:

(1) Regulation (EC) No 216/2008 aims at establishing and maintaining a high uniform level of civil aviation safety in Europe. That Regulation provides for the means of achieving that objective and other objectives in the field of civil aviation safety.

(2) Pilots involved in the operation of certain aircraft, as well as flight simulation training devices, persons and organisations involved in training, testing or checking of those pilots, have to comply with the relevant essential requirements set out in Annex III to Regulation (EC) No 216/2008. According to that Regulation pilots as well as persons and organisations involved in their training should be certified once they have been found to comply with essential requirements.

(3) Similarly, pilots should be issued with a medical certificate and aero-medical examiners, responsible for assessing the medical fitness of pilots, should be certified once they have been found to comply with the relevant essential requirements. However, Regulation (EC) No 216/2008 envisages the possibility of general medical practitioners to act as aero-medical examiners under certain conditions and if permitted under national law.

(4) Cabin crew involved in the operation of certain aircraft have to comply with the relevant essential requirements set out in Annex IV to Regulation (EC) No 216/2008. According to that Regulation, cabin crew should be periodically assessed for medical fitness to safely exercise their assigned safety duties. Compliance must be shown by an appropriate assessment based on aero-medical best practice.

(5) Regulation (EC) No 216/2008 requires the Commission to adopt the necessary implementing rules for establishing the conditions for certifying pilots as well as persons involved in their training, testing or checking, for the attestation of cabin crew members and for the assessment of their medical fitness.

(6) The requirements and procedures for the conversion of national pilot licences and national flight engineer licences into pilot licences should be laid down, to ensure that they are allowed

[1] OJ L 79, 19.3.2008, p. 1.

to perform their activities under harmonised conditions; flight test qualifications should also be converted in accordance with this Regulation.

(7) It should be possible for Member States to accept licences issued by third countries where a level of safety equivalent to that specified by Regulation (EC) No 216/2008 can be guaranteed; Conditions for the acceptance of licences issued by third countries should be laid down.

(8) In order to ensure that training commenced before the application of this Regulation may be taken into account for the purposes of obtaining pilots' licences, the conditions for recognising training already completed should be laid down; the conditions for recognising military licences should also be laid down.

(9) It is necessary to provide sufficient time for the aeronautical industry and Member State administrations to adapt to the new regulatory framework, to allow Member States the time to issue specific types of pilot licences and medical certificates not covered by the 'JAR', and to recognise under certain conditions the validity of licences and certificates issued, as well as aero-medical assessment performed, before this Regulation applies.

(10) Council Directive 91/670/EEC of 16 December 1991 on mutual acceptance of personnel licences for the exercise of functions in civil aviation[1] is repealed in accordance with Article 69(2) of Regulation (EC) No 216/2008. The measures adopted by this Regulation are to be regarded as the corresponding measures.

(11) In order to ensure a smooth transition and a high uniform level of civil aviation safety in the Union, implementing measures should reflect the state of the art, including best practices, and scientific and technical progress in the field of pilot training and aircrew aero- medical fitness. Accordingly, technical requirements and administrative procedures agreed by the International Civil Aviation Organisation (ICAO) and the Joint Aviation Authorities until 30 June 2009 as well as existing legislation pertaining to a specific national environment, should be considered.

(12) The Agency prepared draft implementing rules and submitted them as an opinion to the Commission in accordance with Article 19(1) of Regulation (EC) No 216/2008.

(13) The measures provided for in this Regulation are in accordance with the opinion of the Committee established by Article 65 of Regulation (EC) No 216/2008,

HAS ADOPTED THIS REGULATION:

Article 1 Subject matter

Regulation (EU) No 290/2012

This Regulation lays down detailed rules for:

(1) different ratings for pilots' licences, the conditions for issuing, maintaining, amending, limiting, suspending or revoking licences, the privileges and responsibilities of the holders of licences, the conditions for the conversion of existing national pilots' licences and of national flight engineers' licences into pilots' licences, as well as the conditions for the acceptance of licences from third countries;

(2) the certification of persons responsible for providing flight training or flight simulation training and for assessing pilots' skills;

(3) different medical certificates for pilots, the conditions for issuing, maintaining, amending, limiting, suspending or revoking medical certificates, the privileges and responsibilities of the

[1] OJ L 373, 31.12.1991, p. 21.

holders of medical certificates as well as the conditions for the conversion of national medical certificates into commonly recognised medical certificates;

(4) the certification of aero-medical examiners, as well as the conditions under which general medical practitioners may act as aero-medical examiners;

(5) the periodical aero-medical assessment of cabin crew members, as well as the qualification of persons responsible for this assessment;

(6) the conditions for issuing, maintaining, amending, limiting, suspending or revoking cabin crew attestations, as well as the privileges and responsibilities of the holders of cabin crew attestations;

(7) the conditions for issuing, maintaining, amending, limiting, suspending or revoking certificates of pilot training organisations and of aero-medical centres involved in the qualification and aero-medical assessment of civil aviation aircrew;

(8) the requirements for the certification of flight simulation training devices and for organisations operating and using those devices;

(9) the requirements for the administration and management system to be fulfilled by the Member States, the Agency and the organisations in relation with the rules referred to in points 1 to 8.

Article 2 Definitions

Regulation (EU) 2019/27

For the purposes of this Regulation, the following definitions shall apply:

(1) 'Part-FCL licence' means a flight crew licence which complies with the requirements of Annex I;

(2) 'JAR' means joint aviation requirements adopted by the Joint Aviation Authorities as applicable on 30 June 2009;

(3) 'Light aircraft pilot licence (LAPL)' means the leisure pilot licence referred to in Article 7 of Regulation (EC) No 216/2008;

(4) 'JAR-compliant licence' means the pilot licence and attached ratings, certificates, authorisations and/or qualifications, issued or recognised, in accordance with the national legislation reflecting JAR and procedures, by a Member State having implemented the relevant JAR and having being recommended for mutual recognition within the Joint Aviation Authorities' system in relation to such JAR;

(5) 'Non-JAR-compliant licence' means the pilot licence issued or recognised by a Member State in accordance with national legislation and not having been recommended for mutual recognition in relation to the relevant JAR;

(6) 'Credit' means the recognition of prior experience or qualifications;

(7) 'Credit report' means a report on the basis of which prior experience or qualifications may be recognised;

(8) 'Conversion report' means a report on the basis of which a licence may be converted into a Part-FCL licence;

(9) 'JAR-compliant pilots' medical certificate and aero-medical examiners' certificate' means the certificate issued or recognised, in accordance with the national legislation reflecting JAR and procedures, by a Member State having implemented the relevant JAR and having been recommended for mutual recognition within the Joint Aviation Authorities' system in relation to such JAR;

(10) 'Non-JAR-compliant pilots' medical certificate and aero- medical examiners' certificate' means the certificate issued or recognised by a Member State in accordance with national legislation and not having been recommended for mutual recognition in relation to the relevant JAR;

(11) 'Cabin crew member' means an appropriately qualified crew member, other than a flight crew or technical crew member, who is assigned by an operator to perform duties related to the safety of passengers and flight during operations;

(12) 'Aircrew' means flight crew and cabin crew;

(13) 'JAR-compliant certificate, approval or organisation' means the certificate or approval issued or recognised or the organisation certified, approved, registered or recognised, in accordance with the national legislation reflecting JAR and procedures, by a Member State having implemented the relevant JAR and having been recommended for mutual recognition within the Joint Aviation Authorities' system in relation to such JAR;

(14) "acceptable means of compliance (AMC)" means non-binding standards adopted by the Agency to illustrate means to establish compliance with Regulation (EC) No 216/2008 and its implementing rules;

(15) "alternative means of compliance (AltMoC)" means those means that propose an alternative to an existing AMC or those that propose new means to establish compliance with Regulation (EC) No 216/2008 and its implementing rules for which no associated AMC have been adopted by the Agency;

(16) "approved training organisation (ATO)" means an organisation which is entitled to provide training to pilots on the basis of an approval issued in accordance with the first subparagraph of Article 10a(1);

(17) "basic instrument training device (BITD)" means a ground-based training device for the training of pilots representing the student pilot's station of a class of aeroplanes, which may use screen-based instrument panels and spring-loaded flight controls, and providing a training platform for at least the procedural aspects of instrument flight;

(18) "certification specifications (CS)" mean technical standards adopted by the Agency indicating means to be used by an organisation for the purpose of certification;

(19) "flight instructor (FI)" means an instructor with the privileges to provide training, in accordance with Subpart J of Annex I (Part-FCL), in an aircraft;

(20) "flight simulation training device (FSTD)" means a device for the training of pilots which is:

(a) in the case of aeroplanes, a full flight simulator (FFS), a flight training device (FTD), a flight and navigation procedures trainer (FNPT) or a basic instrument training device (BITD);

(b) in the case of helicopters, a full flight simulator (FFS), a flight training device (FTD) or a flight and navigation procedures trainer (FNPT);

(21) "FSTD qualification" means the level of technical ability of an FSTD as specified in the certification specifications relating to the FSTD in question;

(22) "principal place of business" of an organisation means the head office or registered office of the organisation within which the principal financial functions and operational control of the activities referred to in this Regulation are exercised;

(22a) "ARO.RAMP" means the Subpart RAMP of Annex II to the Regulation on Air Operations;

(22b) "Automatically validated" means the acceptance, without formalities, by an ICAO contracting State listed in the ICAO attachment of a flight crew licence issued by a State in accordance with Annex 1 to the Chicago Convention;

(22c) "ICAO attachment" means an attachment to an automatically validated flight crew licence issued in accordance with Annex 1 to the Chicago Convention, which is mentioned under item XIII of the flight crew licence;

(23) "qualification test guide (QTG)" means a document established to demonstrate that the performance and handling qualities of an FSTD represent those of the aircraft, class of aeroplane or type of helicopter, simulated within prescribed limits and that all applicable requirements have been met. The QTG includes both the data of the aircraft, class of aeroplane or type of helicopter and FSTD data used to support the validation;

(24) "declared training organisation (DTO)" means an organisation which is entitled to provide training to pilots on the basis of a declaration made in accordance with the second subparagraph of Article 10a(1);

(25) "DTO training programme" means a document established by a DTO, describing in detail the training course provided by that DTO.

Article 3 Pilot licensing and medical certification

Regulation (EU) No 245/2014

1. Without prejudice to Article 8 of this Regulation, pilots of aircraft referred to in Article 4(1)(b) and (c) and Article 4(5) of Regulation (EC) No 216/2008 shall comply with the technical requirements and administrative procedures laid down in Annex I and Annex IV to this Regulation.

2. Notwithstanding the privileges of the holders of licences as defined in Annex I to this Regulation, holders of pilot licences issued in accordance with Subpart B or C of Annex I to this Regulation may carry out flights referred to in Article 6(4a) of Regulation (EU) No 965/2012. This is without prejudice to compliance with any additional requirements for the carriage of passengers or the development of commercial operations defined in Subparts B or C of Annex I to this Regulation.

Article 4 Existing national pilots' licences

Regulation (EU) 2018/1119

1. JAR-compliant licences issued or recognised by a Member State before this Regulation applies shall be deemed to have been issued in accordance with this Regulation. Member States shall replace these licences with licences complying with the format laid down in Part-ARA by 8 April 2018 at the latest.

2. Non-JAR-compliant licences including any associated ratings, certificates, authorisations and/or qualifications issued or recognised by a Member State before the applicability of this Regulation shall be converted into Part-FCL licences by the Member State that issued the licence.

3. Non-JAR-compliant licences shall be converted into Part- FCL licences and associated ratings or certificates in accordance with:

   (a) the provisions of Annex II; or

   (b) the elements laid down in a conversion report.

4. The conversion report shall:

   (a) be established by the Member State that issued the pilot licence in consultation with the European Aviation Safety Agency (the Agency);

   (b) describe the national requirements on the basis of which the pilot licences were issued;

   (c) describe the scope of the privileges that were given to the pilots;

   (d) indicate for which requirements in Annex I credit is to be given;

   (e) indicate any limitations that need to be included on the Part-FCL licences and any requirements the pilot has to comply with in order to remove those limitations.

5. The conversion report shall include copies of all documents necessary to demonstrate the elements set out in points (a) to (e) of paragraph 4, including copies of the relevant national requirements and procedures. When developing the conversion report, Member States shall aim at allowing pilots to, as far as possible, maintain their current scope of activities.

6. Notwithstanding paragraphs 1 and 3, holders of a class rating instructor certificate or an examiner certificate who have privileges for single-pilot high performance complex aircraft shall have those privileges converted into a type rating instructor certificate or an examiner certificate for single-pilot aeroplanes.

7. A Member State may authorise a student pilot to exercise limited privileges without supervision before he/she meets all the requirements necessary for the issuance of an LAPL under the following conditions:

   (a) the privileges shall be limited to its national territory or a part of it;

   (b) the privileges shall be restricted to a limited geographical area and to single-engine piston aeroplanes with a maximum take-off mass not exceeding 2 000 kg, and shall not include the carriage of passengers;

   (c) those authorisations shall be issued on the basis of an individual safety risk assessment carried out by an instructor following a concept safety risk assessment carried out by the Member State;

   (d) the Member State shall submit periodical reports to the Commission and the Agency every 3 years.

8. Until 8 April 2019, a Member State may issue an authorisation to a pilot to exercise specified limited privileges to fly aeroplanes under instrument flight rules before the pilot complies with all of the requirements necessary for the issue of an instrument rating in accordance with this Regulation, subject to the following conditions:

   (a) the Member State shall only issue these authorisations when justified by a specific local need which cannot be met by the ratings established under this Regulation;

   (b) the scope of the privileges granted by the authorisation shall be based on a safety risk assessment carried out by the Member State, taking into account the extent of training necessary for the intended level of pilot competence to be achieved;

   (c) the privileges of the authorisation shall be limited to the airspace of the Member State's national territory or parts of it;

   (d) the authorisation shall be issued to applicants having completed appropriate training with qualified instructors and demonstrated the required competencies to a qualified examiner, as determined by the Member State;

(e) the Member State shall inform the Commission, EASA and the other Member States of the specificities of this authorisation, including its justification and safety risk assessment.

(f) the Member State shall monitor the activities associated with the authorisation to ensure an acceptable level of safety and take appropriate action in case of identifying an increased risk or any safety concerns;

(g) the Member State shall carry out a review of the safety aspects of the implementation of the authorisation and submit a report to the Commission by 8 April 2017 at the latest.

9. For licences issued before 19 August 2018, Member States shall comply with the requirements laid down in the second paragraph of point (a) of ARA.FCL.200 as amended by Commission Regulation (EU) 2018/1065[1] by 31 December 2022 at the latest.

Article 4a Performance-based navigation instrument rating privileges

Regulation (EU) 2016/539

1. Pilots may only fly in accordance with performance-based navigation ("PBN") procedures after they have been granted PBN privileges as an endorsement to their instrument rating ("IR").

2. A pilot shall be granted PBN privileges where he or she fulfils all of the following requirements:

(a) the pilot has successfully completed a course of theoretical knowledge including PBN, in accordance with FCL.615 of Annex I (Part-FCL);

(b) the pilot has successfully completed flying training including PBN, in accordance with FCL.615 of Annex I (Part-FCL);

(c) the pilot has successfully completed either a skill test in accordance with Appendix 7 to Annex I (Part-FCL) or a skill test or a proficiency check in accordance with Appendix 9 of Annex I (Part-FCL).

3. The requirements of paragraph 2(a) and (b) shall be deemed to have been fulfilled where the competent authority considers that the competence acquired, either through training or from familiarity with PBN operations, is equivalent to the competence acquired through the courses referred to in paragraph 2(a) and (b) and the pilot demonstrates such competence to the satisfaction of the examiner at the proficiency check or skill test referred to in paragraph 2(c).

4. A record of the successful demonstration of competency in PBN shall, upon completion of the skill test or the proficiency check referred to in paragraph 2(c), be entered in the pilot's logbook or equivalent record and signed by the examiner who conducted the test or check.

5. IR pilots without PBN privileges may only fly on routes and approaches that do not require PBN privileges and no PBN items shall be required for the renewal of their IR, until 25 August 2020; after that date, PBN privileges shall be required for every IR.

Article 4b Upset prevention and recovery training

Regulation (EU) 2018/1974

1. Upset prevention and recovery training shall become a mandatory part of a training course for a multi-crew pilot licence (MPL), an integrated training course for airline transport pilots for

[1] Commission Regulation (EU) 2018/1065 of 27 July 2018 amending Regulation (EU) No 1178/2011 as regards the automatic validation of Union flight crew licences and take-off and landing training (OJ L 192, 30.7.2018, p. 31).

aeroplanes (ATP(A)), a training course for a commercial pilot licence for aeroplanes (CPL(A)) and training courses for a class or type rating for:

(a) single-pilot aeroplanes operated in multi-pilot operations;

(b) single-pilot non-high-performance complex aeroplanes;

(c) single-pilot high-performance complex aeroplanes; or

(d) multi-pilot aeroplanes;

in accordance with Annex I (Part-FCL).

2. For training courses referred to in paragraph 1 that commence before 20 December 2019 at an approved training organisation (ATO), upset prevention and recovery training shall not be mandatory provided that:

(a) CPL(A), ATP(A) or MPL training course is otherwise completed in accordance with Annex I (Part-FCL) and the skill test is completed in compliance with points FCL.320 (CPL), FCL.620 (IR) or FCL.415.A (MPL) of Annex I (Part-FCL) by 20 December 2021 at the latest; or

(b) class or type rating training course for the aeroplanes is otherwise completed in accordance with Annex I (Part-FCL) and the skill test is completed in compliance with the second subparagraph of paragraph (c) of point FCL.725 of Annex I (Part-FCL) to this Regulation by 20 December 2021 at the latest.

For the purpose of paragraph 1, the competent authority may on its own assessment and pursuant to a recommendation from an ATO give credit for any upset prevention and recovery training completed before 20 December 2019 under national training requirements.;

Article 5 Existing national pilots' medical certificates and aero-medical examiners certificates

Regulation (EU) No 1178/2011

1. JAR-compliant pilots' medical certificates and aero-medical examiners' certificates issued or recognised by a Member State before this Regulation applies shall be deemed to have been issued in accordance with this Regulation.

2. Member States shall replace pilots' medical certificates and aero-medical examiners' certificates with certificates complying with the format laid down in Part-ARA by 8 April 2017 at the latest.

3. Non-JAR-compliant pilot medical certificates and aero- medical examiners' certificates issued by a Member State before this Regulation applies shall remain valid until the date of their next revalidation or until 8 April 2017, whichever is the earlier.

4. The revalidation of the certificates referred to in paragraphs 1 and 2 shall comply with the provisions of Annex IV.

Article 6 Conversion of flight test qualifications

Regulation (EU) No 1178/2011

1. Pilots who before this Regulation applies conducted category 1 and 2 flight tests as defined in the Annex to Commission Regulation (EC) No 1702/2003[1], or who provided instruction to flight test pilots, shall have their flight test qualifications converted into flight test ratings in

[1] OJ L 243, 27.9.2003, p. 6.

accordance with Annex I to this Regulation and, where applicable, flight test instructor certificates by the Member State that issued the flight test qualifications.

2. This conversion shall be carried out in accordance with the elements established in a conversion report that complies with the requirements set out in Article 4(4) and (5).

Article 7 Existing national flight engineers' licences

Regulation (EU) No 1178/2011

1. In order to convert flight engineer licences, issued in accordance with Annex 1 to the Chicago Convention, into Part-FCL licences, holders shall apply to the Member State that issued the licences.

2. Flight engineer licences shall be converted into Part-FCL licences in accordance with a conversion report that complies with the requirements set out in Article 4(4) and (5).

3. When applying for the airline transport pilot licence (ATPL) for aeroplanes, the provisions on credit in FCL.510.A(c)(2) of Annex I shall be complied with.

Article 8 Conditions for the acceptance of licences from third countries

Regulation (EU) 2015/445

1. Without prejudice to Article 12 of Regulation (EC) No 216/2008 and where there are no agreements concluded between the Union and a third country covering pilot licensing, Member States may accept third country licences, ratings or certificates, and associated medical certificates issued by or on behalf of third countries, in accordance with the provisions of Annex III to this Regulation.

2. Applicants for Part-FCL licences already holding at least an equivalent licence, rating or certificate issued in accordance with Annex 1 to the Chicago Convention by a third country shall comply with all the requirements of Annex I to this Regulation, except that the requirements of course duration, number of lessons and specific training hours may be reduced.

3. The credit given to the applicant shall be determined by the Member State to which the pilot applies on the basis of a recommendation from an approved training organisation.

4. Holders of an ATPL issued by or on behalf of a third country in accordance with Annex 1 to the Chicago Convention who have completed the experience requirements for the issue of an ATPL in the relevant aircraft category as set out in Subpart F of Annex I to this Regulation may be given full credit as regards the requirements to undergo a training course prior to undertaking the theoretical knowledge examinations and the skill test, provided that the third country licence contains a valid type rating for the aircraft to be used for the ATPL skill test.

5. Aeroplane or helicopter type ratings may be issued to holders of Part-FCL licences that comply with the requirements for the issue of those ratings established by a third country. Such ratings will be restricted to aircraft registered in that third country. This restriction may be removed when the pilot complies with the requirements in point C.1 of Annex III.

Article 9 Credit for training commenced prior to the application of this Regulation

Regulation (EU) No 1178/2011

1. In respect of issuing Part-FCL licences in accordance with Annex I, training commenced prior to the application of this Regulation in accordance with the Joint Aviation Authorities

requirements and procedures, under the regulatory oversight of a Member State recommended for mutual recognition within the Joint Aviation Authorities' system in relation to the relevant JAR, shall be given full credit provided that the training and testing were completed by 8 April 2016 at the latest.

2. Training commenced prior to the application of this Regulation in accordance with Annex 1 to the Chicago Convention shall be given credit for the purposes of issuing Part-FCL licences on the basis of a credit report established by the Member State in consultation with the Agency.

3. The credit report shall describe the scope of the training, indicate for which requirements of Part-FCL licences credit is given and, if applicable, which requirements applicants need to comply with in order to be issued with Part-FCL licences. It shall include copies of all documents necessary to demonstrate the scope of the training and of the national regulations and procedures in accordance with which the training was commenced.

Article 9a Type rating training and operational suitability data

Regulation (EU) No 70/2014

1. Where the Annexes to this Regulation make reference to the operational suitability data established in accordance with Regulation (EU) No 748/2012, and that data is not available for the relevant type aircraft, the applicant for a type rating training course shall comply with the provisions of the Annexes of Regulation (EU) No 1178/2011 only.

2. Type rating training courses approved before the approval of the minimum syllabus of pilot type rating training in the operational suitability data for the relevant type of aircraft in accordance with Regulation (EU) No 748/2012 shall include the mandatory training elements not later than 18 December 2017 or within two years after the operational suitability data was approved, whichever is the latest.

Article 10 Credit for pilot licences obtained during military service

Regulation (EU) No 1178/2011

1. In order for holders of military flight crew licences to obtain Part-FCL licences, they shall apply to the Member State where they served.

2. The knowledge, experience and skill gained in military service shall be given credit for the purposes of the relevant requirements of Annex I in accordance with the elements of a credit report established by the Member State in consultation with the Agency.

3. The credit report shall:

   (a) describe the national requirements on the basis of which the military licences, ratings, certificates, authorisations and/or qualifications were issued;

   (b) describe the scope of the privileges that were given to the pilots;

   (c) indicate for which requirements of Annex I credit is to be given;

   (d) indicate any limitations that need to be included on the Part-FCL licences and indicate any requirements pilots have to comply with to remove those limitations;

   (e) include copies of all documents necessary to demonstrate the elements above, accompanied by copies of the relevant national requirements and procedures.

Article 10a Pilot training organisations

Regulation (EU) 2018/1119

1 Organisations shall, in accordance with Article 7(3) of Regulation (EC) No 216/2008, be entitled to provide training to pilots involved in the operation of aircraft referred to in Article 4(1)(b) and (c) of Regulation (EC) No 216/2008 only where those organisations have been issued by the competent authority with an approval confirming that they comply with the essential requirements set out in Annex III to Regulation (EC) No 216/2008 and with the requirements of Annex VII to this Regulation.

However, by derogation from Article 7(3) of Regulation (EC) No 216/2008 and the first subparagraph of this paragraph, organisations shall be entitled to provide the training referred to in point DTO.GEN.110 of Annex VIII to this Regulation without such approval where they have made a declaration to the competent authority in accordance with the requirements laid down in point DTO.GEN.115 of that Annex and, where so required pursuant to point DTO.GEN.230(c) of that Annex, the competent authority has approved the training programme.

2. Pilot training organisations holding JAR-compliant certificates issued or recognised by a Member State before this Regulation applies shall be deemed to hold a certificate issued in accordance with this Regulation.

In such case the privileges of these organisations shall be limited to the privileges included in the approval issued by the Member State.

Without prejudice to Article 2, pilot training organisations shall adapt their management system, training programmes, procedures and manuals to be compliant with Annex VII by 8 April 2014 at the latest.

3. JAR-compliant training organisations shall be allowed to provide training for a Part-FCL private pilot licence (PPL), for the associated ratings included in the registration and for a light aircraft pilot licence (LAPL) until 8 April 2019 without complying with the provisions of Annex VII and Annex VIII, provided that they were registered before 8 April 2015.

4. Member States shall replace the certificates referred to in the first subparagraph of paragraph 2 with certificates complying with the format laid down in Annex VI by 8 April 2017 at the latest.

5. Pilot training organisations shall ensure that the IR training course they offer include training for PBN privileges compliant with the requirements of Annex I (Part-FCL) by 25 August 2020 at the latest.

Article 10b Flight simulation training devices

Regulation (EU) No 290/2012

1. Flight simulation training devices (FSTDs) used for pilot training, testing and checking, with the exception of developmental training devices used for flight test training, shall comply with the technical requirements and administrative procedures laid down in Annexes VI and VII and shall be qualified.

2. JAR-compliant FSTD qualification certificates issued or recognised before this Regulation applies shall be deemed to have been issued in accordance with this Regulation.

3. Member States shall replace the certificates referred to in paragraph 2 with qualification certificates complying with the format laid down in Annex VI by 8 April 2017 at the latest.

Article 10c Aero-medical centres

Regulation (EU) No 290/2012

1. Aero-medical centres shall comply with the technical requirements and administrative procedures laid down in Annexes VI and VII and shall be certified.

2. JAR-compliant aero-medical centre approvals issued or recognised by a Member State before this Regulation applies shall be deemed to have been issued in accordance with this Regulation.

   Aero-medical centres shall adapt their management system, training programmes, procedures and manuals to be compliant with Annex VII by 8 April 2014 at the latest.

3. Member States shall replace aero-medical centres' approvals referred to in the first subparagraph of paragraph 2 with certificates complying with the format laid down in Annex VI by 8 April 2017 at the latest.

Article 11 Cabin crew medical fitness

Regulation (EU) No 1178/2011

1. Cabin crew members involved in the operation of aircraft referred to in Article 4(1)(b) and (c) of Regulation (EC) No 216/2008 shall comply with the technical requirements and administrative procedures laid down in Annex IV.

2. The medical examinations or assessments of cabin crew members that were conducted in accordance with Council Regulation (EEC) No 3922/91[1] and which are still valid at the date of application of this Regulation shall be deemed to be valid according to this Regulation until the earlier of the following:

   (a) the end of the validity period determined by the competent authority in accordance with Regulation (EEC) No 3922/91; or

   (b) the end of the validity period provided for in point MED.C.005 of Annex IV.

   The validity period shall be counted from the date of the last medical examination or assessment.

   By the end of the validity period any subsequent aero-medical re-assessment shall be conducted in accordance with Annex IV.

Article 11a Cabin crew qualifications and related attestations

Regulation (EU) No 290/2012

1. Cabin crew members involved in commercial operation of aircraft referred to in Article 4(1)(b) and (c) of Regulation (EC) No 216/2008 shall be qualified and hold the related attestation in accordance with the technical requirements and administrative procedures laid down in Annexes V and VI.

2. Cabin crew members holding, before this Regulation applies, an attestation of safety training issued in accordance with Regulation (EEC) No 3922/91 ("EU-OPS"):

   (a) shall be deemed to be compliant with this Regulation if they comply with the applicable training, checking and recency requirements of EU-OPS; or

[1] OJ L 373, 31.12.1991, p. 4.

(b) if they do not comply with the applicable training, checking and recency requirements of EU-OPS, they shall complete all required training and checking before being deemed to be compliant with this Regulation; or

(c) if they have not operated in commercial operations by aeroplanes for more than 5 years, they shall complete the initial training course and shall pass the related examination as required in Annex V before being deemed to be compliant with this Regulation.

3. The attestations of safety training issued in accordance with EU-OPS shall be replaced with cabin crew attestations complying with the format laid down in Annex VI by 8 April 2017 at the latest.

4. Cabin crew members involved in commercial operations of helicopters on the date of application of this Regulation:

(a) shall be deemed to be compliant with the initial training requirements of Annex V if they comply with the applicable training, checking and recency provisions of the JARs for commercial air transportation by helicopters; or

(b) if they do not comply with the applicable training, checking and recency requirements of the JARs for commercial air transportation by helicopters, they shall complete all relevant training and checking required to operate on helicopter(s), except the initial training, before being deemed to be compliant with this Regulation; or

(c) if they have not operated in commercial operations by helicopters for more than 5 years, they shall complete the initial training course and shall pass the related examination as required in Annex V before being deemed to be compliant with this Regulation.

5. Without prejudice to Article 2, cabin crew attestations complying with the format laid down in Annex VI shall be issued to all cabin crew members involved in commercial operations by helicopters by 8 April 2013 at the latest.

Article 11b Oversight capabilities

Regulation (EU) No 290/2012

1. Member States shall designate one or more entities as the competent authority within that Member State with the necessary powers and allocated responsibilities for the certification and oversight of persons and organisations subject to Regulation (EC) No 216/2008 and its implementing rules.

2. If a Member State designates more than one entity as competent authority:

(a) the areas of competence of each competent authority shall be clearly defined in terms of responsibilities and geographic limitation;

(b) coordination shall be established between those entities to ensure effective oversight of all organisations and persons subject to Regulation (EC) No 216/2008 and its implementing rules within their respective remits.

3. Member States shall ensure that the competent authority(ies) has/have the necessary capability to ensure the oversight of all persons and organisations covered by their oversight programme, including sufficient resources to fulfil the requirements of this Regulation.

4. Member States shall ensure that competent authority personnel do not perform oversight activities when there is evidence that this could result directly or indirectly in a conflict of interest, in particular when relating to family or financial interest.

5. Personnel authorised by the competent authority to carry out certification and/or oversight tasks shall be empowered to perform at least the following tasks:

(a) examine the records, data, procedures and any other material relevant to the execution of the certification and/or oversight task;

(b) take copies of or extracts from such records, data, procedures and other material;

(c) ask for an oral explanation on site;

(d) enter relevant premises, operating sites or means of transport;

(e) perform audits, investigations, assessments and inspections, including ramp inspections and unannounced inspections; and

(f) take or initiate enforcement measures as appropriate.

6. The tasks under paragraph 5 shall be carried out in compliance with the legal provisions of the relevant Member State.

Article 11c Transitional measures

Regulation (EU) No 290/2012

As regards organisations for which the Agency is the competent authority in accordance with Article 21(1)(b) of Regulation (EC) No 216/2008:

(a) Member States shall transfer to the Agency all records related to the oversight of such organisations by 8 April 2013 at the latest;

(b) certification processes initiated before 8 April 2012 by a Member State shall be finalised by that Member State in coordination with the Agency. The Agency shall assume all its responsibilities as competent authority concerning such organisation after the issuance of the certificate by that Member State.

Article 12 Entry into force and application (of the Commission Regulation 1178/2011)

Regulation (EU) 2018/1974

1. This Regulation shall enter into force on the 20th day following its publication in the Official Journal of the European Union.

   It shall apply from 8 April 2012.

1b. By way of derogation from paragraph 1, Member States may decide not to apply the provisions of Annexes I to IV until 8 April 2013.

2. By way of derogation from paragraph 1, Member States may decide not to apply the following provisions of Annex I until 8 April 2015:

   (a) the provisions related to pilot licences of powered-lift aircraft and airships;

   (b) the provisions of point FCL.820;

   (c) in the case of helicopters, the provisions of Section 8 of Subpart J;

   (d) the provisions of Section 11 of Subpart J.

2a. By way of derogation from paragraph 1, Member States may decide not to apply until 8 April 2020:

   (1) the provisions of Annex I related to pilot licenses for sailplanes and balloons;

   (2) the provisions of Annexes VII and VIII to a training organisation providing training only for a national licence that is eligible in accordance with Article 4(3) of Regulation (EU) No

1178/2011, for conversion into a Part-FCL light aircraft pilot licence (LAPL) for sailplanes or balloons, a Part-FCL sailplane pilot licence (SPL) or a Part-FCL balloon pilot licence (BPL);

(3) the provisions of Subpart B of Annex I;

3. By way of derogation from paragraph 1, Member States may decide not to convert non-JAR-compliant aeroplane and helicopter licences that they have issued until 8 April 2014.

4. By way of derogation from paragraph 1, Member States may decide not to apply the provisions of this Regulation until 20 June 2020, to pilots holding a licence and associated medical certificate issued by a third country involved in the non-commercial operation of aircraft as specified in Article 2(1)(b), points (i) or (ii), of Regulation (EU) 2018/1139. Member States shall make those decisions publicly available.

5. By way of derogation from paragraph 1, Member States may decide not to apply the provisions of Section 3 of Subpart B of Annex IV until 8 April 2015.

6. By way of derogation from paragraph 1, Member States may decide not to apply the provisions of Subpart C of Annex IV until 8 April 2014.

7. When a Member State makes use of the provisions of paragraphs 1b to 6 it shall notify the Commission and the Agency. This notification shall describe the reasons for such derogation as well as the programme for implementation containing actions envisaged and related timing.

8. By way of derogation from paragraph 1, point FCL.315.A, the second sentence of paragraph (a) of point FCL.410.A and paragraph (c) of point FCL.725.A of Annex I (Part-FCL) shall apply from 20 December 2019.

COMMISSION REGULATION (EU) NO 290/2012 OF 30 MARCH 2012

Regulation (EU) 2015/445

1. This Regulation shall enter into force on the 20th day following its publication in the *Official Journal of the European Union*.

   It shall apply from 8 April 2012.

2. By way of derogation from the second subparagraph of paragraph 1, Member States may decide not to apply the following provisions:

   (a) Annexes V to VII until 8 April 2013;

   (b) point ORA.GEN.200(a)(3) of Annex VII to FSTD qualification certificate holders not being an approved training organisation and not holding an air operator certificate until 8 April 2014;

   (c) Annexes VI and VII to non-JAR-compliant approved training organisations and aero-medical centres until 8 April 2014;

   (d) point CC.GEN.030 of Annex V until 8 April 2015;

   (e) Annex V to cabin crew members involved in commercial operations by helicopters until 8 April 2015;

   (f) Annexes VI and VII to training organisations providing training for flight test ratings in accordance with point FCL.820 of Annex I to Regulation (EU) No 1178/2011 until 8 April 2015.

3. When a Member State makes use of the provisions of paragraph 2, it shall notify the Commission and the Agency. This notification shall describe the duration and the reasons for such derogation as well as the programme for implementation containing actions envisaged and related timing.

COMMISSION REGULATION (EU) NO 70/2014 OF 27 JANUARY 2014

Regulation (EU) No 70/2014

This Regulation shall enter into force on the twentieth day following that of its publication in the *Official Journal of the European Union*.

COMMISSION REGULATION (EU) NO 245/2014 OF 13 MARCH 2014

Regulation (EU) No 245/2014

This Regulation shall enter into force on the twentieth day following that of its publication in the *Official Journal of the European Union*.

COMMISSION REGULATION (EU) 2015/445 OF 17 MARCH 2015

Regulation (EU) 2015/445

1. This Regulation shall enter into force on 8 April 2015.
2. By way of derogation from paragraph 1, the amendments to the provisions in FCL315.A, FCL.410.A, FCL.725.A of Annex I shall apply from 8 April 2018.
3. By way of derogation from paragraph 1, Member States may decide not to apply the provisions of Annexes VI and VII to a training organisation providing training only for a national licence that is eligible in accordance with Article 4(3) of Regulation (EU) No 1178/2011, for conversion into a Part-FCL light aircraft pilot licence (LAPL), sailplane pilot licence (SPL) or balloon pilot licence (BPL) until 8 April 2018.

COMMISSION REGULATION (EU) 2016/539 OF 6 APRIL 2016

Regulation (EU) 2016/539

This Regulation shall enter into force on the day of its publication in the *Official Journal of the European Union*.

It shall apply from 8 April 2016.

However, points 1, 2 and 4 of Article 1 shall apply from 25 August 2018, with the exception of point 1(g) of the Annex, which shall apply from 8 April 2016.

COMMISSION REGULATION (EU) 2018/1065 OF 27 JULY 2018

Regulation (EU) 2018/1065

This Regulation shall enter into force on the twentieth day following that of its publication in the *Official Journal of the European Union*.

COMMISSION REGULATION (EU) 2018/1119 OF 31 JULY 2018

Regulation (EU) 2018/1119

This Regulation shall enter into force on the twentieth day following that of its publication in the *Official Journal of the European Union*.

COMMISSION REGULATION (EU) 2018/1974 OF 14 DECEMBER 2018

Regulation (EU) 2018/1974

This Regulation shall enter into force on the twentieth day following that of its publication in the *Official Journal of the European Union*.

However:

(a) Article 1(1) shall apply from 20 December 2019.

(b) Article 1(4) shall apply from 20 December 2019.

(c) Notwithstanding point (b) above, points (2), (4), (5) and (12) of the Annex to this Regulation shall apply from 31 January 2022.

COMMISSION REGULATION (EU) 2019/27 OF 19 DECEMBER 2018

Regulation (EU) 2019/27

This Regulation shall enter into force on the twentieth day following that of its publication in the *Official Journal of the European Union*.

Regulation (EU) No 1178/2011

This Regulation shall be binding in its entirety and directly applicable in all Member States.

Done at Brussels, 3 November 2011.

For the Commission

The President

José Manuel BARROSO

ANNEX IV (PART-MED)

SUBPART A – GENERAL REQUIREMENTS

SECTION 1 – GENERAL

MED.A.001 Competent authority

Regulation (EU) 2019/27

For the purpose of this Annex (Part-MED), the competent authority shall be:

(a) for aero-medical centres (AeMCs):

(1) the authority designated by the Member State, where the AeMC has its principal place of business;

(2) the Agency, if the AeMC is located in a third country;

(b) for aero-medical examiners (AMEs):

(1) the authority designated by the Member State where the AME has its principal place of practice;

(2) if the principal place of practice of an AME is located in a third country, the authority designated by the Member State to which the AME applies for the issue of the AME certificate;

(c) for general medical practitioners (GMPs), the authority designated by the Member State to which the GMP notify their activity;

(d) for occupational health medical practitioners (OHMPs) assessing the medical fitness of cabin crew, the authority designated by the Member State to which the OHMP notify their activity.

MED.A.005 Scope

Regulation (EU) 2019/27

This Annex (Part-MED) establishes the requirements for:

(a) the issuance, validity, revalidation and renewal of the medical certificate required for exercising the privileges of a pilot licence or of a student pilot;

(b) the medical fitness of cabin crew;

(c) the certification of AMEs;

(d) the qualification of GMPs and OHMPs.

MED.A.010 Definitions

Regulation (EU) 2019/27

For the purpose of this Annex (Part-MED), the following definitions shall apply:

– ‘limitation’ means a condition placed on the medical certificate or cabin crew medical report that shall be complied with whilst exercising the privileges of the licence or cabin crew attestation;

- ‘aero-medical examination’ means an inspection, palpation, percussion, auscultation or any other means of investigation for determining the medical fitness to exercise the privileges of the licence, or to carry out cabin crew safety duties;
- ‘aero-medical assessment’ means the conclusion on the medical fitness of an applicant based on the evaluation of the applicant as required in this Annex (Part-MED) and further examinations and medical tests as clinically indicated;
- ‘significant’ means a degree of a medical condition, the effect of which would prevent the safe exercise of the privileges of the licence or of the cabin crew safety duties;
- ‘applicant’ means a person applying for, or being the holder of, a medical certificate who undergoes an aero-medical assessment of fitness to exercise the privileges of the licence, or to carry out cabin crew safety duties;
- ‘medical history’ means a narrative or record of past diseases, injuries, treatments or other medical facts, including unfit assessment(s) or limitation of a medical certificate, that are or may be relevant to an applicant’s current state of health and aero-medical fitness;
- ‘licensing authority’ means the competent authority of the Member State that issued the licence, or to which a person applies for the issuance of a licence, or, when a person has not yet applied for a licence, the competent authority as determined in accordance with FCL.001 of Annex I (Part-FCL);
- ‘colour safe’ means the ability of an applicant to readily distinguish the colours used in air navigation and to correctly identify aviation coloured lights;
- ‘investigation’ means the assessment of a suspected pathological condition of an applicant by means of examinations and tests in order to verify the presence or absence of a medical condition;
- ‘accredited medical conclusion’ means the conclusion reached by one or more medical experts acceptable to the licensing authority, on the basis of objective and non-discriminatory criteria, for the purposes of the case concerned, in consultation with flight operations or other experts as necessary, for which an operational risk assessment may be appropriate;
- ‘misuse of substances’ means the use of one or more psychoactive substances by aircrew in a way that, alternatively or jointly:
  (a) constitutes a direct hazard to the user or endangers the lives, health or welfare of others;
  (b) causes or worsens an occupational, social, mental or physical problem or disorder;
- ‘psychoactive substances’ means alcohol, opioids, cannabinoids, sedatives and hypnotics, cocaine, other psychostimulants, hallucinogens, and volatile solvents, with the exception of caffeine and tobacco;;
- ‘refractive error’ means the deviation from emmetropia measured in dioptres in the most ametropic meridian, measured by standard methods.

MED.A.015 Medical confidentiality

Regulation (EU) 2019/27

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

AMC1 MED.A.015 Medical confidentiality

ED Decision 2019/002/R

To ensure medical confidentiality, all medical reports and records should be securely held with accessibility restricted to personnel authorised by the medical assessor or, where applicable, by the head of the aero-medical centre (AEMC), the aero-medical examiner (AME), general medical practitioner (GMP) or occupational health medical practitioner (OHMP).

MED.A.020 Decrease in medical fitness

Regulation (EU) 2019/27

(a) Licence holders shall not exercise the privileges of their licence and related ratings or certificates, and student pilots shall not fly solo, at any time when they:

(1) are aware of any decrease in their medical fitness which might render them unable to safely exercise those privileges;

(2) take or use any prescribed or non-prescribed medication which is likely to interfere with the safe exercise of the privileges of the applicable licence;

(3) receive any medical, surgical or other treatment that is likely to interfere with the safe exercise of the privileges of the applicable licence.

(b) In addition, holders of a medical certificate shall, without undue delay and before exercising the privileges of their licence, seek aero-medical advice from the AeMC, AME or GMP, as applicable, when they:

(1) have undergone a surgical operation or invasive procedure;

(2) have commenced the regular use of any medication;

(3) have suffered any significant personal injury involving incapacity to function as a member of the flight crew;

(4) have been suffering from any significant illness involving incapacity to function as a member of the flight crew;

(5) are pregnant;

(6) have been admitted to hospital or medical clinic;

(7) first require correcting lenses.

(c) In the cases referred to in point (b):

(1) holders of class 1 and class 2 medical certificates shall seek the aero-medical advice of an AeMC or AME. In that case, the AeMC or AME shall assess their medical fitness and decide whether they are fit to resume the exercise of their privileges;

(2) holders of light aircraft pilot licence medical certificates shall seek the aero-medical advice of an AeMC, an AME or the GMP who signed the medical certificate. In that case, the AeMC, AME or GMP shall assess their medical fitness and decide whether they are fit to resume the exercise of their privileges.

(d) Cabin crew members shall not perform duties on an aircraft and, where applicable, shall not exercise the privileges of their cabin crew attestation when they are aware of any decrease in their medical fitness, to the extent that this medical condition might render them unable to discharge their safety duties and responsibilities.

(e) In addition, if any of the medical conditions specified in points (1) to (5) of point (b) apply, cabin crew members shall, without undue delay, seek the advice of an AME, AeMC or OHMP, as applicable. In that case, the AME, AeMC or OHMP shall assess the medical fitness of the cabin crew members and decide whether they are fit to resume their safety duties.

GM1 MED.A.020 Decrease in medical fitness

ED Decision 2019/002/R

MEDICATION – GUIDANCE FOR PILOTS AND CABIN CREW MEMBERS

(a) Any medication can cause side effects, some of which may impair the safe performance of flying duties. Equally, symptoms of colds, sore throats, diarrhoea and other abdominal upsets may cause little or no problem whilst on the ground but may distract the pilot or cabin crew member and degrade their performance whilst on duty. The in-flight environment may also increase the severity of symptoms which may only be minor whilst on the ground. Therefore, one issue with medication and flying is the underlying condition and, in addition, the symptoms may be compounded by the side effects of the medication prescribed or bought over the counter for treatment. This guidance material provides some help to pilots and cabin crew in deciding whether expert aero-medical advice by an AME, AeMC, GMP, OHMP or medical assessor is needed.

(b) Before taking any medication and acting as a pilot or cabin crew member, the following three basic questions should be satisfactorily answered:

(1) Do I feel fit to fly?

(2) Do I really need to take medication at all?

(3) Have I given this particular medication a personal trial on the ground to ensure that it will not have any adverse effects on my ability to fly?

(c) Confirming the absence of adverse effects may well need expert aero-medical advice.

(d) The following are some widely used medicines with a description of their compatibility with flying duties:

(1) Antibiotics. Antibiotics may have short-term or delayed side effects which can affect pilot or cabin crew performance. More significantly, however, their use usually indicates that an infection is present and, thus, the effects of this infection may mean that a pilot or cabin crew member is not fit to fly and should obtain expert aero-medical advice.

(2) Anti-malaria drugs. The decision on the need for anti-malaria drugs depends on the geographical areas to be visited, and the risk that the pilot or cabin crew member has of being exposed to mosquitoes and of developing malaria. An expert medical opinion should be obtained to establish whether anti-malaria drugs are needed and what kind of drugs should be used. Most of the anti-malaria drugs (atovaquone plus proguanil, chloroquine, doxycycline) are compatible with flying duties. However, adverse effects associated with mefloquine include insomnia, strange dreams, mood changes, nausea, diarrhoea and headaches. In addition, mefloquine may cause spatial disorientation and lack of fine coordination and is, therefore, not compatible with flying duties.

(3) Antihistamines. Antihistamines can cause drowsiness. They are widely used in ‘cold cures’ and in treatment of hay fever, asthma and allergic rashes. They may be in tablet form or a constituent of nose drops or sprays. In many cases, the condition itself may preclude flying, so that, if treatment is necessary, expert aero-medical advice should be sought so

that so-called non-sedative antihistamines, which do not degrade human performance, can be prescribed.

(4) Cough medicines. Antitussives often contain codeine, dextromethorfan or pseudo-ephedrine which are not compatible with flying duties. However, mucolytic agents (e.g. carbocysteine) are well-tolerated and are compatible with flying duties.

(5) Decongestants. Nasal decongestants with no effect on alertness may be compatible with flying duties. However, as the underlying condition requiring the use of decongestants may be incompatible with flying duties, expert aero-medical advice should be sought. For example, oedema of the mucosal membranes causes difficulties in equalising the pressure in the ears or sinuses.

(6) Nasal corticosteroids are commonly used to treat hay fever, and they are compatible with flying duties.

