

## **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) 2024/2076

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;
- 'helicopter emergency medical services (HEMS) operation' means a "HEMS flight" as defined in point 61 of Annex I to Regulation (EU) No 965/2012;
  - [applicable from 13 February 2025 Regulation (EU) 2024/2076]
- '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 pseudoephedrine 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/F

- (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:
    - 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 <a href="MED.A.025(b)">MED.A.025(b)</a> 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) 2020/359

- (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), a balloon pilot licence (BPL) issued in accordance with Annex III (Part-BFCL) to <u>Commission Regulation (EU 2018/395</u>, or a sailplane pilot licence (SPL) issued in accordance with Annex III (Part-SFCL) to <u>Commission Implementing</u> <u>Regulation (EU) 2018/1976</u>, the pilot shall hold at least a valid LAPL medical certificate;
  - (2) private pilot licence (PPL), the pilot shall hold at least a valid class 2 medical certificate;
  - (3) BPL for the purpose of:
    - (i) commercial passenger ballooning, the pilot shall hold at least a valid class 2 medical certificate;
    - (ii) commercial operation other than commercial passenger ballooning, with more than 4 persons on board the aircraft, the pilot shall hold at least a valid class 2 medical certificate;
  - (4) SPL for the purpose of commercial sailplane operations other than those specified in Article 3(2) of Commission Implementing Regulation (EU) 2018/1976, the pilot shall hold at least a valid class 2 medical certificate;
  - (5) a 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 basic instrument rating is added to a PPL, the licence holder shall undergo 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) 2024/2076

- (a) A medical certificate shall only be issued, revalidated or renewed once the required aeromedical 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.

[applicable until 12 February 2025 - Regulation (EU) 2019/27]



(1) Class 1 and class 2 medical certificates shall be revalidated and renewed by an AeMC or an AME. Specifically, class 1 medical certificates for applicants who have reached the age of 60 and are involved in single-pilot HEMS operations shall be revalidated and renewed primarily by an AeMC or, at the discretion of the competent authority, by an experienced AME designated by the competent authority.

[applicable from 13 February 2025 - Regulation (EU) 2024/2076]

- (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:
  - 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 <u>MED.B.005</u> and <u>MED.B.095</u>.

## 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) 2019/2

(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 <u>MED.B.001</u>, 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 <u>MED.B.001</u>, 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:
    - 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 <a href="MMC2 MED.B.001(a">AMC2 MED.B.001(a)</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 <u>AMC2 MED.B.001(a)</u> should only be imposed:
    - for class 1 medical certificates, by the medical assessor of the licensing authority where a referral is required according to <u>MED.B.001</u>;
    - (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 <u>MED.B.001</u>;
    - (iii) for LAPL medical certificates, by an AME or AeMC.



SUBPART B – REQUIREMENTS FOR PILOT MEDICAL CERTIFICATES

- (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 reexamination 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.



SUBPART B – REQUIREMENTS FOR PILOT MEDICAL CERTIFICATES

(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) 2024/2076

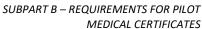
Applicants for a medical certificate shall be assessed in accordance with the detailed medical requirements set out in Sections 2 and 3.

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.

In their examination AMEs shall give proper consideration to the degenerative effects of ageing on the body systems.

[applicable from 13 February 2025 - Regulation (EU) 2024/2076]





## SECTION 2 — MEDICAL REQUIREMENTS FOR CLASS 1 AND CLASS 2 MEDICAL CERTIFICATES

## MED.B.010 Cardiovascular System

Regulation (EU) 2024/2076

#### (a) Examination

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

### [applicable until 12 February 2025 - Regulation (EU) 2019/27]

(3) For a class 1 medical certificate, an extended cardiovascular assessment shall be completed at the first revalidation or renewal examination after the age of 65 and every 4 years thereafter. For applicants involved in single-pilot HEMS operations, an extended cardiovascular assessment shall be completed at the first revalidation or renewal examination after the age of 60 and subject to a cardiovascular risk factor assessment thereafter.

[applicable from 13 February 2025 - Regulation (EU) 2024/2076]

(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.

## [applicable until 12 February 2025 - Regulation (EU) 2019/27]

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

[applicable from 13 February 2025 - Regulation (EU) 2024/2076]

- (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-;

**MEDICAL CERTIFICATES** 



- (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.
- (5) A cardiovascular risk factor assessment shall form part of examinations for class 1 and class 2 medical certificates at the first examination after reaching the age of 40 and at regular intervals thereafter.

[applicable from 13 February 2025 - Regulation (EU) 2024/2076]

## (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 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:
    - 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<sup>2</sup>/m<sup>2</sup> 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 postoperative 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:
  - 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:
  - 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.
- (I) 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 suprarenal 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 cm² 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.
- (I) 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:
    - 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) 2024/2076

- (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.

### [applicable until 12 February 2025 - Regulation (EU) 2019/27]

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

[applicable from 13 February 2025 - Regulation (EU) 2024/2076]

(ba) For class 1 medical certificate holders involved in single-pilot HEMS operations, pulmonary functional tests and obstructive sleep apnoea (OSA) screening shall be completed at the first revalidation or renewal examination after the age of 60.

[applicable from 13 February 2025 - Regulation (EU) 2024/2076]

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

### [applicable until 12 February 2025 - Regulation (EU) 2019/27]

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

[applicable from 13 February 2025 - Regulation (EU) 2024/2076]

- (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  $\geq$  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 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 aeromedical 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 26<sup>th</sup> 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.

SUBPART B – REQUIREMENTS FOR PILOT MEDICAL CERTIFICATES

### (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/F

- (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 selfharm 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 <u>AMC1 MED.B.055(d)(1)</u> 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 <u>GM1 MED.B.055</u> 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 <u>GM2 MED.B.055(a)</u> 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 <u>AMC1 MED.B.050</u> 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 <u>AMC1 MED.B.050</u> 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 <a href="MMC2 MED.B.050"><u>AMC2 MED.B.050</u></a> 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 <u>AMC2 MED.B.050</u> are met. A cardiological evaluation and medical flight test should be undertaken for applicants with residual deficiencies.



# MED.B.070 Visual System

Regulation (EU) 2024/2076

#### (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.
  - (iii) when holders are involved in single-pilot HEMS operations, a comprehensive eye examination shall be completed at the first revalidation or renewal examination after the age of 60 and every year thereafter.

[applicable from 13 February 2025 - Regulation (EU) 2024/2076]

- (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.
- (i) 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:

- the binocular visual field or, in the case of monocularity, the monocular visual field is (1) 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

- The assessment after eye surgery should include an ophthalmological examination. (1)
- (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)

#### Test distance: 40 cm (a)

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) 2024/2076

- (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.

[applicable until 12 February 2025 - Regulation (EU) 2019/27]

(1) Applicants shall be subjected to the Ishihara test for the initial issue of a medical certificate. For class 1 medical certificate holders involved in single-pilot HEMS operations, a colour vision assessment shall be completed at the first revalidation or renewal examination after the age of 60 and every year thereafter. Applicants who pass that test may be assessed as fit.

[applicable from 13 February 2025 - Regulation (EU) 2024/2076]

- (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) 2024/2076

- (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.

#### [applicable until 12 February 2025 - Regulation (EU) 2019/27]

(i) For a class 1 medical certificate, and for a class 2 medical certificate when an instrument rating or a basic 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 until the licence holder reaches the age of 60 and every year thereafter.

### [applicable from 13 February 2025 - Regulation (EU) 2024/2076]

- (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.
- (3) For class 1 medical certificate holders involved in single-pilot HEMS operations, a comprehensive ear, nose and throat examination shall be completed at the first revalidation or renewal examination after the age of 60.

#### [applicable from 13 February 2025 - Regulation (EU) 2024/2076]

- (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/F

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 <u>AMC5 MED.B.095(d)</u>, 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.

**MEDICAL CERTIFICATES** 

SUBPART B - REQUIREMENTS FOR PILOT



### (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:
  - 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.

**MEDICAL CERTIFICATES** 



- (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 goaround/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 <u>AMC2 MED.B.095(b)(4)</u>.

# 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 <u>AMC10 MED.B.095</u> 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 <a href="MMC10 MED.B.095"><u>AMC10 MED.B.095</u></a> 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.



SUBPART B – REQUIREMENTS FOR PILOT MEDICAL CERTIFICATES

#### (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.

**MEDICAL CERTIFICATES** 



# AMC17 MED.B.095 Medical examination and assessment of applicants for LAPL medical certificates

FD 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;



SUBPART C – REQUIREMENTS FOR MEDICAL FITNESS OF CABIN CREW

- (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 <u>AMC2 MED.C.025(c)</u>.

### 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 <u>GM2 MED.B.070</u>)
- (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 <u>GM1 MED.B.070</u>).
- (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:
    - 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 <u>MED.A.015</u>.

#### 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

GF	N	С	R	Λ	ı

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	
3446 51 13346	
CABIN CREW MEDICAL REPORT	
FOR CABIN CREW ATTESTATION (CCA)	
APPLICANT OR HOLDER	



l is con	The State where the aero-medical assessment aducted:	II Aero-medical assessment result (fit/unfit):		
III	Cabin crew attestation reference number:	Expiry date of the previous cabin crew medical report (dd/mm/yyyy):		
IV	Last and first name:	Date of aero-medical assessment (dd/mm/yyyy):		
XIV	Date of birth (dd/mm/yyyy):	X Date of issue* (dd/mm/yyyy):		
VI	Nationality:	X Signature of the AeMC, AME or OHMP:		
VII	Signature of CCA applicant/holder:	XI Seal or stamp of the AeMC, AME or OHMP:		
	2	3		
	* Data of issue is the data the Cahin Crew Medical Penert is issued and sign			

<sup>\*</sup> Date of issue is the date the Cabin Crew Medical Report is issued and signed.

MEDICAL FITNESS OF CABIN CREW



XII	Limitation(s), if applicable:	IX Expiry date of this medical report
	Code:	(dd/mm/yyyy):
	Description:	
	Code:	
	Description:	
	Code:	
	Description:	
	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) 2024/2076

- (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.
- (aa) For demonstrating compliance with points <u>MED.D.010(b)</u> and <u>MED.D.015(c)</u>, an aviation medicine training course completed by an applicant outside the territories for which Member States are responsible under the Chicago Convention may be accepted by the competent authority, provided that the following conditions are met:
  - (i) the competent authority has assessed and verified the course syllabus in accordance with point ARA.MED.200(c)(1) of Annex VI;
  - (ii) the applicant has completed a specific training module on the aero-medical requirements detailed in this Annex (Part-MED) as provided by the competent authority.

[applicable from 13 February 2025 - Regulation (EU) 2024/2076]

- (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;

ANNEX IV (Part-MED)

SUBPART D – AERO-MEDICAL EXAMINERS (AME), GENERAL MEDICAL PRACTITIONERS (GMP), OCCUPATIONAL HEALTH MEDICAL PRACTITIONERS (OHMP)

- (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

- (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)

- (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

ANNEX IV (Part-MED)

SUBPART D – AERO-MEDICAL EXAMINERS (AME), GENERAL MEDICAL PRACTITIONERS (GMP), OCCUPATIONAL HEALTH MEDICAL PRACTITIONERS (OHMP)

- (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

ANNEX IV (Part-MED)

SUBPART D – AERO-MEDICAL EXAMINERS (AME), GENERAL MEDICAL PRACTITIONERS (GMP), OCCUPATIONAL HEALTH MEDICAL PRACTITIONERS (OHMP)

(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

ANNEX IV (Part-MED)

SUBPART D – AERO-MEDICAL EXAMINERS (AME), GENERAL MEDICAL PRACTITIONERS (GMP), OCCUPATIONAL HEALTH MEDICAL PRACTITIONERS (OHMP)

(15)	Visua	ıl syste	em 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)	Mon	ocularity and medical flight tests	
	(v)	Colo	ur vision	
	(vi)	Meth	nods of testing: pseudoisochromatic plates, lantern	tests, anomaloscopy
	(vii)	ii) Importance of standardisation of tests and of test protocols		
	(viii)	Asse	ssment after eye surgery	
(16)	Otorl	ninolai	ryngology	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)	Onco	ology		
	(i)	Relation to aviation, risk of metastasis and incapacitation		
	(ii)	Risk management		
	(iii) Different methods of treatment and assessment			
(18)		dents and accidents, escape and survival 1 hour		
	(i)		dent statistics	
	(ii)	Injur		
	(iii)	Aviation pathology, post-mortem examination, identification		

(iv)

Aircraft evacuation

ANNEX IV (Part-MED)

SUBPART D – AERO-MEDICAL EXAMINERS (AME), GENERAL MEDICAL PRACTITIONERS (GMP), OCCUPATIONAL HEALTH MEDICAL PRACTITIONERS (OHMP)

- (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

ANNEX IV (Part-MED)

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

(24) Practical demonstrations of basic aeronautical knowledge 8 hours (25) Concluding items 2 hours

Final examination (i)

(ii) De-briefing and critique

#### GM2 MED.D.020 Training courses in aviation medicine

ED Decision 2019/002/R **ADVANCED TRAINING COURSE** Advanced training course in aviation medicine 66 hours Pilot working environment 6 hours 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 Air traffic control (v) (vi) Single-pilot/multi-pilot Exposure to radiation and other harmful agents (2) Aerospace physiology 4 hours Brief review of basics in physiology (hypoxia, rapid/slow decompression, (i) hyperventilation, acceleration, ejection, spatial disorientation) (ii) Simulator sickness (3) Clinical medicine 5 hours Complete physical examination (i) Review of basics with relationship to commercial flight operations (ii) Class 1 requirements (iii) (iv) Clinical cases Communication and interview techniques (v) (4)Cardiovascular system 4 hours Cardiovascular examination and review of basics (i) (ii) Class 1 requirements Diagnostic steps in cardiovascular system (iii) (iv) Clinical cases

Brief review of basics (neurological and psychiatric examination)

Neurology

(5)

ANNEX IV (Part-MED)

SUBPART D – AERO-MEDICAL EXAMINERS (AME), GENERAL MEDICAL PRACTITIONERS (GMP), OCCUPATIONAL HEALTH MEDICAL PRACTITIONERS (OHMP)

- (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

- (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

ANNEX IV (Part-MED)

SUBPART D – AERO-MEDICAL EXAMINERS (AME), GENERAL MEDICAL PRACTITIONERS (GMP), OCCUPATIONAL HEALTH MEDICAL PRACTITIONERS (OHMP)

- (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

- (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;

ANNEX IV (Part-MED)

SUBPART D – AERO-MEDICAL EXAMINERS (AME), GENERAL MEDICAL PRACTITIONERS (GMP), OCCUPATIONAL HEALTH MEDICAL PRACTITIONERS (OHMP)

- (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 10 hours credit (ICASM)

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)

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 V (PART-CC)**

#### **SUBPART GEN – GENERAL REQUIREMENTS**

#### **CC.GEN.001** Competent authority

Regulation (EU) No 1178/2011

For the purpose of this Part, the competent authority shall be the authority designated by the Member State where a person applies for the issue of a cabin crew attestation.

#### CC.GEN.005 Scope

Regulation (EU) No 1178/2011

This Part establishes the requirements for the issue of cabin crew attestations and the conditions for their validity and use by their holders.

#### CC.GEN.015 Application for a cabin crew attestation

Regulation (EU) No 1178/2011

The application for a cabin crew attestation shall be made in a form and manner established by the competent authority.

# CC.GEN.020 Minimum age

Regulation (EU) No 1178/2011

The applicant for a cabin crew attestation shall be at least 18 years of age.

# **CC.GEN.025** Privileges and conditions

Regulation (EU) No 1178/2011

- (a) The privileges of holders of a cabin crew attestation are to act as cabin crew members in commercial air transport operation of aircraft referred to in Article 4(1)(b) and (c) of Regulation (EC) No 216/2008.
- (b) Cabin crew members may exercise the privileges specified in (a) only if they:
  - (1) hold a valid cabin crew attestation as specified in <a href="CC.CCA.105">CC.CCA.105</a>; and
  - (2) comply with <u>CC.GEN.030</u>, <u>CC.TRA.225</u> and the applicable requirements of Part-MED.

#### CC.GEN.030 Documents and record-keeping

Regulation (EU) No 1178/2011

To show compliance with the applicable requirements as specified in <a href="CC.GEN.025(b)">CC.GEN.025(b)</a>, each holder shall keep, and provide upon request, the cabin crew attestation, the list and the training and checking records of his/her aircraft type or variant qualification(s), unless the operator employing his/her services keeps such records and can make them readily available upon request by a competent authority or by the holder.



SUBPART CCA – SPECIFIC REQUIREMENTS FOR THE CABIN CREW ATTESTATION

# SUBPART CCA – SPECIFIC REQUIREMENTS FOR THE CABIN CREW ATTESTATION

#### CC.CCA.100 Issue of the cabin crew attestation

Regulation (EU) No 1178/2011

- (a) Cabin crew attestations shall only be issued to applicants who have passed the examination following completion of the initial training course in accordance with this Part.
- (b) Cabin crew attestations shall be issued:
  - (1) by the competent authority; and/or
  - (2) by an organisation approved to do so by the competent authority.

#### CC.CCA.105 Validity of the cabin crew attestation

Regulation (EU) No 1178/2011

The cabin crew attestation shall be issued with unlimited duration and shall remain valid unless:

- (a) it is suspended or revoked by the competent authority; or
- (b) its holder has not exercised the associated privileges during the preceding 60 months on at least one aircraft type.

# CC.CCA.110 Suspension and revocation of the cabin crew attestation

Regulation (EU) No 1178/2011

- (a) If holders do not comply with this Part, their cabin crew attestation may be suspended or revoked by the competent authority.
- (b) In case of suspension or revocation of their cabin crew attestation by the competent authority, holders shall:
  - (1) be informed in writing of this decision, and of their right of appeal in accordance with national law;
  - (2) not exercise the privileges granted by their cabin crew attestation;
  - (3) inform, without undue delay, the operator(s) employing their services; and
  - (4) return their attestation in accordance with the applicable procedure established by the competent authority.



SUBPART TRA – TRAINING REQUIREMENTS FOR CABIN CREW ATTESTATION APPLICANTS AND HOLDERS

# SUBPART TRA – TRAINING REQUIREMENTS FOR CABIN CREW ATTESTATION APPLICANTS AND HOLDERS

#### CC.TRA.215 Provision of training

Regulation (EU) No 1178/2011

Training required in this Part shall be:

- (a) provided by training organisations or commercial air transport operators approved to do so by the competent authority;
- (b) performed by personnel suitably experienced and qualified for the training elements to be covered; and
- (c) conducted according to a training programme and syllabus documented in the organisation's approval.

#### CC.TRA.220 Initial training course and examination

Regulation (EU) No 1178/2011

- (a) Applicants for a cabin crew attestation shall complete an initial training course to familiarise themselves with the aviation environment and to acquiresufficient general knowledge and basic proficiency required to perform the duties and discharge the responsibilities related to the safety of passengers and flight during normal, abnormal and emergency operations.
- (b) The programme of the initial training course shall cover at least the elements specified in Appendix 1 to this Part. It shall include theoretical and practical training.
- (c) Applicants for a cabin crew attestation shall undergo an examination covering all elements of the training programme specified in (b), except CRM training, to demonstrate that they have attained the level of knowledge and proficiency required in (a).

### CC.TRA.225 Aircraft type or variant qualification(s)

Regulation (EU) No 1178/2011

- (a) Holders of a valid cabin crew attestation shall only operate on an aircraft if they are qualified in accordance with the applicable requirements of Part-ORO.
- (b) To be qualified for an aircraft type or a variant, the holder:
  - (1) shall comply with the applicable training, checking and validity requirements, covering as relevant to the aircraft to be operated:
    - (i) aircraft-type specific training, operator conversion training and familiarisation;)
    - (ii) differences training;
    - (iii) recurrent training; and
  - (2) shall have operated within the preceding 6 months on the aircrafttype, or shall have completed the relevant refresher training and checking before operating again on that aircraft type.



#### **APPENDIX TO ANNEX V**

### Appendix 1 to Part-CC Initial training course and examination

Regulation (EU) No 290/2012

#### TRAINING PROGRAMME

The training programme of the initial training course shall include at least the following:

- 1. General theoretical knowledge of aviation and aviation regulations covering all elements relevant to the duties and responsibilities required from cabin crew:
  - aviation terminology, theory of flight, passenger distribution, areas of operation, meteorology and effects of aircraft surface contamination;
  - 1.2. aviation regulations relevant to cabin crew and the role of the competent authority;
  - 1.3. duties and responsibilities of cabin crew during operations and the need to respond promptly and effectively to emergency situations;
  - 1.4. continuing competence and fitness to operate as a cabin crew member, including as regards flight and duty time limitations and rest requirements;
  - 1.5. the importance of ensuring that relevant documents and manuals are kept up-to-date, with amendments provided by the operator as applicable;
  - 1.6. the importance of cabin crew performing their duties in accordance with the operations manual of the operator;
  - 1.7. the importance of the cabin crew's pre-flight briefing and the provision of necessary safety information with regards to their specific duties; and
  - 1.8. the importance of identifying when cabin crew members have the authority and responsibility to initiate an evacuation and other emergency procedures.

#### 2. Communication:

During training, emphasis shall be placed on the importance of effective communication between cabin crew and flight crew, including communication techniques, common language and terminology.

3. Introductory course on human factors (HF) in aviation and crew resource management (CRM)

This course shall be conducted by at least one cabin crew CRM instructor. The training elements shall be covered in depth and shall include at least the following:

- 3.1. General: human factors in aviation, general instructions on CRM principles and objectives, human performance and limitations;
- 3.2. Relevant to the individual cabin crew member: personality awareness, human error and reliability, attitudes and behaviours, self-assessment; stress and stress management; fatigue and vigilance; assertiveness; situation awareness, information acquisition and processing.

#### 4. Passenger handling and cabin surveillance:

4.1. the importance of correct seat allocation with reference to aeroplane mass and balance, special categories of passengers and the necessity of seating able-bodied passengers adjacent to unsupervised exits;



- 4.2. rules covering the safe stowage of cabin baggage and cabin service items and the risk of it becoming a hazard to occupants of the passenger compartment or otherwise obstruction or damaging emergency equipment or exits;
- 4.3. advice on the recognition and management of passengers who are, or become, intoxicated with alcohol or are under the influence of drugs or are aggressive;
- 4.4. precautions to be taken when live animals are carried in the passenger compartment;
- 4.5. duties to be undertaken in the event of turbulence, including securing the passenger compartment; and
- 4.6. methods used to motivate passengers and the crowd control necessary to expedite an emergency evacuation.

#### 5. Aero-medical aspects and first-aid:

- 5.1. general instruction on aero-medical aspects and survival;
- 5.2. the physiological effects of flying with particular emphasis on hypoxia, oxygen requirements, Eustachian tubal function and barotraumas;
- 5.3. basic first-aid, including care of:
  - (a) air sickness;
  - (b) gastro-intestinal disturbances;
  - (c) hyperventilation;
  - (d) burns;
  - (e) wounds;
  - (f) the unconscious; and
  - (g) fractures and soft tissue injuries;
- 5.4. in-flight medical emergencies and associated first-aid covering at least:
  - (a) asthma;
  - (b) stress and allergic reactions;
  - (c) shock;
  - (d) diabetes;
  - (e) choking;
  - (f) epilepsy;
  - (g) childbirth;
  - (h) stroke; and
  - (i) heart attack;)
- 5.5. the use of appropriate equipment including first-aid oxygen, first-aid kits and emergency medical kits and their contents;
- 5.6. practical cardio-pulmonary resuscitation training by each cabin crew member using a specifically designed dummy and taking account of the characteristics of an aircraft environment; and
- 5.7. travel health and hygiene, including:



- (a) hygiene on board;
- (b) risk of contact with infectious diseases and means to reduce such risks;
- (c) handling of clinical waste;
- (d) aircraftdisinsection;
- (e) handling of death on board; and
- (f) alertness management, physiological effects of fatigue, sleep physiology, circadian rhythm and time zone changes.
- 6. Dangerous goods in accordance with the applicable ICAO Technical Instructions.
- 7. General security aspects in aviation, including awareness of the provisions laid down in Regulation (EC) No 300/2008.

#### 8. Fire and smoke training:

- 8.1. emphasis on the responsibility of cabin crew to deal promptly with emergencies involving fire and smoke and, in particular, emphasis on the importance of identifying the actual source of the fire;
- 8.2. the importance of informing the flight crew immediately, as well as the specific actions necessary for coordination and assistance, when fire or smoke is discovered;
- 8.3. the necessity for frequent checking of potential fire-risk areas including toilets, and the associated smoke detectors;
- 8.4. the classification of fires and the appropriate type of extinguishing agents and procedures for particular fire situations;
- 8.5. the techniques of application of extinguishing agents, the consequences of misapplication, and of use in a confined space including practical training in fire-fighting and in the donning and use of smoke protection equipment used in aviation; and
- 8.6. the general procedures of ground-based emergency services at aerodromes.

#### 9. Survival training:

- 9.1. principles of survival in hostile environments (e.g. polar, desert, jungle, sea); and
- 9.2. water survival training which shall include the actual donning and use of personal flotation equipment in water and the use of slide-rafts or similar equipment, as well as actual practice in water.



# AMC1 Appendix 1 to Part-CC(3) Initial training course and examination

ED Decision 2015/023/R

#### **CREW RESOURCE MANAGEMENT TRAINING TABLE**

The CRM training table recapitulates all elements relevant to CRM training for cabin crew, specifying the following:

- (a) The elements of the introductory course on CRM required for the cabin crew initial training course, where 'in-depth' means a training that should be instructional or interactive in style taking full advantage of group discussions, team task analysis, team task simulation, etc., for the acquisition of knowledge, skills and attitudes.
- (b) The elements identified as 'not required' for the cabin crew initial training are listed for information as they are covered during other training in accordance with the applicable requirements of Annex III (Part-ORO) to Commission Regulation (EU) No 965/2012.

CRM TRAINING TABLE	Introductory course on CRM		
Training elements	· ·		
General Principles			
Human factors in aviation; General instructions on CRM principles and objectives; Human performance and limitations; Threat and error management.	In-depth		
Relevant to the individual cabin crew member			
Personality awareness, human error and reliability, attitudes and behaviours, selfassessment and self-critique; Stress and stress management; Fatigue and vigilance; Assertiveness; situation awareness, information acquisition and processing.	In-depth		
Relevant to the entire aircraft crew			
Shared situation awareness, shared information acquisition and processing; Workload management; Effective communication and coordination between all crew members including the flight crew as well as inexperienced cabin crew members; Leadership, cooperation, synergy, delegation, decision-making, actions; Resilience development; Surprise and startle effect; Cultural differences; Identification and management of passenger human factors: crowd control, passenger stress, conflict management, medical factors.  Specifics related to aircraft types (narrow-/wide-bodied, single-/multi-deck), flight crew and cabin crew composition and number of passengers	Not required (covered under CRM training required by Part-ORO)		
Relevant to the operator and the organisation (principles)			
Operator's safety culture and company culture, standard operating procedures (SOPs), organisational factors, factors linked to the type of operations;  Effective communication and coordination with other operational personnel and ground services;  Participation in cabin safety incident and accident reporting.  Case studies	Not required (covered under CRM training required by Part-ORO)		
Cube State Co			



# **ANNEX VI (PART-ARA)**

# List of acronyms used throughout this Annex

ED Decision 2018/009/R

The following provides a list of acronyms used throughout this Annex:

(A) aeroplane (H) helicopter A/C aircraft

ACAS airborne collision avoidance system

AD airworthiness directive

AIS aeronautical information services

AM accountable manager AeMC aero-medical centre

AMC acceptable means of compliance

AME aero-medical examiner

APP approach

APU auxiliary power unit

ARA authority requirements for aircrew

ATC air traffic control

ATO approved training organisation
ATPL airline transport pilot licence
BITD basic instrument training device

BPL balloon pilot licence bpm beats per minute

CAT category

CBT computer-based training

CC cabin crew

CFI chief flying instructor

cm centimetres

CM compliance monitoring

CMP compliance-monitoring programme CMS compliance-monitoring system

COP code of practice

CPL commercial pilot licence
CRM crew resource management
CS certification specifications

CS-FSTD(A) Certification Specifications for aeroplane flight simulation training devices CS-FSTD(H) Certification Specifications for helicopter flight simulation training devices

CTKI chief theoretical-knowledge instructor

dB decibel

DG dangerous goods DH decision height

DPATO defined point after take-off DPBL decision point before landing

EC European Community
ECG electrocardiogram
ENT ear, nose and throat
EOG electro-oculography
ERP emergency response plan

ETOPS extended-range operations with twin-engined aeroplanes

FANS future air navigation system



FATO final approach and take-off area

FD flight director

FEV<sub>1</sub> forced expiratory volume in 1 second

FFS full flight simulator

FMGC flight management and guidance computer

FMS flight management system

FNPT flight navigation and procedures trainer

FSTD flight simulation training device

ft feet

FTD flight training device
FTI flight test instructor
FVC forced vital capacity
GM guidance material

GMP general medical practitioner GPS global positioning system

HEMS helicopter emergency medical service

HF human factors Hg mercury

HHO helicopter hoist operation

HT head of training

Hz Hertz

IATA International Air Transport Association ICAO International Civil Aviation Organization

IFR instrument flight rules IGE in-ground effect

ILS instrument landing system

IMC instrument meteorological conditions

IOS instructor operating station

IR instrument rating

kg kilogram

LAPL light aircraft pilot licence
LDP landing decision point
LIFUS line flying under supervision
LVO low-visibility operation
LVTO low visibility take-off
MCC multi-crew cooperation

MMEL master minimum equipment list

MPA multi-pilot aeroplane
MPL multi-crew pilot licence
NVIS night vision imaging system

m metre mm millimetre

OGE out-of-ground effect
OPC operator proficiency check

ORA organisation requirements for aircrew
ORO organisation requirements for air operations

OSD operational suitability data
OTD other training device

PBN performance-based navigation

PF pilot flying

PIC pilot-in-command
PM pilot monitoring
POM proof of match
PPL private pilot licence
QTG qualification test guide



ROD rate of descent RVR runway visual range

RWY runway

SMM safety management manual SOP standard operating procedure

SPL sailplane pilot licence

TAWS terrain avoidance and warning system

TDP take-off decision point
TRE type rating examiner
TRI type rating instructor

TWY taxiway

VDR validation data road map

VFR visual flight rules

ZFTT zero-flight-time training



### **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) 2023/203

- (a) The competent authority shall notify the Agency in case of any significant problems with the implementation of <u>Regulation (EU) 2018/1139</u> and the delegated and implementing acts adopted on the basis thereof within 30 days from the time the authority became aware of the problems.
- (b) Without prejudice to Regulation (EU) No 376/2014 of the European Parliament and of the Council¹ and the delegated and implementing acts adopted on the basis thereof, the competent authority shall provide the Agency with safety-significant information stemming from the occurrence reports stored in the national database, as soon as possible.
- (c) The competent authority of the Member State shall provide the Agency as soon as possible with safety-significant information stemming from the information security reports it has received pursuant to point IS.I.OR.230 of Annex II (Part-IS.I.OR) to <a href="Implementing Regulation">Implementing Regulation</a> (EU) 2023/203.

[applicable from 22 February 2026 — Implementing Regulation (EU) 2023/203]

## ARA.GEN.135 Immediate reaction to a safety problem

Regulation (EU) No 1178/2011

- (a) Without prejudice to Regulation (EU) No 376/2014 and the delegated and implementing acts adopted on the basis thereof, 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

Regulation (EU) No 376/2014 of the European Parliament and of the Council of 3 April 2014 on the reporting, analysis and follow-up of occurrences in civil aviation, amending Regulation (EU) No 996/2010 of the European Parliament and of the Council and repealing Directive 2003/42/EC of the European Parliament and of the Council and Commission Regulations (EC) No 1321/2007 and (EC) No 1330/2007 (OJ L 122, 24.4.2014, p. 18).



- to react in a timely manner to a safety problem involving products, parts, non-installed equipment, persons or organisations subject to <u>Regulation (EU) 2018/1139</u> and the delegated and implementing acts adopted on the basis thereof.
- (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 point (c) shall immediately be notified to all persons or organisations that need to comply with them under <a href="Regulation">Regulation</a> (EU) 2018/1139 and the delegated and implementing acts adopted on the basis thereof. The competent authority shall also notify those measures to the Agency and, when combined action is required, the other Member States concerned.

# ARA.GEN.135A Immediate reaction to an information security incident or vulnerability with an impact on aviation safety

Regulation (EU) 2023/203

- (a) The competent authority shall implement a system to appropriately collect, analyse, and disseminate information related to information security incidents and vulnerabilities with a potential impact on aviation safety that are reported by organisations. This shall be done in coordination with any other relevant authorities responsible for information security or cybersecurity within the Member State to increase the coordination and compatibility of reporting schemes.
- (b) The Agency shall implement a system to appropriately analyse any relevant safety-significant information received in accordance with point ARA.GEN.125(c), and without undue delay provide the Member States and the Commission with any information, including recommendations or corrective actions to be taken, necessary for them to react in a timely manner to an information security incident or vulnerability with a potential impact on aviation safety involving products, parts, non-installed equipment, persons or organisations subject to Regulation (EU) 2018/1139 and its delegated and implementing acts.
- (c) Upon receiving the information referred to in points (a) and (b), the competent authority shall take adequate measures to address the potential impact on aviation safety of the information security incident or vulnerability.
- (d) Measures taken in accordance with point (c) shall immediately be notified to all persons or organisations that shall comply with them under <u>Regulation (EU) 2018/1139</u> and its delegated and implementing acts. The competent authority of the Member State shall also notify those measures to the Agency and, when combined action is required, the competent authorities of the other Member States concerned.

[applicable from 22 February 2026 — Implementing Regulation (EU) 2023/203]



# AMC1 ARA.GEN.135A Immediate reaction to an information security incident or vulnerability with an impact on aviation safety

ED Decision 2023/010/R

- (a) To appropriately collect and analyse information related to information security incidents and vulnerabilities with a potential impact on aviation safety, the competent authority should implement means that ensure the necessary confidentiality.
- (b) When disseminating information related to information security incidents and vulnerabilities with a potential impact on aviation safety, the competent authority should properly select the appropriate recipient(s) to prevent the content of a report from being exploited to the detriment of aviation safety, by revealing, for instance, uncorrected vulnerabilities.

[applicable from 22 February 2026 — ED Decision 2023/010/R]

# GM1 ARA.GEN.135A Immediate reaction to an information security incident or vulnerability with an impact on aviation safety

ED Decision 2023/010/R

When deemed necessary, a two-step mechanism could be used: a report alerting about the information security event or incident and the availability of additional data that would require controlled and confidential distribution. This report should only alert recipients of the urgency and the necessity for organisations and competent authorities to establish further communication through secure means.

Therefore, the report should consist of two parts: one limited to mostly public information and one containing the sensitive data that should be restricted to the recipients who need to know. Wherever possible, reports should be based on an agreed taxonomy.

[applicable from 22 February 2026 — ED Decision 2023/010/R]



#### **SECTION II – MANAGEMENT**

## ARA.GEN.200 Management system

Regulation (EU) 2023/203

- (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 <a href="Regulation">Regulation</a> (EU) 2018/1139 and the delegated and implementing acts adopted on the basis thereof. The procedures shall be kept up to date and serve as the basic working documents within that competent authority for all related tasks;
  - (2) a sufficient 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, whether from within the Member State or in other Member States, including the following information:
  - (1) 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;
  - (2) stemming from mandatory and voluntary occurrence reporting as required by point ORA.GEN.160 of Annex VII.
- (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.
- (e) In addition to the requirements contained in point (a), the management system established and maintained by the competent authority shall comply with Annex I (Part-IS.AR) to <u>Implementing Regulation (EU) 2023/203</u> in order to ensure the proper management of information security risks which may have an impact on aviation safety.

[applicable from 22 February 2026 — Implementing Regulation (EU) 2023/203]



### 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<sup>1</sup> 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;

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.



- (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.
- (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 crossreferences 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:
    - 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;



- iii) 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 ining the AMC & GM to the implementing rules of Commission Regulation (EU) (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 <u>AMC2 ARA.GEN.200(a)(2)</u> 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 <u>AMC2 ARA.GEN.200(a)(2)</u>, 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) 2023/203

[applicable until 21 February 2026 — Regulation (EU) No 290/2012]

#### **ARA.GEN.205** Allocation of tasks

[applicable from 22 February 2026 — Implementing Regulation (EU) 2023/203]

- (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 with a 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 <u>ARA.GEN.200(a)(4)</u> cover all certification or continuing oversight tasks performed on its behalf.
- (c) With regard to the certification and oversight of the organisation's compliance with point ORA.GEN.200A, the competent authority may allocate tasks to qualified entities in accordance with point (a), or to any relevant authority responsible for information security or cybersecurity within the Member State. When allocating tasks, the competent authority shall ensure that:



- (1) all aspects related to aviation safety are coordinated and taken into account by the qualified entity or relevant authority;
- (2) the results of the certification and oversight activities performed by the qualified entity or relevant authority are integrated in the overall certification and oversight files of the organisation;
- (3) its own information security management system established in accordance with point <u>ARA.GEN.200(e)</u> covers all the certification and continuing oversight tasks performed on its behalf.

[applicable from 22 February 2026 — Implementing Regulation (EU) 2023/203]

## GM1 ARA.GEN.205 Allocation of tasks to qualified entities

ED Decision 2023/010/R

[applicable until 21 February 2026 — ED Decision 2012/006/R]

#### **GM1 ARA.GEN.205 Allocation of tasks**

[applicable from 22 February 2026 — ED Decision 2023/010/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 <a href="Regulation">Regulation</a> (EU) 2018/1139 and the delegated and implementing acts adopted on the basis thereof. That 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 (EU) 2018/1139 and the delegated and implementing acts adopted on the basis thereof 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 <u>Regulation (EU) 2018/1139</u> and the delegated and implementing acts adopted on the basis thereof.



## ARA.GEN.220 Record-keeping

Regulation (EU) 2020/359

- (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 <u>ARA.GEN.205</u> 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;
  - (12) the use of flexibility provisions in accordance with Article 71 of Regulation (EU) 2018/1139; and
  - (13) the evaluation and authorisation process of aircraft laid down in points ORA.ATO.135 (a) and DTO.GEN.240 (a).
- (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), Annex III (Part-BFCL) to Commission Regulation (EU) 2018/395, or Annex III (Part-SFCL) to Commission Implementing Regulation (EU) 2018/1976.
- (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 <a href="ARA.GEN.220(c">ARA.GEN.220(c</a>).

## 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) 2023/203

- (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 <u>ARA.GEN.350</u> and <u>ARA.GEN.355</u>.
- (c) The scope of oversight defined in (a) and (b) shall take 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 determined on 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.
- (g) With regard to the certification and oversight of the organisation's compliance with point ORA.GEN.200A, in addition to complying with points (a) to (f), the competent authority shall review any approval granted under point IS.I.OR.200(e) of <a href="this Regulation">this Regulation</a> or point IS.D.OR.200(e) of <a href="Delegated Regulation">Delegated Regulation</a> (EU) 2022/1645 following the applicable oversight audit cycle and whenever changes are implemented in the scope of work of the organisation.

[applicable from 22 February 2026 — Implementing Regulation (EU) 2023/203]



## AMC1 ARA.GEN.300(a);(b);(c) Oversight

ED Decision 2020/018/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
  - (1) The competent authority should establish a methodology for evaluating the safety risk assessment processes of the ATO's management system.
  - (2) 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:
    - (i) understand the hazards identified and their consequences on its operations;
    - (ii) be clear on where these hazards may exceed acceptable safety risk limits;
    - (iii) identify and implement mitigations including suspension of operations where mitigation cannot reduce the risk to within safety risk limits;
    - (iv) develop and execute effectively, robust procedures for the preparation and the safe operation of the flights subject to the hazards identified;
    - (v) assess the competence and currency of its staff in relation to the duties for the intended operations and implement any necessary training; and
    - (vi) ensure sufficient numbers of qualified and competent staff for such duties.
  - (3) The competent authority should take into account:
    - (i) the ATO's recorded mitigations for each unacceptable risk identified are in place;
    - (ii) the operational procedures specified by the ATO with the most significance to safety appear to be robust; and
    - (iii) 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**

- (b) 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:
  - 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 preflight, 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:
  - 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) 2024/2076

- (a) The competent authority shall establish and maintain an oversight programme covering the oversight activities required by <u>ARA.GEN.300</u> and by ARO.RAMP.
- (b) For organisations certified by the competent authority and FSTD qualification certificate holders, the oversight programme shall be developed taking 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 <u>ARA.GEN.350(d)(2)</u>.
  - 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 <a href="ARA.GEN.350(d)(2)">ARA.GEN.350(d)(2)</a>.
- (d) For persons that hold a licence, certificate, rating, or attestation issued by the competent authority, the oversight programme shall include an appropriate volume of inspections and unannounced inspections.
- (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/F

#### 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 <a href="https://example.com/ARA.GEN.305(f)">ARA.GEN.305(f)</a>.
- (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 <u>ARA.GEN.305(f)</u>.



### 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;
- 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 2021/002/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.
- (d) In addition to the requirements in points (a), (b) and (c) above, in order to verify that the applicant meets the requirements for revalidation or renewal under the EBT programme, the competent authority should request the applicant to provide the application and report form of <u>Appendix 10</u>, including the declaration of the operator as per point (b) of <u>AMC1 to Appendix 10</u> 'Revalidation and renewal of type ratings, and revalidation and renewal of IRs when combined with the revalidation or renewal of type ratings EBT practical assessment'.

### 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 <a href="ARA.DTO.105">ARA.DTO.105</a> and <a href="ARA.DTO.110">ARA.DTO.110</a>, 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.330A Changes to the information security management system

Regulation (EU) 2023/203

- (a) With regard to changes managed and notified to the competent authority in accordance with the procedure set out in point IS.I.OR.255(a) of Annex II (Part-IS.I.OR) to <u>Implementing</u> <u>Regulation (EU) 2023/203</u>, the competent authority shall include the review of such changes in its continuing oversight in accordance with the principles laid down in point <u>ARA.GEN.300</u>. If any non-compliance is found, the competent authority shall notify the organisation thereof, request further changes and act in accordance with point <u>ARA.GEN.350</u>.
- (b) With regard to other changes requiring an application for approval in accordance with point IS.I.OR.255(b) of Annex II (Part-IS.I.OR) to <u>Implementing Regulation (EU) 2023/203</u>:



- (1) upon receiving the application for the change, the competent authority shall check the organisation's compliance with the applicable requirements before issuing the approval;
- (2) the competent authority shall establish the conditions under which the organisation may operate during the implementation of the change;
- (3) if it is satisfied that the organisation complies with the applicable requirements, the competent authority shall approve the change.

[applicable from 22 February 2026 — Implementing Regulation (EU) 2023/203]

## ARA.GEN.350 Findings and corrective actions – organisations

Regulation (EU) 2020/359

- (a) The competent authority for oversight in accordance with <u>ARA.GEN.300(a)</u> 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 <a href="ORA.GEN.140">ORA.GEN.140</a> 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 are sufficient 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) By way of derogation from paragraphs (a) to (d), in the case of DTOs, if during oversight or by any other means the competent authority finds evidence that indicates DTO non-compliance with the essential requirements set out in Annex IV to Regulation (EU) 2018/1139, with the requirements of Annex I (Part-FCL) and Annex VIII (Part-DTO) to this Regulation, or with the requirements of Annex III (Part-BFCL) to Commission Regulation (EU) 2018/395 and of Annex III (Part-SFCL) to Commission Implementing Regulation (EU) 2018/1976, 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 <u>DTO.GEN.150</u> 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 <u>DTO.GEN.230(c)</u> 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, if the authority of a Member State that acts in accordance with point <a href="ARA.GEN.300(d">ARA.GEN.300(d</a>) identifies any non-compliance with the essential requirements set out in Annex IV to <a href="Regulation (EU) 2018/1139">Regulation (EU) 2018/1139</a>, with the requirements of Annex I (Part-FCL), Annex VII (Part-ORA) and Annex VIII (Part-DTO) to this Regulation, or with the requirements of Annex III (Part-BFCL) to <a href="Commission Regulation (EU) 2018/395">Commission Regulation (EU) 2018/395</a> and of Annex III (Part-SFCL) to <a href="Commission Implementing Regulation (EU) 2018/1976">Commission Implementing Regulation (EU) 2018/1976</a> 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 <u>ARA.GEN.350(e)</u> 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 <u>ARA.GEN.350(e)</u> 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 <u>ARA.GEN.300(a)</u> 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 <u>ARA.GEN.300(d)</u> 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.

## **ARA.GEN.360 Change of competent authority**

Regulation (EU) 2024/2076

(a) Upon receiving a licence holder's request for a change of competent authority as specified in point FCL.015(e) of Annex I (Part-FCL), point BFCL.015(f) of Annex III (Part-BFCL) to Commission Regulation (EU) 2018/395 or point SFCL.015(f) of Annex III (Part-SFCL) to Commission Implementing Regulation (EU) 2018/1976, the receiving competent authority shall, without undue delay, request the competent authority of the licence holder to transfer, without undue delay, all of the following:



- (1) a verification of the licence;
- (2) copies of the licence holder's medical records kept by that competent authority in accordance with points <a href="ARA.GEN.220">ARA.GEN.220</a> and <a href="ARA.MED.150">ARA.MED.150</a>. The medical records shall be transferred in accordance with point <a href="MED.A.015">MED.A.015</a> of Annex IV (Part-MED) and shall include a summary of the relevant medical history of the applicant, verified and signed by the medical assessor.
- (b) The transferring competent authority shall keep the licence holder's original licensing and medical records in accordance with points ARA.GEN.220, ARA.FCL.120 and ARA.MED.150.
- (c) The receiving competent authority shall, without undue delay, reissue the licence and medical certificate provided that it has received and processed all documents specified in point (a). Upon the reissuance of the licence and medical certificate, the receiving competent authority shall immediately request the licence holder to surrender to it the licence issued by the transferring competent authority and the associated medical certificate.
- (d) The receiving competent authority shall immediately notify the transferring competent authority once it has reissued the licence and medical certificate to the licence holder and the licence holder has surrendered the licence and medical certificate pursuant to point (c). Until such a notification is received, the transferring competent authority remains responsible for the licence and the medical certificate originally issued to that licence holder.
- (e) When a competent authority receives an medical certificate holder's request for a change of competent authority, as specified in the requirements referred to in point (a), the procedure specified in points (a) to (d) shall apply.

# AMC1 ARA.GEN.360(a) Change of competent authority

ED Decision 2020/005/F

When transferring the summary of the applicant's relevant medical history and copies of medical records to the receiving competent authority in accordance with point <u>ARA.GEN.360(a)</u>, the transferring competent authority should include at least all of the following:

- (a) copies of:
  - (1) the most recent aeromedical report containing the detailed results of the aeromedical examinations and assessments that are required for the class of medical certificate;
  - (2) the application form, examination form, and medical certificate issued;
  - (3) the most recent electrocardiogram (ECG), ophthalmological and ear-nose-throat (ENT), including audiometry, examination reports, as applicable for the class of medical certification;
  - (4) the initial medical examination or the supporting documents for the last medical-file transfer between licensing authorities; where this is not available, a copy of the medical report from the last three aeromedical examinations should be transferred as an alternative;
  - (5) the mental health assessment, as applicable for the class of medical certificate; and
  - (6) any other relevant medical documentation; and
- (b) the 'Summary of medical history' form of <u>AMC1 ARA.GEN.360(a)(2)</u>, filled in and signed by the medical assessor.



# AMC1 ARA.GEN.360(a)(1) Change of competent authority

ED Decision 2020/005/R

### LICENCE VERIFICATION FORM

In this form, 'issuing competent authority of the license' means the 'transferring competent authority' of <u>ARA.GEN.360</u>.

		ERIFICATION FO		P h	· · · · · · · · · · · · · · · · · · ·			
	It is required that this form is filled in and signed by t	ne issuing compete	nt authority of the	licence be	ning transferred.			
ITEM	DESCRIPTION							
1	State of licence(s) issue	Country	Country					
2	Title of licences/certificates (including restriction(s)) and corresponding licences/certificates numbers1*	e.g. PPL(A) — UN country code.FCL.xxx — no valid rating or SPL — UN country code.FCL.xxx						
3	Licence issue date and expiry date (if applicable)	Issue PPL(A): x Issue SPL: xx/x						
4	Full name (Last and first names)	· · · · · · · · · · · · · · · · · · ·	LAST NAME 2, First name 2, et					
5	Date of birth (dd/mm/yyyy)	xx/xx/xxxx						
6	Address (as on the licence)							
7	Contact details: email and phone number.	e.g. example@exa +(country code						
8	Nationality	Country						
9	Issuing authority (conditions under which the licence was issued, where necessary)	Country and authority						
10	Valid and non-expired ratings/privileges and certificates held	Ratings and co	ertificates		Valid until (dd/mm/yyyy)			
	(Type/class/instrument/additional ratings	e.g. TMG (Sail	plane)		xx/xx/xxxx			
	and instructor/examiner certificates) Note: indicate all applicable restrictions	e.g. FI (Sailpla with extension	ne) ns for TMG and	FI	xx/xx/xxxx			
	and extensions.							
	Expired ratings and certificates held (Type/class/instrument/additional ratings	Ratings and co	ertificates		Valid until (dd/mm/yyyy)			
11	and instructor/examiner certificates) Note: indicate all applicable restrictions and extensions.	e.g. TMG (Aer	oplane)		xx/xx/xxxx			
12	Remarks, i.e. special endorsements relating to limitations, restrictions, or	Special endors	ements					
	endorsements for privileges	Language	Level	Vali	idity (dd/mm/yyyy)			
	(e.g. language proficiency level and validity (English, others))	5 - 5 -			, , , , , , , , , , , , , , , , , , , ,			
13	Details on completion of theoretical-knowledge or flight instruction, theoretical-knowledge examination or skill test in other Member States, if applicable (e.g validity of the ATPL theoretical knowledge)	e.g. IR theory	valid until xx/xx	(/xxxx				

Indicate all licences and certificates held. Indicate the certificate(s) if you do not hold a valid licence anymore.



