

II

(Non-legislative acts)

REGULATIONS

COMMISSION IMPLEMENTING REGULATION (EU) 2019/27

of 19 December 2018

amending Regulation (EU) No 1178/2011 laying down technical requirements and administrative procedures related to civil aviation aircrew pursuant to Regulation (EU) 2018/1139 of the European Parliament and of the Council

(Text with EEA relevance)

THE EUROPEAN COMMISSION,

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

Having regard to Regulation (EU) 2018/1139 of the European Parliament and of the Council of 4 July 2018 on common rules in the field of civil aviation and establishing a European Union Aviation Safety Agency, and amending Regulations (EC) No 2111/2005, (EC) No 1008/2008, (EU) No 996/2010, (EU) No 376/2014 and Directives 2014/30/EU and 2014/53/EU of the European Parliament and of the Council, and repealing Regulation (EC) No 552/2004 and (EC) No 216/2008 of the European Parliament and of the Council and Council Regulation (EEC) No 3922/91 ⁽¹⁾, and in particular Article 23(1), Article 27(1), Article 62(14) and (15), Article 72(5) and Article 74(8) thereof,

Whereas:

- (1) Commission Regulation (EU) No 1178/2011 ⁽²⁾ lays down detailed rules for certain pilots' licences and for the conversion of 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. It also sets out rules for pilots' medical certificates, the conditions for the conversion of national medical certificates and the certification of aero-medical examiners and it includes provisions on medical fitness of the cabin crew.
- (2) The implementation of Regulation (EU) No 1178/2011 revealed that certain of its provisions contain editorial errors or are ambiguous. This leads to implementation problems and to problems in maintaining a uniform level of civil aviation safety in all Member States. Those provisions should therefore be clarified and corrected.
- (3) During standardisation visits conducted by the European Union Aviation Safety Agency ('the Agency') and meetings of the medical expert group hosted by the Agency, several loopholes were identified in Annex IV to Regulation (EU) No 1178/2011 that could potentially have safety implications and that should therefore be addressed.
- (4) Following the accident of the Germanwings Flight 9525, the Germanwings Task Force led by the Agency identified a number of safety risks and issued six recommendations to mitigate those risks ⁽³⁾. Four of those recommendations, namely recommendation 2 'Mental health assessment of flight crew', recommendation 3 'Prevention of misuse of alcohol and other psychoactive substances by the flight crew', recommendation 4

⁽¹⁾ OJ L 212, 22.8.2018, p. 1.

⁽²⁾ Commission Regulation (EU) No 1178/2011 of 3 November 2011 laying down technical requirements and administrative procedures related to civil aviation aircrew pursuant to Regulation (EC) No 216/2008 of the European Parliament and of the Council (OJ L 311, 25.11.2011, p. 1).

⁽³⁾ <http://ec.europa.eu/transport/sites/transport/files/modes/air/news/doc/2015-07-17-germanwings-report/germanwings-task-force-final-report.pdf>

'Training, oversight and network of AMEs' and recommendation 5 'Creation of a European aero-medical data repository', concern amendments to the rules on aircrew medical certification of Regulation (EU) No 1178/2011. It is appropriate to now act upon those four recommendations.

- (5) The provisions of Regulation (EU) No 1178/2011 regarding medical requirements and aero-medical examination should be aligned with the relevant provisions of Commission Regulation (EU) 2015/340 ⁽⁴⁾.
- (6) The Agency submitted draft implementing rules to the European Commission together with its Opinion 09/2016.
- (7) The measures provided for in this Regulation are in accordance with the opinion of the Committee established by Article 127 of Regulation (EU) 2018/1139,

HAS ADOPTED THIS REGULATION:

Article 1

Regulation (EU) No 1178/2011 is amended as follows:

- (1) in Article 2, the following points (22a), (22b) and (22c) are inserted:

'(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.;

- (2) Annex IV is amended in accordance with Annex I to this Regulation;
- (3) Annex VI is amended in accordance with Annex II to this Regulation.

Article 2

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

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

Done at Brussels, 19 December 2018.

For the Commission
The President
Jean-Claude JUNCKER

⁽⁴⁾ Commission Regulation (EU) 2015/340 of 20 February 2015 laying down technical requirements and administrative procedures relating to air traffic controllers' licences and certificates pursuant to Regulation (EC) No 216/2008 of the European Parliament and of the Council, amending Commission Implementing Regulation (EU) No 923/2012 and repealing Commission Regulation (EU) No 805/2011 (OJ L 63, 6.3.2015, p. 1).

ANNEX I

Annex IV to Regulation (EU) No 1178/2011 is amended as follows:

(1) Subparts A and B are replaced by the following:

‘SUBPART A

GENERAL REQUIREMENTS

SECTION 1

General**MED.A.001 Competent authority**

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

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

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

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

MED.A.020 Decrease in medical fitness

- (a) Licence holders shall not exercise the privileges of their licence 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.

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

- (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 (d) of point ARA.MED.160.

SECTION 2

Requirements for medical certificates

MED.A.030 Medical certificates

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

MED.A.035 Application for a medical certificate

- (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.

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

- (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

- (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

- (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

- (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***(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.

MED.B.005 General medical requirements

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**(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 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 having any 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.

MED.B.015 Respiratory System

- (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.

MED.B.020 Digestive System

(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.

MED.B.025 Metabolic and Endocrine Systems

(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.

MED.B.030 Haematology

- (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.

MED.B.035 Genitourinary System

- (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.

MED.B.040 Infectious Disease

- (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.

MED.B.045 Obstetrics and Gynaecology

- (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.

MED.B.050 Musculoskeletal System

- (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.

MED.B.055 Mental Health

- (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.

MED.B.065 Neurology

- (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.

MED.B.070 Visual System

- (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 monocular vision 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 monocular vision 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.

MED.B.075 Colour vision

(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.

MED.B.080 Otorhinolaryngology (ENT)

(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.

MED.B.085 Dermatology

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.

MED.B.090 Oncology

- (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.

SECTION 3

Specific requirements for LAPL medical certificates

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

- (a) An applicant for a LAPL medical certificate shall be assessed based on aero-medical best practice.
- (b) Special attention shall be given to the applicant's complete medical history.

- (c) The initial assessment, all subsequent re-assessments after 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.;
- (2) Subpart D is replaced by the following:

‘SUBPART D

**AERO-MEDICAL EXAMINERS, GENERAL MEDICAL PRACTITIONERS, OCCUPATIONAL HEALTH
MEDICAL PRACTITIONERS**

SECTION 1

Aero-Medical Examiners

MED.D.001 Privileges

- (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

- (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

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

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

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

- (a) Training courses in aviation medicine referred 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.

MED.D.025 Changes to the AME certificate

- (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

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.

SECTION 2

General Medical Practitioners

MED.D.035 Requirements for general medical practitioners

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

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.’
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ANNEX II

The following point is added in Section I of Subpart MED of Annex VI to Regulation (EU) No 1178/2011:

‘ARA.MED.160 Exchange of information on medical certificates through a central repository.

- (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 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.

⁽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).

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- (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.'
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