(7) (i) Common pain killers and antifebrile drugs. Non-Steroidal Anti-Inflammatory Drugs (NSAIDs) and paracetamol, commonly used to treat pain, fever or headaches, may be compatible with flying duties. However, the pilot or cabin crew member should give affirmative answers to the three basic questions listed in (b) before using the medication and carrying out flying duties.

(ii) Strong analgesics. The more potent analgesics including codeine are opiate derivatives, and may produce a significant decrement in human performance and, therefore, are not compatible with flying duties.

(8) Anti-ulcer medicines. Gastric secretion inhibitors such as H2 antagonists (e.g. ranitidine, cimetidine) or proton pump inhibitors (e.g. omeprazole) may be acceptable after diagnosis of the pathological condition. It is important to seek for the medical diagnosis and not to only treat the dyspeptic symptoms.

(9) Anti-diarrhoeal drugs. Loperamide is one of the more common anti-diarrhoeal drugs and is usually safe to take whilst flying. However, the diarrhoea itself often makes the pilot and cabin crew member unfit for flying duties.

(10) Hormonal contraceptives and hormone replacement therapy usually have no adverse effects and are compatible with flying duties.

(11) Erectile dysfunction medication. This medication may cause disturbances in colour vision and dizziness. There should be at least 6 hours between taking sildenafil and flying duty; and 36 hours between taking vardenafil or tadalafil and flying duty.

(12) Smoking cessation. Nicotine replacement therapy may be acceptable. However, other medication affecting the central nervous system (buproprion, varenicline) is not acceptable for pilots.

(13) High blood pressure medication. Most anti-hypertensive drugs are compatible with flying duties However, if the level of blood pressure is such that drug therapy is required, the pilot or cabin crew member should be monitored for any side effects before carrying out flying duties. Therefore, consultation with the AME, AeMC, GMP, OHMP or medical assessor as applicable, is needed.

(14) Asthma medication. Asthma has to be clinically stable before a pilot or cabin crew member can return to flying duties. The use of respiratory aerosols or powders, such as corticosteroids, beta-2-agonists or chromoglycic acid may be compatible with flying duties. However, the use of oral steroids or theophylline derivatives is incompatible with

flying duty. Pilots or cabin crew members using medication for asthma should consult the AME, AeMC, GMP, OHMP or medical assessor, as applicable.

(15) Tranquillisers and sedatives. The inability to react, due to the use of this group of medicines, has been a contributory cause to fatal aircraft accidents. In addition, the underlying condition for which these medications have been prescribed will almost certainly mean that the mental state of a pilot or cabin crew member is not compatible with flying duties.

(16) Sleeping tablets. Sleeping tablets dull the senses, may cause confusion and slow reaction times. The duration of effect may vary from individual to individual and may be unduly prolonged. Expert aero-medical advice should be obtained before using sleeping tablets.

(17) Melatonin. Melatonin is a hormone that is involved with the regulation of the circadian rhythm. In some countries it is a prescription medicine, whereas in most other countries it is regarded as a 'dietary supplement' and can be bought without any prescription. The results from the efficiency of melatonin in treatment of jet lag or sleep disorders have been contradictory. Expert aero-medical advice should be obtained.

(18) Coffee and other caffeinated drinks may be acceptable, but excessive coffee drinking may have harmful effects, including disturbance of the heart's rhythm. Other stimulants including caffeine pills, amphetamines, etc. (often known as 'pep' pills) used to maintain wakefulness or suppress appetite can be habit forming. Susceptibility to different stimulants varies from one individual to another, and all may cause dangerous overconfidence. Overdosage causes headaches, dizziness and mental disturbance. These other stimulants should not be used.

(19) Anaesthetics. Following local, general, dental and other anaesthetics, a period of time should elapse before returning to flying. The period will vary considerably from individual to individual, but a pilot or cabin crew member should not fly for at least 12 hours after a local anaesthetic, and for at least 48 hours after a general, spinal or epidural anaesthetic (see MED.A.020).

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

(f) Other treatments

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

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

Regulation (EU) 2019/27

(a) When conducting aero-medical examinations and aero-medical assessments as required in this Annex (Part-MED), the AeMC, AME, GMP and OHMP shall:

(1) ensure that communication with the applicant can be established without language barriers;

(2) make the applicant aware of the consequences of providing incomplete, inaccurate or false statements on their medical history;

(3) notify the licensing authority, or, in the case of cabin crew attestation holders, notify the competent authority, if the applicant provides incomplete, inaccurate or false statements on their medical history;

(4) notify the licensing authority if an applicant withdraws the application for a medical certificate at any stage of the process.

(b) After completion of the aero-medical examinations and assessments, the AeMC, AME, GMP and OHMP shall:

(1) inform the applicant whether he or she is fit, unfit or referred to the medical assessor of the licensing authority, AeMC or AME, as applicable;

(2) inform the applicant of any limitation that may restrict flight training or the privileges of his or her licence or cabin crew attestation, as applicable;

(3) if the applicant has been assessed as unfit, inform him or her of his or her right to have the decision reviewed in accordance with the procedures of the competent authority;

(4) in the case of applicants for a medical certificate, submit without delay to the medical assessor of the licensing authority a signed, or electronically authenticated, report containing the detailed results of the aero-medical examinations and assessments as required for the class of medical certificate–and a copy of the application form, the examination form, and the medical certificate;

(5) inform the applicant of his or her responsibilities in the case of decrease in medical fitness, as specified in point MED.A.020.

(c) Where consultation with the medical assessor of the licensing authority is required in accordance with this Annex (Part-MED), the AeMC and AME shall follow the procedure established by the competent authority.

(d) AeMCs, AMEs, GMPs and OHMPs shall maintain records with details of aero-medical examinations and assessments performed in accordance with this Annex (Part-MED) and their results for a minimum of 10 years, or for a longer period if so determined by national legislation.

(e) AeMCs, AMEs, GMPs and OHMPs shall submit to the medical assessor of the competent authority, upon request, all aero-medical records and reports, and any other relevant information, when required for:

(1) medical certification;

(2) oversight functions.

(f) AeMCs and AMEs shall enter or update the data included in the European Aero-Medical Repository in accordance with point (c) of point ARA.MED.160.

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

ED Decision 2019/002/R

(a) If the medical examination is carried out by two or more AMEs or GMPs, only one of them should be responsible for coordinating the results of the examination, evaluating the findings with regard to medical fitness, and signing the report.

(b) The applicant should be made aware that the associated medical certificate or cabin crew report may be suspended or revoked if the applicant provides incomplete, inaccurate or false statements on their medical history to the AeMC, AME, GMP or OHMP.

(c) In cases where the AeMC or AME is required to assess the fitness of an applicant for a class 2 medical certificate in consultation with the medical assessor of the licensing authority, they should document the consultation in accordance with the procedure established by the competent authority.

(d) The AeMC, AME, GMP or OHMP should give advice to the applicant on treatment and preventive measures if, during the course of the examination, medical conditions or risk factors are identified which may endanger the medical fitness of the applicant in the future.

(e) When data is not being properly recorded in the European aero-medical data repository (EAMR due to unserviceability of the system, the AeMCs and AMEs should enter, or correct the existing data, in the EAMR without undue delay when the system recovers.

(f) In case of denial or referral to the licensing authority, the AeMC, AME, GMP or OHMP should inform the applicant in writing regarding the result of the assessment in a form and manner established by the competent authority.

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

ED Decision 2019/002/R

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

(a) Before performing the medical examination, the AeMC, AME or GMP should:

(1) verify the applicant's identity by checking their identity card, passport, driving licence or other official document containing a photograph of the applicant;

(2) obtain details of the applicant's flight crew licence from the applicant's licensing authority if they do not have their licence with them;

(3) except for initial applicants, obtain details of the applicant's most recent medical certificate from the medical assessor of the applicant's licensing authority if they do not have their certificate with them;

(4) in the case of a specific medical examination(s) (SIC) limitation on the existing medical certificate, obtain details of the specific medical condition and any associated instructions from the medical assessor of the applicant's licensing authority. This could include, for example, a requirement to undergo a specific examination or test;

(5) except for initial applicants, ascertain, from the previous medical certificate, which routine medical test(s) should be conducted, for example electrocardiography (ECG);

(6) provide the applicant with the application form for a medical certificate and the instructions for completion and ask the applicant to complete the form but not to sign it yet;

(7) go through the form with the applicant and give information to help the applicant understand the significance of the entries and ask any questions which might help the applicant to recall important historical medical data;

(8) verify that the form is complete and legible, ask the applicant to sign and date the form and then sign it as well. If the applicant declines to complete the application form fully, inform the applicant that it may not be possible to issue a medical certificate regardless of the outcome of the clinical examination and assessment.

(b) Once all the items in (a) have been addressed, the AeMC, AME or GMP should:

(1) perform the medical examination of the applicant in accordance with the applicable rules;

(2) arrange for additional specialist medical examinations, such as otorhinolaryngology (ENT) or ophthalmology, to be conducted as applicable and obtain the associated report forms or reports;

(3) complete the medical examination report form in accordance with the associated instructions for completion;

(4) ensure that all of the report forms are complete, accurate and legible.

(c) Once all the actions in (b) have been carried out, the AeMC, AME or GMP should review the report forms and:

(1) if satisfied that the applicant meets the applicable medical requirements as set out in Part-MED, issue a medical certificate for the appropriate class, with limitations if necessary. The applicant should sign the certificate once signed by the AeMC, AME or GMP; or

(2) if the applicant does not meet the applicable medical requirements, or if the fitness of the applicant for the class of medical certificate applied for is in doubt:

(i) refer the decision on medical fitness to, or consult the decision on medical fitness with, the medical assessor of the licensing authority or AME in compliance with MED.B.001; or

(ii) deny issuance of a medical certificate, explain the reason(s) for denial to the applicant and inform them of their right of a review according to the procedures of the competent authority.

(d) The AeMC, AME or GMP should send the documents as required by MED.A.025(b) to the medical assessor of the applicant's licensing authority within 5 days from the date of the medical examination. If a medical certificate has been denied or the decision has been referred, the documents should be sent to the medical assessor of the licensing authority on the same day that the denial or referral decision is reached.

SECTION 2 - REQUIREMENTS FOR MEDICAL CERTIFICATES

MED.A.030 Medical certificates

Regulation (EU) 2019/27

(a) A student pilot shall not fly solo unless that student pilot holds a medical certificate, as required for the relevant licence.

(b) An applicant for a licence, in accordance with Annex I (Part-FCL), shall hold a medical certificate issued in accordance with this Annex (Part-MED) and appropriate to the licence privileges applied for.

(c) When exercising the privileges of a:

(1) light aircraft pilot licence (LAPL), the pilot shall hold at least a valid LAPL medical certificate;

(2) private pilot licence (PPL), a sailplane pilot licence (SPL) or a balloon pilot licence (BPL), the pilot shall hold at least a valid class 2 medical certificate;

(3) SPL or a BPL involved in commercial sailplane or balloon flights, the pilot shall hold at least a valid class 2 medical certificate;

(4) commercial pilot licence (CPL), a multi-crew pilot licence (MPL) or an airline transport pilot licence (ATPL), the pilot shall hold a valid class 1 medical certificate.

(d) If a night rating is added to a PPL or LAPL, the licence holder shall be colour safe.

(e) If an instrument rating or *en route* instrument rating is added to a PPL, the licence holder shall undertake pure tone audiometry examinations in accordance with the periodicity and the standard required for class 1 medical certificate holders.

(f) A licence holder shall not at any time hold more than one medical certificate issued in accordance with this Annex (Part-MED).

AMC1 MED.A.030 Medical certificates

ED Decision 2019/002/R

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

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

MED.A.035 Application for a medical certificate

Regulation (EU) 2019/27

(a) Applications for a medical certificate shall be made in a form and manner established by the competent authority.

(b) Applicants for a medical certificate shall provide the AeMC, AME or GMP, as applicable, with:

(1) proof of their identity;

(2) a signed declaration:

(i) of medical facts concerning their medical history;

(ii) as to whether they have previously applied for a medical certificate or have undergone an aero-medical examination for a medical certificate and, if so, by whom and with what result;

(iii) as to whether they have ever been assessed as unfit or had a medical certificate suspended or revoked.

(c) When applying for a revalidation or renewal of the medical certificate, applicants shall present the most recent medical certificate to the AeMC, AME or GMP, as applicable, prior to the relevant aero-medical examinations.

AMC1 MED.A.035 Application for a medical certificate

ED Decision 2019/002/R

Except for initial applicants, the AeMC, AME or GMP should not start the aero-medical examination for the issue of the medical certificate where applicants do not present the most recent medical certificate, unless relevant information is received from the medical assessor of the licensing authority.

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

Regulation (EU) 2019/27

(a) A medical certificate shall only be issued, revalidated or renewed once the required aero-medical examinations and assessments, as applicable, have been completed and the applicant has been assessed as fit.

(b) *Initial issuance*

(1) Class 1 medical certificates shall be issued by an AeMC.

(2) Class 2 medical certificates shall be issued by an AeMC or an AME.

(3) LAPL medical certificates shall be issued by an AeMC or an AME. They may also be issued by a GMP if so permitted under the national law of the Member State of the licensing authority to which the application for the medical certificate has been made.

(c) *Revalidation and renewal*

(1) Class 1 and class 2 medical certificates shall be revalidated and renewed by an AeMC or an AME.

(2) LAPL medical certificates shall be revalidated and renewed by an AeMC or an AME. They may also be revalidated or renewed by a GMP if so permitted under the national law of the Member State of the licensing authority to which the application for the medical certificate has been made.

(d) The AeMC, AME or GMP shall only issue, revalidate or renew a medical certificate if both of the following conditions have been met:

(1) the applicant has provided them with a complete medical history and, if required by the AeMC, AME or GMP, with results of medical examinations and tests conducted by the applicant's physician or any medical specialists;

(2) the AeMC, AME or GMP has conducted the aero-medical assessment based on the medical examinations and tests as required for the relevant medical certificate to verify that the applicant complies with all the relevant requirements of this Annex (Part-MED).

(e) The AME, AeMC or, in the case of referral, the medical assessor of the licensing authority may require the applicant to undergo additional medical examinations and investigations when there is a clinical or epidemiological indication before the medical certificate is issued, revalidated or renewed.

(f) The medical assessor of the licensing authority may issue or reissue a medical certificate.

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

Regulation (EU) 2019/27

(a) *Validity*

(1) Class 1 medical certificates shall be valid for a period of 12 months.

(2) By derogation from point (1), the period of validity of class 1 medical certificates shall be 6 months for licence holders who:

(i) are engaged in single-pilot commercial air transport operations carrying passengers and have reached the age of 40;

(ii) have reached the age of 60.

(3) Class 2 medical certificates shall be valid for a period of:

(i) 60 months, until the licence holder reaches the age of 40. A medical certificate issued prior to the licence holder reaching the age of 40 shall cease to be valid after the licence holder reaches the age of 42;

(ii) 24 months, for licence holders aged between 40 and 50. A medical certificate issued prior to the licence holder reaching the age of 50 shall cease to be valid after the licence holder reaches the age of 51;

(iii) 12 months, for licence holders aged above 50.

(4) LAPL medical certificates shall be valid for a period of:

(i) 60 months, until the licence holder reaches the age of 40. A medical certificate issued prior to the licence holder reaching the age of 40 shall cease to be valid after the licence holder reaches the age of 42;

(ii) 24 months, for licence holders aged above 40.

(5) The validity period of a medical certificate, including any associated examination or special investigation, shall be calculated from the date of the aero-medical examination in the case of initial issue and renewal, and from the expiry date of the previous medical certificate in the case of revalidation.

(b) *Revalidation*

Aero-medical examinations and assessments, as applicable, for the revalidation of a medical certificate may be undertaken up to 45 days prior to the expiry date of the medical certificate.

(c) *Renewal*

(1) If the holder of a medical certificate does not comply with point (b), a renewal examination and assessment, as applicable, shall be required.

(2) In the case of class 1 and class 2 medical certificates:

(i) if the medical certificate has expired for less than 2 years, a routine revalidation aero-medical examination shall be performed;

(ii) if the medical certificate has expired for more than 2 years but less than 5 years, the AeMC or AME shall only conduct the renewal aero-medical examination after assessment of the aero-medical records of the applicant;

(iii) if the medical certificate has expired for more than 5 years, the aero-medical examination requirements for initial issue shall apply and the assessment shall be based on the revalidation requirements.

(3) In the case of LAPL medical certificates, the AeMC, AME or GMP shall assess the medical history of the applicant and perform the aero-medical examinations and assessments, as applicable, in accordance with points MED.B.005 and MED.B.095.

MED.A.046 Suspension or revocation of medical certificates

Regulation (EU) 2019/27

(a) A medical certificate may be suspended or revoked by the licensing authority.

(b) Upon suspension of the medical certificate, the holder shall return the medical certificate to the licensing authority on request of that authority.

(c) Upon revocation of the medical certificate, the holder shall immediately return the medical certificate to the licensing authority.

MED.A.050 Referral

Regulation (EU) 2019/27

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

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

SUBPART B – REQUIREMENTS FOR PILOT MEDICAL CERTIFICATES

SECTION 1 – GENERAL

MED.B.001 Limitations to medical certificates

Regulation (EU) 2019/27

(a) *Limitations to class 1 and class 2 medical certificates*

(1) If the applicant does not fully comply with the requirements for the relevant class of medical certificate but is considered to be not likely to jeopardise the safe exercise of the privileges of the applicable licence, the AeMC or AME shall:

(i) in the case of applicants for a class 1 medical certificate, refer the decision on fitness of the applicant to the medical assessor of the licensing authority as indicated in this Subpart;

(ii) in cases where a referral to the medical assessor of the licensing authority is not indicated in this Subpart, evaluate whether the applicant is able to perform his/her duties safely when complying with one or more limitations endorsed on the medical certificate and issue the medical certificate with limitation(s) as necessary;

(iii) in the case of applicants for a class 2 medical certificate, evaluate, in consultation with the medical assessor of the licensing authority as indicated in this Subpart, whether the applicant is able to perform his/her duties safely when complying with one or more limitations endorsed on the medical certificate and issue the medical certificate, with limitation(s) as necessary.

(2) The AeMC or AME may revalidate or renew a medical certificate with the same limitation(s) without referring to or consulting with the medical assessor of the licensing authority.

(b) *Limitations to LAPL medical certificates*

(1) If a GMP, after due consideration of the applicant's medical history, concludes that the applicant for a LAPL medical certificate does not fully meet the requirements for medical fitness, the GMP shall refer the applicant to an AeMC or AME, unless the applicant requires only limitation(s) related to the use of corrective lenses or to the period of validity of the medical certificate.

(2) If an applicant for a LAPL medical certificate has been referred in accordance with point (1), the AeMC or AME shall give due consideration to points MED.B.005 and MED.B.095, evaluate whether the applicant is able to perform his or her duties safely when complying with one or more limitations endorsed on the medical certificate and issue the medical certificate with limitation(s) as necessary. The AeMC or AME shall always consider the need to restrict the applicant from carrying passengers (operational passenger limitation, OPL).

(3) The GMP may revalidate or renew a LAPL medical certificate with the same limitation without referring the applicant to an AeMC or AME.

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

(1) whether accredited medical conclusion indicates that in special circumstances the applicant's failure to meet any requirement, whether numerical or otherwise, is such that the exercise of the privileges of the licence applied for is not likely to jeopardise flight safety;

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

(d) *Operational limitation codes*

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

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

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

(iii) The OML for class 1 medical certificates shall be initially imposed and only removed by the medical assessor of the licensing authority.

(2) Operational safety pilot limitation (OSL – class 2 and LAPL privileges)

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

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

(iii) The OSL for LAPL medical certificates may be imposed and removed by the medical assessor of the licensing authority, an AeMC or an AME.

(3) Operational passenger limitation (OPL – class 2 and LAPL privileges)

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

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

(iii) The OPL for LAPL medical certificates may be imposed and removed by the medical assessor of the licensing authority, an AeMC or an AME.

(4) Operational pilot restriction limitation (ORL – class 2 and LAPL privileges)

(i) The holder of a medical certificate with an ORL shall only operate an aircraft if one of the two following conditions have been met:

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

(B) there are no passengers on board the aircraft.

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

(iii) The ORL for LAPL medical certificates may be imposed and removed by the medical assessor of the licensing authority, an AeMC or an AME.

(5) Special restriction as specified (SSL)

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

(e) Any other limitation may be imposed on the holder of a medical certificate by the medical assessor of the licensing authority, AeMC, AME or GMP, as applicable, if required to ensure flight safety.

(f) Any limitation imposed on the holder of a medical certificate shall be specified therein.

AMC1 MED.B.001 Limitations to medical certificates

ED Decision 2019/002/R

GENERAL

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

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

(c) Initial application of limitations

(1) The limitations TML, VDL, VML, VNL and VCL, as listed in AMC2 MED.B.001(a), may be imposed by an AME or an AeMC for class 1, class 2, and LAPL medical certificates, or a GMP for LAPL medical certificates.

(2) All other limitations listed in AMC2 MED.B.001(a) should only be imposed:

(i) for class 1 medical certificates, by the medical assessor of the licensing authority where a referral is required according to MED.B.001;

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

(iii) for LAPL medical certificates, by an AME or AeMC.

(d) Removal of limitations

(1) For class 1 medical certificates, all limitations should only be removed by the medical assessor of the licensing authority.

(2) For class 2 medical certificates, limitations may be removed by the medical assessor of the licensing authority or by an AeMC or AME in consultation with the medical assessor of the licensing authority.

(3) For LAPL medical certificates, limitations may be removed by an AeMC or AME.

AMC2 MED.B.001 Limitations to medical certificates

ED Decision 2019/002/R

LIMITATION CODES

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

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

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

(1) TML Time limitation

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

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

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

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

Correction for defective distant, intermediate and near vision: whilst exercising the privileges of the licence, the holder of the medical certificate should wear spectacles that correct for defective distant, intermediate and near vision as examined and approved by the AeMC, AME or GMP. Contact lenses or full frame spectacles, when either correct for

near vision only, may not be worn. A spare set of spectacles, approved by the AeMC, AME or GMP, should be readily available.

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

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

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

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

(6) VCL Valid by day only

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

(7) RXO Specialist ophthalmological examination(s)

Specialist ophthalmological examination(s), other than the examinations stipulated in Part-MED, are required for a significant reason.

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

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

(9) HAL Wear hearing aid(s)

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

(10) APL Valid only with approved prosthesis

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

(11) AHL Valid only with approved hand controls

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

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

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

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

This limitation is an extension of the OML and are restricted to the role of co-pilot.

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

This limitation applies to holders of a class 2 or a LAPL medical certificate only. The safety pilot should be made aware of the type(s) of possible incapacity that the pilot whose medical certificate has been issued with this limitation may suffer and should be prepared to take over the aircraft controls during flight. Refer to MED.B.001(d)(2).

(15) OPL Valid only without passengers

This limitation applies to holders of a class 2 or LAPL medical certificate with a medical condition that may lead to an increased level of risk to flight safety when exercising the privileges of the licence. This limitation is to be applied when this risk is not acceptable for the carriage of passengers. Refer to MED.B.001(d)(3).

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

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

(17) OAL Restricted to demonstrated aircraft type

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

(18) SSL Special restriction(s) as specified

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

MED.B.005 General medical requirements

Regulation (EU) 2019/27

Applicants for a medical certificate shall be assessed in accordance with the detailed medical requirements set out in Sections 2 and 3.

They shall, in addition, be assessed as unfit where they have any of the following medical conditions which entails a degree of functional incapacity which is likely to interfere with the safe exercise of the privileges of the licence applied for or could render the applicant likely to become suddenly unable to exercise those privileges:

(a) abnormality, either congenital or acquired;

(b) active, latent, acute or chronic disease or disability;

(c) wound, injury or sequelae from operation;

(d) effect or side effect of any prescribed or non-prescribed therapeutic, diagnostic or preventive medication taken.

SECTION 2 – MEDICAL REQUIREMENTS FOR CLASS 1 AND CLASS 2 MEDICAL CERTIFICATES

MED.B.010 Cardiovascular System

Regulation (EU) No 2019/27

(a) *Examination*

(1) A standard 12-lead resting electrocardiogram (ECG) and report shall be completed when clinically indicated and at the following moments:

(i) for a class 1 medical certificate, at the initial examination, then every 5 years until age 30, every 2 years until age 40, annually until age 50, and at all revalidation or renewal examinations thereafter;

(ii) for a class 2 medical certificate, at the initial examination, at the first examination after age 40 and then at the first examination after age 50, and every 2 years thereafter.

(2) An extended cardiovascular assessment shall be required when clinically indicated.

(3) For a class 1 medical certificate, an extended cardiovascular assessment shall be completed at the first revalidation or renewal examination after age 65 and every 4 years thereafter.

(4) For a class 1 medical certificate, estimation of serum lipids, including cholesterol, shall be required at the initial examination, and at the first examination after having reached the age of 40.

(b) *Cardiovascular System – General*

(1) Applicants for a class 1 medical certificate with any of the following medical conditions shall be assessed as unfit:

(i) aneurysm of the thoracic or supra-renal abdominal aorta, before surgery;

(ii) significant functional or symptomatic abnormality of any of the heart valves;

(iii) heart or heart/lung transplantation~~.~~;

(iv) symptomatic hypertrophic cardiomyopathy.

(2) Before further consideration is given to their application, applicants for a class 1 medical certificate with a documented medical history or diagnosis of any of the following medical conditions shall be referred to the medical assessor of the licensing authority:

(i) peripheral arterial disease before or after surgery;

(ii) aneurysm of the thoracic or supra-renal abdominal aorta after surgery;

(iii) aneurysm of the infra-renal abdominal aorta before or after surgery;

(iv) functionally insignificant cardiac valvular abnormalities;

(v) after cardiac valve surgery;

(vi) abnormality of the pericardium, myocardium or endocardium;

(vii) congenital abnormality of the heart, before or after corrective surgery;

(viii) vasovagal syncope of uncertain cause;

(ix) arterial or venous thrombosis;

(x) pulmonary embolism;

(xi) cardiovascular condition requiring systemic anticoagulant therapy.

(3) Applicants for a class 2 medical certificate with an established diagnosis of one of the conditions specified in points (1) and (2) shall be evaluated by a cardiologist before they may be assessed as fit, in consultation with the medical assessor of the licensing authority.

(4) Applicants with cardiac disorders other than those specified in points (1) and (2) may be assessed as fit subject to satisfactory cardiological evaluation.

(c) *Blood Pressure*

(1) Applicants' blood pressure shall be recorded at each examination.

(2) Applicants whose's blood pressure is not within normal limits shall be further assessed with regard to their cardiovascular condition and medication with a view to determining whether they are to be assessed as unfit in accordance with points (3) and (4).

(3) Applicants for a class 1 medical certificate with any of the following medical conditions shall be assessed as unfit:

(i) symptomatic hypotension;

(ii) blood pressure at examination consistently exceeding 160 mmHg systolic or 95 mmHg diastolic, with or without treatment.

(4) Applicants who have commenced the use of medication for the control of blood pressure shall be assessed as unfit until the absence of significant side effects has been established.

(d) *Coronary Artery Disease*

(1) Before further consideration is given to their application, applicants for a class 1 medical certificate with any of the following medical conditions shall be referred to the medical assessor of the licensing authority and undergo cardiological evaluation to exclude myocardial ischaemia:

(i) suspected myocardial ischaemia;

(ii) asymptomatic minor coronary artery disease requiring no anti-anginal treatment.

(2) Before further consideration is given to their application, applicants for a class 2 medical certificate with any of the medical conditions set out in point (1) shall undergo satisfactory cardiological evaluation.

(3) Applicants with any of the following medical conditions shall be assessed as unfit:

(i) myocardial ischaemia;

(ii) symptomatic coronary artery disease;

(iii) symptoms of coronary artery disease controlled by medication.

(4) Applicants for the initial issue of a class 1 medical certificate with a medical history or diagnosis of any of the following medical conditions shall be assessed as unfit:

(i) myocardial ischaemia;

(ii) myocardial infarction;

(iii) revascularisation or stenting for coronary artery disease.

(5) Before further consideration is given to their application, applicants for a class 2 medical certificate who are asymptomatic following myocardial infarction or surgery for coronary artery disease shall undergo satisfactory cardiological evaluation, in consultation with the medical assessor of the licensing authority. Such applicants for the revalidation of a class 1 medical certificate shall be referred to the medical assessor of the licensing authority.

(e) *Rhythm/Conduction Disturbances*

(1) Applicants with any of the following medical conditions shall be assessed as unfit:

(i) symptomatic sinoatrial disease;

(ii) complete atrioventricular block;

(iii) symptomatic QT prolongation;

(iv) an automatic implantable defibrillating system;

(v) a ventricular anti-tachycardia pacemaker.

(2) Before further consideration is given to their application, applicants for a class 1 medical certificate havingany significant disturbance of cardiac conduction or rhythm, including any of the following, shall be referred to the medical assessor of the licensing authority:

(i) disturbance of supraventricular rhythm, including intermittent or established sinoatrial dysfunction, atrial fibrillation and/or flutter and asymptomatic sinus pauses;

(ii) complete left bundle branch block;

(iii) Mobitz type 2 atrioventricular block;

(iv) broad and/or narrow complex tachycardia;

(v) ventricular pre-excitation;

(vi) asymptomatic QT prolongation;

(vii) Brugada pattern on electrocardiography.

(3) Before further consideration is given to their application, applicants for a class 2 medical certificate with any of the medical conditions specified in point (2) shall undergo satisfactory cardiological evaluation, in consultation with the medical assessor of the licensing authority.

(4) Applicants with any of the following medical conditions may be assessed as fit subject to satisfactory cardiological evaluation and in the absence of any other abnormality:

(i) incomplete bundle branch block;

(ii) complete right bundle branch block;

(iii) stable left axis deviation;

(iv) asymptomatic sinus bradycardia;

(v) asymptomatic sinus tachycardia;

(vi) asymptomatic isolated uniform supra-ventricular or ventricular ectopic complexes;

(vii) first degree atrioventricular block;

(viii) Mobitz type 1 atrioventricular block.

(5) Applicants with a medical history of any of the following medical conditions shall undergo satisfactory cardiovascular evaluation before they may be assessed as fit:

(i) ablation therapy;

(ii) pacemaker implantation.

Such applicants for a class 1 medical certificate shall be referred to the medical assessor of the licensing authority. Such applicants for a class 2 medical certificate shall be assessed in consultation with the medical assessor of the licensing authority.

AMC1 MED.B.010 Cardiovascular system

ED Decision 2019/002/R

(a) Examination

Exercise electrocardiography

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

(b) General

(1) Cardiovascular risk factor assessment

(i) Serum lipid estimation is case finding and significant abnormalities should be reviewed, investigated and supervised by the AeMC or AME in consultation with the medical assessor of the licensing authority.

(ii) Applicants with an accumulation of risk factors (smoking, family history, lipid abnormalities, hypertension, etc.) should undergo a cardiovascular evaluation by the AeMC or AME, if necessary in consultation with the medical assessor of the licensing authority.

(2) Cardiovascular assessment

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

(ii) The extended cardiovascular assessment should be undertaken at an AeMC or may be delegated to a cardiologist.

(c) Peripheral arterial disease

If there is no significant functional impairment, a fit assessment may be considered provided:

(1) applicants without symptoms of coronary artery disease have reduced any vascular risk factors to an appropriate level;

(2) applicants should be on appropriate secondary prevention treatment;

(3) exercise electrocardiography is satisfactory. Further tests may be required which should show no evidence of myocardial ischaemia or significant coronary artery stenosis.

(d) Aortic aneurysm

(1) Applicants with an aneurysm of the infra-renal abdominal aorta of less than 5 cm in diameter may be assessed as fit before surgery, with an OML subject to satisfactory

evaluation by a cardiologist. Follow-up by ultra-sound scans or other imaging techniques, as necessary, should be determined by the medical assessor of the licensing authority.

(2) Applicants may be assessed as fit with an OML after surgery for an aneurysm of the thoracic or abdominal aorta if the blood pressure and cardiovascular evaluation is satisfactory. Regular evaluations by a cardiologist should be carried out.

(e) Cardiac valvular abnormalities

(1) Applicants with previously unrecognised cardiac murmurs should undergo evaluation by a cardiologist and assessment by the medical assessor of the licensing authority. If considered significant, further investigation should include at least 2D Doppler echocardiography or equivalent imaging.

(2) Applicants with minor cardiac valvular abnormalities may be assessed as fit. Applicants with significant abnormality of any of the heart valves should be assessed as unfit.

(3) Aortic valve disease

(i) Applicants with a bicuspid aortic valve may be assessed as fit if no other cardiac or aortic abnormality is demonstrated. Follow-up with echocardiography, as necessary, should be determined by the medical assessor of the licensing authority.

(ii) Applicants with aortic stenosis may be assessed as fit provided the left ventricular function is intact and the mean pressure gradient is less than 20 mmHg. Applicants with an aortic valve orifice with indexation on the body surface of more than 0.6 cm^2/m^2 and a mean pressure gradient above 20 mmHg, but not greater than 50 mmHg, may be assessed as fit with an OML. Follow-up with 2D Doppler echocardiography, as necessary, should be determined by the medical assessor of the licensing authority in all cases. Alternative measurement techniques with equivalent ranges may be used. Regular evaluation by a cardiologist should be considered. Applicants with a history of systemic embolism or significant dilatation of the thoracic aorta should be assessed as unfit.

(iii) Applicants with trivial aortic regurgitation may be assessed as fit. A greater degree of aortic regurgitation should require an OML. There should be no demonstrable abnormality of the ascending aorta on 2D Doppler echocardiography. Follow-up, as necessary, should be determined by the medical assessor of the licensing authority.

(4) Mitral valve disease

(i) Asymptomatic applicants with an isolated mid-systolic click due to mitral leaflet prolapse may be assessed as fit.

(ii) Applicants with rheumatic mitral stenosis should normally be assessed as unfit.

(iii) Applicants with minor regurgitation may be assessed as fit. Periodic cardiological review should be determined by the medical assessor of the licensing authority.

(iv) Applicants with moderate mitral regurgitation may be considered as fit with an OML 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 medical assessor of the licensing authority.

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

(f) Valvular surgery

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

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

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

(i) a satisfactory symptom limited exercise ECG. Myocardial perfusion imaging/stress echocardiography should be required if the exercise ECG is abnormal or any coronary artery disease is suspected;

(ii) a 2D Doppler echocardiogram showing no significant selective chamber enlargement, a tissue valve with minimal structural alteration and a normal Doppler blood flow, and no structural or functional abnormality of the other heart valves. Left ventricular fractional shortening should be normal.

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

(3) Where anticoagulation is needed after valvular surgery, a fit assessment with an OML may be considered if the haemorrhagic risk is acceptable and the anticoagulation is stable. Anticoagulation should be considered stable if, within the last 6 months, at least 5 international normalised ratio (INR) values are documented, of which at least 4 are within the INR target range. The INR target range should be determined by the type of surgery performed.

(g) Thromboembolic disorders

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

(h) Other cardiac disorders

(1) Applicants with a primary or secondary abnormality of the pericardium, myocardium or endocardium should be assessed as unfit. A fit assessment may be considered following complete resolution and satisfactory cardiological evaluation which may include 2D Doppler echocardiography, exercise ECG and/or myocardial perfusion imaging/stress

echocardiography and 24-hour ambulatory ECG. Coronary angiography may be indicated. Frequent review and an OML may be required after fit assessment.

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

(i) Syncope

(1) In the case of a single episode of vasovagal syncope which can be explained and is compatible with flight safety, a fit assessment may be considered.

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

(i) a satisfactory symptom limited 12 lead exercise ECG to Bruce Stage IV, or equivalent. If the exercise ECG is abnormal, myocardial perfusion imaging/stress echocardiography or equivalent test should be carried out;

(ii) a 2D Doppler echocardiogram showing neither significant selective chamber enlargement nor structural or functional abnormality of the heart, valves or myocardium;

(iii) a 24-hour ambulatory ECG recording showing no conduction disturbance, complex or sustained rhythm disturbance or evidence of myocardial ischaemia.

(3) A tilt test, or equivalent, carried out to a standard protocol showing no evidence of vasomotor instability may be required.

(4) Neurological review should be required.

(5) An OML should be required until a period of 5 years has elapsed without recurrence. The medical assessor of the licensing authority may determine a shorter or longer period of OML according to the individual circumstances of the case.

(6) Applicants who experienced loss of consciousness without significant warning should be assessed as unfit.

(j) Blood pressure

(1) The diagnosis of hypertension should require cardiovascular evaluation to include potential vascular risk factors.

(2) Anti-hypertensive treatment should be agreed by the medical assessor of the licensing authority. Acceptable medication may include:

(i) non-loop diuretic agents;

(ii) ACE inhibitors;

(iii) angiotensin II receptor blocking agents (sartans);

(iv) channel calcium blocking agents;

(v) certain (generally hydrophilic) beta-blocking agents.

(3) Following initiation of medication for the control of blood pressure, applicants should be re-assessed to verify that satisfactory control has been achieved and the treatment is compatible with the safe exercise of the privileges of the applicable licence(s).

(k) Coronary artery disease

(1) Chest pain of uncertain cause should require full investigation. Applicants with angina pectoris should be assessed as unfit, whether or not it is alleviated by medication.

(2) In suspected asymptomatic coronary artery disease, exercise electrocardiography should be required. Further tests may be required, which should show no evidence of myocardial ischaemia or significant coronary artery stenosis.

(3) Applicants with evidence of exercise-induced myocardial ischaemia should be assessed as unfit.

(4) After an ischaemic cardiac event or revascularisation procedure, applicants should have reduced cardiovascular risk factors to an appropriate level. Medication, when used to control cardiac symptoms, is not acceptable. All applicants should be on appropriate secondary prevention treatment.

(i) A coronary angiogram obtained around the time of, or during, the ischaemic myocardial event or revasculisation procedure and a complete, detailed clinical report of the ischaemic event and of any operative procedures should be made available to the medical assessor of the licensing authority:

(A) there should be no stenosis more than 50 % in any major untreated vessel, in any vein or artery graft or at the site of an angioplasty/stent, except in a vessel subtending a myocardial infarction;

(B) the whole coronary vascular tree should be assessed as satisfactory by a cardiologist, and particular attention should be paid to multiple stenoses and/or multiple revascularisations;

(C) Applicants with an untreated stenosis greater than 30 % in the left main or proximal left anterior descending coronary artery should be assessed as unfit.

(ii) At least 6 months from the ischaemic myocardial event or revascularisation procedure, the following investigations should be completed (equivalent tests may be substituted):

(A) an exercise ECG showing neither evidence of myocardial ischaemia nor rhythm or conduction disturbance;

(B) an echocardiogram showing satisfactory left ventricular function with no important abnormality of wall motion (such as dyskinesia or akinesia) and a left ventricular ejection fraction of 50 % or more;

(C) in cases of angioplasty/stenting, a myocardial perfusion scan or stress echocardiogram, or equivalent test, which should show no evidence of reversible myocardial ischaemia. If there is any doubt about myocardial perfusion in other cases (infarction or bypass grafting) a perfusion scan, or equivalent test, should also be carried out;

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

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

(A) 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 5 years from the procedure.

(B) In all cases, coronary angiography should be considered at any time if symptoms, signs or non-invasive tests indicate myocardial ischaemia.

(iv) Successful completion of the 6-month or subsequent review will allow a fit assessment with an OML.

(l) Rhythm and conduction disturbances

(1) Applicants with significant rhythm or conduction disturbance should undergo evaluation by a cardiologist before a fit assessment with an OML, as necessary, may be considered. Appropriate follow-up should be carried out at regular intervals. Such evaluation should include:

(i) exercise ECG to the Bruce protocol or equivalent. Bruce stage 4 should be achieved and no significant abnormality of rhythm or conduction, or evidence of myocardial ischaemia should be demonstrated. Withdrawal of cardioactive medication prior to the test should normally be required;

(ii) 24-hour ambulatory ECG which should demonstrate no significant rhythm or conduction disturbance;

(iii) 2D Doppler echocardiogram which should show no significant selective chamber enlargement or significant structural or functional abnormality, and a left ventricular ejection fraction of at least 50 %.

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

(iv) 24-hour ECG recording repeated as necessary;

(v) electrophysiological study;

(vi) myocardial perfusion imaging;

(vii) cardiac magnetic resonance imaging (MRI);

(viii) coronary angiogram.

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

(3) Where anticoagulation is needed for a rhythm disturbance, a fit assessment with an OML may be considered if the haemorrhagic risk is acceptable and the anticoagulation is stable. Anticoagulation should be considered stable if, within the last 6 months, at least 5 INR values are documented, of which at least 4 are within the INR target range. In cases of anticoagulation medication not requiring INR monitoring, a fit assessment with an OML may be considered after review by the medical assessor of the licensing authority after a stabilisation period of 3 months.

(4) Ablation

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

(5) Supraventricular arrhythmias

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

(i) Atrial fibrillation/flutter

(A) For initial applicants, a fit assessment should be limited to those with a single episode of arrhythmia which is considered by the medical assessor of the licensing authority to be unlikely to recur.

(B) For revalidation, applicants may be assessed as fit if cardiological evaluation is satisfactory and the stroke risk is sufficiently low. A fit assessment with an OML may be considered after a period of stable anticoagulation as prophylaxis, after review by the medical assessor of the licensing authority. Anticoagulation should be considered stable if, within the last 6 months, at least 5 INR values are documented, of which at least 4 are within the INR target range. In cases of anticoagulation medication not requiring INR monitoring, a fit assessment with an OML may be considered after review by the medical assessor of the licensing authority after a stabilisation period of 3 months.

(ii) Applicants with asymptomatic sinus pauses up to 2.5 seconds on resting electrocardiography may be assessed as fit if exercise electrocardiography, echocardiography and 24-hour ambulatory ECG are satisfactory.

(iii) Applicants with symptomatic sino-atrial disease should be assessed as unfit.

(6) Mobitz type 2 atrio-ventricular block

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

(7) Complete right bundle branch block

(i) Applicants with complete right bundle branch block should undergo a cardiological evaluation on first presentation. A fit assessment may be considered if there is no underlying pathology.

(ii) Applicants with bifascicular block may be assessed as fit with an OML after a satisfactory cardiological evaluation. The OML may be considered for removal if an electrophysiological study demonstrates no infra-Hissian block, or a 3-year period of satisfactory surveillance has been completed.

(8) Complete left bundle branch block

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

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

(9) Ventricular pre-excitation

(i) Asymptomatic initial applicants with pre-excitation may be assessed as fit if an electrophysiological study, including adequate drug-induced autonomic stimulation reveals no inducible re-entry tachycardia and the existence of multiple pathways is excluded.

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

(10) Pacemaker

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

(i) there is no other disqualifying condition;

(ii) a bipolar lead system, programmed in bipolar mode without automatic mode change has been used;

(iii) the applicant is not pacemaker dependent; and

(iv) the applicant has a follow-up at least every 12 months, including a pacemaker check.

(11) QT prolongation

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

(12) Brugada pattern on electrocardiography

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

AMC2 MED.B.010 Cardiovascular system

ED Decision 2019/002/R

(a) Examination

Exercise electrocardiography

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

(b) General

(1) Cardiovascular risk factor assessment

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

(2) Cardiovascular assessment

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

(c) Peripheral arterial disease

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

(d) Aortic aneurysm

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

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

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

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

(e) Cardiac valvular abnormalities

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

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

(3) Aortic valve disease

(i) Applicants with a bicuspid aortic valve may be assessed as fit if no other cardiac or aortic abnormality is demonstrated. Follow-up with echocardiography, as necessary, should be determined in consultation with the medical assessor of the licensing authority.

(ii) Applicants with aortic stenosis may be assessed as fit provided the left ventricular function is intact and the mean pressure gradient is less than 20 mmHg. Applicants with an aortic valve orifice of more than 1 cm^2 and a mean pressure gradient above 20 mmHg, but not greater than 50 mmHg, may be assessed as fit with an ORL or OSL. Follow-up with 2D Doppler echocardiography, as necessary, should be determined in consultation with the medical assessor of the licensing authority in all cases. Alternative measurement techniques with equivalent ranges may be

used. Regular cardiological evaluation should be considered. Applicants with a history of systemic embolism or significant dilatation of the thoracic aorta should be assessed as unfit.

(iii) Applicants with trivial aortic regurgitation may be assessed as fit. Applicants with a greater degree of aortic regurgitation may be assessed as fit with an OSL. There should be no demonstrable abnormality of the ascending aorta on 2D Doppler echocardiography. Follow-up, as necessary, should be determined in consultation with the medical assessor of the licensing authority.

(4) Mitral valve disease

(i) Asymptomatic applicants with an isolated mid-systolic click due to mitral leaflet prolapse may be assessed as fit.

(ii) Applicants with rheumatic mitral stenosis should be assessed as unfit.

(iii) Applicants with minor regurgitation may be assessed as fit. Periodic cardiological review should be determined in consultation with the medical assessor of the licensing authority.

(iv) Applicants with moderate mitral regurgitation may be considered as fit with an ORL or OSL if the 2D Doppler echocardiogram demonstrates satisfactory left ventricular dimensions and satisfactory myocardial function is confirmed by exercise electrocardiography. Periodic cardiological review should be determined in consultation with the medical assessor of the licensing authority.

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

(f) Valvular surgery

(1) Applicants who have undergone cardiac valve replacement or repair may be assessed as fit without limitations subject to satisfactory post-operative cardiological evaluation and if no anticoagulants are needed.

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

(g) Thromboembolic disorders

Applicants with arterial or venous thrombosis or pulmonary embolism should be assessed as unfit. A fit assessment with an ORL or OSL may be considered after a period of stable anticoagulation as prophylaxis in consultation with the medical assessor of the licensing authority. Anticoagulation should be considered stable if, within the last 6 months, at least 5

INR values are documented, of which at least 4 are within the INR target range and the haemorrhagic risk is acceptable. Applicants who measure their INR on a 'near patient' testing system within 12 hours prior to flight and only exercise the privileges of their licence(s) if the INR is within the target range may be assessed as fit without the above-mentioned limitation. The INR results should be recorded and the results should be reviewed at each aero-medical assessment. Applicants taking anticoagulation medication not requiring INR monitoring, may be assessed as fit without the above-mentioned limitation in consultation with the medical assessor of the licensing authority after a stabilisation period of 3 months. Applicants with pulmonary embolism should also undergo a cardiological evaluation. Following cessation of anticoagulant therapy for any indication, applicants should undergo a re-assessment in consultation with the medical assessor of the licensing authority.

(h) Other cardiac disorders

(1) Applicants with a primary or secondary abnormality of the pericardium, myocardium or endocardium may be assessed as fit subject to satisfactory cardiological evaluation.

(2) Applicants with a congenital abnormality of the heart, including those who have undergone surgical correction, may be assessed as fit subject to satisfactory cardiological evaluation. Cardiological follow-up may be necessary and should be determined in consultation with the medical assessor of the licensing authority.

(i) Syncope

(1) In the case of a single episode of vasovagal syncope which can be explained and is compatible with flight safety, a fit assessment may be considered.

(2) Applicants with a history of recurrent vasovagal syncope should be assessed as unfit. A fit assessment may be considered after a 6-month period without recurrence, providing cardiological evaluation is satisfactory. Neurological review may be indicated.

(j) Blood pressure

(1) When the blood pressure at examination consistently exceeds 160 mmHg systolic and/or 95 mmHg diastolic, with or without treatment, the applicant should be assessed as unfit.

(2) The diagnosis of hypertension requires review of other potential vascular risk factors.

(3) Applicants with symptomatic hypotension should be assessed as unfit.