ANNEX VI (Part-ARA)

SUBPART GEN – GENERAL

REQUIREMENTS

14	Past or pending enforcement action <sup>1</sup>	Yes □	No □				
		(If yes, please give o	etails on a separate page.)				
l,		certify that the	details entered on this information				
form a	re true, complete, and correct.						
For an	y comments, please use the space provided	below or on the next	page, and tick here: □				
Autho	rity:						
Contac	ct details:	Position:					
Signat	ure:Stam	p/seal:	Date:				
Comm	ents:						

# AMC1 ARA.GEN.360(a)(2) Change of competent authority

ED Decision 2020/005/R

### SUMMARY OF MEDICAL HISTORY — FORM FOR THE TRANSFER OF MEDICAL RECORDS

	SUMMARY OF MEDICAL HISTORY — FORM FOR TH	IE TRANSFER OF MEDICAL RECORDS
	MEDICAL DETAILS IN CO	NFIDENCE
Item	Description	
1	State of licence(s) issue	Country
2	Title of licence(s)/certificate(s) and corresponding	e. g. PPL(A) — UN country code.FCL.xxx
	serial number of licence(s) held (or national medical	or SPL — UN country code.FCL.xxx
	reference number)	
3	Full name	LAST NAME 1, LAST NAME 2, etc.
	(Last and first names)	First name 1, First name 2, etc.
4	Date of birth (dd/mm/yyyy)	xx/xx/xxxx
5	Address	
6	Contact details:	e.g.
	email; and	(a) example@example.eu
	phone number.	(b) +(country code) xxxxxxxxxx
7	Nationality	Country
8	Issuing authority	Country and authority
9	Initial medical certificate:	Date of issue xx/xx/xxxx
		Date of examination xx/xx/xxxx
		Type of certificate
		(Joint Aviation
		Authorities (JAR),
		Part-Med or national)
		Class
10	Dates of last three revalidation/renewal	
	examinations (if any)	
11	Limitations (if any)	

Item 14: specify if there is a current investigation into the medical certificate and licence, or suspension or revocation thereof.



ANNEX VI (Part-ARA)

SUBPART GEN – GENERAL

REQUIREMENTS

12	Comments on any relevant aspect of the applicant's	
	medical history or examination (if applicable, please	
	enclose reports)	
	Please enclose at least the latest examination report	
	and electrocardiogram (ECG). In addition, where	
	applicable for the class of medical certification,	
	please enclose the latest ophthalmological, ear-nose-	
	throat (ENT), and mental health assessment reports.	
13	Past or pending enforcement action <sup>1</sup>	Yes □ No □
		(If yes, please give details on a separate
		page.)
• '	·	· · · · · · · · · · · · · · · · · · ·

If there is insufficient space on this form for any information, please use additional pages.

CERTIFICATION								
I, Dr	, Dr, as medical assessor of the (NAA name)							
	, ce	rtify that the details given above and						
on any additional pages included a	re true, complete, and correct.							
Date	Signature	Licensing authority and stamp/seal						

\_

<sup>&</sup>lt;sup>1</sup> Item 13: specify if there is a current investigation into the medical certificate and licence, or suspension or revocation thereof.



# GM1 ARA.GEN.360 Change of competent authority

ED Decision 2020/005/R

### **APPLICATION FORM FOR CHANGE OF COMPETENT AUTHORITY**

In this form, 'current competent authority' means the 'transferring competent authority' of <u>ARA.GEN.360</u>, and 'future competent authority' means the 'receiving competent authority' of <u>ARA.GEN.360</u>.

	APPLICATION FORM FOR CHANGE	OF COM	PETENT AUTHORITY
Applicant details:	Full name		LAST NAME 1, LAST NAME 2, etc.
	(Last and first names)		First name 1, First name 2, etc.
	Title of licence(s)/certificate(s) (inc	luding	e.g. PPL(A) — UN country code.FCL.xxx
	restriction(s)) and corresponding		e.g. SPL — UN country code.FCL.xxx
	licence(s)/certificate(s) number(s) <sup>2</sup>	l .	
	Current competent authority		Country and authority
	Future competent authority		Country and authority
l,	(last name, first name) he	ereby app	ly for a change of competent authority
from my current com	petent authority to the future comp	oetent au	thority. To that end, I consent to a transfer
·	cluding the transfer of medical reco		
	·		transfer of all my licences issued in
_	ulations (EU) No 1178/2011, (EU) 20	)18/395, a	and (EU) 2018/1976 within the different
categories.			
•	•		nedical certificate to the future competent
	ving the 'new' licences/certificates a		
	•	•	mpetent authority until I have received
•	ificates and medical certificate, as a	pplicable	, issued by the future competent
authority.			
· · · · · · · · · · · · · · · · · · ·		uest to ar	other competent authority than the
·	thority as indicated above.	_	
•			mpetent authority's relevant information
	ubmitted all the necessary paperwor	-	• •
	ormation provided on this application		•
			e essential requirements of Annex IV to
_	· · · · · · · · · · · · · · · · · · ·		No 1178/2011, (EU) 2018/395, and (EU) transferred from the current to the future
competent authority.	-	records	transferred from the current to the future
Signature:		Date:	
Jigilature.		Date.	

Indicate all licences and certificates currently held. Indicate only the related certificate(s) if you do not hold a valid licence anymore (e.g. SFI(A)).



# GM2 ARA.GEN.360 Change of competent authority

ED Decision 2020/005/R

### LICENCE VERIFICATION

The licence verification includes the verification of all associated privileges, ratings, certificates, and endorsements that were obtained in accordance with the technical requirements of Regulations (EU) No 1178/2011, (EU) 2018/395, and (EU) 2018/1976. This means that for example, senior examiner privileges are not included.

### **AVAILABLE RECORDS**

Available medical records are all medical records of the licence holder that are related to the history of the medical certificate.

#### **RECORDS**

Original licensing and medical records are the original records of the licence holder or electronic records kept by the competent authority.

#### **VALIDITY PERIODS**

When reissuing the licence(s) and medical certificate(s), the receiving competent authority should ensure that the validity periods and limitations (if any) are in accordance with the ones of the licence(s) and medical certificate(s) transferred.

### **PROCESSING**

Processing all documents means that the receiving competent authority checks the completeness, and correctness of all the information provided by the transferring competent authority and asks the transferring competent authority for clarification, if needed. If by any means, the receiving competent authority becomes aware of non-compliance with the essential requirements of Annex IV to the Basic Regulation or with the requirements of Regulations (EU) No 1178/2011, (EU) 2018/395, and (EU) 2018/1976 during the processing of the documents, it should reject the application for change of competent authority and inform the transferring competent authority in accordance with its national administration rules.

# GM3 ARA.GEN.360 Change of competent authority

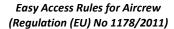
FD Decision 2020/005/F

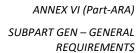
The competent authority can establish and implement its administrative procedures as it considers appropriate. The following practical guidance is considered best practice that may facilitate the work of, and coordination between, competent authorities.

### CASES OF SUSPENSION, REVOCATION, OR CURRENT INVESTIGATION

In case of suspension of a licence or medical certificate, the competent authority responsible for the suspension is the only one entitled to remove the suspension. Therefore, a licence holder with a suspended licence or medical certificate cannot apply for change of competent authority until the suspension is revoked.

In case of revocation of a licence, the licence holder can apply for change of competent authority. The licence holder does not immediately receive a new licence after the change of competent authority, but is able to apply for a new licence to the new authority after all necessary requirements of Annex I (Part-FCL) to Regulation (EU) No 1178/2011 and/or Annex III (Part-BFCL) to Regulation (EU) 2018/395 and/or Annex III (Part-SFCL) to Regulation (EU) 2018/1976 are met. However, the licence holder may immediately receive a medical certificate from the receiving competent authority, if applicable.







In case of revocation of a medical certificate, the certificate holder can apply for change of competent authority. The certificate holder does not immediately receive a new licence after the change of competent authority, but is able to apply for a new certificate and licence to the new authority after all necessary requirements of Annexes I (Part-FCL) and IV (Part-MED) to Regulation (EU) No 1178/2011 and/or Annex III (Part-BFCL) to Regulation (EU) 2018/395 and/or Annex III (Part-SFCL) to Regulation (EU) 2018/1976 are met.

In case of an ongoing investigation that is based on evidence of non-compliance, the licence holder cannot immediately apply for change of competent authority. Sufficient time to investigate the case should be provided to reach a conclusion whether or not the licence or medical certificate must be suspended or revoked before the licence holder can apply for change of competent authority.



# SUBPART FCL – SPECIFIC REQUIREMENTS RELATING TO FLIGHT CREW LICENSING

**SECTION I – GENERAL** 

# ARA.FCL.120 Record-keeping

Regulation (EU) No 1178/2011

In addition to the records required in <u>ARA.GEN.220(a)</u>, the competent authority shall include in its system of record-keeping results of theoretical knowledge examinations and the assessments of pilots' skills.



### **SECTION II – Licences, RATINGS AND CERTIFICATES**

# ARA.FCL.200 Procedure for issue, revalidation or renewal of a licence, rating or certificate

Regulation (EU) 2024/2076

- (a) Issue of licences and ratings. The competent authority shall issue a pilot licence and associated ratings, using the form as established in <u>Appendix I</u> to this Part.
  - If a pilot intends to fly outside Union territory on an aircraft registered in a Member State other than the Member State that issued the flight crew licence, the competent authority shall:
  - (1) add the following remark on the flight crew licence under item XIII: "This licence is automatically validated as per the ICAO attachment to this licence"; and
  - (2) make the ICAO attachment available to the pilot in print or electronic format.
- (b) Issue of instructor and examiner certificates. The competent authority shall issue an instructor or examiner certificate as:
  - (1) an endorsement of the relevant privileges in the pilot licence as established in <a href="Appendix I">Appendix I</a> to this Part; or
  - (2) a separate document, in a form and manner specified by the competent authority.
- (c) Endorsement of licences by examiners. Before specifically authorising an examiner to revalidate or renew ratings or certificates, the competent authority shall develop appropriate procedures.
- (d) Endorsement of licence by instructors. Before specifically authorising certain instructors to revalidate an SEP aeroplane class rating, a TMG class rating or a type rating for a single-engine helicopter up to a MTOM of 3 175 kg, the competent authority shall develop appropriate procedures.
- (e) Instructors for FI(B) or FI(S) certificates: The competent authority shall develop appropriate procedures for the conduct of the training flights under supervision specified in:
  - (1) points BFCL.315(a)(4)(ii) and BFCL.360(a)(2) of Annex III (Part-BFCL) to Regulation (EU) 2018/395; and
  - (2) points SFCL.315(a)(7)(ii) and SFCL.360(a)(2) of Annex III (Part-SFCL) to Commission Implementing Regulation (EU) 2018/1976.

# AMC1 ARA.FCL.200(a)(1) Remark on the licence

ED Decision 2018/011/R

When issuing the licence with the remark on the licence item XIII: 'This licence is automatically validated as per the ICAO attachment to this licence', the competent authority should provide the holder of the licence with the ICAO attachment.



## AMC1 ARA.FCL.200(a)(2) ICAO attachment

ED Decision 2018/011/R

The format of the ICAO attachment in electronic or paper format is the following:



### **EUROPEAN UNION**

ICAO attachment to automatically validate licences

(Issue 1)

issued in accordance with Annex VII to Commission Regulation (EU) No 1178/2011

- 1. The licence is automatically validated by all the ICAO States listed in point (2) under an agreement registered with ICAO. The ICAO Registration Number is: XXXX.
- 2. The ICAO Contracting States that automatically validate this licence are:

[Austria, Belgium, Bulgaria, Croatia, Cyprus, Czech Republic, Denmark, Estonia, Finland, France, Germany, Greece, Hungary, Iceland, Ireland, Italy, Latvia, Liechtenstein, Lithuania, Luxembourg, Malta, Netherlands, Norway, Poland, Portugal, Romania, Slovakia, Slovenia, Spain, Sweden, Switzerland, United Kingdom.]\*

\* Please select the applicable ICAO Contracting States

European Aviation Safety Agency
Date of issue:

# **ARA.FCL.205 Monitoring of examiners**

Regulation (EU) No 245/2014

- (a) The competent authority shall develop an oversight programme to monitor the conduct and performance of examinerstaking into account:
  - (1) the number of examiners it has certified; and
  - (2) the number of examiners certified by other competent authorities exercising their privileges within the territory where the competent authority exercises oversight.
- (b) The competent authority shall maintain a list of examiners it has certified. The list shall state the privileges of the examiners and be published and kept updated by the competent authority.
- (c) The competent authority shall develop procedures to designate examiners for the conduct of skill tests.



## AMC1 ARA.FCL.205 Monitoring of examiners

ED Decision 2012/006/R

### **QUALIFICATION OF INSPECTORS**

Inspectors of the competent authority supervising examiners should ideally meet the same requirements as the examiners being supervised. However, it is unlikely that they could be so qualified on the large variety of types and tasks for which they have a responsibility and, since they normally only observe training and testing, it is acceptable if they are qualified for the role of an inspector.

## **AMC2 ARA.FCL.205 Monitoring of examiners**

ED Decision 2021/002/R

### **EBT PROGRAMME**

The operator's competent authority should include the EBT manager(s) in the programme of monitoring of examiners even if they hold an examiner certificate issued by another competent authority. At the discretion of the competent authority, this may also include an inspection of training delivery within the EBT programme.

## **GM1 ARA.FCL.205 Monitoring of examiners**

ED Decision 2021/002/R

#### **EBT PROGRAMME — INSPECTION OF TRAINING DELIVERY**

When the authority conducts an inspection of the FCL requirements (e.g. training delivery), it is advisable that the inspector of the competent authority follow the content of AMC1 ARO.OPS.226(a). This inspection may be combined with the oversight required in ARO.OPS.226 of Regulation (EU) No 965/2012.

### **ARA.FCL.210 Information for examiners**

Regulation (EU) No 245/2014

- (a) The competent authority shall notify the Agency of the national administrative procedures, requirements for protection of personal data, liability, accident insurance and fees applicable in its territory, which shall be used by examiners when conducting skill tests, proficiency checks or assessments of competence of an applicant for which the competent authority is not the same that issued the examiner's certificate.
- (b) To facilitate dissemination and access to the information received from competent authorities under (a), the Agency shall publish this information according to a format prescribed by it.
- (c) The competent authority may provide examiners it has certified and examiners certified by other competent authorities exercising their privileges in their territory with safety criteria to be observed when skill tests and proficiency checks are conducted in an aircraft.



# **ARA.FCL.215 Validity period**

Regulation (EU) No 290/2012

- (a) When issuing or renewing a rating or certificate, the competent authority or, in the case of renewal, an examiner specifically authorised by the competent authority, shall extend the validity period until the end of the relevant month.
- (b) When revalidating a rating, an instructor or an examiner certificate, the competent authority, or an examiner specifically authorised by the competent authority, shall extend the validity period of the rating or certificate until the end of the relevant month.
- (c) The competent authority, or an examiner specifically authorised for that purpose by the competent authority, shall enter the expiry date on the licence or the certificate.
- (d) The competent authority may develop procedures to allow privileges to be exercised by the licence or certificate holder for a maximum period of 8 weeks after successful completion of the applicable examination(s), pending the endorsement on the licence or certificate.

# ARA.FCL.220 Procedure for the re-issue of a pilot licence

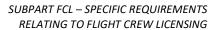
Regulation (EU) No 290/2012

- (a) The competent authority shall re-issue a licence whenever necessary for administrative reasons and:
  - (1) after initial issue of a rating; or
  - (2) when paragraph XII of the licence established in Appendix I to this Part is completed and no further spaces remain.
- (b) Only valid ratings and certificates shall be transferred to the new licence document.

# ARA.FCL.250 Limitation, suspension or revocation of licences, ratings and certificates

Regulation (EU) 2020/359

- (a) The competent authority shall limit, suspend or revoke as applicable a pilot licence and associated ratings or certificates in accordance with <a href="ARA.GEN.355">ARA.GEN.355</a> in, but not limited to, the following circumstances:
  - (1) obtaining the pilot licence, rating or certificate by falsification of submitted documentary evidence;
  - (2) falsification of the logbook and licence or certificate records;
  - (3) the licence holder no longer complies with the applicable requirements of Annex I (Part-FCL), Annex III (Part-BFCL) to <u>Commission Regulation (EU) 2018/395</u> or Annex III (Part-SFCL) to <u>Commission Implementing Regulation (EU) 2018/1976</u>;
  - (4) exercising the privileges of a licence, rating or certificate when adversely affected by alcohol or drugs;
  - (5) non-compliance with the applicable operational requirements;
  - (6) evidence of malpractice or fraudulent use of the certificate; or
  - (7) unacceptable performance in any phase of the flight examiner's duties or responsibilities.





- (b) The competent authority may also limit, suspend or revoke a licence, rating or certificate upon the written request of the licence or certificate holder.
- (c) All skill tests, proficiency checks or assessments of competence conducted during suspension or after the revocation of an examiner's certificate will be invalid.



### **SECTION III – THEORETICAL KNOWLEDGE EXAMINATIONS**

# ARA.FCL.300 Examination procedures

Regulation (EU) 2024/2076

- (a) The competent authority shall put in place the necessary arrangements and procedures to allow applicants to take theoretical knowledge examinations in accordance with the applicable requirements of Annex I (Part-FCL), Annex III (Part-BFCL) to Commission Regulation (EU) 2018/395 or Annex III (Part-SFCL) to Commission Implementing Regulation (EU) 2018/1976.
- (b) In the case of the ATPL, MPL, commercial pilot licence (CPL), and instrument ratings, those procedures shall comply withall of the following:
  - (1) Examinations shall be done in written or computer-based form.
  - (2) Questions for an examination shall be selected by the competent authority, according to a common method which allows coverage of the entire syllabus in each subject, from the European Central Question Bank (ECQB). The ECQB is a database ofmultiple choice questions held by the Agency.
  - (3) The examination in communications may be provided separately from those in other subjects.
- (c) The competent authority shall inform applicants of the languages available for examinations.
- (d) The competent authority shall establish appropriate procedures to ensure the integrity of the examinations.
- (e) If the competent authority finds that the applicant is not complying with the examination procedures during the examination, this shall be assessed with a view to failing the applicant, either in the examination of a single subject or in the examination as a whole.
- (f) The competent authority shall ban applicants who are proven to be cheating from taking any further examination for a period of at least 12 months from the date of the examination in which they were found cheating.

# **AMC1 ARA.FCL.300 Examination procedures**

ED Decision 2019/017/R

#### **GENERAL**

- (a) The competent authority should provide suitable facilities for the conduct of examinations.
- (b) The content of the examination papers should retain a confidential status until the end of the examination session.
- (c) The identity of the applicant should be confirmed before an examination is taken.
- (d) Examination applicants should be seated in a way so that they cannot read each other's examination papers. They should not speak to any person other than the invigilators.
- (e) All examination papers, associated documents and additional papers handed out to the applicants for the examination should be handed back to the invigilator at the end of the examination.
- (f) Only the examination paper, specific documentation and tools needed for the examination should be available to the applicant during the examination.



- (g) Applicants may use the following equipment during an examination:
  - (1) a scientific, non-programmable, non-alphanumeric calculator without specific aviation functions;
  - (2) mechanical navigation slide-rule (DR calculator);
  - (3) protractor;
  - (4) compasses and dividers;
  - (5) ruler.
- (h) Applicants may use a translation dictionary at the discretion of the competent authority.
- (i) Except equipment specified above, applicant(s) should not use any electronic equipment during the examination(s).

# AMC1 ARA.FCL.300(b) Examination procedures

ED Decision 2020/018/R

# THEORETICAL KNOWLEDGE EXAMINATIONS FOR PROFESSIONAL LICENCES AND INSTRUMENT RATINGS

With regard to the IR(A), CBIR(A) and BIR, these tables apply to theoretical knowledge examinations for applicants who have completed the appropriate elements of theoretical knowledge instruction of a modular training course for the IR(A) according to Appendix 6 Section A, for the CBIR(A) according to Appendix 6 Section Aa, and for the BIR according to FCL.835.



Subject 010	Subject 010 — AIR LAW									
Theoretical	Theoretical knowledge examination									
Exam length	Exam length, total number of questions, and distribution of questions									
	ATPL(A)	CPL(A)	ATPL(H)/IR	ATPL(H)	CPL(H)	IR(A) and IR(H)	CB- IR(A)	BIR M01	BIR M02	BIR M03
Time allowed (hours)	1:00	0:45	1:00	0:45	0:45	0:45	0:30	*	*	*
Distribution	of question	s with rega	ard to the to	pics of the s	yllabus					
010 01	02	02	02	02	02	XX	XX	XX	XX	XX
010 02	01	01	01	01	01	XX	XX	XX	XX	XX
010 03	XX	XX	XX	XX	XX	XX	XX	XX	XX	XX
010 04	01	01	01	01	01	01	01	XX	XX	XX
010 05	09	09	09	09	09	06	05	XX	XX	02
010 06	10	05	10	05	05	08	06	XX	06	XX
010 07	06	04	06	04	04	06	03	XX	XX	06
010 08	01	01	01	01	01	02	01	XX	01	XX
010 09	08	05	08	05	05	07	02	XX	02	XX
010 10	01	01	01	01	01	XX	XX	XX	XX	XX
010 11	01	01	01	01	01	XX	XX	XX	XX	XX
010 12	02	02	02	02	02	XX	XX	XX	XX	XX
010 13	02	01	02	01	01	XX	XX	XX	XX	XX
Total number of questions	44	33	44	33	33	30	18	XX	09	08



### Subject 021 — AIRCRAFT GENERAL KNOWLEDGE — AIRFRAME/SYSTEMS/POWER PLANT

Theoretical knowledge examination

Exam length, total number of questions, and distribution of questions

	ATPL(A)	CPL(A)	ATPL(H)/ IR	ATPL(H)	CPL(H)	IR(A) and IR(H)	CB- IR(A)	BIR M01	BIR M02	BIR M03
Time allowed (hours)	2:00	1:30	2:00	2:00	1:30	XX	XX	XX	XX	XX
Distribution	of question	s with reg	ard to the to	pics of the s	syllabus					
021 01	02	01	02	02	01	XX	XX	XX	XX	XX
021 02	02	02	02	02	01	XX	XX	XX	XX	XX
021 03	05	03	03	03	02	XX	XX	XX	XX	XX
021 04	05	04	03	03	02	XX	XX	XX	XX	XX
021 05	08	06	05	05	04	XX	XX	XX	XX	XX
021 06	05	02	02	02	02	XX	XX	XX	XX	XX
021 07	02	02	02	02	02	XX	XX	XX	XX	XX
021 08	05	03	05	05	03	XX	XX	XX	XX	XX
021 09	15	11	14	14	09	XX	XX	XX	XX	XX
021 10	06	11	06	06	09	XX	XX	XX	XX	XX
021 11	19	11	17	17	09	XX	XX	XX	XX	XX
021 12	03	02	03	03	02	XX	XX	XX	XX	XX
021 13	03	02	XX	XX	XX	XX	XX	XX	XX	XX
021 14	XX	XX	01	01	01	XX	XX	XX	XX	XX
021 15	XX	XX	04	04	03	XX	XX	XX	XX	XX
021 16	XX	XX	06	06	05	XX	XX	XX	XX	XX
021 17	XX	XX	05	05	05	XX	XX	XX	XX	XX
Total number of questions	80	60	80	80	60	XX	XX	XX	XX	XX



Subject 022	2 — AIRCRAF	T GENERA	L KNOWLED	GE — INSTR	UMENTAT	ION					
Theoretical	knowledge 6	examinatio	n								
Exam lengtl	Exam length, total number of questions, and distribution of questions										
	ATPL(A)	CPL(A)	ATPL(H)/ IR	ATPL(H)	CPL(H)	IR(A) and IR(H)	CB- IR(A)	BIR M01	BIR M02	BIR M03	
Time allowed (hours)	1:30	1:00	1:30	1:30	1:00	0:30	0:20	*	*	*	
Distribution	n of question	ns with reg	ard to the t	opics of the	syllabus						
022 01	03	03	03	03	03	XX	XX	XX	XX	XX	
022 02	08	08	09	09	08	04	04	03	XX	XX	
022 03	02	02	03	03	02	01	01	01	XX	XX	
022 04	04	04	06	06	04	02	02	03	XX	XX	
022 05	03	XX	03	03	XX	XX	XX	XX	XX	XX	
022 06	11	09	XX	XX	XX	02	XX	XX	XX	XX	
022 07	XX	XX	14	14	11	XX	XX	XX	XX	XX	
022 08	03	02	XX	XX	XX	01	XX	XX	XX	XX	
022 09	04	XX	XX	XX	XX	XX	XX	XX	XX	XX	
022 10	02	XX	XX	XX	XX	XX	XX	XX	XX	XX	
022 11	06	01	06	06	XX	03	01	XX	XX	01	
022 12	08	07	09	09	07	03	XX	XX	XX	XX	
022 13	04	03	05	05	04	03	03	04	XX	XX	
022 14	01	01	01	01	01	XX	XX	XX	XX	XX	
022 15	01	XX	01	01	XX	01	01	XX	XX	XX	
Total number of questions	60	40	60	60	40	20	12	11	XX	01	



Subject 031 — FLIGHT PERFORMANCE AND PLANNING — MASS AND BALANCE										
	Theoretical knowledge examination									
Exam length, total number of questions, and distribution of questions										
	ATPL(A)	CPL(A)	ATPL(H)/ IR	ATPL(H)	CPL(H)	IR(A) and IR(H)	CB- IR(A)	BIR M01	BIR M02	BIR M03
Time allowed (hours)	1:15	1:00	1:15	1:15	1:00	XX	XX	XX	XX	XX
Distribution	of question	ns with reg	gard to the t	opics of the	syllabus					
031 01	01	01	01	01	01	XX	XX	XX	XX	XX
031 02	08	07	09	09	07	XX	XX	XX	XX	XX
031 03	XX	XX	XX	XX	XX	XX	XX	XX	XX	XX
031 04	05	04	04	04	04	XX	XX	XX	XX	XX
031 05	09	07	09	09	07	XX	XX	XX	XX	XX
031 06	02	02	02	02	02	XX	XX	XX	XX	XX
Total number of questions	25	21	25	25	21	XX	XX	XX	XX	XX

0.11000										
	Subject 032 — FLIGHT PERFORMANCE AND PLANNING — PERFORMANCE (AEROPLANES)									
Theoretical knowledge examination										
Exam length, total number of questions, and distribution of questions										
	ATPL(A)	CPL(A)	ATPL(H) /IR	ATPL(H)	CPL(H)	IR(A) and IR(H)	CB- IR(A)	BIR M01	BIR M02	BIR M03
Time allowed (hours)	2:00	1:15	XX	XX	XX	XX	XX	XX	XX	XX
Distribution	n of question	s with reg	gard to the	topics of the	syllabus					
032 01	12	12	XX	XX	XX	XX	XX	XX	XX	XX
032 02	06	09	XX	XX	XX	XX	XX	XX	XX	XX
032 03	03	06	XX	XX	XX	XX	XX	XX	XX	XX
032 04	18	01	XX	XX	XX	XX	XX	XX	XX	XX
032 05	06	XX	XX	XX	XX	XX	XX	XX	XX	XX
Total number of questions	45	28	XX	XX	XX	XX	XX	XX	XX	XX



Subject 033 — FLIGHT PERFORMANCE AND PLANNING — FLIGHT PLANNING AND MONITORING										
-	knowledge e			LAMMING	T EIGITT T E	ANTINGA		TOMINE		
				distribution o	f augstions	•				
LAGIII ICIIGU	ATPL(A)	CPL(A)	ATPL(H)	ATPL(H)	CPL(H)	IR(A)	СВ-	BIR	BIR	BIR
	A11 <b>2</b> (A)	C. L(A)	/IR	A. (11)	C. E()	and	IR(A)	M01	M02	M03
						IR(H)				
Time allowed (hours)	2:00	1:30	2:00	1:30	1:30	1:15	1:00	*	*	*
Distribution	n of question	s with reg	gard to the	topics of the	syllabus					
033 01	06	11	07	11	11	XX	XX	XX	XX	XX
033 02	13	XX	13	XX	XX	13	12	XX	07	XX
033 03	11	10	10	10	10	05	05	XX	XX	01
033 04	06	06	06	06	06	05	04	XX	XX	02
033 05	01	01	01	01	01	01	01	XX	XX	01
033 06	05	05	05	05	05	03	XX	XX	XX	XX
Total number of questions	42	33	42	33	33	27	22	XX	07	04

Subject 034	— FLIGHT PI	ERFORMA	NCE AND P	— PERFORMANCE (HELICOPTERS)						
Theoretical I	knowledge e	xaminatio	n							
Exam length	, total numb	er of ques	tions, and o	distribution o	f questions	i				
	ATPL(A)	CPL(A)	ATPL(H) /IR	ATPL(H)	CPL(H)	IR(A) and IR(H)	CB- IR(A)	BIR M01	BIR M02	BIR M03
Time allowed (hours)	XX	XX	1:15	1:15	0:45	XX	XX	XX	XX	XX
Distribution	of question	s with reg	ard to the t	opics of the	syllabus					
034 01	XX	XX	12	12	11	XX	XX	XX	XX	XX
034 02	XX	XX	07	07	09	XX	XX	XX	XX	XX
034 03	XX	XX	03	03	XX	XX	XX	XX	XX	XX
034 04	XX	XX	13	13	XX	XX	XX	XX	XX	XX
Total number of questions	XX	XX	35	35	20	XX	XX	XX	XX	XX



Subject 040 — HUMAN PERFORMANCE												
Theoretical knowledge examination												
Exam length, total number of questions, and distribution of questions												
	ATPL(A)	CPL(A)	ATPL(H) /IR	ATPL(H)	CPL(H)	IR(A) and IR(H)	CB- IR(A)	BIR M01	BIR M02	BIR M03		
Time allowed (hours)	1:30	1:00	1:30	1:30	1:00	1:00	0:30	*	*	*		
Distribution	of question	s with reg	ard to the	topics of the	syllabus							
040 01	04	03	04	04	03	03	01	01	XX	XX		
040 02	24	18	24	24	18	18	08	07	XX	XX		
040 03	20	14	20	20	14	14	07	08	XX	XX		
Total number of questions	48	35	48	48	35	35	16	16	XX	XX		

Subject 050	Subject 050 — METEOROLOGY											
Theoretical knowledge examination												
Exam length, total number of questions, and distribution of questions												
	ATPL(A)	CPL(A)	ATPL(H) /IR	ATPL(H)	CPL(H)	IR(A) and IR(H)	CB- IR(A)	BIR M01	BIR M02	BIR M03		
Time allowed (hours)	2:00	1:30	2:00	2:00	1:30	1:30	0:50	*	*	*		
Distribution	of question	s with reg	gard to the	topics of the	syllabus							
050 01	10	08	10	10	08	08	04	02	XX	XX		
050 02	10	06	10	10	06	06	03	02	XX	XX		
050 03	03	03	03	03	03	03	01	01	XX	XX		
050 04	08	06	08	08	06	06	05	05	XX	XX		
050 05	02	02	02	02	02	02	02	03	XX	XX		
050 06	07	06	07	07	06	06	04	XX	XX	04		
050 07	06	02	06	06	02	02	01	XX	XX	01		
050 08	08	03	08	08	03	03	01	XX	XX	XX		
050 09	14	13	14	14	13	13	08	XX	XX	10		
050 10	16	14	16	16	14	14	06	XX	06	XX		
Total number of questions	84	63	84	84	63	63	35	13	06	15		



Subject 061 — GENERAL NAVIGATION												
Theoretical knowledge examination												
Exam length, total number of questions, and distribution of questions												
	ATPL(A)	CPL(A)	ATPL(H) /IR	ATPL(H)	CPL(H)	IR(A) and IR(H)	CB- IR(A)	BIR M01	BIR M02	BIR M03		
Time allowed (hours)	2:15	2:00	2:15	2:15	2:00	XX	XX	XX	XX	XX		
Distribution	of question	s with reg	ard to the	topics of the	syllabus							
061 01	28	22	28	28	22	XX	XX	XX	XX	XX		
061 02	07	06	07	07	06	XX	XX	XX	XX	XX		
061 03	05	05	05	05	05	XX	XX	XX	XX	XX		
061 04	12	09	12	12	09	XX	XX	XX	XX	XX		
061 05	03	03	03	03	03	XX	XX	XX	XX	XX		
Total number of	55	45	55	55	45	XX	XX	XX	XX	XX		

Subject 062	Subject 062 — RADIO NAVIGATION										
Theoretical knowledge examination											
Exam length, total number of questions, and distribution of questions											
	ATPL(A)	CPL(A)	ATPL(H) /IR	ATPL(H)	CPL(H)	IR(A) and IR(H)	CB- IR(A)	BIR M01	BIR M02	BIR M03	
Time allowed (hours)	1:30	0:30	1:30	1:00	0:30	1:00	0:40	*	*	*	
Distribution	of questions	s with reg	ard to the t	topics of the s	yllabus						
062 01	05	04	05	05	04	03	XX	XX	XX	XX	
062 02	22	11	22	20	11	22	13	XX	06	XX	
062 03	11	02	11	08	02	05	03	XX	02	XX	
062 04	XX	XX	XX	XX	XX	XX	XX	XX	XX	XX	
062 05	XX	XX	XX	XX	XX	XX	XX	XX	XX	XX	
062 06	15	05	15	11	05	08	04	XX	04	XX	
062 07	13	XX	13	XX	XX	06	04	XX	07	XX	
Total number of questions	66	22	66	44	22	44	24	XX	19	XX	



Subject 070 — OPERATIONAL PROCEDURES											
Theoretical knowledge examination											
Exam length, total number of questions, and distribution of questions											
	ATPL(A)	CPL(A)	ATPL(H) /IR	ATPL(H)	CPL(H)	IR(A) and IR(H)	CB- IR(A)	BIR M01	BIR M02	BIR M03	
Time allowed (hours)	1:15	1:00	1:15	1:00	0:45	XX	XX	XX	XX	XX	
Distribution	of question	s with reg	ard to the	topics of the s	yllabus						
071 01	17	09	10	08	08	XX	XX	XX	XX	XX	
071 02	24	20	22	17	17	XX	XX	XX	XX	XX	
071 03	XX	XX	06	05	05	XX	XX	XX	XX	XX	
071 04	01	01	02	02	02	XX	XX	XX	XX	XX	
Total number of	42	30	40	32	32	XX	XX	XX	XX	XX	

Subject 081 — PRINCIPLES OF FLIGHT (AEROPLANES)												
Theoretical knowledge examination												
Exam length, total number of questions, and distribution of questions												
	ATPL(A)	CPL(A)	ATPL(H) /IR	ATPL(H)	CPL(H)	IR(A) and IR(H)	CB- IR(A)	BIR M01	BIR M02	BIR M03		
Time allowed (hours)	1:30	1:15	XX	XX	XX	XX	XX	XX	XX	XX		
Distribution	of question	s with reg	ard to the	topics of the	syllabus							
081 01	14	13	XX	XX	XX	XX	XX	XX	XX	XX		
081 02	04		XX	XX	XX	XX	XX	XX	XX	XX		
081 03	09	07	XX	XX	XX	XX	XX	XX	XX	XX		
081 04	04	03	XX	XX	XX	XX	XX	XX	XX	XX		
081 05	03	03	XX	XX	XX	XX	XX	XX	XX	XX		
081 06	03	03	XX	XX	XX	XX	XX	XX	XX	XX		
081 07	04	04	XX	XX	XX	XX	XX	XX	XX	XX		
081 08	05	04	XX	XX	XX	XX	XX	XX	XX	XX		
Total number of questions	46	37	XX	XX	XX	XX	XX	XX	XX	XX		



Subject 082	Subject 082 — PRINCIPLES OF FLIGHT (HELICOPTERS)										
Theoretical knowledge examination											
Exam length, total number of questions, and distribution of questions											
	ATPL(A)	CPL(A)	ATPL(H) /IR	ATPL(H)	CPL(H)	IR(A) and IR(H)	CB- IR(A)	BIR M01	BIR M02	BIR M03	
Time allowed (hours)	XX	XX	1:15	1:15	1:15	XX	XX	XX	XX	XX	
Distribution	of question	s with reg	ard to the	topics of the s	syllabus						
082 01	XX	XX	06	06	06	XX	XX	XX	XX	XX	
082 02	XX	XX	03	03	03	XX	XX	XX	XX	XX	
082 03	XX	XX	01	01	01	XX	XX	XX	XX	XX	
082 04	XX	XX	11	11	11	XX	XX	XX	XX	XX	
082 05	XX	XX	08	08	08	XX	XX	XX	XX	XX	
082 06	XX	XX	04	04	04	XX	XX	XX	XX	XX	
082 07	XX	XX	06	06	06	XX	XX	XX	XX	XX	
082 08	XX	XX	03	03	03	XX	XX	XX	XX	XX	
Total number of questions	XX	XX	42	42	42	XX	XX	XX	XX	XX	

Subject 090 - COMMUNICATION													
Theoretical I	Theoretical knowledge examination												
Exam length, total number of questions, and distribution of questions													
	ATPL(A)	CPL(A)	ATPL(H) /IR	ATPL(H)	CPL(H)	IR(A) and IR(H)	CB- IR(A)	BIR M01	BIR M02	BIR M03			
Time allowed (hours)	1:00	1:00	1:00	1:00	1:00	1:00	1:00	*	*	*			
Distribution	Distribution of questions with regard to the topics of the syllabus												
090 01	04	04	04	04	04	04	04	XX	XX	02			
090 02	17	17	17	17	17	17	17	XX	XX	06			
090 03	02	02	02	02	02	02	02	XX	XX	01			
090 04	04	04	04	04	04	04	04	XX	XX	02			
090 05	03	03	03	03	03	03	03	XX	XX	03			
090 06	02	02	02	02	02	02	02	XX	XX	01			
090 07	02	02	02	02	02	02	02	XX	XX	01			
Total number of questions	34	34	34	34	34	34	34	XX	XX	16			

<sup>\*</sup>Refer to AMC2 ARA.FCL.300(b)



# AMC2 ARA.FCL.300(b) Examination procedures

ED Decision 2020/018/R

### TOTAL TIME ALLOWED AND TOTAL NUMBER OF QUESTIONS FOR BIR EXAMINATION

- (a) The total number of questions for the examination for Module 1 is 40 questions and the total time allowed for the Module 1 examination is 1:20 hours.
- (b) The total number of questions for the examination for Module 2 is 41 questions and the total time allowed for the Module 2 examination is 1:30 hours.
- (c) The total number of questions for the examination for Module 3 is 44 questions and the total time allowed for the Module 3 examination is 1:30 hours.



# SUBPART CC – SPECIFIC REQUIREMENTS RELATING TO CABIN CREW

### **SECTION I – CABIN CREW ATTESTATIONS**

### ARA.CC.100 Procedures for cabin crew attestations

Regulation (EU) No 1178/2011

- (a) The competent authority shall establish procedures for the issue, record-keeping and oversight of cabin crew attestations in accordance with <u>ARA.GEN.315</u>, <u>ARA.GEN.220</u> and <u>ARA.GEN.300</u> respectively.
- (b) Cabin crew attestations shall be issued, using the format and specifications established in Appendix II to this Part, either
  - (1) by the competent authority; and/or, if so decided by a Member State
  - (2) by an organisation approved to do so by the competent authority.
- (c) The competent authority shall make publicly available:
  - (1) which body(ies) issue cabin crew attestations in their territory; and
  - (2) if organisations are approved to do so, the list of such organisations.

### ARA.CC.105 Suspension or revocation of cabin crew attestations

Regulation (EU) No 290/2012

The competent authority shall take measures in accordance with <u>ARA.GEN.355</u>, including the suspension or revocation of a cabin crew attestation, at least in the following cases:

- (a) non-compliance with Part-CC or with the applicable requirements of Part-ORO and Part-CAT, where a safety issue has been identified;
- (b) obtaining or maintaining the validity of the cabin crew attestation by falsification of submitted documentary evidence;
- (c) exercising the privileges of the cabin crew attestation when adversely affected by alcohol or drugs; and
- (d) evidence of malpractice or fraudulent use of the cabin crew attestation.



# SECTION II — ORGANISATIONS PROVIDING CABIN CREW TRAINING OR ISSUING CABIN CREW ATTESTATIONS

# ARA.CC.200 Approval of organisations to provide cabin crew training or to issue cabin crew attestations

Regulation (EU) No 1178/2011

- (a) Before issuing an approval to a training organisation or a commercial air transport operator to provide cabin crew training, the competent authority shall verify that:
  - (1) the conduct, the syllabi and associated programmes of the training courses provided by the organisation comply with the relevant requirements of Part-CC;
  - (2) the training devices used by the organisation realistically represent the passenger compartment environment of the aircraft type(s) and the technical characteristics of the equipment to be operated by the cabin crew; and
  - (3) the trainers and instructors conducting the training sessions are suitably experienced and qualified in the training subject covered.
- (b) If in aMember State organisations may be approved to issue cabin crew attestations, the competent authority shall only grant such approvals to organisations complying with the requirements in (a). Before granting such an approval, the competent authority shall:
  - (1) assess the capability and accountability of the organisation to perform the related tasks;
  - (2) ensure that the organisation has established documented procedures for the performance of the related tasks, including for the conduct of examination(s) by personnel who are qualified for this purpose and free from conflict of interest, and for the issue of cabin crew attestations in accordance with <u>ARA.GEN.315</u> and <u>ARA.CC.100(b)</u>; and
  - (3) require the organisation to provide information and documentation related to the cabin crew attestations it issues and their holders, as relevant for the competent authority to conduct its record-keeping, oversight and enforcement tasks.

# AMC1 ARA.CC.200(b)(2) Approval of organisations to provide cabin crew training or to issue cabin crew attestations

ED Decision 2012/006/R

### PERSONNEL CONDUCTING EXAMINATIONS

For any element being examined for the issue of a cabin crew attestation as required in Part-CC, the person who delivered the associated training or instruction should not also conduct the examination. However, if the organisation has appropriate procedures in place to avoid conflict of interest regarding the conduct of the examination and/or the results, this restriction need not apply.



# SUBPART ATO – SPECIFIC REQUIREMENTS RELATED TO APPROVED TRAINING ORGANISATIONS (ATOs)

### **SECTION I – GENERAL**

# ARA.ATO.105 Oversight Programme

Regulation (EU) No 1178/2011

The oversight programme for ATOs shall include the monitoring of course standards, including the sampling of training flights with students, if appropriate to the aircraft used.

### AMC1 ARA.ATO.105 Oversight programme

ED Decision 2012/006/R

### **GENERAL**

- (a) The audit or inspection of an ATO should be conducted on the basis of checking the facility for compliance, interviewing personnel and sampling any relevant training course for its conduct and standard.
- (b) In addition to the items required in <u>AMC1 ARA.GEN.310(a)</u>, such an audit or inspection should focus on:
  - (1) information on flight instructors, validity of licences, certificates, ratings and log books;
  - (2) evidence of sufficient funding;
  - (3) training aircraft in use, including their registration, associated documents and maintenance records;
  - (4) aerodromes, operating sites and associated facilities;
  - (5) facilities with regard to their adequacy to the courses being conducted and number of students;
  - (6) FSTDs, including their qualification certificates, associated documents and maintenance records;
  - (7) documentation, in particular documents related to courses, information on the updating system, and training and operations manual(s);
  - (8) training records and checking forms; and
  - (9) flight instruction, including pre-briefing, actual flight and debriefing.

## **ARA.ATO.110** Approval of minimum equipment lists

Regulation (EU) 2020/359

When the competent authority receives an application for approval of a minimum equipment list under points ORO.MLR.105 of Annex III (Part-ORO) and NCC.GEN.101 of Annex VI (Part-NCC) to Regulation (EU) No 965/2012, it shall act in accordance with point ARO.OPS.205 of Annex II (Part-ARO) to that Regulation.



SUBPART ATO – SPECIFIC REQUIREMENTS RELATED TO APPROVED TRAINING ORGANISATIONS (ATOS)

# ARA.ATO.120 Record-keeping

Regulation (EU) No 290/2012

In addition to the records required in <u>ARA.GEN.220</u>, the competent authority shall include in its system of record-keeping details of courses provided by the ATO, and if applicable, records relating to FSTDs used for training.

# AMC1 ARA.ATO.120 Record-keeping

ED Decision 2012/006/R

### **FSTDs**

Records relating to FSTDs should include, as a minimum:

- (a) the application for an FSTD qualification;
- (b) the FSTD qualification certificate including any changes;
- (c) a copy of the evaluation programme listing the dates when evaluations are due and when evaluations were carried out;
- (d) initial and recurrent evaluation records;
- (e) copies of all relevant correspondence;
- (f) details of any exemption and enforcement actions; and
- (g) any report from other competent authorities relating to initial and recurrent evaluations.



# SUBPART FSTD – SPECIFIC REQUIREMENTS RELATED TO THE QUALIFICATION OF FLIGHT SIMULATION TRAINING DEVICES (FSTDs)

### **SECTION I – GENERAL**

# ARA.FSTD.100 Initial evaluation procedure

Regulation (EU) No 1178/2011

- (a) Upon receiving an application for an FSTD qualification certificate, the competent authority shall:
  - (1) evaluate the FSTD submitted for initial evaluation or for upgrading against the applicable qualification basis;
  - (2) assess the FSTD in those areas that are essential to completing the flight crew member training, testing and checking process, as applicable;
  - (3) conduct objective, subjective and functions tests in accordance with the qualification basis and review the results of such tests to establish the qualification test guide (QTG); and
  - (4) verify if the organisation operating the FSTDis in compliance with the applicable requirements. This does not apply to the initial evaluation of basic instrument training devices (BITDs).
- (b) The competent authority shall only approve the QTG after completion of the initial evaluation of the FSTD and when all discrepancies in the QTG have been addressed to the satisfaction of the competent authority. The QTG resulting from the initial evaluation procedure shall be the master QTG (MQTG), which shall be the basis for the FSTD qualification and subsequent recurrent FSTD evaluations.
- (c) Qualification basis and special conditions.
  - (1) The competent authority may prescribe special conditions for the FSTD qualification basis when the requirements of ORA.FSTD.210(a) are met and when it is demonstrated that the special conditions ensure an equivalent level of safety to that established in the applicable certification specification.
  - (2) When the competent authority, if other than the Agency, has established special conditions for the qualification basis of an FSTD, it shall without undue delay notify the Agency thereof. The notification shall be accompanied by a full description of the special conditions prescribed, and a safety assessment demonstrating that an equivalent level of safety to that established in the applicable Certification Specification is met.



# AMC1 ARA.FSTD.100(a)(1) Initial evaluation procedure

ED Decision 2012/006/R

### ASSESSMENT PROCESS LEADING TO THE ISSUE OF AN FSTD QUALIFICATION

- (a) FSTDs require evaluation leading to qualification. The required process should be accomplished in two distinct steps. First, a check should be made to determine whether or not the FSTD complies with the applicable requirements. When making this check, the competent authority should ensure that accountability for the issue of an FSTD qualification is clearly defined. In all cases an individual department manager of the competent authority should be appointed under whose personal responsibility the issue of an FSTD qualification is to be considered. The second step should be the grant (or refusal) of an FSTD qualification.
- (b) When checking compliance with the applicable requirements, the competent authority should ensure that the following steps are taken:
  - (1) Once an FSTD is contracted to be built, the organisation that is to operate the FSTD should ensure that the regulatory standard upon which the FSTD will eventually be qualified against is acceptable to the competent authority. This should be the current applicable version of CS-FSTD(A) or CS-FSTD(H) at the time of application.
  - (2) A written application for an FSTD qualification should be submitted, in a format according to ORA.FSTD.200, at least 3 months before the date of intended operation. However, the qualification test guide (QTG) may be submitted later, but not less than 30 days before the date of intended evaluation. The application form should be printed in English and any other language(s) of the competent authority's choosing.
  - (3) An individual should be nominated by the department manager of the competent authority to oversee, and become the focal point for, all aspects of the FSTD qualification process, and to coordinate all necessary activity. The nominated person should be responsible to the department manager for confirming that all appropriate evaluations/inspections are made.
  - (4) The ability of the applicant to secure, in compliance with the applicable requirements and certification specifications, the safe and reliable operation and proper maintenance of the FSTD should be assessed.
  - (5) The applicant's proposed compliance monitoring system should be scrutinised with particular regard to the allocated resources. Care should be taken to verify that the system is comprehensive and likely to be effective.
  - (6) The competent authority should inform the applicant of its final decision concerning the qualification within 14 days of completion of the evaluation process irrespective of any temporary qualification issued.
  - (7) On completion of the evaluation process, the application, together with a written recommendation and evidence of the result of all evaluations or assessments, should be presented to the nominated person responsible for FSTD qualification. The presentation should be made by the person with overall responsibility, nominated in accordance with (b)(3).
  - (8) The department manager of the competent authority should only issue an FSTD qualification certificate if he/she is completely satisfied that all requirements have been



- met. If he/she is not satisfied, the applicant should be informed in writing of the improvements that are required in order to satisfy the competent authority.
- (9) If an application for an FSTD qualification is refused, the applicant should be informed of such rights of appeal as exist under national regulations.

# AMC2 ARA.FSTD.100(a)(1) Initial evaluation procedure

ED Decision 2012/006/R

### **GENERAL**

- (a) During initial and recurrent FSTD evaluations it should be necessary for the competent authority to conduct an appropriate sample of the objective and subjective tests described in Part-ORA and detailed in CS-FSTD(A) and CS-FSTD(H), as applicable. There may be occasions when all tests cannot be completed for example during recurrent evaluations on a convertible FSTD but arrangements should be made for all tests to be completed within a reasonable time.
- (b) Following an evaluation, it is possible that a number of defects are identified. Generally, these defects should be rectified and the competent authority notified of such action within 30 days. Serious defects, which affect flight crew training, testing and checking, could result in an immediate downgrading of the qualification level I. If any defect remains unattended without good reason for a period greater than 30 days, subsequent downgrading may occur or the FSTD qualification could be revoked.
- (c) For the evaluation of an FSTD the standard form as mentioned in <u>AMC5 ARA.FSTD.100(a)(1)</u> should be used.