(4) Anti-hypertensive treatment should be compatible with flight safety.

(5) Following initiation of medication for the control of blood pressure, applicants should be re-assessed to verify that satisfactory control has been achieved and that the treatment is compatible with the safe exercise of the privileges of the applicable licence(s).

(k) Coronary artery disease

(1) Chest pain of uncertain cause requires full investigation.

(2) Applicants with suspected asymptomatic coronary artery disease should undergo cardiological evaluation which should show no evidence of myocardial ischaemia or significant coronary artery stenosis.

(3) Applicants with evidence of exercise-induced myocardial ischaemia should be assessed as unfit.

(4) After an ischaemic cardiac event, or revascularisation, applicants without symptoms should have reduced cardiovascular risk factors to an appropriate level. Medication,

when used to control angina pectoris, is not acceptable. All applicants should be on appropriate secondary prevention treatment.

(i) A coronary angiogram obtained around the time of, or during, the ischaemic myocardial event and a complete, detailed clinical report of the ischaemic event and of any operative procedures should be available to the AME.

(A) There should be no stenosis more than 50 % in any major untreated vessel, in any vein or artery graft or at the site of an angioplasty/stent, except in a vessel subtending a myocardial infarction.

(B) The whole coronary vascular tree should be assessed as satisfactory by a cardiologist and particular attention should be paid to multiple stenoses and/or multiple revascularisations.

(C) Applicants with an untreated stenosis greater than 30 % in the left main or proximal left anterior descending coronary artery should be assessed as unfit.

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

(A) an exercise ECG showing neither evidence of myocardial ischaemia nor rhythm disturbance;

(B) an echocardiogram showing satisfactory left ventricular function with no important abnormality of wall motion and a satisfactory left ventricular ejection fraction of 50 % or more;

(C) in cases of angioplasty/stenting, a myocardial perfusion scan or stress echocardiogram, or equivalent test, which should show no evidence of reversible myocardial ischaemia. If there is doubt about revascularisation in myocardial infarction or bypass grafting, a perfusion scan, or equivalent test, should also be carried out;

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

(iii) Periodic follow-up should include a cardiological evaluation.

(A) 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 five years from the procedure for a fit assessment without an OSL, OPL or ORL.

(B) In all cases, coronary angiography should be considered at any time if symptoms, signs or non-invasive tests indicate myocardial ischaemia.

(iv) Successful completion of the six-month or subsequent review will allow a fit assessment. Applicants may be assessed as fit with an ORL or OSL having successfully completed only an exercise ECG.

(5) Applicants with angina pectoris should be assessed as unfit, whether or not it is alleviated by medication.

(l) Rhythm and conduction disturbances

(1) Applicants with significant rhythm or conduction disturbance should undergo cardiological evaluation before a fit assessment may be considered with an ORL or OSL, as appropriate. Such evaluation should include:

(i) exercise ECG to the Bruce protocol or equivalent. Bruce stage 4 should be achieved and no significant abnormality of rhythm or conduction, or evidence of myocardial ischaemia should be demonstrated. Withdrawal of cardioactive medication prior to the test should normally be required;

(ii) 24-hour ambulatory ECG which should demonstrate no significant rhythm or conduction disturbance;

(iii) 2D Doppler echocardiogram which should show no significant selective chamber enlargement or significant structural or functional abnormality, and a left ventricular ejection fraction of at least 50 %.

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

(iv) 24-hour ECG recording repeated as necessary;

(v) electrophysiological study;

(vi) myocardial perfusion imaging;

(vii) cardiac magnetic resonance imaging (MRI);

(viii) coronary angiogram.

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

(3) Ablation

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

(4) Supraventricular arrhythmias

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

(ii) Applicants with atrial fibrillation/flutter may be assessed as fit if cardiological evaluation is satisfactory and the stroke risk is sufficiently low. Where anticoagulation is needed, a fit assessment with an ORL or OSL may be considered after a period of stable anticoagulation as prophylaxis, in consultation with the medical assessor of the licensing authority. Anticoagulation should be considered stable if, within the last 6 months, at least 5 INR values are documented, of which

at least 4 are within the INR target range. Applicants who measure their INR on a 'near patient' testing system within 12 hours prior to flight and only exercise the privileges of their licence(s) if the INR is within the target range may be assessed as fit without the above-mentioned limitation. The INR results should be recorded and the results should be reviewed at each aero-medical assessment. Applicants taking anticoagulation medication not requiring INR monitoring, may be assessed as fit without the above-mentioned limitation in consultation with the medical assessor of the licensing authority after a stabilisation period of 3 months.

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

(5) Heart block

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

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

(6) Complete right bundle branch block

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

(7) Complete left bundle branch block

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

(8) Ventricular pre-excitation

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

(9) Pacemaker

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

(i) there is no other disqualifying condition;

(ii) a bipolar lead system, programmed in bipolar mode without automatic mode change, has been used;

(iii) the applicant is not pacemaker dependent; and

(iv) the applicant has a follow-up at least every 12 months, including a pacemaker check.

(10) QT prolongation

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

(11) Brugada pattern on electrocardiography

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

(m) Heart or heart/lung transplantation

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

(i) no rejection in the first year following transplantation;

(ii) no significant arrhythmias;

(iii) a left ventricular ejection fraction ≥ 50%;

(iv) a symptom limited exercise ECG; and

(v) a coronary angiogram if indicated;

(2) Regular cardiological evaluations should be carried out.

GM1 MED.B.010 Cardiovascular system

ED Decision 2019/002/R

MITRAL VALVE DISEASE

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

(b) The following may indicate severe regurgitation:

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

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

(3) Left atrial internal diameter > 4.5 cm.

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

GM2 MED.B.010 Cardiovascular system

ED Decision 2019/002/R

VENTRICULAR PRE-EXCITATION

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

(a) refractory period > 300 ms;

(b) no induced atrial fibrillation.

GM3 MED.B.010 Cardiovascular system

ED Decision 2019/002/R

ANTICOAGULATION

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

GM4 MED.B.010 Cardiovascular system

ED Decision 2019/002/R

MITRAL VALVE DISEASE

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

(b) The following may indicate severe regurgitation:

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

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

(3) Left atrial internal diameter > 4.5 cm.

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

GM5 MED.B.010 Cardiovascular system

ED Decision 2019/002/R

VENTRICULAR PRE-EXCITATION

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

(a) no inducible re-entry tachycardia;

(b) refractory period > 300 ms;

(c) no induced atrial fibrillation;

(d) no evidence of multiple accessory pathways.

MED.B.015 Respiratory System

Regulation (EU) 2019/27

(a) Applicants with significant impairment of pulmonary function shall be assessed as unfit. However, they may be assessed as fit once pulmonary function has recovered and is satisfactory.

(b) Applicants for a class 1 medical certificate shall undertake pulmonary morphological and functional tests at the initial examination and when clinically indicated.

(c) Applicants for a class 2 medical certificate shall undertake pulmonary morphological and functional tests when clinically indicated.

(d) Applicants with a medical history or diagnosis of any of the following medical conditions shall undertake respiratory evaluation with a satisfactory result before they may be assessed as fit:

(1) asthma requiring medication;

(2) active inflammatory disease of the respiratory system;

(3) active sarcoidosis;

(4) pneumothorax;

(5) sleep apnoea syndrome;

(6) major thoracic surgery;

(7) pneumonectomy;

(8) chronic obstructive pulmonary disease.

Before further consideration is given to their application, applicants with an established diagnosis of any of the medical conditions specified in points (3) and (5) shall undergo satisfactory cardiological evaluation.

(e) Aero-medical assessment

(1) Applicants for a class 1 medical certificate with any of the medical conditions specified in point (d) shall be referred to the medical assessor of the licensing authority.

(2) Applicants for a class 2 medical certificate with any of the medical conditions specified in point (d) shall be assessed in consultation with the medical assessor of the licensing authority.

(f) Applicants for a class 1 medical certificate who have undergone a pneumonectomy shall be assessed as unfit.

AMC1 MED.B.015 Respiratory system

ED Decision 2019/002/R

(a) Examination

(1) Spirometry

A spirometric examination is required for initial examination and on clinical indication. Applicants with an FEV1/FVC ratio of less than 70 % should be evaluated by a specialist in respiratory disease.

(2) Chest radiography

Posterior/anterior chest radiography may be required at initial, revalidation or renewal examinations if clinically or epidemiologically indicated

(b) Chronic obstructive pulmonary disease

Applicants with chronic obstructive pulmonary disease should be assessed as unfit. Applicants with only minor impairment of pulmonary function may be assessed as fit.

(c) Asthma

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

(d) Inflammatory disease

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

(e) Sarcoidosis

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

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

(f) Pneumothorax

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

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

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

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

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

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

(g) Thoracic surgery

(1) Applicants requiring major thoracic surgery should be assessed as unfit until recovery is complete, the applicant is asymptomatic, and the risk of secondary complication is minimal.

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

(h) Sleep apnoea syndrome/sleep disorder

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

AMC2 MED.B.015 Respiratory system

ED Decision 2019/002/R

(a) Examination

(1) A spirometric examination should be performed on clinical indication. Applicants with a forced expiratory volume in the first one second (FEV1)/forced vital capacity (FVC) ratio of less than 70 % should be evaluated by a specialist in respiratory disease.

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

(b) Chronic obstructive pulmonary disease

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

(c) Asthma

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

(d) Inflammatory disease

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

(e) Sarcoidosis

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

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

(f) Pneumothorax

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

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

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

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

(g) Thoracic surgery

Applicants requiring major thoracic surgery should be assessed as unfit until recovery is complete, the applicant is asymptomatic, and the risk of secondary complication is minimal.

(h) Sleep apnoea syndrome

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

MED.B.020 Digestive System

Regulation (EU) 2019/27

(a) Applicants with any sequelae of disease or surgical intervention in any part of the digestive tract or its adnexa likely to cause incapacitation in flight, in particular any obstruction due to stricture or compression, shall be assessed as unfit.

(b) Applicants who have herniae that might give rise to incapacitating symptoms shall be assessed as unfit.

(c) Applicants with any of the following disorders of the gastrointestinal system may be assessed as fit subject to satisfactory gastrointestinal evaluation after successful treatment or full recovery after surgery:

(1) recurrent dyspeptic disorder requiring medication;

(2) pancreatitis;

(3) symptomatic gallstones;

(4) a clinical diagnosis or documented medical history of chronic inflammatory bowel disease;

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

(d) Aero-medical assessment

(1) Applicants for a class 1 medical certificate with the diagnosis of any of the medical conditions specified in points (2), (4) and (5) of point (c) shall be referred to the medical assessor of the licensing authority.

(2) The fitness of applicants for a class 2 medical certificate with the diagnosis of the medical condition specified in point (2) of point (c) shall be assessed in consultation with the medical assessor of the licensing authority.

AMC1 MED.B.020 Digestive system

ED Decision 2019/002/R

(a) Oesophageal varices

Applicants with oesophageal varices should be assessed as unfit.

(b) Pancreatitis

Applicants with pancreatitis should be assessed as unfit pending assessment. A fit assessment may be considered if the cause is removed.

(c) Gallstones

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

(2) Applicants with asymptomatic multiple gallstones may be assessed as fit with an OML.

(d) Inflammatory bowel disease

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

(e) Peptic ulceration

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

(f) Digestive tract and abdominal surgery

Applicants who have undergone a surgical operation for medical conditions of the digestive tract or its adnexa, including a total or partial excision or a diversion of any of these organs or herniae should be assessed as unfit. A fit assessment may be considered if recovery is complete, the applicant is asymptomatic, and there is only a minimal risk of secondary complication or recurrence.

(g) Liver disease

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

AMC2 MED.B.020 Digestive system

ED Decision 2019/002/R

(a) Oesophageal varices

Applicants with oesophageal varices should be assessed as unfit.

(b) Pancreatitis

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

(c) Gallstones

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

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

(d) Inflammatory bowel disease

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

(e) Peptic ulceration

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

(f) Digestive tract and abdominal surgery

Applicants who have undergone a surgical operation:

(1) for herniae; or

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

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

(g) Liver disease

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

MED.B.025 Metabolic and Endocrine Systems

Regulation (EU) 2019/27

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

(b) *Diabetes mellitus*

(1) Applicants with diabetes mellitus requiring insulin shall be assessed as unfit.

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

(c) Aero-medical assessment

(1) Applicants for a class 1 medical certificate requiring medication other than insulin for blood sugar control shall be referred to the medical assessor of the licensing authority.

(2) The fitness of applicants for a class 2 medical certificate requiring medication other than insulin for blood sugar control shall be assessed in consultation with the medical assessor of the licensing authority.

AMC1 MED.B.025 Metabolic and endocrine systems

ED Decision 2019/002/R

(a) Metabolic, nutritional or endocrine dysfunction

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

(b) Obesity

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

(c) Addison's disease

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

(d) Gout

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

(e) Thyroid dysfunction

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

(f) Abnormal glucose metabolism

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

(g) Diabetes mellitus

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

(1) applicants with diabetes mellitus not requiring medication may be assessed as fit;

(2) the use of antidiabetic medications that are not likely to cause hypoglycaemia may be acceptable for a fit assessment with an OML.

AMC2 MED.B.025 Metabolic and endocrine systems

ED Decision 2019/002/R

(a) Metabolic, nutritional or endocrine dysfunction

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

(b) Obesity

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

(c) Addison's disease

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

(d) Gout

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

(e) Thyroid dysfunction

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

(f) Abnormal glucose metabolism

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

(g) Diabetes mellitus

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

MED.B.030 Haematology

Regulation (EU) 2019/27

(a) Applicants for a class 1 medical certificate shall be subjected to an haemoglobin test at each aero-medical examination.

(b) Applicants with a haematological condition may be assessed as fit subject to satisfactory aero-medical evaluation.

(c) Applicants for a class 1 medical certificate with any of the following haematological conditions shall be referred to the medical assessor of the licensing authority:

(1) abnormal haemoglobin, including, but not limited to anaemia, erythrocytosis or haemoglobinopathy;

(2) significant lymphatic enlargement;

(3) enlargement of the spleen;

(4) coagulation, haemorrhagic or thrombotic disorder;

(5) leukaemia.

(d) The fitness of applicants for a class 2 medical certificate with any of the haematological conditions specified in points (4) and (5) of point (c) shall be assessed in consultation with the medical assessor of the licensing authority.

AMC1 MED.B.030 Haematology

ED Decision 2019/002/R

(a) Abnormal haemoglobin

Applicants with abnormal haemoglobin should be investigated.

(b) Anaemia

(1) Applicants with anaemia demonstrated by a reduced haemoglobin level require investigation. Applicants with an haematocrit of less than 32 % should be assessed as unfit. A fit assessment may be considered in cases where the primary cause, such as iron or B12 deficiency, has been treated and the haemoglobin or haematocrit has stabilised at a satisfactory level.

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

(c) Erythrocytosis

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

(d) Haemoglobinopathy

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

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

(e) Coagulation disorders

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

(2) Applicants with thrombocytopenia with a platelet count less than $75x10^9$/L should be assessed as unfit. A fit assessment may be considered once the platelet count is above $75x10^9$/L and stable.

(f) Haemorrhagic disorders

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

(g) Thromboembolic disorders

(1) Applicants with a thrombotic disorder require investigation. A fit assessment may be considered when the applicant is asymptomatic and there is only minimal risk of secondary complication or recurrence.

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

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

(h) Disorders of the lymphatic system

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

(i) Leukaemia

(1) Applicants with acute leukaemia should be assessed as unfit. Once in established remission, applicants may be assessed as fit.

(2) Applicants with chronic leukaemia should be assessed as unfit. After a period of demonstrated stability a fit assessment may be considered.

(3) Applicants with a history of leukaemia should have no history of central nervous system involvement and no continuing side-effects from treatment of flight safety importance. Haemoglobin and platelet levels should be satisfactory. Regular follow-up is required.

(j) Splenomegaly

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

AMC2 MED.B.030 Haematology

ED Decision 2019/002/R

(a) Abnormal haemoglobin

Haemoglobin should be tested when clinically indicated.

(b) Anaemia

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

(c) Erythrocytosis

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

(d) Haemoglobinopathy

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

(e) Coagulation and haemorrhagic disorders

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

(f) Thromboembolic disorders

Applicants with a thrombotic disorder may be assessed as fit if there is minimal likelihood of significant clotting episodes. If anticoagulation is used as treatment, refer to AMC2 MED.B.010(g).

(g) Disorders of the lymphatic system

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

(h) Leukaemia

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

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

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

(i) Splenomegaly

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

MED.B.035 Genitourinary System

Regulation (EU) 2019/27

(a) Urinalysis shall form part of each aero-medical examination. Applicants shall be assessed as unfit where their urine contains abnormal elements considered to be of pathological significance that could entail a degree of functional incapacity which is likely to jeopardise the safe exercise of the privileges of the license or could render the applicant likely to become suddenly unable to exercise those privileges.

(b) Applicants with any sequelae of disease or surgical procedures on the genitourinary system or its adnexa likely to cause incapacitation, in particular any obstruction due to stricture or compression, shall be assessed as unfit.

(c) Applicants with a diagnosis or medical history of the following may be assessed as fit subject to satisfactory genitourinary evaluation, as applicable:

(1) renal disease;

(2) one or more urinary calculi, or a medical history of renal colic.

(d) Applicants who have undergone a major surgical operation in the genitourinary system or its adnexa involving a total or partial excision or a diversion of their organs shall be assessed as unfit. However, after full recovery, they may be assessed as fit.

(e) The applicants for a class 1 medical certificate referred to in points (c) and (d) shall be referred to the medical assessor of the licensing authority.

AMC1 MED.B.035 Genitourinary system

ED Decision 2019/002/R

(a) Abnormal urinalysis

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

(b) Renal disease

(1) Applicants presenting with any signs of renal disease should be assessed as unfit. A fit assessment may be considered if blood pressure is satisfactory and renal function is acceptable.

(2) Applicants requiring dialysis should be assessed as unfit.

(c) Urinary calculi

(1) Applicants with an asymptomatic calculus or a history of renal colic require investigation.

(2) Applicants presenting with one or more urinary calculi should be assessed as unfit and require investigation.

(3) Whilst awaiting assessment or treatment, a fit assessment with an OML may be considered.

(4) After successful treatment for a calculus a fit assessment without an OML may be considered.

(5) Applicants with parenchymal residual calculi may be considered for a fit assessment with an OML.

(d) Renal and urological surgery

(1) Applicants who have undergone a major surgical operation on the genitourinary system or its adnexa involving a total or partial excision or a diversion of any of its organs, should be assessed as unfit until recovery is complete, the applicant is asymptomatic, and the risk of secondary complication is minimal.

(2) After other urological surgery, a fit assessment may be considered when the applicant is completely asymptomatic and there is only minimal risk of secondary complication or recurrence.

(3) Applicants with compensated nephrectomy without hypertension or uraemia may be considered for a fit assessment.

(4) Applicants who have undergone renal transplantation may be considered for a fit assessment with an OML if it is fully compensated and tolerated with only minimal immuno-suppressive therapy after at least 12 months.

(5) Applicants who have undergone total cystectomy may be considered for a fit assessment with an OML if there is satisfactory urinary function, no infection and no recurrence of primary pathology.

AMC2 MED.B.035 Genitourinary system

ED Decision 2019/002/R

(a) Renal disease

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

(b) Urinary calculi

(1) Applicants presenting with one or more urinary calculi should be assessed as unfit.

(2) Applicants with an asymptomatic calculus or a history of renal colic require investigation.

(3) While awaiting assessment or treatment, a fit assessment with an OSL may be considered.

(4) After successful treatment the applicant may be assessed as fit.

(5) Applicants with parenchymal residual calculi may be assessed as fit.

(c) Renal and urological surgery

(1) Applicants who have undergone a major surgical operation on the genitourinary system or its adnexa involving a total or partial excision or a diversion of any of its organs, should be assessed as unfit until recovery is complete, the applicant is asymptomatic, and the risk of secondary complication is minimal.

(2) After other urological surgery, a fit assessment may be considered when the applicant is completely asymptomatic and there is only minimal risk of secondary complication or recurrence.

(3) Applicants with compensated nephrectomy without hypertension or uraemia may be assessed as fit.

(4) Applicants who have undergone renal transplantation may be considered for a fit assessment if it is fully compensated and with only minimal immuno-suppressive therapy.

(5) Applicants who have undergone total cystectomy may be considered for a fit assessment if there is satisfactory urinary function, no infection and no recurrence of primary pathology.

MED.B.040 Infectious Disease

Regulation (EU) 2019/27

(a) Applicants shall be assessed as unfit where they have a clinical diagnosis or medical history of any infectious disease which is likely to jeopardise the safe exercise of the privileges of the licence.

(b) Applicants who are HIV positive may be assessed as fit subject to satisfactory aero-medical evaluation. Such applicants for a class 1 medical certificate shall be referred to the medical assessor of the licensing authority.

AMC1 MED.B.040 Infectious disease

ED Decision 2019/002/R

(a) Infectious disease General

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

(b) Tuberculosis

(1) Applicants with active tuberculosis should be assessed as unfit. A fit assessment may be considered following completion of therapy.

(2) Applicants with quiescent or healed lesions may be assessed as fit. Specialist evaluation should consider the extent of the disease, the treatment required and possible side effects of medication.

(c) Syphilis

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

(d) HIV positivity

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

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

(e) Infectious hepatitis

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

AMC2 MED.B.040 Infectious disease

ED Decision 2019/002/R

(a) Tuberculosis

(1) Applicants with active tuberculosis should be assessed as unfit. A fit assessment may be considered following completion of therapy.

(2) Applicants with quiescent or healed lesions may be assessed as fit. Specialist evaluation should consider the extent of the disease, the treatment required and possible side effects of medication.

(b) HIV positivity

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

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

MED.B.045 Obstetrics and Gynaecology

Regulation (EU) 2019/27

(a) Applicants who have undergone a major gynaecological operation shall be assessed as unfit. However, they may be assessed as fit after full recovery.

(b) *Pregnancy*

(1) In the event of pregnancy, an applicant may continue to exercise her privileges until the end of the 26th week of gestation only if the AeMC or AME considers that she is fit to do so.

(2) For holders of a class 1 medical certificate who are pregnant, an OML shall apply. Notwithstanding point MED.B.001, in that case, the OML may be imposed and removed by the AeMC or AME.

(3) An applicant may resume exercising her privileges after recovery following the end of the pregnancy.

AMC1 MED.B.045 Obstetrics and gynaecology

ED Decision 2019/002/R

(a) Gynaecological surgery

Applicants who have undergone a major gynaecological operation should be assessed as unfit. A fit assessment may be considered if recovery is complete, the applicant is asymptomatic, and the risk of

(b) Pregnancy

(1) A pregnant licence holder may be assessed as fit with an OML during the first 26 weeks of gestation following review of the obstetric evaluation by the AeMC or AME who should inform the medical assessor of the licensing authority.

(2) The AeMC or AME should provide written advice to the applicant and the supervising physician regarding potentially significant complications of pregnancy.

AMC2 MED.B.045 Obstetrics and gynaecology

ED Decision 2019/002/R

(a) Gynaecological surgery

Applicants who have undergone a major gynaecological operation should be assessed as unfit until recovery is complete, the applicant is asymptomatic, and the risk of secondary complication or recurrence is minimal.

(b) Pregnancy

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

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

MED.B.050 Musculoskeletal System

Regulation (EU) 2019/27

(a) Applicants who do not have sufficient sitting height, arm and leg length and muscular strength for the safe exercise of the privileges of the licence shall be assessed as unfit. However, where their sitting height, arm and leg length and muscular strength is sufficient for the safe exercise of the privileges in respect of a certain aircraft type, which can be demonstrated where

necessary through a medical flight or a simulator flight test, the applicant may be assessed as fit and their privileges shall be limited accordingly.

(b) Applicants who do not have satisfactory functional use of the musculoskeletal system to enable them to safely exercise the privileges of the licence shall be assessed as unfit. However, where their functional use of the musculoskeletal system is satisfactory for the safe exercise the privileges in respect of a certain aircraft type, which may be demonstrated where necessary through a medical flight or a simulator flight test, the applicant may be assessed as fit and their privileges shall be limited accordingly.

(c) In case of doubt arising in the context of the assessments referred to in points (a) and (b), applicants for a class 1 medical certificate shall be referred to the medical assessor of the licensing authority and applicants for a class 2 medical certificate shall be assessed in consultation with the medical assessor of the licensing authority.

AMC1 MED.B.050 Musculoskeletal system

ED Decision 2019/002/R

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

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

(c) Applicants with abnormal musculoskeletal system, including obesity, undertaking medical fight or flight simulator testing should satisfactorily perform all tasks required for the type of flight intended, including the emergency and evacuation procedures.

AMC2 MED.B.050 Musculoskeletal system

ED Decision 2019/002/R

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

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

(c) Applicants with abnormal musculoskeletal system, including obesity, undertaking a medical flight test should satisfactorily perform all tasks required for the type of flight intended, including the emergency and evacuation procedures.

MED.B.055 Mental Health

Regulation (EU) 2019/27

(a) Comprehensive mental health assessment shall form part of the initial class 1 aero-medical examination.

(b) Drugs and alcohol screening shall form part of the initial class 1 aero-medical examination.

(c) Applicants with a mental or behavioural disorder due to use or misuse of alcohol or other psychoactive substances shall be assessed as unfit pending recovery and freedom from psychoactive substance use or misuse and subject to satisfactory psychiatric evaluation after successful treatment.

(d) Applicants with a clinical diagnosis or documented medical history of any of the following psychiatric conditions shall undergo satisfactory psychiatric evaluation before they may be assessed as fit:

(1) mood disorder;

(2) neurotic disorder;

(3) personality disorder;

(4) mental or behavioural disorder;

(5) misuse of a psychoactive substance.

(e) Applicants with a documented medical history of a single or repeated acts of deliberate self-harm or suicide attempt shall be assessed as unfit. However, they may be assessed as fit after satisfactory psychiatric evaluation.

(f) Aero-medical assessment

(1) Applicants for a class 1 medical certificate with any of the conditions specified in point (c), (d) or (e) shall be referred to the medical assessor of the licensing authority.

(2) The fitness of applicants for a class 2 medical certificate with any of the conditions specified in point (c), (d) or (e) shall be assessed in consultation with the medical assessor of the licensing authority.

(g) Applicants with a documented medical history or clinical diagnosis of schizophrenia, schizotypal or delusional disorder shall be assessed as unfit.

AMC1 MED.B.055 Mental health

ED Decision 2019/002/R

(a) Mental health assessment as part of the initial class 1 aero-medical examination

(1) A comprehensive mental health assessment should be conducted and recorded taking into account social, environmental and cultural contexts.

(2) The applicant's history and symptoms of disorders that might pose a threat to flight safety should be identified and recorded.

(3) The mental health assessment should include assessment and documentation of:

(i) general attitudes to mental health, including understanding possible indications of reduced mental health in themselves and others;

(ii) coping strategies under periods of psychological stress or pressure in the past, including seeking advice from others;

(iii) childhood behavioural problems;

(iv) interpersonal and relationship issues;

(v) current work and life stressors; and

(vi) overt personality disorders.

(4) Where there are signs or is established evidence that an applicant may have a psychiatric or psychological disorder, the applicant should be referred for specialist opinion and advice.

(b) Mental health assessment as part of revalidation or renewal class 1 medical examination

(1) The assessment should include review and documentation of:

(i) current work and life stressors;

(ii) coping strategies under periods of psychological stress or pressure in the past, including seeking advice from others;

(iii) any difficulties with operational crew resource management (CRM);

(iv) any difficulties with employer and/or other colleagues and managers; and

(v) interpersonal and relationship issues, including difficulties with relatives, friends, and work colleagues.

(2) Where there are signs or is established evidence that an applicant may have a psychiatric or psychological disorder, the applicant should be referred for specialist opinion and advice.

(3) Established evidence should be verifiable information from an identifiable source related to the mental fitness or personality of a particular individual. Sources for this information can be accidents or incidents, problems in training or proficiency checks, behaviour or knowledge relevant to the safe exercise of the privileges of the applicable licence(s).

(c) Assessment of holders of a class 1 medical certificate referenced in MED.B.055(d)

Assessment of holders of a class 1 medical certificate referenced in MED.B.055(d) may require psychiatric and psychological evaluation as determined by the medical assessor of the licensing authority. A SIC limitation should be imposed in case of a fit assessment. Follow-up and removal of SIC limitation, as necessary, should be determined by the medical assessor of the licensing authority.

(d) Psychoactive substance testing

(1) Drug tests should screen for opioids, cannabinoids, amphetamines, cocaine, hallucinogens and sedative hypnotics. Following a risk assessment performed by the competent authority on the target population, screening tests may include additional drugs.

(2) For renewal/revalidation, random psychoactive substance screening test may be performed based on the risk assessment by the competent authority on the target population. If random psychoactive substance screening test is considered, it should be performed and reported in accordance with the procedures developed by the competent authority.

(3) In the case of a positive psychoactive substance screening result, confirmation should be required in accordance with national standards and procedures for psychoactive substance testing.

(4) In case of a positive confirmation test, a psychiatric evaluation should be undertaken before a fit assessment may be considered by the medical assessor of the licensing authority.

(e) Assessment and referral decisions

(1) Psychotic disorder

Applicants with a history, or the occurrence, of a functional psychotic disorder should be assessed as unfit. A fit assessment may be considered if a cause can be unequivocally identified as one which is transient, has ceased and the risk of recurrence is minimal.

(2) Organic mental disorder

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

(3) Psychoactive medication

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

(4) Schizophrenia, schizotypal or delusional disorder

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

(5) Mood disorder

Applicants with an established mood disorder should be assessed as unfit. After full recovery and after full consideration of the individual case, a fit assessment may be considered, depending on the characteristics and severity of the mood disorder.

(6) Neurotic, stress-related or somatoform disorder

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

(7) Personality or behavioural disorders

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

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

(i) Applicants with mental or behavioural disorders due to alcohol or other psychoactive substance(s) use or misuse, with or without dependency, should be assessed as unfit.

(ii) A fit assessment may be considered after a period of two years of documented sobriety or freedom from psychoactive substance use or misuse. At revalidation or renewal, a fit assessment may be considered earlier with an OML. Depending on the individual case, treatment and evaluation may include in-patient treatment of

some weeks and inclusion into a support programme followed by ongoing checks, including drug and alcohol testing and reports resulting from the support programme, which may be required indefinitely.

(9) Deliberate self-harm and suicide attempt

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

(10) Assessment

The assessment should take into consideration if the indication for the treatment, side effects and addiction risks of such treatment and the characteristics of the psychiatric disorder are compatible with flight safety.

(f) Specialist opinion and advice

(1) In case a specialist evaluation is needed, following the evaluation, the specialist should submit a written report to the AME, AeMC or medical assessor of the licensing authority as appropriate, detailing their opinion and recommendation.

(2) Psychiatric evaluations should be conducted by a qualified psychiatrist having adequate knowledge and experience in aviation medicine.

(3) The psychological opinion and advice should be based on a clinical psychological assessment conducted by a suitably qualified and accredited clinical psychologist with expertise and experience in aviation psychology.

(4) The psychological evaluation may include a collection of biographical data, the administration of aptitude as well as personality tests and clinical interview.

AMC2 MED.B.055 Mental health

ED Decision 2019/002/R

(a) Mental health assessment as part of class 2 aero-medical examination

(1) A mental health assessment should be conducted and recorded taking into account social, environmental and cultural contexts.

(2) The applicant's history and symptoms of disorders that might pose a threat to flight safety should be identified and recorded.

(3) Where there are signs or is established evidence that an applicant may have a psychiatric or psychological disorder, the applicant should be referred for specialist opinion and advice.

(4) Established evidence should be verifiable information from an identifiable source related to the mental fitness or personality of a particular individual. Sources for this information can be accidents or incidents, problems in training or proficiency checks, behaviour or knowledge relevant to the safe exercise of the privileges of the applicable licence(s).

(b) Assessment of holders of a class 2medical certificate referenced in MED.B.055(d)

Assessment of holders of a class 2 medical certificate referenced in MED.B.055(d) may require psychiatric and psychological evaluation as determined by the AME, AeMC or medical assessor

of the licensing authority. Follow-up, as necessary, should be determined in consultation with the medical assessor of the licensing authority.

(c) Assessment and referral decisions

(1) Psychotic disorder

Applicants with a history, or the occurrence, of a functional psychotic disorder should be assessed as unfit. A fit assessment may be considered if a cause can be unequivocally identified as one which is transient, has ceased and the risk of recurrence is minimal.

(2) Organic mental disorder

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

(3) Schizophrenia, schizotypal or delusional disorder

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

(4) Mood disorder

Applicants with an established mood disorder should be assessed as unfit. After full recovery and after full consideration of the individual case, a fit assessment may be considered, depending on the characteristics and severity of the mood disorder.

(5) Neurotic, stress-related or somatoform disorder

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

(6) Personality or behavioural disorders

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

(7) Psychoactive medication

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

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

(i) Applicants with mental or behavioural disorders due to alcohol or other psychoactive substance(s) use or misuse, with or without dependency, should be assessed as unfit.

(ii) Drug and alcohol tests

(A) In the case of a positive drug or alcohol result, confirmation should be required in accordance with national procedures for drugs and alcohol testing.

(B) In case of a positive confirmation test, a psychiatric evaluation should be undertaken before a fit assessment may be considered.

(iii) A fit assessment may be considered after a period of two years of documented sobriety or freedom from psychoactive substance use or misuse. At revalidation or renewal, a fit assessment may be considered earlier with an OSL or OPL. Depending on the individual case, treatment and evaluation may include in-patient treatment of some weeks and inclusion into a support programme followed by ongoing checks, including drug and alcohol testing and reports resulting from the support programme, which may be required indefinitely.

(9) Deliberate self-harm

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

(e) Specialist opinion and advice

(1) In case a specialist evaluation is needed, following the evaluation, the specialist should submit a written report to the AME, AeMC or medical assessor of the licensing authority as appropriate, detailing their opinion and recommendation.

(2) Psychiatric evaluations should be conducted by a qualified psychiatrist having adequate knowledge and experience in aviation medicine.

(3) The psychological opinion and advice should be based on a clinical psychological assessment conducted by a suitably qualified and accredited clinical psychologist with expertise and experience in aviation psychology.

(4) The psychological evaluation may include a collection of biographical data, the administration of aptitude as well as personality tests and clinical interview.

GM1 MED.B.055 Mental health

ED Decision 2019/002/R

(a) Symptoms of concern may include but are not limited to:

(1) use of alcohol or other psychoactive substances;

(2) loss of interest/energy;

(3) eating and weight changes;

(4) sleeping problems;

(5) low mood and, if present, any suicidal thoughts;

(6) family history of psychiatric disorders, particularly suicide;

(7) anger, agitation or high mood; and

(8) depersonalisation or loss of control.

(b) The following aspects should be taken into consideration when conducting the mental health examination:

(1) Appearance;

(2) Attitude;

(3) Behaviour;

(4) Mood;

(5) Speech;

(6) Thoughts process and content;

(7) Perception;

(8) Cognition;

(9) Insight; and

(10) Judgement.

GM2 MED.B.055 Mental health

ED Decision 2019/002/R

(a) Drugs and alcohol screening tests used should:

(1) provide information regarding medium-term consumption;

(2) be accepted on national level by the competent authority based on the availability and suitability for the scope mentioned in point(a)(1) above.

(b) Statistical data of the screening campaign mentioned in AMC1 MED.B.055(d)(1) should be made available to the Agency on a yearly basis.

GM3 MED.B.055 Mental health

ED Decision 2019/002/R

(a) The mental health assessment for class 2 applicants should include assessment and documentation of:

(1) general attitudes to mental health, including understanding possible indications of reduced mental health in themselves and others;

(2) coping strategies under periods of psychological stress or pressure in the past, including seeking advice from others;

(3) childhood behavioural problems;

(4) interpersonal and relationship issues, including difficulties with relatives, friends, and work colleagues;

(5) current work and life stressors, including difficulties with aviation operational environment; and

(6) overt personality disorders.

(b) In regard to symptoms of concern and aspects to be taken into consideration when conducting mental health examination for class 2 applicants, guidance presented in GM1 MED.B.055 should be used.

GM4 MED.B.055 Mental health

ED Decision 2019/002/R

Drugs and alcohol screening tests used should:

(a) provide information regarding medium-term consumption;

(b) be accepted on national level by the competent authority based on the availability and suitability with the scope mentioned in GM2 MED.B.055(a) above.

MED.B.065 Neurology

Regulation (EU) 2019/27

(a) Applicants with clinical diagnosis or a documented medical history of any of the following medical conditions shall be assessed as unfit:

(1) epilepsy, except in the cases referred to in points (1) and (2) of point (b);

(2) recurring episodes of disturbance of consciousness of uncertain cause.

(b) Applicants with clinical diagnosis or a documented medical history of any of the following medical conditions shall undergo further evaluation before they may be assessed as fit:

(1) epilepsy without recurrence after age 5;

(2) epilepsy without recurrence and off all treatment for more than 10 years;

(3) epileptiform EEG abnormalities and focal slow waves;

(4) progressive or non-progressive disease of the nervous system;

(5) inflammatory disease of the central or peripheral nervous system;

(6) migraine;

(7) a single episode of disturbance of consciousness of uncertain cause;

(8) loss of consciousness after head injury;

(9) penetrating brain injury;

(10) spinal or peripheral nerve injury;

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

Applicants for a class 1 medical certificate shall be referred to the medical assessor of the licensing authority. The fitness of applicants for a class 2 medical certificate shall be assessed in consultation with the medical assessor of the licensing authority.

AMC1 MED.B.065 Neurology

ED Decision 2019/002/R

(a) Epilepsy

(1) Applicants with a diagnosis of epilepsy should be assessed as unfit unless there is unequivocal evidence of a syndrome of benign childhood epilepsy associated with a very low risk of recurrence, and unless the applicant has been free of recurrence and off treatment for more than 10 years. One or more convulsive episode after the age of 5 should lead to unfitness. In the case of an acute symptomatic seizure, which is considered

to have a very low risk of recurrence, a fit assessment may be considered after neurological evaluation.

(2) Applicants may be assessed as fit with an OML if:

(i) there is a history of a single afebrile epileptiform seizure;

(ii) there has been no recurrence after at least 10 years off treatment;

(iii) there is no evidence of continuing predisposition to epilepsy.

(b) EEG

(1) Electroencephalography is required when indicated by the applicant's history or on clinical grounds.

(2) Applicants with epileptiform paroxysmal EEG abnormalities and focal slow waves should be assessed as unfit.

(c) Neurological disease

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

(d) Migraine

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

(e) Episode of disturbance of consciousness

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

(f) Head injury

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

(g) Spinal or peripheral nerve injury

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

(h) Vascular deficiencies

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

AMC2 MED.B.065 Neurology

ED Decision 2019/002/R

(a) Epilepsy

Applicants may be assessed as fit if:

(1) there is a history of a single afebrile epileptiform seizure, considered to have a very low risk of recurrence;

(2) there has been no recurrence after at least 10 years off treatment; and

(3) there is no evidence of continuing predisposition to epilepsy.

(b) Neurological disease

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

(c) Migraine

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

(d) Head injury

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

(e) Spinal or peripheral nerve injury

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

(f) Vascular deficiencies

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

MED.B.070 Visual System

Regulation (EU) 2019/27

(a) Examination

(1) For a class 1 medical certificate:

(i) a comprehensive eye examination shall form part of the initial examination and shall be undertaken when clinically indicated and periodically, depending on the refraction and the functional performance of the eye.

(ii) a routine eye examination shall form part of all revalidation and renewal examinations.

(2) For a class 2 medical certificate:

(i) a routine eye examination shall form part of the initial and all revalidation and renewal examinations.

(ii) a comprehensive eye examination shall be undertaken when clinically indicated.

(b) Visual acuity

(1) For a class 1 medical certificate:

(i) Distant visual acuity, with or without correction, shall be 6/9 (0,7) or better in each eye separately and visual acuity with both eyes shall be 6/6 (1,0) or better.

(ii) At the initial examination, applicants with substandard vision in one eye shall be assessed as unfit.

(iii) At revalidation and renewal examinations, notwithstanding point (b)(1)(i), applicants with acquired substandard vision in one eye or acquired monocularity shall be referred to the medical assessor of the licensing authority and may be assessed as fit subject to a satisfactory ophthalmological evaluation.

(2) For a class 2 medical certificate:

(i) Distant visual acuity, with or without correction, shall be 6/12 (0,5) or better in each eye separately and visual acuity with both eyes shall be 6/9 (0,7) or better.

(ii) Notwithstanding point (b)(2)(i), applicants with substandard vision in one eye or monocularity may be assessed as fit, in consultation with the medical assessor of the licensing authority and subject to a satisfactory ophthalmological evaluation.

(3) Applicants shall be able to read an N5 chart or equivalent at 30-50 cm and an N14 chart or equivalent at 100 cm, if necessary with correction.

(c) Refractive error and anisometropia

(1) Applicants with refractive errors or anisometropia may be assessed as fit subject to satisfactory ophthalmic evaluation.

(2) Notwithstanding point (c)(1), applicants for a class 1 medical certificate with any of the following medical conditions shall be referred to the medical assessor of the licensing authority and may be assessed as fit subject to a satisfactory ophthalmological evaluation:

(i) myopia exceeding –6.0 dioptres;

(ii) astigmatism exceeding 2.0 dioptres;

(iii) anisometropia exceeding 2.0 dioptres.

(3) Notwithstanding point (c)(1), applicants for a class 1 medical certificate with hypermetropia exceeding +5.0 dioptres shall be referred to the medical assessor of the licensing authority and may be assessed as fit subject to a satisfactory ophthalmological evaluation, provided that there are adequate fusional reserves, normal intraocular pressures and anterior angles and no significant pathology has been demonstrated. Notwithstanding point (b)(1)(i), corrected visual acuity in each eye shall be 6/6 or better.

(4) Applicants with a clinical diagnosis of keratoconus may be assessed as fit subject to a satisfactory examination by an ophthalmologist. Such applicants for a class 1 medical certificate shall be referred to the medical assessor of the licensing authority.

(d) Binocular function

(1) Applicants for a class 1 medical certificate shall be assessed as unfit, where they do not have normal binocular function and that medical condition is likely to jeopardise the safe exercise of the privileges of the license, taking account of any appropriate corrective measures where relevant.

(2) Applicants with diplopia shall be assessed as unfit.

(e) Visual fields

Applicants for a class 1 medical certificate shall be assessed as unfit, where they do not have normal fields of vision and that medical condition is likely to jeopardise the safe exercise of the privileges of the license, taking account of any appropriate corrective measures where relevant.

(f) Eye surgery

Applicants who have undergone eye surgery shall be assessed as unfit. However, they may be assessed as fit after full recovery of their visual function and subject to satisfactory ophthalmological evaluation.

(g) Spectacles and contact lenses

(1) If satisfactory visual function is achieved only with the use of correction, the spectacles or contact lenses shall provide optimal visual function, be well-tolerated and suitable for aviation purposes.

(2) No more than one pair of spectacles shall be used to meet the visual requirements when exercising the privileges of the applicable licence(s).

(3) For distant vision, spectacles or contact lenses shall be worn when exercising the privileges of the applicable licence(s).

(4) For near vision, a pair of spectacles shall be kept available when exercising the privileges of the applicable licence(s).

(5) A spare set of similarly correcting spectacles, for distant or near vision as applicable, shall be readily available for immediate use when exercising the privileges of the applicable licence(s).

(6) If contact lenses are worn when exercising the privileges of the applicable licence(s), they shall be for distant vision, monofocal, and non-tinted and well-tolerated.

(7) Applicants with a large refractive error shall use contact lenses or high-index spectacle lenses.

(8) Orthokeratological lenses shall not be used.

AMC1 MED.B.070 Visual system

ED Decision 2019/002/R

(a) Eye examination

(1) At each aero-medical examination, an assessment of the visual fitness should be undertaken and the eyes should be examined with regard to possible pathology.

(2) All abnormal and doubtful cases should be referred to an ophthalmologist. Conditions which indicate ophthalmological examination include but are not limited to a substantial decrease in the uncorrected visual acuity, any decrease in best corrected visual acuity and/or the occurrence of eye disease, eye injury, or eye surgery.

(3) Where specialist ophthalmological examinations are required for any significant reason, this should be imposed as a limitation on the medical certificate.

(4) The possible cumulative effect of more than one eye condition should be evaluated by an ophthalmologist.

(b) Comprehensive eye examination

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

(1) history;

(2) visual acuities - near, intermediate and distant vision (uncorrected and with best optical correction if needed);

(3) examination of the external eye, anatomy, media (slit lamp) and fundoscopy;

(4) ocular motility;

(5) binocular vision;

(6) visual fields;

(7) tonometry on clinical indication;

(8) objective refraction: hyperopic initial applicants with a hyperopia of more than +2 dioptres and under the age of 25 should undergo objective refraction in cycloplegia;

(9) assessment of mesopic contrast sensitivity; and

(10) colour vision.

(c) Routine eye examination

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

(1) history;

(2) visual acuities - near, intermediate and distant vision (uncorrected and with best optical correction if needed);

(3) examination of the external eye, anatomy, media and fundoscopy; and

(4) further examination on clinical indication.

(d) Refractive error and anisometropia

(1) Applicants with the following conditions may be assessed as fit subject to satisfactory ophthalmic evaluation and provided that optimal correction has been considered and no significant pathology is demonstrated:

(i) hypermetropia not exceeding +5.0 dioptres;

(ii) myopia not exceeding –6.0 dioptres;

(iii) astigmatism not exceeding 2.0 dioptres;

(iv) anisometropia not exceeding 2.0 dioptres.

(2) Applicants should wear contact lenses if:

(i) hypermetropia exceeds +5.0 dioptres;

(ii) anisometropia exceeds 3.0 dioptres.

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

(i) the refractive error is between –3.0 and –6.0 dioptres or +3 and +5 dioptres;

(ii) astigmatism or anisometropia is between 2.0 and 3.0 dioptres.

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

(i) the refractive error is greater than –6.0 dioptres or +5.0 dioptres;

(ii) astigmatism or anisometropia exceeds 3.0 dioptres.

(e) Uncorrected visual acuity

No limits apply to uncorrected visual acuity.

(f) Visual acuity

(1) Reduced vision in one eye or monocularity: Applicants for revalidation or renewal with reduced central vision or acquired loss of vision in one eye may be assessed as fit with an OML if:

(i) the binocular visual field or, in the case of monocularity, the monocular visual field is acceptable;

(ii) in the case of monocularity, a period of adaptation time has passed from the known point of visual loss, during which the applicant should be assessed as unfit;

(iii) the unaffected eye achieves distant visual acuity of 6/6 (1,0) corrected or uncorrected;

(iv) the unaffected eye achieves intermediate visual acuity of N14 and N5 for near;

(v) the underlying pathology is acceptable according to ophthalmological assessment and there is no significant ocular pathology in the unaffected eye; and

(vi) a medical flight test is satisfactory.

(2) Visual fields

Applicants with a visual field defect, who do not have reduced central vision or acquired loss of vision in one eye, may be assessed as fit if the binocular visual field is normal.

(g) Keratoconus

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

(h) Binocular function

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

(1) at 6 metres:

2.0 prism dioptres in hyperphoria,

10.0 prism dioptres in esophoria,

8.0 prism dioptres in exophoria

and

(2) at 33 centimetres:

1.0 prism dioptre in hyperphoria,

8.0 prism dioptres in esophoria,

12.0 prism dioptres in exophoria

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

(i) Eye surgery

The assessment after eye surgery should include an ophthalmological examination.

(1) After refractive surgery, a fit assessment may be considered, provided that:

(i) stability of refraction of less than 0.75 dioptres variation diurnally has been achieved;

(ii) examination of the eye shows no post-operative complications;

(iii) glare sensitivity is within normal standards;

(iv) mesopic contrast sensitivity is not impaired;

(v) an evaluation is undertaken by an eye specialist.

(2) Following intraocular lens surgery, including cataract surgery, a fit assessment may be considered once recovery is complete and the visual requirements are met with or without correction. Intraocular lenses should be monofocal and should not impair colour vision and night vision.

(3) Retinal surgery entails unfitness. A fit assessment may be considered 6 months after surgery, or earlier if recovery is complete. A fit assessment may also be considered earlier after retinal laser therapy. Regular follow-up by an ophthalmologist should be carried out.

(4) Glaucoma surgery entails unfitness. A fit assessment may be considered 6 months after surgery or earlier if recovery is complete. Regular follow-up by an ophthalmologist should be carried out.

(j) Visual correction

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

AMC2 MED.B.070 Visual system

ED Decision 2019/002/R

(a) Eye examination

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

(2) At the initial assessment, the examination should include:

(i) history;

(ii) visual acuities - near, intermediate and distant vision (uncorrected and with best optical correction if needed);

(iii) examination of the external eye, anatomy, media and fundoscopy;

(iv) ocular motility;

(v) binocular vision;

(vi) visual fields;

(vii) colour vision;

(viii) further examination on clinical indication.

(3) At the initial assessment the applicant should submit a copy of the recent spectacle prescription if visual correction is required to meet the visual requirements.

(b) Routine eye examination

A routine eye examination should include:

(1) history;

(2) visual acuities - near, intermediate and distant vision (uncorrected and with best optical correction if needed);

(3) examination of the external eye, anatomy, media and fundoscopy;

(4) further examination on clinical indication.

(c) Visual acuity

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

(1) the binocular visual field or, in the case of monocularity, the monocular visual field is acceptable;

(2) in the case of monocularity, a period of adaptation time has passed from the known point of visual loss, during which the applicant should be assessed as unfit;

(3) the unaffected eye achieves distant visual acuity of 6/6 (1,0), corrected or uncorrected;

(4) the unaffected eye achieves intermediate visual acuity of N14 or equivalent and N5 or equivalent for near (Refer to GM1 MED.B.070);

(5) there is no significant ocular pathology in the unaffected eye; and

(6) a medical flight test is satisfactory.

(d) Binocular function

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

(e) Eye surgery

(1) The assessment after eye surgery should include an ophthalmological examination.

(2) After refractive surgery a fit assessment may be considered provided that there is satisfactory stability of refraction, there are no post-operative complications and no increase in glare sensitivity.

(3) After cataract, retinal or glaucoma surgery a fit assessment may be considered once recovery is complete and the visual requirements are met with or without correction.

(f) Visual correction

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

GM1 MED.B.070 Visual system

ED Decision 2019/002/R

COMPARISON OF DIFFERENT READING CHARTS (APPROXIMATE FIGURES)

(a) Test distance: 40 cm

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

(b) Test distance: 80 cm

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

GM2 MED.B.070 Visual system

ED Decision 2019/002/R

EYE SPECIALIST

The term 'eye specialist' refers to an ophthalmologist or a vision care specialist qualified in optometry and trained to recognise pathological conditions.

MED.B.075 Colour vision

Regulation (EU) 2019/27

(a) Applicants shall be assessed as unfit, where they cannot demonstrate their ability to readily perceive the colours that are necessary for the safe exercise of the privileges of the licence.

(b) *Examination and assessment*

(1) Applicants shall be subjected to the Ishihara test for the initial issue of a medical certificate. Applicants who pass that test may be assessed as fit.

(2) For a class 1 medical certificate:

(i) Applicants who do not pass the Ishihara test shall be referred to the medical assessor of the licensing authority and shall undergo further colour perception testing to establish whether they are colour safe.

(ii) Applicants shall be normal trichromats or shall be colour safe.

(iii) Applicants who fail further colour perception testing shall be assessed as unfit.

(3) For a class 2 medical certificate:

(i) Applicants who do not pass the Ishihara test shall undergo further colour perception testing to establish whether they are colour safe.

(ii) Applicants who do not have satisfactory perception of colours shall be limited to exercising the privileges of the applicable licence in daytime only.

AMC1 MED.B.075 Colour vision

ED Decision 2019/002/R

(a) At revalidation and renewal examinations, colour vision should be tested on clinical indication.

(b) The Ishihara test (24 plate version) is considered passed if the first 15 plates, presented in a random order, are identified without error.

(c) Those failing the Ishihara test should be examined either by:

(1) anomaloscopy (Nagel or equivalent). This test is considered passed if the colour match is trichromatic and the matching range is 4 scale units or less, or if the anomalous quotient is acceptable; or by

(2) lantern testing with a Spectrolux, Beynes or Holmes-Wright lantern. This test is considered passed if the applicant passes without error a test with accepted lanterns.

(3) Colour Assessment and Diagnosis (CAD) test. This test is considered passed if the threshold is less than 6 standard normal (SN) units for deutan deficiency, or less than 12 SN units for protan deficiency. A threshold greater than 2 SN units for tritan deficiency indicates an acquired cause which should be investigated.

AMC2 MED.B.075 Colour vision

ED Decision 2019/002/R

(a) Colour vision should be tested on clinical indication at revalidation and renewal examinations.

(b) The Ishihara test (24 plate version) is considered passed if the first 15 plates, presented in a random order, are identified without error.

(c) Those failing the Ishihara test should be examined either by:

(1) anomaloscopy (Nagel or equivalent). This test is considered passed if the colour match is trichromatic and the matching range is 4 scale units or less, or if the anomalous quotient is acceptable; or by

(2) lantern testing with a Spectrolux, Beynes or Holmes-Wright lantern. This test is considered passed if the applicant passes without error a test with accepted lanterns.

(3) Colour Assessment and Diagnosis (CAD) test. This test is considered passed if the threshold is less than 6 standard normal (SN) units for deutan deficiency, or less than 12 SN units for protan deficiency. A threshold greater than 2 SN units for tritan deficiency indicates an acquired cause which should be investigated.

MED.B.080 Otorhinolaryngology (ENT)

Regulation (EU) *2019/27*

(a) Examination

(1) Applicants' hearing shall be tested at all examinations.

(i) For a class 1 medical certificate, and for a class 2 medical certificate when an instrument rating or en route instrument rating is to be added to the licence, hearing shall be tested with pure-tone audiometry at the initial examination, then every 5 years until the licence holder reaches the age of 40 and then every 2 years thereafter.

(ii) When tested on a pure-tone audiometer, initial applicants shall not have a hearing loss of more than 35 dB at any of the frequencies 500, 1 000 or 2 000 Hz, or more than 50 dB at 3 000 Hz, in either ear separately. Applicants for revalidation or renewal with greater hearing loss shall demonstrate satisfactory functional hearing ability.

(2) A comprehensive ear, nose and throat examination shall be undertaken for the initial issue of a class 1 medical certificate and periodically thereafter when clinically indicated.

(b) Applicants with any of the following medical conditions shall undergo further examination to establish that the medical condition does not interfere with the safe exercise of the privileges of the applicable licence(s):

(1) hypoacusis;

(2) an active pathological process of the internal or middle ear;

(3) unhealed perforation or dysfunction of the tympanic membrane(s);

(4) dysfunction of the Eustachian tube(s);

(5) disturbance of vestibular function;

(6) significant restriction of the nasal passages;

(7) sinus dysfunction;

(8) significant malformation or significant infection of the oral cavity or upper respiratory tract;

(9) significant disorder of speech or voice;

(10) any sequelae of surgery of the internal or middle ear.

(c) Aero-medical assessment

(1) Applicants for a class 1 medical certificate with any of the medical conditions specified in points (1), (4) and (5) of point (b) shall be referred to the medical assessor of the licensing authority.

(2) The fitness of applicants for a class 2 medical certificate with any of the medical conditions specified in point (4) and (5) of point (b) shall be assessed in consultation with the medical assessor of the licensing authority.

(3) The fitness of applicants for a class 2 medical certificate for an instrument rating or en route instrument rating to be added to the licence with the medical condition specified in point (1) of point (b) shall be assessed in consultation with the medical assessor of the licensing authority.

AMC1 MED.B.080 Otorhinolaryngology (ENT)

ED Decision 2019/002/R

(a) Hearing

(1) Applicants should understand correctly conversational speech when tested with each ear at a distance of 2 metres from and with the applicant's back turned towards the AME.

(2) Applicants with hypoacusis may be assessed as fit if a speech discrimination test or functional flight deck hearing test demonstrates satisfactory hearing ability. A vestibular function test may be appropriate.

(3) If the hearing requirements can only be met with the use of hearing aids, the hearing aids should provide optimal hearing function, be well tolerated and suitable for aviation purposes.

(b) Comprehensive ENT examination

A comprehensive ENT examination should include:

(1) history;

(2) clinical examination including otoscopy, rhinoscopy, and examination of the mouth and throat;

(3) tympanometry or equivalent;

(4) clinical examination of the vestibular system.

(c) Ear conditions

(1) Applicants with an active pathological process of the internal or middle ear should be assessed as unfit. A fit assessment may be considered once the condition has stabilised or there has been a full recovery.

(2) Applicants with an unhealed perforation or dysfunction of the tympanic membranes should be assessed as unfit. An applicant with a single dry perforation of non-infectious origin and which does not interfere with the normal function of the ear may be considered for a fit assessment.

(d) Vestibular disturbance

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

(e) Sinus dysfunction

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

(f) Oral/upper respiratory tract infections

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

(g) Speech disorder

Applicants with a significant disorder of speech or voice should be assessed as unfit.

(h) Air passage restrictions

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

(i) Eustachian tube(s)

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

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

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

AMC2 MED.B.080 Otorhinolaryngology (ENT)

ED Decision 2019/002/R

(a) Hearing

(1) Applicants should understand correctly conversational speech when tested with each ear at a distance of 2 metres from and with the applicant's back turned towards the AME.

(2) Applicants with hypoacusis may be assessed as fit if a speech discrimination test or functional cockpit hearing test demonstrates satisfactory hearing ability.

(3) If the hearing requirements can be met only with the use of hearing aids, the hearing aids should provide optimal hearing function, be well tolerated and suitable for aviation purposes.

(4) Applicants with profound deafness or major disorder of speech, or both, may be assessed as fit with an SSL, such as 'limited to areas and operations where the use of radio is not mandatory'. The aircraft should be equipped with appropriate alternative warning devices in lieu of sound warnings.

(b) Examination

An ENT examination should form part of all initial, revalidation and renewal examinations.

(c) Ear conditions

(1) Applicants with an active pathological process of the internal or middle ear should be assessed as unfit until the condition has stabilised or there has been a full recovery.

(2) Applicants with an unhealed perforation or dysfunction of the tympanic membranes should be assessed as unfit. An applicant with a single dry perforation of non-infectious origin which does not interfere with the normal function of the ear may be considered for a fit assessment.

(d) Vestibular disturbance

Applicants with disturbance of vestibular function should be assessed as unfit pending full recovery.

(e) Sinus dysfunction

Applicants with any dysfunction of the sinuses should be assessed as unfit pending full recovery.

(f) Oral/upper respiratory tract infections

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

(g) Speech disorder

Applicants with a significant disorder of speech or voice should be assessed as unfit.

(h) Air passage restrictions

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

(i) Eustachian tube dysfunction

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

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

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

GM1 MED.B.080 Otorhinolaryngology (ENT)

ED Decision 2019/002/R

PURE TONE AUDIOGRAM

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

GM2 MED.B.080 Otorhinolaryngology (ENT)

ED Decision 2019/002/R

PURE TONE AUDIOGRAM

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

MED.B.085 Dermatology

Regulation (EU) 2019/27

Applicants shall be assessed as unfit, where they have an established dermatological condition which is likely to jeopardise the safe exercise of the privileges of the licence.

AMC1 MED.B.085 Dermatology

ED Decision 2019/002/R

(a) If doubt exists about the fitness of applicants with eczema (exogenous and endogenous), severe psoriasis, bacterial infections, drug induced or bullous eruptions or urticaria, the AME should refer the case to the medical assessor of the licensing authority.

(b) Systemic effects of radiant or pharmacological treatment for a dermatological condition should be reviewed before a fit assessment may be considered.

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

AMC2 MED.B.085 Dermatology

ED Decision 2019/002/R

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

MED.B.090 Oncology

Regulation (EU) 2019/27

(a) Before further consideration is given to their application, applicants with primary or secondary malignant disease shall undergo satisfactory oncological evaluation. Such applicants for a class 1 medical certificate shall be referred to the medical assessor of the licensing authority. Such applicants for a class 2 medical certificate shall be assessed in consultation with the medical assessor of the licensing authority.

(b) Applicants with a documented medical history or clinical diagnosis of an intracerebral malignant tumour shall be assessed as unfit.

AMC1 MED.B.090 Oncology

ED Decision 2019/002/R

(a) Applicants who have been diagnosed with a malignant disease may be assessed as fit provided that:

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

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

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

(4) there is no evidence of short or long-term sequelae from treatment. Special attention should be paid to applicants who have received anthracycline chemotherapy;

(5) satisfactory oncology follow-up reports are provided to the medical assessor of the licensing authority.

(b) An OML should be applied as appropriate.

(c) Applicants receiving ongoing chemotherapy or radiation treatment should be assessed as unfit.

(d) Applicants with pre-malignant conditions of the skin may be assessed as fit if treated or excised as necessary and there is regular follow-up.

AMC2 MED.B.090 Oncology

ED Decision 2019/002/R

(a) Applicants who have been diagnosed with a malignant disease may be considered for a fit assessment provided that:

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

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

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

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

(5) arrangements for an oncological follow-up have been made for an appropriate period of time.

(b) Applicants receiving ongoing chemotherapy or radiation treatment should be assessed as unfit.

(c) Applicants with pre-malignant conditions of the skin may be assessed as fit if treated or excised as necessary and there is a regular follow-up.

SECTION 3 – SPECIFIC REQUIREMENTS FOR LAPL MEDICAL CERTIFICATES

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

Regulation (EU) 2019/27

(a) An applicant for a LAPL medical certificate shall be assessed based on aero-medical best practice.

(b) Special attention shall be given to the applicant's complete medical history.

(c) The initial assessment, all subsequent re-assessments after the licence holder reaches the age of 50 and any assessments in cases where the medical history of the applicant is not available to the examiner shall include at least all of the following:

(1) clinical examination;

(2) blood pressure;

(3) urine test;

(4) vision;

(5) hearing ability.

(d) After the initial assessment, subsequent re-assessments until the licence holder reaches the age of 50 shall include at least both of the following:

(1) an assessment of the LAPL holder's medical history;

(2) the items specified in point(c) as deemed necessary by the AeMC, AME or GMP in accordance with aero-medical best practice.

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

ED Decision 2019/002/R

When a specialist evaluation is required under this section, the aero-medical assessment of the applicant should be performed by an AeMC, an AME or, in the case of AMC5 MED.B.095(d), by the medical assessor of the licensing authority.

AMC2 MED.B.095 Medical examination and assessment of applicants for LAPL medical certificates

ED Decision 2019/002/R

CARDIOVASCULAR SYSTEM

(a) Examination

Pulse and blood pressure should be recorded at each examination.

(b) General

(1) Cardiovascular risk factor assessment

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

(2) Aortic aneurysm

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

(3) Cardiac valvular abnormalities

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

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

(4) Valvular surgery

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

(5) Other cardiac disorders

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

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

(c) Blood pressure

(1) When the blood pressure consistently exceeds 160 mmHg systolic and/or 95 mmHg diastolic, with or without treatment, the applicant should be assessed as unfit.

(2) Applicants initiating medication for the control of blood pressure should be assessed as unfit until the absence of significant side effects has been established.

(d) Coronary artery disease

(1) Applicants with suspected myocardial ischaemia should undergo a cardiological evaluation before a fit assessment may be considered.

(2) Applicants with angina pectoris requiring medication for cardiac symptoms should be assessed as unfit.

(3) After an ischaemic cardiac event, including myocardial infarction or revascularisation, applicants without symptoms should have reduced cardiovascular risk factors to an appropriate level. Medication, when used to control cardiac symptoms, is not acceptable. All applicants should be on appropriate secondary prevention treatment.

(4) In cases (d)(1), (d)(2) and (d)(3), applicants who have had a satisfactory cardiological evaluation to include an exercise test or equivalent that is negative for ischaemia may be assessed as fit.

(e) Rhythm and conduction disturbances

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

(2) Pre-excitation

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

(3) Automatic implantable defibrillating system

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

(4) Pacemaker

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

AMC3 MED.B.095 Medical examination and assessment of applicants for LAPL medical certificates

ED Decision 2019/002/R

RESPIRATORY SYSTEM

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

(b) Asthma and chronic obstructive pulmonary disease

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

(c) Sarcoidosis

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

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

(d) Pneumothorax

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

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

(e) Thoracic surgery

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

(f) Sleep apnoea syndrome/sleep disorder

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

AMC4 MED.B.095 Medical examination and assessment of applicants for LAPL medical certificates

ED Decision 2019/002/R

DIGESTIVE SYSTEM

(a) Gallstones

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

(b) Inflammatory bowel disease

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

(c) Peptic ulceration

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

(d) Digestive tract and abdominal surgery

Applicants who have undergone a surgical operation:

(1) for herniae; or

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

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

(e) Pancreatitis

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

(f) Liver disease

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

AMC5 MED.B.095 Medical examination and assessment of applicants for LAPL medical certificates

ED Decision 2019/002/R

METABOLIC AND ENDOCRINE SYSTEMS

(a) Metabolic, nutritional or endocrine dysfunction

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

(b) Obesity

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

(c) Thyroid dysfunction

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

(d) Diabetes mellitus

(1) Applicants using antidiabetic medications that are not likely to cause hypoglycaemia may be assessed as fit.

(2) Applicants with diabetes mellitus Type 1 should be assessed as unfit.

(3) Applicants with diabetes mellitus Type 2 treated with insulin may be assessed as fit with limitations for revalidation if blood sugar control has been achieved and the process under (e) and (f) is followed. An ORL is required. A TML for 12 months may be needed to ensure compliance with the follow-up requirements below. Licence privileges should not include rotary aircraft flying.

(e) Aero-medical assessment by, or under the guidance of, the medical assessor of the licensing authority:

(1) A diabetology review at yearly intervals, including:

(i) symptom review;

(ii) review of data logging of blood sugar;

(iii) cardiovascular status. Exercise ECG at age 40, at 5-yearly intervals thereafter and on clinical indication, including an accumulation of risk factors;

(iv) nephropathy status.

(2) Ophthalmological review at yearly intervals, including:

(i) visual fields — Humphrey-perimeter;

(ii) retinae — full dilatation slit lamp examination;

(iii) cataract — clinical screening.

The development of retinopathy requires a full ophthalmological review.

(3) Blood testing at 6-monthly intervals:

(i) HbA1c;

(ii) renal profile;

(iii) liver profile;

(iv) lipid profile.

(4) Applicants should be assessed as temporarily unfit after:

(i) changes of medication/insulin leading to a change to the testing regime until stable blood sugar control can be demonstrated;

(ii) a single unexplained episode of severe hypoglycaemia until stable blood sugar control can be demonstrated.

(5) Applicants should be assessed as unfit in the following cases:

(i) loss of hypoglycaemic awareness;

(ii) development of retinopathy with any visual field loss;

(iii) significant nephropathy;

(iv) any other complication of the disease where flight safety may be jeopardised.

(f) Pilot responsibility

Blood sugar testing is carried out during non-operational and operational periods. A whole blood glucose measuring device with memory should be carried and used. Equipment for continuous glucose monitoring (CGMS) should not be used. Pilots should prove to the AME or AeMC or medical assessor of the licensing authority that testing has been performed as indicated below and with which results.

(1) Testing during non-operational periods: normally 3–4 times/day or as recommended by the treating physician, and on any awareness of hypoglycaemia.

(2) Testing frequency during operational periods:

(i) 120 minutes before departure;

(ii) <30 minutes before departure;

(iii) 60 minutes during flight;

(iv) 30 minutes before landing.

(3) Actions following glucose testing:

(i) 120 minutes before departure: if the test result is >15 mmol/l, piloting should not be commenced.

(ii) 10–15g of carbohydrate should be ingested and a re-test performed within 30 minutes if:

(A) any test result is <4,5 mmol/l;

(B) the pre-landing test measurement is missed or a subsequent go-around/diversion is performed.

AMC6 MED.B.095 Medical examination and assessment of applicants for LAPL medical certificates

ED Decision 2019/002/R

HAEMATOLOGY

Applicants with a haematological condition, such as:

(a) abnormal haemoglobin including, but not limited to, anaemia, erythrocytosis or haemoglobinopathy;

(b) coagulation, haemorrhagic or thrombotic disorder;

(c) significant lymphatic enlargement;

(d) acute or chronic leukaemia;

(e) splenomegaly;

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

AMC7 MED.B.095 Medical examination and assessment of applicants for LAPL medical certificates

ED Decision 2019/002/R

GENITOURINARY SYSTEM

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

(1) renal disease; or

(2) one or more urinary calculi, or a history of renal colic

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

(b) Applicants who have undergone a major surgical operation on the genitourinary system or its adnexa may be assessed as fit following recovery.

(c) Applicants who have undergone renal transplantation may be assessed as fit subject to satisfactory renal evaluation.

AMC8 MED.B.095 Medical examination and assessment of applicants for LAPL medical certificates

ED Decision 2019/002/R

INFECTIOUS DISEASE

(a) Applicants who are HIV positive may be assessed as fit subject to satisfactory aero-medical evaluation.

(b) Applicants with other chronic infections may be assessed as fit provided the infections are not likely to interfere with the safe exercise of the privileges of the licence.

AMC9 MED.B.095 Medical examination and assessment of applicants for LAPL medical certificates

ED Decision 2019/002/R

OBSTETRICS AND GYNAECOLOGY

(a) Pregnancy

Holders of a LAPL medical certificate should only exercise the privileges of their licences until the end of the 26th week of gestation under routine antenatal care.

(b) Applicants who have undergone a major gynaecological operation may be assessed as fit after recovery.

AMC10 MED.B.095 Medical examination and assessment of applicants for LAPL medical certificates

ED Decision 2019/002/R

MUSCULOSKELETAL SYSTEM

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

AMC11 MED.B.095 Medical examination and assessment of applicants for LAPL medical certificates

ED Decision 2019/002/R

MENTAL HEALTH

(a) Applicants with a mental or behavioural disorder due to use or misuse of alcohol or other psychoactive substances, with or without dependency, should be assessed as unfit. A fit assessment may be considered after a period of two years of documented sobriety or freedom from psychoactive substance use or misuse, subject to satisfactory psychiatric evaluation after successful treatment. At revalidation or renewal, a fit assessment may be considered earlier. Depending on the individual case, treatment and evaluation may include in-patient treatment of some weeks followed by ongoing checks, including blood testing and peer reports, which may be required indefinitely.

(b) Applicants with a history of, or the occurrence of, a functional psychotic disorder should be assessed as unfit. A fit assessment may be considered if a cause can be unequivocally identified as one which is transient, has ceased, and the risk of recurrence is minimal.

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

(d) Psychoactive substances

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

(e) Applicants with a psychiatric condition, such as:

(1) mood disorder;

(2) neurotic disorder;

(3) personality disorder;

(4) mental or behavioural disorder

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

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

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

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

(i) In case a specialist evaluation is needed, following the evaluation, the specialist should submit a written report to the AME, AeMC, GMP or medical assessor of the licensing authority as appropriate, detailing their opinion and recommendation.

AMC12 MED.B.095 Medical examination and assessment of applicants for LAPL medical certificates

ED Decision 2019/002/R

NEUROLOGY

(a) Epilepsy and seizures

(1) Applicants with an established diagnosis of and under treatment for epilepsy should be assessed as unfit. A re-assessment after all treatment has been stopped for at least 5 years should include a review of neurological reports.

(2) Applicants may be assessed as fit if:

(i) there is a history of a single afebrile epileptiform seizure considered to have a very low risk of recurrence;

(ii) there has been no recurrence after at least 5 years off treatment;

(iii) a cause has been identified and treated and there is no evidence of continuing predisposition to epilepsy.

(b) Neurological disease

Applicants with any disease of the nervous system which is likely to cause a hazard to flight safety should be assessed as unfit. However, in certain cases, including cases of functional loss associated with stable disease, a fit assessment may be considered after full evaluation including, if necessary, a medical flight test.

(c) Migraine

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

(d) Head injury

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

(e) Spinal or peripheral nerve injury

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

(f) Vascular deficiencies

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

AMC13 MED.B.095 Medical examination and assessment of applicants for LAPL medical certificates

ED Decision 2019/002/R

VISUAL SYSTEM

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

(b) Eye examination

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

(c) Visual acuity

(1) Visual acuity with or without corrective lenses should be 6/9 (0,7) binocularly and 6/12 (0,5) in each eye.

(2) Applicants who do not meet the required visual acuity should be assessed by an AME or AeMC, taking into account the privileges of the licence held and the risk involved.

(3) Applicants should be able to read, binocularly, an N5 chart (or equivalent) at 30-50 cm and an N14 chart (or equivalent) at 100 cm, with correction if prescribed (Refer to GM1 MED.B.070).

(d) Visual acuity

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

(1) achieves distant visual acuity of 6/6 (1,0), corrected or uncorrected;

(2) achieves distant visual acuity less than 6/6 (1,0) but not less than 6/9 (0,7), after ophthalmological evaluation.

(e) Visual field defects

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

(f) Eye surgery

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

(2) After cataract, retinal or glaucoma surgery a fit assessment may be considered once recovery is complete.

(g) Visual correction

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

AMC14 MED.B.095 Medical examination and assessment of applicants for LAPL medical certificates

ED Decision 2019/002/R

COLOUR VISION

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

AMC15 MED.B.095 Medical examination and assessment of applicants for LAPL medical certificates

ED Decision 2019/002/R

OTORHINOLARYNGOLOGY (ENT)

(a) Hearing

(1) Applicants should understand correctly conversational speech when tested with or without hearing aids at a distance of 2 metres from and with the applicant's back turned towards the examiner.

(2) If the hearing requirements can only be met with the use of hearing aid(s), the hearing aid(s) should provide optimal hearing function, be well-tolerated, and be suitable for aviation purposes.

(3) Applicants with hypoacusis should demonstrate satisfactory functional hearing ability.

(4) Applicants with profound deafness or major disorder of speech, or both, may be assessed as fit with an SSL such as 'limited to areas and operations where the use of radio is not mandatory'. The aircraft should be equipped with appropriate alternative warning devices in lieu of sound warnings.

(b) Ear conditions

Applicants with:

(1) an active pathological process of the internal or middle ear;

(2) unhealed perforation or dysfunction of the tympanic membrane(s);

(3) disturbance of vestibular function;

(4) significant restriction of the nasal passages;

(5) sinus dysfunction;

(6) significant malformation or significant infection of the oral cavity or upper respiratory tract; or

(7) significant disorder of speech or voice

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

AMC16 MED.B.095 Medical examination and assessment of applicants for LAPL medical certificates

ED Decision 2019/002/R

DERMATOLOGY

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

AMC17 MED.B.095 Medical examination and assessment of applicants for LAPL medical certificates

ED Decision 2019/002/R

ONCOLOGY

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

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

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

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

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

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

(c) Applicants with an established history or clinical diagnosis of intracerebral malignant tumour should be assessed as unfit.

GM1 MED.B.095 Medical examination and assessment of applicants for LAPL medical certificates

ED Decision 2019/002/R

DIABETES MELLITUS TYPE 2 TREATED WITH INSULIN – GENERAL

(a) Pilots and their treating physician should be aware that if the HbA1c target level was set to normal (non-diabetic) levels, this will significantly increase the chance of hypoglycaemia. For safety reasons the target level of HbA1c is therefore set to 7,5–8,5 % even though there is evidence that lower HbA1c levels are correlated with fewer diabetic complications.

(b) The safety pilot should be briefed pre-flight on the potential condition of the pilot. The results of blood sugar testing before and during flight should be shared with the safety pilot for the acceptability of the values obtained.

GM2 MED.B.095 Medical examination and assessment of applicants for LAPL medical certificates

ED Decision 2019/002/R

DIABETES MELLITUS TYPE 2 TREATED WITH INSULIN – CONVERSION TABLE FOR HbA1c IN % AND MMOL/MOL

HbA1c in %	HbA1c in mmol/mol
4,7	28
5,0	31
5,3	34
5,6	38
5,9	41
6,2	44
6,5	48
6,8	51
7,4	57

8,0	64
8,6	70
9,2	77
9,8	84
10,4	90
11,6	103

GM3 MED.B.095 Medical examination and assessment of applicants for LAPL medical certificates

ED Decision 2019/002/R

MOOD DISORDER

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

SUBPART C – REQUIREMENTS FOR MEDICAL FITNESS OF CABIN CREW

SECTION 1 – GENERAL REQUIREMENTS

MED.C.001 General

Regulation (EU) No 1178/2011

Cabin crew members shall only perform the duties and responsibilities required by aviation safety rules on an aircraft if they comply with the applicable requirements of this Part.

MED.C.005 Aero-medical assessments

Regulation (EU) No 1178/2011

(a) Cabin crew members shall undergo aero-medical assessments to verify that they are free from any physical or mental illness which might lead to incapacitation or an inability to perform their assigned safety duties and responsibilities.

(b) Each cabin crew member shall undergo an aero-medical assessment before being first assigned to duties on an aircraft, and after that at intervals of maximum 60 months.

(c) Aero-medical assessments shall be conducted by an AME, AeMC, or by an OHMP if the requirements of MED.D.040 are complied with.

AMC1 MED.C.005 Aero-medical assessments

ED Decision 2019/002/R

(a) When conducting aero-medical examinations and assessments of cabin crew members, as applicable, their medical fitness should be assessed with particular regard to their physical and mental ability to:

(1) undergo the training required for cabin crew to acquire and maintain competence, e.g. actual fire-fighting, slide descending, using Protective Breathing Equipment (PBE) in a simulated smoke-filled environment, providing first aid;

(2) manipulate the aircraft systems and emergency equipment to be used by cabin crew, e.g. cabin management systems, doors/exits, escape devices, fire extinguishers, taking also into account the class and type of aircraft operated, e.g. narrow-bodied or wide-bodied, single/multi-deck, single/multi-cabin crew operation;

(3) continuously tolerate the aircraft environment whilst performing duties, e.g. altitude, pressure, re-circulated air, noise; and the type of operations such as short/medium/long/ultra long haul; and

(4) perform the required duties and responsibilities efficiently during normal and abnormal operations, and in emergency situations and psychologically demanding circumstances, e.g. assistance to crew members and passengers in case of decompression; stress management, decision-making, crowd control and effective crew coordination, management of disruptive passengers and of security threats. When relevant, operating as single cabin crew should also be taken into account when assessing the medical fitness of cabin crew.

(b) Intervals

(1) The interval between aero-medical assessments should be determined by the competent authority. The intervals established by the competent authority apply to cabin crew members who:

(i) undergo aero-medical assessments by an AME, AeMC or OHMP under the oversight of that competent authority; or

(ii) are employed by an operator under the oversight of that competent authority.

(2) The interval between aero-medical assessments may be reduced by the AME, AeMC or OHMP for medical reasons and in accordance with MED.C.035.

(3) Aero-medical assessments for the revalidation of a cabin crew medical report may be undertaken up to 45 days prior to the expiry date of the previous medical report. The validity period of the aero-medical assessment should be calculated from the expiry date of the previous aero-medical assessment.

SECTION 2 – REQUIREMENTS FOR AERO-MEDICAL ASSESSMENT OF CABIN CREW

MED.C.020 General

Regulation (EU) No 1178/2011

Cabin crew members shall be free from any:

(a) abnormality, congenital or acquired;

(b) active, latent, acute or chronic disease or disability;

(c) wound, injury or sequelae from operation; and

(d) effect or side effect of any prescribed or non-prescribed therapeutic, diagnostic or preventive medication taken that would entail a degree of functional incapacity which might lead to incapacitation or an inability to discharge their safety duties and responsibilities.

MED.C.025 Content of aero-medical assessments

Regulation (EU) No 1178/2011

(a) An initial aero-medical assessment shall include at least:

(1) an assessment of the applicant cabin crew member's medical history; and

(2) a clinical examination of the following:

(i) cardiovascular system;

(ii) respiratory system;

(iii) musculoskeletal system;

(iv) otorhino-laryngology;

(v) visual system; and

(vi) colour vision.

(b) Each subsequent aero-medical re-assessment shall include:

(1) an assessment of the cabin crew member's medical history; and

(2) a clinical examination if deemed necessary in accordance with aero-medical best practice.

(c) For the purpose of (a) and (b), in case of any doubt or if clinically indicated, a cabin crew member's aero-medical assessment shall also include any additional medical examination, test or investigation that are considered necessary by the AME, AeMC or OHMP.

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

ED Decision 2019/002/R

Aero-medical examinations and assessments of cabin crew members should be conducted in accordance with AMC2 to AMC18 MED.C.025.

AMC2 MED.C.025 Content of aero-medical assessments

ED Decision 2019/002/R

CARDIOVASCULAR SYSTEM

(a) Examination

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

(2) Extended cardiovascular assessment should be required when clinically indicated.

(b) Cardiovascular system - general

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

(i) aneurysm of the thoracic or supra-renal abdominal aorta, before surgery;

(ii) significant functional abnormality of any of the heart valves; or

(iii) heart or heart/lung transplantation

should be assessed as unfit.

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

(i) peripheral arterial disease before or after surgery;

(ii) aneurysm of the abdominal aorta, before or after surgery;

(iii) minor cardiac valvular abnormalities;

(iv) after cardiac valve surgery;

(v) abnormality of the pericardium, myocardium or endocardium;

(vi) congenital abnormality of the heart, before or after corrective surgery;

(vii) a cardiovascular condition requiring systemic anticoagulation;

(viii) vasovagal syncope of uncertain cause;

(ix) arterial or venous thrombosis; or

(x) pulmonary embolism

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

(c) Thromboembolic disorders

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

(d) Syncope

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

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

(e) Blood pressure

Blood pressure should be recorded at each examination.

(1) The blood pressure should be within normal limits and should not consistently exceed 160 mmHg systolic and/or 95 mmHg diastolic, with or without treatment, taking into account other risk factors.

(2) Cabin crew members initiating medication for the control of blood pressure should be assessed as unfit until the absence of any significant side effects has been established and verification that the treatment is compatible with the safe exercise of cabin crew duties has been achieved.

(f) Coronary artery disease

(1) Cabin crew members with:

(i) cardiac ischaemia;

(ii) symptomatic coronary artery disease; or

(iii) symptoms of coronary artery disease controlled by medication

should be assessed as unfit.

(2) Cabin crew members who are asymptomatic after myocardial infarction or surgery for coronary artery disease should have fully recovered before a fit assessment may be considered. The affected cabin crew members should be on appropriate secondary prevention treatment.

(g) Rhythm/conduction disturbances

(1) Cabin crew members with any significant disturbance of cardiac conduction or rhythm should undergo cardiological evaluation before a fit assessment may be considered.

(2) Cabin crew members with a history of:

(i) ablation therapy; or

(ii) pacemaker implantation

should undergo satisfactory cardiovascular evaluation before a fit assessment may be made.

(3) Cabin crew members with:

(i) symptomatic sinoatrial disease;

(ii) symptomatic hypertrophic cardiomyopathy

(iii) complete atrioventricular block;

(iv) symptomatic QT prolongation;

(v) an automatic implantable defibrillating system; or

(vi) a ventricular anti-tachycardia pacemaker

should be assessed as unfit.

AMC3 MED.C.025 Content of aero-medical assessments

ED Decision 2019/002/R

RESPIRATORY SYSTEM

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

(b) Cabin crew members should undergo pulmonary morphological or functional tests on when clinically indicated.

(c) Cabin crew members with a history or established diagnosis of:

(1) asthma;

(2) active inflammatory disease of the respiratory system;

(3) active sarcoidosis;

(4) pneumothorax;

(5) sleep apnoea syndrome/sleep disorder; or

(6) major thoracic surgery

should undergo respiratory evaluation with a satisfactory result before a fit assessment may be considered.

(d) Cabin crew members who have undergone a pneumonectomy should be assessed as unfit.

AMC4 MED.C.025 Content of aero-medical assessments

ED Decision 2019/002/R

DIGESTIVE SYSTEM

(a) Cabin crew members with any disease or sequelae of surgical intervention in any part of the digestive tract or its adnexa likely to cause incapacitation in flight, in particular any obstruction due to stricture or compression, should be assessed as unfit.

(b) Cabin crew members should be free from herniae that might give rise to incapacitating symptoms.

(c) Cabin crew members with disorders of the gastro-intestinal system, including:

(1) recurrent severe dyspeptic disorder requiring medication;

(2) peptic ulceration;

(3) pancreatitis;

(4) symptomatic gallstones;

(5) an established diagnosis or history of chronic inflammatory bowel disease;

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

(7) morphological or functional liver disease; or

(8) after surgery, including liver transplantation

may be assessed as fit subject to satisfactory gastroenterological evaluation.

AMC5 MED.C.025 Content of aero-medical assessments

ED Decision 2019/002/R

METABOLIC AND ENDOCRINE SYSTEMS

(a) Cabin crew members should not possess any functional or structural metabolic, nutritional or endocrine disorder which is likely to interfere with the safe exercise of their duties and responsibilities.

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

(c) Diabetes mellitus

(1) Cabin crew members with diabetes mellitus requiring insulin may be assessed as fit:

(i) if it can be demonstrated that adequate blood sugar control has been achieved and hypoglycaemia awareness is established and maintained; and

(ii) in the absence, within the preceding 12 months, of any;

(A) hospitalisation related to diabetes; or

(B) hypoglycaemia that resulted in a seizure, loss of consciousness, impaired cognitive function or that required the intervention by another party; or

(C) episode of hypoglycaemia unawareness.

(2) Limitations should be imposed as appropriate. A limitation to undergo specific medical examinations (SIC) and a restriction to operate only in multi-cabin crew operations (MCL) should be placed as a minimum.

(3) Cabin crew members with diabetes mellitus not requiring insulin may be assessed as fit if it can be demonstrated that adequate blood sugar control has been achieved and hypoglycaemia awareness, if applicable considering the medication, is achieved.

AMC6 MED.C.025 Content of aero-medical assessments

ED Decision 2019/002/R

HAEMATOLOGY

Cabin crew members with a haematological condition, such as:

(a) abnormal haemoglobin including, but not limited to, anaemia, erythrocytosis or haemoglobinopathy;

(b) coagulation, haemorrhagic or thrombotic disorder;

(c) significant lymphatic enlargement;

(d) acute or chronic leukaemia; or

(e) splenomegaly

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

AMC7 MED.C.025 Content of aero-medical assessments

ED Decision 2019/002/R

GENITOURINARY SYSTEM

(a) Urine analysis should form part of every aero-medical examination and assessment. The urine should not contain any abnormal element(s) considered to be of pathological significance.

(b) Cabin crew members with any disease or sequelae of surgical procedures on the kidneys or the urinary tract, in particular any obstruction due to stricture or compression likely to cause incapacitation should be assessed as unfit.

(c) Cabin crew members with a genitourinary disorder, such as:

(1) renal disease; or

(2) a history of renal colic due to one or more urinary calculi

may be assessed as fit subject to satisfactory renal/urological evaluation.

(d) Cabin crew members who have undergone a major surgical operation in the genitourinary apparatus involving a total or partial excision or a diversion of its organs should be assessed as unfit and be re-assessed after recovery before a fit assessment may be made.

(e) Cabin crew members who have undergone renal transplantation may be considered for a fit assessment if it is fully compensated and tolerated with only minimal immuno-suppressive therapy after at least 12 months. A requirement to undergo specific medical examinations (SIC) and a restriction to operate only in multi-cabin crew operations (MCL) should be considered.

(f) Cabin crew members requiring dialysis should be assessed as unfit.

AMC8 MED.C.025 Content of aero-medical assessments

ED Decision 2019/002/R

INFECTIOUS DISEASE

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

AMC9 MED.C.025 Content of aero-medical assessments

ED Decision 2019/002/R

OBSTETRICS AND GYNAECOLOGY

(a) Cabin crew members who have undergone a major gynaecological operation should be assessed as unfit until after recovery.

(b) Pregnancy

(1) A pregnant cabin crew member may be assessed as fit only during the first 16 weeks of gestation following review of the obstetric evaluation by the AME or OHMP.

(2) A limitation not to perform duties as single cabin crew member should be considered.

(3) The AME or OHMP should provide written advice to the cabin crew member and supervising physician regarding potentially significant complications of pregnancy resulting from flying duties.

AMC10 MED.C.025 Content of aero-medical assessments

ED Decision 2019/002/R

MUSCULOSKELETAL SYSTEM

(a) Cabin crew members should have sufficient standing height, arm and leg length and muscular strength for the safe exercise of their duties and responsibilities.

(b) Cabin crew members should have satisfactory functional use of the musculoskeletal system. Particular attention should be paid to emergency procedures and evacuation, and related training.

(c) Cabin crew members with any significant sequelae from disease, injury or congenital abnormality affecting the bones, joints, muscles or tendons with or without surgery require full evaluation prior to a fit assessment.

(d) Cabin crew members with inflammatory, infiltrative, traumatic or degenerative disease of the musculoskeletal system may be assessed as fit provided the condition is in remission or is stable and the affected cabin crew member is not taking any medication that may lead to unfitness.

AMC11 MED.C.025 Content of aero-medical assessments

ED Decision 2019/002/R

MENTAL HEALTH

(a) Cabin crew members with a mental or behavioural disorder due to use or misuse of alcohol or other psychoactive substances should be assessed as unfit pending recovery and freedom from psychoactive substance use or misuse and subject to satisfactory psychiatric evaluation after successful treatment.

(b) Cabin crew members with an established history or clinical diagnosis of schizophrenia, schizotypal or delusional disorder should be assessed as unfit.

(c) Cabin crew members with a psychiatric condition such as:

(1) mood disorder;

(2) neurotic disorder;

(3) personality disorder; or

(4) mental or behavioural disorder

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

(d) Cabin crew members with a history of a single or repeated acts of deliberate self-harm should be assessed as unfit. Cabin crew members should undergo satisfactory psychiatric evaluation before a fit assessment may be considered.

(e) Where there is established evidence that a cabin crew member has a psychological disorder, he/she should be referred for psychological opinion and advice.

(f) The psychological evaluation may include a collection of biographical data, the review of aptitudes, and personality tests and psychological interview.

(g) The psychologist should submit a report to the AME or OHMP, detailing the results and recommendation.

AMC12 MED.C.025 Content of aero-medical assessments

ED Decision 2019/002/R

NEUROLOGY

(a) Cabin crew members with an established history or clinical diagnosis of:

(1) epilepsy; or

(2) recurring episodes of disturbance of consciousness of uncertain cause

should be assessed as unfit.

(b) Cabin crew members with an established history or clinical diagnosis of:

(1) epilepsy without recurrence after 5 years of age and without treatment for more than 10 years;

(2) epileptiform EEG abnormalities and focal slow waves;

(3) progressive or non-progressive disease of the nervous system;

(4) inflammatory disease of the central or peripheral nervous system;

(5) migraine;

(6) a single episode of disturbance of consciousness of uncertain cause;

(7) loss of consciousness after head injury;

(8) penetrating brain injury; or

(9) spinal or peripheral nerve injury

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

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

AMC13 MED.C.025 Content of aero-medical assessments

ED Decision 2019/002/R

VISUAL SYSTEM

(a) Examination

(1) a routine eye examination should form part of the initial and all further examinations and assessments; and

(2) an extended eye examination should be undertaken by an eye specialist when clinically indicated.(Refer to GM2 MED.B.070)

(b) Distant visual acuity, with or without correction, should be with both eyes 6/9 (0,7) or better.

(c) Cabin crew members should be able to read an N5 chart (or equivalent) at 30–50 cm, with correction if prescribed (Refer to GM1 MED.B.070).

(d) The binocular visual field or, in the case of monocularity, the monocular visual field should be acceptable.

(e) Cabin crew members who have undergone refractive surgery may be assessed as fit subject to satisfactory ophthalmic evaluation.

(f) Cabin crew members with diplopia should be assessed as unfit.

(g) Spectacles and contact lenses:

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

(1) in the case of myopia or hyperopia or both, spectacles or contact lenses should be worn whilst on duty;

(2) in the case of presbyopia, spectacles should be readily available for immediate use;

(3) the correction should provide optimal visual function and be well-tolerated;

(4) a spare set of similarly correcting spectacles should be readily available for immediate use whilst on duty;

(5) orthokeratologic lenses should not be used.

AMC14 MED.C.025 Content of aero-medical assessments

ED Decision 2019/002/R

COLOUR VISION

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

AMC15 MED.C.025 Content of aero-medical assessments

ED Decision 2019/002/R

OTORHINOLARYNGOLOGY (ENT)

(a) Hearing should be satisfactory for the safe exercise of cabin crew duties and responsibilities. Cabin crew with hypoacusis should demonstrate satisfactory functional hearing abilities.

(b) Examination

(1) An ear, nose and throat (ENT) examination should form part of all examinations and assessments. A tympanometry or equivalent should be performed at the initial examination and when clinically indicated.

(2) Hearing should be tested at all examinations and assessments:

(i) the cabin crew member should understand correctly conversational speech when tested with each ear at a distance of 2 metres from and with the cabin crew member's back turned towards the examiner;

(ii) notwithstanding (b)(2)(i), hearing should be tested with pure tone audiometry at the initial examination and when clinically indicated;

(iii) at initial examination the cabin crew member should not have a hearing loss of more than 35 dB at any of the frequencies 500 Hz, 1 000 Hz or 2 000 Hz, or more than 50 dB at 3 000 Hz, in either ear separately.

(3) If the hearing requirements can be met only with the use of hearing aid(s), the hearing aid(s) should provide optimal hearing function, be well-tolerated, and suitable for aviation purposes.

(c) Cabin crew members with:

(1) an active pathological process of the internal or middle ear;

(2) unhealed perforation or dysfunction of the tympanic membrane(s);

(3) disturbance of vestibular function;

(4) significant restriction of the nasal passages;

(5) sinus dysfunction;

(6) significant malformation or significant infection of the oral cavity or upper respiratory tract;

(7) significant disorder of speech or voice

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

AMC16 MED.C.025 Content of aero-medical assessments

ED Decision 2019/002/R

DERMATOLOGY

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

AMC17 MED.C.025 Content of aero-medical assessments

ED Decision 2019/002/R

ONCOLOGY

(a) After treatment for malignant disease, cabin crew members should undergo satisfactory oncological and aero-medical evaluation before a fit assessment may be considered.

(b) Cabin crew members with an established history or clinical diagnosis of intracerebral malignant tumour should be assessed as unfit. Considering the histology of the tumour, a fit assessment may be considered after successful treatment and recovery.

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

ED Decision 2019/002/R

(a) When conducting aero-medical examinations and assessments, typical cabin crew duties as listed in (b) and (c), particularly those to be performed during abnormal operations and emergency situations, and cabin crew responsibilities to the travelling public should be considered in order to identify:

(1) any physical and/or mental conditions that could be detrimental to the performance of the duties required from cabin crew; and

(2) which examination(s), test(s) or investigation(s) should be undergone to complete an appropriate aero-medical assessment.