# AMC3 ARA.FSTD.100(a)(1) Initial evaluation procedure

ED Decision 2012/006/R

### **INITIAL EVALUATION**

- (a) The main focus of objective testing is the QTG. Well in advance of the evaluation date, the aircraft manufacturer and the competent authority should agree on the content and acceptability of the validation tests contained in the QTG data package. This will ensure that the content of the QTG is acceptable to the competent authority and avoid time being wasted during the initial qualification. The acceptability of all tests depends upon their content, accuracy, completeness and recency of the results.
- (b) Much of the time allocated to objective tests depends upon the speed of the automatic and manual systems set up to run each test and whether or not special equipment is required. The competent authority should not necessarily warn the organisation operating an FSTD of the sample validations tests which should be run on the day of the evaluation, unless special equipment is required.
- (c) The FSTD cannot be used for subjective tests while part of the QTG is being run. Therefore, sufficient time (at least 8 consecutive hours) should be set aside for the examination and running of the QTG.
- (d) The subjective tests for the evaluation can be found in CS-FSTD(A) or CS-FSTD(H), and a suggested subjective test profile is described in <a href="MMC1 ARA.FSTD.100(a)(3)">AMC1 ARA.FSTD.100(a)(3)</a>. Essentially, 1 working day should be required for the subjective test routine, which effectively denies use of the FSTD for any other purpose.





(e) To ensure adequate coverage of subjective and objective tests and to allow for cost effective rectification and re-test before departure of the inspection team, adequate time (up to 3 consecutive days) should be dedicated to an initial evaluation of an FSTD.

# AMC4 ARA.FSTD.100(a)(1) Initial evaluation procedure

ED Decision 2012/006/R

### **COMPOSITION OF THE EVALUATION TEAM**

- (a) The competent authority should appoint a technical team to evaluate an FSTD in accordance with a structured routine to gain a qualification level. The team should normally consist of at least the following personnel:
  - (1) A technical FSTD inspector of the competent authority, or an accredited inspector from another competent authority, qualified in all aspects of flight simulation hardware, software and computer modelling or, exceptionally, a person designated by the competent authority with equivalent qualifications; and
  - (2) One of the following:
    - (i) a flight inspector of the competent authority, or an accredited inspector from another competent authority, who is qualified in flight crew training procedures and holds a valid type rating on the aeroplane/helicopter (or for flight navigation procedures trainer (FNPT) and basic instrument training device (BITD), class rated on the class of aeroplane/type of helicopter) being simulated; or
    - (ii) a flight inspector of the competent authority who is qualified in flight crew training procedures, assisted by a type rating instructor holding a valid type rating on the aeroplane/helicopter (or for FNPT and BITD, class rated on the class of aeroplane/type of helicopter) being simulated; or, exceptionally,
    - (iii) a person designated by the competent authority who is qualified in flight crew training procedures and holds a valid type rating on the aeroplane/helicopter (or for FNPT and BITD, class rated on the class of aeroplane/type of helicopter) being simulated and sufficiently experienced to assist the technical team. This person should fly out at least part of the functions and subjective test profiles.
  - (3) Where a designee is used as a substitute for one of the competent authority's inspectors, the other person shall be a properly qualified inspector of the competent authority or an accredited inspector from another Member State's competent authority.
- (b) For a flight training device (FTD) level 1 and FNPT Type I, one suitably qualified inspector may combine the functions in (a)(1) and (a)(2).
- (c) For a BITD this team should consist of an inspector from a competent authority and one from another competent authority, including the manufacturer's competent authority, if applicable.
- (d) Additionally, the following persons should be present:
  - (1) for a full flight simulator (FFS), FTD and FNPT a type or class rated instructor from the ATO operating an FSTD or from the main FSTD user;
  - (2) for all types, sufficient FSTD support staff to assist with the running of tests and operation of the instructor's station.

ANNEX VI (Part-ARA)

SUBPART FSTD – SPECIFIC REQUIREMENTS RELATED TO THE QUALIFICATION OF FLIGHT SIMULATION TRAINING DEVICES (FSTDs)

# AMC5 ARA.FSTD.100(a)(1) Initial evaluation procedure

ED Decision 2012/006/R

### **FSTD EVALUATION REPORT FOR INITIAL AND RECURRENT EVALUATION**

FSTD Evaluation Report	
Date:	
	[competent authority] FSTD EVALUATION REPORT

[Member State] FSTD code (if applicable): EASA FSTD code (if applicable): Aircraft type and variant: Class of aeroplane / type of helicopter: Engine fit(s) simulated:

### Contents

- 1. Flight simulation training device (FSTD) characteristics
- 2. Evaluation details
- 3. Supplementary information
- 4. Training, testing and checking considerations
- 5. Classification of items
- 6. Results
- 7. Evaluation team

The conclusions presented are those of the evaluation team. The competent authority reserves the right to change these after internal review.

1.	Flight simulation training device (FSTD)							
(a)	Organisation operating the FSTD:							
(b)	FSTD Location:							
(c)	FSTD Identification (Member State FSTD code /	EASA FS	TD Code):					
(d)	FSTD Manufacturer and FSTD Identification seri	al numb	er:					
(e)	First entry into service (month/year):							
(f)	Visual system (manufacturer and type):							
(g)	Motion system (manufacturer and type) :							
(h)	Aircraft type and variant:							
(i)	Engine fit(s):							
(k)	Engine instrumentation: Flight instrumentation:							
2.	Evaluation details							
(a)	Date of evaluation:	(b)	Date of previous evaluation:					
(c)	Type of evaluation: initial recurrent special							



ANNEX VI (Part-ARA)

SUBPART FSTD – SPECIFIC REQUIREMENTS RELATED TO THE QUALIFICATION OF FLIGHT SIMULATION TRAINING DEVICES (FSTDs)

(d)	FSTD (	FSTD Qualification Level recommended:										
	FFS	Α	В	С	D	AG	BG	CG	DG	SC		
ENIDT	FTD	1	2	3								
FNPT BITD	ı	II	III	MCC								
Techn	Technical criteria primary reference document:											
Validation data roadmap (VDR) ID-No.:												
3. Supplementary information												
Company representative(s) (FSTD operator, Main FSTD user)												
FSTD seats available												
Visual databases used during evaluation												
Other												
4. Training, testing and checking considerations												
CAT I			RVR	m		DH	ft					
CAT II			RVR	m		DH	ft					
CAT III	st minir	num)	RVR	m		DH	ft					
LVTO		RVR	m									-
Recen	су											
IFR-training/check												
Type rating												
Proficiency checks												
Autocoupled approach												
Autoland/Roll out guidance												
ACAS I / II												
Windshear warning system/predictive windshear												
WX-Radar												
HUD/HUGS												
FANS	FANS											
GPWS/EGPWS												
ETOPS	ETOPS capability											
RNP A	PCH LN	IAV										
RNP A	PCH LN	IAV/VN	IAV									
RNP A	RNP APCH LPV											



ANNEX VI (Part-ARA)

SUBPART FSTD – SPECIFIC REQUIREMENTS RELATED TO THE QUALIFICATION OF FLIGHT SIMULATION TRAINING DEVICES (FSTDs)

RNP AR APCH	
Other	

#### 5. Classification of items

### **UNACCEPTABLE**

An item that fails to comply with the required standard and, therefore, affects the level of qualification or the qualification itself. If these items will not be corrected or clarified within a given time limit, the (competent authority) should have to vary, limit, suspend or revoke the FSTD qualification.

#### **RESERVATION**

An item where compliance with the required standard is not clearly proven and the issue will be reserved for a later decision. Resolution of these items will require either:

- 1. a competent authority policy ruling; or
- 2. additional substantiation.

#### UNSERVICEABILITY

A device that is temporarily inoperative or performing below its nominal level.

### **LIMITATION**

An item that prevents the full usage of the FSTD according to the training, testing and checking considerations due to the unusable devices, systems or parts thereof.

### RECOMMENDATION FOR IMPROVEMENT

An item that meets the required standard, but where considerable improvement is strongly recommended.

### **COMMENT**

Self-explanatory

### **Period of Rectification**

As set out in AMC2 ARA.FSTD.100(a)(1) point (b):

Following an evaluation, it is possible that a number of defects are identified. Generally, these defects should be rectified and the competent authority notified of such action within 30 days. Serious defects, which affect flight crew training, testing and checking, could result in an immediate downgrading of the qualification level, or if any defect remains unattended without good reason for a period greater than 30 days, subsequent downgrading may occur or the FSTD qualification could be revoked.

### 6. Results

### 6.1 Subjective/Functional



ANNEX VI (Part-ARA)

SUBPART FSTD – SPECIFIC REQUIREMENTS RELATED TO THE QUALIFICATION OF FLIGHT SIMULATION TRAINING DEVICES (FSTDs)

	Α	Unacceptable
1		
	В	Reservation
1		
	С	Unserviceability
1		
	D	Restriction
1		
	E	Recommendation for improvement
1		
	F	Comment
1		
6.2	Obje	ctive
	Α	Unacceptable
1		·
	В	Reservation
1		
	E	Recommendation for improvement
1		
	F	Comment
1		

## 7. Evaluation Team

Name	Position	Organisation	Signature
	Technical Inspector or		
	person designated by		
	the competent authority		
	Flight Inspector or		
	person designated by		
	the competent authority		
		[FSTD User]	
		[Organisation operating	
		the FSTD]	

_	
Signed:	For the competent sutherity
519(160:	For the competent authority



# GM1 ARA.FSTD.100(a)(1) Initial evaluation procedure

ED Decision 2012/006/R

### **INITIAL EVALUATION**

A useful explanation of how the validation tests should be run is contained in the 'RAeS Aeroplane Flight Simulator Evaluation Handbook' (February 1995 or as amended) produced in support of the ICAO Doc 9625, 'Manual of Criteria for the Qualification of Flight Simulators'.

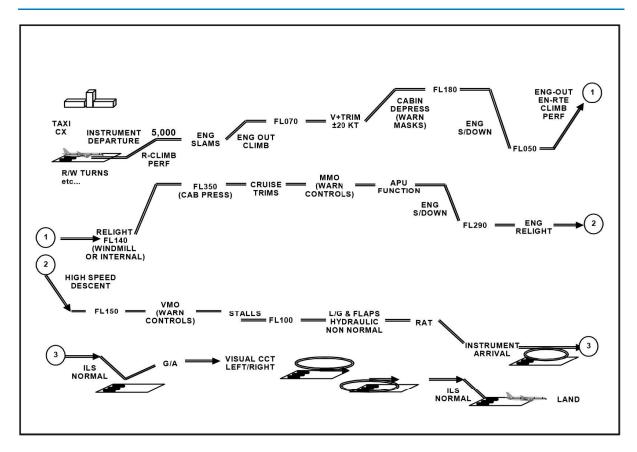
# AMC1 ARA.FSTD.100(a)(3) Initial evaluation procedure

ED Decision 2012/006/R

### **FUNCTIONS AND SUBJECTIVE TESTS – SUGGESTED TEST ROUTINE**

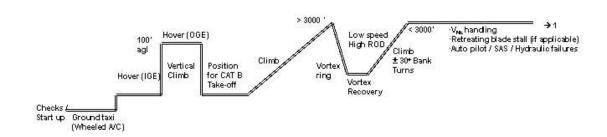
- (a) During initial and recurrent evaluations of an FSTD, the competent authority should conduct a series of functions and subjective tests that together with the objective tests complete the comparison of the FSTD with the aircraft, the class of aeroplane or type of helicopter.
- (b) Functions tests verify the acceptability of the simulated aircraft systems and their integration. Subjective tests verify the fitness of the FSTD in relation to training, checking and testing tasks.
- (c) The FSTD should provide adequate flexibility to permit the accomplishment of the desired and required tasks while maintaining an adequate perception by the flight crew that they are operating in a real aircraft environment. Additionally, the instructor operating station (IOS) should not present an unnecessary distraction from observing the activities of the flight crew whilst providing adequate facilities for the tasks.
- (d) It is important that both the competent authority and the organisation operating an FSTD understand what to expect from the routine of FSTD functions and subjective tests. Part of the subjective tests routine for an FSTD should involve an uninterrupted fly-out (except for FTD level 1) comparable with the duration of typical training sessions in addition to assessment of flight freeze and repositioning. An example of such a profile is to be found under points (f) and (g) (for BITD point (h)).
- (e) The competent authorities, and organisations operating FSTD, who are unfamiliar with the evaluation process should contact the Agency or the competent authority of another Member State with adequate expertise in this field.
- (f) Typical test profile for an FSTD aeroplane:

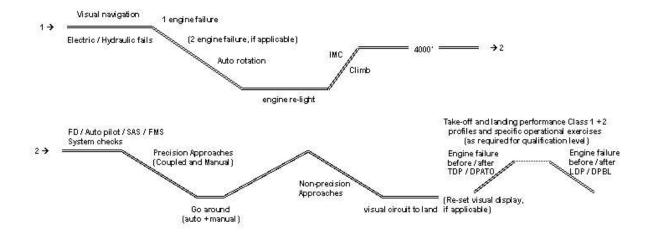




(g) Typical test profile for an FSTD helicopter:







- (h) Typical subjective test profile for BITDs (approximately 2 hours) items and altitudes, as applicable:
  - (1) instrument departure, climb performance,
  - (2) level-off at 4 000 ft,
  - (3) fail engine (if applicable),
  - (4) engine out climb to 6 000 ft (if applicable),
  - (5) engine out cruise performance (if applicable), restart engine,
  - (6) all engine cruise performance with different power settings,
  - (7) descent to 2 000 ft,
  - (8) all engine performance with different configurations, followed by instrument landing system (ILS) approach,
  - (9) all engine go-around,
  - (10) non-precision approach,
  - (11) go-around with engine failure (if applicable),
  - (12) engine out ILS approach (if applicable),
  - (13) go-around engine out (if applicable),



- (14) non-precision approach engine out (if applicable), followed by go-around,
- (15) restart engine (if applicable),
- (16) climb to 4 000 ft,
- (17) manoeuvring,
- (18) normal turns left and right,
- (19) steep turns left and right,
- (20) acceleration and deceleration within operational range,
- (21) approaching to stall in different configurations,
- (22) recovery from spiral dive,
- (23) auto flight performance (if applicable),
- (24) system malfunctions,
- (25) approach.

# GM1 ARA.FSTD.100(a)(3) Initial evaluation procedure

ED Decision 2012/006/R

### **GENERAL**

A useful explanation of functions and subjective tests and an example of subjective test routine checklist may be found in the 'RAeS Airplane Flight Simulator Evaluation Handbook' Volume II (February 1995 or as amended) produced in support of ICAO Doc 9625, 'Manual of Criteria for the Qualification of Flight Simulators'.

# ARA.FSTD.110 Issue of an FSTD qualification certificate

Regulation (EU) No 290/2012

(a) After completion of an evaluation of the FSTD and when satisfied that the FSTD meets the applicable qualification basis in accordance with ORA.FSTD.210 and that the organisation operating it meets the applicable requirements to maintain the qualification of the FSTD in accordance with ORA.FSTD.100, the competent authority shall issue the FSTD qualification certificate of unlimited duration, using the form as established in Appendix IV to this Part.

# AMC1 ARA.FSTD.110 Issue of an FSTD qualification certificate

ED Decision 2012/006/R

### **BASIC INSTRUMENT TRAINING DEVICE (BITD)**

- (a) The competent authority should only grant a BITD qualification for the BITD model to a BITD manufacturer following satisfactory completion of an evaluation.
- (b) This qualification should be valid for all serial numbers of this model without further technical evaluation.
- (c) The BITD model should be clearly identified by a BITD model number. A running serial number should follow the BITD model identification number.



(d) The competent authority should establish and maintain a list of all BITD qualifications it has issued, containing the number of the BITD model with a reference to the hardware and software configuration.

# ARA.FSTD.115 Interim FSTD qualification

Regulation (EU) No 1178/2011

- (a) In the case of the introduction of new aircraft programmes, when compliance with the requirements established in this Subpart for FSTD qualification is not possible, the competent authority may issue an interim FSTD qualification level.
- (b) For full flight simulators (FFS) an interim qualification level shall only be granted at level A, B or C.
- (c) This interim qualification level shall be valid until a final qualification level can be issued and, in any case, shall not exceed 3 years.

# AMC1 ARA.FSTD.115 Interim FSTD qualification

ED Decision 2012/006/R

### **NEW AIRCRAFT FFS / FTD QUALIFICATION – ADDITIONAL INFORMATION**

- (a) Aircraft manufacturers' final data for performance, handling qualities, systems or avionics are seldom available until well after a new or derivative aircraft has entered service. Because it is often necessary to begin flight crew training and certification several months prior to the entry of the first aircraft into service, it may be necessary to use aircraft manufacturer-provided preliminary data for interim qualification of FSTDs. This is consistent with the possible interim approval of operational suitability data (OSD) relative to FFS in the type certification process under Part-21.
- (b) In recognition of the sequence of events that should occur and the time required for final data to become available, the competent authority may accept the use of certain partially validated preliminary aircraft and systems data, and early release ('red label') avionics in order to permit the necessary programme schedule for training, certification and service introduction.
- (c) Organisations seeking qualification based on preliminary data should, however, consult the competent authority as soon as it is known that special arrangements will be necessary, or as soon as it is clear that preliminary data will need to be used for FSTD qualification. Aircraft and FSTD manufacturers should also be made aware of the needs and agree on the data plan and FSTD qualification plan. There should be periodic meetings to keep the interested parties informed of the project's status.
- (d) The precise procedure to be followed to gain competent authority acceptance to use preliminary data should vary from case to case and between aircraft manufacturers. Each aircraft manufacturer's new aircraft development and test programme is designed to suit the needs of the particular project and may not contain the same events or sequence of events as another manufacturer's programme or even the same manufacturer's programme for a different aircraft. Hence, there cannot be a prescribed invariable procedure for acceptance to use preliminary data. Instead there should be a statement describing the final sequence of events, data sources, and validation procedures agreed by the FSTD operator, the aircraft manufacturer, the FSTD manufacturer and the competent authority. The approval by the Agency of the definition of scope of the aircraft validation source data to support the objective



- qualification as part of the OSD can also be an interim approval in case of preliminary data. The preliminary data to be used should be based on this interim approval.
- (e) There should be assurance that the preliminary data are the manufacturer's best representation of the aircraft and reasonable certainty that final data will not deviate to a large degree from these preliminary, but refined, estimates. First of all there should be an interim approval of OSD relative to flight simulators in the type certification process under Part-21. Furthermore, the data derived from these predictive or preliminary techniques should be validated by available sources including, at least, the following:
  - (1) Manufacturer's engineering report. Such reports explain the predictive method used and illustrate past successes of the method on similar projects. For example, the manufacturer could show the application of the method to an earlier aircraft model or predict the characteristics of an earlier model and compare the results to final data for that model.
  - (2) Early flight tests results. Such data will often be derived from aircraft certification tests, and should be used to maximum advantage for early FSTD validation. Certain critical tests, which would normally be done early in the aircraft certification programme, should be included to validate essential pilot training and certification manoeuvres. These include cases in which a pilot is expected to cope with an aircraft failure mode, including engine failures. The early data available will, however, depend on the aircraft manufacturer's flight test programme design and may not be the same in each case. However it is expected that the flight test programme of the aircraft manufacturer includes provisions for generation of very early flight tests results for FSTD validation.
- (f) The use of preliminary data is not indefinite. The aircraft manufacturer's final data should be available within 6 months after the aircraft's first 'service entry' or as agreed by the competent authority, the organisation and the aircraft manufacturer, but usually not later than 1 year. When an organisation applies for an interim qualification using preliminary data, the organisation and the competent authority should agree upon the update programme. This should normally specify that the final data update will be installed in the FSTD within a period of 6 months following the final data release unless special conditions exist and a different schedule agreed. The FSTD performance and handling validation would then be based on data derived from flight tests. Initial aircraft systems data should be updated after engineering tests. Final aircraft systems data should also be used for FSTD programming and validation.
- (g) FSTD avionics should stay essentially in step with aircraft avionics (hardware and software) updates. The permitted time lapse between aircraft and FSTD updates is not a fixed time but should be minimal. It may depend on the magnitude of the update and whether the QTG and pilot training and certification are affected. Permitted differences in aircraft and FSTD avionics versions and the resulting effects on FSTD qualification should be agreed between the organisation and the competent authority. Consultation with the FSTD manufacturer is desirable throughout the agreement of the qualification process.
- (h) The following describes an example of the design data and sources which might be used in the development of an interim qualification plan:
  - (1) The plan should consist of the development of a QTG based upon a mix of flight test and engineering simulation data. For data collected from specific aircraft flight tests or other flights, the required designed model and data changes necessary to support an acceptable proof of match (POM) should be generated by the aircraft manufacturer.



- (2) In order that the two sets of data are properly validated, the aircraft manufacturer should compare their simulation model responses against the flight test data, when driven by the same control inputs and subjected to the same atmospheric conditions as were recorded in the flight test. The model responses should result from a simulation where the following systems are run in an integrated fashion and are consistent with the design data released to the FSTD manufacturer:
  - (i) propulsion,
  - (ii) aerodynamics,
  - (iii) mass properties,
  - (iv) flight controls,
  - (v) stability augmentation,
  - (vi) brakes and landing gear.
- (i) For the qualification of FSTD of new aircraft types, it may be beneficial that the services of a suitably qualified test pilot are used for the purpose of assessing handling qualities and performance evaluation.

# GM1 ARA.FSTD.115 Interim FSTD qualification

ED Decision 2012/006/R

## NEW AIRCRAFT FFS/FTD QUALIFICATION – ADDITIONAL INFORMATION

- (a) A description of aircraft manufacturer-provided data needed for flight simulator modelling and validation is to be found in the IATA Document *Flight Simulator Design and Performance Data Requirements* (Edition 6 2000 or as amended).
- (b) The proof of match should meet the relevant tolerances in AMC1 CS-FSTD(A).300 respectively AMC1 CS-FSTD(H).300.

# ARA.FSTD.120 Continuation of an FSTD qualification

Regulation (EU) 2024/2076

- (a) The competent authority shall continuously monitor the organisation operating the FSTD, as part of the oversight programme, to verify that the following conditions are met:
  - (1) the complete set of tests in the master QTG is rerun progressively over a 12-month period;
  - (2) the results of recurrent evaluations continue to comply with the qualification basis and are dated and retained;
  - (3) a configuration control system is in place to ensure the continued integrity of the hardware and software of the qualified FSTD.
- (b) The competent authority shall conduct recurrent evaluations of the FSTD in accordance with the procedures detailed in point <u>ARA.FSTD.100</u>. Those evaluations shall take place:
  - (1) every year, in the case of a full flight simulator (FFS), flight training device (FTD) or flight and navigation procedures trainer (FNPT). The start for each recurrent 12-month period is the end of the month of the initial qualification unless another date is agreed between



the competent authority and the organisation operating the FSTD. Each FSTD recurrent evaluation shall take place within a period of 60 days before and 30 days after the start of each recurrent 12-month period;

- (2) every 3 years, in the case of a BITD.
- (c) The competent authority may extend the recurrent evaluation period of an FSTD specified in point ARA.FSTD.120(b)(1) to a maximum of 36 months, provided that all of the following apply:
  - (1) during the preceding 36 months, the organisation operating that FSTD complies with the criteria specified in points <u>ARA.GEN.305(c)(1)</u> to (c)(4);
  - (2) the FSTD has been subject to an initial and at least one recurrent evaluation that have established its continuous compliance with the qualification basis;
  - (3) the competent authority performs an audit of the elements of the management system of the organisation, as specified in points <a href="https://orange.com/ORA.GEN.200">ORA.GEN.200</a>(a)(3) and (a)(6) of Annex VII, every 12 months;
  - (4) the organisation has developed procedures to conduct the tasks specified in point ORA.FSTD.225(b) of Annex VII.

# AMC1 ARA.FSTD.120 Continuation of an FSTD qualification

ED Decision 2012/006/R

### **GENERAL**

- (a) Objective Testing. During recurrent evaluations, the competent authority should wish to see evidence of the successful running of the QTG between evaluations. The competent authority should select a number of tests to be run during the evaluation, including those that may be cause for concern. Again adequate notification would be given when special equipment is required for the test.
- (b) Essentially the time taken to run the objective tests depends upon the need for special equipment, if any, and the test system, and the FSTD cannot be used for subjective tests or other functions whilst testing is in progress.
- (c) For a modern FSTD incorporating an automatic test system, four hours would normally be required. FSTDs that rely upon manual testing may require a longer period of time.
- (d) Subjective Testing. Essentially the same subjective test routine should be flown as per the profile described in AMC1 ARA.FSTD.100(a)(3) with a selection of the subjective tests taken from CS-FSTD(A) or CS-FSTD(H), as appropriate.
- (e) Normally, the time taken for recurrent subjective testing is about 4 hours, and the FSTD should not perform other functions during this time.
- (f) To ensure adequate coverage of subjective and objective tests during a recurrent evaluation, a total of 8 hours should be allocated, (4 hours for a BITD). However, it should be remembered that any FSTD deficiency that arises during the evaluation could necessitate the extension of the evaluation period.



# AMC2 ARA.FSTD.120 Continuation of an FSTD qualification

ED Decision 2012/006/R

### **COMPOSITION OF THE EVALUATION TEAM**

- (a) The composition of the evaluation team for a recurrent evaluation should be the same as for the initial evaluation (see <u>AMC4 ARA.FSTD.100(a)(1)</u>.
  - On a case-by-case basis (except for BITD), when a specific FSTD in operation by a specific organisation is being evaluated, the competent authority may reduce the evaluation team to:
  - (1) the competent authority's flight inspector; and
  - (2) a type rated instructor (or class rated instructor for FNPT) from a main FSTD user.
- (b) Evaluations with a reduced evaluation team in line with (a) may only take place if:
  - (1) this composition is not being used prior to the second recurrent evaluation;
  - (2) such an evaluation is followed by an evaluation with a full competent authority evaluation team;
  - (3) the competent authority's flight inspector performs some spot checks in the area of objective testing;
  - (4) no major change or upgrading has been applied since the directly preceding evaluation;
  - (5) no relocation of the FSTD has taken place since the last evaluation;
  - (6) a system is established enabling the competent authority to monitor and analyse the status of the FSTD on a continuous basis; and
  - (7) the FSTD hardware and software has been working reliably for the previous years. This should be reflected in the number and kind of discrepancies (technical log entries) and the results of the compliance monitoring system audits.
- (c) In the case of a BITD, the recurrent evaluation may be conducted by one suitably qualified flight inspector only, in conjunction with the inspection of any ATO, using the BITD.

# **ARA.FSTD.130 Changes**

Regulation (EU) No 1178/2011

- (a) Upon receipt of an application for any changes to the FSTD qualification certificate, the competent authority shall comply with the applicable elements of the initial evaluation procedure requirements as described in <a href="ARA.FSTD.100(a)">ARA.FSTD.100(a)</a> and (b).
- (b) The competent authority may complete a special evaluation following major changes or when an FSTD appears not to be performing at its initial qualification level.
- (c) The competent authority shall always conduct a special evaluation before granting a higher level of qualification to the FSTD.



# AMC1 ARA.FSTD.130 Changes

ED Decision 2012/006/R

### **GENERAL**

- (a) The organisation operating an FSTD who wishes to modify, upgrade, de-activate or relocate its FSTD should notify the competent authority. When considering applications for a change of the existing FSTD qualification level, the competent authority should ensure that accountability for the change is clearly defined.
- (b) An individual department manager of the competent authority should be appointed under whose personal authority an FSTD qualification may be changed.
- (c) The written application for a change, including appropriate extracts from the qualification test guide indicating proposed amendments should be submitted in a format and manner as specified by the competent authority. This application should be submitted no later than 30 days before the date of intended change, unless otherwise agreed with the competent authority.
- (d) On receipt of an application for a change of the existing FSTD qualification level, the competent authority should conduct such evaluations and inspections as are necessary to ensure that the full implications of the request have been addressed by the organisation operating the FSTD.
- (e) During the processing of a change request, the continued adequacy of the compliance monitoring should be reviewed.
- (f) When the request has been considered and examined, the competent authority should decide on the depth of inspection of the FSTD that is required.
- (g) The department manager, if satisfied that the organisation operating the FSTD remains competent and the qualification level of the FSTD can be maintained, should issue revised FSTD qualification documentation, as appropriate.
- (h) The competent authority should inform the organisation operating the FSTD of its decision within 30 days of receipt of all documentation where no evaluation is required, or within 14 days of any subsequent evaluation.
- (i) Such documentation includes the appropriate extracts from the QTG amended, when necessary, to the competent authority's satisfaction.

# **GM1 ARA.FSTD.130 Changes**

ED Decision 2012/006/R

### **QUALIFICATION OF NEW TECHNOLOGY OR SYSTEMS**

Where an update to an FSTD involves a change of technology or the addition of a new system or equipment that is not covered by the qualification basis used for the existing qualification, an evaluation of such changes may not be possible using this original qualification basis. For these cases, the specific changes can be qualified by using newer Certification Specifications, new AMCs or alternative means of compliance, that apply to these changes, without affecting the overall qualification of the FSTD. This approach should be documented.



# ARA.FSTD.135 Findings and corrective actions – FSTD qualification certificate

Regulation (EU) No 290/2012

The competent authority shall limit, suspend or revoke, as applicable, an FSTD qualification certificate in accordance with <u>ARA.GEN.350</u> in, but not limited to, the following circumstances:

- (a) obtaining the FSTD qualification certificate by falsification of submitted documentary evidence;
- (b) the organisation operating the FSTD can no longer demonstrate that the FSTD complies with its qualification basis; or
- (c) the organisation operating the FSTD no longer complies with the applicable requirements of Part-ORA.

# AMC1 ARA.FSTD.135 Findings and corrective actions – FSTD qualification certificate

ED Decision 2012/006/R

### **GENERAL**

- (a) The competent authority's inspection and monitoring process should confirm the competent authority's continued confidence in the effectiveness of the compliance monitoring system of the organisation operating an FSTD, and its ability to maintain an adequate standard.
- (b) If the competent authority is not satisfied, the organisation operating an FSTD should be informed in writing of the details of the conduct of its operation which are causing the competent authority concern. The competent authority should require corrective action to be taken within a specified period (see <a href="MMC2 ARA.FSTD.100(a)(1)">AMC2 ARA.FSTD.100(a)(1)</a> point (b)).
- (c) In the event that an organisation operating an FSTD fails, in spite of warning and advice, to satisfy the competent authority's concerns, a final written warning should, whenever possible, be given to the organisation together with a firm date by which specified action to satisfy the competent authority should be taken. It should be made clear that failure to comply may result in enforced limitation or suspension of the FSTD's qualification.
- (d) Circumstances may, however, preclude recourse to the process described under (a) to (c). In such cases the competent authority's duty to preserve quality of training, testing and checking is of paramount importance and therefore the competent authority may immediately limit or suspend any FSTD qualification which it has issued.

# AMC2 ARA.FSTD.135 Findings and corrective actions – FSTD qualification certificate

ED Decision 2012/006/R

### SUSPENSION AND LIMITATION

- (a) When a decision has been taken to suspend, or limit, an FSTD qualification certificate, the organisation operating an FSTD should be informed immediately by the quickest available means.
- (b) In the event of full suspension of an FSTD qualification certificate, the organisation operating an FSTD should be instructed that the FSTD concerned cannot be used for any credited training,



- testing or checking. The "quickest available means" will in most situations mean the use of a facsimile or email message.
- (c) This should be followed by a formal letter giving notice of suspension, or limitation, restating the requirement to cease operations as applicable, and also setting out the conditions on which suspension may be lifted.
- (d) If it becomes apparent to the competent authority that all operations have ceased over a period in excess of 6 months, the competent authority should consider opening the warning process described in <a href="MMC1 ARA.FSTD.135">AMC1 ARA.FSTD.135</a>, points (a) to (d).
- (e) The FSTD qualification certificate should not remain suspended indefinitely. Further steps may be taken by the organisation operating an FSTD to reinstate the FSTD qualification or, in default, should be taken by the competent authority to revoke the FSTD qualification certificate. Should an organisation operating an FSTD wish to dispute the suspension of its FSTD's qualification certificate, it should be informed of such rights of appeal as exist under national regulations. If an appeal is lodged, the FSTD qualification may remain suspended until the appeal process is complete.
- (f) Suspension of an FSTD qualification certificate may be lifted on appeal or if the organisation operating an FSTD restores the FSTD to its previously acceptable standard.
- (g) In neither case should operations be permitted to restart until it has been demonstrated that the cause of the suspension or limitation has been rectified. The competent authority may require a special evaluation depending on the severity of the problem.
- (h) The competent authority should issue a formal notice of the lifting of suspension before the organisation operating an FSTD is permitted to resume use of an FSTD.

# AMC3 ARA.FSTD.135 Findings and corrective actions – FSTD qualification certificate

ED Decision 2012/006/R

### **REVOCATION**

- (a) The competent authority should give the organisation operating an FSTD notice that it intends to revoke the FSTD qualification followed by a formal letter of revocation.
- (b) Should an organisation operating an FSTD wish to dispute this revocation, it should be informed of such rights of appeal as exist under applicable regulations. Once revoked, there can be no further activities under the terms of the FSTD qualification.

# **ARA.FSTD.140 Record keeping**

Regulation (EU) No 1178/2011

In addition to the records required in <u>ARA.GEN.220</u>, the competent authority shall keep and update a list of the qualified FSTDs under its supervision, the dates when evaluations are due and when such evaluations were carried out.





# 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) 2024/2076

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.

[applicable until 12 February 2025 - Regulation (EU) 1178/2011]

The competent authority shall appoint one or more medical assessor(s) to undertake the aero-medical tasks described in this Regulation. The medical assessor shall be licensed and qualified in medicine and have the following:

- (a) postgraduate work experience in clinical medicine;
- (b) specific knowledge and experience in aviation medicine and aero-medical practice;
- (c) specific training in aero-medical certification.

[applicable from 13 February 2025 - Regulation (EU) 2024/2076]

# **AMC1 ARA.MED.120 Medical assessors**

ED Decision 2012/006/R

### **EXPERIENCE AND KNOWLEDGE**

Medical assessors should:

- (a) have considerable experience of aero-medical practice and have undertaken a minimum of 200 class 1 medical examinations or equivalent; and
- (b) maintain their medical professional competence in aviation medicine. The following should count towards maintaining medical professional competence:
  - (1) undertaking regular refresher training;
  - (2) participating in international aviation medicine conferences;
  - (3) undertaking research activities, including publication of results of the research.



# **AMC2 ARA.MED.120 Medical assessors**

ED Decision 2012/006/R

### **TASKS**

Medical assessors should:

- (a) provide lectures in basic, advanced and refresher training courses for aero-medical examiners (AMEs) and aero-medical centres (AeMCs);
- (b) carry out supervision and audits of AeMCs, AMEs and AME training facilities; and
- (c) perform the aero-medical assessment of applicants for, or holders of, medical certificates after referral to the licensing authority.

# ARA.MED.125 Referral to the licensing authority

Regulation (EU) 2024/2076

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.

### [applicable until 12 February 2025 - Regulation (EU) 290/2012]

When an AeMC or aero-medical examiner (AME) has referred the decision on the fitness of an applicant to the medical assessor of the licensing authority, the following steps shall be taken:

- (a) the medical assessor or medical staff designated by the medical assessor shall evaluate the relevant medical documentation and request further medical documentation, examinations and tests where necessary;
- (b) the medical assessor shall determine the applicant's fitness for the issuance of a medical certificate with one or more limitation(s) if necessary;
- (c) the medical assessor shall inform the AeMC or AME of the decision;
- (d) in case the applicant is assessed as fit, the medical assessor shall issue, if appropriate, the medical certificate or delegate the issuance to the AeMC or AME that referred the respective applicant.

[applicable from 13 February 2025 - Regulation (EU) 2024/2076]

# AMC1 ARA.MED.125 Referral to the licensing authority

ED Decision 2012/006/R

### REFERRAL TO THE LICENSING AUTHORITY

- (a) The licensing authority should supply the AeMC or AME with all necessary information that led to the decision on aero-medical fitness.
- (b) The licensing authority should ensure that unusual or borderline cases are evaluated on a common basis.



# ARA.MED.126 Limitation, suspension or revocation of medical certificates

Regulation (EU) 2024/2076

- (a) The licensing authority shall establish a procedure to limit, suspend or revoke a medical certificate.
- (b) The licensing authority shall limit, suspend or revoke a medical certificate if there is evidence that:
  - (1) a medical certificate is falsified or obtained by a false declaration or false evidence;
  - (2) a medical certificate is used in violation of the provisions of point <u>MED.A.020</u> of Annex IV;
  - (3) the holder of a medical certificate is no longer compliant with Annex IV (Part-MED);
- (c) The licensing authority may also suspend or revoke a medical certificate upon the written request of the holder of a medical certificate.
- (d) In case of limitation, suspension or revocation of a medical certificate, the licensing authority shall inform the issuing AME or AeMC about the reason for limitation, suspension or revocation.
- (e) In case of suspension or revocation of a medical certificate, the licensing authority shall ensure that the provisions of point <u>MED.A.046</u> of Annex IV (Part-MED) are complied with.
- (f) The licensing authority shall establish a procedure for reinstating a medical certificate.

[applicable from 13 February 2025 - Regulation (EU) 2024/2076]

# ARA.MED.128 Consultation procedure

Regulation (EU) 2024/2076

The competent authority shall establish a consultation procedure for the AeMCs and AMEs in accordance with Annex IV (Part-MED).

[applicable from 13 February 2025 - Regulation (EU) 2024/2076]

## ARA.MED.130 Medical certificate format

Regulation (EU) 2024/2076

The medical certificate shall conform to the following specifications:

- (a) Content
  - (1) State where the pilot licence has been issued or applied for (I),
  - Class of medical certificate (II),

[applicable until 12 February 2025 - Regulation (EU) 245/2014]

(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 and at in script (III),

[applicable until 12 February 2025 - Regulation (EU) 245/2014]



(3) Medical 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 and Latin script (III)

[applicable from 13 February 2025 - Regulation (EU) 2024/2076]

- (4) Name of holder (IV),
- (5) Nationality of holder (VI),
- (6) Date of birth of holder: (dd/mm/yyyy) (XIV),

## [applicable until 12 February 2025 - Regulation (EU) 245/2014]

(6) Date of birth of holder: (dd/mm/yyyy) (IVa)

[applicable from 13 February 2025 - Regulation (EU) 2024/2076]

- (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

## [applicable until 12 February 2025 - Regulation (EU) 245/2014]

- (9) Expiry date of the medical certificate (IX) for:
  - (i) Class 1,
  - (ii) Class 1 single-pilot commercial operations carrying passengers,
  - (iii) Class 2,
  - (iv) LAPL

[applicable from 13 February 2025 - Regulation (EU) 2024/2076]

- (10) Date of medical examination
- (11) Date of last electrocardiogram

### [applicable until 12 February 2025 - Regulation (EU) 245/2014]

(11) Date of last and next electrocardiogram

[applicable from 13 February 2025 - Regulation (EU) 2024/2076]

(12) Date of last audiogram

### [applicable until 12 February 2025 - Regulation (EU) 245/2014]

(12) Date of last and next audiogram

[applicable from 13 February 2025 - Regulation (EU) 2024/2076]

(12a) Date of last and next ophthalmological examination

[applicable from 13 February 2025 - Regulation (EU) 2024/2076]



- (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)
- (15) Other information

[applicable from 13 February 2025 - Regulation (EU) 2024/2076]

(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.

### [applicable until 12 February 2025 - Regulation (EU) 245/2014]

(b) 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.

[applicable from 13 February 2025 - Regulation (EU) 2024/2076]

(c) Language: Certificates shall be written in the national language(s) and in English and such other languages as the licensing authority deems appropriate.

## [applicable until 12 February 2025 - Regulation (EU) 245/2014]

(c) Language: Medical certificates shall be written in the national language(s) and in English and such other languages as the competent authority deems appropriate.

[applicable from 13 February 2025 - Regulation (EU) 2024/2076]

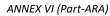
(d) All dates on the medical certificate shall be written in a dd/mm/yyyy format.

# 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.





SUBPART MED – SPECIFIC REQUIREMENTS RELATING TO AERO-MEDICAL CERTIFICATION

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

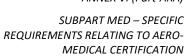
(English and any language(s) determined by the competent authority)

Requirements

"European Union" to be deleted for non-EU Member States

Size of each page shall be one eighth A4

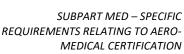
1	National language(s)/
	Authority that issued or is to issue the pilot licence
Ш	National language(s):/Certificate number
IV	National language(s):/
	Last and first name of holder:
XIV	National language(s):/Date of birth: (dd/mm/yyyy)
VI	National language(s)/Nationality:
VII	National language(s)/
	Signature of holder:
	2
	2





	3
XI	National language(3)/ Stamp.
XI	National language(s)/Stamp:
	Signature of issuing AME/medical assessor /(GMP):
х	National language(s)/* Date of issue: (dd/mm/yyyy)
XIII	National language(s)/Limitations: Code. Description:

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 aeromedical 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

# **ARA.MED.135 Aero-medical forms**

Regulation (EU) 2024/2076

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.

[applicable until 12 February 2025 - Regulation (EU) 290/2012]

The competent authority shall provide the AMEs with the format for the following documents:

- (a) the application form for a medical certificate;
- (b) the examination report form for class 1 and class 2 applicants;
- (c) the examination report form for light aircraft pilot licence (LAPL) applicants.

[applicable from 13 February 2025 - Regulation (EU) 2024/2076]

<sup>\*</sup> Date of issue is the date the certificate is issued and signed





# AMC1 ARA.MED.135(a) Aero-medical forms

ED Decision 2019/002/R

### **APPLICATION FORM FOR A MEDICAL CERTIFICATE**

The form referred to in <u>ARA.MED.135(a)</u> 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

(1) State of licence issue:	(2) Medical certificate applied for: class 1 □ class 2 □ LAPL □					
(3) Surname:	(4) Previous surname(s):		(12) Application Initial □ Revalidation/Renewal □			
(5) Forenames:	(6) Date of birth (dd/mm/yyyy):		(7) Sex Male □ Female □	(13) Reference number:		
(8) Place and country of birth:	(9) Nationality	:		(14) Ty	pe of licence applied for:	
(10) Permanent address:	(11) Postal add	dress	(if different)	(15) O	ccupation (principal)	
Carreton	Country			(16) Employer		
Country: Telephone No.: Mobile No.: e-mail:  Country: Telephone No.:				(17) Last medical examination Date: Place:		
(18) Aviation licence(s) held (type): Licence number: State of issue:	(19) Any Limitations on Licence/ Medical Certificate No □ Yes □ Details:					
(20) Have you ever had an aviation moderatificate denied, suspended or revolutioning authority?  No □ Yes □ Date: Co		(21) Flight time hours total: (22) Flight time hours since last medical:				
Details:	(23) Aircraft class /type(s) presently flown:					
(24) Any aviation accident or reporte since last medical examination?		(25) Type of flying intended:				
No ☐ Yes ☐ Date: Place: Details:			(26) Present flying activity: Single pilot □ Multi pilot □			
(27) Do you drink alcohol?  ☐ No ☐ Yes, amount (29) Do you smoke tobacco? ☐ No, n date stopped:  ☐ Yes, state type and amount:		Do you current □ Yes □ Stat	•	ny medication? lose, date started and why:		

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)

ANNEX VI (Part-ARA)

SUBPART MED – SPECIFIC REQUIREMENTS RELATING TO AERO-MEDICAL CERTIFICATION

	Yes	No		Yes	No		Yes	No	Family history of:	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			113 Head injury or			124 A positive HIV test			171 High blood		
contact lenses ever			concussion		-			ļ	pressure	-	+
worn			114 Frequent or severe headaches			125 Sexually transmitted disease			172 High cholesterol		
103 Spectacle/contact	+	$\vdash$	115 Dizziness or fainting	+		126 Sleep disorder/	+		173 Epilepsy	+	+
lens prescriptions			spells			apnoea syndrome			-   -   -		
change since last medical exam.			116 Unconsciousness for any reason			127 Musculoskeletal illness/impairment			174 Mental illness or suicide		
104 Hay fever, other allergy			117 Neurological disorders; stroke,			128 Any other illness or injury			175 Diabetes		
105 Asthma, lung disease			epilepsy, seizure, paralysis, etc			129 Admission to hospital			176 Tuberculosis		
106 Heart or vascular trouble			118 Psychological/ psychiatric trouble of			130 Visit to medical practitioner since last			177 Allergy/ asthma/eczema		
107 High or low blood pressure			any sort			medical examination			178 Inherited disorders		
108 Kidney stone or blood in urine			119 Alcohol/drug/ substance abuse			131 Refusal of life insurance			179 Glaucoma		
109 Diabetes, hormon disorder	е		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			Females only:		
						service			150 Gynaecological,		
111 Deafness, ear			122 Anaemia / Sickle			134 Award of pension	T		menstrual problems		
disorder			cell trait/other blood disorders			or compensation for injury or illness			151 Are you pregnant?		

(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).

Date Signature of applicant Signature of AME/(GMP)/ (medical assessor)	

### INSTRUCTIONS FOR COMPLETION OF THE APPLICATION FORM FOR A MEDICAL CERTIFICATE

This application form and all attached report forms will be transmitted to the licensing authority. Medical confidentiality shall be respected at all times.

The applicant should personally complete, in full, all questions (sections) on the application form. Writing should be legible and in block capitals, using a ball-point pen. Completion of this form by typing/printing is also



SUBPART MED – SPECIFIC REQUIREMENTS RELATING TO AERO-MEDICAL CERTIFICATION

acceptable. If more space is required to answer any questions, a plain sheet of paper should be used, bearing the applicant's name and signature, and the date of signing. The following numbered instructions apply to the numbered headings on the application form for a medical certificate.

Failure to complete the application form in full, or to write legibly, may result in non-acceptance of the application form. The making of false or misleading statements or the withholding of relevant information in respect of this application may result in criminal prosecution, denial of this application and/or withdrawal of any medical certificate(s) granted.

1.	LICENSING AUTHORITY: State name of country this application is to be forwarded to.	17. LAST APPLICATION FOR A MEDICAL CERTIFICATE: State date (day, month, year) and place (town, country) Initial applicants state 'NONE'.
2	MEDICAL CERTIFICATE APPLIED FOR:	18. LICENCE(S) HELD (TYPE):
۷.	Tick appropriate box.	State type of licence(s) held.
	Class 1: Professional Pilot	Enter licence number and State of issue.
	Class 2: Private Pilot	If no licences are held, state 'NONE'.
	LAPL	·
3.	SURNAME:	19. ANY LIMITATIONS ON THE LICENCE(S)/MEDICAL
	State surname/family name.	CERTIFICATE:
		Tick appropriate box and give details of any limitations on your
		licence(s)/medical certificate, e.g. vision, colour vision, safety pilot, etc.
4.	PREVIOUS SURNAME(S):	20. MEDICAL CERTIFICATE DENIAL, SUSPENSION OR
	If your surname or family name has changed for	REVOCATION:
	any reason, state previous name(s).	Tick 'YES' box if you have ever had a medical certificate denied,
		suspended or revoked, even if only temporary.
		If 'YES', state date (dd/mm/yyyy) and country where it occurred.
5.	FORENAME(S):	21. FLIGHT TIME TOTAL:
	State first and middle names (maximum three).	State total number of hours flown.
6.	DATE OF BIRTH:	22. FLIGHT TIME SINCE LAST MEDICAL:
	Specify in order dd/mm/yyyy.	State number of hours flown since your last medical examination.
7.	SEX:	23. AIRCRAFT CLASS/TYPE(S) PRESENTLY FLOWN:
	Tick appropriate box.	State name of principal aircraft flown, e.g. Boeing 737, Cessna 150, etc.
8.	PLACE AND COUNTRY OF BIRTH:	24. ANY AVIATION ACCIDENT OR REPORTED INCIDENT SINCE
	State town and country of birth.	LAST MEDICAL EXAMINATION:
		If 'YES' box ticked, state date (dd/mm/yyyy) and country of
		accident/incident.
9.	NATIONALITY:	25. TYPE OF FLYING INTENDED:
	State name of country of citizenship.	State whether airline, charter, single-pilot, commercial air transport,
- 10	DED. A. MENT ADDRESS	carrying passengers, agriculture, pleasure, etc.
10.	PERMANENT ADDRESS:	26. PRESENT FLYING ACTIVITY:
	State permanent postal address and country. Enter telephone area code as well as telephone number.	Tick appropriate box to indicate whether you fly as the SOLE pilot or
11	POSTAL ADDRESS (IF DIFFERENT):	not. 27. DO YOU DRINK ALCOHOL?
11.	If different from permanent address, state full	Tick applicable box. If yes, state weekly alcohol consumption e.g. 2
	current postal address including telephone number	litres beer.
	and area code. If the same, enter 'SAME'.	18.65 265.1
12.	APPLICATION:	28. DO YOU CURRENTLY USE ANY MEDICATION?:
	Tick appropriate box.	If 'YES', give full details - name, how much you take and when, etc.
		Include any non-prescription medication.
13.	REFERENCE NUMBER:	29. DO YOU SMOKE TOBACCO?
	State reference number allocated to you by the	Tick applicable box. Current smokers state type (cigarettes, cigars, pipe)
	licensing authority	and amount (e.g. 2 cigars daily; pipe – 1 oz. weekly)
	Initial applicants enter 'NONE'.	
14.	TYPE OF LICENCE APPLIED FOR:	GENERAL AND MEDICAL HISTORY
	State type of licence applied for from the following	All items under this heading from number 101 to 179 inclusive should have
	list:	the answer 'YES' or 'NO' ticked. You should tick 'YES' if you have ever had
	Aeroplane Transport Pilot Licence	the condition in your life and describe the condition and approximate date
	Aeroplane Transport Pilot Licence Multi-Pilot Licence	the condition in your life and describe the condition and approximate date in the (30) remarks section. All questions asked are medically important
	Aeroplane Transport Pilot Licence	the condition in your life and describe the condition and approximate date

ANNEX VI (Part-ARA)

SUBPART MED - SPECIFIC REQUIREMENTS RELATING TO AERO-MEDICAL CERTIFICATION

Private Pilot Licence	Items numbered 170 to 179 relate to immediate family history, whereas
Sailplane Pilot Licence	items numbered 150 to 151 should be answered by female applicants only.
Balloon Pilot Licence Light Aircraft Pilot Licence And whether Fixed Wing / Rotary Wing / Both Other – Please specify  15. OCCUPATION (PRINCIPAL):	If information has been reported on a previous application form for a medical certificate and there has been no change in your condition, you may state 'Previously reported; no change since'. However, you should still tick 'YES' to the condition.
Indicate your principal employment.	Do not report occasional common illnesses such as colds.
16. EMPLOYER:  If principal occupation is pilot, then state employer's name or if self-employed, state 'self'.	31. DECLARATION AND CONSENT TO OBTAINING AND RELEASING INFORMATION:  Do not sign or date these declarations until indicated to do so by the AME/GMP who will act as witness and sign accordingly.