(b) Main cabin crew duties and responsibilities during day-to-day normal operations

(1) During pre/post-flight ground operations with/without passengers on board:

(i) monitoring of situation inside the aircraft cabin and awareness of conditions outside the aircraft including observation of visible aircraft surfaces and information to flight crew of any surface contamination such as ice or snow;

(ii) assistance to special categories of passengers (SCPs) such as infants and children (accompanied or unaccompanied), persons with disabilities or reduced mobility, medical cases with or without medical escort, and inadmissible persons, deportees and passengers in custody;

(iii) observation of passengers (any suspicious behaviour, passengers under the influence of alcohol and/or drugs, mentally disturbed), observation of potential able-bodied persons, crowd control during boarding and disembarkation;

(iv) safe stowage of cabin luggage, safety demonstrations and cabin secured checks, management of passengers and ground services during re-fuelling, observation of use of portable electronic devices;

(v) preparedness to carry out safety and emergency duties at any time, and security alertness.

(2) During flight:

(i) operation and monitoring of aircraft systems, surveillance of the cabin, lavatories, galleys, crew areas and flight crew compartment;

(ii) coordination with flight crew on situation in the cabin and turbulence events/effects;

(iii) management and observation of passengers (consumption of alcohol, behaviour, potential medical issues), observation of use of portable electronic devices;

(iv) safety and security awareness and preparedness to carry out safety and emergency duties at any time, and cabin secured checks prior to landing.

(c) Main cabin crew duties and responsibilities during abnormal and emergency operations

(1) In case of planned or unplanned emergency evacuation: briefing and/or commands to passengers including SCPs and selection and briefing to able-bodied persons; crowd control monitoring and evacuation conduct including in the absence of command from the flight crew; post-evacuation duties including assistance, first aid and management of survivors and survival in particular environments; activation of applicable communication means towards search and rescue services.

(2) In case of decompression: checking of crew members, passengers, cabin, lavatories, galleys, crew rest areas and flight crew compartment, and administering oxygen to crew members and passengers as necessary.

(3) In case of pilot incapacitation: secure pilot in his/her seat or remove from flight crew compartment; administer first aid and assist operating pilot as required.

(4) In case of fire or smoke: identify source/cause/type of fire/smoke to perform the necessary required actions; coordinate with other cabin crew members and flight crew; select appropriate extinguisher/agent and fight the fire using portable breathing equipment (PBE), gloves, and protective clothing as required; management of necessary passengers' movement if possible; instructions to passengers to prevent smoke inhalation/suffocation; give first aid as necessary; monitor the affected area until landing; preparation for possible emergency landing.

(5) In case of first aid and medical emergencies: assistance to crew members and/or passengers; correct assessment and correct use of therapeutic oxygen, defibrillator, first-aid kits/emergency medical kit contents as required; management of events, of incapacitated person(s) and of other passengers; coordination and effective communication with other crew members, in particular when medical advice is transmitted by frequency to flight crew or by a telecommunication connection.

(6) In case of disruptive passenger behaviour: passenger management as appropriate including use of restraint technique as considered required.

(7) In case of security threats (bomb threat on ground or in-flight and/or hijack): control of cabin areas and passengers' management as required by the type of threat, management of suspicious device, protection of flight crew compartment door.

(8) In case of handling of dangerous goods: observing safety procedures when handling the affected device, in particular when handling chemical substances that are leaking; protection and management of self and passengers and effective coordination and communication with other crew members.

GM2 MED.C.025 Content of aero-medical assessments

ED Decision 2019/002/R

DIABETES MELLITUS TREATED WITH INSULIN

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

GM3 MED.C.025 Content of aero-medical assessments

ED Decision 2019/002/R

COLOUR VISION – GENERAL

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

GM4 MED.C.025 Content of aero-medical assessments

ED Decision 2019/002/R

OTORHINOLARYNGOLOGY (ENT) – PURE TONE AUDIOGRAM

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

SECTION 3 – ADDITIONAL REQUIREMENTS FOR APPLICANTS FOR, OR HOLDERS OF, A CABIN CREW ATTESTATION

MED.C.030 Cabin crew medical report

Regulation (EU) No 1178/2011

(a) After completion of each aero-medical assessment, applicants for, and holders of, a cabin crew attestation:

(1) shall be provided with a cabin crew medical report by the AME,AeMC or OHMP; and

(2) shall provide the related information, or a copy of their cabin crew medical report to the operator(s) employing their services.

(b) Cabin crew medical report

A cabin crew medical report shall indicate the date of the aero-medical assessment, whether the cabin crew member has been assessed fit or unfit, the date of the next required aero-medical assessment and, if applicable, any limitation(s). Any other elements shall be subject to medical confidentiality in accordance with MED.A.015.

AMC1 MED.C.030 Cabin crew medical report

ED Decision 2019/002/R

The cabin crew medical report to be provided in writing to the applicants for, and holders of, a cabin crew attestation:

(a) should be issued in the national language(s) and/or in English; and

(b) should include the following elements:

(1) The State where the aero-medical assessment of the Cabin Crew Attestation (CCA) applicant/holder was conducted (I);

(2) Last and first name of the CCA applicant/holder (IV);

(3) Date of birth of the CCA applicant/holder (*dd/mm/yyyy*) (XIV);

(4) Nationality of the CCA applicant/holder (VI);

(5) Signature of the CCA applicant/holder (VII);

(6) Aero-medical assessment result (fit or unfit) (II);

(7) Expiry date of the previous cabin crew medical report (*dd/mm/yyyy*);

(8) Date of issue (*dd/mm/yyyy*) and signature of the AeMC, AME, or OHMP (X);

(9) Date of the aero-medical assessment (*dd/mm/yyyy*);

(10) Seal or stamp of the AeMC, AME or OHMP (XI);

(11) Limitation(s), if applicable (XII);

(12) Expiry date of medical report (*dd/mm/yyyy*) (IX).

GM1 MED.C.030(b) Cabin crew medical report

ED Decision 2019/002/R

GENERAL

The format of the cabin crew medical report may be as shown in the example below, with the size of each sheet being 1/8 of A4.

State of issue CABIN CREW MEDICAL REPORT FOR CABIN CREW ATTESTATION (CCA) APPLICANT OR HOLDER		

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

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

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

MED.C.035 Limitations

Regulation (EU) No 1178/2011

(a) If holders of a cabin crew attestation do not fully comply with the medical requirements specified in Section 2, the AME, AeMC or OHMP shall consider whether they may be able to perform cabin crew duties safely if complying with one or more limitations.

(b) Any limitation(s) to the exercise of the privileges granted by the cabin crew attestation shall be specified on the cabin crew medical report and shall only be removed by an AME, AeMC or by an OHMP in consultation with an AME.

AMC1 MED.C.035 Limitations

ED Decision 2019/002/R

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

(a) a restriction to operate only in multi-cabin crew operations (MCL);

(b) a restriction to specified aircraft type(s) (OAL) or to a specified type of operation (OOL);

(c) a requirement to undergo the next aero-medical examination and assessment at an earlier date than required by MED.C.005(b) (TML);

(d) a requirement to undergo specific medical examination(s) (SIC);

(e) a requirement for visual correction (CVL), or by means of contact lenses that correct for defective vision (CCL);

(f) a requirement to use hearing aids (HAL); and

(g) special restriction as specified (SSL).

SUBPART D – AERO-MEDICAL EXAMINERS (AME), GENERAL MEDICAL PRACTITIONERS (GMP), OCCUPATIONAL HEALTH MEDICAL PRACTITIONERS (OHMP)

SECTION 1 – AERO-MEDICAL EXAMINERS

MED.D.001 Privileges

Regulation (EU) 2019/27

(a) The privileges of holders of an aero-medical examiner (AME) certificate are to issue, revalidate and renew class 2 medical certificates and LAPL medical certificates and to conduct the relevant medical examinations and assessments.

(b) Holders of an AME certificate may apply for an extension of their privileges to include medical examinations for the revalidation and renewal of class 1 medical certificates, if they comply with the requirements set out in point MED.D.015.

(c) The privileges of a holder of an AME certificate referred to in points (a) and (b) shall include the privileges to conduct cabin crew members' aero-medical examinations and assessments and to provide the related cabin crew members' medical reports, as applicable, in accordance with this Annex (Part-MED).

(d) The scope of the privileges of the holder of an AME certificate, and any condition thereof, shall be specified in that certificate.

(e) A holder of an AME certificate shall not at any time hold more than one AME certificate issued in accordance with this Regulation.

(f) Holders of an AME certificate shall not undertake aero-medical examinations and assessments in a Member State other than the Member State that issued their AME certificate, unless they have completed all the following steps:

(1) they have been granted access by the other Member State concerned to exercise their professional activities as a specialised doctor;

(2) they have informed the competent authority of that other Member State of their intention to conduct aero-medical examinations and assessments and to issue medical certificates within the scope of their privileges as AME;

(3) they have received a briefing from the competent authority of that other Member State.

MED.D.005 Application

Regulation (EU) 2019/27

(a) An application for an AME certificate or for an extension of the privileges of an AME certificate shall be made in a form and manner specified by the competent authority.

(b) Applicants for an AME certificate shall provide the competent authority with:

(1) their personal details and professional address;

(2) documentation demonstrating that they comply with the requirements of point MED.D.010, including evidence of successful completion of the training course in aviation medicine appropriate to the privileges they apply for;

(3) a written declaration that, once the AME certificate has been issued, the AME will issue medical certificates on the basis of the requirements of this Regulation.

(c) When AMEs undertake aero-medical examinations in more than one location, they shall provide the competent authority with relevant information regarding all practice locations and practice facilities.

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

Regulation (EU) 2019/27

Applicants shall be issued an AME certificate, where they meet all of the following conditions:

(a) they are fully qualified and licensed for the practice of medicine and have evidence of completion of specialist medical training;

(b) they have successfully completed a basic training course in aviation medicine, including practical training in the examination methods and aero-medical assessments;

(c) they have demonstrated to the competent authority that they:

(1) have adequate facilities, procedures, documentation and functioning equipment suitable for aero-medical examinations;

(2) have in place the necessary procedures and conditions to ensure medical confidentiality.

MED.D.011 Privileges of an AME certificate holder

Regulation (EU) 2019/27

Through the issuance of an AME certificate, the holder shall be granted the privileges to initially issue, revalidate and renew all of the following:

(a) class 2 medical certificates;

(b) LAPL medical certificates;

(c) cabin crew members' medical reports.

MED.D.015 Requirements for the extension of privileges

Regulation (EU) 2019/27

Applicants shall be issued an AME certificate extending their privileges to the revalidation and renewal of class 1 medical certificates where they meet all of the following conditions:

(a) they hold a valid AME certificate;

(b) they conducted at least 30 examinations for the issue, revalidation or renewal of class 2 medical certificates or equivalent over a period of no more than 3 years preceding the application;

(c) they successfully completed an advanced training course in aviation medicine, including practical training in the examination methods and aero-medical assessments;

(d) they have successfully completed practical training of a duration of at least 2 days, either at an AeMC or under the supervision of the competent authority.

MED.D.020 Training courses in aviation medicine

Regulation (EU) 2019/27

(a) Training courses in aviation medicine refered to in MED.D.010(b) and MED.D.015(c) shall only be provided after the prior approval of the course by the competent authority of the Member State where the training organisation has its principal place of business. In order to obtain such approval, the training organisation shall demonstrate that the course syllabus contains the learning objectives to acquire the necessary competencies and that the persons in charge of providing the training have adequate knowledge and experience.

(b) Except in the case of refresher training, the courses shall be concluded by a written examination on the subjects included in the course content.

(c) The training organisation shall issue a certificate of successful completion to participants when they have obtained a pass in the examination.

AMC1 MED.D.020 Training courses in aviation medicine

ED Decision 2019/002/R

BASIC TRAINING COURSE

(a) Basic training course for AMEs

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

(b) The learning objectives to acquire the necessary competencies should include theoretical knowledge, risk management, and decision-making principles in the following subjects. Demonstrations and practical skills should also be included, where appropriate.

(1) Introduction to aviation medicine;

(2) Basic aeronautical knowledge;

(3) Aviation physiology;

(4) Cardiovascular system;

(5) Respiratory system;

(6) Digestive system;

(7) Metabolic and endocrine systems;

(8) Haematology;

(9) Genitourinary system;

(10) Obstetrics and gynaecology;

(11) Musculoskeletal system;

(12) Psychiatry;

(13) Psychology;

(14) Neurology;

(15) Visual system and colour vision;

(16) Otorhinolaryngology;

(17) Oncology;

(18) Incidents and accidents escape and survival;

(19) Medication and flying;

(20) Legislation, rules and regulations;

(21) Cabin crew working environment;

(22) In-flight environment; and

(23) Space medicine.

AMC2 MED.D.020 Training courses in aviation medicine

ED Decision 2019/002/R

ADVANCED TRAINING COURSE

(a) Advanced training course for AMEs

The advanced training course for AMEs should consist of 66 hours of theoretical and practical training, including specific examination techniques.

(b) The learning objectives to acquire the necessary competencies should include theoretical knowledge, risk management, and decision-making principles in the following subjects. Demonstrations and practical skills should also be included, where appropriate.

(1) Pilot working environment;

(2) Aerospace physiology;

(3) Clinical medicine;

(4) Cardiovascular system;

(5) Neurology;

(6) Psychiatry/psychology;

(7) Visual system and colour vision;

(8) Otorhinolaryngology;

(9) Dentistry;

(10) Human factors in aviation;

(11) Incidents and accidents, escape and survival; and

(12) Tropical medicine.

(c) Practical training in an AeMC should be under the guidance and supervision of the head of the AeMC.

(d) After the successful completion of the practical training, a report of demonstrated competency should be issued.

GM1 MED.D.020 Training courses in aviation medicine

ED Decision 2019/002/R

BASIC TRAINING COURSE

(a)	Basic training course in aviation medicine	60 hours
(1)	Introduction to aviation medicine	2 hours
(i)	History of aviation medicine	
(ii)	Specific aspects of civil aviation medicine	
(iii)	Different types of recreational flying	
(iv)	AME and pilots relationship	
(v)	Responsibility of the AME in aviation safety	
(vi)	Communication and interview techniques	
(2)	Basic aeronautical knowledge	2 hours
(i)	Flight mechanisms	
(ii)	Man-machine interface, informational processing	
(iii)	Propulsion	
(iv)	Conventional instruments, ‘glass cockpit’	
(v)	Recreational flying	
(vi)	Simulator/aircraft experience	
(3)	Aviation physiology	9 hours
(i)	Atmosphere	
(A)	Functional limits for humans in flight	
(B)	Divisions of the atmosphere	
(C)	Gas laws — physiological significance	
(D)	Physiological effects of decompression	
(ii)	Respiration	
(A)	Blood gas exchange	
(B)	Oxygen saturation	
(iii)	Hypoxia signs and symptoms	
(A)	Average time of useful consciousness (TUC)	
(B)	Hyperventilation signs and symptoms	
(C)	Barotrauma	
(D)	Decompression sickness	
(iv)	Acceleration	
(A)	G-Vector orientation	

(B) Effects and limits of G-load

(C) Methods to increase Gz-tolerance

(D) Positive/negative acceleration

(E) Acceleration and the vestibular system

(v) Visual disorientation

(A) Sloping cloud deck

(B) Ground lights and stars confusion

(C) Visual autokinesis

(vi) Vestibular disorientation

(A) Anatomy of the inner ear

(B) Function of the semicircular canals

(C) Function of the otolith organs

(D) The oculogyral and coriolis illusion

(E) 'Leans'

(F) Forward acceleration illusion of 'nose up'

(G) Deceleration illusion of 'nose down'

(H) Motion sickness — causes and management

(vii) Noise and vibration

(A) Preventive measures

(4) Cardiovascular system 3 hours

(i) Relation to aviation; risk of incapacitation

(ii) Examination procedures: ECG, laboratory testing and other special examinations

(iii) Cardiovascular diseases:

(A) Hypertension, treatment and assessment

(B) Ischaemic heart disease

(C) ECG findings

(D) Assessment of satisfactory recovery from myocardial infarction, interventional procedures and surgery

(E) Cardiomyopathies; pericarditis; rheumatic heart disease; valvular diseases

(F) Rhythm and conduction disturbances, treatment and assessment

(G) Congenital heart disease: surgical treatment, assessment

(H) Cardiovascular syncope: single and repeated episodes

Topics (5) to (11) inclusive, and (17) 10 hours

(5) Respiratory system

(i) Relation to aviation, risk of incapacitation

(ii) Examination procedures: spirometry, peak flow, x-ray, other examinations

(iii) Pulmonary diseases: asthma, chronic obstructive pulmonary diseases

(iv) Infections, tuberculosis

(v) Bullae, pneumothorax

(vi) Obstructive sleep apnoea

(vii) Treatment and assessment

(6) Digestive system

(i) Relation to aviation, risk of incapacitation

(ii) Examination of the system

(iii) Gastro-intestinal disorders: gastritis, ulcer disease

(iv) Biliary tract disorders

(v) Hepatitis and pancreatitis

(vi) Inflammatory bowel disease, irritable colon/irritable bowel disease

(vii) Herniae

(viii) Treatment and assessment including post-abdominal surgery

(7) Metabolic and endocrine systems

(i) Relation to aviation, risk of incapacitation

(ii) Endocrine disorders

(iii) Diabetes mellitus Type 1 & 2

(A) Diagnostic tests and criteria

(B) Anti-diabetic therapy

(C) Operational aspects in aviation

(D) Satisfactory control criteria for aviation

(iv) Hyper/hypothyroidism

(v) Pituitary and adrenal glands disorders

(vi) Treatment and assessment

(8) Haematology

(i) Relation to aviation, risk of incapacitation

(ii) Blood donation aspects

(iii) Erythrocytosis; anaemia; leukaemia; lymphoma

(iv) Sickle cell disorders

(v) Platelet disorders

(vi) Haemoglobinopathies; geographical distribution; classification

(vii) Treatment and assessment

(9) Genitourinary system

(i) Relation to aviation, risk of incapacitation

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

(iii) Urinary system disorders:

(A) Nephritis; pyelonephritis; obstructive uropathies

(B) Tuberculosis

(C) Lithiasis: single episode; recurrence

(D) Nephrectomy, transplantation, other treatment and assessment

(10) Obstetrics and gynaecology

(i) Relation to aviation, risk of incapacitation

(ii) Pregnancy and aviation

(iii) Disorders, treatment and assessment

(11) Musculoskeletal system

(i) Vertebral column diseases

(ii) Arthropathies and arthroprosthesis

(iii) Pilots with a physical impairment

(iv) Treatment of musculoskeletal system, assessment for flying

(12) Psychiatry 2 hours

(i) Relation to aviation, risk of incapacitation

(ii) Psychiatric examination

(iii) Psychiatric disorders: neurosis; personality disorders; psychosis; organic mental illness

(iv) Alcohol and other psychoactive substance(s) use

(v) Treatment, rehabilitation and assessment

(13) Psychology 2 hours

(i) Introduction to psychology in aviation as a supplement to psychiatric assessment

(ii) Methods of psychological examination

(iii) Behaviour and personality

(iv) Workload management and situational awareness

(v) Flight motivation and suitability

(vi) Group social factors

(vii) Psychological stress, stress coping, fatigue

(viii) Psychomotor functions and age

(ix) Mental fitness and training

(14) Neurology 3 hours

(i) Relation to aviation, risk of incapacitation

(ii) Examination procedures

(iii) Neurological disorders

(A) Seizures — assessment of single episode

(B) Epilepsy

(C) Multiple sclerosis

(D) Head trauma

(E) Post-traumatic states

(F) Vascular diseases

(G) Tumours

(H) Disturbance of consciousness — assessment of single and repeated episodes

(iv) Degenerative diseases

(v) Sleep disorders

(vi) Treatment and assessment

(15) Visual system and colour vision 4 hours

(i) Anatomy of the eye

(ii) Relation to aviation duties

(iii) Examination techniques

(A) Visual acuity assessment

(B) Visual aids

(C) Visual fields — acceptable limits for certification

(D) Ocular muscle balance

(E) Assessment of pathological eye conditions

(F) Glaucoma

(iv) Monocularity and medical flight tests

(v) Colour vision

(vi) Methods of testing: pseudoisochromatic plates, lantern tests, anomaloscopy

(vii) Importance of standardisation of tests and of test protocols

(viii) Assessment after eye surgery

(16) Otorhinolaryngology 3 hours

(i) Anatomy of the systems

(ii) Clinical examination in ORL

(iii) Functional hearing tests

(iv) Vestibular system; vertigo, examination techniques

(v) Assessment after ENT surgery

(vi) Barotrauma ears and sinuses

(vii) Aeronautical ENT pathology

(viii) ENT requirements

(17) Oncology

(i) Relation to aviation, risk of metastasis and incapacitation

(ii) Risk management

(iii) Different methods of treatment and assessment

(18) Incidents and accidents, escape and survival 1 hour

(i) Accident statistics

(ii) Injuries

(iii) Aviation pathology, post-mortem examination, identification

(iv) Aircraft evacuation

(A) Fire

(B) Ditching

(C) By parachute

(19) Medication and flying 2 hours

(i) Hazards of medications

(ii) Common side effects; prescription medications; over-the-counter medications; herbal medications; 'alternative' therapies

(iii) Medication for sleep disturbance

(20) Legislation, rules and regulations 4 hours

(i) ICAO Standards and Recommended Practices, European provisions (e.g. Implementing Rules, AMC and GM)

(ii) Incapacitation: acceptable aero-medical risk of incapacitation; types of incapacitation; operational aspects

(iii) Basic principles in assessment of fitness for aviation

(iv) Operational and environmental conditions

(v) Use of medical literature in assessing medical fitness; differences between scientific study populations and licensed populations

(vi) Flexibility

(vii) Annex 1 to the Chicago Convention, paragraph 1.2.4.9

(viii) Accredited Medical Conclusion; consideration of knowledge, skill and experience

(ix) Trained versus untrained crews; incapacitation training

(x) Medical flight tests

(21) Cabin crew working environment 1 hour

(i) Cabin environment, workload, duty and rest time, fatigue risk management

(ii) Cabin crew safety duties and associated training

(iii) Types of aircraft and types of operations

(iv) Single-cabin crew and multi-cabin crew operations

(22) In-flight environment 1 hour

(i) Hygiene aboard aircraft: water supply, oxygen supply, disposal of waste, cleaning, disinfection and disinsection

(ii) Catering

(iii) Crew nutrition

(iv) Aircraft and transmission of diseases

(23) Space medicine 1 hour

(i) Microgravity and metabolism, life sciences

(24) Practical demonstrations of basic aeronautical knowledge 8 hours

(25) Concluding items 2 hours

(i) Final examination

(ii) De-briefing and critique

GM2 MED.D.020 Training courses in aviation medicine

ED Decision 2019/002/R

ADVANCED TRAINING COURSE

(a) Advanced training course in aviation medicine 66 hours

(1) Pilot working environment 6 hours

(i) Commercial aircraft flight crew compartment

(ii) Business jets, commuter flights, cargo flights

(iii) Professional airline operations

(iv) Fixed wing and helicopter, specialised operations including aerial work

(v) Air traffic control

(vi) Single-pilot/multi-pilot

(vii) Exposure to radiation and other harmful agents

(2) Aerospace physiology 4 hours

(i) Brief review of basics in physiology (hypoxia, rapid/slow decompression, hyperventilation, acceleration, ejection, spatial disorientation)

(ii) Simulator sickness

(3) Clinical medicine — 5 hours

(i) Complete physical examination

(ii) Review of basics with relationship to commercial flight operations

(iii) Class 1 requirements

(iv) Clinical cases

(v) Communication and interview techniques

(4) Cardiovascular system — 4 hours

(i) Cardiovascular examination and review of basics

(ii) Class 1 requirements

(iii) Diagnostic steps in cardiovascular system

(iv) Clinical cases

(5) Neurology — 3 hours

(i) Brief review of basics (neurological and psychiatric examination)

(ii) Alcohol and other psychoactive substance(s) use

(iii) Class 1 requirements

(iv) Clinical cases

(6) Psychiatry/psychology — 5 hours

(i) Brief review of basics (psychiatric/psychological evaluation techniques)

(ii) Alcohol and other psychoactive substance(s) use

(iii) Class 1 requirements

(iv) Clinical cases

(7) Visual system and colour vision — 5 hours

(i) Brief review of basics (visual acuity, refraction, colour vision, visual fields, night vision, stereopsis, monocularity)

(ii) Class 1 visual requirements

(iii) Implications of refractive and other eye surgery

(iv) Clinical cases

(8) Otorhinolaryngology — 4 hours

(i) Brief review of basics (barotrauma — ears and sinuses, functional hearing tests)

(ii) Noise and its prevention

(iii) Vibration, kinetosis

(iv) Class 1 hearing requirements

(v) Clinical cases

(9) Dentistry 2 hours

(i) Oral examination including dental formula

(ii) Oral cavity, dental disorders and treatment, including implants, fillings, prosthesis, etc.

(iii) Barodontalgia

(iv) Clinical cases

(10) Human factors in aviation, including 8 hours demonstration and practical experience 22 hours

(i) Long-haul flight operations

(A) Flight time limitations

(B) Sleep disturbance

(C) Extended/expanded crew

(D) Jet lag/time zones

(ii) Human information processing and system design

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

(B) Adaptation to the glass cockpit

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

(D) Practical simulator training

(E) Ergonomics

(iii) Crew commonality

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

(iv) Human factors in aircraft incidents and accidents

(v) Flight safety strategies in commercial aviation

(vi) Fear and refusal of flying

(vii) Psychological selection criteria

(viii) Operational requirements (flight time limitation, fatigue risk management, etc.)

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

(i) Accident statistics

(ii) Types of injuries

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

(iv) Rescue and emergency evacuation

(12) Tropical medicine 2 hours

(i) Endemicity of tropical disease

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

(iii) Vaccination of flight crew and passengers

(iv) Diseases transmitted by vectors

(v) Food and water-borne diseases

(vi) Parasitic diseases

(vii) International health regulations

(viii) Personal hygiene of aviation personnel

(13) Concluding items 2 hours

(i) Final examination

(ii) De-briefing and critique

GM3 MED.D.020 Training courses in aviation medicine

ED Decision 2019/002/R

GENERAL

(a) Principles of training:

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

(1) based on regulations;

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

(3) based on knowledge of the different risk assessments required for various types of medical certification;

(4) based on an understanding of the limits of the decision-making competences of an AME in assessing safety-critical medical conditions for when to defer and when to deny;

(5) based on knowledge of the aviation environment; and

(6) exemplified by clinical cases and practical demonstrations.

(b) Training outcomes:

The trainee should demonstrate a thorough understanding of:

(1) the aero-medical examination and assessment process:

(i) principles, requirements and methods;

(ii) ability to investigate all clinical aspects that present aero-medical risks, the reasonable use of additional investigations;

(iii) the role in the assessment of the ability of the pilot or cabin crew member to safely perform their duties in special cases, such as the medical flight test;

(iv) aero-medical decision-making based on risk management;

(v) medical confidentiality; and

(vi) correct use of appropriate forms, and the reporting and storing of information;

(2) the conditions under which the pilots and cabin crew carry out their duties; and

(3) principles of preventive medicine, including aero-medical advice in order to help prevent future limitations.

(c) The principles and training outcomes stated at (a) and (b) should also be taken into consideration for refresher training programmes

MED.D.025 Changes to the AME certificate

Regulation (EU) 2019/27

(a) Holders of an AME certificate shall, without undue delay, notify the competent authority of the following circumstances which could affect their AME certificate:

(1) the AME is subject to disciplinary proceedings or investigation by a medical regulatory body;

(2) there are changes to the conditions under which the certificate was granted, including the content of the statements provided with the application;

(3) the requirements for the issuance of the AME certificate are no longer met;

(4) there is a change to the aero-medical examiner's practice location(s) or correspondence address.

(b) Failure to notify the competent authority in accordance with point (a) shall result in the suspension or revocation of the AME certificate in accordance with point ARA.MED.250 of Annex II (Part-ARA).

MED.D.030 Validity of AME certificates

Regulation (EU) 2019/27

An AME certificate shall be valid for a period of 3 years, unless the competent authority decides to reduce that period for duly justified reasons related to the individual case.

Upon application by the holder, the certificate shall be:

(a) revalidated, provided that the holder:

(1) continues to fulfil the general conditions required for medical practice and maintains his or her licence for the practice of medicine;

(2) has undertaken refresher training in aviation medicine within the last 3 years;

(3) has performed at least 10 aero-medical examinations or equivalent every year;

(4) remains in compliance with the terms of the certificate;

(5) exercises the privileges in accordance with the requirements of this Annex (Part-MED);

(6) has demonstrated that he or she maintains his or her aero-medical competency in accordance with the procedure established by the competent authority.

(b) renewed, provided that the holder complies with either the requirements for revalidation set out in point (a) or with all of the following requirements:

(1) continues to fulfil the general conditions required for medical practice and maintains his or her licence for the practice of medicine;

(2) has undertaken refresher training in aviation medicine within the previous year;

(3) has successfully completed practical training within the previous year, either at an AeMC or under the supervision of the competent authority;

(4) remains in compliance with the requirements of point MED.D.010;

(5) has demonstrated that he or she maintains his or her aero-medical competency in accordance with the procedure established by the competent authority.

AMC1 MED.D.030 Validity of AME certificates

ED Decision 2019/002/R

REFRESHER TRAINING

(a) It is the responsibility of the AME to continuously maintain and improve their competencies.

(b) During the period of validity of the AME certificate, an AME should attend a minimum of 20 hours of refresher training.

(c) An AME exercising class 1 privileges should attend at least 10 hours of refresher training per year.

(d) A proportionate number of refresher training hours should be provided by, or conducted under the direct supervision of, the competent authority or the medical assessor.

(e) The curricula of refresher training hours referred to in (c) should be decided by the competent authority following a risk-based assessment.

(f) Attendance at scientific meetings and congresses, and flight deck experience may be credited by the competent authority for a specified number of hours against the training obligations of the AME, provided the competent authority has assessed it in advance as being relevant for crediting purposes.

(g) In case of renewal of an AME certificate, the practical training should include at least 10 aero-medical assessments, in accordance with the type of the requested AME certificate.

GM1 MED.D.030 Validity of AME certificates

ED Decision 2019/002/R

REFRESHER TRAINING

(a) The curricula for the refresher training hours that should be provided by, or conducted under the direct supervision of, the competent authority or the medical assessor may include but are not limited to subjects such as:

(1) Psychiatry

(i) Relation to aviation, risk of incapacitation;

(ii) Psychiatric examination;

(iii) Psychiatric disorders: neurosis, personality disorders, psychosis, organic mental illness;

(iv) Alcohol and other psychoactive substance(s) use; and

(v) Treatment, rehabilitation and assessment.

(2) Psychology

(i) Introduction to psychology in aviation as a supplement to psychiatric assessment;

(ii) Methods of psychological examination;

(iii) Behaviour and personality;

(iv) Workload management and situational awareness;

(v) Flight motivation and suitability;

(vi) Group social factors;

(vii) Psychological stress, stress coping, fatigue;

(viii) Psychomotor functions and age; and

(ix) Mental fitness and training.

(3) Communication and interview techniques

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

International Academy of Aviation and Space Medicine Annual Congresses (ICASM)	10 hours credit
European Conference of Aerospace Medicine (ECAM)	10 hours credit
Aerospace Medical Association Annual Scientific Meetings (AsMA)	10 hours credit
Other scientific meetings (A minimum of 6 hours to be under the direct supervision of the medical assessor of the competent authority)	10 hours credit

Flight crew compartment experience (a maximum of 5 hours credit per 3 years):

(i)	Jump seat	5 sectors — 1 hour credit
(ii)	Simulator	4 hours — 1 hour credit
(iii)	Aircraft piloting	4 hours — 1 hour credit

(c) An AME exercising class 1 revalidation/renewal privileges should attend international aviation medicine scientific meetings or congresses at regular intervals.

(d) Aero-medical examinations of military pilots may be considered as equivalent in accordance with MED.D.030(a)(3), subject to approval by the medical assessor of the competent authority.

GM2 MED.D.030 Validity of AME certificates

ED Decision 2019/002/R

AME PEER SUPPORT GROUPS

(a) The competent authority should promote better performance of AMEs by supporting the establishment of AME peer support groups that could provide both professional support and educational enhancement.

(b) Attendance to AME peer support group meetings may be credited by the competent authority as refresher training. The competent authority should determine a maximum of hours that can be credited as refresher training during the period of authorisation.

(c) AME peer support groups may be established as part of, or complementary to, national associations of aerospace medicine.

SECTION 2 – GENERAL MEDICAL PRACTITIONERS

MED.D.035 Requirements for general medical practitioners

Regulation (EU) 2019/27

General medical practitioners (GMPs) may act as AMEs for issuing LAPL medical certificates, where they meet all of the following conditions:

(a) they exercise their activity in a Member State where GMPs have access to the full medical records of applicants;

(b) they exercise their activity in accordance with any additional requirements established in the national law of the Member State of their competent authority;

(c) they are fully qualified and licensed for the practice of medicine in accordance with national law of the Member State of their competent authority;

(d) they have notified the competent authority before starting such activity.

SECTION 3 – OCCUPATIONAL HEALTH MEDICAL PRACTITIONERS

MED.D.040 Requirements for occupational health medical practitioners

Regulation (EU) 2019/27

In Member States where the competent authority is satisfied that the requirements of the national health system applicable to occupational health medical practitioners (OHMPs) are such as to ensure compliance with the requirements of this Annex (Part-MED) applicable to OHMPs, OHMPs may conduct aero-medical assessments of cabin crew, provided that:

(a) they are fully qualified and licensed in the practice of medicine and qualified in occupational medicine;

(b) the in-flight working environment and safety duties of the cabin crew were included in their occupational medicine qualification syllabus or other training or operational experience;

(c) they have notified the competent authority before starting such activity.

ANNEX VI (PART-ARA)

SUBPART GEN – GENERAL REQUIREMENTS

SECTION I – GENERAL

ARA.GEN.115 Oversight documentation

Regulation (EU) No 1178/2011

The competent authority shall provide all legislative acts, standards, rules, technical publications and related documents to relevant personnel in order to allow them to perform their tasks and to discharge their responsibilities.

ARA.GEN.120 Means of compliance

Regulation (EU) No 290/2012

(a) The Agency shall develop Acceptable Means of Compliance (AMC) that may be used to establish compliance with Regulation (EC) No 216/2008 and its Implementing Rules. When the AMC are complied with, the related requirements of the Implementing Rules are met.

(b) Alternative means of compliance may be used to establish compliance with the Implementing Rules.

(c) The competent authority shall establish a system to consistently evaluate that all alternative means of compliance used by itself or by organisations and persons under its oversight allow the establishment of compliance with Regulation (EC) No 216/2008 and its Implementing Rules.

(d) The competent authority shall evaluate all alternative means of compliance proposed by an organisation in accordance with ORA.GEN.120 by analysing the documentation provided and, if considered necessary, conducting an inspection of the organisation.

When the competent authority finds that the alternative means of compliance are in accordance with the Implementing Rules, it shall without undue delay:

(1) notify the applicant that the alternative means of compliance may be implemented and, if applicable, amend the approval or certificate of the applicant accordingly; and

(2) notify the Agency of their content, including copies of all relevant documentation;

(3) inform other MS about alternative means of compliance that were accepted.

(e) When the competent authority itself uses alternative means of compliance to achieve compliance with Regulation (EC) No 216/2008 and its Implementing Rules it shall:

(1) make them available to all organisations and persons under its oversight; and

(2) without undue delay notify the Agency.

The competent authority shall provide the Agency with a full description of the alternative means of compliance, including any revisions to procedures that may be relevant, as well as an assessment demonstrating that the Implementing Rules are met.

AMC1 ARA.GEN.120(d)(3) Means of compliance

ED Decision 2012/006/R

GENERAL

The information to be provided to other Member States following approval of an alternative means of compliance should contain a reference to the Acceptable Means of Compliance (AMC) to which such means of compliance provides an alternative, as well as a reference to the corresponding Implementing Rule, indicating as applicable the subparagraph(s) covered by the alternative means of compliance.

GM1 ARA.GEN.120 Means of compliance

ED Decision 2012/006/R

GENERAL

Alternative means of compliance used by a competent authority or by organisations under its oversight may be used by other competent authorities or organisations only if processed again in accordance with ARA.GEN.120(d) and (e).

ARA.GEN.125 Information to the Agency

Regulation (EU) No 1178/2011

(a) The competent authority shall without undue delay notify the Agency in case of any significant problems with the implementation of Regulation (EC) No 216/2008 and its Implementing Rules.

(b) The competent authority shall provide the Agency with safety-significant information stemming from the occurrence reports it has received.

ARA.GEN.135 Immediate reaction to a safety problem

Regulation (EU) No 1178/2011

(a) Without prejudice to Directive 2003/42/EC of the European Parliament and of the Council ([1]) the competent authority shall implement a system to appropriately collect, analyse and disseminate safety information.

(b) The Agency shall implement a system to appropriately analyse any relevant safety information received and without undue delay provide to Member States and the Commission any information, including recommendations or corrective actions to be taken, necessary for them to react in a timely manner to a safety problem involving products, parts, appliances, persons or organisations subject to Regulation (EC) No 216/2008 and its Implementing Rules.

(c) Upon receiving the information referred to in (a) and (b), the competent authority shall take adequate measures to address the safety problem.

(d) Measures taken under (c) shall immediately be notified to all persons or organisations which need to comply with them under Regulation (EC) No 216/2008 and its Implementing Rules. The competent authority shall also notify those measures to the Agency and, when combined action is required, the other Member States concerned.

[1] OJ L 167, 4.7.2003, p. 23.

SECTION II – MANAGEMENT

ARA.GEN.200 Management system

Regulation (EU) 2018/1119

(a) The competent authority shall establish and maintain a management system, including as a minimum:

(1) documented policies and procedures to describe its organisation, means and methods to achieve compliance with Regulation (EC) No 216/2008 and its Implementing Rules. The procedures shall be kept up-to-date and serve as the basic working documents within that competent authority for all related tasks;

(2) asufficient number of personnel to perform its tasks and discharge its responsibilities. Such personnel shall be qualified to perform their allocated tasks and have the necessary knowledge, experience, initial and recurrent training to ensure continuing competence. A system shall be in place to plan the availability of personnel, in order to ensure the proper completion of all tasks;

(3) adequate facilities and office accommodation to perform the allocated tasks;

(4) a function to monitor compliance of the management system with the relevant requirements and adequacy of the procedures including the establishment of an internal audit process and a safety risk management process. Compliance monitoring shall include a feedback system of audit findings to the senior management of the competent authority to ensure implementation of corrective actions as necessary; and

(5) a person or group of persons, ultimately responsible to the senior management of the competent authority for the compliance monitoring function.

(b) The competent authority shall, for each field of activity including management system, appoint one or more persons with the overall responsibility for the management of the relevant task(s).

(c) The competent authority shall establish procedures for participation in a mutual exchange of all necessary information and assistance with other competent authorities concerned, including information on all findings raised, corrective follow-up actions taken pursuant to such findings and enforcement measures taken as a result of oversight of persons and organisations exercising activities in the territory of a Member State but certified by or having made declarations to the competent authority of another Member State or the Agency.

(d) A copy of the procedures related to the management system and their amendments shall be made available to the Agency for the purpose of standardisation.

AMC1 ARA.GEN.200(a) Management system

ED Decision 2018/009/R

GENERAL

(a) All of the following should be considered when deciding upon the required organisational structure:

(1) the number of certificates, attestations, authorisations and approvals to be issued;

(2) the number of declared training organisations;

(3) the number of certified persons and organisations exercising an activity within that Member State, including persons or organisations certified by, or having made a declaration to, other competent authorities;

(4) the possible use of qualified entities and of resources of other competent authorities to fulfil the continuing oversight obligations;

(5) the level of civil aviation activity in terms of:

(i) number and complexity of aircraft operated;

(ii) size and complexity of the Member State's aviation industry;

(6) the potential growth of activities in the field of civil aviation.

(b) The set-up of the organisational structure should ensure that the various tasks and obligations of the competent authority do not rely solely on individuals. A continuous and undisturbed fulfilment of these tasks and obligations of the competent authority should also be guaranteed in case of illness, accident or leave of individual employees.

GM1 ARA.GEN.200(a) Management system

ED Decision 2012/006/R

GENERAL

(a) The competent authority designated by each Member State should be organised in such a way that:

(1) there is specific and effective management authority in the conduct of all relevant activities;

(2) the functions and processes described in the applicable requirements of Regulation (EC) No 216/2008[1] and its Implementing Rules and AMCs, Certification Specifications (CSs) and Guidance Material (GM) may be properly implemented;

(3) the competent authority's organisation and operating procedures for the implementation of the applicable requirements of Regulation (EC) No 216/2008 and its Implementing Rules are properly documented and applied;

(4) all competent authority personnel involved in the related activities are provided with training where necessary;

(5) specific and effective provision is made for the communication and interface as necessary with the Agency and the competent authorities of other Member States; and

(6) all functions related to implementing the applicable requirements are adequately described.

(b) A general policy in respect of activities related to the applicable requirements of Regulation (EC) No 216/2008 and its Implementing Rules should be developed, promoted and implemented by the manager at the highest appropriate level; for example the manager at the top of the functional area of the competent authority that is responsible for such activities.

[1] Regulation (EC) No 216/2008 of the European Parliament and of the Council of 20 February 2008 on common rules in the field of civil aviation and establishing a European Aviation Safety Agency, and repealing Council Directive 91/670/EEC, Regulation (EC) No 1592/2002 and Directive 2004/36/EC. OJ L 79, 19.3.2008, p. 1.

(c) Appropriate steps should be taken to ensure that the policy is known and understood by all personnel involved, and all necessary steps should be taken to implement and maintain the policy.

(d) The general policy, whilst also satisfying additional national regulatory responsibilities, should in particular take into account:

(1) the provisions of Regulation (EC) No 216/2008;

(2) the provisions of the applicable Implementing Rules and their AMCs, CSs and GM;

(3) the needs of industry; and

(4) the needs of the Agency and of the competent authority.

(e) The policy should define specific objectives for key elements of the organisation and processes for implementing related activities, including the corresponding control procedures and the measurement of the achieved standard.

AMC1 ARA.GEN.200(a)(1) Management system

ED Decision 2012/006/R

DOCUMENTED POLICIES AND PROCEDURES

(a) The various elements of the organisation involved with the activities related to Regulation (EC) No 216/2008 and its Implementing Rules should be documented in order to establish a reference source for the establishment and maintenance of this organisation.

(b) The documented procedures should be established in a way that facilitates their use. They should be clearly identified, kept up-to-date and made readily available to all personnel involved in the related activities.

(c) The documented procedures should cover, as a minimum, all of the following aspects:

(1) policy and objectives;

(2) organisational structure;

(3) responsibilities and associated authority;

(4) procedures and processes;

(5) internal and external interfaces;

(6) internal control procedures;

(7) training of personnel;

(8) cross-references to associated documents;

(9) assistance from other competent authorities or the Agency (where required).

(d) It is likely that the information is held in more than one document or series of documents, and suitable cross-referencing should be provided. For example, organisational structure and job descriptions are not usually in the same documentation as the detailed working procedures. In such cases it is recommended that the documented procedures include an index of cross-references to all such other related information, and the related documentation should be readily available when required.

AMC1 ARA.GEN.200(a)(2) Management system

ED Decision 2012/006/R

QUALIFICATION AND TRAINING - GENERAL

(a) The competent authority should ensure appropriate and adequate training of its personnel to meet the standard that is considered necessary to perform the work. To ensure personnel remain qualified, arrangements should be made for initial and recurrent training as required.

(b) The basic capability of the competent authority's personnel is a matter of recruitment and normal management functions in selection of personnel for particular duties. Moreover, the competent authority should provide training in the basic skills as required for those duties. However, to avoid differences in understanding and interpretation, all personnel should be provided with further training specifically related to Regulation (EC) No 216/2008, its Implementing Rules and related AMCs, CSs and GM, as well as related to the assessment of alternative means of compliance.

(c) The competent authority may provide training through its own training organisation with qualified trainers or through another qualified training source.

(d) When training is not provided through an internal training organisation, adequately experienced and qualified persons may act as trainers, provided their training skills have been assessed. If required, an individual training plan should be established covering specific training skills. Records should be kept of such training and of the assessment, as appropriate.

AMC2 ARA.GEN.200(a)(2) Management system

ED Decision 2017/022/R

QUALIFICATION AND TRAINING - INSPECTORS

(a) Qualification

(1) All inspectors should receive, as appropriate to their role, training in the following areas:

(i) auditing techniques, as relevant to the particular duties and responsibilities of the inspector;

(ii) safety management systems (SMSs);

(iii) compliance monitoring system (CMSs);

(iv) the requirements of Regulation (EU) No 1178/2011 related to their duties, in particular of Annex VII (Part-ORA) and Annex VI (Part ARA) thereto; and

(v) ICAO Annexes and guidance material relevant to their duties.

(2) Additional qualification criteria:

(i) inspectors conducting sampling of training flights in aircraft or FSTD sessions should hold or have held a pilot licence and relevant ratings and certificates appropriate to the level of the training conducted;

(ii) inspectors conducting sampling of training flights in aircraft as a member of the flight crew should hold a pilot licence and relevant ratings and certificates appropriate to the level of the training conducted;

(iii) inspectors conducting sampling of theoretical-knowledge instruction should have a practical background in aviation in the areas relevant to the training provided as well as practical experience in instructional techniques;

(iv) inspectors approving training programmes should have relevant experience in the same area; and

(v) inspectors not involved in activities referred to in (i)-(iv) above should have a relevant background in aviation related to their duties.

(b) Initial training programme

The initial training programme for inspectors should include, as appropriate to their role, current knowledge of, as well as experience and skills in, at least the following:

(1) air law – organisation and structure;

(2) Regulation (EC) No 216/2008, as well as its implementing regulations and related AMC/GM;

(3) the Chicago Convention, as well as relevant ICAO Annexes and guidance;

(4) relevant national aviation and administrative legislation;

(5) the applicable requirements and procedures (including the correct formulation of findings);

(6) management systems, including assessment of SMSs and CMSs, as well as auditing, risk assessment, and reporting techniques;

(7) competency-based training, including approval of training organisations;

(8) criteria for the qualification of FSTDs;

(9) evidence-based training;

(10) HF training (including 'just culture' in aviation and conflict management);

(11) performance-based oversight;

(12) rights and obligations of the competent authority's inspecting personnel;

(13) 'on-the-job training';

(14) the relevant Annexes to Regulation (EU) No 965/2012; and

(15) suitable technical training appropriate to the role and tasks of the inspector, in particular for those areas requiring approvals.

(c) Recurrent training programme

The recurrent training programme should reflect, at least, changes in aviation legislation and industry. It should also cover the specific needs of the inspectors and of the competent authority, and include at least the following:

(1) an inspection on behalf of the competent authority, supervised by another inspector;

(2) licence proficiency check(LPC)/OPC on an appropriate aircraft type/class (if applicable);

(3) instructor refresher seminar (if applicable);

(4) audit techniques course for regulators (refresher course); and

(5) SMS refresher course.

GM1 ARA.GEN.200(a)(2) Management system

ED Decision 2018/009/R

SUFFICIENT PERSONNEL

(a) This GM on the determination of the required personnel is limited to the performance of certification and oversight tasks, excluding personnel required to perform tasks subject to any national regulatory requirements.

(b) The elements to be considered when determining required personnel and planning their availability may be divided into quantitative and qualitative elements:

(1) Quantitative elements:

(i) the estimated number of initial certificates to be issued and declarations to be received;

(ii) the number of:

(A) organisations certified by the competent authority; and

(B) organisations having declared their activity to the competent authority;

(iii) the number of persons to whom the competent authority has issued a licence, certificate, rating, authorisation or attestation;

(iv) the estimated number of persons and organisations exercising their activity within the territory of the Member State and established or residing in another Member State.

(2) Qualitative elements:

(i) the size, nature and complexity of activities of certified and declared organisations as well as FSTD qualification certificate holders (cf. AMC1 ORA.GEN.200(b)),taking into account:

(A) privileges of the organisation;

(B) type and scope of approval or declared activities, multiple certification or declaration;

(C) possible certification or declaration to industry standards;

(D) types of aircraft / flight simulation training devices (FSTDs) operated;

(E) number of personnel; and

(F) organisational structure, existence of subsidiaries;

(ii) the safety priorities identified;

(iii) the results of past oversight activities, including audits, inspections and reviews, in terms of risks and regulatory compliance, taking into account:

(A) number and level of findings;

(B) timeframe for implementation of corrective actions; and

(C) maturity of management systems implemented by organisations and their ability to effectively manage safety risks, taking into account also information provided by other competent authorities related to activities in the territory of the Member States concerned; and

(iv) the size and complexity of the Member State's aviation industry and the potential growth of activities in the field of civil aviation, which may be an indication of the number of new applications and declarations as well as changes to existing certificates and declarations to be expected.

(c) Based on existing data from previous oversight planning cycles and taking into account the situation within the Member State's aviation industry, the competent authority may estimate:

(1) the standard working time required for processing:

(i) applications for new certificates (for persons, organisations and FSTD qualification);

(ii) new declarations;

(2) for each planning period, the number of:

(i) new certificates to be issued;

(ii) declarations to be received; and

(iii) changes to existing certificates and declarations to be processed;

(3) the number of changes to existing certificates to be processed for each planning period.

(d) In line with the competent authority's oversight policy, the following planning data should be determined specifically for each type of organisation certified by the competent authority (approved training organisations (ATOs) and aero-medical centres (AeMCs)) and for FSTD qualification certificate holders as well as for declared training organisations:

(1) standard number of audits to be performed per oversight planning cycle;

(2) standard duration of each audit;

(3) standard working time for audit preparation, on-site audit, reporting and follow-up, per inspector;

(4) standard number of ramp and unannounced inspections to be performed;

(5) standard duration of inspections, including preparation, reporting and follow-up, per inspector;

(6) minimum number and required qualification of inspectors for each audit/inspection.

(e) Standard working time could be expressed either in working hours per inspector or in working days per inspector. All planning calculations should then be based on the same unit (hours or working days).

(f) It is recommended to use a spreadsheet application to process data defined under (c) and (d), to assist in determining the total number of working hours / days per oversight planning cycle required for certification, oversight and enforcement activities. This application could also serve as a basis for implementing a system for planning the availability of personnel.

(g) For each type of organisation certified by the competent authority, FSTD qualification certificate holders and declared training organisations, the number of working hours/days per planning period for each qualified inspector that may be allocated for certification, oversight and enforcement activities should be determined, taking into account:

(1) purely administrative tasks not directly related to oversight and certification;

(2) training;

(3) participation in other projects;

(4) planned absence; and

(5) the need to include a reserve for unplanned tasks or unforeseeable events.

(h) The determination of working time available for certification, oversight and enforcement activities should also consider:

(1) the possible use of qualified entities; and

(2) possible cooperation with other competent authorities for approvals and declarations involving more than one Member State.

(i) Based on the elements listed above, the competent authority should be able to:

(1) monitor dates when audits and inspections are due and when they have been carried out;

(2) implement a system to plan the availability of personnel; and

(3) identify possible gaps between the number and qualification of personnel and the required volume of certification and oversight.

Care should be taken to keep planning data up-to-date in line with changes in the underlying planning assumptions, with particular focus on risk-based oversight principles.

GM2 ARA.GEN.200(a)(2) Management system

ED Decision 2017/022/R

(a) The content of the initial training programme for inspectors referred to in AMC2 ARA.GEN.200(a)(2) may be selected from the following documents, as relevant to the particular duties and responsibilities of the inspector:

(1) ICAO Annex 1 ‘Personnel Licensing’;

(2) ICAO Annex 19 ‘Safety Management’;

(3) ICAO Doc 9841 ‘Manual on the Approval of Flight Crew Training Organisations’;

(4) ICAO Doc 9868 ‘Procedures for Air Navigation Services – Training’;

(5) ICAO Doc 9859 ‘Safety Management Manual’;

(6) ICAO Doc 9379 ‘Manual of Procedures for Establishment and Management of a States Personnel Licensing System’;

(7) ICAO Doc 9625 ‘Manual of Criteria for the Qualification of Flight Simulation Training Devices’;

(8) ICAO Doc 9995 ‘Manual of Evidence-based Training’;

(9) ICAO Doc 10011 ‘Manual on Aeroplane Upset Prevention and Recovery Training’;

(10) ‘Airplane Upset Prevention and Recovery Training Aid’ (AUPRTA), Revision 3.

(b) A minimum of activities should be performed according to the initial training programme:

(1) observations; and

(2) inspections as a team member.

GM3 ARA.GEN.200(a)(2) Management system

ED Decision 2017/022/R

The meaning of 'relevant ratings and certificates appropriate to the level of the training conducted', as used in AMC2 ARA.GEN.200(a)(2), is explained below:

- the range of activities in an ATO may vary from instructions for the simple single-engined aircraft to type training for CS-25-certified multi-pilot aircraft;
- in the context of the general approval of the ATO, experience in similar types or classes of aircraft is acceptable;
- the inspector has the instructional experience in the same or similar types or the same class of aircraft intended to be flown within the ATO (e.g. a type rating to assess the type training programmes); and
- the experience in CS-25-certified multi-pilot aircraft will not, for example, equip the inspector to assess the training programme in an ATO operating only single-engine piston (SEP) (land) aircraft; similarly, experience as a PPL instructor will not necessarily equip the inspector to assess a type training course for a CS-25 aircraft; in both cases, additional appropriate training in the applicable environment is necessary.

AMC1 ARA.GEN.200(d) Management system

ED Decision 2018/009/R

PROCEDURES AVAILABLE TO THE AGENCY

(a) Copies of the procedures related to the competent authority's management system and their amendments to be made available to the Agency for the purpose of standardisation should provide at least the following information:

(1) Regarding continuing oversight functions undertaken by the competent authority, the competent authority's organisational structure with description of the main processes. This information should demonstrate the allocation of responsibilities within the competent authority, and that the competent authority is capable of carrying out the full range of tasks regarding the size and complexity of the Member State's aviation industry. It should also consider overall proficiency and authorisation scope of competent authority personnel.

(2) For personnel involved in oversight activities, the minimum professional qualification requirements and experience and principles guiding appointment (e.g. assessment).

(3) How the following are carried out: assessing applications and evaluating compliance of applications and declarations, issue of certificates, performance of continuing oversight, follow-up of findings, enforcement measures and resolution of safety concerns.

(4) Principles of managing exemptions and derogations.

(5) Processes in place to disseminate applicable safety information for timely reaction to a safety problem.

(6) Criteria for planning continuing oversight (oversight programme), including adequate management of interfaces when conducting continuing oversight (air operations, flight crew licensing, continuing airworthiness management for example).

(7) Outline of the initial training of newly recruited oversight personnel (taking future activities into account), and the basic framework for continuation training of oversight personnel.

(b) As part of the continuous monitoring of a competent authority, the Agency may request details of the working methods used, in addition to the copy of the procedures of the competent authority's management system (and amendments). These additional details are the procedures and related guidance material describing working methods for competent authority personnel conducting oversight.

(c) Information related to the competent authority's management system may be submitted in electronic format.

ARA.GEN.205 Allocation of tasks to qualified entities

Regulation (EU) No 290/2012

(a) Tasks related to the initial certification or continuing oversight of persons or organisations subject to Regulation (EC) No 216/2008 and its Implementing Rules shall be allocated by Member States only to qualified entities. When allocating tasks, the competent authority shall ensure that it has:

(1) a system in place to initially and continuously assess that the qualified entity complies with Annex V to Regulation (EC) No 216/2008.

This system and the results of the assessments shall be documented;

(2) established a documented agreement witha the qualified entity, approved by both parties at the appropriate management level, which clearly defines:

(i) the tasks to be performed;)

(ii) the declarations, reports and records to be provided;

(iii) the technical conditions to be met in performing such tasks;

(iv) the related liability coverage; and

(v) the protection given to information acquired in carrying out such tasks.

(b) The competent authority shall ensure that the internal audit process and a safety risk management process required by ARA.GEN.200(a)(4) cover all certification or continuing oversight tasks performed on its behalf.

GM1 ARA.GEN.205 Allocation of tasks to qualified entities

ED Decision 2012/006/R

CERTIFICATION TASKS

The tasks that may be performed by a qualified entity on behalf of the competent authority include those related to the initial certification and continuing oversight of persons and organisations as defined in this Regulation, with the exclusion of the issuance of certificates, licences, ratings or approvals.

ARA.GEN.210 Changes in the management system

Regulation (EU) No 1178/2011

(a) The competent authority shall have a system in place to identify changes that affect its capability to perform its tasks and discharge its responsibilities as defined in Regulation (EC) No 216/2008 and its Implementing Rules. This system shall enable it to take action as appropriate to ensure that its management system remains adequate and effective.

(b) The competent authority shall update its management system to reflect any change to Regulation (EC) No 216/2008 and its Implementing Rules in a timely manner, so as to ensure effective implementation.

(c) The competent authority shall notify the Agency of changes affecting its capability to perform its tasks and discharge its responsibilities as defined in Regulation (EC) No 216/2008 and its Implementing Rules.

ARA.GEN.220 Record-keeping

Regulation (EU) 2018/1119

(a) The competent authority shall establish a system of record-keeping providing for adequate storage, accessibility and reliable traceability of:

(1) the management system's documented policies and procedures;

(2) training, qualification and authorisation of its personnel;

(3) the allocation of tasks, covering the elements required by ARA.GEN.205 as well as the details of tasks allocated;

(4) certification and declaration processes as well as oversight of certified and declared organisations;

(5) processes for issuing personnel licences, ratings, certificates and attestations and for the continuing oversight of the holders of those licences, ratings, certificates and attestations;

(6) processes for issuing FSTD qualification certificates and for the continuing oversight of the FSTD and of the organisation operating it;

(7) oversight of persons and organisations exercising activities within the territory of the Member State, but overseen or certified by the competent authority of another Member State or the Agency, as agreed between these authorities;

(8) the evaluation and notification to the Agency of alternative means of compliance proposed by organisations and the assessment of alternative means of compliance used by the competent authority itself;

(9) findings, corrective actions and date of action closure;

(10) enforcement measures taken;

(11) safety information and follow-up measures; and

(12) the use of flexibility provisions in accordance with Article 14 of Regulation (EC) No 216/2008.

(b) The competent authority shall establish and keep up-to-date a list of all organisation certificates, FSTD qualification certificates and personnel licences, certificates and attestations

it issued, DTO declarations it received and the DTO training programmes it verified or approved for compliance with Annex I (Part-FCL).

(c) All records shall be kept for the minimum period specified in this Regulation. In the absence of such indication, records shall be kept for a minimum period of 5 years subject to applicable data protection law.

AMC1 ARA.GEN.220(a) Record-keeping

ED Decision 2012/006/R

GENERAL

(a) The record-keeping system should ensure that all records are accessible whenever needed within a reasonable time. These records should be organised in a way that ensures traceability and retrievability throughout the required retention period.

(b) Records should be kept in paper form or in electronic format or a combination of both media. Records stored on microfilm or optical disc form are also acceptable. The records should remain legible and accessible throughout the required retention period. The retention period starts when the record has been created.

(c) Paper systems should use robust material, which can withstand normal handling and filing. Computer systems should have at least one backup system, which should be updated within 24 hours of any new entry. Computer systems should include safeguards against unauthorised alteration of data.

(d) All computer hardware used to ensure data backup should be stored in a different location from that containing the working data and in an environment that ensures they remain in good condition. When hardware- or software-changes take place, special care should be taken that all necessary data continue to be accessible at least through the full period specified in the relevant Subpart or by default in ARA.GEN.220(c).

AMC1 ARA.GEN.220(a)(1);(2);(3) Record-keeping

ED Decision 2012/006/R

COMPETENT AUTHORITY MANAGEMENT SYSTEM

Records related to the competent authority's management system should include, as a minimum and as applicable:

(a) the documented policies and procedures;

(b) the personnel files of competent authority personnel, with supporting documents related to training and qualifications;

(c) the results of the competent authority's internal audit and safety risk management processes, including audit findings and corrective actions; and

(d) the contract(s) established with qualified entities performing certification or oversight tasks on behalf of the competent authority.

AMC1 ARA.GEN.220(a)(4) Record-keeping

ED Decision 2018/009/R

ORGANISATIONS

Records related to an organisation certified by, or having declared its activity to, the competent authority should include, as appropriate to the type of organisation:

(a) the application for an organisation approval or the declaration received;

(b) the documentation based on which the approval has been granted and any amendments to that documentation or, in the case of declared training organisations, the documentation required to be submitted with the declaration and any amendments thereto;

(c) the organisation approval certificate or any approval, including any changes;

(d) a copy of the continuing oversight programme listing the dates when audits or inspections are due and when such audits or inspections were carried out;

(e) continuing oversight records including all audit and inspection records;

(f) copies of all relevant correspondence;

(g) details of any exemption and enforcement actions;

(h) any report from other competent authorities relating to the oversight of the organisation; and

(i) a copy of any other document approved by the competent authority.

GM1 ARA.GEN.220(a)(4) Record-keeping

ED Decision 2018/009/R

CERTIFIED ORGANISATIONS - DOCUMENTATION

Documentation to be kept as records in support of the approval include the management system documentation, including any technical manuals, such as the operations manual, and training manual, that have been submitted with the initial application, and any amendments to these documents.

GM2 ARA.GEN.220(a)(4) Record-keeping

ED Decision 2018/009/R

DECLARED TRAINING ORGANISATIONS - DOCUMENTATION

Documents to be kept as records in support of the declaration process include the declaration form and all required attachments to it (training programmes) as well as any amendments to these documents.

AMC1 ARA.GEN.220(a)(5) Record-keeping

ED Decision 2018/011/R

PERSONS

Records related to personnel licences, certificates, ratings, authorisations or attestations issued by the competent authority should include, as a minimum:

(a) the application for a licence, certificate, rating, authorisation or attestation or change to a licence, certificate, rating, authorisation or attestation;

(b) documentation in support of the application for a licence, certificate, rating, authorisation or attestation or change to a licence, certificate, rating, authorisation or attestation, covering as applicable:

(1) the course Area 100 KSA assessment;

(2) theoretical examination(s);

(3) skill test(s);

(4) proficiency check(s); and

(5) certificates attesting required experience;

(c) a copy of the licence or certificate including any changes;

(d) all relevant correspondence or copies thereof;

(e) details of any exemption;

(f) details of any enforcement action(s); and

(g) any report from other competent authorities relating to personnel licences, certificates, ratings, authorisations or attestations issued by the competent authority.

AMC1 ARA.GEN.220(a)(7) Record-keeping

ED Decision 2018/009/R

ACTIVITIES PERFORMED IN THE TERRITORY OF A MEMBER STATE BY PERSONS OR ORGANISATIONS ESTABLISHED OR RESIDING IN ANOTHER MEMBER STATE

(a) Records related to the oversight of activities performed in the territory of a Member State by persons or organisations established or residing in another Member State should include, as a minimum:

(1) oversight records including all audit and inspection records and related correspondence;

(2) copies of all relevant correspondence to exchange information with other competent authorities relating to the oversight of such persons/organisations;

(3) details of any enforcement measures and penalties; and

(4) any report from other competent authorities relating to the oversight of these persons/organisations, including any notification of evidence showing non-compliance with the applicable requirements.

(b) Records should be kept by the competent authority having performed the audit or inspection and should be made available to other competent authorities at least in the following cases:

(1) serious incidents or accidents;

(2) findings through the oversight programme where organisations certified by, or having declared its activities to, another competent authority are involved to determine the root cause;

(3) an organisation being certified by, having approvals issued by, or having declared its activities to, competent authorities in several Member States.

(c) When records are requested by another competent authority, the reason for the request should be clearly stated.

(d) The records can be made available by sending a copy or by allowing access to them for consultation.

GM1 ARA.GEN.220 Record-keeping

ED Decision 2012/006/R

GENERAL

Records are required to document results achieved or to provide evidence of activities performed. Records become factual when recorded. Therefore, they are not subject to version control. Even when a new record is produced covering the same issue, the previous record remains valid.

SECTION III – OVERSIGHT, CERTIFICATION AND ENFORCEMENT

ARA.GEN.300 Oversight

Regulation (EU) 2018/1119

(a) The competent authority shall verify:

(1) compliance with the requirements applicable to organisations or persons prior to the issue of an organisation certificate, approval, FSTD qualification certificate or personnel licence, certificate, rating, or attestation, as applicable;

(2) continued compliance with the requirements applicable to the persons holding licences, ratings and certificates, the organisations it has certified, the holders of a FSTD qualification and the organisations from which it received a declaration;

(3) implementation of appropriate safety measures mandated by the competent authority as defined in ARA.GEN.135(c) and (d).

(b) This verification shall:

(1) be supported by documentation specifically intended to provide personnel responsible for safety oversight with guidance to perform their functions;

(2) provide the persons and organisations concerned with the results of safety oversight activity;

(3) be based on audits and inspections, including ramp and unannounced inspections; and

(4) provide the competent authority with the evidence needed in case further action is required, including the measures foreseen by ARA.GEN.350 and ARA.GEN.355.

(c) The scope of oversight defined in (a) and (b) shalltake into account the results of past oversight activities and the safety priorities.

(d) Without prejudice to the competences of the Member States and to their obligations as set out in ARO.RAMP, the scope of the oversight of activities performed in the territory of a Member State by persons or organisations established or residing in another Member State shall be determinedon the basis of the safety priorities, as well as of past oversight activities.

(e) Where the activity of a person or organisation involves more than one Member State or the Agency, the competent authority responsible for the oversight under (a) may agree to have oversight tasks performed by the competent authority(ies) of the Member State(s) where the activity takes place or by the Agency. Any person or organisation subject to such agreement shall be informed of its existence and of its scope.

(f) The competent authority shall collect and process any information deemed useful for oversight, including for ramp and unannounced inspections.

AMC1 ARA.GEN.300(a);(b);(c) Oversight

ED Decision 2013/006/R

EVALUATION OF APPROVED TRAINING ORGANISATIONS' OPERATIONAL SAFETY RISK ASSESSMENT

As part of the initial certification or the continuing oversight of an ATO, the competent authority should normally evaluate its safety risk assessment processes related to hazards identified by the ATO as having an interface with its operations. These safety risk assessments should be identifiable

processes of the ATO's management system. As part of its continuing oversight, the competent authority should also remain satisfied as to the effectiveness of these safety risk assessments.

(a) General methodology for operational hazards

The competent authority should establish a methodology for evaluating the safety risk assessment processes of the ATO's management system.

When related to operational hazards, the competent authority's evaluation under its normal oversight process should be considered satisfactory if the ATO demonstrates its competence and capability to:

(1) understand the hazards identified and their consequences on its operations;

(2) be clear on where these hazards may exceed acceptable safety risk limits;

(3) identify and implement mitigations including suspension of operations where mitigation cannot reduce the risk to within safety risk limits;

(4) develop and execute effectively, robust procedures for the preparation and the safe operation of the flights subject to the hazards identified;

(5) assess the competence and currency of its staff in relation to the duties for the intended operations and implement any necessary training; and

(6) ensure sufficient numbers of qualified and competent staff for such duties.

The competent authority should take into account:

(1) the ATO's recorded mitigations for each unacceptable risk identified are in place;

(2) the operational procedures specified by the ATO with the most significance to safety appear to be robust; and

(3) that the staff on which the ATO depends in respect of those duties necessary for the intended operations are trained and assessed as competent in the relevant procedures.

EVALUATION OF APPROVED TRAINING ORGANISATIONS' VOLCANIC ASH SAFETY RISK ASSESSMENT

In addition to the general methodology for operational hazards, the competent authority's evaluation under its normal oversight process should also assess the ATO's competence and capability to:

(1) choose the correct information sources to use to interpret the information related to volcanic ash contamination forecast and to resolve correctly any conflicts among such sources; and

(2) take account of all information from its type certificate holders (TCHs) concerning volcanic ash-related airworthiness aspects of the aircraft it operates, and the related pre-flight, in-flight and post flight precautions to be observed;

GM1 ARA.GEN.300(a);(b);(c) Oversight

ED Decision 2013/006/R

VOLCANIC ASH SAFETY RISK ASSESSMENT - ADDITIONAL GUIDANCE

Further guidance on the assessment of an ATO volcanic ash safety risk assessment is given in ICAO Doc. 9974 (Flight safety and volcanic ash – Risk management of flight operations with known or forecast volcanic ash contamination).

GM1 ARA.GEN.300(d) Oversight

ED Decision 2018/009/R

ACTIVITIES WITHIN THE TERRITORY OF THE MEMBER STATE

(a) Activities performed in the territory of the Member State by persons or organisations established or residing in another Member State include:

(1) activities of organisations certified by the competent authority of any other Member State or the Agency as well as activities of organisations having declared their activities to the competent authority of any other Member State;

(2) activities of persons holding a licence, certificate, rating, or attestation issued by the competent authority of any other Member State; and

(3) activities of persons making declarations to the competent authority of any other Member State.

(b) Audits and inspections of such activities, including ramp and unannounced inspections, should be prioritised towards those areas of greater safety concern, as identified through the analysis of data on safety hazards and their consequences in operations.

ARA.GEN.305 Oversight programme

Regulation (EU) 2018/1119

(a) The competent authority shall establish and maintain an oversight programme covering the oversight activities required by ARA.GEN.300 and by ARO.RAMP.

(b) For organisations certified by the competent authority and FSTD qualification certificate holders, the oversight programme shall be developedtaking into account the specific nature of the organisation, the complexity of its activities, the results of past certification and/or oversight activities and shall be based on the assessment of associated risks. It shall include within each oversight planning cycle:

(1) audits and inspections, including ramp and unannounced inspections as appropriate; and

(2) meetings convened between the accountable manager and the competent authority to ensure both remain informed of significant issues.

(c) For organisations certified by the competent authority and FSTD qualification certificate holders an oversight planning cycle not exceeding 24 months shall be applied.

The oversight planning cycle may be reduced if there is evidence that the safety performance of the organisation or the FTSD qualification certificate holder has decreased.

The oversight planning cycle may be extended to a maximum of 36 months if the competent authority has established that, during the previous 24 months:

(1) the organisation has demonstrated an effective identification of aviation safety hazards and management of associated risks;

(2) the organisation has continuously demonstrated under ORA.GEN.130 that it has full control over all changes;

(3) no level 1 findings have been issued; and

(4) all corrective actions have been implemented within the time period accepted or extended by the competent authority as defined in ARA.GEN.350(d)(2).

The oversight planning cycle may be further extended to a maximum of 48 months if, in addition to the above, the organisation has established, and the competent authority has approved, an effective continuous reporting system to the competent authority on the safety performance and regulatory compliance of the organisation itself.

(ca) Notwithstanding (c), for organisations only providing training towards the LAPL, PPL, SPL or BPL and associated ratings and certificates, an oversight planning cycle not exceeding 48 months shall be applied. The oversight planning cycle shall be reduced if there is evidence that the safety performance of the organisation holder has decreased.

The oversight planning cycle may be extended to a maximum of 72 months, if the competent authority has established that, during the previous 48 months:

(1) the organisation has demonstrated an effective identification of aviation safety hazards and management of associated risks, as demonstrated by the results of the annual review in accordance with ORA.GEN.200(c);

(2) the organisation has continuously maintained control over all changes in accordance with ORA.GEN.130 as demonstrated by the results of the annual review in accordance with ORA.GEN.200(c);

(3) no level 1 findings have been issued; and

(4) all corrective actions have been implemented within the time period accepted or extended by the competent authority as defined in ARA.GEN.350(d)(2).

(d) For persons holding a licence, certificate, rating, or attestation issued by the competent authority the oversight programme shall include inspections, including unannounced inspections, as appropriate.

(e) The oversight programme shall include records of the dates when audits, inspections and meetings are due and when such audits, inspections and meetings have been carried out.

(f) Notwithstanding points (b), (c), and (ca), the oversight programme of DTOs shall be developed taking into account the specific nature of the organisation, the complexity of its activities and the results of past oversight activities and shall be based on the assessment of risks associated with the type of training provided. The oversight activities shall include inspections, including unannounced inspections, and may, as deemed necessary by the competent authority, include audits.

AMC1 ARA.GEN.305(b) Oversight programme

ED Decision 2012/006/R

SPECIFIC NATURE AND COMPLEXITY OF THE ORGANISATION, RESULTS OF PAST OVERSIGHT

(a) When determining the oversight programme for an organisation the competent authority should consider in particular the following elements, as applicable:

(1) the implementation by the organisation of industry standards, directly relevant to the organisation's activity subject to this Regulation;

(2) the procedure applied for and scope of changes not requiring prior approval;

(3) specific approvals held by the organisation;

(4) specific procedures implemented by the organisation related to any alternative means of compliance used.

(b) For the purpose of assessing the complexity of an organisation's management system, AMC1 ORA.GEN.200(b) should be used.

(c) Regarding results of past oversight, the competent authority should also take into account relevant results of ramp inspections of organisations it has certified that were performed in other Member States in accordance with ARO.RAMP.

AMC1 ARA.GEN.305(b)(1) Oversight programme

ED Decision 2012/006/R

AUDIT

(a) The oversight programme should indicate which aspects of the approval will be covered with each audit.

(b) Part of an audit should concentrate on the organisation's compliance monitoring reports produced by the compliance monitoring personnel to determine if the organisation is identifying and correcting its problems.

(c) At the conclusion of the audit, an audit report should be completed by the auditing inspector, including all findings raised.

AMC2 ARA.GEN.305(b)(1) Oversight programme

ED Decision 2012/006/R

RAMP INSPECTIONS

When conducting a ramp inspection of aircraft used by organisations under its regulatory oversight the competent authority should, in as far as possible, comply with the requirements defined in ARO.RAMP.

AMC1 ARA.GEN.305(b);(c) Oversight programme

ED Decision 2012/006/R

INDUSTRY STANDARDS

(a) For organisations having demonstrated compliance with industry standards, the competent authority may adapt its oversight programme, in order to avoid duplication of specific audit items.

(b) Demonstrated compliance with industry standards should not be considered in isolation from the other elements to be considered for the competent authority's risk-based oversight.

(c) In order to be able to credit any audits performed as part of certification in accordance with industry standards, the following should be considered:

(1) the demonstration of compliance is based on certification auditing schemes providing for independent and systematic verification;

(2) the existence of an accreditation scheme and accreditation body for certification in accordance with the industry standards has been verified;

(3) certification audits are relevant to the requirements defined in Annex VII (Part-ORA) and other Annexes to this Regulation as applicable;

(4) the scope of such certification audits can easily be mapped against the scope of oversight in accordance with Part-ORA;

(5) audit results are accessible to the competent authority and open to exchange of information in accordance with Article 15(1) of Regulation (EC) No 216/2008; and

(6) the audit planning intervals of certification audits i.a.w. industry standards are compatible with the oversight planning cycle.

AMC1 ARA.GEN.305(c) Oversight programme

ED Decision 2012/006/R

OVERSIGHT PLANNING CYCLE

(a) When determining the oversight planning cycle and defining the oversight programme, the competent authority should assess the risks related to the activity of each organisation and adapt the oversight to the level of risk identified and to the organisation's ability to effectively manage safety risks.

(b) The competent authority should establish a schedule of audits and inspections appropriate to each organisation. The planning of audits and inspections should take into account the results of the hazard identification and risk assessment conducted and maintained by the organisation as part of the organisation's management system. Inspectors should work in accordance with the schedule provided to them.

(c) When the competent authority, having regard to an organisation's safety performance, varies the frequency of an audit or inspection it should ensure that all aspects of the organisation's activity are audited and inspected within the applicable oversight planning cycle.

(d) The section(s) of the oversight programme dealing with ramp inspections should be developed based on geographical locations, taking into account aerodrome activity, and focusing on key issues that can be inspected in the time available without unnecessarily delaying the operations.

AMC2 ARA.GEN.305(c) Oversight programme

ED Decision 2012/006/R

OVERSIGHT PLANNING CYCLE

(a) For each organisation certified by the competent authority and each FSTD qualification certificate holder all processes should be completely audited at periods not exceeding the applicable oversight planning cycle. The beginning of the first oversight planning cycle is normally determined by the date of issue of the first certificate. If the competent authority wishes to align the oversight planning cycle with the calendar year, it should shorten the first oversight planning cycle accordingly.

(b) The interval between two audits for a particular process should not exceed the interval of the applicable oversight planning cycle.

(c) Audits should include at least one on-site audit within each oversight planning cycle. For organisations exercising their regular activity at more than one site, the determination of the sites to be audited should consider the results of past oversight, the volume of activity at each site, as well as main risk areas identified.

(d) For organisations holding more than one certificate, the competent authority may define an integrated oversight schedule to include all applicable audit items. In order to avoid duplication of audits, credit may be granted for specific audit items already completed during the current oversight planning cycle, subject to four conditions:

(1) the specific audit item should be the same for all certificates under consideration;

(2) there should be satisfactory evidence on record that such specific audit items were carried out and that all corrective actions have been implemented to the satisfaction of the competent authority;

(3) the competent authority should be satisfied that there is no reason to believe standards have deteriorated in respect of those specific audit items being granted a credit;

(4) the interval between two audits for the specific item being granted a credit should not exceed the applicable oversight planning cycle.

AMC1 ARA.GEN.305(d) Oversight programme

ED Decision 2012/006/R

PERSONS HOLDING A LICENCE, CERTIFICATE, RATING OR ATTESTATION

The oversight of persons holding a licence, certificate, rating or attestation should normally be ensured as part of the oversight of organisations. Additionally, the competent authority should verify compliance with applicable requirements when endorsing or renewing ratings.

To properly discharge its oversight responsibilities, the competent authority should perform a certain number of unannounced verifications.

AMC1 ARA.GEN.305(f) Oversight programme

ED Decision 2018/009/R

(a) When determining the oversight programme for organisations that have declared their activities, the competent authority should make a selection of the DTOs to be inspected based on the elements specified in point ARA.GEN.305(f).

(b) For each selected DTO, an inspection is a sample inspection of the predefined inspection criteria on the basis of key risk elements and the applicable requirements.

(c) The results of past oversight activities should include information from the DTO's annual internal review and the DTO's annual activity reports as well as information from the verification of the DTO's training programme for Part-FCL compliance and occurrence reports linked to the activity of the DTO, if applicable.

(d) The oversight programme should follow a risk-based approach and should be developed on a yearly basis. At least one inspection should be performed for each DTO not later than 72 months starting from the date on which the declaration was received or, subsequently, the last inspection, as applicable.

(e) Additional inspections or unannounced inspections to specific DTOs may be included in the oversight programme on the basis of the elements specified in point ARA.GEN.305(f).

AMC2 ARA.GEN.305(f) Oversight programme

ED Decision 2018/009/R

An inspection of a DTO should at least focus on:

(a) the existence of a safety policy statement and its adequacy regarding the DTO activities;

(b) the existence of appropriate measures aiming to achieve the objectives of the safety policy including risk mitigation measures, results of annual reviews and respective corrective actions, if applicable;

(c) flight training in accordance with the DTO training programme, its conduct and standards as well as training records;

(d) training aircraft in use, including their registration, associated documents and maintenance records;

(e) use of FSTDs;

(f) operating sites and associated facilities as appropriate; and

(g) information on flight instructors and on the validity of their licences, certificates, ratings and logbooks.

ARA.GEN.310 Initial certification procedure – organisations

Regulation (EU) No 1178/2011

(a) Upon receiving an application for the initial issue of a certificate for an organisation, the competent authority shall verify the organisation's compliance with the applicable requirements.

(b) When satisfied that the organisationis in compliance with the applicable requirements, the competent authority shall issue the certificate(s), as established in Appendixes III and V to this Part. The certificate(s) shall be issued for an unlimited duration. The privileges and scope of the activities that the organisation is approved to conduct shall be specified in the terms of approval attached to the certificate(s).

(c) To enable an organisation to implement changes without prior competent authority approval in accordance with ORA.GEN.130, the competent authority shall approve the procedure submitted by the organisation defining the scope of such changes and describing how such changes will be managed and notified.

AMC1 ARA.GEN.310(a) Initial certification procedure – organisations

ED Decision 2012/006/R

VERIFICATION OF COMPLIANCE

(a) In order to verify the organisation's compliance with the applicable requirements, the competent authority should conduct an audit of the organisation, including interviews of personnel and inspections carried out at the organisation's facilities.

(b) The competent authority should only conduct such audit after being satisfied that the application shows compliance with the applicable requirements.

(c) The audit should focus on the following areas:

(1) detailed management structure, including names and qualifications of personnel required by ORA.GEN.210 and adequacy of the organisation and management structure;

(2) personnel:

(i) adequacy of number and qualifications with regard to the intended terms of approval and associated privileges;

(ii) validity of licences, ratings, certificates or attestations as applicable;

(3) processes for safety risk management and compliance monitoring;

(4) facilities – adequacy with regard to the organisation's scope of work;

(5) documentation based on which the certificate should be granted (organisation documentation as required by Part-ORA, including technical manuals, such as operations manual or training manual).

(d) In case of non-compliance, the applicant should be informed in writing of the corrections that are required.

(e) In cases where an application for an organisation certificate is refused, the applicant should be informed of the right of appeal as exists under national law.

ARA.GEN.315 Procedure for issue, revalidation, renewal or change of licences, ratings, certificates or attestations – persons

Regulation (EU) No 1178/2011

(a) Upon receiving an application for the issue, revalidation, renewal or change of a personal licence, rating, certificate or attestation and any supporting documentation, the competent authority shall verify whether the applicant meets the applicable requirements.

(b) When satisfied that the applicant meets the applicable requirements, the competent authority shall issue, revalidate, renew or change the licence, certificate, rating, or attestation.

AMC1 ARA.GEN.315(a) Procedure for issue, revalidation, renewal or change of licences, ratings or certificates – persons

ED Decision 2012/006/R

VERIFICATION OF COMPLIANCE

(a) In order to verify that the applicant meets the requirements, the competent authority should review the application and any supporting documents submitted, for completeness and compliance with applicable requirements.

(b) As part of the verification that the applicant meets the requirements, the competent authority should check that he/she:

(1) was not holding any personnel licence, certificate, rating, authorisation or attestation with the same scope and in the same category issued in another Member State;

(2) has not applied for any personnel licence, certificate, rating, authorisation or attestation with the same scope and in the same category in another Member State; and

(3) has never held any personnel licence, certificate, rating, authorisation or attestation with the same scope and in the same category issued in another Member State which was revoked or suspended in any other Member State.

(c) The competent authority should request the applicant to make a declaration covering items (b)(1) to (b)(3). Such declaration should include a statement that any incorrect information could disqualify the applicant from being granted a personnel licence, certificate, rating, authorisation or attestation. In case of doubts, the competent authority should contact the competent authority of the Member State where the applicant may have previously held any personnel licence, certificate, rating, authorisation or attestation.

ARA.GEN.330 Changes – organisations

Regulation (EU) 2018/1119

(a) Upon receiving an application for a change that requires prior approval, the competent authority shall verify the organisation's compliance with the applicable requirements before issuing the approval.

The competent authority shall prescribe the conditions under which the organisation may operate during the change, unless the competent authority determines that the organisation's certificate needs to be suspended.

When satisfied that the organisation is in compliance with the applicable requirements, the competent authority shall approve the change.

(b) Without prejudice to any additional enforcement measures, when the organisation implements changes requiring prior approval without having received competent authority approval as defined in (a), the competent authority shall suspend, limit or revoke the organisation's certificate.

(c) For changes not requiring prior approval, the competent authority shall assess the information provided in the notification sent by the organisation in accordance with ORA.GEN.130 to verify compliance with the applicable requirements. In case of any non-compliance, the competent authority shall:

(1) notify the organisation about the non-compliance and request further changes; and

(2) in case of level 1 or level 2 findings, act in accordance with ARA.GEN.350.

(d) Notwithstanding points (a), (b) and (c), in the case of changes to the information contained in the declarations received from a DTO or to the training programme used by the DTO, notified to it in accordance with point DTO.GEN.116 of Annex VIII (Part-DTO), the competent authority shall act in accordance with the requirements of points ARA.DTO.105 and ARA.DTO.110, as applicable.

AMC1 ARA.GEN.330 Changes – organisations

ED Decision 2012/006/R

GENERAL

(a) Changes in nominated persons:

The competent authority should be informed of any changes to personnel specified in Part-ORA that may affect the certificate or terms of approval/approval schedule attached to it. When an organisation submits the name of a new nominee for any of the persons nominated as per ORA.GEN.210(b), the competent authority should require the organisation to produce a written résumé of the proposed person's qualifications. The competent authority should reserve the right to interview the nominee or call for additional evidence of his/her suitability before deciding upon his/her acceptability.

(b) A simple management system documentation status sheet should be maintained, which contains information on when an amendment was received by the competent authority and when it was approved.

(c) The organisation should provide each management system documentation amendment to the competent authority, including for the amendments that do not require prior approval by the competent authority. Where the amendment requires competent authority approval, the competent authority, when satisfied, should indicate its approval in writing. Where the

amendment does not require prior approval, the competent authority should acknowledge receipt in writing within 10 working days.

(d) For changes requiring prior approval, in order to verify the organisation's compliance with the applicable requirements, the competent authority should conduct an audit of the organisation, limited to the extent of the changes. If required for verification, the audit should include interviews and inspections carried out at the organisation's facilities.

GM1 ARA.GEN.330 Changes – organisations

ED Decision 2012/006/R

CHANGE OF NAME OF THE ORGANISATION

(a) On receipt of the application and the relevant parts of the organisation's documentation as required by Part-ORA, the competent authority should re-issue the certificate.

(b) A name change alone does not require the competent authority to audit the organisation, unless there is evidence that other aspects of the organisation have changed.

ARA.GEN.350 Findings and corrective actions – organisations

Regulation (EU) 2018/1119

(a) The competent authority for oversight in accordance with ARA.GEN.300(a) shall have a system to analyse findings for their safety significance.

(b) A level 1 finding shall be issued by the competent authority when any significant non-compliance is detected with the applicable requirements of Regulation (EC) No 216/2008 and its Implementing Rules, with the organisation's procedures and manuals or with the terms of an approval or certificate which lowers safety or seriously hazards flight safety.

The level 1 findings shall include:

(1) failure to give the competent authority access to the organisation's facilities as defined in ORA.GEN.140 during normal operating hours and after two written requests;

(2) obtaining or maintaining the validity of the organisation certificate by falsification of submitted documentary evidence;

(3) evidence of malpractice or fraudulent use of the organisation certificate; and

(4) the lack of an accountable manager.

(c) A level 2 finding shall be issued by the competent authority when any non-compliance is detected with the applicable requirements of Regulation (EC) No 216/2008 and its Implementing Rules, with the organisation's procedures and manuals or with the terms of an approval or certificate which could lower safety or hazard flight safety.

(d) When a finding is detected during oversight or by any other means, the competent authority shall, without prejudice to any additional action required by Regulation (EC) No 216/2008 and its Implementing Rules, communicate the finding to the organisation in writing and request corrective action to address the non-compliance(s) identified. Where relevant, the competent authority shall inform the State in which the aircraft is registered.

(1) In the case of level 1 findings the competent authority shall take immediate and appropriate action to prohibit or limit activities and, if appropriate, it shall take action to revoke the certificate or specific approval or to limit or suspend it in whole or in part,

depending upon the extent of the level 1 finding, until successful corrective action has been taken by the organisation.

(2) In the case of level 2 findings, the competent authority shall:

(i) grant the organisation a corrective action implementation period appropriate to the nature of the finding that in any case initially shall not be more than 3 months. At the end of this period, and subject to the nature of the finding, the competent authority may extend the 3-month period subject to a satisfactory corrective action plan agreed by the competent authority; and)

(ii) assess the corrective action and implementation plan proposed by the organisation and, if the assessment concludes that they aresufficient to address the non-compliance(s), accept these.

(3) Where an organisation fails to submit an acceptable corrective action plan, or to perform the corrective action within the time period accepted or extended by the competent authority, the finding shall be raised to a level 1 finding and action taken as laid down in (d)(1).

(4) The competent authority shall record all findings it has raised or that have been communicated to it and, where applicable, the enforcement measures it has applied, as well as all corrective actions and date of action closure for findings.

(da) Notwithstanding points (a) to (d), in the case of DTOs, if during oversight or by any other means the competent authority finds evidence indicating non-compliance with the essential requirements set out in Annex III to Regulation (EC) No 216/2008 or with the requirements of Annex I (Part-FCL) and Annex VIII (Part-DTO) to this Regulation by a DTO, the competent authority shall:

(1) raise a finding, record it, communicate it in writing to the representative of the DTO and determine a reasonable period of time within which the DTO is to take the steps specified in point DTO.GEN.150 of Annex VIII (Part-DTO);

(2) take immediate and appropriate action to limit or prohibit the training activities affected by the non-compliance until the DTO has taken the corrective action referred to in point (1), where any of the following situations occurs:

(i) a safety problem has been identified;

(ii) the DTO fails to take corrective action in accordance with point DTO.GEN.150;

(3) in respect of the training programmes referred to in point DTO.GEN.230(c) of Annex VIII (Part-DTO), limit, suspend or revoke the approval of the training programme;

(4) take any further enforcement measures necessary in order to ensure the termination of the non-compliance and, where relevant, remedy the consequences thereof.

(e) Without prejudice to any additional enforcement measures, when the authority of a Member State acting in accordance with point ARA.GEN.300(d) identifies any non-compliance with the essential requirements set out in Annex III to Regulation (EC) No 216/2008 or with the requirements of Annex I (Part-FCL) and Annex VIII (Part-DTO) to this Regulation by an

organisation certified by, or having made a declaration to, the competent authority of another Member State or the Agency, it shall inform that competent authority of that non-compliance.

GM1 ARA.GEN.350 Findings and corrective actions – organisations

ED Decision 2012/006/R

TRAINING

For a level 1 finding it may be necessary for the competent authority to ensure that further training by the organisation is carried out and audited by the competent authority before the activity is resumed, dependent upon the nature of the finding.

GM1 ARA.GEN.350(e) Findings and corrective actions – organisations

ED Decision 2018/009/R

LEVELS OF FINDINGS ISSUED TO A DTO

Part-ARA requirements do not require competent authorities to categorise findings issued to a DTO. As a consequence, point ARA.GEN.350(e) does not require competent authorities to provide other competent authorities with an indication of the level of the findings issued to a DTO. However, point ARA.GEN.350(e) must not be understood as a prohibition for competent authorities to inform other competent authorities about the level of a finding in such a case, if such finding levels are used by that competent authority on a voluntary basis.

ARA.GEN.355 Findings and enforcement measures – persons

Regulation (EU) No 290/2012

(a) If, during oversight or by any other means, evidence is found by the competent authority responsible for oversight in accordance with ARA.GEN.300(a) that shows a non-compliance with the applicable requirements by a person holding a licence, certificate, rating or attestation issued in accordance with Regulation (EC) No 216/2008 and its Implementing Rules, the competent authority shall raise a finding, record it and communicate it in writing to the licence, certificate, rating or attestation holder.

(b) When such finding is raised, the competent authority shall carry out an investigation. If the finding is confirmed, it shall:

(1) limit, suspend or revoke the licence, certificate, rating or attestation as applicable, when a safety issue has been identified; and

(2) take any further enforcement measures necessary to prevent the continuation of the non-compliance.

(c) Where applicable, the competent authority shall inform the person or organisation that issued the medical certificate or attestation.

(d) Without prejudice to any additional enforcement measures, when the authority of a Member State acting under the provisions of ARA.GEN.300(d) finds evidence showing a non-compliance with the applicable requirements by a person holding a licence, certificate, rating or attestation issued by the competent authority of any other Member State, it shall inform that competent authority.

(e) If, during oversight or by any other means, evidence is found showing a non-compliance with the applicable requirements by a person subject to the requirements laid down in Regulation

(EC) No 216/2008 and its Implementing Rules and not holding a licence, certificate, rating or attestation issued in accordance with that Regulation and its Implementing Rules, the competent authority that identified the non-compliance shall take any enforcement measures necessary to prevent the continuation of that non-compliance.

GM1 ARA.GEN.355(b)(1) Limitation, suspension or revocation of licences, ratings, certificates or attestations

ED Decision 2018/009/R

ENFORCEMENT MEASURES IN CASE OF NON-COMPLIANCE WITH PART-FCL

If the holder of a licence, rating, certificate or attestation does not or no longer comply with the applicable requirements, the competent authority, when acting in accordance with point ARA.GEN.355(b), should take enforcement measures which should be commensurate with the nature of the non-compliance. For example, if the training required for the issuing of the pilot licence was not fully completed as required, the competent authority may decide, subject to the amount and nature of the missing training elements, to suspend the licence in accordance with point ARA.FCL.250 until the missing training elements and a new skill test have been completed rather than revoking the licence.

GM1 ARA.GEN.355(e) Findings and enforcement measures – persons

ED Decision 2018/009/R

This provision is necessary to ensure that enforcement measures will be taken also in cases where the competent authority may not act on the licence, certificate or attestation. The type of enforcement measure will depend on the applicable national law and may include for example the payment of a fine or the prohibition from exercising.

It covers two cases:

(a) persons subject to the requirements laid down in Regulation (EC) No 216/2008 and its Implementing Rules who are not required to hold a licence, certificate or attestation - for example general medical practitioners (GMPs); and

(b) persons who are required to hold a licence, rating, certificate or attestation, but who do not hold the appropriate licence, rating, certificate or attestation as required for the activity they perform.

SUBPART AEMC – SPECIFIC REQUIREMENTS RELATING TO AERO-MEDICAL CENTRES (AEMCS)

SECTION I – GENERAL

ARA.AeMC.110 Initial certification procedure

Regulation (EU) No 1178/2011

The certification procedure for an AeMC shall follow the provisions laid down in ARA.GEN.310.

ARA.AeMC.150 Findings and corrective actions – AeMC

Regulation (EU) No 1178/2011

Without prejudice to ARA.GEN.350, level 1 findings include, but are not limited to, the following:

(a) failure to nominate a head of the AeMC;

(b) failure to ensure medical confidentiality of aero-medical records; and

(c) failure to provide the competent authority with the medical and statistical data for oversight purposes.

SUBPART MED – SPECIFIC REQUIREMENTS RELATING TO AERO-MEDICAL CERTIFICATION

SECTION I – GENERAL

ARA.MED.120 Medical assessors

Regulation (EU) No 1178/2011

The competent authority shall appoint one or more medical assessor(s) to undertake the tasks described in this Section. The medical assessor shall be licensed and qualified in medicine and have:

(a) postgraduate work experience in medicine of at least 5 years;

(b) specific knowledge and experience in aviation medicine; and

(c) specific training in medical certification.

ARA.MED.125 Referral to the licensing authority

Regulation (EU) No 290/2012

When an AeMC, or aero-medical examiner (AME) has referred the decision on the fitness of an applicant to the licensing authority:

(a) the medical assessor or medical staff designated by the competent authority shall evaluate the relevant medical documentation and request further medical documentation, examinations and tests where necessary; and

(b) the medical assessor shall determine the applicant's fitness for the issue of a medical certificate with one or more limitation(s) as necessary.