# AMC1 ARA.MED.135(b);(c) Aero-medical forms

ED Decision 2012/006/R

MEDICAL EXAMINAT	ION REPO	RT FO	RMS											
The forms referred following forms and								e inf	ormatio	n indic	ate	d in the		
MEDICAL EXAMINAT	ION REPO	RT FO	RM FC	R CLASS	1 & CLASS	2 APF	PLICANT	S		A A E DI CAI	IN C	ONIFIDENCE		
(221) = 1 11 1		Los	_, I	(2.2.2)	Lan	/	, .	\		_		ONFIDENCE		
(201) Examination catego	ry	(20:	'	(203)	(204)	(205	, I	206) BI		<u> </u>	_	- resting		
Initial □ Revalidation □ Re	enewal 🗆	Hei	٠ I	Weight	Colour eye	Colo			e-seated	Rate		nythm:		
	enewai 🗀	(cm	'	(kg)			<b>—</b>	mmHg)	_	(bpm)		gular 🗆		
Special referral  Clinical exam: Check each	itam Narma	lAhnar	mal Nor	mal Abaarm	hal		;	Systolic	Diastolic		1111	egular 🗆		
(208) Head, face, neck, sci		IOIIDAII	mai Nor	I	(218) Abdoi	mon k	aornia liv	or colo	n .			T		
(209) Mouth, throat, teetl	•				(219) Anus,			er, spied	211					
(210) Nose, sinuses	11				(220) Genit			1						
(211) Ears, drums, eardru	m motility				(221) Endo									
(212) Eyes - orbit & adnex		de			(222) Uppe		•	ioints						
(213) Eyes - pupils and op	•	u3		+	(223) Spine									
(214) Eyes - ocular motilit		s												
(215) Lungs, chest, breast					(224) Neurologic - reflexes, etc. (225) Psychiatric									
(216) Heart					(226) Skin, identifying marks and lymphatics									
(217) Vascular system		(227) Gener			.5 4.14 1									
(228) Notes: Describe eve	rv abnormal	finding	. Enter a	pplicable ite	<u> </u>			nent.		- 1				
,	•													
Visual acuity														
(229) Distant vision at 5m/	′6m(236) <b>Pul</b> ¬	monary	y functio	<del>``</del>	aemoglobin									
Uncorrected		Spe	ectacles	Contact lenses	FEV <sub>1</sub> /FV	ε		%				_ (unit)		
Right eye	Corr. to				<u> </u>									
Left eye	Corr. to				Normal	□Ab	normal		Normal	☐ Abn	Abnormal $\square$			
Both eyes	Corr. to				<u> </u>									
					· · · · · ·				onormal 🗆					
(230) Intermediate vision	Uncorre			rrected	Glucos	Glucose Proteir		ein	Blo	od		Other		
N14 at 100 cm	Yes	No	Yes	No	L									
Right eye					Accomp	anying	g reports							
Left eye								Not		Normal	- 1	Abnormal/		
Both eyes					(220) 50			per	formed			Comment		
(224) Managirian			6		(238) EC			+						
` '	Uncorrected			ected	(239) Au			+-			-			
N5 at 30-50 cm Y	res N	-	Yes	No	(240) Op (241) OR			+			-			
Left eye		_			(241) OR						-			
		_			<del>    `                                 </del>		iry functio	n			-			
Both eyes					(244) Ot			11			$\dashv$			
(232) Spectacles	(233)	Contact	lenses		(244) 00	1101 (00								
/ - [	,/							1		1				



ANNEX VI (Part-ARA) SUBPART MED - SPECIFIC

REQUIREMENTS RELATING TO AERO-MEDICAL CERTIFICATION

Yes □ No	) <b></b>			□ No				(2.25)								
Type:		Carla	Type		Т	A				commen		th. Dafa				
Refraction		Sph		Cyl	+ '	Axis	Add	- Name	эт арр	licant: L	ate of bir	th: Refe	renc	e num	iber:	
Right eye Left eye			-		╁		+	-								
(313) Colou	ır nercentii	าท	Norn	nal П	I A	bnorm	<u> </u>	]	for cla	cc·		_				
Pseudo-iso							olates)	_				undersig	ned i	(conv.	attac	hed) for
No of plate		nates	,,	of er		٠.	natesj	class: -			. Issucu by	unacisigi	iicu i	(сору с	attac	rica, ioi
(234) Heari								Un								
(when 239/		rforme	ed) Rig	ht ear	r	Left	ear				er evaluat	ion. If yes,	, why	and t	to wh	nom?
Conversation	•			s 🗆		Yes		7				•				
with back to	urned to ex	amine	er No			No		(248)	omme	ents, limit	tations					
Audiometry	/															
Hz	500	10	000	20	000		3000									
Right																
Left																
								<u> </u>								
(249) <b>AME</b> d	leclaration	:														
I hereby ce	rtify that I/	my AN	/IE group	have	pers	onally	examined 1	the applicant	name	d on this	medical ex	kaminatio	n rep	ort an	nd th	at this
		ment	embodie	s my	findi	ngs co	mpletely ar	nd correctly.								
(250) Place	and date:					AM	1E name and	d address:					AME	certif	icate	No.:
						_										
AME signat	ure:															
						- 1	nail:									
							lephone No.	.:								
						rei	efax No.:									
Shaaca	ireas do	not	requi	re cc	omp	oletic	on									
								\PPLICANT	'S				MED	DICAL I	IN CC	ONFIDENCE
	EXAMIN	ATIO		ORT		RM FC		APPLICANT	rs (20	5)	(206) Blc		_			ONFIDENCE - resting
MEDICAL (201) Exam	EXAMIN	ATIO		ORT (	FOR	RM FC	OR LAPL A	_	(20	5) our hair	(206) Blo	od	(2		ulse -	
MEDICAL (201) Exam	EXAMIN	<b>ATIO</b> egory		ORT I	FOR (202)	RM FC	OR LAPL A	(204)	(20	•	pressure (mmHg)	od	(2 R	207) Pı	Rh reg	resting ythm: gular
MEDICAL  (201) Exam Initial E Revalidatio Special refe	EXAMIN ination cate n	ATIO egory Rene	N REP(	ORT I	FOR (202) Heigh (cm)	RM FC	(203) Weight (kg)	(204) Colour eye	(20	•	pressure	od	(2 R (k	207) Pı ate	Rh reg	resting
MEDICAL (201) Exam Initial E Revalidatio Special refe Clinical exam	EXAMIN ination cat  n	ATIO egory Rene	N REPO	ORT I	FOR (202) Heigh (cm)	RM FC	(203) Weight (kg)	(204) Colour eye	(20 Col	our hair	pressure (mmHg) Systolic	ood -seated Diastolio	(2 R (k	207) Pı ate	Rh reg	resting ythm: gular
MEDICAL  (201) Exam Initial [ Revalidatio Special refe Clinical exar (208) Head	EXAMIN ination cat in	ATIO egory Rene ach ite	N REPO	ORT I	FOR (202) Heigh (cm)	RM FC	(203) Weight (kg)	(204) Colour eye	(20 Col omen,	our hair hernia, li	pressure (mmHg) Systolic	ood -seated Diastolio	(2 R (k	207) Pı ate	Rh reg	resting ythm: gular
MEDICAL  (201) Exam Initial [ Revalidatio Special refe Clinical exar (208) Head (209) Mout	EXAMIN ination cat in	ATIO egory Rene ach ite	N REPO	ORT I	FOR (202) Heigh (cm)	RM FC	(203) Weight (kg)	(204) Colour eye nal (218) Abd (219) Anu	(20 Col	our hair hernia, li um	pressure (mmHg) Systolic iver, splee	ood -seated Diastolio	(2 R (k	207) Pı ate	Rh reg	resting ythm: gular
MEDICAL  (201) Exam Initial [ Revalidatio Special refe Clinical exar (208) Head (209) Mout (210) Nose,	ination cat  n	egory Rene ach iter , scalp	ewal 🗆	ORT I	FOR (202) Heigh (cm)	RM FC	(203) Weight (kg)	(204) Colour eye nal (218) Abd (219) Anu (220) Gen	(20 Col	hernia, li um nary syste	pressure (mmHg) Systolic iver, splee	ood -seated Diastolio	(2 R (k	207) Pı ate	Rh reg	resting ythm: gular
MEDICAL  (201) Exam Initial [ Revalidatio Special refe Clinical exar (208) Head (209) Mout (210) Nose, (211) Ears,	ination cat in	Rene ach iter , scalp eeth	ewal  motility	ORT I	FOR (202) Heigh (cm)	RM FC	(203) Weight (kg)	(204) Colour eye nal (218) Abd (219) Anu (220) Gen (221) Ende	omen, s, recti	hernia, li um nary syste system	pressure (mmHg) Systolic iver, splee	ood -seated Diastolio	(2 R (k	207) Pı ate	Rh reg	resting ythm: gular
MEDICAL  (201) Exam Initial [ Revalidatio Special refe Clinical exar (208) Head (209) Mout (210) Nose, (211) Ears, (212) Eyes	ination cat  n n: Check ea , face, neck h, throat, t sinuses drums, ear orbit & ad	Rene ach iter , scalp eeth drum r	ewal  motility visual fie	ORT I	FOR (202) Heigh (cm)	RM FC	(203) Weight (kg)	(204) Colour eye nal (218) Abd (219) Anu (220) Gen (221) Ende (222) Upp	omen, s, rectrito-uri ocrine er & lo	hernia, li um nary syste system ower limb	pressure (mmHg) Systolic iver, splee em	ood -seated Diastolio	(2 R (k	207) Pı ate	Rh reg	resting ythm: gular
MEDICAL  (201) Exam Initial [I Revalidatio Special refe Clinical exar (208) Head (209) Mout (210) Nose, (211) Ears, (212) Eyes (213) Eyes	ination cat  n	Rene ach iter , scalp eeth drum r nexa;	ewal  motility visual fie fundi	ORT I	FOR (202) Heigh (cm)	RM FC	(203) Weight (kg)	(204) Colour eye  (218) Abd (219) Anu (220) Gen (221) Ende (222) Upp (223) Spin	omen, s, rectrito-uri corine er & lo	hernia, li um nary syste system ower limb er muscul	pressure (mmHg) Systolic iver, splee em	ood -seated Diastolio	(2 R (k	207) Pı ate	Rh reg	resting ythm: gular
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MEDICAL  (201) Exam Initial E Revalidatio Special refe Clinical exar (208) Head (209) Mout (210) Nose, (211) Ears, (212) Eyes (213) Eyes (213) Eyes (214) Eyes (215) Lungs (216) Heart (217) Vascu (228) Notes Visual acuit (229) Distan  Right eye Left eye Both eyes	ination cat:  n	Rene ach itee , scalp peeth drum r nexa; v optic tility; r easts	motility visual fie fundi nystagmi  Corr. to Corr. to Corr. to	ORT     (	FOR (202) Heigh (cm) norm	nnt nal Noi	(203) Weight (kg)  rmalAbnorn  applicable it  Contact lenses	(204) Colour eye  nal (218) Abd (219) Anu (220) Gen (221) Ende (222) Upp (223) Spin (224) Neu (225) Psyc (226) Skin (227) Gen tem number b	omen, s, rectrito-uri cocrine er & lcl e, othhrologic i, ident eral sy oefore	hernia, li um nary syste system ower limb er muscul c - reflexe ifying ma stemic each con	pressure (mmHg) Systolic  iver, splee em s, joints loskeletal s, etc.  irks and ly  nment.	Diastolic  Diastolic  n  mphatics  Normal		207) Pri ate ppm)	ulse - Rh regging irre	resting ythm: gular  egular   egular   (unit)
MEDICAL  (201) Exam Initial E Revalidatio Special refe Clinical exar (208) Head (209) Mout (210) Nose, (211) Ears, (212) Eyes (213) Eyes (213) Eyes (214) Eyes (215) Lungs (216) Heart (217) Vascu (228) Notes Visual acuit (229) Distan  Right eye Left eye Both eyes	ination cat:  n	Rene ach itee , scalp peeth drum r nexa; v optic tility; r easts	motility visual fie fundi nystagmi  Corr. to Corr. to Corr. to Uncorr	ORT     (	FOR (202) Heigh (cm) norm	enter a	(203) Weight (kg)  rmalAbnorn  applicable it  Contact lenses	(204) Colour eye  (218) Abd (219) Anu (220) Gen (221) Ende (222) Upp (223) Spin (224) Neu (225) Psyc (226) Skin (227) Gen em number b	omen, s, rectrito-uri cocrine er & lcl e, othhrologic i, ident eral sy oefore	hernia, li um nary syste system ower limb er muscul c - reflexe ifying ma stemic each con	pressure (mmHg) Systolic  iver, splee em s, joints loskeletal s, etc.  irks and ly  mment.	Diastolic  Diastolic  mphatics  Normal		207) Pri ate ppm)	ulse - Rh regging irre	resting ythm: gular  egular   egular   (unit)
MEDICAL  (201) Exam Initial E Revalidatio Special refe Clinical exar (208) Head (209) Mout (210) Nose, (211) Ears, (212) Eyes (213) Eyes (213) Eyes (214) Eyes (215) Lungs (216) Heart (217) Vascu (228) Notes Visual acuit (229) Distan  Right eye Left eye Both eyes  (230) Interr N14 at 100	ination cat:  n	Rene ach itee , scalp peeth drum r nexa; v optic tility; r easts	motility visual fie fundi nystagmi  Corr. to Corr. to Corr. to	ORT     (	FOR (202) Heigh (cm) norm	nnt nal Noi	(203) Weight (kg)  rmalAbnorn  applicable it  Contact lenses	(204) Colour eye  nal (218) Abd (219) Anu (220) Gen (221) Ende (222) Upp (223) Spin (224) Neu (225) Psyc (226) Skin (227) Gen tem number b	omen, s, rectrictorine er & lcl e, other rologic i, ident eral sy pefore	hernia, li um nary syste system ower limb er muscul c - reflexe ifying ma stemic each con	pressure (mmHg) Systolic  iver, splee em s, joints loskeletal s, etc.  irks and ly  nment.   Abotein	Diastolic  Diastolic  n  mphatics  Normal		207) Pri ate ppm)	ulse - Rh regging irre	resting ythm: gular  egular   egular   (unit)
MEDICAL  (201) Exam Initial E Revalidatio Special refe Clinical exar (208) Head (209) Mout (210) Nose, (211) Ears, (212) Eyes (213) Eyes (213) Eyes (214) Eyes (215) Lungs (216) Heart (217) Vascu (228) Notes Visual acuit (229) Distan  Right eye Left eye Both eyes	ination cat:  n	Rene ach itee , scalp peeth drum r nexa; v optic tility; r easts	motility visual fie fundi nystagmi  Corr. to Corr. to Corr. to Uncorr	ORT     (	FOR (202) Heigh (cm) norm	enter a	(203) Weight (kg)  rmalAbnorn  applicable it  Contact lenses	(204) Colour eye  nal (218) Abd (219) Anu (220) Gen (221) Ende (222) Upp (223) Spin (224) Neu (225) Psyc (226) Skin (227) Gen tem number b	omen, s, rectrictorine er & lcl e, other rologic i, ident eral sy pefore	hernia, li um nary syste system ower limb er muscul c - reflexe ifying ma stemic each con	pressure (mmHg) Systolic  iver, splee em s, joints loskeletal s, etc.  irks and ly  nment.   Abotein	Diastolic  Diastolic  n  mphatics  Normal		207) Pri ate ppm)	ulse - Rh reg	resting ythm: gular  egular   egular   (unit)



(250) Place and date:

AME/GMP signature:

# Easy Access Rules for Aircrew (Regulation (EU) No 1178/2011)

ANNEX VI (Part-ARA)

AME certificate No./GMP

identification No.:

SUBPART MED – SPECIFIC REQUIREMENTS RELATING TO AERO-MEDICAL CERTIFICATION

(231) <i>Near vision</i> N5 at 30-50 cm	Uncor				(238) ECG
N5 at 30-50 cm	Uncor				(238) ECG
		rected	Corr	rected	(239) Audiogram
	Yes	No	Yes	No	(240) Ophthalmology
Right eye					(241) ORL (ENT)
Left eye					(242) Blood lipids
Both eyes					(243) Pulmonary function
					(244) Other (what?)
(232) Spectacles		(233) Cont	act lenses		
Yes □ No □		Yes 🗆 No			
Туре:		Туре:			(247) AME/GMP recommendation:
Refraction	Sph	Cyl	Axis	Add	Name of applicant: Date of birth: Reference number:
Right eye					
Left eye					
(313) Colour perception	n	Normal	Abnorm	nal 🗆	☐ Fit for medical certificate for LAPL
Pseudo-isochromatic pla	ates	• •	iihara (24 p	olates)	☐ Medical certificate issued by undersigned (copy attached)
No of plates:		No of err	ors:		LAPL
(234) Hearing					☐ Unfit for class:
(when 239/241 not per				ear	☐ Deferred for further evaluation. If yes, why and to whom?
Conversational voice te	٠,	Yes 🗆	Yes		(248) Comments, limitations
with back turned to exa	miner	No 🗆	No		
Audiometry	1		1		
Hz 500	1000	20	00	3000	
Right					
Left					

## INSTRUCTIONS FOR COMPLETION OF THE MEDICAL EXAMINATION REPORT FORMS

E-mail: Telephone No.: Telefax No.:

The AME performing the examination should verify the identity of the applicant.

All questions (sections) on the medical examination report form should be completed in full. If an otorhinolaryngology examination report form is attached, then questions 209, 210, 211, and 234 may be omitted. If an ophthalmology examination report form is attached, then questions 212, 213, 214, 229, 230, 231, 232, and 233 may be omitted.

AME name and address:

Writing should be legible and in block capitals using a ball-point pen. Completion of this form by typing/printing is also acceptable. If more space is required to answer any question, a plain sheet of paper should be used, bearing the applicant's name, the AME's name and signature, and the date of signing. The following numbered instructions apply to the numbered headings on the medical examination report form.

Failure to complete the medical examination report form in full, as required, or to write legibly, may result in non-acceptance of the application in total and may lead to withdrawal of any medical certificate issued. The making of false or misleading statements or the withholding of relevant information by an AME may result in criminal prosecution, denial of an application or withdrawal of any medical certificate(s) granted.

### Shaded areas do not require completion for the medical examination report form for the LAPL.

201 EXAMINATION CATEGORY – Tick appropriate box.

Initial – Initial examination for either LAPL, class 1 or 2; also initial examination for upgrading from LAPL to class 2, or class 2 to 1 (notate 'upgrading' in box 248).

Renewal/Revalidation – Subsequent ROUTINE examinations.

ANNEX VI (Part-ARA)

SUBPART MED – SPECIFIC
REQUIREMENTS RELATING TO AEROMEDICAL CERTIFICATION

- Extended Renewal/Revalidation Subsequent ROUTINE examinations, which include comprehensive ophthalmological and otorhinolaryngology examinations.
- 202 HEIGHT Measure height, without shoes, in centimetres to nearest cm.
- 203 WEIGHT Measure weight, in indoor clothes, in kilograms to nearest kg.
- 204 COLOUR EYE State colour of applicant's eyes from the following list: brown, blue, green, hazel, grey, multi.
- 205 COLOUR HAIR State colour of applicant's hair from the following list: brown, black, red, fair, bald.
- 206 BLOOD PRESSURE Blood pressure readings should be recorded as Phase 1 for Systolic pressure and Phase 5 for Diastolic pressure. The applicant should be seated and rested. Recordings in mm Hg.
- 207 PULSE (RESTING) The pulse rate should be recorded in beats per minute and the rhythm should be recorded as regular or irregular. Further comments if necessary may be written in section 228, 248 or separately.
- 208 to 227 inclusive constitute the general clinical examination, and each of the boxes should be marked (with a tick) as normal or abnormal.
- 208 HEAD, FACE, NECK, SCALP To include appearance, range of neck and facial movements, symmetry, etc.
- MOUTH, THROAT, TEETH To include appearance of buccal cavity, palate motility, tonsillar area, pharynx and also gums, teeth and tongue.
- NOSE, SINUSES To include appearance and any evidence of nasal obstruction or sinus tenderness on palpation.
- EARS, DRUMS, EARDRUM MOTILITY To include otoscopy of external ear, canal, tympanic membrane. Eardrum motility by valsalva manoeuvre or by pneumatic otoscopy.
- 212 EYES ORBIT AND ADNEXA; VISUAL FIELDS To include appearance, position and movement of eyes and their surrounding structures in general, including eyelids and conjunctiva. Visual fields check by campimetry, perimetry or confrontation.
- 213 EYES PUPILS AND OPTIC FUNDI To include appearance, size, reflexes, red reflex and fundoscopy. Special note of corneal scars.
- 214 EYES OCULAR MOTILITY, NYSTAGMUS To include range of movement of eyes in all directions; symmetry of movement of both eyes; ocular muscle balance; convergence; accommodation; signs of nystagmus.
- 215 LUNGS, CHEST, BREASTS To include inspection of chest for deformities, operation scars, abnormality of respiratory movement, auscultation of breath sounds. Physical examination of female applicant's breasts should only be performed with informed consent.
- 216 HEART To include apical heartbeat, position, auscultation for murmurs, carotid bruits, palpation for trills.
- 217 VASCULAR SYSTEM To include examination for varicose veins, character and feel of pulse, peripheral pulses, evidence of peripheral circulatory disease.
- ABDOMEN, HERNIA, LIVER, SPLEEN To include inspection of abdomen; palpation of internal organs; check for inquinal hernias in particular.
- 219 ANUS, RECTUM Examination only with informed consent.
- 220 GENITO-URINARY SYSTEM To include renal palpation; inspection palpation male/female reproductive organs only with informed consent.
- 221 ENDOCRINE SYSTEM To include inspection, palpation for evidence of hormonal abnormalities/imbalance; thyroid gland.

ANNEX VI (Part-ARA)

SUBPART MED – SPECIFIC REQUIREMENTS RELATING TO AERO-MEDICAL CERTIFICATION

- 222 UPPER AND LOWER LIMBS, JOINTS To include full range of movements of joints and limbs, any deformities, weakness or loss. Evidence of arthritis.
- 223 SPINE, OTHER MUSCULOSKELETAL To include range of movements, abnormalities of joints.
- 224 NEUROLOGIC REFLEXES ETC. To include reflexes, sensation, power, vestibular system balance, romberg test, etc.
- 225 PSYCHIATRIC To include appearance, appropriate mood/thought, unusual behaviour.
- 226 SKIN, IDENTIFYING MARKS AND LYMPHATICS To include inspection of skin; inspection, palpation for lymphadenopathy, etc. Briefly describe scars, tattoos, birthmarks, etc. which could be used for identification purposes.
- 227 GENERAL SYSTEMIC All other areas, systems and nutritional status.
- NOTES Any notes, comments or abnormalities to be described extra notes if required on separate sheet of paper, signed and dated.
- 229 DISTANT VISION AT 5/6 METRES Each eye to be examined separately and then both together. First without correction, then with spectacles (if used) and lastly with contact lenses, if used. Record visual acuity in appropriate boxes. Visual acuity to be tested at either 5 or 6 metres with the appropriate chart for the distance.
- 230 INTERMEDIATE VISION AT 100 CM Each eye to be examined separately and then both together. First without correction, then with spectacles if used and lastly with contact lenses if used. Record visual acuity in appropriate boxes as ability to read N14 at 100 cm (Yes/No).
- NEAR VISION AT 30-50 CM. Each eye to be examined separately and then both together. First without correction, then with spectacles if used and lastly with contact lenses, if used. Record visual acuity in appropriate boxes as ability to read N5 at 30-50 cm (Yes/No).

Note: Bifocal contact lenses and contact lenses correcting for near vision only are not acceptable.

- SPECTACLES Tick appropriate box signifying if spectacles are or are not worn by applicant. If used, state whether unifocal, bifocal, varifocal or look-over.
- 233 CONTACT LENSES Tick appropriate box signifying if contact lenses are or are not worn. If worn, state type from the following list; hard, soft, gas-permeable or disposable.
- 313 COLOUR PERCEPTION Tick appropriate box signifying if colour perception is normal or not. If abnormal; state number of plates of the first 15 of the pseudo-isochromatic plates (Ishihara 24 plates) have not been read correctly.
- HEARING Tick appropriate box to indicate hearing level ability as tested separately in each ear at 2 m.
- URINALYSIS State whether result of urinalysis is normal or not by ticking appropriate box. If no abnormal constituents, state NIL in each appropriate box.
- PULMONARY FUNCTION When required or on indication, state actual FEV1/FVC value obtained in % and state if normal or not with reference to height, age, sex and race.
- HAEMOGLOBIN Enter actual haemoglobin test result and state units used. Then state whether normal value or not, by ticking appropriate box.
- 238 to 244 inclusive: ACCOMPANYING REPORTS One box opposite each of these sections must be ticked. If the test is not required and has not been performed, then tick the NOT PERFORMED box. If the test has been performed (whether required or on indication) complete the normal or abnormal box as appropriate. In the case of question 244, the number of other accompanying reports must be stated.
- 247 AME RECOMMENDATION The applicant's name, date of birth and reference number, should be entered here in block capitals. The applicable class of medical certificate should be indicated by a tick in the appropriate box. If a fit assessment is recommended and a medical certificate has been issued, this should be indicated in the appropriate box. An applicant may be recommended as fit for a lower class of medical

ANNEX VI (Part-ARA)

SUBPART MED – SPECIFIC REQUIREMENTS RELATING TO AERO-MEDICAL CERTIFICATION

certificate (e.g. class 2), but also be deferred or recommended as unfit for a higher class of medical certificate (e.g. class 1). If an unfit recommendation is made, applicable Part-MED paragraph references should be entered. If an applicant is deferred for further evaluation, the reason and the doctor or licensing authority to whom the applicant is referred should be indicated.

- 248 COMMENTS, LIMITATIONS, ETC. The AME's findings and assessment of any abnormality in the history or examination, should be entered here. The AME should also state any limitation required.
- 249 AME DETAILS The AME should sign the declaration, complete his/her name and address in block capitals, contact details and lastly stamp the relevant section with his/her designated AME stamp incorporating his/her AME number. The GMP identification no. is the number provided by the national medical system.
- 250 PLACE AND DATE The place (town or city) and the date of examination should be entered here. The date of examination is the date of the general examination and not the date of finalisation of the form. If the medical examination report is finalised on a different date, the date of finalisation should be entered in section 248 as 'Report finalised on ......'.

# GM1 ARA.MED.135(b);(c) Aero-medical forms

ED Decision 2012/006/R

### OPHTHALMOLOGY AND OTORHINOLARYNGOLOGY EXAMINATION REPORT FORMS

The ophthalmology and otorhinolaryngology examination report forms may be used as indicated in the following forms and corresponding instructions for completion.

### **OPHTHALMOLOGY EXAMINATION REPORT FORM**

Applicant's details

Complete this page fully and in block capitals – Refer to instructions for completion.

MEDICAL IN CONFIDENCE

(1) State applied to:		(2) Medical	certificate applied	for: class 1		class 2		
(3) Surname:		(4) Previous	surname(s):				cation: Initia on/Renewal	
(5) Forename(s):		(6) Date of b	oirth:	(7) Sex: Male Female		(13) Refer	ence numbe	r:
(301) Consent to release of mediattachments to the AME and, we lectronically stored data, are to licensing authority, providing the respected at all times.	where necessary, to o be used for com	the medical appletion of a m	assessor of the lice edical assessment	ensing author and will beco	ity, reco	ognising that d remain th	at these doc ne property o	uments or of the
Date	Signa	ature of applic	cant		Signat	ture of AM	E	
(302) Examination category: Initial  Revalidation  Renewal  Special referral	(303) Ophtha	almological his	story:					
Special referral -								
Clinical examination Check each item	Normal	Abnormal	` '	t vision at 5m	n/6m	S	Spectacles	Contact lenses

Left eye

Both eyes

Right eye

Left eye

Both eyes

(315) Intermediate vision at 1m

Uncorrected

(309) Fundi (Ophthalmoscopy)

(305) Eyes, Exterior

(slit lamp, ophth.)

(308) Pupillary reflexes

(306) Eye position and movements

(307) Visual fields (confrontation)

Spectacles

Contact

lenses

Corrected to

Corrected to

Corrected to

Corrected to

Corrected to



ANNEX VI (Part-ARA) SUBPART MED - SPECIFIC

REQUIREMENTS RELATING TO AERO-**MEDICAL CERTIFICATION** 

(310) Convergence	cm		(316) Near vision at 30-50cm				Spectacles	Contact	
			Un	correct				lenses	
(311) Accommodation	D		Right eye		Co	rrected to			
			Left eye		Co	rrected to			
(312) Ocular muscle balar	nce (in prisme did	optres)	Both eyes		Co	rrected to			
Distant at 5m/6m	Near at 30	-50 cm							
Ortho	Ortho		(317) Refrac	ction	Sph	Cylinder	Axis	Near (add)	
Eso	Eso		Right eye						
Exo	Exo		Left eye						
Hyper	Hyper		Actual refra	ction e	xamined	Spectacles p	orescription ba	sed	
Cyclo	Cyclo								
Tropia Yes No PhoriaY	es No		(318) Specto	acles		(319) C	ontact lenses		
Fusional reserve testing	Not performed	Normal Abnormal	Yes □No □			Yes □	No 🗆		
(313) Colour perception		Type:			Type:				
Pseudo-Isochromatic plat	tes Type: Ish	hara (24 plates)							
No of plates:	No of err	ors:	(320) Intra-	ocular <sub>l</sub>	oressure				
Advanced colour percept	ion testing indica	ted YesNo	Right (mmH	lg)		Left (m	mHg)		
Method:									
Colour SAFE Colour UNSA	\FE		Method			Norma	I □Abnormal		
			1						
(321) Ophthalmological re	marks and recon	nmendation:							
(322) Examiner's declarati	on:								
I hereby certify that I/my	• .	•	• •	ned on	this medic	cal examina	tion report and	that this	
report with any attachme	ent embodies my	findings completely and	d correctly.						
(323) Place and date:		Ophth examiner's na	me and address	: (blocl	k capitals)	AME or s	specialist stam	p with No.:	
AME signature:									
		E-mail:							
		Telephone No.:							
		Telefax No.:							

## INSTRUCTIONS FOR COMPLETION OF THE OPHTHALMOLOGY EXAMINATION REPORT FORM

Writing should be legible and in block capitals using a ball-point pen. Completion of this form by typing or printing is also acceptable. If more space is required to answer any question, a plain sheet of paper should be used, bearing the applicant's name, the name and signature of the AME or ophthalmology specialist performing the examination and the date of signing. The following numbered instructions apply to the numbered headings on the ophthalmology examination report form.

Failure to complete the medical examination report form in full, as required, or to write legibly may result in non-acceptance of the application in total and may lead to withdrawal of any medical certificate issued. The making of false or misleading statements or the withholding of relevant information by an examiner may result in criminal prosecution, denial of an application or withdrawal of any medical certificate granted.

The AME or ophthalmology specialist performing the examination should verify the identity of the applicant. The applicant should then be requested to complete the sections 1, 2, 3, 4, 5, 6, 7, 12 and 13 on the form and then sign and date the consent to release of medical information (section 301) with the examiner countersigning as witness.

#### 302 EXAMINATION CATEGORY – Tick appropriate box.

Initial – Initial examination for either class 1 or 2; also initial examination for upgrading from class 2 to 1 (notate 'upgrading' in section 303).

Renewal/Revalidation - Subsequent comprehensive ophthalmological examinations (due to refractive

Special referral – NON-ROUTINE examination for assessment of an ophthalmological symptom or finding.



ANNEX VI (Part-ARA)

SUBPART MED – SPECIFIC REQUIREMENTS RELATING TO AERO-MEDICAL CERTIFICATION

- 303 OPHTHALMOLOGICAL HISTORY Detail here any history of note or reasons for special referral.
- 304 to 309 inclusive: CLINICAL EXAMINATION These sections together cover the general clinical examination and each of the sections should be marked (with a tick) as normal or abnormal. Any abnormal findings or comments on findings should be entered in section 321.
- 310 CONVERGENCE Enter near point of convergence in cm, as measured using RAF near point rule or equivalent. Tick whether normal or abnormal. Any abnormal findings or comments on findings should be entered in section 321.
- ACCOMMODATION Enter measurement recorded in dioptres using RAF near point rule or equivalent. Tick whether normal or abnormal. Any abnormal findings or comments on findings should be entered in section 321.
- OCULAR MUSCLE BALANCE Ocular muscle balance is tested at distant 5 or 6 m and near at 30-50 cm and results recorded. Presence of tropia or phoria must be entered accordingly and also whether fusional reserve testing was NOT performed and if performed whether normal or not.
- 313 COLOUR PERCEPTION Enter type of pseudo-isochromatic plates (ishihara) as well as number of plates presented with number of errors made by examinee. State whether advanced colour perception testing is indicated and what methods used (which colour lantern or anomaloscopy) and finally whether judged to be colour safe or unsafe. Advanced colour perception testing is usually only required for initial assessment, unless indicated by change in applicant's colour perception.
- 314–316 VISUAL ACUITY TESTING AT 5 m/6 m, 1 m and 30-50 cm Record actual visual acuity obtained in appropriate boxes. If correction not worn nor required, put line through corrected vision boxes. Distant visual acuity to be tested at either 5 m or 6 m with the appropriate chart for that distance.
- 317 REFRACTION Record results of refraction. Indicate also whether for class 2 applicants, refraction details are based upon spectacle prescription.
- 318 SPECTACLES Tick appropriate box signifying if spectacles are or are not worn by applicant. If used, state whether unifocal, bifocal, varifocal or look-over.
- 319 CONTACT LENSES Tick appropriate box signifying if contact lenses are or are not worn. If worn, state type from the following list; hard, soft, gas-permeable, disposable.
- 320 INTRA-OCULAR PRESSURE Enter intra-ocular pressure recorded for right and left eyes and indicate whether normal or not. Also indicate method used applanation, air etc.
- OPHTHALMOLOGICAL REMARKS AND RECOMMENDATION Enter here all remarks, abnormal findings and assessment results. Also enter any limitations recommended. If there is any doubt about findings or recommendations, the examiner may contact the AMS for advice before finalising the report form.
- 322 OPHTHALMOLOGY EXAMINER'S DETAILS The ophthalmology examiner must sign the declaration, complete his/her name and address in block capitals, contact details and lastly stamp the report with his/her designated stamp incorporating his/her AME or specialist number.
- 323 PLACE AND DATE Enter the place (town or city) and the date of examination. The date of examination is the date of the clinical examination and not the date of finalisation of form. If the ophthalmology examination report is finalised on a different date, enter date of finalisation on section 321 as 'Report finalised on ............'.

ANNEX VI (Part-ARA)

SUBPART MED - SPECIFIC REQUIREMENTS RELATING TO AERO-MEDICAL CERTIFICATION

## OTORHINOLARYNGOLOGY EXAMINATION REPORT FORM

applicant's details											
(1) State applied to:			certificate appli	ed for: class	1 🗆	class 2					
(3) Surname:		(4) Previous	surname(s):						: Initial		
(-) -		(5) 5				_			Renew		
(5) Forename(s):		(6) Date of b	oirth:		Sex:	(13)	Refer	ence r	number	:	
				<b>I</b>	ale 🗆						
(101) 0					male 🗆	<u> </u>					
(401) Consent to release of medical		-								-	
all attachments to the AME and, wh or any electronically stored data, are											
the licensing authority, providing the		•								•	
be respected at all times.	at For Thy phrys	iciaii iiiay ii	ave access to th	em according	, to nationa	i iaw. i	vicuica	ii com	naciitie	ility vvi	
be respected at an times.											
Date	Signa	ture of appli	cant	Si	gnature of	AME					
(402) Examination category:	(403) Otorhin	olaryngologi	ical history:								
Initial											
Special referral											
M											
Clinical examination	г	Newsel	Al	(440) D							
Check each item		Normal	Abnormal		re tone aud		У				
(404) Head, face, neck, scalp		dB HL (hearing lev						٠.	۲.		
(405) Buccal cavity, teeth				Hz	Right ea	ar		Le	ft ear		
(406) Pharynx				250	_			-			
(407) Nasal passages and naso-phar			500	_			-				
(incl. anterior rhinoscopy)			1000	_			-				
(408) Vestibular system incl. Rombe	rg test			2000	_			-			
(409) Speech				3000	_			-			
(410) Sinuses				4000				_			
(411) Ext acoustic meati, tympanic n	nembranes			6000				_			
(412) Pneumatic otoscopy				8000							
(413) Impedance tympanometry inc	-										
Valsalva menoeuvre (initial on	ly)			(420) Au	_						
						Right Left			r		
		Τ						Done			
Additional testing (if indicated)	Not	Normal	Abnormal	dB/HL							
	performed			-10							
(414) Speech audiometry				0							
(415) Posterior rhinoscopy				10							
(416) EOG; spontaneous and				20							
positional nystagnus				30							
(417) Differential caloric test or				40							
vestibular autorotation test				50							
(418) Mirror or fibre laryngoscopy				60							
	<u> </u>			70							
				80							
(421) Otorhinolaryngology remarks	and recomme	ndation:		90				!			
(421) Otorhinolaryngology remarks	and recomme	endation:		100						$\dashv$	
(421) Otorhinolaryngology remarks	and recomme	endation:								+	



ANNEX VI (Part-ARA)

SUBPART MED - SPECIFIC REQUIREMENTS RELATING TO AERO-**MEDICAL CERTIFICATION** 

#### (422) Examiner's declaration:

I hereby certify that I/my AME group have report with any attachment embodies my	<ul> <li>personally examined the applicant named on this me findings completely and correctly.</li> </ul>	dical examination report and that this
(423) Place and date:	ORL examiner's name and address: (block capitals)	AME or specialist stamp with No:
AME signature:		
	E-mail:	
	Telephone No.:	
	Telefax No.:	

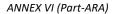
### INSTRUCTIONS FOR COMPLETION OF THE OTORHINOLARYNGOLOGY EXAMINATION REPORT FORM

Writing should be legible and in block capitals using a ball-point pen. Completion of this form by typing or printing is also acceptable. If more space is required to answer any question, a plain sheet of paper should be used, bearing the applicant's name, the name and signature of the AME or otorhinolaryngology specialist performing the examination and the date of signing. The following numbered instructions apply to the numbered headings on the otorhinolaryngology examination report form.

Failure to complete the medical examination report form in full, as required, or to write legibly may result in non-acceptance of the application in total and may lead to withdrawal of any medical certificate issued. The making of false or misleading statements or the withholding of relevant information by an examiner may result in criminal prosecution, denial of an application or withdrawal of any medical certificate granted.

The AME or otorhinolaryngology specialist performing the examination should verify the identity of the applicant. The applicant should then be requested to complete the sections 1, 2, 3, 4, 5, 6, 7, 12 and 13 on the form and then sign and date the consent to release of medical information (section 401) with the examiner countersigning as witness.

- EXAMINATION CATEGORY Tick appropriate box.
  - Initial Initial examination for class 1; also initial examination for upgrading from class 2 to 1 (notate upgrading' in section 403)
  - Special Referral NON-ROUTINE examination for assessment of an ORL symptom or finding
- OTORHINOLARYNGOLOGICAL HISTORY Detail here any history of note or reasons for special referral.
- 404-413 inclusive: CLINICAL EXAMINATION These sections together cover the general clinical examination and each of the sections should be marked (with a tick) as normal or abnormal. Any abnormal findings or comments on findings should be entered in section 421.
- 414-418 inclusive: ADDITIONAL TESTING These tests are only required to be performed if indicated by history or clinical findings and are not routinely required. For each test one of the boxes must be completed – if the test is not performed then tick that box – if the test has been performed then tick the appropriate box for a normal or abnormal result. All remarks and abnormal findings should be entered in section 421.
- 419 PURE TONE AUDIOMETRY – Complete figures for dB HL (hearing level) in each ear at all listed frequencies.
- AUDIOGRAM Complete audiogram from figures as listed in section 419. 420
- OTORHINOLARYNGOLOGY REMARKS AND RECOMMENDATION Enter here all remarks, abnormal 421 findings and assessment results. Also enter any limitations recommended. If there is any doubt about findings or recommendations the examiner may contact the AMS for advice before finalising the report form.
- 422 OTORHINOLARYNGOLOGY EXAMINER'S DETAILS - The otorhinolaryngology examiner must sign the declaration, complete his/her name and address in block capitals, contact details and lastly stamp the report with his/her designated stamp incorporating his/her AME or specialist number.
- 423 PLACE AND DATE – Enter the place (town or city) and the date of examination. The date of examination is the date of the clinical examination and not the date of finalisation of form. If the ORL examination





SUBPART MED – SPECIFIC REQUIREMENTS RELATING TO AERO-MEDICAL CERTIFICATION

report is finalised on a different date, enter date of finalisation in section 421 as 'Report finalised on .......'.

# ARA.MED.145 GMP notification to the competent authority

Regulation (EU) 2024/2076

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.

[applicable until 12 February 2025 - Regulation (EU) 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 applicable requirements laid down in this Regulation.

[applicable from 13 February 2025 - Regulation (EU) 2024/2076]

# ARA.MED.150 Record-keeping

Regulation (EU) 2024/2070

- (a) In addition to the records required in <u>ARA.GEN.220</u>, 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.



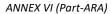
- (e) The competent authority shall maintain lists:
  - (1) of all AMEs that hold a valid certificate issued by that authority; and
  - (2) where applicable, of all GMPs acting as AMEs on their territory.

These lists shall be disclosed to other Member States and the Agency upon request.

## [applicable until 12 February 2025 - Regulation (EU) 1178/2011]

- (a) In addition to the records required in point <u>ARA.GEN.220</u>, 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 applicants/licence holders shall be kept for a minimum period of 10 years after the expiry date 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 the following entities:
  - (1) an AeMC, 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;
  - (6) the Agency for standardisation purposes, in a manner that ensures that medical confidentiality is respected at all times.
- (d) The competent authority may make aero-medical records available for other purposes than those mentioned in point (c) in accordance with Regulation (EU) 2016/679.
- (e) The competent authority shall maintain a list of:
  - (1) AeMCs and AMEs that it has certified;
  - (2) AMEs certified by other competent authorities exercising their privileges in its territory and to whom it has provided a briefing in accordance with point <a href="MED.D.001">MED.D.001</a>(f)(3) of Annex IV (Part-MED);
  - (3) GMPs exercising their privileges in accordance with point <u>MED.A.040</u> of Annex IV (Part-MED), where applicable;
  - (4) OHMPs having notified the competent authority of their intention to perform cabin crew aero-medical assessments in accordance with points <a href="MED.C.005">MED.C.005</a>(c) and <a href="MED.D.040">MED.D.040</a> of Annex IV (Part-MED), where applicable.

The list shall state the privileges of the persons and organisations specified in points (1) to (4) of the first paragraph and shall be published and kept updated by the competent authority.





SUBPART MED – SPECIFIC REQUIREMENTS RELATING TO AERO-MEDICAL CERTIFICATION

(f) The competent authority shall analyse the health data of pilots above the age of 60, especially of those involved in single-pilot HEMS operations, and report such health data in an anonymised and aggregated manner to EASA on a yearly basis.

[applicable from 13 February 2025 - Regulation (EU) 2024/2076]

## AMC1 ARA.MED.150 Record-keeping

ED Decision 2012/006/R

#### **RELEASE OF AERO-MEDICAL RECORDS**

In accordance with Directive 95/46/EC as implemented under national law, aero-medical records may also be released:

- (a) upon written request of the applicant, to management of the competent authority, for review in response to a complaint;
- (b) to research institutes for the purpose of scientific research, with assurance of de-identification prior to publication;
- (c) to any investigation body (accident, security, police), when required under national law; and
- (d) for any other circumstances, as required under national law.

# 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;





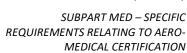
- (2) AMEs and any duly authorised personnel of AeMCs to whom that applicant or holder has provided a declaration in accordance with point MED.A.035(b)(2);
- (3) any duly authorised personnel of the competent authority responsible for the oversight of AMEs or AeMCs conducting aero-medical assessments 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 45/2001¹, 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.
- (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.'

1

<sup>&</sup>lt;sup>1</sup> 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).





# 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 <u>ARA.MED.160(b)(2)</u>

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:

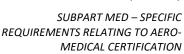
- (a) designate its EAMR administrator;
- (b) ensure control and oversight of all personnel managing or using the EAMR.

# 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 AMC2 ARA.MED.160(a)	Restri	cted 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.

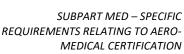
# AMC1 ARA.MED.160(d) Exchange of information on medical certificates

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 <a href="ARA.MED.160(b)(1)">ARA.MED.160(b)(1)</a>. 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 <a href="https://example.com/ARA.MED.150">ARA.MED.150</a>.





(d) the data recorded in the EAMR is complete as relevant for the purpose of the EAMR as described in <u>AMC1 ARA.MED.160(b)</u>.

# 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 <u>ARA.MED.160(b)(1)</u> will be lawfully processed in a European central repository, in accordance with Article 72 of Regulation (EU) 2018/1139 and <u>ARA.GEN.200(c)</u> and <u>ARA.MED.160</u> 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 <a href="ARA.MED.160(b)(2">ARA.MED.160(b)(2)</a>, 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) 2024/2076

- (a) The certification procedure for an AME shall follow the provisions laid down in <u>ARA.GEN.315</u>. 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.

## [applicable until 12 February 2025 - Regulation (EU) 245/2014]

Without prejudice to the provisions laid down in point ARA.GEN.315, all of the following shall apply:

- (a) the competent authority shall ensure that before the issue, revalidation, renewal or extension of privileges of an AME certificate, applicants demonstrate their aero-medical competency in accordance with points MED.D.030 (a)(6) and (b)(5) of Annex IV;
- (b) the competent authority shall have a procedure in place to ensure that, before issuing the AME certificate, it has the evidence that the AME practice is equipped and the appropriate processes are in place to perform aero- medical examinations within the scope of the AME certificate applied for. In the case of multiple AME practice locations, all of them shall be specified on the AME certificate;
- (c) for applicants referred to in point <u>MED.D.020</u>(aa) of Annex IV, the competent authority may accept an aviation medicine training course completed by an applicant outside the territories for which Member States are responsible under the Chicago Convention, provided that the competent authority has done all of the following:
  - (1) assessed and verified that the course syllabus is equivalent to the aviation medicine training courses available in the Member States;
  - (2) provided to the applicant a specific training module on the aero-medical requirements detailed in Annex IV (Part-MED);
- (d) 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.

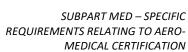
[applicable from 13 February 2025 - Regulation (EU) 2024/2076]

# AMC1 ARA.MED.200 Procedure for the issue, revalidation, renewal or change of an AME certificate

ED Decision 2012/006/R

## INSPECTION OF THE AME PRACTICE

Before issuing the AME certificate, the competent authority should conduct an inspection of the AME practice to verify compliance with <u>ARA.MED.200(a)</u>.





# 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

Reaulation (EU) 2024/2076

[applicable until 12 February 2025 - Regulation (EU) 290/2012]

# ARA.MED.240 General medical practitioners (GMPs) exercising the privileges in accordance with point MED.A.040 of Annex IV (Part-MED)

[applicable from 13 February 2025 - Regulation (EU) 2024/2076]

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) 2024/2076

When developing the continuing oversight programme referred to in <u>ARA.GEN.305</u>, 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.

[applicable until 12 February 2025 - Regulation (EU) 290/2012]

When developing the continuing oversight programme referred to in point <u>ARA.GEN.305</u>, the competent authority shall take into account:

- (1) the number of AMEs and GMPs exercising their privileges within the territory where the competent authority exercises oversight;
- (2) the number of AMEs certified by competent authorities of other Member States exercising their privileges within the territory where the competent authority exercises oversight;
- (3) a risk-based assessment of the AMEs' and GMPs' activity.

[applicable from 13 February 2025 - Regulation (EU) 2024/2076]



## ARA.MED.246 Cooperative oversight of AMEs and AeMCs

Regulation (EU) 2024/2076

Without prejudice to the provisions laid down in point ARA.GEN.300(e):

- (a) where an AME or AeMC carries out their activity in more than one Member State, the competent authority that certified the AME or AeMC shall have a procedure in place to ensure the exchange of information in accordance with point <u>ARA.GEN.200(c)</u> and points <u>ARA.GEN.300(d)</u> and (e) with the competent authority of the other Member State(s) where the AME or AeMC carries out their activity. The procedure shall be agreed upon by the competent authorities involved;
- (b) in the case mentioned in point (a), the competent authority of the other Member State(s) where the AME or AeMC carries out their activity shall share all information relevant to the oversight of the AME or AeMC with the competent authority certificating the AME or AeMC.

[applicable from 13 February 2025 - ED Decision 2024/2076]

# ARA.MED.250 Limitation, suspension or revocation of an AME certificate

Regulation (EU) 2024/2076

- (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.