ARA.MED.130 Medical certificate format

Regulation (EU) No 245/2014

The medical certificate shall conform to the following specifications:

(a) Content

(1) State where the pilot licence has been issued or applied for (I),

(2) Class of medical certificate (II),

(3) Certificate number commencing with the UN country code of the State where the pilot licence has been issued or applied for and followed by a code of numbers and/or letters in Arabic numerals andlatin script (III),

(4) Name of holder (IV),

(5) Nationality of holder (VI),

(6) Date of birth of holder: (*dd/mm/yyyy*) (XIV),

(7) Signature of holder (VII),

(8) Limitation(s) (XIII),

(9) Expiry date of the medical certificate (IX) for:

(i) Class 1 single pilot commercial operations carrying passengers,

(ii) Class 1 other commercial operations,

(iii) Class 2,

(iv) LAPL

(10) Date of medical examination

(11) Date of last electrocardiogram

(12) Date of last audiogram

(13) Date of issue and signature of the AME or medical assessor that issued the certificate. GMP may be added to this field if they have the competence to issue medical certificates under the national law of the Member State where the licence is issued.

(14) Seal or stamp (XI)

(b) Material: Except for the case of LAPL issued by a GMP the paper or other material used shall prevent or readily show any alterations or erasures. Any entries or deletions to the form shall be clearly authorised by the licensing authority.

(c) Language: Certificates shall be written in the national language(s) and in English and such other languages as the licensing authority deems appropriate.

(d) All dates on the medical certificate shall be written in a dd/mm/yyyy format.

AMC1 ARA.MED.130 Medical certificate format

ED Decision 2014/020/R

STANDARD EASA MEDICAL CERTIFICATE FORMAT

The format of the medical certificate should be as shown below.

Competent authority name and logo (English and any language(s) determined by the competent authority) EUROPEAN UNION (English only) Class 1/2/LAPL MEDICAL CERTIFICATE pertaining to a Part-FCL licence (English and any language(s) determined by the competent authority) Issued in accordance with Part-MED This medical certificate complies with ICAO standards, except for the LAPL medical certificate (English and any language(s) determined by the competent authority)		Requirements "European Union" to be deleted for non-EU Member States Size of each page shall be one eighth A4

I	National language(s)/ Authority that issued or is to issue the pilot licence
III	National language(s):/Certificate number
IV	National language(s):/ Last and first name of holder:
XIV	National language(s):/Date of birth: (dd/mm/yyyy)
VI	National language(s)/Nationality:
VII	National language(s)/ Signature of holder:

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XIII	National language(s)/Limitations: Code. Description :
X	National language(s)/* Date of issue: (dd/mm/yyyy) Signature of issuing AME/medical assessor /(GMP):
XI	National language(s)/Stamp:
	3

IX Nat. lang(s)/ Expiry date of this certificate	Class 1 single pilot commercial operations carrying passengers (dd/mm/yyyy)
	Class 1 (dd/mm/yyyy)
	Class 2 (dd/mm/yyyy)
	LAPL (dd/mm/yyyy)
Nat. lang(s)./Examination date: (dd/mm/yyyy)	
MED.A.020 Decrease in medical fitness (a) Licence holders shall not exercise the privileges of their licence and related ratings or certificates at any time when they: (1) are aware of any decrease in their medical fitness that might render them unable to safely exercise those privileges; (2) take or use any prescribed or non-prescribed medication that is likely to interfere with the safe exercise of the privileges of the applicable licence; or (3) receive any medical, surgical or other treatment that is likely to interfere with flight safety. (b) In addition, licence holders shall, without undue delay, seek aero-medical advice when they: (1) have undergone a surgical operation or invasive procedure; (2) have commenced the regular use of any medication; (3) have suffered any significant personal injury involving incapacity to function as a member of the flight crew; (4) have been suffering from any significant illness involving incapacity to function as a member of the flight crew; (5) are pregnant; (6) have been admitted to hospital or medical clinic; or (7) first require correcting lenses.	
4	

* Date of issue is the date the certificate is issued and signed

ARA.MED.135 Aero-medical forms

Regulation (EU) No 290/2012

The competent authority shall use forms for:

(a) the application form for a medical certificate;

(b) the examination report form for class 1 and class 2 applicants; and

(c) the examination report form for light aircraft pilot licence (LAPL) applicants.

AMC1 ARA.MED.135(a) Aero-medical forms

ED Decision 2019/002/R

APPLICATION FORM FOR A MEDICAL CERTIFICATE

The form referred to in ARA.MED.135(a) should reflect the information indicated in the following form and corresponding instructions for completion.

LOGO

CIVIL AVIATION ADMINISTRATION / MEMBER STATE

APPLICATION FORM FOR A MEDICAL CERTIFICATE
Complete this page fully and in block capitals - Refer to instructions pages for details.

MEDICAL IN CONFIDENCE

<table>
<tr><td>(1) State of licence issue:</td><td colspan="3">(2) Medical certificate applied for: class 1 ☐ class 2 ☐ LAPL ☐</td></tr>
<tr><td>(3) Surname:</td><td colspan="2">(4) Previous surname(s):</td><td>(12) Application Initial ☐
Revalidation/Renewal ☐</td></tr>
<tr><td>(5) Forenames:</td><td>(6) Date of birth (dd/mm/yyyy):</td><td>(7) Sex
Male ☐
Female ☐</td><td>(13) Reference number:</td></tr>
<tr><td>(8) Place and country of birth:</td><td colspan="2">(9) Nationality:</td><td>(14) Type of licence applied for:</td></tr>
<tr><td rowspan="2">(10) Permanent address:

Country:
Telephone No.:
Mobile No.:
e-mail:</td><td colspan="2" rowspan="2">(11) Postal address (if different)

Country:
Telephone No.:</td><td>(15) Occupation (principal)</td></tr>
<tr><td>(16) Employer</td></tr>
<tr><td colspan="3">(17) Last medical examination
Date:
Place:</td></tr>
<tr><td colspan="2">(18) Aviation licence(s) held (type):
Licence number:
State of issue:</td><td colspan="2">(19) Any Limitations on Licence/ Medical Certificate
No ☐ Yes ☐
Details:</td></tr>
<tr><td colspan="2" rowspan="2">(20) Have you ever had an aviation medical certificate denied, suspended or revoked by any licensing authority?
No ☐ Yes ☐ Date: Country:
Details:</td><td>(21) Flight time hours total:</td><td>(22) Flight time hours since last medical:</td></tr>
<tr><td colspan="2">(23) Aircraft class /type(s) presently flown:</td></tr>
<tr><td colspan="2" rowspan="2">(24) Any aviation accident or reported incident since last medical examination?
No ☐ Yes ☐ Date: Place:
Details:</td><td colspan="2">(25) Type of flying intended:</td></tr>
<tr><td colspan="2">(26) Present flying activity:
Single pilot ☐ Multi pilot ☐</td></tr>
<tr><td colspan="2">(27) Do you drink alcohol?
☐ No ☐ Yes, amount</td><td colspan="2" rowspan="2">(28) Do you currently use any medication?
No ☐ Yes ☐ State drug, dose, date started and why:</td></tr>
<tr><td colspan="2">(29) Do you smoke tobacco? ☐ No, never ☐ No, date stopped:
☐ Yes, state type and amount:</td></tr>
</table>

General and medical history: Do you have, or have you ever had, any of the following? (Please tick). If yes, give details in remarks section (30).

	Yes	No		Yes	No		Yes	No		Yes	No
101 Eye trouble/eye operation			112 Nose, throat or speech disorder			123 Malaria or other tropical disease			170 Heart disease		
102 Spectacles and/or contact lenses ever worn			113 Head injury or concussion			124 A positive HIV test			171 High blood pressure		
			114 Frequent or severe headaches			125 Sexually transmitted disease			172 High cholesterol level		
103 Spectacle/contact lens prescriptions change since last medical exam.			115 Dizziness or fainting spells			126 Sleep disorder/ apnoea syndrome			173 Epilepsy		
			116 Unconsciousness for any reason			127 Musculoskeletal illness/impairment			174 Mental illness or suicide		
104 Hay fever, other allergy			117 Neurological disorders; stroke, epilepsy, seizure, paralysis, etc			128 Any other illness or injury			175 Diabetes		
105 Asthma, lung disease						129 Admission to hospital			176 Tuberculosis		
106 Heart or vascular trouble			118 Psychological/ psychiatric trouble of any sort			130 Visit to medical practitioner since last medical examination			177 Allergy/ asthma/eczema		
107 High or low blood pressure									178 Inherited disorders		
108 Kidney stone or blood in urine			119 Alcohol/drug/ substance abuse			131 Refusal of life insurance			179 Glaucoma		
109 Diabetes, hormone disorder			120 Attempted suicide or self-harm			132 Refusal of flying licence					
110 Stomach, liver or intestinal trouble			121 Motion sickness requiring medication			133 Medical rejection from or for military service			Females only:		
									150 Gynaecological, menstrual problems		
111 Deafness, ear disorder			122 Anaemia / Sickle cell trait/other blood disorders			134 Award of pension or compensation for injury or illness			151 Are you pregnant?		

(30) Remarks: If previously reported and no change since, so state.

(31) Declaration: I hereby declare that I have carefully considered the statements made above and to the best of my belief they are complete and correct and that I have not withheld any relevant information or made any misleading statements. I understand that, if I have made any false or misleading statements in connection with this application, or fail to release the supporting medical information, the licensing authority may refuse to grant me a medical certificate or may withdraw any medical certificate granted, without prejudice to any other action applicable under national law.

CONSENT TO RELEASE OF MEDICAL INFORMATION: I hereby authorise the release of all information contained in this report and any or all attachments to the AME and, where necessary, to the medical assessor of the my licensing authority , to the medical assessor of the competent authority of my AME and to relevant medical professionals for the purpose of completion of an aero-medical assessment or a secondary review, recognising that these documents or electronically stored data are to be used for completion of a medical assessment and will become and remain the property of the licensing authority, providing that I or my physician may have access to them according to national law. Medical confidentiality will be respected at all times.

NOTIFICATION OF DISCLOSURE OF PERSONAL DATA: I hereby declare that I have been informed and I understand that the data contained in my medical certificate according to ARA.MED.130 may be electronically stored and made available to my AME in order to provide historical data required in MED.A.035(b)(2)(ii)/(iii) and to the medical assessors of the competent authorities of the Member States in order to facilitate the enforcement of ARA.MED.150(c)(4).

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Date Signature of applicant Signature of AME/(GMP)/ (medical assessor)

ARA.MED.145 GMP notification to the competent authority

Regulation (EU) No 290/2012

The competent authority, when applicable, shall establish a notification process for general medical practitioners (GMPs) to ensure that the GMP is aware of the medical requirements laid down in MED.B.095.

ARA.MED.150 Record-keeping

Regulation (EU) No 1178/2011

(a) In addition to the records required in ARA.GEN.220, the competent authority shall include in its system of record-keeping details of aero-medical examinations and assessments submitted by AMEs,AeMCs or GMPs.

(b) All aero-medical records of licence holders shall be kept for a minimum period of 10 years after the expiry of their last medical certificate.

(c) For the purpose of aero-medical assessments and standardisation, aero-medical records shall be made available after written consent of the applicant/licence holder to:

(1) anAeMC, AME or GMP for the purpose of completion of an aero-medical assessment;

(2) a medical review board that may be established by the competent authority for secondary review of borderline cases;

(3) relevant medical specialists for the purpose of completion of an aero-medical assessment;

(4) the medical assessor of the competent authority of another Member State for the purpose of cooperative oversight;

(5) the applicant/licence holder concerned upon their written request; and

(6) after disidentification of the applicant/licence holder to the Agency for standardisation purposes.

(d) The competent authority may make aero-medical records available for other purposes than those mentioned in (c) in accordance with Directive 95/46/EC as implemented under national law.

(e) The competent authority shall maintain lists:

(1) of all AMEs that hold a valid certificate issued by that authority; and

(2) where applicable, of all GMPs acting as AMEs on their territory.

These lists shall be disclosed to other Member States and the Agency upon request.

ARA.MED.160 Exchange of information on medical certificates through a central repository

Regulation (EU) 2019/27

(a) The Agency shall establish and manage a central repository, the European Aero-Medical Repository (EAMR).

(b) For the purposes of medical certification and oversight of applicants for and holders of class 1 medical certificates and for the oversight of AMEs and AeMCs, the persons referred to in point (c) shall exchange the following information through EAMR:

(1) basic data of the applicant for or holder of a class 1 medical certificate: licensing authority; surname and forename; date of birth; nationality; email address and the number of one or more identification documents (national identity card or passport) as provided by the applicant;

(2) class 1 medical certificate data: date of the medical examination or, in case the medical examination is not finalised, the date of initiation of the medical examination; dates of issuing and of expiration of the class 1 medical certificate; place of the examination; status of limitations; status of that certificate (new, released, suspended or revoked); unique reference number of the medical assessor of the licensing authority; AME or AeMC issuing that certificate and of its competent authority.

(c) For the purposes of point (b), the following persons shall have access to EAMR and the information contained therein:

(1) medical assessors of the licensing authority of the applicant for or holder of a class 1 medical certificate, as well as any other duly authorised personnel of that authority in charge of creating or managing the record of that applicant or holder as required by this Regulation;

(2) AMEs and any duly authorised personnel of AeMCs to whom that applicant or holder has provided a declaration in accordance with point MED.A.035(b)(2);

(3) any duly authorised personnel of the competent authority responsible for the oversight of AMEs or AeMCs conducting aero-medical assessments of those applicants or holders.

In addition, the Agency and national competent authorities may grant access to EAMR and the information contained therein to other persons, where necessary for the purposes of ensuring the proper functioning of EAMR, in particular its technical maintenance. In that case, the Agency or the national competent authority concerned shall ensure that those persons are duly authorised and qualified, that their access remains limited to what is necessary for the purposes for which they have been granted access and that they have received prior training on the applicable personal data protection legislation and related safeguards. Whenever a competent authority grants a person such access, it shall inform the Agency beforehand.

(d) The licensing authorities, AMEs and AeMCs referred to in point (c) shall, each time immediately upon having examined an applicant for or a holder of a class 1 medical certificate, enter the data referred to in point (b) into EAMR or update that data where necessary.

(e) Where the data constitutes personal data as defined in point a of Article 2 of Regulation (EC) No 45/2001[1], they shall, each time when entering or updating that data, inform, ex ante, the applicant for or holder of the class 1 certificate thereof.

(f) The Agency shall ensure the integrity and security of EAMR and the information contained therein by appropriate information technology infrastructure. It shall establish and apply, in consultation with the national competent authorities, the protocols and technological measures necessary to ensure that any access to EAMR and the information contained therein is lawful and secure.

(g) The Agency shall ensure that any information contained in EAMR is deleted after a period of 10 years. That period shall be calculated from the date of expiration of the last class 1 certificate

[1] Regulation (EC) No 45/2001 of the European Parliament and of the Council of 18 December 2000 on the protection of individuals with regard to the processing of personal data by the Community institutions and bodies and on the free movement of such data (OJ L 8, 12.1.2001, p. 1).

issued in respect of the applicant or holder concerned, or from the date of the last entry or update of data in respect of that applicant or holder, whichever date is later.

(h) The Agency shall ensure that applicants for or holders of class 1 medical certificates can access any information relating to them contained in EAMR and that they are informed that they can request that information to be rectified or deleted. The licensing authorities shall assess such requests and, where they consider that the information concerned is incorrect or not necessary for the purposes specified in point (b), ensure that the information is rectified or deleted.'

AMC1 ARA.MED.160(b) Exchange of information on medical certificates

ED Decision 2019/002/R

DATA CATEGORIES

For the purpose of the EAMR, the information processed is divided into two categories as follows:

Category 1: Basic applicant data as described in ARA.MED.160(b)(1)

Category 2: Medical certificate data as described in ARA.MED.160(b)(2)

Typically, the following information should not be recorded:

– Reasons for which a medical certificate has not been issued

  Only the fact that no certificate has been issued should be indicated. Any need for further clarification on whether the certificate has not been issued because of medical reasons, administrative matters or interruption of the medical assessment process before reaching the conclusion should be addressed, outside the scope of the EAMR, by the medical assessor of the licensing authority associated with the applicant's class 1 medical certificate.

– Details of the limitations associated with a given medical certificate

  Only a 'Yes/No' status on the existence of such a limitation should be recorded. Any need for further clarification on the limitation(s) should be addressed, outside the scope of the EAMR, by the medical assessor of the licensing authority associated with the applicant's class 1 medical certificate.

AMC1 ARA.MED.160(c) Exchange of information on medical certificates

ED Decision 2019/002/R

ROLE OF THE COMPETENT AUTHORITIES

Each competent authority should:

(a) designate its EAMR administrator;

(b) ensure control and oversight of all personnel managing or using the EAMR.

AMC2 ARA.MED.160(c) Exchange of information on medical certificates

ED Decision 2019/002/R

RESTRICTED ACCESS TO INFORMATION

Each competent authority should restrict access to personal data in the EAMR on need-to-know basis as follows:

Category as determined by AMC1 ARA.MED.160(b)	Restricted access
Category 1	(a) to relevant authorised administrative personnel of the licensing authority, to the extent needed to create and manage the applicant's record for licensing purposes, as required by Commission Regulation (EU) No 1178/2011.
Category 1 & 2	(b) to the AeMC(s) or the AME(s) to whom the applicant submits a declaration in accordance with MED.A.035(b)(2) for a class 1 medical certificate, to the extent needed to verify their previous medical certificate history, as required by Commission Regulation (EU) No 1178/2011; (c) to the medical assessor(s) of the licensing authority and the competent authority(ies) exercising oversight on the AeMC(s) or the AME(s) to whom the application for a class 1 medical certificate is submitted, to the extent needed to ensure proper implementation of Commission Regulation (EU) No 1178/2011.

AMC3 ARA.MED.160(c) Exchange of information on medical certificates

ED Decision 2019/002/R

USE OF THE EAMR

The competent authority should ensure that:

(a) all personnel accessing the EAMR are trained and proficient in using the system and having the necessary knowledge for implementing the applicable data protection legislation;

(b) the oversight of persons and organisations, subject to Regulation (EU) No 2018/1139 and its implementing rules, includes the assessment of compliance with the provisions applicable to the use and functioning of the EAMR.

AMC1 ARA.MED.160(d) Exchange of information on medical certificates

ED Decision 2019/002/R

APPLICANT'S RECORD

Each competent authority should ensure that:

(a) for each applicant for a class 1 medical certificate, a unique personal record is created in the EAMR, containing the category 1 personal data listed in ARA.MED.160(b)(1). This record is referred to as the 'applicant's record';

(b) the applicant's record is managed in accordance with the applicable regulation (typically for inserting, updating, viewing, validating data, etc.).

(c) an applicant is granted the right to obtain, without undue delay, the rectification of inaccurate personal data concerning them and, taking into account the purposes of the EAMR, the applicant is granted the right to have incomplete personal data completed. Such corrections should also be mirrored in the associated records kept in accordance with ARA.MED.150.

(d) the data recorded in the EAMR is complete as relevant for the purpose of the EAMR as described in AMC1 ARA.MED.160(b).

AMC1 ARA.MED.160(d) Exchange of information on medical certificates

ED Decision 2019/002/R

RECOVERY FROM UNSERVICEABILITY

The competent authority should ensure that class 1 medical certificates issued or amended without being properly recorded in the EAMR, due to unserviceability of the system, are entered in the EAMR without undue delay when the system recovers.

AMC1 ARA.MED.160(h) Exchange of information on medical certificates

ED Decision 2019/002/R

INFORMATION OF APPLICANTS

The competent authority should ensure at least the following:

(a) At the time of the creation of the applicant's record at the latest, the applicants should be informed:

(1) that their personal data as listed in ARA.MED.160(b)(1) will be lawfully processed in a European central repository, in accordance with Article 72 of Regulation (EU) 2018/1139 and ARA.GEN.200(c) and ARA.MED.160 of Commission Regulation (EU) No 1178/2011.

(2) that the purpose of the processing is to verify that the information, as regards their previous medical certificates, provided in their declaration submitted in accordance with MED.A.035(b)(2), is consistent with the records available to all competent authorities in accordance with ARA.MED.150;

(3) of the contact details of the data protection officer as applicable;

(4) that the period for which the personal data will be stored is determined in accordance with ARA.MED.160(g);

(5) of the existence of their right to request access to, and rectification of personal data;

(6) of the contact details of the data controller;

(7) of their right to lodge a complaint with the competent data protection authority in accordance with the applicable data protection legislation;

(8) that it is ensured that access to personal data contained in the EAMR is restricted to authorised personnel in accordance with Commission Regulation (EU) No 1178/2011.

(b) When applying for a class 1 medical certificate, the applicants should be informed that the category 2 data of their medical certificate, as listed in ARA.MED.160(b)(2), will be processed to verify that the information provided in their declaration, as regards their previous medical certificates, is consistent with the information available in the EAMR.

SECTION II – AERO-MEDICAL EXAMINERS (AMEs)

ARA.MED.200 Procedure for the issue, revalidation, renewal or change of an AME certificate

Regulation (EU) No 245/2014

(a) The certification procedure for an AME shall follow the provisions laid down in ARA.GEN.315. Before issuing the certificate, the competent authority shall have evidence that the AME practice is fully equipped to perform aero-medical examinations within the scope of the AME certificate applied for.

(b) When satisfied that the AME is in compliance with the applicable requirements, the competent authority shall issue, revalidate, renew or change the AME certificate for a period not exceeding 3 years, using the form established in appendix VII to this Part.

AMC2 ARA.MED.200 Procedure for the issue, revalidation, renewal or change of an AME certificate

ED Decision 2019/002/R

The competent authority should implement a procedure to ensure, before revalidation, renewal or extension of privileges of an AME certificate, that applicants retain their level of aero-medical competency.

ARA.MED.240 General medical practitioners (GMPs) acting as AMEs

Regulation (EU) No 290/2012

The competent authority of a Member State shall notify the Agency and competent authorities of other Member States if aero-medical examinations for the LAPL can be carried out on its territory by GMPs.

ARA.MED.245 Continuing oversight of AMEs and GMPs

Regulation (EU) No 290/2012

When developing the continuing oversight programme referred to in ARA.GEN.305, the competent authority shall take into account the number of AMEs and GMPs exercising their privileges within the territory where the competent authority exercises oversight.

ARA.MED.250 Limitation, suspension or revocation of an AME certificate

Regulation (EU) No 1178/2011

(a) The competent authority shall limit, suspend or revoke an AME certificate in cases where:

(1) the AME no longer complies with applicable requirements;

(2) failure to meet the criteria for certification or continuing certification;

(3) deficiency of aero-medical record-keeping or submission of incorrect data or information;

(4) falsification of medical records, certificates or documentation;

(5) concealment of facts appertaining to an application for, or holder of, a medical certificate or false or fraudulent statements or representations to the competent authority;

(6) failure to correct findings from audit of the AME practice; and

(7) at the request of the certified AME.

(b) The certificate of an AME shall be automatically revoked in either of the following circumstances:

(1) revocation of medical licence to practice; or

(2) removal from the Medical Register.

ARA.MED.255 Enforcement measures

Regulation (EU) No 1178/2011

If, during oversight or by any other means, evidence is found showing a non-compliance of an AeMC, an AME or a GMP, the licensing authority shall have a process to review the medical certificates issued by that AeMC, AME or GMP and may render them invalid where required to ensure flight safety.

SECTION III – MEDICAL CERTIFICATION

ARA.MED.315 Review of examination reports

Regulation (EU) No 1178/2011

The licensing authority shall have a process in place to:

(a) review examination and assessment reports received from the AeMCs, AMEs and GMPs and inform them of any inconsistencies, mistakes or errors made in the assessment process; and

(b) assist AMEs and AeMCs on their request regarding their decision on aero-medical fitness in contentious cases.

ARA.MED.325 Secondary review procedure

Regulation (EU) No 1178/2011

The competent authority shall establish a procedure for the review of borderline and contentious cases with independent medical advisors, experienced in the practice of aviation medicine, to consider and advise on an applicant's fitness for medical certification.

ARA.MED.330 Special medical circumstances

Regulation (EU) 2015/445

(a) When new medical technology, medication or procedures are identified that may justify a fit assessment of applicants otherwise not in compliance with the requirements, research may be carried out to gather evidence on the safe exercise of the privileges of the licence.

(b) In order to undertake research, a competent authority, in cooperation with at least one other competent authority, may develop and evaluate a medical assessment protocol based on which these competent authorities may issue a defined number of pilot medical certificates with appropriate limitations.

(c) AeMCs and AMEs may only issue medical certificates on the basis of a research protocol if instructed to do so by the competent authority.

(d) The protocol shall be agreed between the competent authorities concerned and shall include as a minimum:

(1) a risk assessment;

(2) a literature review and evaluation to provide evidence that issuing a medical certificate based on the research protocol would not jeopardise the safe exercise of the privileges of the licence;

(3) detailed selection criteria for pilots to be admitted to the protocol;

(4) the limitations that will be endorsed on the medical certificate;

(5) the monitoring procedures to be implemented by the competent authorities concerned;

(6) the determination of end points for terminating the protocol.

(e) The protocol shall be compliant with relevant ethical principles.

(f) The exercise of licence privileges by licence holders with a medical certificate issued on the basis of the protocol shall be restricted to flights in aircraft registered in the Member States involved in the research protocol. This restriction shall be indicated on the medical certificate.

(g) The participating competent authorities shall:

(1) provide the Agency with:

(i) the research protocol before implementation;

(ii) the details and qualifications of the nominated focal point of each participating competent authority;

(iii) documented reports of regular evaluations of its effectiveness;

(2) provide the AeMCs and AMEs within their jurisdiction with details of the protocol before implementation for their information.

AMC1 ARA.MED.330 Special medical circumstances

ED Decision 2016/008/R

GENERAL

The protocol should:

(a) assess the incapacitation risk;

(b) assess the risk of subtle impairment of performance;

(c) undertake a risk-benefit analysis;

(d) include a review of the regulations in use in other major aviation States and ICAO;

(e) determine which class of medical certificate is included in the scope;

(f) estimate the number of pilots likely to be included;

(g) list all anticipated risks to the protocol and provide a risk management strategy including appropriate limitations for every anticipated risk; where the risk of subtle impairment of performance is identified, the protocol should include requirements for minimum simulator testing or minimum line-flying under supervision or both;

(h) nominate medical research experts, if necessary, to provide advice on research methods.

AMC1 ARA.MED.330(b)(c) Special medical circumstances

ED Decision 2016/008/R

GENERAL

Initial medical certificates issued on the basis of a protocol should only be issued by the competent authority. Thereafter, the competent authority should decide whether the AeMC or AME may issue the medical certificate.

GM1 ARA.MED.330 Special medical circumstances

ED Decision 2016/008/R

GENERAL

(a) When the terms ‘medical assessment protocol’, ‘research protocol’ and ‘protocol’ (as mentioned in ARA.MED.330 and its associated AMC) are used, they all refer to a ‘medical assessment protocol’.

(b) The protocol is to enable experience to be gained in special medical circumstances in a controlled manner. This is to facilitate a better understanding of the treatment or condition, so that an evidence-based decision concerning its implementation may be considered.

(c) The protocol and its implementation should comply with the principles described in the following publication of the World Medical Association (WMA): “WMA Declaration of Helsinki - Ethical Principles for Medical Research Involving Human Subjects”, as last amended.

APPENDICES TO ANNEX VI

Appendix V to ANNEX VI (Part-ARA) – Certificate for Aeromedical Centres (AeMCs)

Regulation (EU) No 245/2014

CERTIFICATE FOR AERO-MEDICAL CENTRES (AeMCs)

European Union[1]

Competent Authority

AERO-MEDICAL CENTRE CERTIFICATE

REFERENCE:

Pursuant to Commission Regulation (EU) No 1178/2011 and subject to the conditions specified below, the [competent authority] hereby certifies

[NAME OF THE ORGANISATION]

[ADDRESS OF THE ORGANISATION]

As Part-ORA certifies Aero-medical centre with the privileges and the scope of activities as listed in the attached terms of approval.

CONDITIONS:

1. This certificate is limited to that specified in the scope of approval section of the approved organisation manual;
2. This certificate requires compliance with the procedures specified in the organisation documentation as required by Part-ORA.
3. This certificate shall remain valid subject to compliance with the requirements of Part-ORA unless it has been surrendered, superseded, suspended or revoked.

Date of issue: …… Signature: ……

EASA Form 146 Issue 1

[1] 'European Union' to be deleted for non-EU Member States

Appendix VII to ANNEX VI (Part-ARA) – Certificate for Aeromedical Examiners (AMEs)

Regulation (EU) No 290/2012

CERTIFICATE FOR AERO-MEDICAL EXAMINERS (AMEs)

European Union[1]

Competent Authority

AERO-MEDICAL EXAMINER CERTIFICATE

CERTIFICATE NUMBER/REFERENCE:

Pursuant to Commission Regulation (EU) No 1178/2011 and subject to the conditions specified below, the [competent authority] hereby certifies

[NAME OF THE AERO-MEDICAL EXAMINER]

[ADDRESS OF THE AERO-MEDICAL EXAMINER]

as aero-medical examiner

CONDITIONS:

1. This certificate is limited to the privileges specified in the attachment to this AME certificate;
2. This certificate requires compliance with the implementing rules and procedures specified in Part-MED.
3. This certificate shall remain valid for a period of 3 years until [xx/yy/zzzz[2]] subject to compliance with the requirements of Part-MED unless it has been surrendered, superseded, suspended or revoked.

Date of issue: xx/yy/zzzz

Signature: [Competent Authority]

EASA Form 148 Issue 1

[1] 'European Union' to be deleted for non-EU Member States

[2] Expiry date: day/month/year

AERO-MEDICAL EXAMINER CERTIFICATE

Attachment to AME certificate number:

PRIVILEGES AND SCOPE

[Name and academic title of the aero-medical examiner] has obtained the privilege(s) to undertake aero-medical examinations and assessments for the issuance of medical certificates as stated in the table below and to issue these medical certificates for:

LAPL	[yes/date]
Class 2	[yes/date]
Class 1 revalidation /renewal	[yes/date]/[no]

Date of issue: xx/yy/zzzz

Signature: [Competent Authority]

ANNEX VII (PART-ORA)

SUBPART GEN – GENERAL REQUIREMENTS

SECTION I – GENERAL

ORA.GEN.105 Competent authority

Regulation (EU) No 1178/2011

(a) For the purpose of this Part, the competent authority exercising oversight over:

(1) organisations subject to a certification obligation shall be:

(i) for organisations having their principal place of business in a Member State, the authority designated by that Member State;

(ii) for organisations having their principal place of business located in a third country, the Agency;

(2) FSTDs shall be:

(i) the Agency, for FSTDs:

– located outside the territory of the Member States, or,

– located within the territory of the Member States and operated by organisations having their principal place of business located in a third country,

(ii) for FSTDs located within the territory of the Member States and operated by organisations having their principal place of business in a Member State, the authority designated by the Member State where the organisation operating it has its principle place of business, or the Agency, ifso requested by the Member State concerned.

(b) When the FSTD located outside the territory of the Member States is operated by an organisation certified by a Member State, the Agency shall qualify this FSTD in coordination with the Member State that has certified the organisation that operates such FSTD.

ORA.GEN.115 Application for an organisation certificate

Regulation (EU) No 1178/2011

(a) The application for an organisation certificate or an amendment to an existing certificate shall be made in a form and manner established by the competent authority, taking into account the applicable requirements of Regulation (EC) No 216/2008 and its Implementing Rules.

(b) Applicants for an initial certificate shall provide the competent authority with documentation demonstrating how they will comply with the requirements established in Regulation (EC) No 216/2008 and its Implementing Rules. Such documentation shall include a procedure describing how changes not requiring prior approval will be managed and notified to the competent authority.

ORA.GEN.120 Means of compliance

Regulation (EU) No 290/2012

(a) Alternative means of compliance to the AMC adopted by the Agency may be used by an organisation to establish compliance with Regulation (EC) No 216/2008 and its Implementing Rules.

(b) When an organisation wishes to use an alternative means of compliance, it shall, prior to implementing it, provide the competent authority with a full description of the alternative means of compliance. The description shall include any revisions to manuals or procedures that may be relevant, as well as an assessment demonstrating that Regulation (EC) No 216/2008 and its Implementing Rules are met.

The organisation may implement these alternative means of compliance subject to prior approval by the competent authority and upon receipt of the notification as prescribed in ARA.GEN.120(d).

AMC1 ORA.GEN.120(a) Means of compliance

ED Decision 2012/007/R

DEMONSTRATION OF COMPLIANCE

In order to demonstrate that the Implementing Rules are met, a risk assessment should be completed and documented. The result of this risk assessment should demonstrate that an equivalent level of safety to that established by the Acceptable Means of Compliance (AMC) adopted by the Agency is reached.

ORA.GEN.125 Terms of approval and privileges of an organisation

Regulation (EU) No 1178/2011

A certified organisation shall comply with the scope and privileges defined in the terms of approval attached to the organisation's certificate.

AMC1 ORA.GEN.125 Terms of approval and privileges of an organisation

ED Decision 2012/007/R

MANAGEMENT SYSTEM DOCUMENTATION

The management system documentation should contain the privileges and detailed scope of activities for which the organisation is certified, as relevant to the applicable requirements. The scope of activities defined in the management system documentation should be consistent with the terms of approval.

ORA.GEN.130 Changes to organisations

Regulation (EU) No 1178/2011

(a) Any change affecting:

(1) the scope of the certificate or the terms of approval of an organisation; or

(2) any of the elements of the organisation's management system as required in ORA.GEN.200(a)(1) and (a)(2),

shall require prior approval by the competent authority.

(b) For any changes requiring prior approval in accordance with Regulation (EC) No 216/2008 and its Implementing Rules, the organisation shall apply for and obtain an approval issued by the competent authority. The application shall be submitted before any such change takes place, in order to enable the competent authority to determine continued compliance with Regulation (EC) No 216/2008 and its Implementing Rules and to amend, if necessary, the organisation certificate and related terms of approval attached to it.

The organisation shall provide the competent authority with any relevant documentation.

The change shall only be implemented upon receipt of formal approval by the competent authority in accordance with ARA.GEN.330.

The organisation shall operate under the conditions prescribed by the competent authority during such changes, as applicable.

(c) All changes not requiring prior approval shall be managed and notified to the competent authority as defined in the procedure approved by the competent authority in accordance with ARA.GEN.310(c).

AMC1 ORA.GEN.130 Changes to organisations

ED Decision 2012/007/R

APPLICATION TIME FRAMES

(a) The application for the amendment of an organisation certificate should be submitted at least 30 days before the date of the intended changes.

(b) In the case of a planned change of a nominated person, the organisation should inform the competent authority at least 10 days before the date of the proposed change.

(c) Unforeseen changes should be notified at the earliest opportunity, in order to enable the competent authority to determine continued compliance with the applicable requirements and to amend, if necessary, the organisation certificate and related terms of approval.

GM1 ORA.GEN.130(a) Changes to organisations

ED Decision 2017/022/R

GENERAL

(a) Typical examples of changes requiring prior approval which may affect the certificate or the terms of approval are listed below:

(1) the name of the organisation;

(2) the organisation's principal place of business;

(3) the organisation's scope of activities;

(4) additional locations of the organisation;

(5) the accountable manager;

(6) any of the persons referred to in ORA.GEN.210(a) and (b);

(7) the organisation's documentation as required by this Part, safety policy and procedures;

(8) the facilities.

(b) Prior approval by the competent authority is required for any changes to the organisation's procedure describing how changes not requiring prior approval will be managed and notified to the competent authority.

(c) Changes requiring prior approval may only be implemented upon receipt of formal approval by the competent authority.

GM2 ORA.GEN.130(a) Changes to organisations

ED Decision 2012/007/R

CHANGE OF NAME OF THE ORGANISATION

A change of name requires the organisation to submit a new application as a matter of urgency.

Where this is the only change to report, the new application can be accompanied by a copy of the documentation previously submitted to the competent authority under the previous name, as a means of demonstrating how the organisation complies with the applicable requirements.

GM1 ORA.GEN.130(c) Changes to organisations

ED Decision 2017/022/R

GENERAL

Typical examples of changes not requiring prior approval are to the following items:

(a) medical equipment (e.g. electrocardiograph (ECG), ophthalmoscope);

(b) flight simulation training device (FSTD) operator's technical personnel;

(c) change in schedule of preventive maintenance; and

(d) list of instructors.

It is recommended that all information on changes not requiring prior approval be included as annexes to the approved training organisation (ATO)'s, FSTD operator's, as well as aeromedical centre's documentation

ORA.GEN.135 Continued validity

Regulation (EU) No 1178/2011

(a) The organisation's certificate shall remain valid subject to:

(1) the organisation remaining in compliance with the relevant requirements of Regulation (EC) No 216/2008 and its Implementing Rules,taking into account the provisions related to the handling of findings as specified under ORA.GEN.150;

(2) the competent authority being granted access to the organisation as defined in ORA.GEN.140 to determine continued compliance with the relevant requirements of Regulation (EC) No 216/2008 and its Implementing Rules; and

(3) the certificate not being surrendered or revoked.

(b) Upon revocation or surrender the certificate shall be returned to the competent authority without delay.

ORA.GEN.140 Access

Regulation (EU) No 290/2012

For the purpose of determining compliance with the relevant requirements of Regulation (EC) No 216/2008 and its Implementing Rules, the organisation shall grant access to any facility, aircraft, document, records, data, procedures or any other material relevant to its activity subject to certification, whether it is contracted or not, to any person authorised by:

(a) the competent authority defined in ORA.GEN.105; or

(b) the authority acting under the provisions of ARA.GEN.300(d), ARA.GEN.300(e) or ARO.RAMP.

ORA.GEN.150 Findings

Regulation (EU) No 1178/2011

After receipt of notification of findings, the organisation shall:

(a) identify the root cause of the non-compliance;

(b) define a corrective action plan; and

(c) demonstrate corrective action implementation to the satisfaction of the competent authority within a period agreed with that authority as defined in ARA.GEN.350(d).

AMC1 ORA.GEN.150(b) Findings

ED Decision 2012/007/R

GENERAL

The corrective action plan defined by the organisation should address the effects of the non-conformity, as well as its root-cause.

GM1 ORA.GEN.150 Findings

ED Decision 2012/007/R

GENERAL

(a) Corrective action is the action to eliminate or mitigate the root cause(s) and prevent recurrence of an existing detected non-compliance or other undesirable condition or situation.

(b) Proper determination of the root cause is crucial for defining effective corrective actions.

ORA.GEN.155 Immediate reaction to a safety problem

Regulation (EU) No 1178/2011

The organisation shall implement:

(a) any safety measures mandated by the competent authority in accordance with ARA.GEN.135(c); and

(b) any relevant mandatory safety information issued by the Agency, including airworthiness directives.

ORA.GEN.160 Occurrence reporting

Regulation (EU) No 70/2014

(a) The organisation shall report to the competent authority, and to any other organisation required by the State of the operator to be informed, any accident, serious incident and occurrence as defined in Regulation (EU) No 996/2010 of the European Parliament and of the Council[1] and Directive 2003/42/EC of the European Parliament and of the Council[2].

(b) Without prejudice to paragraph (a) the organisation shall report to the competent authority and to the organisation responsible for the design of the aircraft any incident, malfunction, technical defect, exceeding of technical limitations and any occurrence that would highlight inaccurate, incomplete or ambiguous information contained in the operational suitability data established in accordance with Commission Regulation (EU) No 748/2012[3] or other irregular circumstance that has or may have endangered the safe operation of the aircraft and that has not resulted in an accident or serious incident.

(c) Without prejudice to Regulation (EU) No 996/2010, Directive 2003/42/EC, Commission Regulation (EC) No 1321/2007[4] and Commission Regulation (EC) No 1330/2007[5], the reports referred in paragraphs (a) and (b) shall be made in a form and manner established by the competent authority and contain all pertinent information about the condition known to the organisation.

(d) Reports shall be made as soon as practicable, but in any case within 72 hours of the organisation identifying the condition to which the report relates, unless exceptional circumstances prevent this.

(e) Where relevant, the organisation shall produce a follow-up report to provide details of actions it intends to take to prevent similar occurrences in the future, as soon as these actions have been identified. This report shall be produced in a form and manner established by the competent authority.

AMC1 ORA.GEN.160 Occurrence reporting

ED Decision 2012/007/R

GENERAL

(a) The organisation should report all occurrences defined in AMC 20-8, and as required by the applicable national rules implementing Directive 2003/43/EC[6] on occurrence reporting in civil aviation.

(b) In addition to the reports required by AMC 20-8 and Directive 2003/43/EC, the organisation should report volcanic ash clouds encountered during flight.

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1 OJ L 295, 12.11.2010, p. 35.

2 OJ L 167, 4.7.2003, p. 23.

3 OJ L 224, 21.8.2012, p. 1.

4 OJ L 294, 13.11.2007, p. 3.

5 OJ L 295, 14.11.2007, p. 7.

6 Directive 2003/42/EC of the European Parliament and of the Council of 13 June 2003 on occurrence reporting in civil aviation OJ L 167, 4.7.2003, p. 23-36.

SECTION II – MANAGEMENT

ORA.GEN.200 Management system

Regulation (EU) 2015/445

(a) The organisation shall establish, implement and maintain a management system that includes:

(1) clearly defined lines of responsibility and accountability throughout the organisation, including a direct safety accountability of the accountable manager;

(2) a description of the overall philosophies and principles of the organisationwith regard to safety, referred to as the safety policy;

(3) the identification of aviation safety hazards entailed by the activities of the organisation, their evaluation and the management of associated risks, including taking actions to mitigate the risk and verify their effectiveness;

(4) maintaining personnel trained and competent to perform their tasks;

(5) documentation of all management system key processes, including a process for making personnel aware of their responsibilities and the procedure for amending this documentation;

(6) a function to monitor compliance of the organisation with the relevant requirements. Compliance monitoring shall include a feedback system of findings to the accountable manager to ensure effective implementation of corrective actions as necessary; and

(7) any additional requirements that are prescribed in the relevant subparts of this Part or other applicable Parts.

(b) The management system shall correspond to the size of the organisation and the nature and complexity of its activities, taking into account the hazards and associated risks inherent in these activities.

(c) Notwithstanding point (a), in an organisation providing training only for the LAPL, PPL, SPL or BPL and the associated ratings or certificates, safety risk management and compliance monitoring defined in points (a)(3) and (a)(6) may be accomplished by an organisational review, to be performed at least once every calendar year. The competent authority shall be notified about the results of this review by the organisation without undue delay.

AMC1 ORA.GEN.200(a)(1);(2);(3);(5) Management system

ED Decision 2012/007/R

NON-COMPLEX ORGANISATIONS - GENERAL

(a) Safety risk management may be performed using hazard checklists or similar risk management tools or processes, which are integrated into the activities of the organisation.

(b) The organisation should manage safety risks related to a change. The management of change should be a documented process to identify external and internal change that may have an adverse effect on safety. It should make use of the organisation's existing hazard identification, risk assessment and mitigation processes.

(c) The organisation should identify a person who fulfils the role of safety manager and who is responsible for coordinating the safety management system. This person may be the accountable manager or a person with an operational role in the organisation.

(d) Within the organisation, responsibilities should be identified for hazard identification, risk assessment and mitigation.

(e) The safety policy should include a commitment to improve towards the highest safety standards, comply with all applicable legal requirements, meet all applicable standards, consider best practices and provide appropriate resources.

(f) The organisation should, in cooperation with other stakeholders, develop, coordinate and maintain an emergency response plan (ERP) that ensures orderly and safe transition from normal to emergency operations and return to normal operations. The ERP should provide the actions to be taken by the organisation or specified individuals in an emergency and reflect the size, nature and complexity of the activities performed by the organisation.

AMC1 ORA.GEN.200(a)(1) Management system

ED Decision 2012/007/R

COMPLEX ORGANISATIONS - ORGANISATION AND ACCOUNTABILITIES

The management system of an organisation should encompass safety by including a safety manager and a safety review board in the organisational structure.

(a) Safety manager

(1) The safety manager should act as the focal point and be responsible for the development, administration and maintenance of an effective safety management system.

(2) The functions of the safety manager should be to:

(i) facilitate hazard identification, risk analysis and management;

(ii) monitor the implementation of actions taken to mitigate risks, as listed in the safety action plan;

(iii) provide periodic reports on safety performance;

(iv) ensure maintenance of safety management documentation;

(v) ensure that there is safety management training available and that it meets acceptable standards;

(vi) provide advice on safety matters; and

(vii) ensure initiation and follow-up of internal occurrence / accident investigations.

(b) Safety review board

(1) The Safety review board should be a high level committee that considers matters of strategic safety in support of the accountable manager's safety accountability.

(2) The board should be chaired by the accountable manager and be composed of heads of functional areas.

(3) The safety review board should monitor:

(i) safety performance against the safety policy and objectives;

(ii) that any safety action is taken in a timely manner; and

(iii) the effectiveness of the organisation's safety management processes.

(c) The safety review board should ensure that appropriate resources are allocated to achieve the established safety performance.

(d) The safety manager or any other relevant person may attend, as appropriate, safety review board meetings. He/she may communicate to the accountable manager all information, as necessary, to allow decision making based on safety data.

GM1 ORA.GEN.200(a)(1) Management system

ED Decision 2012/007/R

SAFETY MANAGER

(a) Depending on the size of the organisation and the nature and complexity of its activities, the safety manager may be assisted by additional safety personnel for the performance of all safety management related tasks.

(b) Regardless of the organisational set-up it is important that the safety manager remains the unique focal point as regards the development, administration and maintenance of the organisation's safety management system.

GM2 ORA.GEN.200(a)(1) Management system

ED Decision 2012/007/R

COMPLEX ORGANISATIONS - SAFETY ACTION GROUP

(a) A safety action group may be established as a standing group or as an ad-hoc group to assist or act on behalf of the safety review board.

(b) More than one safety action group may be established depending on the scope of the task and specific expertise required.

(c) The safety action group should report to and take strategic direction from the safety review board and should be comprised of managers, supervisors and personnel from operational areas.

(d) The safety action group should:

(1) monitor operational safety;

(2) resolve identified risks;

(3) assess the impact on safety of operational changes; and

(4) ensure that safety actions are implemented within agreed timescales.

(e) The safety action group should review the effectiveness of previous safety recommendations and safety promotion.

AMC1 ORA.GEN.200(a)(2) Management system

ED Decision 2012/007/R

COMPLEX ORGANISATIONS - SAFETY POLICY

(a) The safety policy should:

(1) be endorsed by the accountable manager;

(2) reflect organisational commitments regarding safety and its proactive and systematic management;

(3) be communicated, with visible endorsement, throughout the organisation; and

(4) include safety reporting principles.

(b) The safety policy should include a commitment:

(1) to improve towards the highest safety standards;

(2) to comply with all applicable legislation, meet all applicable standards and consider best practices;

(3) to provide appropriate resources;

(4) to enforce safety as one primary responsibility of all managers; and

(5) not to blame someone for reporting something which would not have been otherwise detected.

(c) Senior management should:

(1) continually promote the safety policy to all personnel and demonstrate their commitment to it;

(2) provide necessary human and financial resources for its implementation; and

(3) establish safety objectives and performance standards.

GM1 ORA.GEN.200(a)(2) Management system

ED Decision 2012/007/R

SAFETY POLICY

The safety policy is the means whereby the organisation states its intention to maintain and, where practicable, improve safety levels in all its activities and to minimise its contribution to the risk of an aircraft accident as far as is reasonably practicable.

The safety policy should state that the purpose of safety reporting and internal investigations is to improve safety, not to apportion blame to individuals.

AMC1 ORA.GEN.200(a)(3) Management system

ED Decision 2012/007/R

COMPLEX ORGANISATIONS - SAFETY RISK MANAGEMENT

(a) Hazard identification processes

(1) Reactive and proactive schemes for hazard identification should be the formal means of collecting, recording, analysing, acting on and generating feedback about hazards and the associated risks that affect the safety of the operational activities of the organisation.

(2) All reporting systems, including confidential reporting schemes, should include an effective feedback process.

(b) Risk assessment and mitigation processes

(1) A formal risk management process should be developed and maintained that ensures analysis (in terms of likelihood and severity of occurrence), assessment (in terms of tolerability) and control (in terms of mitigation) of risks to an acceptable level.

(2) The levels of management who have the authority to make decisions regarding the tolerability of safety risks, in accordance with (b)(1), should be specified.

(c) Internal safety investigation

(1) The scope of internal safety investigations should extend beyond the scope of occurrences required to be reported to the competent authority.

(d) Safety performance monitoring and measurement

(1) Safety performance monitoring and measurement should be the process by which the safety performance of the organisation is verified in comparison to the safety policy and objectives.

(2) This process should include:

(i) safety reporting;

(ii) safety studies, that is, rather large analyses encompassing broad safety concerns;

(iii) safety reviews including trends reviews, which would be conducted during introduction and deployment of new technologies, change or implementation of procedures, or in situations of structural change in operations;

(iv) safety audits focussing on the integrity of the organisation's management system, and periodically assessing the status of safety risk controls; and

(v) safety surveys, examining particular elements or procedures of a specific operation, such as problem areas or bottlenecks in daily operations, perceptions and opinions of operational personnel and areas of dissent or confusion.

(e) The management of change

The organisation should manage safety risks related to a change. The management of change should be a documented process to identify external and internal change that may have an adverse effect on safety. It should make use of the organisation's existing hazard identification, risk assessment and mitigation processes.

(f) Continuous improvement

The organisation should continuously seek to improve its safety performance. Continuous improvement should be achieved through:

(1) proactive and reactive evaluations of facilities, equipment, documentation and procedures through safety audits and surveys;

(2) proactive evaluation of individuals' performance to verify the fulfilment of their safety responsibilities; and

(3) reactive evaluations in order to verify the effectiveness of the system for control and mitigation of risk.

(g) The emergency response plan (ERP)

(1) An ERP should be established that provides the actions to be taken by the organisation or specified individuals in an emergency. The ERP should reflect the size, nature and complexity of the activities performed by the organisation.

(2) The ERP should ensure:

(i) an orderly and safe transition from normal to emergency operations;

(ii) safe continuation of operations or return to normal operations as soon as practicable; and

(iii) coordination with the emergency response plans of other organisations, where appropriate.

GM1 ORA.GEN.200(a)(3) Management system

ED Decision 2012/007/R

INTERNAL OCCURRENCE REPORTING SCHEME

(a) The overall purpose of the scheme is to use reported information to improve the level of safety performance of the organisation and not to attribute blame.

(b) The objectives of the scheme are to:

(1) enable an assessment to be made of the safety implications of each relevant incident and accident, including previous similar occurrences, so that any necessary action can be initiated; and

(2) ensure that knowledge of relevant incidents and accidents is disseminated, so that other persons and organisations may learn from them.

(c) The scheme is an essential part of the overall monitoring function and it is complementary to the normal day-to-day procedures and 'control' systems and is not intended to duplicate or supersede any of them. The scheme is a tool to identify those instances where routine procedures have failed.

(d) All occurrence reports judged reportable by the person submitting the report should be retained as the significance of such reports may only become obvious at a later date.

GM3 ORA.GEN.200(a)(3) Management system

ED Decision 2013/008/R

APPROVED TRAINING ORGANISATIONS - RISK MANAGEMENT OF FLIGHT OPERATIONS WITH KNOWN OR FORECAST VOLCANIC ASH CONTAMINATION

(a) Responsibilities

The ATO is responsible for the safety of its operations, including within an area with known or forecast volcanic ash contamination.

The ATO should complete this assessment of safety risks related to known or forecast volcanic ash contamination as part of its management system before initiating operations into airspace forecast to be or aerodromes/operating sites known to be contaminated with volcanic ash.

This process is intended to ensure the ATO takes into account the likely accuracy and quality of the information sources it uses in its management system and to demonstrate its own competence and capability to interpret data from different sources in order to achieve the necessary level of data integrity reliably and correctly resolve any conflicts among data sources that may arise.

In order to decide whether or not to operate into airspace forecast to be or aerodromes/operating sites known to be contaminated with volcanic ash, the ATO should make use of the safety risk assessment within its management system as required by ORA.GEN.200.

The ATO's safety risk assessment should take into account all relevant data including data from the type certificate holders (TCHs) regarding the susceptibility of the aircraft they operate to volcanic cloud-related airworthiness effects, the nature and severity of these effects and the related pre-flight, in-flight and post-flight precautions to be observed by the ATO.

The ATO should ensure that personnel required to be familiar with the details of the safety risk assessments receives all relevant information (both pre-flight and in-flight) in order to be in a position to apply appropriate mitigation measures as specified by the safety risk assessments.

(b) Procedures

The ATO should have documented procedures for the management of operations into airspace forecast to be or aerodromes/operating sites known to be contaminated with volcanic ash.

These procedures should ensure that, at all times, flight operations remain within the accepted safety boundaries as established through the management system allowing for any variations in information sources, equipment, operational experience or organisation. Procedures should include those for flight crew and any other relevant personnel such that they are in a position to evaluate correctly the risk of flights into airspace forecast to be contaminated by volcanic ash and to plan accordingly.

Continuing airworthiness personnel should be provided with procedures allowing them to correctly assess the need for and to execute relevant maintenance or continuing airworthiness interventions.

The ATO should retain sufficient qualified and competent staff to generate well supported operational risk management decisions and ensure that its staff are appropriately trained and current. It is recommended that the ATO make the necessary arrangements for its relevant staff to take up opportunities to be involved in volcanic ash exercises conducted in their areas of operation.

(c) Volcanic activity information and the ATO's potential response

Before and during operations, information valuable to the ATO is generated by various volcano agencies worldwide. The ATO's risk assessment and mitigating actions need to take account of and respond appropriately to the information likely to be available during each phase of the eruptive sequence from pre-eruption through to end of eruptive activity. It is nevertheless noted that eruptions rarely follow a deterministic pattern of behaviour. A typical ATO's response may consist of the following:

(1) Pre-eruption

The ATO should have in place a robust mechanism for ensuring that it is constantly vigilant for any alerts of pre-eruption volcanic activity relevant to its operations. The staff involved need to understand the threat to safe operations that such alerts represent.

An ATO whose areas of activity include large, active volcanic areas for which immediate International Airways Volcano Watch (IAVW) alerts may not be available, should define its strategy for capturing information about increased volcanic activity before pre-eruption alerts are generated. For example, an ATO may combine elevated activity information with information concerning the profile and history of the volcano to determine an operating policy, which could include re-routing or restrictions at night. This would be useful when dealing with the 60% of volcanoes which are unmonitored.

Such an ATO should also ensure that its crews are aware that they may be the first to observe an eruption and so need to be vigilant and ready to ensure that this information is made available for wider dissemination as quickly as possible.

(2) Start of an eruption

Given the likely uncertainty regarding the status of the eruption during the early stages of an event and regarding the associated volcanic cloud, the ATO's procedures should include a requirement for crews to initiate re-routes to avoid the affected airspace.

The ATO should ensure that flights are planned to remain clear of the affected areas and that consideration is given to available aerodromes/operating sites and fuel requirements.

It is expected that the following initial actions will be taken by the ATO:

(i) determine if any aircraft in flight could be affected, alert the crew and provide advice on re-routing as required;

(ii) alert management;

(iii) for flight departures, brief flight crew and revise flight and fuel planning in accordance with the safety risk assessment;

(iv) alert flight crew to the need for increased monitoring of information (e.g. special air report (AIREP), volcanic activity report (VAR), significant weather information (SIGMET), NOTAMs and company messages);

(v) initiate the gathering of all data relevant to determining the risk; and

(vi) apply mitigations identified in the safety risk assessment.

(3) On-going eruption

As the eruptive event develops, the ATO can expect the responsible Volcanic Ash Advisory Centre (VAAC) to provide volcanic ash advisory messages (VAA/VAGs) defining, as accurately as possible, the vertical and horizontal extent of areas and layers of volcanic clouds. As a minimum, the ATO should monitor, and take account of, this VAAC information as well as of relevant SIGMETs and NOTAMs.

Other sources of information are likely to be available such as VAR/AIREPs, satellite imagery and a range of other information from State and commercial organisations. The ATO should plan its operations in accordance with its safety risk assessment taking into account the information that it considers accurate and relevant from these additional sources.

The ATO should carefully consider and resolve differences or conflicts among the information sources, notably between published information and observations (pilot reports, airborne measurements, etc.).

Given the dynamic nature of the volcanic hazards, the ATO should ensure that the situation is monitored closely and operations adjusted to suit changing conditions.

The ATO should be aware that, depending on the State concerned the affected or danger areas may be established and presented in a different way than the one currently used in Europe as described in EUR Doc 019-NAT Doc 006.

The ATO should require reports from its crews concerning any encounters with volcanic emissions. These reports should be passed immediately to the appropriate air traffic services (ATS) unit and to the ATO's competent authority.

For the purpose of flight planning, the ATO should treat the horizontal and vertical limits of the temporary danger area (TDA) or airspace forecast to be contaminated by volcanic ash as applicable, to be over-flown as it would mountainous terrain, modified in

accordance with its safety risk assessment. The ATO should take account of the risk of cabin depressurisation or engine failure resulting in the inability to maintain level flight above a volcanic cloud. Additional minimum Equipment List (MEL) provisions, if applicable, should be considered in consultation with the TCHs.

Flying below a volcanic ash contaminated airspace should be considered on a case by case basis. It should only be planned to reach or leave an aerodrome/operating site close to the boundary of this airspace or where the ash contamination is very high and stable. The establishment of Minimum Sector Altitude (MSA) and the availability of aerodromes/operating sites should be considered.

(d) Safety risk assessment

When directed specifically at the issue of intended flight into airspace forecast to be or aerodromes/operating sites known to be contaminated with volcanic ash, the process should involve the following:

(1) Identifying the hazards

The generic hazard, in the context of this document, is airspace forecast to beor aerodromes/operating sites known to be contaminated with volcanic ash, and whose characteristics are harmful to the airworthiness and operation of the aircraft.

This GM is referring to volcanic ash contamination since it is the most significant hazard for flight operations in the context of a volcanic eruption. Nevertheless, it might not be the only hazard and therefore the operator should consider additional hazards which could have an adverse effect on aircraft structure or passengers safety such as gases.

Within this generic hazard, the ATO should develop its own list of specific hazards taking into account its specific aircraft, experience, knowledge and type of operation, and any other relevant data stemming from previous eruptions.

(2) Considering the severity and consequences of the hazard occurring (i.e. the nature and actual level of damage expected to be inflicted on the particular aircraft from exposure to that volcanic ash cloud).

(3) Evaluating the likelihood of encountering volcanic ash clouds with characteristics harmful to the safe operation of the aircraft.

For each specific hazard within the generic hazard, the likelihood of adverse consequences should be assessed, either qualitatively or quantitatively.

(4) Determining whether the consequent risk is acceptable and within the ATO’s risk performance criteria.

At this stage of the process, the safety risks should be classified as acceptable or unacceptable. The assessment of tolerability will be subjective, based on qualitative data and expert judgement, until specific quantitative data are available in respect of a range of parameters.

(5) Taking action to reduce the safety risk to a level that is acceptable to the ATO’s management.

Appropriate mitigation for each unacceptable risk identified should then be considered in order to reduce the risk to a level acceptable to the ATO’s management.

(e) Procedures to be considered when identifying possible mitigations actions

When conducting a volcanic ash safety risk assessment, the ATO should consider the following non-exhaustive list of procedures and processes as mitigation:

(1) Type certificate holders

Obtaining advice from the TCHs and other engineering sources concerning operations in potentially contaminated airspace and/or aerodromes/operating sites contaminated by volcanic ash.

This advice should set out:

(i) the features of the aircraft that are susceptible to airworthiness effects related to volcanic ash;

(ii) the nature and severity of these effects;

(iii) the effect of volcanic ash on operations to/from contaminated aerodromes/ operating sites, including the effect on take-off and landing aircraft performance;

(iv) the related pre-flight, in-flight and post-flight precautions to be observed by the ATO including any necessary amendments to aircraft operating manuals, aircraft maintenance manuals, master minimum equipment list/dispatch deviation or equivalents required to support the ATO; and

(v) the recommended inspections associated with inadvertent operations in volcanic ash contaminated airspace and operations to/from volcanic ash contaminated aerodromes/operating sites; this may take the form of instructions for continuing airworthiness or other advice.

(2) ATO/contracted organisations' personnel

Definition of procedures for flight planning and operations ensuring that:

(i) flight crews are in a position to evaluate correctly the risk of encountering volcanic ash contaminated airspace, or aerodromes/operating sites, and can plan accordingly;

(ii) flight planning and operational procedures enable crews to avoid areas and aerodromes/operating sites with unacceptable volcanic ash contamination;

(iii) flight crew are aware of the possible signs of entry into a volcanic ash cloud and execute the associated procedures;

(iv) continuing airworthiness personnel are able to assess the need for, and to execute, any necessary maintenance or other required interventions; and

(v) crews are provided with appropriate aircraft performance data when operating to/from aerodromes/operating sites contaminated with volcanic ash.

(3) Provision of enhanced flight watch

This should ensure:

(i) close and continuous monitoring of VAA, VAR/AIREP, SIGMET, NOTAM and ASHTAM and other relevant information, and information from crews, concerning the volcanic ash cloud hazard;

(ii) access to plots of the affected areas from SIGMETs, NOTAMs and other relevant information for crews; and

(iii) communication of the latest information to crews in a timely fashion.

(4) Flight planning

Flexibility of the process to allow re-planning at short notice should conditions change.

(5) Departure, destination and alternate aerodromes

For the airspace to be traversed, or the aerodromes/operating sites in use, parameters to evaluate and take account of:

(i) the probability of contamination;

(ii) any additional aircraft performance requirements;

(iii) required maintenance considerations;

(iv) fuel requirements for re-routeing and extended holding.

(6) Routing policy

Parameters to evaluate and take account of:

(i) the shortest period in and over the forecast contaminated area;

(ii) the hazards associated with flying over the contaminated area;

(iii) drift down and emergency descent considerations;

(iv) the policy for flying below the contaminated airspace and the associated hazards.

(7) Diversion policy

Parameters to evaluate and take account of:

(i) maximum allowed distance from a suitable aerodrome/operating site;

(ii) availability of aerodromes/operating sites outside the forecast contaminated area;

(iii) diversion policy after an volcanic ash encounter.

(8) Minimum equipment list

Additional provisions in the MEL, if applicable, for dispatching aircraft with unserviceabilities that might affect the following non-exhaustive list of systems:

(i) air conditioning packs;

(ii) engine bleeds;

(iii) pressurisation system;

(iv) electrical power distribution system;

(v) air data system;

(vi) standby instruments;

(vii) navigation systems;

(viii) de-icing systems;

(ix) engine driven generators;

(x) auxiliary power unit (APU);

(xi) airborne collision avoidance system (ACAS);

(xii) terrain awareness warning system (TAWS);

(xiii) autoland systems;

(xiv) provision of crew oxygen;

(xv) supplemental oxygen for passengers.

(9) Standard operating procedures

Crew training to ensure they are familiar with normal and abnormal operating procedures and particularly any changes regarding but not limited to:

(i) pre-flight planning;

(ii) in-flight monitoring of volcanic ash cloud affected areas and avoidance procedures;

(iii) diversion;

(iv) communications with ATC;

(v) in-flight monitoring of engine and systems potentially affected by volcanic ash cloud contamination;

(vi) recognition and detection of volcanic ash clouds and reporting procedures;

(vii) in-flight indications of a volcanic ash cloud encounter;

(viii) procedures to be followed if a volcanic ash cloud is encountered;

(ix) unreliable or erroneous airspeed;

(x) non-normal procedures for engines and systems potentially affected by volcanic ash cloud contamination;

(xi) engine-out and engine relight;

(xii) escape routes; and

(xiii) operations to/from aerodromes/operating sites contaminated with volcanic ash.

(10) Provision for aircraft technical log

This should ensure:

(i) Systematic entry in the aircraft continuing airworthiness records or aircraft log if available related to any actual or suspected volcanic ash encounter whether in-flight or at an aerodrome/operating site; and

(ii) Checking, prior to flight, of the completion of maintenance actions related to an entry in the continuing airworthiness records or aircraft log if available for a volcanic ash cloud encounter on a previous flight.

(11) Incident reporting

Crew requirements for:

(i) reporting an airborne volcanic ash cloud encounter (VAR);

(ii) post-flight volcanic ash cloud reporting (VAR);

(iii) reporting non encounters in airspace forecast to be contaminated; and

(iv) filing a mandatory occurrence report in accordance with ORA.GEN.160.

(12) Continuing airworthiness procedures

Procedures when operating in or near areas of volcanic ash cloud contamination:

(i) enhancement of vigilance during inspections and regular maintenance and appropriate adjustments to maintenance practices;

(ii) definition of a follow-up procedure when a volcanic ash cloud encounter has been reported or suspected;

(iii) thorough investigation for any sign of unusual or accelerated abrasions or corrosion or of volcanic ash accumulation;

(iv) reporting to TCHs and the relevant authorities observations and experiences from operations in areas of volcanic ash cloud contamination;

(v) completion of any additional maintenance recommended by the TCH or by the competent authority.

(f) Reporting

The ATO should ensure that reports are immediately submitted to the nearest ATS unit using the VAR/AIREP procedures followed up by a more detailed VAR on landing together with, as applicable, a report as defined in Regulation (EU) No 996/2010 and Directive 2003/42/EC, and an aircraft technical log entry for:

(1) any incident related to volcanic clouds;

(2) any observation of volcanic ash activity and

(3) anytime that volcanic ash is not encountered in an area where it was forecast to be.

(g) Additional guidance

Further guidance on volcanic ash safety risk assessment is given in ICAO Doc. 9974 (Flight safety and volcanic ash – Risk management of flight operations with known or forecast volcanic ash contamination).

GM4 ORA.GEN.200(a)(3) Management system

ED Decision 2013/008/R

SAFETY RISK ASSESSMENT – RISK REGISTER

The results of the assessment of the potential adverse consequences or outcome of each hazard may be recorded by the ATO in a risk register, an example of which is provided below.

AMC1 ORA.GEN.200(a)(4) Management system

ED Decision 2012/007/R

TRAINING AND COMMUNICATION ON SAFETY

(a) Training

(1) All personnel should receive safety training as appropriate for their safety responsibilities.

(2) Adequate records of all safety training provided should be kept.

(b) Communication

(1) The organisation should establish communication about safety matters that:

(i) ensures that all personnel are aware of the safety management activities as appropriate for their safety responsibilities;

(ii) conveys safety critical information, especially relating to assessed risks and analysed hazards;

(iii) explains why particular actions are taken; and

(iv) explains why safety procedures are introduced or changed.

(2) Regular meetings with personnel where information, actions and procedures are discussed may be used to communicate safety matters.

GM1 ORA.GEN.200(a)(4) Management system

ED Decision 2012/007/R

TRAINING AND COMMUNICATION ON SAFETY

The safety training programme may consist of self-instruction via a media (newsletters, flight safety magazines), class-room training, e-learning or similar training provided by training service providers.

AMC1 ORA.GEN.200(a)(5) Management system

ED Decision 2012/007/R

ORGANISATION'S MANAGEMENT SYSTEM DOCUMENTATION

(a) The organisation's management system documentation should at least include the following information:

(1) a statement signed by the accountable manager to confirm that the organisation will continuously work in accordance with the applicable requirements and the organisation's documentation as required by this Part;

(2) the organisation's scope of activities;

(3) the titles and names of persons referred to in ORA.GEN.210(a) and (b);

(4) an organisation chart showing the lines of responsibility between the persons referred to in ORA.GEN.210;

(5) a general description and location of the facilities referred to in ORA.GEN.215;

(6) procedures specifying how the organisation ensures compliance with the applicable requirements;

(7) the amendment procedure for the organisation's management system documentation.

(b) The organisation's management system documentation may be included in a separate manual or in (one of) the manual(s) as required by the applicable Subpart(s). A cross reference should be included.

GM1 ORA.GEN.200(a)(5) Management system

ED Decision 2012/007/R

ORGANISATION'S MANAGEMENT SYSTEM DOCUMENTATION

(a) It is not required to duplicate information in several manuals. The information may be contained in any of the organisation manuals (e.g. operations manual, training manual), which may also be combined.

(b) The organisation may also choose to document some of the information required to be documented in separate documents (e.g. procedures). In this case, it should ensure that manuals contain adequate references to any document kept separately. Any such documents are then to be considered an integral part of the organisation's management system documentation.

AMC1 ORA.GEN.200(a)(5) Management system

ED Decision 2012/007/R

COMPLEX ORGANISATIONS – ORGANISATION'S SAFETY MANAGEMENT MANUAL

(a) The safety management manual (SMM) should be the key instrument for communicating the approach to safety for the whole of the organisation. The SMM should document all aspects of safety management, including the safety policy, objectives, procedures and individual safety responsibilities.

(b) The contents of the safety management manual should include all of the following:

(1) scope of the safety management system;

(2) safety policy and objectives;

(3) safety accountability of the accountable manager;

(4) safety responsibilities of key safety personnel;

(5) documentation control procedures;

(6) hazard identification and risk management schemes;

(7) safety action planning;

(8) safety performance monitoring;

(9) incident investigation and reporting;

(10) emergency response planning;

(11) management of change (including organisational changes with regard to safety responsibilities);

(12) safety promotion.

(c) The SMM may be contained in (one of) the manual(s) of the organisation.

AMC1 ORA.GEN.200(a)(6) Management system

ED Decision 2012/007/R

COMPLIANCE MONITORING - GENERAL

(1) Compliance monitoring

The implementation and use of a compliance monitoring function should enable the organisation to monitor compliance with the relevant requirements of this Part and other applicable Parts.

(1) The organisation should specify the basic structure of the compliance monitoring function applicable to the activities conducted.

(2) The compliance monitoring function should be structured according to the size of the organisation and the complexity of the activities to be monitored.

(2) Organisations should monitor compliance with the procedures they have designed to ensure safe activities. In doing so, they should as a minimum, and where appropriate, monitor:

(1) privileges of the organisation;

(2) manuals, logs, and records;

(3) training standards;

(4) management system procedures and manuals.

(3) Organisational set up

(1) To ensure that the organisation continues to meet the requirements of this Part and other applicable Parts, the accountable manager should designate a compliance monitoring manager. The role of the compliance monitoring manager is to ensure that the activities of the organisation are monitored for compliance with the applicable regulatory requirements , and any additional requirements as established by the organisation, and that these activities are being carried out properly under the supervision of the relevant head of functional area.

(2) The compliance monitoring manager should be responsible for ensuring that the compliance monitoring programme is properly implemented, maintained and continually reviewed and improved.

(3) The compliance monitoring manager should:

(i) have direct access to the accountable manager;

(ii) not be one of the other persons referred to in ORA.GEN.210(b);

(iii) be able to demonstrate relevant knowledge, background and appropriate experience related to the activities of the organisation; including knowledge and experience in compliance monitoring; and

(iv) have access to all parts of the organisation, and as necessary, any contracted organisation.

(4) In the case of a non-complex organisation, this task may be exercised by the accountable manager provided he/she has demonstrated having the related competence as defined in (c)(3)(iii).

(5) In the case the same person acts as compliance monitoring manager and as safety manager, the accountable manager, with regards to his/her direct accountability for safety, should ensure that sufficient resources are allocated to both functions, taking into account the size of the organisation and the nature and complexity of its activities.

(6) The independence of the compliance monitoring function should be established by ensuring that audits and inspections are carried out by personnel not responsible for the function, procedure or products being audited.

(4) Compliance monitoring documentation

(1) Relevant documentation should include the relevant part(s) of the organisation's management system documentation.

(2) In addition, relevant documentation should also include the following:

(i) terminology;

(ii) specified activity standards;

(iii) a description of the organisation;

(iv) the allocation of duties and responsibilities;

(v) procedures to ensure regulatory compliance;

(vi) the compliance monitoring programme, reflecting:

(A) schedule of the monitoring programme;

(B) audit procedures;

(C) reporting procedures;

(D) follow-up and corrective action procedures; and

(E) recording system.

(vii) the training syllabus referred to in (e)(2);

(viii) document control.

(5) Training

(1) Correct and thorough training is essential to optimise compliance in every organisation. In order to achieve significant outcomes of such training, the organisation should ensure that all personnel understand the objectives as laid down in the organisation's management system documentation.

(2) Those responsible for managing the compliance monitoring function should receive training on this task. Such training should cover the requirements of compliance monitoring, manuals and procedures related to the task, audit techniques, reporting and recording.

(3) Time should be provided to train all personnel involved in compliance management and for briefing the remainder of the personnel.

(4) The allocation of time and resources should be governed by the volume and complexity of the activities concerned.

GM1 ORA.GEN.200(a)(6) Management system

ED Decision 2012/007/R

COMPLIANCE MONITORING - GENERAL

(a) The organisational set-up of the compliance monitoring function should reflect the size of the organisation and the nature and complexity of its activities. The compliance monitoring manager may perform all audits and inspections himself/herself or appoint one or more auditors by choosing personnel having the related competence as defined in AMC1 ORA.GEN.200(a)(6) point (c)(3)(iii), either from within or outside the organisation.

(b) Regardless of the option chosen it must be ensured that the independence of the audit function is not affected, in particular in cases where those performing the audit or inspection are also responsible for other functions within the organisation.

(c) In case external personnel are used to perform compliance audits or inspections:

(1) any such audits or inspections are performed under the responsibility of the compliance monitoring manager; and

(2) the organisation remains responsible to ensure that the external personnel has relevant knowledge, background and experience as appropriate to the activities being audited or inspected; including knowledge and experience in compliance monitoring.

(d) The organisation retains the ultimate responsibility for the effectiveness of the compliance monitoring function in particular for the effective implementation and follow-up of all corrective actions.

GM2 ORA.GEN.200(a)(6) Management system

ED Decision 2012/007/R

COMPLEX ORGANISATIONS - COMPLIANCE MONITORING PROGRAMME FOR ATOs

(a) Typical subject areas for compliance monitoring audits and inspections for approved training organisations (ATOs) should be the following:

(1) facilities;

(2) actual flight and ground training;

(3) technical standards.

(b) ATOs should monitor compliance with the training and operations manuals they have designed to ensure safe and efficient training. In doing so, they should, where appropriate, additionally monitor the following:

(1) training procedures;

(2) flight safety;

(3) flight and duty time limitations, rest requirements and scheduling;

(4) aircraft maintenance/operations interface.

GM3 ORA.GEN.200(a)(6) Management system

ED Decision 2012/007/R

AUDIT AND INSPECTION

(a) 'Audit' means a systematic, independent and documented process for obtaining evidence and evaluating it objectively to determine the extent to which requirements are complied with.

(b) 'Inspection' means an independent documented conformity evaluation by observation and judgement accompanied as appropriate by measurement, testing or gauging, in order to verify compliance with applicable requirements.

AMC1 ORA.GEN.200(b) Management system

ED Decision 2012/007/R

SIZE, NATURE AND COMPLEXITY OF THE ACTIVITY

(a) An organisation should be considered as complex when it has a workforce of more than 20 full time equivalents (FTEs) involved in the activity subject to Regulation (EC) No 216/2008[1] and its Implementing Rules.

[1] Regulation (EC) No 216/2008 of the European Parliament and of the Council of 20 February 2008 on common rules in the field of civil aviation and establishing a European Aviation Safety Agency, and repealing Council Directive 91/670/EEC, Regulation (EC) No 1592/2002 and Directive 2004/36/EC. OJ L 79, 19.3.2008, p. 1.

(b) Organisations with up to 20 full time equivalents (FTEs) involved in the activity subject to Regulation (EC) No 216/2008 and its Implementing Rules, may also be considered complex based on an assessment of the following factors:

(1) in terms of complexity, the extent and scope of contracted activities subject to the approval;

(2) in terms of risk criteria, whether any of the following are present:

(i) operations requiring the following specific approvals: performancebased navigation (PBN), low visibility operation (LVO), extended range operations with two-engined aeroplanes (ETOPS), helicopter hoist operation (HHO), helicopter emergency medical service (HEMS), night vision imaging system (NVIS) and dangerous goods (DG);

(ii) different types of aircraft used;

(iii) the environment (offshore, mountainous area etc.);

(c) Regardless of the criteria mentioned in (a) and (b), the following organisations should always be considered as non-complex:

(1) Approved Training Organisations (ATOs) only providing training for the light aircraft pilot licence (LAPL), private pilot licence (PPL), sailplane pilot licence (SPL) or balloon pilot licence (BPL) and the associated ratings and certificates;

(2) Aero-Medical Centres (AeMCs).

AMC1 ORA.GEN.200(c) Management system

ED Decision 2015/011/R

ATOs PROVIDING TRAINING ONLY FOR THE LAPL, PPL, SPL AND BPL AND THE ASSOCIATED RATINGS OR CERTIFICATES – ORGANISATIONAL REVIEW

(a) The primary objective of the organisational review is to enable the organisation to ensure that its management system remains effective by verifying that it:

(1) has continually identified its aviation safety hazards;

(2) has effectively mitigated the associated risks; and

(3) monitors compliance with the applicable requirements.

(b) Safety risk management should:

(1) be performed using internal safety or occurrence reports, hazard checklists, risk registers or similar risk management tools or processes, integrated into the activities of the organisation;

(2) in particular address safety risks related to a change; making use of the existing hazard identification, risk assessment and mitigation tools or processes; and

(3) include provisions for emergency response or a formal Emergency Response Plan (ERP).

(c) As part of the management system documentation required by ORA.GEN.200(a)(5), the organisation should describe the organisational review programme and related responsibilities. Persons responsible for the organisational review should have a thorough knowledge of the applicable requirements and of the organisation's procedures.

(d) The status of all corrective and risk mitigation actions should be monitored by the person responsible for the organisational review programme and implemented within a specified time frame. Action closure should be recorded by the person responsible for the organisational review programme, along with a summary of the action taken.

(e) The results of the organisational review, including all non-compliance findings and new risks identified during the review, should be presented to the accountable manager and the person or group of persons nominated in accordance with ORA.GEN.210(b) prior to notification to the competent authority. All level 1 findings in the sense of ARA.GEN.350 should be immediately notified to the competent authority and all necessary actions immediately taken.

(f) Based on the results of the organisational review, the accountable manager should determine the need for and initiate, as appropriate, further actions to address deficiencies in or further improve the organisation's management system.

GM1 ORA.GEN.200(c) Management system

ED Decision 2015/011/R

ATOs PROVIDING TRAINING ONLY FOR THE LAPL, PPL, SPL OR BPL AND THE ASSOCIATED RATINGS OR CERTIFICATES – ORGANISATIONAL REVIEW PROGRAMME

(a) The organisational review programme may consist of:

(1) checklist(s) covering all items necessary to be addressed in order to ensure that the organisation identified its aviation safety hazards, effectively mitigates the associated risks and ensures effective compliance with the applicable requirements. These should address all procedures described in the management system documentation and training manual; and

(2) a schedule for the accomplishment of the different checklist items, with each item being checked at least once within any 12-month period. The organisation may choose to conduct one full review annually or to conduct several partial reviews.

(b) Performance of organisational reviews:

Each review item may be addressed using an appropriate combination of:

(1) review of training records, training documentation;

(2) review of internal safety reports (e.g. notified difficulties in using current procedures and training material, etc.);

(3) review of the risk register and hazard checklists, as applicable;

(4) sample check of training courses;

(5) witnessing of examinations, as appropriate;

(6) interview of the personnel involved; and

(7) review of the feedback provided by students and customers.

(c) It is recommended that internal safety reports and occurrence reports be reviewed on a continual basis with the aim of identifying possible corrective and risk mitigation actions.

GM2 ORA.GEN.200(c) Management system

ED Decision 2015/011/R

ATOs PROVIDING TRAINING ONLY FOR THE LAPL, PPL, SPL OR BPL AND THE ASSOCIATED RATINGS OR CERTIFICATES – ORGANISATIONAL REVIEW ITEMS

The following provides a list of typical items for an organisational review checklist, to be adapted as necessary to cover all relevant procedures described in the management system documentation and training manual:

(a) Terms of approval

Check that:

(1) no training has been performed outside the terms of approval;

(2) changes not requiring prior approval have been properly managed.

(b) Training syllabi and course material

Check that:

(1) training syllabi and course materials are in compliance with the applicable requirements, as last amended;

(2) training practices are in compliance with the documentation; and

(3) instructor training practices are standardised.

(c) Training equipment and tools

Check that all equipment and tools other than aircraft and FSTDs are present and meet the criteria defined in the training manual.

(d) Facilities

Check that the facilities meet the criteria defined in the training manual.

(e) Training aircraft and FSTDs

Check that the training aircraft and FSTDs meet the criteria defined in the training manual.

(f) Personnel

Check that:

(1) the current accountable manager and other nominated persons are correctly identified;

(2) the organisation chart accurately indicates lines of responsibility and accountability throughout the organisation;

(3) the organisation remains in compliance with the applicable requirements, in case the number of personnel has decreased or if the activity has increased;

(4) the qualification of all new personnel (or personnel with new functions) has been appropriately assessed;

(5) staff involved in any safety management-related processes and tasks has been properly trained; and

(6) staff has been trained, as necessary, to cover changes in regulations, in competent authority publications, in the organisation, its management system documentation and in associated procedures, etc.

(g) Contracted activities (In case the organisation has contracted activities):

(1) Check that new providers have been assessed prior to the establishment of any contract;

(2) For existing providers approved for such activities: check the authorisation and approval status of the contracted organisation; and

(3) For existing providers not approved for such activities: check that the service provided conforms to the applicable requirements of this Part.

(h) Training and communication on safety

Check that:

(1) all personnel are aware of safety management policies, processes and tasks;

(2) safety-related documentations and publications are available; and

(3) safety-critical information derived from internal safety or occurrence reporting and hazard identification have been timely communicated to all staff concerned.

(i) Management system documentation

Check that:

(1) the documentation is adequate and updated;

(2) staff are aware of the safety policy; and

(3) staff can easily access such documentation when needed.

(j) Record-keeping

Check that:

(1) the records cover all the training activities and management system processes; and

(2) minimum record-keeping periods (random checks) are complied with.

(k) Emergency response provisions or ERP

Check that:

(1) emergency response information is up to date and readily available; and

(2) all staff are aware of emergency response information or the ERP, as applicable (random checks).

(l) Internal safety or occurrence reporting procedures

(1) Check the number of reports received since the last review;

(2) Check that:

(i) internal reporting and external occurrence reporting are performed in accordance with reporting procedures;

(ii) the safety or occurrence reports are analysed; and

(iii) feedback is provided to reporters.

(m) Other risk management tools or processes implemented

(1) As applicable, check that:

(i) records of hazards and risks are assessed; in particular following analysis of safety or occurrence reports and when significant changes occur (regulations, personnel, training aircraft, training courses, etc.);

(ii) the risks are assessed and the risk mitigation actions followed up and recorded;

(iii) any risk that has been found acceptable is duly justified; and

(iv) the assumptions made for the risk assessment remain valid;

(2) Verify the effectiveness of all risk mitigation actions initiated since the last organisational review.

ORA.GEN.205 Contracted activities

Regulation (EU) No 290/2012

(a) Contracted activities include all activities within the organisation's scope of approval that are performed by another organisation either itself certified to carry out such activity or if not certified, working under the contracting organisation's approval. The organisation shall ensure that when contracting or purchasing any part of its activity, the contracted or purchased service or product conforms to the applicable requirements.

(b) When the certified organisation contracts any part of its activity to an organisation that is not itself certified in accordance with this Part to carry out such activity, the contracted organisation shall work under the approval of the contracting organisation. The contracting organisation shall ensure that the competent authority is given access to the contracted organisation, to determine continued compliance with the applicable requirements.

AMC1 ORA.GEN.205 Contracted activities

ED Decision 2012/007/R

RESPONSIBILITY WHEN CONTRACTING ACTIVITIES

(a) The organisation may decide to contract certain activities to external organisations.

(b) A written agreement should exist between the organisation and the contracted organisation clearly defining the contracted activities and the applicable requirements.

(c) The contracted safety related activities relevant to the agreement should be included in the organisation's safety management and compliance monitoring programmes.

(d) The organisation should ensure that the contracted organisation has the necessary authorisation or approval when required, and commands the resources and competence to undertake the task.

GM1 ORA.GEN.205 Contracted activities

ED Decision 2012/007/R

RESPONSIBILITY WHEN CONTRACTING ACTIVITIES

(a) Regardless of the approval status of the contracted organisation, the contracting organisation is responsible to ensure that all contracted activities are subject to hazard identification and risk management as required by ORA.GEN.200(a)(3) and to compliance monitoring as required by ORA.GEN.200(a)(6).

(b) When the contracted organisation is itself certified to carry out the contracted activities, the organisation's compliance monitoring should at least check that the approval effectively covers the contracted activities and that it is still valid.

(c) If the organisation requires the contracted organisation to conduct an activity which exceeds the contracted organisation's terms of approval, this will be considered as the contracted organisation working under the approval of the contracting organisation.

ORA.GEN.210 Personnel requirements

Regulation (EU) No 290/2012

(a) The organisation shall appoint an accountable manager, who has the authority for ensuring that all activities can be financed and carried out in accordance with the applicable requirements. The accountable manager shall be responsible for establishing and maintaining an effective management system.

(b) A person or group of persons shall be nominated by the organisation, with the responsibility of ensuring that the organisation remains in compliance with the applicable requirements. Such person(s) shall be ultimately responsible to the accountable manager.

(c) The organisation shall havesufficient qualified personnel for the planned tasks and activities to be performed in accordance with the applicable requirements.

(d) The organisation shall maintain appropriate experience, qualification and training records to show compliance with paragraph (c).

(e) The organisation shall ensure that all personnel are aware of the rules and procedures relevant to the exercise of their duties.

ORA.GEN.215 Facility requirements

Regulation (EU) No 1178/2011

The organisation shall have facilities allowing the performance and management of all planned tasks and activities in accordance with the applicable requirements.

AMC1 ORA.GEN.215 Facility requirements

ED Decision 2012/007/R

ATOs PROVIDING TRAINING FOR the CPL, MPL AND ATPL AND THE ASSOCIATED RATINGS AND CERTIFICATES

(a) For ATOs providing flight training, the following flight operations accommodation should be available:

(1) an operations room with facilities to control flying operations;

(2) a flight planning room with the following facilities:

(i) appropriate current maps and charts;

(ii) current aeronautical information service (AIS) information;

(iii) current meteorological information;

(iv) communications to air traffic control (ATC) and the operations room;

(v) any other flight safety related material.

(3) adequate briefing rooms/cubicles of sufficient size and number;

(4) suitable offices for the supervisory personnel and room(s) to allow flight instructors to write reports on students, complete records and other related documentation;

(5) furnished crew-room(s) for instructors and students.

(b) For ATOs providing theoretical knowledge training, the following facilities for theoretical knowledge instruction should be available:

(1) adequate classroom accommodation for the current student population;

(2) suitable demonstration equipment to support the theoretical knowledge instruction;

(3) a radiotelephony training and testing facility;

(4) a reference library containing publications giving coverage of the syllabus;

(5) offices for the instructional personnel.

AMC2 ORA.GEN.215 Facility requirements

ED Decision 2012/007/R

ATOs PROVIDING TRAINING FOR THE LAPL, PPL, SPL OR BPL AND THE ASSOCIATED RATINGS AND CERTIFICATES

(a) The following flight operations accommodation should be available:

(1) a flight planning room with the following facilities:

(i) appropriate current aviation maps and charts;

(ii) current AIS information;

(iii) current meteorological information;

(iv) communications to ATC (if applicable);

(v) any other flight safety related material.

(2) adequate briefing room(s)/cubicles of sufficient size and number;

(3) suitable office(s) to allow flight instructors to write reports on students, complete records and other related documentation;

(4) suitable rest areas for instructors and students, where appropriate to the training task;

(5) in the case of ATOs providing training for the BPL or LAPL(B) only, the flight operations accommodation listed in (a)(1) to (a)(4) may be replaced by other suitable facilities when operating outside aerodromes.

(b) The following facilities for theoretical knowledge instruction should be available:

(1) adequate classroom accommodation for the current student population;

(2) suitable demonstration equipment to support the theoretical knowledge instruction;

(3) suitable office(s) for the instructional personnel.

(c) A single room may be sufficient to provide the functions listed in (a) and (b).

ORA.GEN.220 Record-keeping

Regulation (EU) No 1178/2011

(a) The organisation shall establish a system of record–keeping that allows adequate storage and reliable traceability of all activities developed, coveringin particular all the elements indicated in ORA.GEN.200.

(b) The format of the records shall be specified in the organisation's procedures.

(c) Records shall be stored in a manner that ensures protection from damage, alteration and theft.

AMC1 ORA.GEN.220(b) Record-keeping

ED Decision 2012/007/R

GENERAL

(a) The record-keeping system should ensure that all records are accessible whenever needed within a reasonable time. These records should be organised in a way that ensures traceability and retrievability throughout the required retention period.

(b) Records should be kept in paper form or in electronic format or a combination of both. Records stored on microfilm or optical disc format are also acceptable. The records should remain legible throughout the required retention period. The retention period starts when the record has been created or last amended.

(c) Paper systems should use robust material which can withstand normal handling and filing. Computer systems should have at least one backup system which should be updated within 24 hours of any new entry. Computer systems should include safeguards against the ability of unauthorised personnel to alter the data.

(d) All computer hardware used to ensure data backup should be stored in a different location from that containing the working data and in an environment that ensures they remain in good condition. When hardware or software changes take place, special care should be taken that all necessary data continues to be accessible at least through the full period specified in the relevant Subpart. In the absence of such indication, all records should be kept for a minimum period of 5 years.

GM1 ORA.GEN.220(b) Record-keeping

ED Decision 2012/007/R

RECORDS

Microfilming or optical storage of records may be carried out at any time. The records should be as legible as the original record and remain so for the required retention period.

SUBPART AEMC – AERO-MEDICAL CENTRES

SECTION I – GENERAL

ORA.AeMC.105 Scope

Regulation (EU) No 1178/2011

This Subpart establishes the additional requirements to be met by an organisation to qualify for the issue or continuation of an approval as an aero-medical centre (AeMC) to issue medical certificates, including initial class 1 medical certificates.

ORA.AeMC.115 Application

Regulation (EU) No 1178/2011

Applicants for an AeMC certificate shall:

(a) comply with MED.D.005; and

(b) in addition to the documentation for the approval of an organisation required in ORA.GEN.115, provide details of clinical attachments to or liaison with designated hospitals or medical institutes for the purpose of specialist medical examinations.

AMC1 ORA.AeMC.115 Application

ED Decision 2012/007/R

GENERAL

(a) The documentation for the approval of an AeMC should include the names and qualifications of all medical staff, a list of medical and technical facilities for initial class 1 aero-medical examinations and of supporting specialist consultants.

(b) The AeMC should provide details of clinical attachments to hospitals, medical institutions and/or specialists.

ORA.AeMC.135 Continued validity

Regulation (EU) No 1178/2011

The AeMC certificate shall be issued for an unlimited duration. It shall remain valid subject to the holder and the aero-medical examiners of the organisation:

(a) complying with MED.D.030;and

(b) ensuring their continued experience by performing an adequate number of class 1 medical examinations every year.

AMC1 ORA.AeMC.135 Continued validity

ED Decision 2012/007/R

EXPERIENCE

(a) At least 200 class 1 aero-medical examinations and assessments should be performed at the AeMC every year.

(b) In Member States where the number of aero-medical examinations and assessments mentioned in (a) cannot be reached due a low number of professional pilots, a proportionate number of class 1 aero-medical examinations and assessments should be performed.

(c) In these cases, the continuing experience of the head of the AeMC and aero-medical examiners on staff should also be ensured by them performing aero-medical examinations and assessments for:

(1) class 2 medical certificates as established in Part-MED; and/or

(2) third country class 1 medical certificates.

(d) Aero-medical research including publication in peer reviewed journals may also be accepted as contributing to the continued experience of the head of, and aero-medical examiners at, an AeMC.

SECTION II – MANAGEMENT

ORA.AeMC.200 Management system

Regulation (EU) No 1178/2011

The AeMC shall establish and maintain a management system that includes the items addressed in ORA.GEN.200 and, in addition, processes:

(a) for medical certification in compliance with Part-MED; and

(b) to ensure medical confidentiality at all times.

GM1 ORA.AeMC.200 Management system

ED Decision 2012/007/R

RESEARCH

If aero-medical research is conducted at an AeMC, its management system should include processes to conduct that research and publish the results.

ORA.AeMC.210 Personnel requirements

Regulation (EU) No 1178/2011

(a) The AeMC shall:

(1) have an aero-medical examiner (AME) nominated as head of the AeMC, with privileges to issue class 1 medical certificates and sufficient experience in aviation medicine to exercise his/her duties; and

(2) have on staff an adequate number of fully qualified AMEs and other technical staff and experts.

(b) The head of the AeMC shall be responsible for coordinating the assessment of examination results and signing reports, certificates, and initial class 1 medical certificates.

AMC1 ORA.AeMC.210 Personnel requirements

ED Decision 2012/007/R

GENERAL

(a) The aero-medical examiner (AME) should have held class 1 privileges for at least 5 years and have performed at least 200 aero-medical examinations for a class 1 medical certificate before being nominated as head of an AeMC.

(b) The AeMC may provide practical AME training for persons fully qualified and licensed in medicine.

ORA.AeMC.215 Facility requirements

Regulation (EU) No 1178/2011

The AeMC shall be equipped with medico-technical facilities adequate to perform aero-medical examinations necessary for the exercise of the privileges included in the scope of the approval.

AMC1 ORA.AeMC.215 Facility requirements

ED Decision 2012/007/R

MEDICAL-TECHNICAL FACILITIES

The medical-technical facilities of an AeMC should consist of the equipment of a general medical practice and, in addition, of:

(a) Cardiology

Facilities to perform:

(1) 12-lead resting ECG;

(2) stress ECG;

(3) 24-hour blood pressure monitoring; and

(4) 24-hour heart rhythm monitoring.

(b) Ophthalmology

Facilities for the examination of:

(1) near, intermediate and distant vision;

(2) external eye, anatomy, media and fundoscopy;

(3) ocular motility;

(4) binocular vision;

(5) colour vision (anomaloscopy or equivalent);

(6) visual fields;

(7) refraction; and

(8) heterophoria.

(c) Hearing

(1) pure-tone audiometer

(d) Otorhinolaryngology

Facilities for the clinical examination of mouth and throat and:

(1) otoscopy;

(2) rhinoscopy;

(3) tympanometry or equivalent; and

(4) clinical assessment of vestibular system.

(e) Examination of pulmonary function

(1) spirometry

(f) The following facilities should be available at the AeMC or arranged with a service provider:

(1) clinical laboratory facilities; and

(2) ultrasound of the abdomen.

ORA.AeMC.220 Record-keeping

Regulation (EU) No 1178/2011

In addition to the records required in ORA.GEN.220, the AeMC shall:

(a) maintain records with details of medical examinations and assessments performed for the issue, revalidation or renewal of medical certificates and their results, for a minimum period of 10 years after the last examination date; and

(b) keep all medical records in a way that ensures that medical confidentiality is respected at all times.