## [applicable until 12 February 2025 - Regulation (EU) 1178/2011]

- (a) The competent authority shall limit, suspend or revoke an AME certificate in the following circumstances:
  - (1) the AME does not comply 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;

## Easy Access Rules for Aircrew (Regulation (EU) No 1178/2011)

ANNEX VI (Part-ARA)

SUBPART MED – SPECIFIC REQUIREMENTS RELATING TO AERO-MEDICAL CERTIFICATION

- (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;
- (7) at the request of the certified AME.
- (8) any operational context of the AME that may have a direct or indirect negative impact on flight safety
- (b) The certificate of an AME shall be considered invalid in either of the following circumstances and the competent authority shall immediately revoke it:
  - (1) revocation of medical licence to practice; or
  - (2) removal from the Medical Register.
- (c) The competent authority shall have a process in place for retrieval of the revoked AME certificates, shall update the AME list, and inform the competent authorities of the other Member States accordingly.

[applicable from 13 February 2025 - Regulation (EU) 2024/2076]

## **ARA.MED.255 Enforcement measures**

Regulation (EU) 2024/2076

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.

[applicable until 12 February 2025 - Regulation (EU) 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 competent 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.

For medical certificates issued to applicants who have a licensing authority different from the competent authority that issued the AME certificate, that competent authority shall inform and exchange relevant information with the medical assessor of the licensing authority of the affected medical certificate holder.

[applicable from 13 February 2025 - Regulation (EU) 2024/2076]



## **SECTION III – MEDICAL CERTIFICATION**

## ARA.MED.315 Review of examination reports

Regulation (EU) 2024/2076

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.

## [applicable until 12 February 2025 - Regulation (EU) 1178/2011]

The licensing authority shall have a process in place for the medical assessor to take the following steps:

- (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;
- (aa) take the appropriate corrective actions for any inconsistencies, mistakes or errors identified;
- (b) assist AMEs and AeMCs on their request regarding their decision on aero-medical fitness in borderline and complex cases.

[applicable from 13 February 2025 - Regulation (EU) 2024/2076]

## AMC1 ARA.MED.315(a) Review of examination reports

ED Decision 2012/006/R

### **GENERAL**

- (a) The process to review examination and assessment reports received from AeMCs, AMEs and GMPs should aim to check all reports received.
- (b) The licensing authority should take account of the proportion of inconsistencies or errors found in the assessment process and adapt the sample size accordingly and to review all reports if necessary.

## **ARA.MED.325 Secondary review procedure**

Regulation (EU) 2024/2076

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.

## [applicable until 12 February 2025 - Regulation (EU) 1178/2011]

The competent authority shall establish a procedure for the review of borderline and complex cases and cases where an applicant requests a review in accordance with the applicable medical requirements and accredited medical conclusion as defined in point <a href="MED.A.010">MED.A.010</a> of Annex IV (Part-MED).

[applicable from 13 February 2025 - Regulation (EU) 2024/2076]



## **ARA.MED.330 Special medical circumstances**

Regulation (EU) 2024/2076

- (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.

[applicable until 12 February 2025 - Regulation (EU) 2015/445]



## 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 <u>ARA.MED.330</u> 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.



# SUBPART DTO – SPECIFIC REQUIREMENTS RELATING TO DECLARED TRAINING ORGANISATIONS (DTOs)

## ARA.DTO.100 Declaration to the competent authority

Regulation (EU) 2020/359

- (a) Upon receiving a declaration from a DTO, the competent authority shall verify that the declaration contains all the information specified in point <a href="DTO.GEN.115">DTO.GEN.115</a> of Annex VIII (Part-DTO) and acknowledge receipt of the declaration, including the assignment of an individual DTO reference number to the representative of the DTO.
- (b) If the declaration does not contain the required information or contains information that indicates a non-compliance with the essential requirements set out in Annex IV to Regulation (EU) 2018/1139, with the requirements of Annex I (Part-FCL) and Annex VIII (Part-DTO) to this Regulation, or with the requirements of Annex III (Part-BFCL) to Commission Regulation (EU) 2018/395 and Annex III (Part-SFCL) to Commission Implementing Regulation (EU) 2018/1976, the competent authority shall act in accordance with point ARA.GEN.350(da).

## AMC1 ARA.DTO.100(a) Declaration to the competent authority

ED Decision 2018/009/R

#### **ACKNOWLEDGEMENT OF RECEIPT OF THE DECLARATION**

The competent authority should acknowledge receipt of the declaration to the DTO in writing within 10 working days.

## GM1 ARA.DTO.100(a) Declaration to the competent authority

ED Decision 2018/009/R

## ASSIGNMENT OF AN INDIVIDUAL DTO REFERENCE NUMBER

It is recommended to create DTO reference numbers by commencing with the UN country code of the State of the competent authority to which the declaration is sent, followed by the term '.DTO.' and a consecutive numbering (example: AT.DTO.001).

## GM2 ARA.DTO.100(a) Declaration to the competent authority

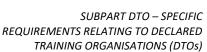
ED Decision 2018/009/R

The verification made by the competent authority upon receipt of the declaration does not imply an inspection. The aim is to check whether the declaration complies with the applicable requirements.

## **ARA.DTO.105 Changes to declarations**

Regulation (EU) 2018/1119

Upon receiving a notification of a change to the information contained in the declaration of a DTO, the competent authority shall act in accordance with point <u>ARA.DTO.100</u>.





## **ARA.DTO.110** Verification of compliance of the training programme

eaulation (EU) 2020/359

- (a) Upon receiving the training programmes of a DTO, and any changes thereto, notified to it in accordance with point <a href="DTO.GEN.115(c">DTO.GEN.115(c</a>) of Annex VIII (Part-DTO) or the application for approval of the training programmes of a DTO submitted to it in accordance with point <a href="DTO.GEN.230(c">DTO.GEN.230(c</a>) of that Annex, the competent authority shall verify the compliance of those training programmes with the requirements of Annex I (Part-FCL), Annex III (Part-BFCL) to <a href="Commission Implementing Regulation (EU) 2018/395">Commission Implementing Regulation (EU) 2018/395</a> and Annex III (Part-SFCL) to <a href="Commission Implementing Regulation (EU) 2018/1976">Commission Implementing Regulation (EU) 2018/1976</a>, as applicable.
- (b) When satisfied that the DTO training programme, and any subsequent changes thereto, are in compliance with those requirements, the competent authority shall inform the representative of the DTO thereof in writing or, in the case referred to in point <a href="DTO.GEN.230(c">DTO.GEN.230(c</a>) of Annex VIII (Part-DTO), approve the training programme. For such approval it shall use the form contained in <a href="Appendix VIII">Appendix VIII</a> to this Annex (Part-ARA).
- (c) In case of any non-compliance, the competent authority shall act in accordance with point <a href="ARA.GEN.350(da">ARA.GEN.350(da</a>) or, in the case referred to in point <a href="DTO.GEN.230(c">DTO.GEN.230(c</a>) of Annex VIII (Part-DTO), reject the application for approval of the training programme.

# AMC1 ARA.DTO.110 Verification of compliance of the training programme(s)

ED Decision 2018/009/R

Without prejudice to national provisions on administrative procedures, and unless the training programme has already been verified for Part-FCL compliance (AMC1 DTO.GEN.115(c)), when receiving an initial declaration, the competent authority should verify the compliance of the training programme(s) attached to that declaration within 6 months from the time it acknowledged receipt of the declaration in accordance with point <u>ARA.DTO.100(a)</u>.



## **APPENDICES TO ANNEX VI**

## Appendix I to ANNEX VI (Part-ARA) – Flight crew licence

Regulation (EU) 2024/2076

The flight crew licence issued by a Member State in accordance with Annex I (Part-FCL), Annex III (Part-BFCL) to Commission Regulation (EU) 2018/395 and Annex III (Part-SFCL) to Commission Implementing Regulation (EU) 2018/1976 shall conform to the following specifications:

- (a) Content. The item number shown shall always be printed in association with the item heading. Items I to XI are the "permanent" items and items XII to XIV are the "variable" items which may appear on a separate or detachable part of the main form. Any separate or detachable part shall be clearly identifiable as part of the licence.
  - (1) Permanent items:
    - (I) State of licence issue;
    - (II) title of licence;
    - (III) serial number of the licence commencing with the UN country code of the State of licence issue and followed by 'FCL', 'BFCL' or 'SFCL', as applicable, and a code of numbers and/or letters in Arabic numerals and in Latin script;
    - (IV) name of holder (in Latin script, even if the script of the national language(s) is other than Latin);
    - (IVa) date of birth;
    - (V) holder's address;
    - (VI) nationality of holder;
    - (VII) signature of holder;
    - (VIII) competent authority and, where necessary, conditions under which the licence was issued;
    - (IX) certification of validity and authorisation for the privileges granted;
    - (X) signature of the officer issuing the licence and the date of issue; and
    - (XI) seal or stamp of the competent authority.
  - (2) Variable items:
    - (XII) ratings, certificates and, in the case of balloons and sailplanes, privileges: class, type, instructor certificates, etc., with dates of expiry, as applicable. Radio telephony (R/T) privileges may appear on the licence or on a separate certificate;
    - (XIII) remarks: i.e. special endorsements relating to limitations and endorsements for privileges, including endorsements of language proficiency, and remarks on the automatic validation of the licence; and
    - (XIV) any other details required by the competent authority (e.g. place of birth/place of origin).
- (b) Material. The paper or other material used will prevent or readily show any alterations or erasures. Any entries or deletions to the form will be clearly authorised by the competent authority.



(c) Language. Licences shall be written in the national language(s) and in English and such other languages as the competent authority deems appropriate.

## **Cover page**

Competent Authority name and logo	Req	uirements
(English and any language(s) determined by the competent authority)		
EUROPEAN UNION		
(English only)		
SUGUT ORSWINGSNOS		
FLIGHT CREW LICENCE		
(English and any language(s) determined by the competent authority)		ropean Union" to be deleted for non-EU nber States
Issued in accordance with Part-FCL/Part-BFCL/Part-SFCL (non-applicable terms to be deleted)	Size	of each page shall be one eighth A4
This licence complies with ICAO standards, except for the LAPL and BIR privileges or when accompanied by an LAPL medical certificate		
(English and any language(s) determined by the competent authority)		
EASA Form 141 Issue 2		



## Page 2

I	State of issue	Requirements
III	Licence number	Serial number of the licence will always commence with the UN country code of the State of the licence issue, followed by "FCL.", "BFCL." or "SFCL.", as applicable.
IV	Last and first name of holder	
IVa	Date of birth (see instructions)	Standard date format is to be used, dd/mm/yyyy in full.
XIV	Place of birth	
٧	Address of holder:	
	Street, town, area, postal code	
VI	Nationality	
VII	Signature of holder	
VIII	Issuing competent authority E.g. This CPL(A) has been issued on the basis of an ATPL issued by (third country)	
Х	Signature of issuing officer and date	
ΧI	Seal or stamp of issuing competent authority	



#### Page 3

II	Title of the licence, date of initial issue and country code	Abbreviations used will be as those used in Part-FCL (e.g. PPL(H), ATPL(A), etc.), Part-BFCL and Part-SFCL Standard format is to be used, dd/mm/yyyy in full.
IX	Validity: The privileges of the licence shall be exercised only if the holder has a valid medical certificate for the required privilege. A document containing a photo shall be carried for the purposes of identification of the licence holder.	This document is not specified, but a passport would suffice when outside the State of licence issue.
XII	Radiotelephony privileges: The holder of this licence has demonstrated competence to operate R/T equipment on board aircraft in (specify the language(s))	
XIII	Remarks:  Language Proficiency:  (language(s)/level/validity date)	All additional licensing information required and privileges established by ICAO, EC or EU Directives/Regulations to be entered here.  Language proficiency endorsement(s), level and validity date shall be included.  In case of LAPL: LAPL not issued in accordance with ICAO standards  In case of SPL, except for the cases referred to in Point (a) of Article 3b(2) of Commission Implementing Regulation (EU) 2018/1976: Privileges for aerobatic and sailplane cloud flying as well as for launching methods to be exercised in accordance with points SFCL.155, SFCL.200 and SFCL.215 of Annex III (Part-SFCL) to Commission Implementing Regulation (EU) 2018/1976, as applicable.

## Additional pages — Requirements:

Pages 1, 2, and 3 of the licence shall be in accordance with the format laid down in the model in this point. The competent authority shall include additional customized pages containing tables which shall contain at least the following information:

- Ratings, certificates, endorsements and privileges;
- Expiry dates of the ratings, the instructor and examiner certificate privileges;
- Dates of the test or check;
- Remarks and restrictions (operational limitations);
- Fields for the examiner and/or instructor certificate number and signature, as applicable;
- Abbreviations.

These additional pages are intended for use by the competent authority, or by specifically authorised instructors or examiners.

Initial issues of ratings or certificates shall be entered by the competent authority. Revalidation or renewal of ratings or certificates may be entered by the competent authority or by specifically authorised instructors or examiners.

Operational limitations shall be entered in "Remarks and Restrictions" against the appropriate restricted privilege, e.g. IR skill test taken with co-pilot, restricted instruction privileges to 1 aircraft type.

Ratings that are not validated may be removed from the licence by the competent authority.



## AMC1 to Appendix I to ANNEX VI (Part-ARA) – Flight crew licence

D Decision 2018/011/R

In case of using privileges outside the Union territory to which the Treaty applies on an aircraft registered in a Member State other than the one that issued the flight crew licence, the following remark should be added to licence item XIII: 'This licence is automatically rendered valid as per the ICAO attachment to this licence.



# Appendix II to ANNEX VI (Part-ARA) – Standard EASA format for cabin crew attestations

Regulation (EU) 2015/44

Cabin crew attestations issued in accordance with Part-CC in a Member State shall conform to the following specifications:

#### 1. CABIN CREW ATTESTATION

Issued in accordance with Part-CC

- 2. Reference number:
- 3. State of issue:
- 4. Full name of holder:
- 5. Date and place of birth:
- 6. Nationality:
- 7. Signature of holder:
- 8. Competent authority:
- 9. Issuing body: Official seal, Stamp or Logo
- 10. Signature of issuing officer:
- 11. Date of issue:
- 12. The holder may only exercise the privileges to act as cabin crew on aircraft engaged in commercial air transport operations if he/she complies with the requirements in Part-CC for continuous fitness and valid aircraft type qualifications.

EASA Form 142 Issue 1

#### Instructions:

- (a) The cabin crew attestation shall include all items specified in EASA Form 142 in accordance with items 1 12 as listed and described below.
- (b) Size shall be either 105mm × 74mm (one-eighth A4) or 85mm × 54mm, and the material used shall prevent or readily show any alterations or erasures.
- (c) The document shall be printed in English and such other languages as the competent authority deems appropriate.
- (d) The document shall be issued by the competent authority or by an organisation approved to issue cabin crew attestations. In that latter case reference to the approval by the competent authority of the Member State shall be stated.
- (e) The cabin crew attestation is recognised in all Member States and it is not necessary to exchange the document when working in another Member State.
  - Item 1: The title "CABIN CREW ATTESTATION" and the reference to Part-CC.
  - Item 2: Attestation reference number shall commence with the UN country code of the Member State followed by at least the two last numbers of the year of issue and an individual reference/number according to a code established by the competent authority (e.g. BE-08-xxxx).
  - Item 3: The Member State where the attestation is issued.
  - Item 4: The full name (surname and first name) stated in the official identity document of the holder
  - Items 5 and 6: Date and place of birth as well as nationality as stated in the official identity document of the holder.



- Item 7: The signature of the holder.
- Item 8: Identification details of the competent authority of the Member State where the attestation is issued shall be entered and shall provide the full name of the competent authority, postal address, and official seal, stamp or logo as applicable.
- Item 9: If the competent authority is the issuing body, the term "competent authority" and official seal, stamp or logo shall be entered. In this case only, the competent authority may determine if its official seal, stamp or logo shall also be entered under Item 8.
  - In the case of an approved organisation, identification details shall be entered and shall at least provide the full name of the organisation, postal address and if applicable, the logo and:
  - (a) in the case of a commercial air transport operator, the air operator certificate (AOC) number and detailed reference to the approvals by the competent authority to provide cabin crew training and to issue attestations; or
  - (b) in the case of an approved training organisation, the reference number of the relevant approval by the competent authority.
- Item 10: The signature of the officer acting on behalf of the issuing body.
- Item 11: Standard date format shall be used: i.e. day/month/year in full (e.g. 22/02/2008).
- Item 12: The same sentence in English and its full and precise translation into such other languages as the competent authority deems appropriate.



# Appendix III to ANNEX VI (Part-ARA) – Certificate for approved training organisations (ATOs)

Regulation (EU) 2024/2076

## European Union (\*) Competent Authority

#### APPROVED TRAINING ORGANISATION CERTIFICATE

[CERTIFICATE NUMBER/REFERENCE]

Pursuant to <u>Commission Regulation</u> (EU) No 1178/2011 [and <u>Commission Regulation</u> (EU) 2018/395/<u>Commission Implementing Regulation</u> (EU) 2018/1976 (ADJUST AS APPLICABLE)] and subject to the conditions specified below, the [Competent Authority] hereby certifies

[NAME OF THE TRAINING ORGANISATION]

[ADDRESS OF THE TRAINING ORGANISATION]

as a Part-ORA certified training organisation with the privilege to provide Part-FCL training courses, including the use of FSTDs, as listed in the attached training course approval/Part-BFCL training courses/Part-SFCL training courses [ADJUST AS APPLICABLE].

## **CONDITIONS:**

This certificate is limited to the privileges and the scope of providing the training courses, including the use of FSTDs, as listed in the attached training course approval.

This certificate is valid whilst the approved organisation remains in compliance with Part-ORA, Part-FCL, Part-BFCL, Part- SFCL [ADJUST AS APPLICABLE] and other applicable regulations.

Subject to compliance with the foregoing conditions, this certificate shall remain valid unless it has been surrendered, superseded, limited, suspended or revoked.

Date of issue:
Signed:

(\*) 'European Union' to be deleted for non-EU Member States or EASA.

EASA FORM 143 Issue 3 - page 1/2

[Competent Authority]



## APPROVED TRAINING ORGANISATION CERTIFICATE TRAINING COURSE APPROVAL

Attachment to ATO Certificate Number:

[CERTIFICATE NUMBER/REFERENCE]

[NAME OF THE TRAINING ORGANISATION]

has obtained the privilege to provide and conduct the following Part-FCL/Part-BFCL/Part-SFCL [ADJUST AS APPLICABLE] training courses and to use the following FSTDs:

Training course	FSTD(s) used, including letter code(1)
(1) as indicated on the qualification certificate	

This training course approval is valid as long as:

- (a) the ATO certificate has not been surrendered, superseded, limited, suspended or revoked; and
- (b) all operations are conducted in compliance with Part-ORA, Part-FCL, Part-BFCL, Part-SFCL [ADJUST AS APPLICABLE], other applicable regulations, and, when relevant, with the procedures in the organisation's documentation as required by Part-ORA.

Date of issue:

Signed: [Competent Authority]

For the Member State/EASA

EASA FORM 143 Issue 3 - page 2/2



# Appendix IV to ANNEX VI (Part-ARA) – Flight simulation training device qualification certificate

Regulation (EU) 2024/2076

#### Introduction

EASA Form 145 shall be used for the FSTD qualification certificate. This document shall contain the FSTD Specification including any limitation(s) and special authorisation(s) or approval(s) as appropriate to the FSTD concerned. The qualification certificate shall be printed in English and in any other language(s) determined by the competent authority.

Convertible FSTDs shall have a separate qualification certificate for each aircraft type. Different engine and equipment fit on one FSTD shall not require separate qualification certificates. All qualification certificates shall carry a serial number prefixed by a code in letters, which shall be specific to that FSTD. The letter code shall be specific to the competent authority of issue.



## European Union (\*) Competent Authority

#### FLIGHT SIMULATION TRAINING DEVICE QUALIFICATION CERTIFICATE

#### REFERENCE:

Pursuant to Commission Regulation (EU) No 1178/2011 and subject to the conditions specified below, the [competent authority] hereby certifies that

## FSTD [TYPE AND LETTER CODE]

### located at [NAME and ADDRESS OF THE ORGANISATION]

has satisfied the qualification requirements prescribed in Part-OR, subject to the conditions of the attached FSTD specification

This qualification certificate shall remain valid subject to the FSTD and the holder of the qualification certificate remaining in compliance with the applicable requirements of Part-OR, unless it has been surrendered, superseded, suspended or revoked.

Date of	issue:	 	 	 ***************************************	
Signed:		 	 	 	

(\*) 'European Union' to be deleted for non-EU Member States or EASA.

EASA Form 145 - Issue 2 - page 1/2



## [competent authority]

## FSTD QUALIFICATION CERTIFICATE: [Reference] FSTD SPECIFICATIONS

A. Type or variant of aircraft:	
A. Type of variant of aircraft.	
B. FSTD qualification level:	
C. Primary reference document:	
D. Visual system:	
E. Motion system:	
F. Engine fit:	
G. Instrument fit:	
H. ACAS fit:	
I. Windshear:	
J. Additional capabilities:	
K. Restrictions or limitations:	
L. Guidance information for training, testing and checking considerations	
CAT I RVR m DH ft	
CAT II RVR m DH ft	
CAT III RVR m DH ft	
(lowest minimum)	
LVTO RVR m	
Recency	
IFR-training/check	1
Type rating	
Proficiency checks	
Autocoupled approach	
Autoland/roll out guidance	1
ACAS I/II	1
Windshear warning system/predictive windshear	1
WX-radar	
HUD/HUGS	į
FANS	
GPWS/EGPWS	1
ETOPS capability	
GPS	
Other	
Date of issue:	
Signed:	

EASA Form 145 - Issue 2 - page 2/2

For the Member State/EASA



# Appendix V to ANNEX VI (Part-ARA) – Certificate for Aeromedical Centres (AeMCs)

Regulation (EU) 2024/2076

CERT	TIFICATE FOR AERO-MEDICAL CENTRES (AeMCs)
Euro	pean Union¹
Com	petent Authority
AERC	D-MEDICAL CENTRE CERTIFICATE
	REFERENCE:
	uant to Commission Regulation (EU) No 1178/2011 and subject to the conditions specified below, the petent authority] hereby certifies
	[NAME OF THE ORGANISATION]
	[ADDRESS OF THE ORGANISATION]
	art-ORA certifies Aero-medical centre with the privileges and the scope of activities as listed in the shed terms of approval.
CONI	DITIONS:
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
[арр	licable until 12 February 2025 - Regulation (EU) 245/2014]

'European Union' to be deleted for non-EU Member States

Powered by EASA eRules



CERTIFICATE FOR AERO-MEDICAL	CENTRES	(AeMCs)
------------------------------	---------	---------

**European Union1** 

**Competent Authority** 

**AERO-MEDICAL CENTRE CERTIFICATE** 

#### REFERENCE:

Pursuant to Commission Regulation (EU) No 1178/2011 and Regulation (EU) 2015/340 (²) and subject to the conditions specified below, the [competent authority] hereby certifies

[NAME OF THE ORGANISATION]

[ADDRESS OF THE ORGANISATION]

as a Part-ORA certified 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: dd/mm/yyyy:	••
Signature: [Competent Authority]:	

EASA Form 146 Issue 2

<sup>&</sup>lt;sup>1</sup> 'European Union' to be deleted for non-EU Member States or EASA.

<sup>&</sup>lt;sup>2</sup> Reference to Regulation (EU) No 1178/2011 or Regulation (EU) 2015/340 shall be modified as per the certificate's scope.



#### **AERO-MEDICAL CENTRE CERTIFICATE**

Attachment (1) to AeMC certificate number:

## **PRIVILEGES AND SCOPE**

[Name of the organisation] has obtained the privilege(s) to undertake aero-medical examinations and assessments for the issuance of medical certificates and medical reports as stated in the table below and to issue these medical certificates and medical reports for:

	Initial/revalidation/renewal	Date of issue
Class 1		
Class 2/LAPL/Cabin Crew		
Class 3 ( <sup>2</sup> )		

Date of issue	e: dd/mm/yy	/yy:	••••••	• • • • • • • • • • • • • • • • • • • •	••••••	•••••
Signature: [(	Competent A	\uthority]: .				

[applicable from 13 February 2025 - Regulation (EU) 2024/2076]

<sup>&</sup>lt;sup>1</sup> Class 3 shall be added only for the AeMCs approved to perform class 3 aero-medical examinations.

 $<sup>^{2}</sup>$  Class 3 shall be added only for the AeMCs approved to perform class 3 aero-medical examinations.



## Appendix VI to ANNEX VI (Part-ARA)

Regulation (EU) No 245/2014

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# Appendix VII to ANNEX VI (Part-ARA) – Certificate for Aeromedical Examiners (AMEs)

Regulation (EU) 2024/2076

CERTIFICATE FOR AERO-MEDICAL EXAMINERS (AMES)					
_	pean Union <sup>1</sup> Petent Authority				
AERO	-MEDICAL EXAMINER CERTIFICATE				
	CERTIFICATE NUMBER/REFERENCE:				
	ant to Commission Regulation (EU) No 1178/2011 and subject to the conditions specified below, the petent authority] hereby certifies				
	[NAME OF THE AERO-MEDICAL EXAMINER]				
	[ADDRESS OF THE AERO-MEDICAL EXAMINER]				
as aer	ro-medical examiner				
COND	DITIONS:				
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/zzzz²] subject to compliance with the requirements of Part-MED unless it has been surrendered, superseded, suspended or revoked.				
Date o	of issue: xx/yy/zzzz Signature: [Competent Authority]				
EASA I	Form 148 Issue 1				

<sup>&</sup>lt;sup>1</sup> 'European Union' to be deleted for non-EU Member States

<sup>&</sup>lt;sup>2</sup> 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]

[applicable until 12 February 2025 - Regulation (EU) 290/2012]



CERTIFICATE FOR AERO-MEDICAL	<b>EXAMINERS</b>	<b>AMEs</b>
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**European Union1** 

**Competent Authority** 

#### **AERO-MEDICAL EXAMINER CERTIFICATE**

#### **CERTIFICATE NUMBER/REFERENCE:**

Pursuant to Commission Regulation (EU) No 1178/2011 and Regulation (EU) 2015/340 (²) and subject to the conditions specified below, the [competent authority] hereby certifies

[NAME OF THE AERO-MEDICAL EXAMINER]

[PRACTICE ADDRESS(ES) 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/Part ATCO.MED (3).
- 3. This certificate shall remain valid from [dd/mm/yyyy] until [dd/mm/yyyy (4)] subject to compliance with the requirements of Part-MED/Part ATCO.MED (2) unless it has been surrendered, superseded, suspended or revoked.

Date of issue: dd/mm/yyyy Signature: [Competent Authority]

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 $^{\mbox{\tiny 1}}$  'European Union' to be deleted for non-EU Member States

<sup>&</sup>lt;sup>2</sup> Reference to Regulation (EU) No 1178/2011 or Regulation (EU) 2015/340 as well as Part-MED and Part ATCO.MED shall be modified as per the certificate's scope.

<sup>&</sup>lt;sup>3</sup> Reference to Regulation (EU) No 1178/2011 or Regulation (EU) 2015/340 as well as Part-MED and Part ATCO.MED shall be modified as per the certificate's scope.

<sup>&</sup>lt;sup>4</sup> Expiry date format: day/month/year.



#### **AERO-MEDICAL EXAMINER CERTIFICATE**

Attachment(1) 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 and medical reports as stated in the table below and to issue these medical certificates and medical reports for:

Class 1 revalidation/renewal	[valid until]/[Not Applicable]
Class 2/LAPL/Cabin crew Initial/revalidation/renewal	[valid until]
Class 3 (2) revalidation/renewal	[valid until]/[Not Applicable]

Date of issue: dd/mm/yyyy Signature: [Competent Authority]

[applicable from 13 February 2025 - Regulation (EU) 2024/2076]

<sup>&</sup>lt;sup>1</sup> This attachment may be issued as part of the AME certificate or as a separate document.

 $<sup>^{2}</sup>$  Class 3 shall be added only for the AMEs approved to perform class 3 aero-medical examinations.



# Appendix VIII to ANNEX VI (Part-ARA) – Training programme approval

Regulation (EU) 2020/2193

## **Training programme approval**

for a declared training organisation (DTO)

European Union (\*)

Competent authority

Issuing authority:					
Name of DTO:					
DTO reference number:					
Training programme(s) approved:	Doc reference:	Remarks:			
Examiner standardisation – FE(S), FE(B) (**)					
Examiner refresher course – FE(S), FE(B) (**)					
The above-mentioned training programme(s) has (have) been verified by the above-mentioned competent authority and found to be in compliance with the requirements of Annex I (Part-FCL) to Commission Regulation (EU) No 1178/2011, Annex III (Part-BFCL) to Commission Regulation (EU) 2018/395 and Annex III (Part-SFCL) to Commission Implementing Regulation (EU) 2018/1976.					
Date of issue:					
Signed: [competent authority]					

- (\*) 'European Union' to be deleted for non-EU Member States.
- (\*\*) To be adjusted as applicable.

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### **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) As part of its management system, the organisation shall establish and maintain an occurrence-reporting system, including mandatory and voluntary reporting. For organisations having their principal place of business in a Member State, that system shall meet the requirements of Regulation (EU) No 376/2014 and Regulation (EU) 2018/1139 as well as the delegated and implementing acts adopted on the basis of those Regulations.
- (b) The organisation shall report to the competent authority and, in case of aircraft not registered in a Member State, the State of Registry any safety-related event or condition that endangers or, if not corrected or addressed, could endanger an aircraft, its occupants or any other person, and in particular any accident or serious incident.
- (c) Without prejudice to point (b), the organisation shall report to the competent authority and the design approval holder of the aircraft any incident, malfunction, technical defect, exceeding of technical limitations, occurrence that would highlight inaccurate, incomplete or ambiguous information, contained in data established in accordance with <u>Regulation (EU) No 748/2012</u>, or other irregular circumstance that has or may have endangered an aircraft, its occupants or any other person and has not resulted in an accident or serious incident.
- (d) Without prejudice to <u>Regulation (EU) No 376/2014</u> and the delegated and implementing acts adopted on the basis thereof, reports in accordance with point (c) shall:
  - (1) be made as soon as practicable, but in any case no later than 72 hours after the organisation has identified the event or condition to which the report relates unless exceptional circumstances prevent this;
  - (2) be made in a form and manner established by the competent authority, as defined in point ORA.GEN.105;
  - (3) contain all pertinent information about the condition known to the organisation.
- (e) For organisations not having their principal place of business in a Member State:
  - (1) initial mandatory reports shall:
    - (i) appropriately safeguard the confidentiality of the identity of the reporter and of the persons mentioned in the report;
    - (ii) be made as soon as practicable, but in any case, no later than 72 hours after the organisation has become aware of the occurrence unless exceptional circumstances prevent this;
    - (iii) be made in a form and manner established by the Agency;
    - (iv) contain all pertinent information about the condition known to the organisation;
  - (2) where relevant, a follow-up report providing details of actions the organisation intends to take to prevent similar occurrences in the future shall be made as soon as those actions have been identified; those follow-up reports shall:
    - (i) be sent to relevant entities initially reported to in accordance with points (b) and (c);
    - (ii) be made in a form and manner established by the Agency.



### **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<sup>1</sup> 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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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) 2020/2193

- (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 organisation with 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 relevant requirements prescribed in Regulation (EU) 2018/1139 and in Regulation (EU) No 376/2014 as well as in the delegated and implementing acts adopted on the basis thereof.
- (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:
  - 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 inflight 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).

#### Easy Access Rules for Aircrew (Regulation (EU) No 1178/2011)

ANNEX VII (Part-ORA)
SUBPART GEN – GENERAL REQUIREMENTS

### 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.

Hazard		Incident Sequence	Existing	Outcome (Pre-Mitigation)			Additional Mitigation	Outcome (Post-Mitigation)		Actions and	Monitoring and Review	
No	Description	Description	Controls	Severity	Likelihood	Risk	required	Severity	Likelihood	Risk	Owners	Requirements

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### 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**

(a) 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.
- (b) 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.
- (c) 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.
- (d) 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.

#### (e) 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 2020/005/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<sup>1</sup> and its Implementing Rules.
- (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: performance based 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).
- (d) Regardless of the criteria mentioned in (a) and (b), the organisations that provide training in the following areas should always be considered as complex:
  - (1) full flight simulators (FFSs); or
  - (2) multi-pilot (MP) type rating; or

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.



- (3) zero-flight-time training (ZFTT); or
- (4) complex aircraft; or
- (5) different categories of aircraft; or
- (6) instructor certificates for point (2) and (4) aircraft; or
- (7) two or more aerodromes/operating sites.

### 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:
  - 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 <u>ORA.GEN.200(a)(5)</u>, 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 <a href="ORA.GEN.210(b)">ORA.GEN.210(b)</a> 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).
- (I) 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:
    - 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.200A Information security management system**

Regulation (EU) 2023/203

In addition to the management system referred to in point <u>ORA.GEN.200</u>, the organisation shall establish, implement and maintain an information security management system in accordance with <u>Implementing Regulation (EU) 2023/203</u> in order to ensure the proper management of information security risks which may have an impact on aviation safety.

[applicable from 22 February 2026 — Implementing Regulation (EU) 2023/203]



### **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 <a href="Mailto:ORA.GEN.200(a)(3)">ORA.GEN.200(a)(6)</a>.
- (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 have sufficient 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 ATO – APPROVED TRAINING ORGANISATIONS

#### **SECTION I – GENERAL**

### ORA.ATO.100 Scope

Regulation (EU) No 1178/2011

**ORGANISATIONS** 

This Subpart establishes the requirements to be met by organisations providing training for pilot licences and associated ratings and certificates.

### **GM1 ORA.ATO.100 Scope**

ED Decision 2012/007/R

The content of this Section contains the requirements applicable to all ATOs providing training for pilot licences and the associated ratings and certificates.

It is applicable to ATOs providing training for:

- (a) the LAPL, PPL, SPL and BPL and the associated ratings and certificates; and
- (b) the commercial pilot licence (CPL), multi-crew pilot licence (MPL) and airline transport pilot licence (ATPL) and the associated ratings and certificates.

### **ORA.ATO.105** Application

Regulation (EU) No 290/2012

- (a) Applicants for the issue of a certificate as an approved training organisation (ATO) shall provide the competent authority with:
  - (1) the following information:
    - (i) name and address of the training organisation;
    - (ii) date of intended commencement of activity;
    - (iii) personal details and qualifications of the head of training (HT), the flight instructor(s), flight simulation training instructors and the theoretical knowledge instructor(s);
    - (iv) name(s) and address(es) of the aerodromes(s) and/or operating site(s) at which the training is to be conducted;
    - (v) list of aircraft to be operated for training, including their group, class or type, registration, owners and category of the certificate of airworthiness, if applicable
    - (vi) list of flight simulation training devices (FSTDs) that the training organisation intends to use, if applicable;
    - (vii) the type of training that the training organisation wishes to provide and the corresponding training programme; and
  - (2) the operations and training manuals.



- (b) Flight test training organisations. Notwithstanding (a)(1)(iv) and (v), training organisations providing flight test training shall only need to provide:
  - (1) the name(s) and address(es) of the main aerodromes and/or operating site(s) at which the training is to be conducted; and
  - (2) a list of the types or categories of aircraft to be used for flight test training.
- (c) In the case of a change to the certificate, applicants shall provide the competent authority with the relevant parts of the information and documentation referred to in (a).

## **AMC1 ORA.ATO.105 Application**

ED Decision 2012/007/R

#### **APPLICATION FORM**

APP	LICATION FORM FOR AN ATO CERTIFICATE		
N°	Question	Supplementary information	
1.	Name of training organisation under which the activity is to take place	address, fax number, e-mail, URL	
2.	Training courses offered	theory and/or flight training	
3.	Name of head of training	type and number of licence full/part-time	
4.	Name of chief flight instructor	as (3)	
5.	Name of chief theoretical knowledge instructor	as (3)	
6.	Name of flight instructor(s), where applicable	as (3)	
7.	Aerodrome(s) / operating site(s) to be used	IFR approaches, if applicable night flying, if applicable air traffic control flight testing facilities, if applicable data reply facilities, if applicable	
8.	Flight operations accommodation	location, number and size of rooms	
9.	Theoretical instruction facilities	location, number and size of rooms	
10.	Description of training devices (as applicable)	FFS, FNPT I, II and III, FTD 1, 2 and 3, and 3, and BITD	
11.	Description of aircraft	Class/type(s) of aircraft registration of aircraft IFR equipped, if applicable Flight test instrumentation, if applicable	
12.	Proposed administration and manuals: (submit with application if required )	<ul><li>(a) course programmes</li><li>(b) training records</li><li>(c) operations manual</li><li>(d) training manual</li></ul>	



Note 1: If answers to any of the above questions are incomplete, the applicant should provide full details of alternative arrangements separately.

Note 2: instrument flight rules (IFR), full flight simulator (FFS), flight and navigation procedures trainer (FNPT), flight training device (FTD), basic instrument training device (BITD)

I, (name), on behalf of (name of training organisation) certify that all the above named persons are in compliance with the applicable requirements and that all the above information given is complete and correct. (Date) (Signature)

## **ORA.ATO.110** Personnel requirements

Regulation (EU) 2020/359

- (a) An HT shall be nominated. The HT shall have extensive experience as an instructor in the areas relevant for the training provided by the ATO and shall possess sound managerial capability.
- (b) The HT's responsibilities shall include:
  - (1) ensuring that the training provided is in compliance with Annex I (Part-FCL), Annex III (Part-BFCL) to Commission Regulation (EU) 2018/395, Annex III (Part-SFCL) to Commission Implementing Regulation (EU) 2018/1976, as applicable, and, in the case of flight test training, that the relevant requirements of Annex I (Part 21) to Commission Regulation (EU) No 748/2012 and the training programme have been established;
  - (2) ensuring the satisfactory integration of flight training in an aircraft or a flight simulation training device (FSTD) and theoretical knowledge instruction; and
  - (3) supervising the progress of individual students.
- (c) Theoretical knowledge instructors shall have:
  - (1) practical background in aviation in the areas relevant for the training provided and have undergone a course of training in instructional techniques; or
  - (2) previous experience in giving theoretical knowledge instruction and an appropriate theoretical background in the subject on which they will provide theoretical knowledge instruction.
- (d) Flight instructors and flight simulation training instructors shall hold the qualifications required by Annex I (Part-FCL), Annex III (Part-BFCL) to <u>Commission Regulation (EU) 2018/395</u> and Annex III (Part-SFCL) to <u>Commission Implementing Regulation (EU) 2018/1976</u> for the type of training they provide.

## AMC1 ORA.ATO.110(b) Personnel requirements

ED Decision 2012/007/R

## **HEAD OF TRAINING**

The nominated head of training (HT) should have the overall responsibility to ensure that the training is in compliance with the appropriate requirements. In an ATO providing training courses for different aircraft categories, the HT shall be assisted by one or more nominated deputy HT(s) for certain flight training courses.



## AMC1 ORA.ATO.110(c) Personnel requirements

ED Decision 2012/007/R

**ORGANISATIONS** 

#### THEORETICAL KNOWLEDGE INSTRUCTORS

Theoretical knowledge instructors should, before appointment, prove their competency by giving a test lecture based on material they have developed for the subjects they are to teach.

## **ORA.ATO.120 Record-keeping**

Regulation (EU) 2018/1119

The following records shall be kept throughout the course and for a period of three years after the completion of the training:

- (a) details of ground, flight, and simulated flight training given to individual students;
- (b) detailed and regular progress reports from instructors including assessments, and regular progress flight tests and ground examinations; and
- (c) information on the licences and associated ratings and certificates of the students, including the expiry dates of medical certificates and ratings.

## AMC1 ORA.ATO.120(a);(b) Record-keeping

ED Decision 2012/007/R

# ATOS PROVIDING TRAINING ONLY FOR THE LAPL, PPL, SPL OR BPL AND THE ASSOCIATED RATINGS AND CERTIFICATES

The details of ground, flight and flight instruction by using FSTD given to a specific individual student and the detailed progress reports from instructors may be kept also in a student's progress card. This progress card should contain all the exercises of the training syllabus. The instructor should sign this card if a certain exercise has been completed or a specific assessment has been conducted.

## **ORA.ATO.125 Training programme**

Regulation (EU) 2020/359

- (a) A training programme shall be developed for each type of course offered.
- (b) The training programme shall comply with the requirements of Annex I (Part-FCL), Annex III (Part-BFCL) to Commission Regulation (EU) 2018/395, Annex III (Part-SFCL) to Commission Implementing Regulation (EU) 2018/1976, as applicable, and, in the case of flight test training, the relevant requirements of Annex I (Part 21) to Commission Regulation (EU) No 748/2012.

## **AMC1 ORA.ATO.125 Training programme**

ED Decision 2012/007/R

## **GENERAL**

Flight training in an FSTD and theoretical knowledge instruction should be phased in such a manner as to ensure that students are able to apply to flight exercises the knowledge gained on the ground. Arrangements should be made so that problems encountered during instruction can be resolved during subsequent training.



SUBPART ATO – APPROVED TRAINING ORGANISATIONS

## **AMC2 ORA.ATO.125 Training programme**

ED Decision 2020/005/R

#### **TYPE RATING COURSES - AEROPLANES**

## (a) Introduction

- (1) When developing the training programme for a type rating course, in addition to complying with the standards included in the operational suitability data (OSD), as established in accordance with Regulation (EC) 1702/2003¹ for the applicable type, the ATO should also follow any further recommendations contained therein.
- (2) The type rating course should, as far as possible, provide for a continual process of ground, FSTD and flight training to enable the student to assimilate the knowledge and skills required to operate a specific aircraft type safely and efficiently. The student's ability to do this should be determined by the demonstration of a satisfactory level of theoretical knowledge of the aircraft determined by progressive checking of knowledge and examination, progressive assessment by the ATO during flight training and the successful completion of a practical skill test with an examiner.
- (3) The type rating course should normally be conducted as a single, fulltime course of study and training. However, in the situation where the course is intended to enable a pilot to fly a further aircraft type while continuing to fly a current type, such as to enable mixed fleet flying with the same operator, some elements of the theoretical knowledge course conducted by self-study may be undertaken while the student continues to fly the current type.

#### (b) Variants

- (1) Familiarisation training: Where an aeroplane type rating also includes variants of the same aircraft type requiring familiarisation training, the additional familiarisation training may be included in the theoretical knowledge training of the initial type rating course. Flight training should be conducted on a single variant within the type.
- (2) Differences training: Where an aeroplane type rating also includes variants of the same aircraft type for which difference training is required, the initial training course should be directed towards a single variant. Additional training to operate other variants within the same type rating should be completed after successful completion of the initial type rating course. However, elements of this differences training may be undertaken at appropriate stages of the initial course, with the agreement of the competent authority.
- (c) Programme of theoretical knowledge and flight training
  - (1) The training programme should specify the time allocated to theoretical knowledge training, FSTD training and, if not approved for zero flighttime training (ZFTT), the aeroplane. The initial type rating course should be programmed on the basis that the student has the minimum licensing and experience requirements for entry to the course. For a first type rating on a multi-pilot aeroplane (MPA), the course should also provide for consolidation and type-specific training in those elements of basic multi-crew cooperation (MCC) training relevant to the type or variant.

Commission Regulation (EC) No 1702/2003 of 24 September 2003 laying down implementing rules for the airworthiness and environmental certification of aircraft and related products, parts and appliances, as well as for the certification of design and production organisations (Part 21) (OJ L 243, 27.9.2003, p. 6). Regulation as last amended by Regulation (EC) No 1194/2009 (OJ L 321, 8.12.2009, p. 5).



- (2) If the ATO wishes to provide a training course that includes credit for previous experience on similar types of aircraft, such as those with common systems or operating procedures with the new type, the entry requirements to such courses should be specified by the ATO and should define the minimum level of experience and qualification required of the flight crew member.
- (3) The ATO is permitted to contract elements of training to a third party training provider. In such cases the contracted organisation should normally be approved to conduct such training. When the contracted organisation is not an ATO, the competent authority should, within the approval process of the ATO, include the contracted organisation and be satisfied that the standard of training intended to be given meets the requirements. The other obligations of the ATO, such as student progress monitoring and an adequate management system, can be exercised by the ATO seeking approval and which retains responsibility for the whole course.

#### **GROUND TRAINING**

#### (d) Syllabus

The ground training syllabus should provide for the student to gain a thorough understanding of the operation, function and, if appropriate, abnormal and emergency operation of all aircraft systems. This training should also include those systems essential to the operation of the aircraft, such as 'fly-by-wire' flight control systems, even if the flight crew have little or no control of their normal or abnormal operation.

## (e) Theoretical knowledge instruction

The theoretical knowledge instruction training should meet the general objectives of (but not be limited to) giving the student:

- a thorough knowledge of the aircraft structure, powerplant and systems, and their associated limitations, including mass and balance, aircraft performance and flight planning considerations;
- (2) a knowledge of the positioning and operation of the cockpit controls and indicators for the aircraft and its systems;
- (3) an understanding of system malfunctions, their effect on aircraft operations and interaction with other systems; and
- (4) the understanding of normal, abnormal and emergency procedures.

## (f) Facilities and training aids

The ATO should provide adequate facilities for classroom instruction and have available appropriately qualified and experienced instructors. Training aids should enable students to gain practical experience of the operation of systems covered by the theoretical knowledge syllabus and, in the case of multi-pilot aeroplanes, enable such practical application of the knowledge to be carried out in a multi-crew environment. Facilities should be made available for student self-study outside the formal training programme.

#### (g) Computer-based training (CBT)

CBT provides a valuable source of theoretical instruction, enabling the students to progress at their own pace within specified time limits. Many such systems ensure that syllabus subjects are fully covered and progress can be denied until a satisfactory assimilation of knowledge has been demonstrated. Such systems may allow self-study or distance learning, if they incorporate adequate knowledge testing procedures. When CBT is used as part of the theoretical knowledge



instruction phase, the student should also have access to a suitably qualified instructor able to assist with areas of difficulty for the student.

(h) Self-study and distance learning

Elements of the theoretical knowledge syllabus may be adequately addressed by distance learning, if approved, or self-study, particularly when utilising CBT. Progress testing, either by self-assessed or instructor-evaluated means should be included in any self-study programme. If self-study or distance learning is included in the theoretical knowledge training, the course should also provide for an adequate period of supervised consolidation and knowledge testing.

- (i) Progress tests and final theoretical knowledge examination
  - (1) The theoretical knowledge training programme should provide for progressive testing of the assimilation of the required knowledge. This testing process should also provide for retesting of syllabus items so that a thorough understanding of the required knowledge is assured. This should be achieved by intervention by a qualified instructor or, if using CBT with a self-testing facility, and by further testing during the supervised consolidation phase of the ground course.
  - (2) The final theoretical knowledge examination should cover all areas of the theoretical knowledge syllabus. The final examination should be conducted as a supervised written (including computer-based) knowledge test without reference to course material. The pass mark of 75% assumes the achievement of satisfactory levels of knowledge during the progressive phase tests of the course. The student should be advised of any areas of lack of knowledge displayed during the examination and, if necessary, given remedial instruction. A successful pass of the theoretical knowledge course and final examination should be a pre-requisite for progression to the flight training phase of the type rating course, unless otherwise determined in the OSD established in accordance with Regulation (EC) 1702/2003.

#### **FLIGHT TRAINING**

(j) Flight simulation training devices (FSTDs)

A type rating course for a multi-pilot aeroplane should include FSTD training.

The amount of training required when using FSTDs will depend on the complexity of the aeroplane concerned, and to some extent on the previous experience of the pilot. Except for those courses giving credit for previous experience (c.2.), a minimum of 32 hours of FSTD training should be programmed for a crew of a multipilot aeroplane, of which at least 16 hours should be in an FFS operating as a crew. FFS time may be reduced if other qualified FSTDs used during the flight training programme accurately replicate the cockpit environment, operation and aeroplane response. Such FSTDs may typically include flight management computer (FMC) training devices using hardware and computer programmes identical to those of the aeroplane.

- (k) Aeroplane training with FFS
  - (1) with the exception of courses approved for ZFTT, certain training exercises normally involving take-off and landing in various configurations should be completed in the aeroplane rather than in an FFS. Unless otherwise specified in the OSD established in accordance with Regulation (EU) No 748/2012 this take-off and landing training should include:
    - (A) at least four landings in the case of MPAs (or single-pilot high performance complex aeroplanes (SP HPAs)) where the student pilot has more than 500 hours of MPA



experience (or SPA experience) in aeroplanes of similar size and performance or, in all other cases, at least six landings;

- (B) at least one full-stop landing; and
- (C) one go-around with all engines operating.

This aeroplane training may be completed after the student pilot has completed the FSTD training and has successfully undertaken the type rating skill test, provided it does not exceed 2 hours of the flight training course.

- (2) courses approved for ZFTT
  - (i) During the specific simulator session before line flying under supervision (LIFUS), consideration should be given to varying conditions, for example:
    - (A) runway surface conditions;
    - (B) runway length;
    - (C) flap setting;
    - (D) power setting;
    - (E) crosswind and turbulence conditions; and
    - (F) maximum take-off mass (MTOM) and maximum landing mass (MLM).
  - (ii) At least one landing should be conducted as full-stop landing. The session should be flown in normal operation. Special attention should be given to the taxiing technique.
  - (iii) A training methodology should be agreed with the competent authority that ensures the trainee is fully competent with the exterior inspection of the aeroplane before conducting such an inspection un-supervised.
  - (iv) The LIFUS should be performed as soon as possible after the specific FFS session.
  - (v) The licence endorsement should be entered on the licence after the skill test, but before the first four take-offs and landings in the aeroplane. At the discretion of the competent authority, provisional or temporary endorsement and any restriction should be entered on the licence.
  - (vi) Where a specific arrangement exists between the ATO and the commercial air transport operator, the operator proficiency check (OPC) and the ZFTT specific details should be conducted using the operator's standard operating procedures (SOPs).
- (3) All training exercises should be designed to remain within the training envelope as determined by the ATO (Note: Further guidance regarding the training envelope can be found in <u>GM1 ORA.ATO.125</u> point (f)).
- (I) Aeroplane without FFS
  - (1) Flight training conducted solely in an aeroplane without the use of FSTDs cannot cover the crew resource management (CRM) and multicrew cockpit (MCC) aspects of MPA flight training, and for safety reasons cannot cover all emergency and abnormal aircraft operation required for the training and skill test. In such cases, the ATO should demonstrate to the competent authority that adequate training in these aspects can be achieved by other means. For training conducted solely on an MPA where two pilots are



trained together without the use of an FSTD, a minimum of 8 hours of flight training as pilot flying (PF) for each pilot should normally be required. For training on a single-pilot aeroplane, 10 hours of flight training should normally be required. It is accepted that for some relatively simple single or multi-engine aircraft without systems such as pressurisation, flight management system (FMS) or electronic cockpit displays, this minimum may be reduced.

- (2) Aeroplane training normally involves an inherent delay in achieving an acceptable flight situation and configuration for training to be carried out in accordance with the agreed syllabus. These could include ATC or other traffic delay on the ground prior to take-off, the necessity to climb to height or transit to suitable training areas and the unavoidable need to physically reposition the aircraft for subsequent or repeat manoeuvres or instrument approaches. In such cases it should be ensured that the training syllabus provides adequate flexibility to enable the minimum amount of required flight training to be carried out.
- (la) Additional UPRT training as per point FCL.725.A(c) UPRT as per point FCL.725.A(c) should include the elements and components in table 1.

Table 1: Elements and respective components of upset prevention training

	Elements and components	TK instruction	FSTD/ Aeroplane training
A.	Aerodynamics		
1.	General aerodynamic characteristics	•	
2.	Aeroplane certification and limitations	•	
3.	Aerodynamics (high and low altitudes)	•	•
4.	Aeroplane performance (high and low altitudes)	•	•
5.	AoA and stall awareness	•	•
6.	Stick shaker or other stall-warning device activation (as applicable)	•	•
7.	Stick pusher (as applicable)	•	•
8.	Mach effects (if applicable to the aeroplane type)	•	•
9.	Aeroplane stability	•	•
10.	Control surface fundamentals	•	•
11.	Use of trims	•	•
12.	Icing and contamination effects	•	•
13.	Propeller slipstream (as applicable)	•	•
В.	Causes of and contributing factors to upsets		
1.	Environmental	•	
2.	Pilot-induced	•	
3.	Mechanical (aeroplane systems)	•	
C.	Safety review of accidents and incidents relating to aeroplane up	psets	
1.	Safety review of accidents and incidents relating to aeroplane upsets	•	
D.	G-load awareness and management		
1.	Positive/negative/increasing/decreasing G-loads	•	•
2.	Lateral G awareness (sideslip)	•	•
3.	G-load management	•	•
E.	Energy management		



	Elements and components	TK instruction	FSTD/ Aeroplane training	
1.	Kinetic energy vs potential energy vs effect of thrust-drag ratio on the total energy	•	•	
F.	Flight path management			
1.	Relationship between pitch, power and performance	•	•	
2.	Performance and effects of differing power plants (if applicable)	•	•	
3.	Manual and automation inputs for guidance and control	•	•	
4.	Type-specific characteristics	•	•	
5.	Management of go-arounds from various stages during the approach	•	•	
6.	Automation management	•	•	
7.	Proper use of rudder	•	•	
G.	Recognition			
1.	Type-specific examples of physiological, visual and instrument clues during developing and developed upsets	•	•	
2.	Pitch/power/roll/yaw	•	•	
3.	Effective scanning (effective monitoring)	•	•	
4.	Type-specific stall protection systems and cues	•	•	
5.	Criteria for identifying stalls and upsets	•	•	
н.	<ul> <li>System malfunction         (including immediate handling and subsequent operational considerations, as applicable)     </li> </ul>			
1.	Flight control defects	•	•	
2.	Engine failure (partial or full)	•	•	
3.	Instrument failures	•	•	
4.	Loss of reliable airspeed (see also point (lb) of this AMC)	•	•	
5.	Automation failures	•	•	
6.	Fly-by-wire (FBW) protection degradations	•	•	
7.	Stall protection system failures including icing alerting systems	•	•	

(lb) Flight path management (manual or automatic, as appropriate) during unreliable airspeed indication and other failures at high altitude in aeroplanes with a maximum cruising altitude above FL300

The following training elements should be integrated into type rating training courses for aeroplanes with a maximum cruising altitude above FL300:

Element	TK instruction	FSTD / Aeroplane training
Basic flight physics principles concerning flight at high altitude, with a particular emphasis on the relative proximity of the critical Mach number and the stall, pitch behaviour, and an understanding of the reduced stall angle of attack when compared with low altitude flight.	•	•
Interaction of the automation (autopilot, flight director, auto-throttle/auto-thrust) and the consequences of failures inducing disconnection of the automation.	•	•
Consequences of an unreliable airspeed and other failures indication at high altitude and the need for the flight crew to promptly identify the	•	•



Element	TK instruction	FSTD / Aeroplane training
failure and react with appropriate (minimal) control inputs to keep the aircraft in a safe envelope.		
Degradation of FBW flight control laws/modes and its consequence on aircraft stability and flight envelope protections, including stall warnings.	•	•
Practical training, using appropriate simulators, on manual handling at high altitude in normal and in non-normal flight control laws/modes, with particular emphasis on pre-stall buffet, the reduced stall angle of attack when compared with low altitude flight, and the effect of pitch inputs on the aircraft trajectory and energy state.		•
The requirement to promptly and accurately apply the stall recovery procedure, as provided by the aircraft manufacturer, at the first indication of an impending stall. Differences between high-altitude and low-altitude stalls must be addressed.	•	•
Procedures for taking over and transferring manual control of the aircraft, especially for FBW aeroplanes with independent side-sticks.	•	•
Task sharing and crew coordination in high workload/stress conditions with appropriate call-out and acknowledgement to confirm changes to the aircraft flight control law/mode.	•	•

#### **SKILL TEST**

(m) Upon completion of the flight training, the pilot will be required to undergo a skill test with an examiner to demonstrate adequate competency of aircraft operation for issue of the type rating. The skill test should be separate from the flight training syllabus, and provision for it cannot be included in the minimum requirements or training hours of the agreed flight training programme. The skill test may be conducted in an FFS, the aeroplane or, in exceptional circumstances, a combination of both.

#### **COURSE COMPLETION CERTIFICATE**

(n) The HT, or a nominated representative, should certify that all training has been carried out before an applicant undertakes a skill test for the type rating to be included in the pilot's licence. If an ATO is unable to provide certain elements of the training that is required to be carried out on an aircraft the ATO may issue such a certificate confirming the completion of the ground training or the training in an FSTD.

## AMC3 ORA.ATO.125 Training programme

ED Decision 2012/007/R

## TYPE RATING COURSES - HELICOPTERS

- (a) Introduction
  - (1) when developing the training programme for a type rating course, in addition to complying with the standards included in the OSD as established in accordance with Regulation (EC) 1702/2003 for the applicable type, the ATO should also follow any further recommendations contained therein.
  - (2) the course should, as far as possible, provide for integrated ground, FSTD and flight training designated to enable the student to operate safely and qualify for the grant of a type rating. The course should be directed towards a helicopter type, but where variants



exist, all flying and ground training forming the basis of the course should relate to a single variant.

#### (b) Variants

- (1) Familiarisation training: where a helicopter type rating also includes variants of the same aircraft type requiring familiarisation training, the additional familiarisation training may be included in the theoretical knowledge training of the initial type rating course.
- (2) Differences training: where a helicopter type rating also includes variants of the same aircraft type for which difference training is required, the initial training course should be directed towards a single variant. Additional training to operate other variants within the same type rating should be completed after successful completion of the initial type rating course, although elements of this differences training may be undertaken at appropriate stages of the initial course, with the agreement of the competent authority.

#### (c) Training in helicopter and FSTDs

The training programme should specify the amounts of flight training in the helicopter type and in FSTDs (FFSs, flight training devices (FTDs), or other training devices (OTDs)). Where a suitable FFS is geographically remote from the normal training base, the competent authority may agree to some additional training being included in the programme at a remote facility.

#### (d) Skill test

The content of the flight training programme should be directed towards the skill test for that type. The practical training given in Part-FCL should be modified as necessary.

The skill test may be completed in a helicopter, in an FFS or partially in a helicopter and in an FSTD. The use of an FSTD for skill tests is governed by the level of approval of the flight simulator and the previous experience of the candidate. Where an FSTD is not available, abnormal operations of systems should not be practised in a helicopter other than as allowed for in the skill test form for the type.

(e) Phase progress tests and final theoretical knowledge examination

Prior to the final theoretical knowledge examination covering the whole syllabus, the training programme should provide for phase progress tests associated with each phase of theoretical knowledge instruction. The phase progress tests should assess the candidate's knowledge on completion of each phase of the training programme.

(f) Facilities: ground school equipment, training facilities and aids

The ATO should provide, as a minimum, facilities for classroom instruction. Additional classroom training aids and equipment including, where appropriate, computers, should reflect the content of the course and the complexity of the helicopter. For multi-engine and multi-pilot helicopters, the minimum level of ground training aids should include equipment that provides a realistic cockpit working environment. Task analysis and the latest state-of—the-art training technology is encouraged and should be fully incorporated into the training facilities wherever possible. Facilities for self and supervised testing should be available to the student.

## (g) Training devices

An FTD or OTD may be provided to supplement classroom training in order to enable students to practice and consolidate theoretical instruction. Where suitable equipment is not available, or is not appropriate, a helicopter or flight simulator of the relevant variant should be available. If an FTD represents a different variant of the same helicopter type for which the student is being trained, then differences or familiarisation training is required.



## (h) Computer-based training (CBT)

Where CBT aids are used as a training tool, the ATO should ensure that a fully qualified ground instructor is available at all times when such equipment is being used by course students. Other than for revision periods, CBT lessons should be briefed and debriefed by a qualified ground instructor.

## (i) Theoretical knowledge instruction

The theoretical knowledge instruction training should meet the general objectives of giving the student:

- (1) a thorough knowledge of the helicopter structure, transmissions, rotors and equipment, powerplant and systems, and their associated limitations;
- (2) a knowledge of the positioning and operation of the cockpit controls and indicators for the helicopter and its systems;
- (3) a knowledge of performance, flight planning and monitoring, mass and balance, servicing and optional equipment items;
- (4) an understanding of system malfunctions, their effect on helicopter operations and interaction with other systems; and
- (5) the understanding of normal, abnormal and emergency procedures and giving the student the understanding of potential control problems near the edge of the handling envelope. In particular, the phenomenon of 'servo transparency' (also known as 'jack stall') should be covered for those helicopter types where it is a known problem.

The amount of time and the contents of the theoretical instruction will depend on the complexity of the helicopter type involved and, to some extent, on the previous experience of the student.

## (j) Flight training

#### (1) FSTDs

The level of qualification and the complexity of the type will determine the amount of practical training that may be accomplished in an FSTD, including completion of the skill test. Prior to undertaking the skill test, a student should demonstrate competency in the skill test items during the practical training.

## (2) Helicopter (with FSTD)

With the exception of courses approved for ZFTT, the amount of flight time in a helicopter should be adequate for completion of the skill test.

## (3) Helicopters (without FSTD)

Whenever a helicopter is used for training, the amount of flight time practical training should be adequate for the completion of the skill test. The amount of flight training will depend on the complexity of the helicopter type involved and, to some extent, on the previous experience of the applicant.



## **AMC4 ORA.ATO.125 Training programme**

ED Decision 2012/007/R

#### FLIGHT TEST TRAINING COURSES - AEROPLANES AND HELICOPTERS

## (a) Introduction

- (1) The flight test training course should, as far as possible, provide for a continuous process of ground and flight training to enable the student to assimilate the knowledge and skills required to conduct flight testing safely and efficiently. The student's ability to do this should be determined by the demonstration of a satisfactory level of theoretical knowledge of flight testing determined by progressive checking of knowledge and examination and progressive assessment by the ATO during flying training. There should be no difference in the level of knowledge or competency required of the student, irrespective of the intended role of the student as test pilot or other flight test personnel (for example, flight test engineer) within the flight crew.
- (2) The flight test training course should normally be conducted as a single, full-time course of study and training.
- (b) Programme of theoretical knowledge and flight training
  - (1) The training programme should specify the time allocated to theoretical knowledge training and flying training.
  - (2) If the ATO wishes to provide a flight test training course that includes credit for previous experience on flight testing activity, the entry requirements to such courses should be specified by the ATO and should define the minimum level of experience and qualification required of the flight test crew member.

## **GROUND TRAINING**

- (c) Syllabus
  - (1) The ground training syllabus should provide for the student to gain a thorough understanding of flight testing techniques.
- (d) Theoretical knowledge instruction
  - (1) The theoretical knowledge instruction training should give the student a thorough knowledge of the academic requirements of flight testing.
- (e) Facilities and training aids
  - (1) The ATO should provide adequate facilities for classroom instruction and have available appropriately qualified and experienced instructors. Training aids should enable students to gain practical experience of flight testing covered by the theoretical knowledge syllabus and enable such practical application of the knowledge to be carried out in a multicrew environment. Facilities should be made available for student selfstudy outside the formal training programme.
- (f) Computer-based training (CBT)
  - (1) CBT provides a valuable source of theoretical instruction, enabling the student to progress at his/her own pace within specified time limits. Many such systems ensure that syllabus subjects are fully covered and progress can be denied until a satisfactory assimilation of knowledge has been demonstrated. Such systems may allow self-study or distance learning, if they incorporate adequate knowledge testing procedures. When CBT is used as part of the theoretical knowledge instruction phase, the student should also



have access to a suitably qualified instructor able to assist with areas of difficulty for the student.

- (g) Self-study and distance learning
  - (1) Elements of the theoretical knowledge syllabus may be adequately addressed by distance learning, if approved, or self-study, particularly when utilising CBT. Progress testing, either by self-assessed or instructor-evaluated means, should be included in any selfstudy programme. If self-study or distance learning is included in the theoretical knowledge training, the course should also provide for an adequate period of supervised consolidation and knowledge testing prior to the commencement of flight training.
- (h) Progress tests and final theoretical knowledge examination
  - (1) The theoretical knowledge training programme should provide for progressive testing of the assimilation of the required knowledge. This testing process should also provide for retesting of syllabus items so that a thorough understanding of the required knowledge is assured. This should be achieved by intervention by a qualified instructor or, if using CBT with a self-testing facility, and by further testing during the supervised consolidation phase of the ground course.
  - (2) The theoretical knowledge examinations should cover all areas of the theoretical knowledge syllabus. The examinations should be conducted as supervised written or oral knowledge tests without reference to course material. The pass mark (as defined by the ATO) assumes the achievement of satisfactory levels of knowledge during the progressive phase tests of the course. The student should be advised of any areas of lack of knowledge displayed during the examination and, if necessary, given remedial instruction.

## FLIGHT TRAINING

- (i) Aeroplane and helicopter training
  - (1) It is widely accepted that flying training normally involves inherent delay in achieving an acceptable flight situation and configuration for training to be carried out in accordance with the agreed syllabus. These could include ATC or other traffic delay on the ground prior to take off, the necessity to climb to height or transit to suitable training areas and the unavoidable need to physically reposition the aircraft for subsequent or repeat manoeuvres or instrument approaches. In such cases it should be ensured that the training syllabus provides adequate flexibility to enable the minimum amount of required flight training to be carried out.

## **FINAL IN-FLIGHT EXERCISE**

(j) Upon completion of the flight test training, the test pilot or flight test engineer will be required to undergo in-flight exercise with a flight test instructor (FTI) to demonstrate adequate competency of flight testing for issue of the flight test rating. The final in-flight exercise must be conducted in an appropriate aeroplane or helicopter (as applicable).

## **COURSE COMPLETION CERTIFICATE**

(k) The HT is required to certify that the applicant has successfully completed the training course.



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## **GM1 ORA.ATO.125 Training programme**

ED Decision 2019/005/R

## **UPSET PREVENTION AND RECOVERY TRAINING (UPRT)**

#### (a) General

The objective of the UPRT is to ensure that pilots are competent to prevent or recover from a developing or developed aeroplane upset. Prevention training prepares pilots to avoid upsets whereas recovery training prepares pilots to prevent an accident once an upset condition has developed.

## (b) Human factors

Threat and Error Management (TEM) and Crew Resource Management (CRM) principles should be integrated into the UPRT. In particular, the surprise and startle effect as well as the importance of resilience development should be emphasised.

Training should also emphasise that an actual upset condition may expose pilots to significant physiological and psychological challenges, such as visual illusions, spatial disorientation and unusual G-forces, with the objective of developing strategies to deal with such challenges.

## (c) Development of training scenarios

During the development of training scenarios, the ATO should ensure that all of the following is avoided:

- (a) negative training and negative transfer of training; and
- (b) training utilising predictive scenarios.

Please refer to Revision 2 of the Airplane Upset Recovery Training Aid (AURTA) for further guidance on the development of training scenarios.

## (d) Additional guidance

Specific guidance to the UPRT elements and exercises is available in:

- (1) the latest revision of the ICAO Doc 10011 'Manual on Aeroplane Upset Prevention and Recovery Training';
- (2) Revision 3 of the Airplane Upset Prevention and Recovery Training Aid (AUPRTA); and
- (3) the Flight Safety Foundation publication 'A Practical Guide for Improving Flight Path Monitoring', November 2014.

## (e) Training platform

- (1) When designing a training course, ATOs should select aeroplanes that are suitable for all the required training exercises. Where certain exercises require particular capabilities, then an ATO may consider the use of different aeroplanes for different exercises. Examples include basic UPRT or instrument flight training and the advanced UPRT course.
- (2) For basic UPRT training conducted during the CPL or ATP courses, it is not anticipated that aerobatic category aeroplanes will be required or that aircraft need to be certificated for intentional spins. Aeroplanes with a maximum bank angle limitation may not be suitable for exercises such as steep turns or recovery from spiral dive.
- (3) For the advanced UPRT course (FCL.745), the use of an aeroplane certificated in the aerobatic category will provide the greatest safety margin. Aeroplanes certificated in the normal or utility category may also be suitable provided the exercises used during the



training take into account the capabilities of the aeroplane and are planned to remain within the training envelope for the aeroplane, as determined by the ATO (see point (f)).

## (f) Training envelope

The training envelope is the envelope within which all training exercises will be carried out. It should be specified by the ATO in terms of the range of attitudes, speed and g-loads that can be used for training, taking into account:

- (1) the training environment;
- (2) the capabilities of the instructors; and
- (3) in the case of training in FSTDs, the limitations of the FSTD (as per GM3 FCL.010 for the FSTD training envelope); and
- (4) in the case of training in aeroplanes, the capabilities and certification of the aircraft, while considering a margin of safety in order to ensure that unintentional deviations from the training envelope will not exceed aircraft limitations. Different training envelopes may be specified for different aeroplane types even within a single training course.

## **ORA.ATO.130 Training manual and operations manual**

Regulation (EU) No 1178/2011

- (a) The ATO shall establish and maintain a training manual and operations manual containing information and instructions to enable personnel to perform their duties and to give guidance to students on how to comply with course requirements.
- (b) The ATO shall make available to staff and, where appropriate, to students the information contained in the training manual, the operations manual and the ATO's approval documentation.
- (c) In the case of ATOs providing flight test training, the operations manual shall comply with the requirements for the flight test operations manual, as established in Part-21.
- (d) The operations manual shall establish flight time limitation schemes for flight instructors, including the maximum flying hours, maximum flying duty hours and minimum rest time between instructional duties in accordance with Part-ORO.

## **ORA.ATO.135 Training aircraft and FSTDs**

Regulation (EU) 2019/1747

- (a) The ATO shall use an adequate fleet of training aircraft or FSTDs appropriately equipped for the training courses provided. The fleet of aircraft shall be composed of aircraft that comply with all requirements defined in Regulation (EU) 2018/1139. Aircraft that fall under points (a), (b), (c) or (d) of Annex I to Regulation (EU) 2018/1139, may be used for training if all of the following conditions are met:
  - (1) during an evaluation process the competent authority has confirmed a level of safety comparable to the one defined by all essential requirements laid down in Annex II to Regulation (EU) 2018/1139;
  - (2) the competent authority has authorised the use of the aircraft for training in the ATO.
- (b) The ATO shall only provide training in FSTDs when it demonstrates to the competent authority:
  - (1) the adequacy between the FSTD specifications and the related training programme;



- (2) that the FSTDs used comply with the relevant requirements of Part-FCL;
- (3) in the case of full flight simulators (FFSs), that the FFS adequately represents the relevant type of aircraft; and
- (4) that it has put in place a system to adequately monitor changes to the FSTD and to ensure that those changes do not affect the adequacy of the training programme.
- (c) If the aircraft used for the skill test is of a different type to the FFS used for the visual flight training, the maximum credit shall be limited to that allocated for flight and navigation procedures trainer II (FNPT II) for aeroplanes and FNPT II/III for helicopters in the relevant flight training programme.
- (d) Flight test training organisations. Aircraft used for flight test training shall be appropriately equipped with flight testing instrumentation, according to the purpose of the training.

## **AMC1 ORA.ATO.135 Training aircraft and FSTDs**

ED Decision 2014/021/R

## ALL ATOS, EXCEPT THOSE PROVIDING FLIGHT TEST TRAINING

- (a) The number of training aircraft may be affected by the availability of FSTDs.
- (b) Each training aircraft should be:
  - (1) equipped as required in the training specifications concerning the course in which it is used:
  - (2) except in the case of balloons or single-seat aircraft, fitted with primary flight controls that are instantly accessible by both the student and the instructor (for example dual flight controls or a centre control stick). Swing-over flight controls should not be used.
- (c) The fleet should include, as appropriate to the courses of training:
  - (1) aircraft suitably equipped to simulate instrument meteorological conditions (IMC) and for the instrument flight training required. For flight training and testing for the instrument rating and the en-route instrument rating (EIR), an adequate number of IFRcertificated aircraft should be available;
  - (2) in the case of aeroplanes and sailplanes, aircraft suitable for demonstrating stalling and spin avoidance;
  - (3) for the flight instructor (FI) training courses on aeroplanes and sailplanes, aircraft suitable for spin recovery at the developed stage;
  - (4) in the case of helicopters, helicopters suitable for autorotation demonstration;
  - (5) in the case of a non-complex ATO, one aircraft fulfilling all the required characteristics for a training aircraft might be sufficient;
  - (6) each FSTD should be equipped as required in the training specifications concerning the course in which it is used.



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## **AMC2 ORA.ATO.135 Training aircraft and FSTDs**

ED Decision 2020/005/R

#### **EVALUATION PROCESS**

Two cases for the evaluation process of Annex-I aircraft are distinguished:

- (a) Annex-I aircraft that hold an ICAO-level certificate of airworthiness (CoA)
  - (1) To support the evaluation process performed by the competent authority and provide the competent authority with sufficient data related to the aircraft in question, an instructor who is qualified in accordance with Annex I (Part-FCL) to Regulation (EU) No 1187/2011 and nominated by the head of training (HT) of the ATO should assess that the aircraft is appropriately equipped and suitable for the training courses provided. The result of this assessment should be submitted to the competent authority and may be included already in the application for the authorisation.
  - (2) During the evaluation process, the competent authority should consider aircraft that hold a CoA issued in accordance with Annex 8 to the Chicago Convention to provide a level of safety comparable to that required by Annex II to the Basic Regulation, unless the competent authority determines that the airworthiness requirements used for certification of the aircraft, or the service experience, or the safety system of the State of design, do not provide for a comparable level of safety.
- (b) Annex-I aircraft that do not hold an ICAO-level CoA

Before the inclusion of these aircraft in the fleet of an ATO and their use in training to obtain Part-FCL licences and ratings, the ATO should apply for the authorisation to the competent authority that should perform the evaluation process in the following order:

- (1) Initial assessment by the competent authority and criteria taken into consideration
  - The competent authority should take into account the following criteria (non-exhaustive list):
  - (i) national airworthiness requirements based on which the aircraft CoA was issued;
  - (ii) aircraft similarities to a certified variant;
  - (iii) aircraft with a satisfactory in-service experience as training aircraft;
  - (iv) simple and conventional aircraft design;
  - (v) aircraft that does not have hazardous design features or details, judging by experience; and
  - (vi) operable aircraft systems, equipment, and appliances that do not require exceptional skills or strength.
- (2) Additional assessment by a qualified instructor

To support the evaluation process performed by the competent authority and provide the competent authority with sufficient data related to the aircraft in question, after the positive initial assessment by the competent authority as per point (1), an instructor who is qualified in accordance with Part-FCL and nominated by the HT of the ATO should show through an evaluation report that the aircraft is appropriately equipped and suitable for the training courses provided. That evaluation report should consider all of the following criteria:



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- (i) the aircraft should be safely controllable and manoeuvrable under all anticipated operating conditions, including after failure of one or more propulsion systems;
- the aircraft should allow for a smooth transition from one flight phase to another without requiring exceptional piloting skills, alertness, strength, or workload under any probable operating conditions;
- (iii) the aircraft should have sufficient stability to ensure that the demands made on the pilot are not excessive, considering the phase and duration of flight; and
- (iv) the assessment should take into account control forces, flight deck environment, pilot workload, and other human factors (HF) considerations, depending on the phase and duration of flight.

Subject to a positive evaluation report as per point (2), the competent authority should issue the authorisation.

## **ORA.ATO.140** Aerodromes and operating sites

Regulation (EU) No 1178/2011

When providing flight training on an aircraft, the ATO shall use aerodromes or operating sites that have the appropriate facilities and characteristics to allow training of the manoeuvres relevant, taking into account the training provided and the category and type of aircraft used.

## AMC1 ORA.ATO.140 Aerodromes and operating sites

ED Decision 2012/007/R

#### **GENERAL**

- (a) Except in the case of balloons, the base aerodrome or operating site and any alternative base aerodromes at which flight training is being conducted should have at least the following facilities:
  - (1) at least one runway or final approach and take-off area (FATO) that allows training aircraft to make a normal take-off or landing within the performance limits of all the aircraft used for the training flights.
  - (2) a wind direction indicator that is visible at ground level from the ends of each runway or at the appropriate holding points;
  - (3) adequate runway electrical lighting if used for night training;
  - (4) an air traffic service, except for uncontrolled aerodromes or operating sites where the training requirements may be satisfied safely by another acceptable means of air-to-ground communication.
- (b) Except in the case of ATOs providing flight test training, in addition to (a), for helicopters, training sites should be available for:
  - (1) confined area operation training;
  - (2) simulated engine off autorotation; and
  - (3) sloping ground operation.
- (c) In the case of balloons, the take-off sites used by the ATO should allow a normal take-off and clearing of all obstacles in the take-off flight path by at least 50 ft.



## ORA.ATO.145 Pre-requisites for training

Regulation (EU) No 70/2014

- (a) The ATO shall ensure that the students meet all the pre-requisites for training established in Part-Medical, Part- FCL, and, if applicable, as defined in the mandatory part of the operational suitability data established in accordance with Regulation (EU) No 748/2012.
- (b) In the case of ATOs providing flight test training, the students shall meet all the pre-requisites for training established in accordance with Regulation (EU) No 748/2012.

## AMC1 ORA.ATO.145 Pre-requisites for training

ED Decision 2012/007/R

#### **ENTRANCE REQUIREMENTS**

ATOs providing training for other than the LAPL, PPL, SPL or BPL and the associated ratings and certificates should establish entrance requirements for students in their procedures. The entrance requirements should ensure that the students have enough knowledge, particularly of physics and mathematics, to be able to follow the courses.

## **ORA.ATO.150 Training in third countries**

Regulation (EU) No 290/2012

When the ATO is approved to provide training for the instrument rating (IR) in third countries:

- (a) the training programme shall include acclimatisation flying in one of the Member States before the IR skilltest is taken; and
- (b) the IR skill test shall be taken in one of the Member States.



# SECTION II — ADDITIONAL REQUIREMENTS FOR ATOS PROVIDING TRAINING FOR CPL, MPL AND ATPL AND THE ASSOCIATED RATINGS AND CERTIFICATES

## **ORA.ATO.210** Personnel requirements

Regulation (EU) No 1178/2011

**ORGANISATIONS** 

- (a) Head of training (HT). Except in the case of ATOs providing flight test training, the nominated HT shall have extensive experience in training as an instructor for professional pilot licences and associated ratings or certificates.
- (b) Chief flight instructor (CFI). The ATO providing flight instruction shall nominate a CFI who shall be responsible for the supervision of flight and flight simulation training instructors and for the standardisation of all flight instruction and flight simulation instruction. The CFI shall hold the highest professional pilot licence and associated ratings related to the flight training courses conducted and hold an instructor certificate with the privilege to instruct for at least one of the training courses provided.
- (c) Chief theoretical knowledge instructor (CTKI). The ATO providing theoretical knowledge instruction shall nominate a CTKI who shall be responsible for the supervision of all theoretical knowledge instructors and for the standardisation of all theoretical knowledge instruction. The CTKI shall have extensive experience as a theoretical knowledge instructor in the areas relevant for the training provided by the ATO.

## **AMC1 ORA.ATO.210 Personnel requirements**

ED Decision 2020/005/R

## **GENERAL**

- (a) The management structure should ensure supervision of all grades of personnel by persons having the experience and qualities necessary to ensure the maintenance of high standards. Details of the management structure, indicating individual responsibilities, should be included in the ATOs operations manual.
- (b) The ATO should demonstrate to the competent authority that an adequate number of qualified, competent staff is employed.
- (c) In the case of an ATO offering integrated courses, the head of training (HT), the chief flying instructor (CFI) and the chief theoretical-knowledge instructor (CTKI) should be employed full-time or part-time, depending upon the scope of training offered.
- (d) In the case of an ATO offering only one of the following:
  - (1) modular courses,
  - (2) type rating courses, and
  - (3) theoretical knowledge instruction,
  - the positions of HT, CFI and CTKI may be combined and filled by one or two persons with extensive experience in the training conducted by the training organisation, full-time or part-time, depending upon the scope of training offered.
- (e) In the case of an ATO that provides flight training only, no CTKI function is required in the ATO. In the case of an ATO that provides theoretical-knowledge instruction only, no CFI function is required in the ATO.



- (f) The ratio of all students to all flight instructors, excluding the HT, should not exceed 6:1.
- (g) Classes in ground subjects that require maximal supervision or intensive practical work should not include more than 28 students.

#### THEORETICAL KNOWLEDGE INSTRUCTORS

- (h) The theoretical knowledge instruction for type or class ratings should be conducted by instructors holding the appropriate type or class rating, or having appropriate experience in aviation and knowledge of the aircraft concerned.
- (i) For this purpose, a flight engineer, a maintenance engineer or a flight operations officer should be considered as having appropriate experience in aviation and knowledge of the aircraft concerned.

## AMC2 ORA.ATO.210 Personnel requirements

ED Decision 2012/007/R

#### QUALIFICATION OF HEAD OF TRAINING AND CHIEF FLIGHT INSTRUCTOR

(a) Head of training (HT)

The nominated HT should hold or have held in the 3 years prior to first appointment as HT, a professional pilot licence and associated ratings or certificates issued in accordance with Part-FCL, related to the flight training courses provided.

- (b) Chief flight instructor (CFI)
  - (1) The CFI may delegate standardisation and supervision to the flight instructors. In all cases it is the CFI who is ultimately responsible for ensuring quality and standards.
  - (2) The CFI should, except in the case of ATOs providing flight test training, have completed 1 000 hours of flight time as pilot-in-command (PIC).
    - At least 500 of those hours should be on flying instructional duties related to the flying courses provided, of which 200 hours may be instrument ground time.

## **ORA.ATO.225 Training programme**

Regulation (EU) No 1178/2011

- (a) The training programme shall include a breakdown of flight and theoretical knowledge instruction, presented in a week-by-week or phase layout, a list of standard exercises and a syllabus summary.
- (b) The content and sequence of the training programme shall be specified in the training manual.

## **ORA.ATO.230 Training manual and operations manual**

Regulation (EU) No 290/2012

- (a) The training manual shall state the standards, objectives and training goals for each phase of training that the students are required to comply with and shall address the following subjects:
  - training plan,
  - briefing and air exercises,
  - flight training in an FSTD, if applicable,
  - theoretical knowledge instruction.



(b) The operations manual shall provide relevant information to particular groups of personnel, as flight instructors, flight simulation training instructors, theoretical knowledge instructors, operations and maintenance personnel, and shall include general, technical, route and staff training information.

## AMC1 ORA.ATO.230(a) Training manual and operations manual

ED Decision 2018/001/R

**ORGANISATIONS** 

#### TRAINING MANUAL

Training manuals for use at an ATO to conduct integrated or modular flight training courses should include the following:

## (a) The training plan:

(1) The aim of the course (ATP, CPL/IR, CPL, etc. as applicable)	A statement of what the student is expected to do as a result of the training, the level of performance, and the training constraints to be observed.
(2) Pre-entry requirements	<ul><li>(i) Minimum age, educational requirements (including language), medical requirements;</li><li>(ii) Any individual Member State requirements.</li></ul>
(3) Credits for previous experience	To be obtained from the competent authority before training begins.
(4) Training syllabi	As applicable, the flying syllabus (single-engine or multiengine, as applicable), the flight simulation training syllabus and the theoretical knowledge training syllabus.
(5) The time scale and scale, in weeks, for each syllabus	Arrangements of the course and the integration of syllabi time.
(6) Training programme	<ul> <li>(i) The general arrangements of daily and weekly programmes for flying, theoretical knowledge training and training in FSTDs, if applicable;</li> <li>(ii) Bad weather constraints;</li> <li>(iii) Programme constraints in terms of maximum student training times, (flying, theoretical knowledge, on FSTDs), for example per day, week or month;</li> <li>(iv) Restrictions in respect of duty periods for students;</li> <li>(v) Duration of dual and solo flights at various stages;</li> <li>(vi) Maximum flying hours in any day or night;</li> <li>(vii) Maximum number of training flights in any day or night;</li> <li>(viii) Minimum rest period between duty periods.</li> </ul>
(7) Training records	<ul> <li>(i) Rules for security of records and documents;</li> <li>(ii) Attendance records;</li> <li>(iii) The form of training records to be kept;</li> <li>(iv) Persons responsible for checking records and students' log books;</li> <li>(v) The nature and frequency of record checks;</li> <li>(vi) Standardisation of entries in training records; (vii) Rules concerning log book entries.</li> </ul>
(8) Safety training	<ul> <li>(i) Individual responsibilities;</li> <li>(ii) Essential exercises;</li> <li>(iii) Emergency drills (frequency);</li> <li>(iv) Dual checks (frequency at various stages);</li> <li>(v) Requirement before first solo day, night or navigation etc. if applicable.</li> </ul>



(9) Assessments, tests and examinations	<ul> <li>(i) Flying: <ul> <li>(A) progress checks;</li> <li>(B) skill tests.</li> </ul> </li> <li>(ii) Theoretical knowledge: <ul> <li>(A) progress tests;</li> <li>(B) theoretical knowledge examinations.</li> <li>(C) Area 100 KSA assessments.</li> </ul> </li> <li>(iii) Authorisation for test;</li> <li>(iv) Rules concerning refresher training before retest;</li> <li>(v) Test and assessment reports and records;</li> <li>(vi) Procedures for examination paper preparation, type of question and assessment, standard required for 'pass';</li> <li>(vii) Procedure for question analysis and review and for raising replacement papers;</li> <li>(viii) Examination resit procedures.</li> </ul>
(10) Training effectiveness	<ul> <li>(i) Individual responsibilities;</li> <li>(ii) General assessment;</li> <li>(iii) Liaison between departments;</li> <li>(iv) Identification of unsatisfactory progress (individual students);</li> <li>(v) Actions to correct unsatisfactory progress;</li> <li>(vi) Procedure for changing instructors;</li> <li>(vii) Maximum number of instructor changes per student;</li> <li>(viii) Internal feedback system for detecting training deficiencies;</li> <li>(ix) Procedure for suspending a student from training;</li> <li>(x) Discipline;</li> <li>(xi) Reporting and documentation.</li> </ul>
(11) Standards and level of performance at various stages	<ul><li>(i) Individual responsibilities;</li><li>(ii) Standardisation;</li><li>(iii) Standardisation requirements and procedures;</li><li>(iv) Application of test criteria.</li></ul>

## (b) Briefing and air exercises:

(1) Air exercise	A detailed statement of the content specification of all the air exercises to be taught, arranged in the sequence to be flown with main and subtitles.
(2) Air exercise reference list	An abbreviated list of the above exercises giving only main and subtitles for quick reference, and preferably in flip-card form to facilitate daily use by instructors.
(3) Course structure: phase of training	A statement of how the course will be divided into phases, indication of how the above air exercises will be divided between the phases and how they will be arranged to ensure that they are completed in the most suitable learning sequence and that essential (emergency) exercises are repeated at the correct frequency. Also, the syllabus hours for each phase and for groups of exercises within each phase should be stated and when progress tests are to be conducted, etc.
(4) Course structure: integration of syllabi	The manner in which theoretical knowledge and flight training in an aircraft or an FSTD will be integrated so that as the flying training exercises are carried out students will be able to apply the knowledge gained from the associated theoretical knowledge instruction and flight training.



(5) Student progress	The requirement for student progress and include a brief but specific statement of what a student is expected to be able to do and the standard of proficiency he/she must achieve before progressing from one phase of air exercise training to the next. Include minimum experience requirements in terms of hours, satisfactory exercise completion, etc. as necessary before significant exercises, for example night flying.
(6) Instructional methods	The ATO requirements, particularly in respect of pre- and postflying briefing, adherence to syllabi and training specifications, authorisation of solo flights, etc.
(7) Progress tests	The instructions given to examining staff in respect of the conduct and documentation of all progress tests.
(8) Glossary of terms	Definition of significant terms as necessary.
(9) Appendices	<ul><li>(i) Progress test report forms;</li><li>(ii) Skill test report forms;</li><li>(iii) ATO certificates of experience, competence, etc. as required.</li></ul>

- (c) Flight training in an FSTD, if applicable: Structure generally as for (b)
- (d) Theoretical knowledge instruction:

(1) Structure of the theoretical knowledge course	A statement of the structure of the course, including the general sequence of the topics to be taught in each subject, the time allocated to each topic, the breakdown per subject and an example of a course schedule. Distance learning courses should include instructions of the material to be studied for individual elements of the course.
(2) Lesson plans	A description of each lesson or group of lessons including teaching materials, training aids, progress test organisation and inter-connection of topics with other subjects.
(3) Teaching materials	Specification of the training aids to be used (for example study materials, course manual references, exercises, self-study materials, demonstration equipment).
(4) Student progress	The requirement for student progress, including a brief but specific statement of the standard that must be achieved and the mechanism for achieving this, before application for theoretical knowledge examinations.
(5) Progress testing	The organisation of progress testing in each subject, including topics covered, evaluation methods and documentation.
(6) Review procedure	The procedure to be followed if the standard required at any stage of the course is not achieved, including an agreed action plan with remedial training if required.
(7) Appendices	<ul><li>(i) Examples of Area 100 KSA summative assessments;</li><li>(ii) Area 100 KSA mental maths test example.</li></ul>



## AMC2 ORA.ATO.230(a) Training manual and operations manual

ED Decision 2018/001/R

## THEORETICAL KNOWLEDGE COURSE DESIGN REQUIREMENTS

An ATO that delivers theoretical knowledge instruction for professional pilot licences should ensure that:

- (a) the courses are designed and developed using the instructional systems design (ISD) methodology, which is supported by a robust and effective management system;
- (b) the courses include a standardised and dynamic assessment and testing system;
- (c) instructors that deliver KSA instruction have received appropriate training covering at least learning styles, teaching methods, facilitation techniques, threat and error management (TEM), the applicable competencies, and the content of the subject(s) and exercises that they are to deliver;
- (d) the recurrent training of instructors is conducted at least annually;
- (e) the instructors that are responsible for assessing Area 100 KSA have received appropriate training regarding the assessment(s) that they are to conduct, and are to be standardised to ensure that the assessment grades awarded are consistent across the ATO; this standardisation should include at least familiarisation with the performance indicators, the ATO's word pictures for grading, and the ATO's debriefing system; and
- (f) recurrent standardisation training is conducted at least annually to ensure continued inter-rater reliability.

## AMC3 ORA.ATO.230(a) Training manual and operations manual

ED Decision 2018/001/R

## AREA KSA 100 02 AND 100 03 LEARNING OBJECTIVES, ASSESSMENTS AND RECORDS

- (a) An ATO that delivers theoretical knowledge instruction for professional pilot licences should ensure that for the learning objectives (LOs) in topics 100 02 and 100 03 of Area 100 KSA there are at least two summative assessments and at least one formative assessment. The summative assessments are to be documented in the student's training records. Both the summative assessments and the formative assessment(s) should be debriefed.
- (b) The formative assessment(s) should:
  - (1) be designed such that the student has the opportunity to ask questions and develop competencies in most of the LOs in 100 02 and 100 03 of Area 100 KSA;
  - (2) be conducted during the training; the ATO may in addition conduct a formative evaluation (continuous assessment) over a specified phase of the course; and
  - (3) be conducted by an instructor that is trained to deliver the formative assessment.
- (c) The summative assessments should:
  - (1) be designed so that they collectively give the student the opportunity to demonstrate competency in all LOs in 100 02 and 100 03 of Area 100 KSA; each individual summative assessment may address some of the LOs in 100 02 and 100 03 of Area 100 KSA;
  - (2) be satisfactorily completed before the student is recommended by the ATO for their first attempt to take the final theoretical knowledge examination paper, and the outcome of the assessments should be included in the student's training record;



- (3) require that for a student to be considered that they have achieved a 'Satisfactory' standard, they:
  - (i) meet at least 35 % (which defines the term 'some' used in the word pictures) of the indicators relevant to the assessment exercise, in each competency;
  - (ii) have an overall positive effect on the outcome or completion of the exercise without any external input from the instructor, or where the assessment requires the instructor to facilitate the exercise, without the instructor providing any knowledge or corrective input to assist in the completion of the exercise; and
- (4) be conducted by an instructor that is trained to deliver the summative assessments.
- (d) The training manual should include the following elements regarding the theoretical knowledge training and assessment of the LOs in topics 100 02 and 100 03 of Area 100 KSA:
  - (1) the positions, or range of positions, of the formative assessment exercise(s) and summative assessment exercises in the training programme;
  - (2) a description of the summative assessments, including a matrix that shows which Area 100 KSA LOs are covered in each exercise;
  - (3) the grading system of the Area 100 KSA summative assessment and a description of the ATO's minimum required standard;
  - (4) the template for the information about Area 100 KSA to be included in the student's training record, which should include at least the dates and result ('Pass' or 'Fail') of the summative assessments and the date and score of the mental maths test;
  - (5) the method of assessment debrief for each summative and formative assessment;
  - (6) for a student who performs below the satisfactory standard in a summative assessment(s), the method to further develop the student's competencies and how to conduct the reassessment.
  - (e) Access to the information on Area 100 KSA kept in the student's training records should be restricted to the student and authorised ATO personnel, and should not be disclosed outside the ATO. The information on the record should first be de-identified before it is used to support course design improvements.

## AMC4 ORA.ATO.230(a) Training manual and operations manual

ED Decision 2018/001/R

#### AREA 100 04 LEARNING OBJECTIVES: MENTAL MATHS TEST AND RECORDS

- (a) An ATO that delivers theoretical knowledge instruction for professional pilot licences should ensure that at least one KSA mental maths test is conducted and the outcome(s) documented in the student's training records.
- (b) The mental maths test(s) may be written or oral in format and should, where possible, be scenario-based, with at least two questions per LO in topic 100 04 of Area 100 KSA.
- (c) The minimum score to pass the Area 100 KSA mental maths test(s) should be 75 % of the marks allocated to a test. However, a higher pass mark may be defined by the ATO.
- (d) The mental maths test(s) should be satisfactorily completed before the student is recommended by the ATO for their first attempt to take their final theoretical knowledge examination paper.



SUBPART ATO – APPROVED TRAINING ORGANISATIONS

## GM1 ORA.ATO.230(a) Training manual and operations manual

ED Decision 2018/001/R

#### **ASSESSMENT OF STUDENTS IN AREA 100 KSA**

- (a) The Area 100 KSA formative assessment(s) and summative assessments may include but not be limited to: written planning exercises combining multiple subjects; practical exercises using training devices (if available); scenario-based oral board (viva voce); scenario-based communications exercises; written assignments or project work; and preparation and delivery of group or individual presentations.
- (b) The format of formative and summative assessment debriefs should be effective, highlighting the student's strengths and weaknesses and enabling future improvement.

## GM2 ORA.ATO.230(a) Training manual and operations manual

ED Decision 2018/001/R

#### **AREA 100 KSA WORD PICTURES**

- (a) 'Word pictures' are a proven assessment tool that standardises pilot core competencies, and can be used to assess student's competency in the Area 100 KSA LOs in topics 100 02 and 100 03. Word pictures describe the student's performance. Each word picture is associated with a numerical grade; within the range of grades, the minimum acceptable standard is defined. Additionally, a word picture describing performance that falls below the minimum satisfactory standard should be included in the range, as well as additional word pictures that relate to grades which exceed this minimum satisfactory standard.
  - Word pictures enable the standardisation of the assessment performance and facilitate interrater reliability within an ATO.
- (b) This GM provides two examples of word pictures.
- (c) The most commonly used word pictures are shown in Section A below. They are based on performance indicators, which explain what the student should demonstrate in order to attain the specific Area 100 KSA LOs that are addressed by the assessment exercise. Word pictures are formed of elements that contain the following:
  - (1) HOW MANY of the performance indicators were observed and, where relevant, HOW OFTEN;
  - (2) HOW WELL the competency was demonstrated in the assessment exercise to have an overall positive effect on the outcome or completion of the assessment exercise;
  - (3) the level of success in the OUTCOME of the assessment exercise.
- (d) An ATO could establish its own set of word picture descriptions as long as they are comparable in the grading of each competency, similar to the 'Communication' and 'Application of knowledge, UPRT and resilience' word pictures example in Section B below.
- (e) The advantage of word pictures is that they provide meaningful and standard data to enable identification of individual, crew, class, instructor and ATO trends, which can be analysed in order to provide feedback for further improvement or development.
- (f) An ATO should ensure that the detailed information obtained through its grading in Area 100 KSA is de-identified before using it to support course improvement.

#### **SECTION A — EXAMPLE 1**

AREA 100 KSA WORD PICTURE GRADE LEVELS (USING INDICATORS)



- (g) The example shown below in this Section contains the most commonly used word pictures, which are formed of elements that contain the following:
  - (1) HOW MANY of the performance indicators in the table further below relevant to that summative assessment were observed in that competency (as a percentage);
  - (2) HOW WELL the competency was demonstrated in the assessment; and
  - (3) the level of success in the OUTCOME of the summative assessment.
- (h) In order to satisfactorily complete an Area KSA 100 summative assessment, the student should reach at least the minimum satisfactory level in each competency covered by that assessment. In case the student fails to reach the minimum satisfactory level in each competency, the student should repeat the summative assessment or another summative assessment that covers the competency(ies) where performance was previously assessed as unsatisfactory.

Table 1: Example generic competency framework that can be applied for assessing the student's level of performance

Competency	Level 1	Level 2	Level 3	Level 4	Level 5
	Unsatisfactory	Satisfactory	Good	Very good	Excellent
General description of each competency level. To be applied to each individual competency in LOS 100 02 and 100 03 of Area 100 KSA.	The student's performance in this competency was ineffective or inadequate, which in relation to this competency had a neutral or negative effect on others or on the outcome of the exercise. The student showed none or few of the relevant performance indicators in this competency.	The student's performance in this competency was satisfactory, which had a slightly positive effect on the satisfactory outcome of the exercise, and in group situations had a slightly positive effect on others.  The student showed at least some* of the relevant performance indicators in this competency.	The student's performance in this competency was effective, which in the case of an exercise where the student is the only participant, significantly contributed to a good outcome. In group situations, the student's contribution had a good effect on others and significantly contributed to the overall outcome of the exercise. The student showed most of the relevant performance indicators to a good standard.	The student's performance in this competency was highly effective, which in the case of an exercise where the student is the only participant, significantly enhanced the very good outcome. In group situations, the student's contribution had a very good effect on others and significantly enhanced the overall outcome of the exercise. The student showed most or all of the relevant performance indicators to a very good standard.	The student's performance in this competency was exemplary, which in the case of an exercise where the student is the only participant, had an outstanding effect on the excellent outcome of the exercise. In group situations, the student's contribution had an excellent effect on others and had an outstanding effect on the overall outcome of the exercise. The student showed all of the relevant performance indicators to an excellent standard.

<sup>\* &#</sup>x27;Some' is defined as showing at least 35 % of the performance indicators in that competency, which were relevant to that exercise.



#### **AREA 100 KSA ASSESSMENT PERFORMANCE INDICATORS**

(i) The performance indicators that relate to the LOs in topics 100 02 and 100 03 of Area 100 KSA can be used to form a word picture.

Table 2: Performance indicators relevant to the LOs in topics 100 02 to 100 03 of Area 100 KSA

Competency	Competency description	Indicators
Communication	Demonstrates effective oral, non-verbal and written communication skills in classroom exercise and assessment situations	<ul> <li>Ensures the recipient is ready and prepared to receive the information.</li> <li>Selects appropriately what, when, how and with whom to communicate.</li> <li>Conveys messages clearly, accurately and concisely.</li> <li>Confirms that the recipient correctly understands important information.</li> <li>Listens actively and demonstrates understanding of the information they receive.</li> <li>Asks relevant and effective questions.</li> <li>Adheres to standard radio-telephony phraseology.</li> <li>Accurately reads, interprets, constructs and responds to given documentation in English.</li> <li>Correctly interprets non-verbal communication.</li> <li>Uses eye contact, body language and gestures that are consistent with and support verbal messages.</li> </ul>
Leadership and teamwork	Displays effective leadership and teamwork.	<ul> <li>Creates an atmosphere of open communication and encourages team participation.</li> <li>Uses initiative and gives directions when required.</li> <li>Admits mistakes and takes responsibility.</li> <li>Anticipates and responds appropriately to others' needs.</li> <li>Carries out instructions when directed.</li> <li>Communicates relevant concerns and intentions.</li> <li>Gives and receives feedback constructively.</li> <li>Demonstrates empathy and shows respect and tolerance for others.</li> <li>Engages others in planning and allocates activities fairly and appropriately according to abilities.</li> <li>Addresses and resolves conflicts and disagreements in a constructive manner.</li> <li>Projects self-control.</li> </ul>



Problem-solving and decision- making	Accurately identifies risks and resolves problems. Uses the appropriate decision-making processes.	<ul> <li>Seeks accurate and adequate information from appropriate sources.</li> <li>Identifies and verifies what and why things have gone wrong.</li> <li>Employs proper problem-solving strategies.</li> <li>Perseveres in working through problems.</li> <li>Uses appropriate decision-making processes in a timely manner.</li> <li>Sets priorities appropriately.</li> <li>Identifies and considers options effectively.</li> <li>Monitors, reviews, and adapts decisions as required.</li> <li>Identifies and manages risks effectively.</li> </ul>
Situation awareness	Perceives and comprehends all the relevant information available, anticipates what could happen that could affect the exercise or situations discussed in the classroom, and gives effective solutions to resolve the situation.	<ul> <li>Identifies and assesses accurately the general environment as it may affect the operation.</li> <li>Identifies and manages threats, errors, and undesirable aircraft states.</li> </ul>
Workload management	Manages available resources or time to efficiently prioritise and complete or perform tasks in a timely manner.	<ul> <li>Maintains self-control.</li> <li>Plans, prioritises and schedules tasks effectively.</li> <li>Manages time efficiently when carrying out tasks.</li> <li>Offers and accepts assistance, delegates when necessary, and asks for help early.</li> <li>Manages and recovers from interruptions, distractions, variations, and failures effectively.</li> </ul>
Application of knowledge, UPRT and resilience	Demonstrates correct and deep understanding of the subject(s), and is able to effectively relate this knowledge between subjects and apply the knowledge for effective threat and error management (TEM).	<ul> <li>Correctly completes pre-flight planning in the practical exercise.</li> <li>Demonstrates KSA and TEM relating to phases of flight in the ground training environment.</li> <li>Correctly and effectively applies knowledge to identify and manage threats and errors that could lead to a potential upset in scenario situations.</li> <li>Recognises potential upset 'threats' and suggests effective 'threat management' in scenario situations.</li> <li>Recognises potential upset 'errors' and suggests effective 'error management' in scenario situations.</li> <li>Identifies the causes of and contributing factors to upsets in aircraft accident and incident reviews and in reported recovered situations or scenarios.</li> <li>Is resilient, i.e. recognises and adapts to disruptions during scenarios and other exercises.</li> <li>Identifies the signs of stress and discusses the effects of stress, fatigue and aviation lifestyle on situation awareness, including</li> </ul>



how to cope with these in order to maintain situation awareness.

## **SECTION B — EXAMPLE 2**

## AREA 100 KSA WORD PICTURES (USING DESCRIPTIONS)

(j) An ATO may devise its own word pictures for each of the competencies, to be used alongside or combined with those given in EXAMPLE 1.

A descriptive word picture typically includes descriptive examples that the ATO's instructors could readily identify and then equate to given competency levels. Below are two examples (for 'Communication' and 'Application of knowledge, UPRT and resilience').

Table 3: Example word pictures using descriptions

Competency	Level 1	Level 2	Level 3	Level 4	Level 5
	Unsatisfactory	Satisfactory	Good	Very good	Excellent
Communication	The student's performance in communication had a neutral or negative effect on the exercise or situation. The student may not have contributed to the exercise or the communication was unclear or insufficient. The student may have occasionally interrupted others, not listened, or showed frustration or inappropriate nonobjective communication. The student may have asked unrelated or unclear questions, or provided insufficient clarity in directions or comments for others to understand.	The student's written or oral communication was sufficient to convey the intent of the exercise. In oral communication the listener may have rarely needed to ask for clarification which the student then positively and clearly provided. The student listened to instructions but may have occasionally been reticent and hesitant to ask questions or make comments. The student may have rarely shown underconfidence or passiveness during the exercise. However, overall their communication was sufficient to	The student's written or oral communication was good. Explanations, discussions, directions and comments were well-structured and clear. The student listened to others actively and when unsure asked appropriate questions to seek clarification. The student showed appropriate confidence and open body language.	The student's written or oral communication was consistently very good. All communication was clear, concise and well-structured, which ensured a very effective outcome. In group situations, the student's ability to interpret others' body language, and the use of body language to ensure a positive outcome, was very effective. At all times the student was calm, engaged and confident.	The student's communication skills were exemplary. At all times the student observed others and ensured that their own communication was extremely effective. In group situations, the student's communication enabled all members to contribute to their greatest ability whilst also ensuring an excellent outcome of the exercise. In group situations, when appropriate, the student proactively and subtly managed the group's mood or motivated the group members appropriately.



	The student may have written without structure or clarity.	ensure a positive outcome of the exercise.			
Competency	Level 1 Unsatisfactory	Level 2 Satisfactory	Level 3 Good	Level 4 Very good	Level 5 Excellent
Application of knowledge, UPRT and resilience	The student's knowledge was at times insufficient or incorrect, which had an adverse effect on the exercise. The student displayed limited ability to relate knowledge between subjects or to apply knowledge to scenarios, exercises or in answers to questions.	The student had the minimum acceptable level of knowledge to complete the exercise to a satisfactory standard. The student occasionally demonstrated the ability to relate knowledge between subjects. The student could identify some threats or errors, and when presented with a threat or error could in most situations suggest at least one possible effective method of mitigation.	The student demonstrated a good level of knowledge with the ability to relate this knowledge effectively between subjects and in scenario exercises or situations. The student identified many threats and errors, and when presented with threats or errors used their knowledge effectively to suggest appropriate mitigations and actions.	The student demonstrated a very good level of knowledge, and correctly and readily related this knowledge across subjects and in scenario situations. The student identified most threats and errors, and immediately used their knowledge to manage them effectively.	The student had an excellent level of understanding which they immediately and appropriately applied across subjects and to the exercise or scenario situation. The student identified all actual threats and errors in scenario situations, anticipated some possible threats and errors (what if's), and used their knowledge to manage them efficiently and very effectively.

## GM3 ORA.ATO.230(a) Training manual and operations manual

ED Decision 2018/001/R

#### AREA 100 KSA EXERCISES AND ASSESSMENTS

Exercises and assessments are to be interwoven into the theoretical knowledge training, utilising a range of learning styles; they should address subject or cross-subject topics, with the application of threat and error management (TEM) and, where possible, be scenario-based. The exercises and assessments do not need to be confined to a classroom.

- (a) Area 100 KSA exercises may be of short duration within a lesson, and the student's performance in the exercises does not need to be recorded, although the main subject and KSA learning points are likely to be discussed (or for distance learning, reviewed) within a post exercise debrief or lesson summary. To allow for flexibility and development, the exercises do not need to be specified in the training plan.
- (b) When a single formative assessment is specified in the training plan, it is likely to be extensive as it will cover many of the LOs in Area KSA 100 02 and 100 03. Alternatively, an ATO may specify



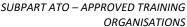
- a number of shorter-duration formative assessments that each covers a narrower range of LOs, and these may build in terms of content difficulty.
- (c) The exercises and formative and summative assessments may include but not be limited to: scenario planning exercises combining multiple subjects; practical exercises using training devices (where available); oral communication exercises; written assignments and/or project work; discussions; the preparation and delivery of group or individual presentations and discussions; and enable scenario-based content and individual, pair or group situation(s).
- (d) The type of assessment and the environment should be recorded in the ATO's training plan.

## GM4 ORA.ATO.230(a) Training manual and operations manual

ED Decision 2018/001/R

#### AREA 100 KSA INSTRUCTION AND ASSESSMENT TRAINING

- (a) The following material has been developed to provide additional guidance to organisations to help them develop an effective KSA 100 instruction and assessment training programme that satisfies the provisions in AMC2 ORA.ATO.230 (c) to (f).
- (b) An ATO should ensure that an instructor who conducts the Area 100 KSA formative assessment(s) has received adequate training to be familiar with the:
  - (1) relevant competencies and performance indicators;
  - (2) Area 100 KSA Learning Objectives (LOs);
  - (3) formative assessment(s) that they will conduct including: the applicable LOs, purpose and content of the assessment(s) and position(s) in the training plan, assessment resources, assessment environment;
  - (4) Area 100 KSA grading system, including familiarisation with the performance indicators and the ATO's word pictures; and
  - (5) student debrief methods and procedure.
- (c) An ATO should ensure that an instructor who conducts the Area 100 KSA summative assessments has received adequate training to be familiar with:
  - (1) the summative assessments that they will conduct including: the applicable LOs, purpose and content of the exercise(s) and position(s) in the training plan, assessment resources, assessment environment, and the minimum acceptable level;
  - (2) the assessment feedback, evaluation and development process; and
  - (3) KSA candidate appeal procedure.
- (d) An Area 100 KSA instruction and assessment course should include practical training on the conduct of an assessment, including grading to achieve inter-rater reliability, and the debrief under supervision.



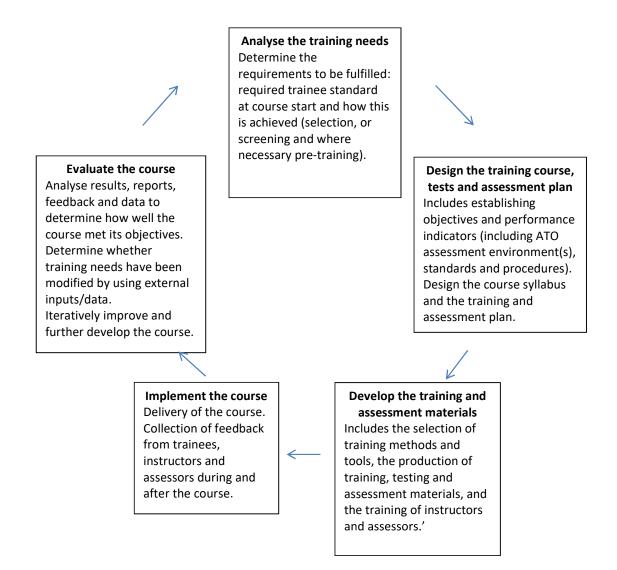


## GM5 ORA.ATO.230(a) Training manual and operations manual

ED Decision 2018/001/R

#### **INSTRUCTIONAL SYSTEMS DESIGN**

- (a) The instructional systems design (ISD) provides a systematic and iterative process for course design based on educational best practices. There are several effective ISD models in use today, with the analyse, design, develop, implement and evaluate (ADDIE) framework being generic to all
  - The purpose of using ISD to design training courses is to facilitate the students' efficient and effective acquisition of knowledge and skills based on current training needs.
- (b) To provide evidence of the effective use of the ISD methodology in the design and continued development of their course(s), an ATO may use documentation and records that relate to the ISD phases.
- (d) ADDIE model example. The 'analysis', 'design', 'development', 'implementation' and 'evaluation' phases of the ADDIE model are shown below with brief phase descriptions.





## AMC1 ORA.ATO.230(b) Training manual and operations manual

ED Decision 2012/007/R

**ORGANISATIONS** 

## ALL ATOS, EXCEPT THOSE PROVIDING FLIGHT TEST TRAINING

#### **OPERATIONS MANUAL**

The operations manual for use at an ATO conducting integrated or modular flight training courses should include the following:

## (a) General:

- (1) a list and description of all volumes in the operations manual;
- (2) administration (function and management);
- (3) responsibilities (all management and administrative staff);
- (4) student discipline and disciplinary action;
- (5) approval or authorisation of flights;
- (6) preparation of flying programme (restriction of numbers of aircraft in poor weather);
- (7) command of aircraft;
- (8) responsibilities of the PIC;
- (9) carriage of passengers;
- (10) aircraft documentation;
- (11) retention of documents;
- (12) flight crew qualification records (licences and ratings);
- (13) revalidation (medical certificates and ratings);
- (14) flight duty period and flight time limitations (flying instructors);
- (15) flight duty period and flight time limitations (students);
- (16) rest periods (flight instructors);
- (17) rest periods (students);
- (18) pilots' log books;
- (19) flight planning (general);
- (20) safety (general): equipment, radio listening watch, hazards, accidents and incidents (including reports), safety pilots etc..

## (b) Technical:

- (1) aircraft descriptive notes;
- (2) aircraft handling (including checklists, limitations, maintenance and technical logs, in accordance with relevant requirements, etc.);
- (3) emergency procedures;
- (4) radio and radio navigation aids;
- (5) allowable deficiencies (based on the master minimum equipment list (MMEL), if available).



## (c) Route:

- (1) performance (legislation, take-off, route, landing etc.);
- (2) flight planning (fuel, oil, minimum safe altitude, navigation equipment etc.);
- (3) loading (load sheets, mass, balance and limitations);
- (4) weather minima (flying instructors);
- (5) weather minima (students at various stages of training);
- (6) training routes or areas.

## (d) Personnel training

- (1) appointments of persons responsible for standards/competence of flight personnel;
- (2) initial training;
- (3) refresher training;
- (4) standardisation training;
- (5) proficiency checks;
- (6) upgrading training;
- (7) ATO personnel standards evaluation.



# SECTION III — ADDITIONAL REQUIREMENTS FOR ATOS PROVIDING SPECIFIC TYPES OF TRAINING

## CHAPTER 1 – DISTANCE LEARNING COURSE

# **ORA.ATO.300** General

Regulation (EU) No 1178/2011

The ATO may be approved to conduct modular course programmes using distance learning in the following cases:

- (a) modular courses of theoretical knowledge instruction;
- (b) courses of additional theoretical knowledge for a class or type rating; or
- (c) courses of approved pre-entry theoretical knowledge instruction for a first type rating for a multi-engined helicopter.

## AMC1 ORA.ATO.300 General

ED Decision 2018/001/R

## **DISTANCE LEARNING**

- (a) A variety of methods is open to ATOs to present course material. It is, however, necessary for ATOs to maintain comprehensive records in order to ensure that students make satisfactory academic progress and meet the time constraints laid down in Part-FCL for the completion of modular courses.
- (b) The following are given as planning guidelines for ATOs developing the distance learning element of modular courses:
  - (1) an assumption that a student will study for at least 15 hours per week;
  - (2) an indication throughout the course material of what constitutes a week's study;
  - (3) a recommended course structure and order of teaching;
  - (4) one progress test for each subject for every 15 hours of study, which should be submitted to the ATO for assessment. Additional self-assessed progress tests should be completed at intervals of five to 10 study hours;
  - (5) appropriate contact times throughout the course when a student can have access to an instructor by telephone, fax, email or the Internet;
  - (6) measurement criteria to determine whether a student has satisfactorily completed the appropriate elements of the course to a standard that, in the judgement of the HT, or CGI, will enable them to be entered for the Part-FCL theoretical examinations with a good prospect of success;
  - (7) if the ATO provides the distance learning by help of IT solutions, for example the Internet, instructors should monitor students' progress by appropriate means.



SUBPART ATO – APPROVED TRAINING ORGANISATIONS

(c) Where an assessment (e.g. planning, written, scenario or practical exercise, or other assessment) is conducted outside the classroom via distance learning, the ATO should have a procedure or process in place to establish that the student themselves have completed the assessment and that the assessment method(s) for that particular exercise has (have) been effective.

## **ORA.ATO.305 Classroom instruction**

Regulation (EU) No 1178/2011

- (a) An element of classroom instruction shall be included in all subjects of modular distance learning courses.
- (b) The amount of time spent in actual classroom instruction shall not be less than 10 % of the total duration of the course.
- (c) To this effect, classroom accommodation shall be available either at the principal place of business of the ATO or within a suitable facility elsewhere.

# AMC1 ORA.ATO.305(b) Classroom instruction

ED Decision 2017/022/R

Classroom instruction delivered by an instructor to a student may include videoconferencing appropriate to the task if the necessary level of communication is ensured and appropriate equipment and tools are available.

# **ORA.ATO.310 Instructors**

Regulation (EU) No 1178/2011

All instructors shall be fully familiar with the requirements of the distance learning course programme.



## CHAPTER 2 - ZERO FLIGHT-TIME TRAINING

## **ORA.ATO.330** General

Regulation (EU) No 1178/2011

- (a) Approval for zero flight-time training (ZFTT), as specified in Part-FCL, shall only be given to ATOs that also have the privileges to conduct commercial air transport operations or ATOs having specific arrangements with commercial air transport operators.
- (b) Approval for ZFTT shall only be given if the operator has at least 90 days of operational experience on the aeroplane type.
- (c) In the case of ZFTT provided by an ATO having a specific arrangement with an operator, the 90 days of operational experience requirements will not apply if the type rating instructor (TRI(A)) involved in the additional take-offs and landings, as required in Part-ORO, has operational experience on the aeroplane type.

## AMC1 ORA.ATO.330 General

ED Decision 2012/007/R

## **INITIAL APPROVAL**

For an initial approval to conduct ZFTT, the operator should have held an air operator's certificate for commercial air transport for at least 1 year. This period may be reduced where the operator and the ATO have experience of type rating training.

# ORA.ATO.335 Full flight simulator

Regulation (EU) No 290/2012

- (a) The FFS approved for ZFTT shall be serviceable according to the management system criteria of the ATO.
- (b) The motion and the visual system of the FFS shall be fully serviceable, in accordance with the applicable certification specifications for FSTD as mentioned in <u>ORA.FSTD.205</u>.



# CHAPTER 3 - MULTI-CREW PILOT LICENCE (MPL) COURSES

# **ORA.ATO.350** General

Regulation (EU) No 1178/2011

The privileges to conduct MPL integrated training courses and MPL instructor courses shall only be given to the ATO if it also has the privilege to conduct commercial air transport operations or a specific arrangement with a commercial air transport operator.



## **CHAPTER 4 – FLIGHT TEST TRAINING**

# **ORA.ATO.355** Flight test training organisations

Regulation (EU) No 1178/2011

- (a) The ATO that has been approved to provide flight test training for the issue of a category 1 or 2 flight test rating in accordance with Part-FCL may have its privileges extended to providing training for other categories of flight tests and other categories of flight test personnel, provided that:
  - (1) the relevant requirements of Part-21 are met; and
  - (2) a specific arrangement exists between the ATO and the Part-21 organisation that employs, or intends to employ, such personnel.
- (b) The training records shall include the written reports by the student, as required by the training programme, including, where applicable, data processing and analysis of recorded parameters relevant to the type of flight test.



# SUBPART FSTD – REQUIREMENTS FOR ORGANISATIONS OPERATING FLIGHT SIMULATION TRAINING DEVICES (FSTDs) AND THE QUALIFICATION OF FSTDs

## **SECTION I – REQUIREMENTS FOR ORGANISATIONS OPERATING FSTDS**

# **ORA.FSTD.100 General**

Regulation (EU) No 1178/2011

- (a) The applicant for an FSTD qualification certificate shall demonstrate to the competent authority that it has established a management system in accordance with ORA.GEN Section II. This demonstration shall ensure that the applicant has, directly or through contract, the capability to maintain the performance, functions and other characteristics specified for the FSTD's qualification level and to control the installation of the FSTD.
- (b) If the applicant is the holder of a qualification certificate issued in accordance with this Part, the FSTD specifications shall be detailed:
  - (1) in the terms of the ATO certificate; or
  - (2) in the case of an AOC holder, in the training manual.

## AMC1 ORA.FSTD.100 General

ED Decision 2012/007/R

## **COMPLIANCE MONITORING PROGRAMME – ORGANISATIONS OPERATING FSTDs**

- (a) Introduction.
  - (1) The purpose of this AMC is to provide additional and specific information to an organisation operating FSTDs on how to establish a compliance monitoring programme (CMP) that enables compliance with the applicable requirements.
- (b) Compliance monitoring programme
  - (1) Typical subject areas for inspections are the following:
    - (i) actual FSTD operation;
    - (ii) maintenance;
    - (iii) technical standards
    - (iv) FSTD safety features.
- (c) Audit scope
  - (1) Organisations operating FSTDs are required to monitor compliance with the procedures they have designed to ensure specified performance and functions. In doing so they should as a minimum, and where appropriate, monitor the following:
    - (i) organisation;
    - (ii) plans and objectives;



- (iii) maintenance procedures;
- (iv) FSTD qualification level;
- (v) supervision;
- (vi) FSTD technical status;
- (vii) manuals, logs and records;
- (viii) defect deferral;
- (ix) personnel training;
- (x) aircraft modifications;
- (xi) FSTD configuration management.

## AMC2 ORA.FSTD.100 General

ED Decision 2012/007/R

#### COMPLIANCE MONITORING PROGRAMME – ORGANISATIONS OPERATING FSTDs

One acceptable means of measuring FSTD performance is contained in ARINC report 433-1 (December 14th, 2007 or as amended) *Standard Measurements for Flight Simulation Quality*.

## AMC3 ORA.FSTD.100 General

ED Decision 2012/007/R

# COMPLIANCE MONITORING PROGRAMME – ORGANISATIONS OPERATING BASIC INSTRUMENT TRAINING DEVICES (BITDs)

- (a) The compliance monitoring programme together with a statement acknowledging completion of a periodic review by the accountable manager should include the following:
  - (1) a maintenance facility that provides suitable BITD hardware and software test and maintenance capability;
  - (2) a recording system in the form of a technical log in which defects, deferred defects and development work are listed, interpreted, actioned and reviewed within a specified time scale; and
  - (3) planned routine maintenance of the BITD and periodic running of the qualification test guide (QTG) with adequate manning to cover BITD operating periods and routine maintenance work.
- (b) A planned audit schedule and a periodic review should be used to verify that corrective action was carried out and that it was effective. The auditor should have adequate knowledge of BITDs.



## **GM1 ORA.FSTD.100 General**

ED Decision 2012/007/R

#### COMPLIANCE MONITORING - ORGANISATIONS OPERATING FSTDs - GENERAL

- (a) The concept of compliance monitoring (CM) is a fundamental requirement for organisations operating FSTDs. An effective CM function is vitally important in supporting operation of the devices, in a structured way, to ensure they remain in compliance with the technical standards of CS-FSTD(A) and CS-FSTD(H) and continue to be effective training tools. An effective CM function is also essential to support any level of extended recurrent evaluation period as permitted by ORA.FSTD.225(b).
- (b) The following guidance has been developed to provide additional material to help both organisations operating FSTDs and competent authorities in developing effective CM that satisfy the applicable requirements and ensure the highest standards of training are maintained.
- (c) Additional GM provide a compliance checklist for organisations operating FSTDs (GM2 ORA.FSTD.100) and guidance detailing the preparation for an evaluation by the competent authority (GM3 ORA.FSTD.100). The compliance checklist should be used by the competent authorities as a standardised checklist for the elements that are expected in the CM function of an organisation operating FSTDs. The organisation should complete as a minimum the second column of the checklist by providing appropriate manual or procedure references for each of the identified elements of the CM function. Additional information can be provided in the third column to aid assessment of the checklist as appropriate. This would then be provided to the competent authority. Use of this checklist should assist in ensuring a consistent approach by the competent authorities and also provide organisations operating FSTDs with additional guidance on all the elements of a CM function that the competent authorities will expect. The guidance is provided to help organisations operating FSTDs to prepare for authority visits.
- (d) The documentation of the CM may be electronic, provided the necessary controls can be demonstrated. This should include control of any paper copies that may be downloaded for use by individuals. It is recommended that any such copies are automatically designated as uncontrolled as part of the download process. Whilst electronic signatures on master documents may be accepted, with appropriate protections, a hardcopy master of the CM manual should be provided, with wet-ink signatures to be held by the applicant.
- (e) It should be recognised that whatever CM is developed, it will not be effective unless it becomes an integral part of the way in which the organisation works. It includes both the necessary procedures for maintaining compliance with all the applicable requirements and a compliance monitoring programme (CMP) to monitor the execution of these procedures. A successful CM will ensure that the highest training tool is available at all times. If the CM is viewed as an addon to existing processes it will become a burden and it will never be wholly effective. It should also be noted that compliance control or inspection is only a small part of a CM. If the CM is working effectively, inspections such as fly-outs should become routine revealing little beyond day-today unserviceabilities. Systematic defects should be captured by the CMP.
- (f) The competent authority should be satisfied that the accountable manager is able to adequately provide the required level of resources to properly support the FSTD. Detailed knowledge of FSTD requirement standards are not necessary, only sufficient to understand his/her responsibility for ensuring the FSTD is properly supported. The assessment of the compliance



monitoring manager should concentrate on establishing that the nominee has sufficient knowledge and experience of both CM management and FSTD operations to operate a compliance monitoring system (CMS) within an organisation operating FSTDs. This is likely to require experience of working in the compliance monitoring field and sufficient knowledge of FSTDs and the technical standards with which they should comply.

- (g) If an organisation operating FSTDs is certified under any international quality standard it should assure that it fully covers the applicable organisation requirements of Part-ORA and the qualification basis.
- (h) For small organisations, it is perfectly acceptable to combine the roles of compliance monitoring manager and accountable manager. For other organisations that hold multiple certificates and may cover multiple sites, it is advantageous to have a common CM function with an overall compliance monitoring manager. However, it is essential, particularly where sites may be significantly separated geographically, that there is a nominated representative at each site and possibly for each certificate. These representatives should hold the delegated responsibility of the CM manager for the day-to-day CM role at their site and in their function and have the necessary direct reporting line to the overall CM manager. It will also be necessary to ensure that local representatives are also acceptable to the local competent authority. In many cases the local representatives may perform other functions in addition to this role. This is acceptable provided the necessary independence of any compliance monitoring activity is maintained.
- (i) CM, as a whole, begins with the requirements with which the system seeks to comply. These include both the technical standards, in this case the relevant parts of CS-FSTD(A)/(H) plus any other specific standards, for example health and safety regulations, and the compliance monitoring objectives, such as defect rates and rectification intervals and FSTD reliability targets. The CM should define the process by which these standards are made available to those who require them.
- (j) The next part of CM is that part which defines the day-to-day procedures or working practices by which the standards will be achieved. These procedures should include as a minimum defect reporting systems, defect rectification processes, tracking mechanisms, preventative maintenance programmes, spares handling, equipment calibration and configuration management of the device. They should include checks to assess the compliance of the performed actions. These procedures and standards should be made readily available to anybody involved in the maintenance and day-to-day operation of the FSTD.
- (k) The third part of CM is the method by which the organisation operating an FSTD confirms the device is maintained in compliance with the defined standards and is being operated in accordance with the defined procedures. This is the compliance monitoring programme (CMP) and includes the audit methods, reporting and corrective action procedures and feedback, management reviews and schedules for audits of all aspects of the FSTD operation.
- (I) Across all aspects of CM, and most important to it, are the people. CM includes the definition of the responsibilities of all staff and should include a declaration of the minimum levels of resource proposed for the direct support of the FSTD plus the levels of support and managerial staff proposed. The levels of resource can be affected by factors such as local health and safety regulations, existence of weekend and/or night usage of the device(s), etc. CM also includes definition of the skills and experience required for staff and leads to definition of any required training programmes. Training needs cover both technical training and audit training, including QTG running and checking and fly-out techniques for flight crew.



- (m) The documentation of CM may be provided in any number of documents provided there are appropriate cross-references in all documents such that the system is fully traceable in both directions from end to end. For all but small organisations at least two documents would be expected:
  - (1) Firstly, a CM manual containing the policy, terminology, organisational charts and responsibilities, an overview of all processes, within the system, including those for maintaining regulatory compliance such as QTG running and fly-outs (function and subjective testing), CMP including the audit schedule and audit procedures including reporting and corrective action procedures. In addition, the CM manual should include, either directly or by reference, the identification of skills and experience and associated training.
  - (2) Secondly, a procedures manual containing, as a minimum, software and hardware control procedures, configuration control procedures including, for example, control of training loads, updates to visual models, navigation and instructor operation station (IOS) databases, QTG running and checking procedures, fly-out procedures, maintenance procedures including both defect rectification and preventative maintenance processes. Any standard forms and checklists should also be included.
- (n) The CM documentation also includes all records such as technical logs, QTG runs, fly-out reports and maintenance job cards.
- (o) For organisations with several certificates, separate and modular procedures manuals with a single CM manual covering all approvals, may be acceptable.
- (p) It is important to understand the difference between compliance assurance and compliance control. An effective CM will contain elements of both. Compliance control is normally done by inspection of the product; it provides confirmation at the time of the inspection that the product conforms to a defined standard.
- (q) The compliance assurance element is essential to ensure the standard is maintained throughout the periods between product (FSTD) inspections. Within a CMP, the processes are defined that are necessary to provide confidence that the FSTD(s) is/are being supported and maintained to the highest possible standard and in compliance with the relevant requirements. A programme of internal audits is then set in place to confirm that the processes are being followed and are effective. The competent authority would normally oversee a certified organisation by process and system audit, however, in the case of FSTDs, authority oversight includes an inspection element in the form of the recurrent FSTD evaluation.
- (r) In addition to the normal process and system audits, the compliance assurance audit schedule should include the schedule for each FSTD for fly-outs and QTG running through the audit year.
- (s) The audit procedure should include, at least, the following: statement of scope, planning, initiation of audit, collection of evidence, analysis, reporting of findings, identification and agreement of corrective actions and feedback, including reporting significant findings to the competent authority, where appropriate. The review of published material could include, in addition to the CM and procedures manuals, QTG records, fly-out reports, technical log sheets, maintenance records and configuration control records.
- (t) In addition to basic knowledge of FSTD requirements and operation, it is expected that auditors have received training in CM and audit techniques.



- (u) The routine fly-outs of the device are a specialised part of the audit programme. It is essential that the pilots tasked with carrying out these fly-outs are adequately experienced. They would be expected to be type rating instructor/examiner (TRI/TRE) qualified on the type, and should have experience of simulator evaluations carried out by the competent authority. The assignment of such pilots can present difficulties, particularly for the independent organisation operating FSTDs not directly associated with an airline. It is vital for the organisation to ensure their users are aware of the importance of the fly-outs as part of the continued qualification of the device and the need to assist in the provision of suitably qualified pilots to carry them out. It is worth noting that simulator users are required to satisfy themselves that the training devices they use are assessed for continued suitability, as part of their own CMP. Involvement in fly-outs assists in meeting this need.
- (v) Whilst it is accepted that the number of audits required in an organisation with a single device will be significantly less than those in larger organisations with multiple devices, the CMP should still meet the same criteria, and cover all aspects of the operation within a 12 month period. The independence of the audit personnel should be maintained at all times. The audit programme, whether by full audit or by using a checklist system should still be sufficiently comprehensive to provide the necessary level of confidence that the device is maintained and operated to the highest possible standard. This includes monitoring and review of corrective actions and feedback processes.
- (w) The successful use of sub-contractors who play a significant role in the provision of services, such as maintenance or engineering services, to an organisation operating FSTDs is reliant on the sub-contractor operating under the CM of the organisation. All requirements that an organisation is expected to meet are equally applicable to his/her sub-contractor. It is the organisation's responsibility to ensure that the sub-contractor complies with its CM.
- (x) It is essential that a proper understanding of the CM and how it applies to each and every staff member is provided by appropriate training to all, not just those directly involved in operating the CM, such as the accountable manager, the CM manager, representatives and the auditors. The training given to those directly involved in CM should cover the CM, audit techniques and applicable technical standards. CM familiarisation training should be an integral part of any induction training and recurrent training. Update training on technical standards for audit personnel, is also of particular importance.
- (y) Any effective CM will include measurement of its effectiveness. The organisation should develop performance measures that can be monitored against objectives. Such measures, often referred to as metrics, should be reviewed by the competent authority as part of its oversight of the CM within the organisation and during recurrent evaluations. In addition they should form part of the data reviewed during scheduled management reviews as part of the CM.
- (z) ARINC 433 provides good guidance on FSTD compliance measurement. Metrics should monitor not only individual FSTD performance but, for larger organisations, how each FSTD is performing within the fleet. It is also recommended that metrics data be shared, regularly, with the FSTD manufacturers to allow monitoring for generic problems such as design issues, which may be best addressed with a fleet-wide solution.

# GM2 ORA.FSTD.100 General

ED Decision 2012/007/R

## **COMPLIANCE MONITORING – ASSESSMENT FOR ORGANISATIONS OPERATING FSTDs**

COMPLIANCE MONITORING ASSESSMENT FOR ORGANISATIONS OPERATING FSTDS				
Organisation:				
Site Assessed:				
Date of Assessment:				
Accountable Manager:				
Compliance Monitoring Manager:				
Number and Type of FSTDs:				
CM Manual Reference:				
Audit Area	CM/Proc Ref	Comments	Satisfactory Y/N	
1. ACCOUNTABLE MANAGER		I	1 /	
Has an accountable manager (AM) with				
overall responsibility for compliance				
monitoring (CM) been nominated?				
Does the accountable manager have				
corporate authority to ensure all necessary				
activities can be financed and carried out to				
the standard required by the competent				
authority?				
Has a formal written compliance policy				
statement been established, included in the				
CM manual and signed by the accountable				
manager?				
2. COMPLIANCE MONITORING MANAGER				
Has a compliance monitoring manager (CM				
manager) been nominated?				
Are the posts of CM manager and AM				
combined? If so, is the independence of				
compliance audits assured?				
Does the CM manager have overall				
responsibility and authority to:				
a) verify that standards are met; and				
b) ensure that the compliance				
monitoring programme is established,				
implemented and maintained?				
Does the CM manager have direct access to				
the AM?				
Does the CM manager have access to all parts				
of the organisation operating an FSTD and as				
necessary any sub-contractor's organisation?				
3. COMPLIANCE MONITORING (CM)				
Has CM been established by the operator?				



Is CN	// properly documented? (see Section 4)		
	e CM structured according to the size		
	complexity of the operator?		
	s the CM include the following as a		
	mum:		
a)	monitoring of compliance with	a)	
a)		a)	
<b>b</b> \	required technical standards; identification of corrective actions and		
b)		b)	
٠,١	person responsible for rectification;		
c)	a feedback system to accountable	(c)	
	manager to ensure corrective action		
۱۱.	are promptly addressed;	d)	
d)	reporting of significant	,	
	noncompliances to the competent		
٠,١	authority;	,	
e)	a compliance monitoring programme	e)	
	to verify continued compliance with		
	applicable requirements, standards		
	and procedures.		
	e CM structured according to the size		
	complexity of the operator?		
	the responsibilities of the CM manager		
	ned to include, as a minimum:		
a)	monitoring of corrective action	a)	
<b>L</b> .\	programme;	 	
b)	ensuring that the corrective actions	b)	
-1	contain the necessary elements;	-1	
c)	providing management with an	c)	
	independent assessment of corrective		
	action, implementation and		
-11	completion;	-11	
d)	evaluation of the effectiveness of the	d)	
	corrective action programme.		
	adequate financial, material and human		
	urces in place to support CM?		
	management evaluations/reviews of CM		
	at least quarterly?		
	the management evaluation ensure		
	the CMS is working effectively and is it		
	prehensive and well documented?		
	the compliance monitoring programme		
	tify the processes necessary and the		
•	ons within the organisation who have the		
	ing, experience, responsibility and		
	ority to carry out the following:	,	
a)	schedule and perform quality	a)	
	inspections and audits, including		
	unscheduled audits when required;		
b)	identify and record any concerns or	b)	
	findings, and the evidence necessary		
	to substantiate such concerns or		
	findings;		
		c)	

# Easy Access Rules for Aircrew (Regulation (EU) No 1178/2011)

ANNEX VII (Part-ORA)

<ul> <li>c) initiate or recommend solutions to concerns or findings through designated reporting channels;</li> <li>d) verify the implementation of solutions within specific timescales.</li> </ul>	d)
Is there sufficient auditor resource available	
and can their required level of independence	
be demonstrated?	
Do the auditors report directly to the	
compliance monitoring manager?	
Does the defined audit schedule cover the	
following areas, within each 12 month period?	
a) organisation	a)
b) plans and objectives	b)
c) maintenance procedures	c)
d) FSTD qualification level;	d)
e) supervision	e)
f) FSTD technical status	f)
g) manuals, logs and records	g)
h) defect deferral	h)
i) personnel training	i)
j) aircraft and simulator configuration	j)
management, including Airworthiness	
Directives	
How are audit noncompliances recorded?	
Are procedures in place to ensure that	
corrective actions are taken in response to	
findings?	
Are records of the compliance monitoring	
programme: a) accurate	2)
b) complete and	a)   b)
c) readily accessible?	c)
Is there an acceptable and effective	•,
procedure for providing a briefing on the CM	
to all personnel?	



Is there an acceptable and effective	
procedure for ensuring that all those	
responsible for managing the CM receive	
training covering:	
a) an introduction to the concept of the	a)
CM;	
b) compliance management;	b)
c) the concept of compliance assurance;	c)
d) CM manuals;	(d)
e) audit techniques;	e)
f) reporting and recording;	f)
g) how the CM supports continuous	g)
improvement within the organisation.	
Are suitable training records maintained?	
Are activities within the CM sub-contracted	
out to external agencies?	
Do written agreements exist between the	
organisation and the sub-contractor clearly	
defining the services and standard to be	
provided?	
Are the procedures in place to ensure that	
the necessary authorisations/ approval when	
required are held by a sub-contractor?	
Are the procedures in place to establish that	
the subcontractor has the necessary technical	
competence?	
4. CM MANUAL	
What is the current status of the CM manual	
- amendment and issue date?	
Is there a procedure in place to control copies and the distribution of the CM manual?	
Is the CM manual signed by the accountable manager and the compliance monitoring	
manager?	
Does the CM manual include, either directly	
or by reference to other documents, the following:	
a) a description of the organisation;	a)
b) reference to appropriate FSTD	b)
technical standards;	
c) allocation of duties and	c)
responsibilities;	
d) audit procedures;	d)
e) reporting procedures;	e)
f) follow-up and corrective action	f)
procedures;	
g) document retention policy;	g)
h) training records	h)
Is there a document retention policy	, i
covering:	
a) audit schedules;	a)
b) inspection and audit reports;	b)
c) responses to findings;	(c)



d)	corrective action reports;		d)		
e)	follow-up and closure reports;		e)		
f)	management evaluation reports.		f)		
Does	the CM manual				
inclu	de, either directly or by reference to				
othe	r documents, the following procedures				
for d	ay to day operation of the FSTD:				
a)	defect reporting systems;		a)		
b)	defect rectification processes;		b)		
c)	tracking mechanisms;		c)		
d)	preventative maintenance		d)		
	programmes;				
e)	spares handling;		e)		
f)	equipment calibration;		f)		
g)	configuration management of the		g)		
	device including visual, IOS and				
	navigation databases;				
h)	configuration control system to ensure		h)		
	the continued integrity of the				
	hardware and software qualified;				
i)	QTG running and function and		i)		
	subjective tests.				
Does	the CM manual				
inclu	de, either directly or by reference to				
othe	r documents, procedures for notification				
of th	e competent authorities of the				
follo	wing:				
a)	any change in the organisation		a)		
	including company name, location,				
	management;				
b)	major changes to a qualified device;		b)		
c)	deactivation or relocation of a		c)		
	qualified device;				
d)	major failures of a qualified device;		d)		
e)	major safety issue associated with the		e)		
	installation.				
Does	the CM manual define acceptable and				
effec	tive procedures to ensure compliance				
with	applicable health and safety regulations,				
inclu	ding:				
a)	safety briefings;		a)		
b)	fire/smoke detection and suppression;		b)		
c)	protection against electrical,		c)		
	mechanical, hydraulic and pneumatic				
	hazards;				
d)	other items as defined in		d)		
	AMC1 ORA.FSTD.115				
Does	the CM manual include acceptable and				
effec	tive procedures for regularly checking				
1	safety features such as emergency stops				
and emergency lighting, and are such tests					
1	recorded?				
5. CC	OMPLIANCE MEASURES		<u> </u>		

# Easy Access Rules for Aircrew (Regulation (EU) No 1178/2011)

ANNEX VII (Part-ORA)

SUBPART FSTD – REQUIREMENTS FOR ORGANISATIONS OPERATING FLIGHT SIMULATION TRAINING DEVICES (FSTDs) AND THE QUALIFICATION OF FSTDs

Have o	compliance monitoring objectives been			
develo	ped from the policy statement, and			
includ	ed either directly or by reference in the			
CMS n	nanual?			
Does t	he CMS include processes to produce			
and re	view appropriate metrics data?			
Do the	ese compliance measures track the			
follow	ing:			
a)	FSTD availability;		a)	
b)	numbers of defects;		b)	
c)	open defects;		c)	
d)	defect closure rates;		d)	
e)	training session interrupt rates;		e)	
f)	training session compliance rating.		f)	
Do the	compliance measures support the			
compl	iance objectives?			
Requi	red actions/Comments			
Signature:				
Date:				

## **GM3 ORA.FSTD.100 General**

ED Decision 2012/007/R

# COMPLIANCE MONITORING SYSTEM – GUIDANCE FOR ORGANISATIONS OPERATING FSTDs TO PREPARE FOR A COMPETENT AUTHORITY EVALUATION

## (a) Introduction

The following material provides guidance on what is expected by the competent authorities to support the discussion during the preliminary briefing, which is a first step of any initial or recurrent evaluation of an FSTD carried out by a competent authority.

This document has been developed as well to standardise working methods throughout Member States and to develop effective CM spot checks to satisfy the applicable requirements and therefore to ensure the highest standards of training are attained.

## (b) Document form

Different document forms can be considered. Nevertheless, it appears that the best solution is a dossier, which includes all the information required by the competent authority to perform an evaluation.

- (c) Contents of the dossier for an initial evaluation:
  - (1) type of FSTD and qualification level requested;
  - (2) evaluation agenda: including date of evaluation, name of people involved for the competent authority, contact details for the FSTD operator, schedules for the subjective flight profile, QTG rerun;



- (3) FSTD identification and detailed technical specification including, type of FSTD, manufacturer, registration number, date of entry into service, host computer, visual system, motion system, type of IOS, simulated version(s), standards of all the aircraft computers, if applicable. Manuals needed for an evaluation (e.g. flight manuals, system manuals, acceptance test manual, IOS user manual etc. if applicable) could already be provided as part of the dossier in an electronic format;
- (4) planned modifications;
- (5) subjective open defect(s);
- (6) airport visual databases including for each visual scene, name of the airport, IATA and ICAO codes, type of visual scene (specific or generic), additional capabilities (e.g. snow model, WGS 84 compliance, enhanced ground proximity warning system (EGPWS)); and
- (7) QTG status: the list should include for each QTG test available the status of the tests following the FSTD operator and competent authority reviews.
- (d) Contents of the dossier for a recurrent evaluation:
  - (1) type of FSTD and qualification level requested;
  - (2) evaluation agenda, including date of evaluation, name of people involved for the competent authority, contact details for the operator, schedules for the subjective flight profile, QTG rerun and QTG review;
  - (3) FSTD identification, including type of FSTD, manufacturer, registration number, date of entry into service, host computer, visual system, motion system, type of IOS, simulated version(s), standards of all the aircraft computers, if applicable;
  - (4) status of items raised during the last evaluation and date of closure;
  - (5) reliability data: training hours month by month during the past year, numbers of complaints mentioned in the technical log, training hours lost, availability rate;
  - (6) operational data: a list of FSTD users over the previous 12 months should be provided, with number of training hours;
  - (7) failure tabulation including categorisation of failures (by ATA chapter and Pareto diagram, ARINC classification);
  - (8) details of main failures leading to training interruption or multiple occurrences of some failures;
  - (9) hardware and/or software updates or changes since last evaluation and planned hardware and/or software updates or changes;
  - (10) subjective open defect(s);
  - (11) airport visual databases including for each visual scene, name of the airport, ATA and ICAO codes, type of visual scene (specific or generic), additional capabilities (snow model, WGS 84 compliance, EGPWS);
  - (12) QTG status: the list should include for each QTG test available, the date of run during the past year, any comment, and the status of the tests; and
  - (13) results of scheduled internal audits and additional quality inspections (if any) since last evaluation and a summary of actions taken.



# **ORA.FSTD.105** Maintaining the FSTD qualification

Regulation (EU) No 290/2012

- (a) In order to maintain the qualification of the FSTD, an FSTD qualification certificate holder shall run the complete set of tests contained within the master qualification test guide (MQTG) and functions and subjective tests progressively over a 12-month period.
- (b) The results shall be dated, marked as analysed and evaluated, and retained in accordance with ORA.FSTD.240, in order to demonstrate that the FSTD standards are being maintained.
- (c) A configuration control system shall be established to ensure the continued integrity of the hardware and software of the qualified FSTD.

## **ORA.FSTD.110 Modifications**

Regulation (EU) No 1178/2011

- (a) The holder of an FSTD qualification certificate shall establish and maintain a system to identify, assess and incorporate any important modifications into the FSTDs it operates, especially:
  - (1) any aircraft modifications that are essential for training, testing and checking, whether or not enforced by an airworthiness directive; and
  - (2) any modification of an FSTD, including motion and visual systems, when essential for training, testing and checking, as in the case of data revisions.
- (b) Modifications of the FSTD hardware and software that affect handling, performance and systems operation or any major modifications of the motion or visual system shall be evaluated to determine the impact on the original qualification criteria. The organisation shall prepare amendments for any affected validation tests. The organisation shall test the FSTD to the new criteria.
- (c) The organisation shall inform the competent authority in advance of any major changes to determine if the tests carried out are satisfactory. The competent authority shall determine if a special evaluation of the FSTD is necessary prior to returning it to training following the modification.

# **AMC1 ORA.FSTD.110 Modifications**

ED Decision 2012/007/R

## **GENERAL**

- (a) The FSTD, where applicable, should be maintained in a configuration that accurately represents the aircraft being simulated. This may be a specific aircraft tail number or may be a representation of a common standard.
- (b) Users of the device should always establish a differences list for any device they intend to use, and to identify how any differences should be covered in training. In order to ensure each device is maintained in the appropriate configuration, the organisation operating an FSTD should have a system that ensures that all relevant airworthiness directives (ADs) are introduced where applicable on affected FSTDs.
- (c) ADs from both the State of Design of the aircraft and the State where the FSTD is located should be monitored. ADs from the State of Design of an aircraft are usually automatically applicable, unless specifically varied by the aircraft's State of Registry.



- (d) Where appropriate, ADs issued by States where users of the device have aircraft registered should also be monitored. In addition to ADs, the FSTD operator should also put in place processes that ensure all aircraft modifications are reviewed for any effect on training, testing and checking. This can be achieved by reviewing the aircraft manufacturer's service bulletins and may require a specific link to the aircraft manufacturer to be developed. In practice this link is often established through aircraft operators who use the device.
- (e) Organisations operating FSTDs should notify the competent authority of major changes.
- (f) This does not imply that the competent authority will always wish to directly evaluate the change. The competent authority should be mindful of the potential burden placed on the organisation by a special evaluation and should always consider that burden when deciding if such an evaluation is necessary.
- (g) The organisation operating FSTDs should have an internal acceptance process for modifications, to be used when implementing all modifications, even if the competent authority has made a decision to carry out an evaluation.

## **GM1 ORA.FSTD.110 Modifications**

ED Decision 2012/007/R

#### **EXAMPLES OF MAJOR MODIFICATIONS**

The following are examples of modifications that should be considered as major. This list is not exhaustive and modifications need to be classified on a case-by-case basis:

- (a) any change that affects the QTG;
- (b) introduction of new standards of equipment such as flight management and guidance computer (FMGC) and updated aerodynamic data packages;
- (c) re-hosting of the FSTD software;
- (d) introduction of features that model new training scenarios; e.g. airborne collision avoidance system (ACAS), EGPWS;
- (e) aircraft modifications that could affect the FSTD qualification; and
- (f) FSTD hardware or software modifications that could affect the handling qualities, performance or system representation.

## **ORA.FSTD.115 Installations**

Regulation (EU) No 1178/2011

- (a) The holder of an FSTD qualification certificate shall ensure that:
  - (1) the FSTD is housed in a suitable environment that supports safe and reliable operation;
  - (2) all FSTD occupants and maintenance personnel are briefed on FSTD safety to ensure that they are aware of all safety equipment and procedures in the FSTD in case of an emergency; and
  - (3) the FSTD and its installations comply with the local regulations for health and safety.
- (b) The FSTD safety features, such as emergency stops and emergency lighting, shall be checked at least annually and recorded.



# **AMC1 ORA.FSTD.115 Installations**

ED Decision 2012/007/R

#### MINIMUM ELEMENTS FOR SAFE OPERATION

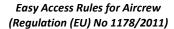
- (a) Introduction
  - (1) This AMC identifies those elements that are expected to be addressed, as a minimum, to ensure that the FSTD installation provides a safe environment for the users and operators of the FSTD under all circumstances.
- (b) Expected elements
  - (1) Adequate fire/smoke detection, warning and suppression arrangements should be provided to ensure safe passage of personnel from the FSTD.
  - (2) Adequate protection should be provided against electrical, mechanical, hydraulic and pneumatic hazards, including those arising from the control loading and motion systems, to ensure maximum safety of all persons in the vicinity of the FSTD.
  - (3) Other areas that should be addressed include the following:
    - (i) a two-way communication system that remains operational in the event of a total power failure;
    - (ii) emergency lighting;
    - (iii) escape exits and escape routes;
    - (iv) occupant restraints (seats, seat belts etc.);
    - (v) external warning of motion and access ramp or stairs activity;
    - (vi) danger area markings;
    - (vii) guard rails and gates;
    - (viii) motion and control loading emergency stop controls accessible from either pilot or instructor seats;
    - (ix) a manual or automatic electrical power isolation switch.

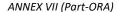
## **GM1 ORA.FSTD.115 Installations**

ED Decision 2012/007/R

### **GENERAL**

- (a) The intent of <u>ORA.FSTD.115</u> is to establish that the organisation operating an FSTD has all the necessary procedures in place to ensure that the FSTD installation remains in compliance with all requirements affecting the safety of the device and its users.
- (b) Based on experience, the competent authority should pay particular attention to the quality of safety briefings on the FSTD provided to users and instructors, and to the execution of regular checks on the FSTD safety features.
- (c) It is recognised that certain checks, such as that of the emergency stop, can have adverse impact on the FSTD if carried out in full.







(d) It is acceptable to develop a procedure that protects elements of the device by shutting them down in advance, in a more controlled manner, provided it can be shown that the procedure still demonstrates the whole device can be shut down by the operation of a single emergency stop button, when required.

# **ORA.FSTD.120 Additional equipment**

Regulation (EU) No 1178/2011

Where additional equipment has been added to the FSTD, even though not required for qualification, it shall be assessed by the competent authority to ensure that it does not adversely affect the quality of training.



## **SECTION II – REQUIREMENTS FOR THE QUALIFICATION OF FSTDS**

# ORA.FSTD.200 Application for FSTD qualification

Regulation (EU) No 1178/2011

- (a) The application for an FSTD qualification certificate shall be made in a form and manner established by the competent authority:
  - (1) in the case of basic instrument training devices (BITDs), by the BITD manufacturer;
  - (2) in all other cases, by the organisation intending to operate the FSTD.
- (b) Applicants for an initial qualification shall provide the competent authority with documentation demonstrating how they will comply with the requirements established in this Regulation. Such documentation shall include the procedure established to ensure compliance with <u>ORA.GEN.130</u> and <u>ORA.FSTD.230</u>.

# AMC1 ORA.FSTD.200 Application for FSTD qualification

ED Decision 2012/007/R

LETTER OF APPLICATION FOR INITIAL QUALIFICATION OF AN FSTD; EXCEPT BASIC INSTRUMENT TRAINING DEVICE (BITD)

A sample of letter of application is provided overleaf.

#### Part A

To be submitted not less than 3 months prior to requested qualification date

(Date)
(Office – Competent Authority)
(Address)
(City)
(Country)

Type of FSTD	Aircraft Type/class	Qualification Level Sought				
Full Flight		Α	В	С	D	Sp./Cat
Simulator						
FFS						
Flight Training		1	2	3		
Device						
FTD						
Flight and		1	П	Ш	II MCC	III MCC
Navigation						
Procedures Trainer						
FNPT						ļ

Interim Qualification Level	requested:	YES/NO
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Dear,



# Easy Access Rules for Aircrew (Regulation (EU) No 1178/2011)

ANNEX VII (Part-ORA)

SUBPART FSTD – REQUIREMENTS FOR ORGANISATIONS OPERATING FLIGHT SIMULATION TRAINING DEVICES (FSTDs) AND THE QUALIFICATION OF FSTDs

<Name of Applicant> requests the evaluation of its flight simulation training device < operator's identification of the FSTD> for qualification. The < FSTD manufacturer's name> FSTD with its < visual system and manufacturer's name, if applicable> visual system.

Evaluation is requested for the e.g. 767 PW/GE and 757RR	following configurations	s and engine fits as applicable:
1		
2		
3		
Dates requested are: <date(s)></date(s)>	and the FSTD will be loo	cated at <place>.</place>
The objective tests of the QTG requested evaluation date unle	=	date and in any event not less than 30 days before the ith the competent authority.
Comments:		
Signed		
	•••••	
Print name:		
Position/appointment held:		
Email address: Telephone number:		
relephone number.		
Part B		
To be completed with attack	ned QTG results	
(Date)		
We have completed tests of the below.	FSTD and declare that	it meets all applicable requirements except as noted
The following QTG tests still have	e to be provided:	
Tests		Comments
(Add boxes as required)		

It is expected that they will be completed and submitted 3 weeks prior to the evaluation date.



# Easy Access Rules for Aircrew (Regulation (EU) No 1178/2011)

ANNEX VII (Part-ORA)

Sign	ed		
Posi E-ma	t name: tion/appointment held: ail address: phone number:		
Part	C C		
To k	e completed not less tha	7 days prior to initial evaluation	
		(Da	ite)
The	FSTD has been assessed by t	e following evaluation team:	
(Nar (Nar (Nar	ne)ne)ne)ne)ne)ne)ne)	QualificationQualification	
	cockpit configuration of <no aeroplane/helicopter within systems and subsystems fu</no 	nat the <type fstd="" of=""> conforms to the aeroplane flight me of aircraft operator (if applicable), type of aeroplane the requirements for <type and="" fstd="" level="" of=""> and that ction equivalently to those in that aeroplane/helicopteressed the performance and the flying qualities of the FS eroplane/helicopter.</type></type>	e/helicopter> the simulated r. The pilot of this
	<pre><aeroplane and="" cl="" fstd="" helicopter="" level="" or=""> and that th helicopter. The pilot of this</aeroplane></pre>	It the <type fstd="" of=""> represents the flight deck or cockess of aeroplane/type of helicopter&gt; within the requirem simulated systems appear to function as in the class of valuation team has also assessed the performance and represents the designated class of aeroplane/type of here</type>	nents for <type aeroplane="" flying="" of="" qualities<="" td="" the="" type=""></type>
(Add	litional comments as require	)	
		······································	
Sign	ed		
Posi E-ma	t name: tion/appointment held: ail address: phone number:		



# GM1 ORA.FSTD.200 Application for FSTD qualification

ED Decision 2012/007/R

#### **USE OF FOOTPRINT TESTS IN QUALIFICATION TEST SUBMISSION**

## (a) Introduction

- (1) Recent experience during initial qualification of some FFSs has required acceptance of increasing numbers of footprint tests. This is particularly true for FFSs of smaller or older aircraft types, where there may be a lack of aircraft flight test data. However, the large number of footprint tests offered in some QTGs has given rise to concern.
- (2) This guidance is applicable to FFS aeroplane, FTD aeroplane, FFS helicopter and FTD helicopter qualifications.

## (b) Terminology

(1) Footprint test - footprint test data are derived from a subjective assessment carried out on the actual FSTD requiring qualification. The assessment and validation of these data are carried out by a pilot appointed by the competent authority. The resulting data are the footprint validation data for the FSTD concerned.

## (c) Recommendation

- (1) It is permitted to use footprint data where flight test data is not available. Only when all other alternative possible sources of data have been thoroughly reviewed without success may a footprint test be acceptable, subject to a case-by-case review with the competent authorities concerned, and taking into consideration the level of qualification sought for the FSTD.
- (2) Footprint test data should be:
  - (i) constructed with initial conditions and FFS set up in the appropriate configuration (e.g. correct engine rating) for the required validation data;
  - (ii) a manoeuvre representative of the particular aircraft being simulated;
  - (iii) manually flown out by a type rated pilot who has current experience on type\* and is deemed acceptable by the competent authority\*\*;
  - (iv) constructed from validation data obtained from the footprint test manoeuvre and transformed into an automatic test;
  - (v) an automatic test run as a fully integrated test with pilot control inputs; and
  - (vi) automatically run for the initial qualification and recurrent evaluations.
  - \* In this context, 'current' refers to the pilot experience on the aircraft and not to the Part-FCL standards.
  - \*\* The same pilot should sign off the complete test as being fully representative.
- (3) A clear rationale should be included in the QTG for each footprint test. These rationales should be added to and clearly recorded within the validation data roadmap (VDR) in accordance with and as defined in Appendix 2 to AMC1-CS-FSTD(A).300.
- (4) Where the number of footprint tests is deemed by the competent authority to be excessive, the maximum level of qualification may be affected. The competent authority should review each area of validation test data where the use of footprint tests as the



basis for the validation data is proposed. Consideration should be given to the extent to which footprint tests are used in any given area.

For example, it would be unacceptable if all or the vast majority of takeoff tests were proposed as footprint tests, with little or no flight test data being presented. It should be recognised, therefore, that it may be necessary for new flight test data to be gathered if the use of footprint tests becomes excessive, not just overall, but also in specific areas.

(5) For recurrent evaluation purposes an essential match is to be expected. Validation tests using footprint data which do not provide an essential match should be justified to the satisfaction of the competent authority.

The competent authority should be consulted at the point of definition of the aircraft data for qualification prior to the procurement of the device if footprint tests need to be used.

# **ORA.FSTD.205 Certification specifications for FSTDs**

Regulation (EU) No 1178/2011

- (a) The Agency shall issue, in accordance with Article 19 of Regulation (EC) No 216/2008, Certification Specifications as standard means to show compliance of FSTDs with the Essential Requirements of Annex III to Regulation (EC) No 216/2008.
- (b) Such Certification Specifications shall be sufficiently detailed and specific to indicate to applicants the conditions under which qualifications will be issued.

## **ORA.FSTD.210 Qualification basis**

Regulation (EU) No 70/2014

- (a) The qualification basis for the issuance of an FSTD qualification certificate shall consist of:
  - (1) the applicable Certification Specifications established by the Agency that are effective on the date of the application for the initial qualification;
  - (2) the aircraft validation data defined by the mandatory part of the operational suitability data as approved under Regulation (EU) No 748/2012, if applicable; and
  - (3) any special conditions prescribed by the competent authority if the related Certification Specifications do not contain adequate or appropriate standards for the FSTD because the FSTD has novel or different features to those upon which the applicable Certification Specifications are based.
- (b) The qualification basis shall be applicable for future recurrent qualifications of the FSTD, unless it is re-categorised.

# **ORA.FSTD.225** Duration and continued validity

Regulation (EU) 2024/2076

- (a) The FSTD qualification certificate shall remain valid subject to the following conditions:
  - (1) the FSTD and the operating organisation remaining in compliance with the applicable requirements;



- (2) the competent authority being granted access to the organisation as defined in point <a href="#ORA.GEN.140">ORA.GEN.140</a> to determine continued compliance with the relevant requirements of Regulation (EU) 2018/1139 and the implementing and delegated acts adopted on the basis thereof;
- (3) the qualification certificate not being surrendered or revoked.
- (b) If the competent authority has extended the recurrent evaluation period for an FSTD in accordance with point <u>ARA.FSTD.120(c)</u> of Annex VI (Part-ARA), the organisation shall assign a person or group of persons with adequate experience who shall do all of the following within a period of 60 days before and 30 days after the start of each recurrent 12-month period in accordance with point <u>ARA.FSTD.120(b)(1)</u> of Annex VI:
  - (1) review the regular reruns of the complete tests in the master QTG;
  - (2) conduct the relevant functions and subjective tests;
  - (3) send a report of the results to the competent authority.
- (c) A BITD qualification shall remain valid subject to regular evaluation for compliance with the applicable qualification basis by the competent authority in accordance with point ARA.FSTD.120 of Annex VI.
- (d) Upon surrender or revocation, the FSTD qualification certificate shall be returned to the competent authority.

# AMC1 ORA.FSTD.225(b)(4) Duration and continued validity

ED Decision 2012/007/F

The assigned person should have experience in FSTDs and training. The person may have FSTD experience or training experience with an education in FSTD evaluation procedures only, provided the other element of expertise is available within the organisation and a procedure for undertaking the annual review and reporting to the competent authority is documented within the compliance monitoring function.

# **ORA.FSTD.230 Changes to the qualified FSTD**

Regulation (EU) No 1178/2011

- (a) The holder of an FSTD qualification certificate shall inform the competent authority of any proposed changes to the FSTD, such as:
  - (1) major modifications;
  - (2) relocation of the FSTD; and
  - (3) any de-activation of the FSTD.
- (b) In case of an upgrade of the FSTD qualification level, the organisation shall apply to the competent authority for an upgrade evaluation. The organisation shall run all validation tests for the requested qualification level. Results from previous evaluations shall not be used to validate FSTD performance for the current upgrade.
- (c) When an FSTD is moved to a new location, the organisation shall inform the competent authority before the planned activity along with a schedule of related events.



Prior to returning the FSTD to service at the new location, the organisation shall perform at least one third of the validation tests, and functions and subjective tests to ensure that the FSTD performance meets its original qualification standard. A copy of the test documentation shall be retained together with the FSTD records for review by the competent authority.

The competent authority may perform an evaluation of the FSTD after relocation. The evaluation shall be in accordance with the original qualification basis of the FSTD.

(d) If an organisation plans to remove an FSTD from active status for prolonged periods, the competent authority shall benotified and suitable controls established for the period during which the FSTD is inactive.

The organisation shall agree with the competent authority a plan for the de-activation, any storage and re-activation to ensure that the FSTD can be restored to active status at its original qualification level.

# AMC1 ORA.FSTD.230(b) Changes to the qualified FSTD

ED Decision 2012/007/R

## **UPDATING AND UPGRADING EXISTING FSTDs**

- (a) An update is a result of a change to the existing device where it retains its existing qualification level. The change may be certified through a recurrent inspection or an extra inspection if deemed necessary by the competent authority according to the applicable requirements in effect at the time of initial qualification.
- (b) If such a change to an existing device would imply that the performance of the device could no longer meet the requirements at the time of initial qualification, but that the result of the change would, in the opinion of the competent authority, clearly mean an improvement to the performance and training capabilities of the device altogether, then the competent authority might accept the proposed change as an update while allowing the device to retain its original qualification level.
- (c) An upgrade is defined as the raising of the qualification level of a device, or an increase in training credits, which can only be achieved by undergoing an initial qualification according to the latest applicable requirements.
- (d) As long as the qualification level of the device does not change, all changes made to the device should be considered to be updates pending approval by the competent authority.
- (e) An upgrade, and consequent initial qualification according to the latest applicable requirements, is only applicable when the organisation requests another qualification level (recategorisation) for the FSTD.

# ORA.FSTD.235 Transferability of an FSTD qualification

Regulation (EU) No 290/2012

- (a) When there is a change of the organisation operating an FSTD, the new organisation shall inform the competent authority in advance in order to agree upon a plan of transfer of the FSTD.
- (b) The competent authority may perform an evaluation in accordance with the original qualification basis of the FSTD.



(c) When the FSTD no longer complies with its initial qualification basis, the organisation shall apply for a new FSTD qualification certificate.

## ORA.FSTD.240 Record-keeping

Regulation (EU) No 1178/2011

The holder of an FSTD qualification certificate shall keep records of:

- (a) all documents describing and proving the initial qualification basis and level of the FSTD for the duration of the FSTD's lifetime; and
- (b) any recurrent documents and reports related to each FSTD and to compliance monitoring activities for a period of at least 5 years.

## AMC1 ORA.FSTD.240 Record-keeping

ED Decision 2012/007/R

#### **FSTD RECORDS**

- (a) FSTD records to be kept should include the following:
  - (1) for the lifetime of the device:
    - (i) the master QTG (MQTG) of the initial evaluation;
    - (ii) the qualification certificate of the initial evaluation; and
    - (iii) the initial evaluation report;
  - (2) for a period of at least 5 years (in paper or electronic format):
    - (i) recurrent QTG runs;
    - (ii) recurrent evaluation reports;
    - (iii) reports of internal functions and subjective testing;
    - (iv) technical log;
    - (v) CMS report;
    - (vi) audit schedule;
    - (vii) evaluation programme;
    - (viii) management evaluation reports;
    - (ix) obsolete procedures and forms.



## SUBPART AEMC – AERO-MEDICAL CENTRES

## **SECTION I – GENERAL**

# ORA.AeMC.105 Scope

Regulation (EU) 2024/2076

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.

## [applicable until 12 February 2025 - Regulation (EU) 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:

- (a) provide aero-medical expertise and practical training for AMEs;
- (b) issue medical certificates and cabin crew medical reports, including initial class 1 medical certificates, or class 3 medical certificates in accordance with Commission Regulation (EU) 2015/340 (¹), or both, as applicable.

[applicable from 13 February 2025 - Regulation (EU) 2024/2076]

# ORA.AeMC.115 Application

Regulation (EU) 2024/2076

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 <u>ORA.GEN.115</u>, provide details of clinical attachments to or liaison with designated hospitals or medical institutes for the purpose of specialist medical examinations.

[applicable until 12 February 2025 - Regulation (EU) 1178/2011]

(b) in addition to the documentation for the approval of an organisation required in point ORA.GEN.115, provide details of activities that are contracted to designated hospitals or medical institutes for the purpose of specialist medical examinations.

[applicable from 13 February 2025 - Regulation (EU) 2024/2076]

<sup>.</sup> 

<sup>&</sup>lt;sup>1</sup> 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, ELI: http://data.europa.eu/eli/reg/2015/340/oj).



## 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.120 AeMC certificate**

Regulation (EU) 2024/2076

An organisation holding an AeMC certificate shall not, at any time, hold more than one AeMC certificate issued with the same scope in accordance with Regulation (EU) 2018/1139 and the implementing and delegated acts adopted on the basis thereof.

[applicable from 13 February 2025 - ED Decision 2024/2076]

# **ORA.AeMC.135** Continued validity

Regulation (EU) 2024/2076

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.

## [applicable until 12 February 2025 - Regulation (EU) 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 complying with the following conditions:

- (a) complying with point <u>MED.D.030</u> of Annex IV (Part-MED) to this Regulation or point ATCO.MED.C.025 of Annex IV (Part-ATCO.MED) to Regulation (EU) 2015/340, as applicable;
- (b) ensuring their continued experience by performing an adequate number of class 1 medical examinations, or class 3 medical examinations in accordance with Regulation (EU) 2015/340, or equivalent military aero- medical examinations, as appropriate, every year.

[applicable from 13 February 2025 - Regulation (EU) 2024/2076]

# 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.

# **ORA.AeMC.160** Reporting

Regulation (EU) 2024/2076

The AeMC shall provide the competent authority with statistical reports regarding the aero-medical assessments of applicants, including reports of the drugs and alcohol screening performed in accordance with point <u>MED.B.055(b)</u> of Annex IV (Part-MED) and any health risk factors or trends identified during the aero-medical assessments.

[applicable from 13 February 2025 - ED Decision 2024/2076]



## **SECTION II – MANAGEMENT**

# ORA.AeMC.200 Management system

Regulation (EU) 2024/2076

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 [applicable until 12 February 2025 Regulation (EU) 1178/2011]
- (a) for medical certification in compliance with Part-MED; [applicable from 13 February 2025 Regulation (EU) 2024/2076]
- (aa) to facilitate cooperation between the AMEs and other medical experts of the AeMC; and [applicable from 13 February 2025 Regulation (EU) 2024/2076]
- (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.205 Contracted activities**

Regulation (EU) 2024/2076

Notwithstanding point **ORA.GEN.205**, all of the following shall apply:

- (a) minimum required aero-medical examinations shall be performed within the organisation of the AeMC, in accordance with the scope and privileges defined in the terms of approval attached to the AeMC's certificate;
- (b) additional medical examinations and investigations may be performed by contracted individual experts or organisations. The organisation shall ensure that when contracting any part of its activity, the contracted service or product conforms to the applicable requirements.

[applicable from 13 February 2025 - ED Decision 2024/2076]



# **ORA.AeMC.210** Personnel requirements

Regulation (EU) 2024/2076

- (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.

## [applicable until 12 February 2025 - Regulation (EU) 1178/2011]

- (a) The AeMC shall have the following in its staff:
  - (1) an aero-medical examiner (AME) nominated as head of the AeMC, with privileges to issue class 1 medical certificates, or class 3 medical certificates in accordance with Regulation (EU) 2015/340, as applicable, in accordance with the scope defined in the terms of approval attached to the AeMC's certificate and sufficient experience in aviation medicine to exercise his or her duties;
  - (2) at least one additional qualified AME with privileges to issue class 1 medical certificates, or class 3 medical certificates in accordance with Regulation (EU) 2015/340, as applicable, in accordance with the scope defined in the terms of approval attached to the AeMC's certificate privileges, and other technical staff;
  - (3) available medical experts.
- (b) The head of the AeMC shall be responsible for:
  - (1) coordinating the assessment of examination results;
  - (2) signing reports, certificates, and initial class 1 medical certificates and class 3 medical certificates in accordance with Regulation (EU) 2015/340.'

[applicable from 13 February 2025 - Regulation (EU) 2024/2076]

# **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.



## **ANNEX VIII (PART-DTO)**

#### DTO.GEN.100 General

Regulation (EU) 2018/1119

In accordance with the second subparagraph of Article 10a(1), this Annex (Part-DTO) sets out the requirements applicable to pilot training organisations providing the training referred to in point DTO.GEN.110 on the basis of an declaration made in accordance with point DTO.GEN.115.

### **DTO.GEN.105** Competent authority

Regulation (EU) 2018/1119

For the purpose of this Annex (Part-DTO), the competent authority in respect of a DTO shall be the authority designated by the Member State on the territory of which the DTO has its principal place of business.

#### **DTO.GEN.110 Scope of the training**

- (a) A DTO shall be entitled to provide the following training, provided that the DTO has submitted a declaration in accordance with point <u>DTO.GEN.115</u>:
  - (1) for aeroplanes:
    - (a) theoretical knowledge instruction for LAPL(A) and PPL(A);
    - (b) flight instruction for LAPL(A) and PPL(A);
    - (c) training towards class rating for SEP(land), SEP(sea) and TMG;
    - (d) training towards additional ratings: night, aerobatics, mountain, sailplane and banner towing;
  - (2) for helicopters:
    - (a) theoretical knowledge instruction for LAPL(H) and PPL(H);
    - (b) flight instruction for LAPL(H), PPL(H);
    - (c) single-engine type rating for helicopters for which the maximum certified seat configuration does not exceed five seats;
    - (d) training towards night rating;
  - (3) for sailplanes, in accordance with the requirements of Annex III (Part-SFCL) to Commission Implementing Regulation (EU) 2018/1976:
    - (a) theoretical knowledge instruction for the SPL;
    - (b) flight instruction for the SPL;
    - (c) training towards extension of privileges to sailplanes or TMGs in accordance with point SFCL.150;
    - (d) training towards additional launching methods in accordance with point SFCL.155;



- training towards additional ratings and privileges: basic aerobatic and advanced aerobatic privileges, sailplane and banner towing rating, TMG night rating, and sailplane cloud flying privileges;
- (f) training towards flight instructor certificate for sailplanes (FI(S));
- (g) FI(S) refresher course;
- (4) for balloons, in accordance with the requirements of Annex III (Part-BFCL) to <u>Commission</u> <u>Implementing Regulation (EU) 2018/1976</u>:
  - (a) theoretical knowledge instruction for the BPL;
  - (b) flight instruction for the BPL;
  - (c) training towards class or group extension in accordance with point BFCL.150;
  - (d) training towards additional ratings: tethered hot-air balloon flight, night, and commercial operation rating;
  - (g) training towards flight instructor certificate for balloons (FI(B));
  - (h) FI(B) refresher course.
- (b) A DTO shall be entitled to also provide the examiner courses referred to in points BFCL.430 and BFCL.460(b)(1) of Annex III (Part-BFCL) to Commission Regulation (EU) 2018/395 for FE(B), as well as in points SFCL.430 and SFCL.460(b)(1) of Annex III (Part-SFCL) to Commission Implementing Regulation (EU) 2018/1976 for FE(S), provided that the DTO has submitted a declaration in accordance with point DTO.GEN.115 and the competent authority has approved the training programme in accordance with point DTO.GEN.230(c).

#### **GM1 DTO.GEN.110 Scope**

ED Decision 2018/009/R

Point <u>DTO.GEN.110</u> lists all the training activities that are regulated by Part-FCL and which can be conducted at a DTO. However, for some of the training activities mentioned, Part-FCL (points FCL.130.S, FCL.130.B, FCL.225.B(b), FCL.810(c)) does not require the involvement of a training organisation at all. In this regard, point <u>DTO.GEN.110</u> does not constitute an obligation for these training activities to be undertaken at a DTO only.

#### **DTO.GEN.115** Declaration

- (a) Prior to providing any of the training specified in point <u>DTO.GEN.110</u>, an organisation intending to provide such training shall submit a declaration to the competent authority. The declaration shall contain at least the following information:
  - (1) the name of the DTO;
  - (2) contact details of the DTO's principal place of business and, where applicable, the contact details of the aerodromes and the operating sites of the DTO;
  - (3) names and contact details of the following persons:
    - (i) the representative of the DTO;
    - (ii) the head of training of the DTO; and
    - (iii) all deputy heads of training, if required by point DTO.GEN.250(b)(1);



- (4) the type of training, as specified in point <u>DTO.GEN.110</u>, provided at each aerodrome and/or operating site;
- (5) a list of all aircraft and FSTDs to be used for the training, if applicable;
- (6) the date of intended commencement of the training;
- (7) a statement confirming that the DTO has developed a safety policy and will apply that policy during all training activities covered by the declaration, in accordance with point DTO.GEN.210(a)(1)(ii);
- (8) a statement that confirms that the DTO complies and will, during all training activities covered by the declaration, continue to comply with the essential requirements set out in Annex IV to Regulation (EU) 2018/1139, with the requirements of Annex I (Part-FCL) and Annex VIII (Part-DTO) to this Regulation and with the requirements of Annex III (Part-BFCL) to Commission Regulation (EU) 2018/395 and Annex III (Part-SFCL) to Commission Implementing Regulation (EU) 2018/1976.
- (b) The declaration, and any subsequent changes thereto, shall be made using the form contained in Appendix 1.
- (c) A DTO shall, together with the declaration, submit to the competent authority the training programme or programmes, which it uses or intends to use to provide the training, as well as its application for approval of the training programme or programmes where such approval is required in accordance with point <a href="DTO.GEN.230(c">DTO.GEN.230(c</a>).
- (d) By derogation from point (c), an organisation which holds an approval issued in accordance with Subpart ATO of Annex VII (Part-ORA) may, together with the declaration, only submit the reference to the already approved training manual or manuals.

## GM1 DTO.GEN.115(a) Declaration

FD Decision 2018/009/R

#### SUBMISSION OF THE DECLARATION

The DTO should submit the declaration (<u>Appendix 1</u> to Part-DTO), and any attachment(s) thereto, in a manner established by the competent authority.

## GM2 DTO.GEN.115(a) Declaration

ED Decision 2018/009/R

#### RESPONSIBILITY OF THE DTO FOR THE SUCCESSFUL SUBMISSION OF THE DECLARATION

It is the responsibility of the DTO to successfully submit the declaration to the competent authority. If the DTO does not receive the acknowledgement of receipt of the declaration from the competent authority pursuant to point ARA.DTO.100 within a reasonable period of time following the submission of the declaration, the DTO should contact the competent authority to investigate whether or not the submission of the declaration has been successful.



## AMC1 DTO.GEN.115(a)(2) Declaration

ED Decision 2018/009/R

#### LIST OF AERODROMES AND OPERATING SITES OF THE DTO

Except for DTOs that provide training for balloons, the list of aerodromes and operating sites on the declaration should contain at least those aerodromes and operating sites where the DTO, either permanently or temporarily (e.g. for training camps), conducts its training activities, where its training aircraft are based and where it has its facilities, as required by Part-DTO.

Aerodromes and operating sites that solely serve as destinations for cross-country training flights do not need to be listed on the declaration.

## AMC1 DTO.GEN.115(a)(5) Declaration

ED Decision 2018/009/R

#### LIST OF AIRCRAFT AND FLIGHT SIMULATION TRAINING DEVICES (FSTDs)

- (a) The list on the declaration of aircraft used by the DTO should contain at least the models used for training (e.g. Cessna 152, Piper PA 28, Robinson R22, etc.). It is not necessary to list on the declaration each individual aircraft with its registration mark.
- (b) The list on the declaration of FSTDs used by the DTO should contain the references to the FTSD qualification certificates.

## AMC1 DTO.GEN.115(c) Declaration

ED Decision 2018/009/R

#### SUBMISSION OF TRAINING PROGRAMMES WITH THE DECLARATION

Except for training programmes for examiner standardisation or refresher courses, a DTO may include in the declaration only a reference to a training programme if this training programme:

- (a) has already been verified for Part-FCL compliance by the competent authority; or
- (b) has been developed by the competent authority as a standard training programme, if applicable.

# DTO.GEN.116 Notification of changes and cessation of training activities

Regulation (EU) 2018/1119

A DTO shall notify the competent authority without undue delay of the following:

- any changes to the information contained in the declaration specified in point <u>DTO.GEN.115(a)</u>
   and to the training programme or programmes or the approved training manual or manuals referred to in points <u>DTO.GEN.115(c)</u> and (d) respectively;
- (b) the cessation of some or all training activities covered by the declaration.



## DTO.GEN.135 Termination of entitlement to provide training

Regulation (EU) 2024/207

- (a) A DTO shall no longer be entitled to provide some or all of the training specified in its declaration on the basis of that declaration, where one of the following occurs:
  - (1) the DTO has notified the competent authority of the cessation of some or all of the training activities covered by the declaration in accordance with point <a href="DTO.GEN.116">DTO.GEN.116</a>(b);
  - (2) the DTO has not provided the training for more than 36 consecutive months.
- (b) A DTO shall return approval certificates in accordance with point <a href="DTO.GEN.230">DTO.GEN.230</a>(c) to the competent authority without delay:
  - (1) in case of cessation of training activities in accordance with point (a);
  - (2) in case of revocation in accordance with point <u>ARA.GEN.350</u>(da)(3) of Annex VI (Part-ARA).

#### **DTO.GEN.140 Access**

Regulation (EU) 2018/1119

For the purpose of determining whether a DTO is acting in compliance with its declaration, the DTO shall grant access at any time to any facility, aircraft, document, records, data, procedures or any other material relevant to its training activities covered by the declaration, to any person authorised by the competent authority

## **DTO.GEN.150 Findings**

Regulation (EU) 2018/1119

After the competent authority has communicated a finding to a DTO in accordance with point ARA.GEN.350(da)(1), the DTO shall take the following steps within the time period determined by the competent authority:

- (a) identify the root cause of the non-compliance;
- (b) take the necessary corrective action to terminate the non-compliance and, where relevant, remedy the consequences thereof;
- (c) inform the competent authority about the corrective action it has taken.

## DTO.GEN.155 Reaction to a safety problem

Regulation (EU) 2018/1119

As a reaction to a safety problem, a DTO shall implement:

- (a) the safety measures mandated by the competent authority in accordance with point ARA.GEN.135(c);
- (b) the relevant mandatory safety information issued by the Agency, including airworthiness directives.



#### **DTO.GEN.210** Personnel requirements

- (a) A DTO shall designate:
  - (1) a representative, who shall be responsible and duly authorised to do at least the following:
    - (i) ensure compliance of the DTO and its activities with the applicable requirements and with its declaration;
    - (ii) develop and establish a safety policy which ensures that the DTO's activities are carried out safely, ensure that the DTO adheres to that safety policy and take the necessary measures in order to achieve the objectives of that safety policy;
    - (iii) promote safety within the DTO;
    - (iv) ensure the availability of sufficient resources within the DTO so that the activities referred to in points (i), (ii) and (iii) can be carried out in an effective manner.
  - (2) a head of training, who shall be responsible and qualified to ensure at least the following:
    - that the training provided complies with the requirements of Annex I (Part-FCL), Annex III (Part-BFCL) to <u>Commission Regulation (EU) 2018/395</u> and Annex III (Part-SFCL) to <u>Commission Regulation (EU) 2018/1976</u> and with the DTO's training programme;
    - (ii) the satisfactory integration of flight training in an aircraft or a flight simulation training device (FSTD) and theoretical knowledge instruction;
    - (iii) the supervision of the progress of students;
    - (iv) in the case referred to in point <u>DTO.GEN.250(b)</u>, the supervision of the deputy head or heads of training.
- (b) A DTO may designate a single person as its representative and its head of training.
- (c) A DTO shall not designate a person as its representative or its head of training if there are objective indications that he or she cannot be trusted to carry out the tasks listed in point (a) in a manner which safeguards and furthers aviation safety. The fact that a person has been subject to an enforcement measure taken in accordance with point ARA.GEN.355 in the past three years shall be deemed to constitute such an objective indication, unless that person can demonstrate that the finding leading to that measure, by reason of its nature, scale or impact on aviation safety, is not such as to indicate that he or she cannot be trusted to carry out those tasks in that manner.
- (d) A DTO shall ensure that its theoretical knowledge instructors have either of the following qualifications:
  - (1) practical background in aviation in the areas relevant for the training provided and have undergone a course of training instructional techniques;
  - (2) previous experience in giving theoretical knowledge instruction and an appropriate theoretical background in the subject on which they will provide theoretical knowledge instruction.



(e) Flight instructors and flight simulation training instructors shall hold the qualifications required by Annex I (Part-FCL), Annex III (Part-BFCL) to <u>Commission Regulation (EU) 2018/395</u> and Annex III (Part-SFCL) to <u>Commission Implementing Regulation (EU) 2018/1976</u> for the type of training they provide.

# GM1 DTO.GEN.210(a)(1)(i) Personnel requirements

ED Decision 2018/009/R

#### OCCURRENCE-REPORTING SYSTEM COMPLIANT WITH REGULATION (EU) No 376/2014

The following list provides an overview of the main elements of the occurrence-reporting system that is compliant with Regulation (EU) No 376/2014 and provides references to the relevant articles of that Regulation.

- (a) Occurrence-reporting system that caters for both mandatory and voluntary reporting (cf. Articles 4 and 5).
  - Note 1: The mandatory reporting system established under Regulation (EU) No 376/2014 is also intended for the reporting of those additional items that qualify for mandatory reporting and are defined in the EASA implementing rules.
  - Note 2: The voluntary reporting system is intended to facilitate the collection of details of occurrences that may not be captured by the mandatory system and of other safety-related information which is perceived by the reporting organisation as an actual or potential hazard to aviation safety.
- (b) Designation of one or more persons to independently handle the collection, evaluation, processing, analysis and storage of details of occurrences with regard to data collection and hazard identification (cf. Article 6(1)).
  - Note 1: In agreement with their competent authority, small-sized organisations may make use of simplified mechanisms to ensure the collection, evaluation, processing, analysis and storage of details of occurrences, possibly by sharing those tasks with other similar organisations.
  - Note 2: An existing internal safety-reporting scheme, which collects safety-relevant data, proposals and information, including data, proposals and information on potential safety issues that have not resulted in any occurrence, may serve as a basis for the mandatory and voluntary occurrence-reporting system. From this pool of safety relevant information and data collected internally, the organisation will determine whether a mandatory report is required or whether a voluntary report may be adequate.
- (c) Reporting details of occurrences collected under the mandatory scheme as soon as possible and in any event no later than 72 hours after becoming aware of the occurrence (cf. Article 4(8) & (9)).
  - Note 1: The reference to 'becoming aware of' an occurrence implies that a person in the organisation identifies the occurrence as falling into the category of a mandatory occurrence report usually through being involved in the occurrence or witnessing it, but also on review or investigation of information reported to the organisation's safety reporting scheme. In the case of design or production organisations, the 72-hour period starts at the point when the unsafe condition is identified.

In the case of automated data collection systems, the 72-hour period starts when the person that is responsible for the analysis of the data detected the reportable occurrence.



Note 2: The 72-hour period does not apply to the reporting of details of occurrences which may involve an actual or potential aviation safety risk and safety-related information collected under the voluntary scheme. These are to be reported in a timely manner (cf. Article 5(5) & (6)).

(d) Establishment of data quality checking processes to ensure that the information initially collected and the data stored in the database(s) are consistent (cf. Article 7(3)).

Note: It is understood that data quality checking processes should address four main areas:

- errors in data entry;
- completeness of data, specially referring to mandatory data;
- proper use of the ADREP¹ taxonomy;
- improve data consistency, notably between the information collected initially and the report stored in the database (cf. Article 7(3)).
- (e) Storage of occurrence reports that qualify for mandatory and voluntary reporting in one or more databases (cf. Article 6(5)) using standardised formats to facilitate information exchange and which are compatible with the ECCAIRS<sup>2</sup> software and ADREP taxonomy (cf. Article 7(4)).

Note: Organisations that are able to report through an ECCAIRS software compatible reporting system provided by their competent authority are deemed to be automatically compliant with the reporting system requirements in Article 7(4) and do not need to have their own ECCAIRS software compatible reporting system.

- (f) Application of the safety policy (cf. AMC1 DTO.GEN.210(a)(1)(ii)) to occurrences:
  - (1) identification of the safety hazards that are associated with identified occurrences or groups of occurrences reported to the competent authority (cf. Article 13(1));
  - (2) analysis of the related risks in terms of probability and severity of the outcome, as well as assessment of the risks in terms of tolerability;
  - (3) based on the result of the risk assessment: determination of the need for mitigation action, as required for improving aviation safety (cf. Article 13(2)); and
  - (4) monitoring the timely implementation and effectiveness of any mitigation action required (cf. Article 13(2)).
- (g) In addition to the actions required under paragraph (6) above, where the organisation identifies an actual or potential aviation safety risk as a result of the analysis of occurrences or group of occurrences:
  - (1) transmission of the following information to the competent authority within 30 days from the date of notification of the occurrence to the authority (cf. Article 13(4)):
    - (i) the preliminary results of the risk assessment performed; and
    - (ii) any preliminary mitigation action to be taken.
  - (2) where required, transmission of the final results of the risk analysis to the competent authority as soon as they are available and, in principle, no later than 3 months from the date of notification of the occurrence to the authority (cf. Article 13(4)).

<sup>&</sup>lt;sup>1</sup> The ICAO Accident/Incident Data Reporting (ADREP) system.

<sup>&</sup>lt;sup>2</sup> European Coordination Centre for Accident and Incident Reporting Systems.



Note: The legal obligation to provide the initial results of the analysis of the occurrence, follow-up reports and final results lies with the other organisation that issued the initial report. Where an organisation receives a copy of a report from another organisation that initially reported the occurrence to the competent authority, depending on its contribution to the actual or potential aviation safety risk underlying the occurrence, it may however be required to perform its own analysis of the issue reported and to provide a follow-up report to the competent authority.

- (h) Safety policy and just culture: Consultation of staff representatives to ensure mutual agreement on and adoption of the rules describing how 'just culture' principles are guaranteed and implemented within the organisation.
  - Note 1: The purpose of those rules is to ensure that employees and contracted personnel that report or are mentioned in occurrence reports, both mandatory or voluntary, are not subject to any prejudice by their employer or any other organisation for which the services are provided on the basis of the information supplied by the reporter (cf. Article 16(9)), unless an exception applies (cf. Article 16(10)).
  - Note 2: Staff representatives may be nominated either by the trade union(s) or by the staff themselves.
- (i) Ensuring that employees and contracted personnel are regularly provided with information concerning the analysis of, and follow-up on, occurrences for which mitigation action is taken (cf. Article 13(3), while ensuring that only disidentified information is disseminated.
- (j) Ensuring that personal details are made available to staff of their organisation, other than the persons designated in accordance with paragraph (2), only where absolutely necessary to investigate occurrences with a view to enhancing aviation safety.
- (k) Ensuring that reports addressed to the competent authority contain at least the information listed in Annex I to Regulation (EU) No 376/2014.

## AMC1 DTO.GEN.210(a)(1)(ii) Personnel requirements

ED Decision 2018/009/R

#### **SAFETY POLICY**

- (a) The safety policy should define, in relation to the DTO training programme, at least the means and methods used for:
  - (1) hazard identification;
  - (2) risk assessment; and
  - (3) effectiveness of the mitigation measures (implementation and follow-up).
- (b) The safety policy should additionally include the procedures required for occurrence reporting pursuant to Regulation (EU) No 376/2014 (cf. GM1 DTO.GEN.210(a)).



## AMC1 DTO.GEN.210(a)(2) Personnel requirements

ED Decision 2018/009/R

#### QUALIFICATION AND EXPERIENCE OF THE HEAD OF TRAINING (HT)

- (a) The HT should, with regard to the size and the training scope of the DTO, possess sufficient managerial capabilities in order to discharge their responsibilities, and should:
  - (1) in the case of a DTO that provides training in aircraft or FSTDs, hold an unrestricted instructor certificate in accordance with Part-FCL with instructional privileges that are relevant to the training provided by the DTO, including sufficient experience as necessary;
  - (2) in the case of a DTO that provides theoretical knowledge training only, have appropriate experience in aviation and knowledge relevant to the training provided.
- (b) At a DTO that provides training courses for different aircraft categories, the HT should be assisted by one or more nominated deputy HTs qualified in accordance with paragraph (a) and with regard to the other category or categories of aircraft.

# GM1 DTO.GEN.210(a)(2) Personnel requirements

ED Decision 2018/009/R

#### SUFFICIENT EXPERIENCE OF THE HEAD OF TRAINING (HT)

'Sufficient experience', as per AMC2 DTO.GEN.210(a)(1) paragraph (a)(1), means that the HT should have gained the required experience as an instructor in order to have the capacity to administer the particular training activity of the DTO in question. The following factors should be taken into consideration for determining the experience required:

- (a) training scope of the DTO, including specific training courses (e.g. aerobatic rating, sailplane cloud flying rating, examiner courses for sailplanes and balloons);
- (b) location of the DTO training area (e.g. mountains, sea, congested airspace);
- (c) size of the DTO (volume of activity, number of training aerodromes and operating sites);
- (d) use of FSTDs;
- (e) training aircraft models used by the DTO.

## **GM1 DTO.GEN.210(c) Personnel requirements**

ED Decision 2018/009/R

CIRCUMSTANCES UNDER WHICH A PERSON CANNOT BE TRUSTED TO CARRY OUT THE TASKS OF A REPRESENTATIVE OR A HEAD OF TRAINING (HT) IN A MANNER WHICH SAFEGUARDS AND FURTHERS AVIATION SAFETY

Examples of objective indications that a person cannot be trusted to carry out the tasks of a representative or an HT in a manner which safeguards and furthers aviation safety.

If that person, within the last 5 years preceding their nomination as representative or HT, in a declaration in accordance with Part-DTO:

- (a) holds or has held a pilot licence and that licence and/or any associated ratings, certificates or authorisations have been subject to limitation, suspension or revocation;
- (b) has knowingly and deliberately been responsible for committing any non-compliance with the Basic Regulation and its implementing rules.



## AMC1 DTO.GEN.210(d);(e) Personnel requirements

ED Decision 2018/009/R

#### **DTO INSTRUCTORS**

In order to ensure and monitor that instructors maintain their required qualification, DTOs should permanently keep a list of all instructors, including information on their instructional privileges as well as on the validity periods of their licences, ratings and certificates, including their medical certificates.

### GM1 DTO.GEN.210(d);(e) Personnel requirements

ED Decision 2018/009/R

#### **RESOURCES (INSTRUCTORS)**

- (a) The ratio of all students to flight instructors should allow maintaining the quality and safety of the training provided.
- (b) Class numbers in ground subjects involving a high degree of supervision or practical work should not exceed 28 students.

## DTO.GEN.215 Facility requirements

Regulation (EU) 2018/1119

A DTO shall have facilities in place allowing the performance and management of all its activities in accordance with the essential requirements of Annex III to Regulation (EC) No 216/2008 and with the requirements of this Annex (Part-DTO).

### **AMC1 DTO.GEN.215 Facility requirements**

ED Decision 2018/009/R

- (a) The facilities of a DTO should comprise:
  - (1) flight planning facilities providing access to at least:
    - (i) appropriate and current aviation maps and charts;
    - (ii) current aeronautical information service (AIS) information;
    - (iii) current meteorological information;
    - (iv) communications to air traffic control (ATC) (if applicable);
    - (v) any other flight-safety-related material;
  - (2) adequate briefing facilities of sufficient size and number;
  - (3) suitable office(s) to allow flight instructors to write reports on students, complete records and other related documentation, as appropriate;
  - (4) suitable rest areas for instructors and students, where appropriate to the training task;
  - (5) in the case of DTOs that provide training for 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.

## DTO.GEN.220 Record-keeping

Regulation (EU) 2018/1119

- (a) A DTO shall keep for each individual student the following records throughout the training course and for three years after completion of the last training session:
  - (1) details of ground, flight and simulated flight training;
  - (2) information on individual progress;
  - (3) information on the licences and associated ratings relevant to the training provided, including expiry dates of ratings and medical certificates.
- (b) A DTO shall keep the report on the annual internal review and the activity report referred to in point <a href="DTO.GEN.270(a)">DTO.GEN.270(a)</a> and (b) respectively for three years from the date at which the DTO established those reports.
- (c) A DTO shall keep its training programme for three years from the date at which it provided the last training course in accordance with that programme.
- (d) A DTO shall, in accordance with the applicable law on the protection of personal data, store the records referred to in point (a) in a manner that ensures protection by appropriate tools and protocols and take the necessary measures to restrict the access to those records to persons who are duly authorised to access them.

#### AMC1 DTO.GEN.220 Record-keeping

ED Decision 2018/009/R

Training records should be kept in a paper or electronic version by the DTO where the candidate is undertaking their training.

## DTO.GEN.230 DTO training programme

- (a) A DTO shall establish a training programme for each of the trainings specified in point <a href="https://doi.org/10.110">DTO.GEN.110</a> which the DTO provides.
- (b) The training programmes shall comply with the requirements of Annex I (Part-FCL), Annex III (Part-BFCL) to Commission Regulation (EU) 2018/395 and Annex III (Part-SFCL) to Commission Implementing Regulation (EU) 2018/1976, as applicable.
- (c) A DTO shall be entitled to provide the training referred to in point <a href="DTO.GEN.110(b)">DTO.GEN.110(b)</a> only when its training programme for that training, and any changes thereto, have been issued by the competent authority, upon application by the DTO, with an approval in accordance with point <a href="ARA.DTO.110">ARA.DTO.110</a>, confirming that the training programme and any changes thereto comply with the requirements of Annex I (Part-FCL), Annex III (Part-BFCL) to <a href="Commission Regulation (EU) 2018/395">Commission Regulation (EU) 2018/395</a> and Annex III (Part-SFCL) to <a href="Commission Implementing Regulation (EU) 2018/1976">Commission Implementing Regulation (EU) 2018/1976</a>, as applicable. A DTO shall apply for such approval through the submission of its declaration in accordance with point <a href="DTO.GEN.115">DTO.GEN.115</a>.
- (d) Point (c) shall not apply to an organisation also holding an approval issued in accordance with Subpart ATO of Annex VII (Part-ORA) that includes privileges for that training.



### AMC1 DTO.GEN.230 DTO training programme

ED Decision 2018/009/R

- (a) The DTO training programme should include at least the following information:
  - (1) the aim of the course;
  - (2) crediting of previous experience and pre-entry requirements (including appropriate procedures for students that wish to complete their training after having started at a different training organisation);
  - (3) a list of all air and FSTD exercises to be taught, including a description of the objective of each exercise;
  - (4) a syllabus summary;
  - (5) structure and content of the theoretical knowledge instruction;
  - (6) structure of the entire course and integration of theoretical knowledge instruction, FSTD and flight training;
  - (7) student progress checks for theoretical knowledge and flight training, as appropriate.
- (b) When developing the training programme for a type rating course, in addition to complying with the mandatory training elements included in the operational suitability data (OSD), as established in accordance with Regulation (EU) No 748/2012<sup>1</sup>, the DTO should also follow any further recommendations (i.e. acceptable means of compliance (AMC)) contained therein.

#### **DTO.GEN.240 Training aircraft and FSTDs**

Regulation (EU) 2019/1747

- (a) A DTO shall use an adequate fleet of training aircraft or FSTDs appropriately equipped for the training course provided. The fleet of aircraft shall be composed of aircraft that comply with all requirements defined in Regulation (EU) 2018/1139. Aircraft that fall under points (a), (b), (c) or (d) of Annex I to Regulation (EU) 2018/1139, may be used for training if all of the following conditions are met:
  - (1) during an evaluation process the competent authority has confirmed a level of safety comparable to the one defined by all essential requirements laid down in Annex II to Regulation (EU) 2018/1139;
  - (2) the competent authority has authorised the use of the aircraft for training in the DTO.
- (b) A DTO shall establish and keep up-to-date a list of all aircraft, including their registration marks, used for the training it provides.

## AMC1 DTO.GEN.240 Training aircraft and FSTDs

ED Decision 2018/009/R

- (a) The number of training aircraft may be affected by:
  - (1) the availability of FSTDs; and
  - (2) the number of aerodromes and operating sites of the DTO (cf. AMC1 DTO.GEN.115(a)(2)).

Commission Regulation (EU) No 748/2012 of 3 August 2012 laying down implementing rules for the airworthiness and environmental certification of aircraft and related products, parts and appliances, as well as for the certification of design and production organisations (OJ L 224, 21.8.2012, p. 1), as amended.



- (b) Each training aircraft should be:
  - (1) equipped as required in the training specifications concerning the exercise for which it is used;
  - (2) except in the case of balloons or single-seat aircraft, fitted with primary flight controls that are instantly accessible by both the student and the instructor (for example, dual flight controls or a centre control stick); swing-over flight controls should not be used.
- (c) The fleet should include, as appropriate to the training courses:
  - (1) in the case of aeroplanes and sailplanes, aircraft suitable for demonstrating stalling and spin avoidance;
  - (2) in the case of helicopters, helicopters suitable for autorotation demonstration;
  - (3) FSTDs; each FSTD should be equipped as required in the training specifications concerning the course for which it is used.
- (d) One single aircraft that has all the required characteristics of a training aircraft mentioned in (b) and (c) above may be sufficient.

### GM1 DTO.GEN.240 Training aircraft and FSTDs

ED Decision 2018/009/R

The DTO is required to use an adequate fleet of training aircraft. However, a DTO is not required to own the aircraft used. In any case, the DTO has the responsibility to use airworthy and appropriately equipped, certified and insured aircraft and FSTDs, as relevant to the particular training exercise.

### **AMC3 DTO.GEN.240 Training aircraft and FSTDs**

ED Decision 2020/005/R

#### **EVALUATION PROCESS**

Two cases for the evaluation process of Annex-I aircraft are distinguished:

- (a) Annex-I aircraft that hold an ICAO-level certificate of airworthiness (CoA)
  - (1) To support the evaluation process performed by the competent authority and provide the competent authority with sufficient data related to the aircraft in question, an instructor who is qualified in accordance with Annex I (Part-FCL) to Regulation (EU) No 1187/2011 and nominated by the head of training (HT) of the DTO should assess that the aircraft is appropriately equipped and suitable for the training courses provided. The result of this assessment should be submitted to the competent authority and may be included already in the application for the authorisation.
  - (2) During the evaluation process, the competent authority should consider aircraft that hold a CoA issued in accordance with Annex 8 to the Chicago Convention to provide a level of safety comparable to that required by Annex II to the Basic Regulation, unless the competent authority determines that the airworthiness requirements used for certification of the aircraft, or the service experience, or the safety system of the State of design, do not provide for a comparable level of safety.



#### (b) Annex-I aircraft that do not hold an ICAO-level CoA

Before the inclusion of these aircraft in the fleet of an DTO and their use in training to obtain Part-FCL licences and ratings, the DTO should apply for the authorisation to the competent authority that should perform the evaluation process in the following order:

- (1) Initial assessment by the competent authority and criteria taken into consideration

  The competent authority should take into account the following criteria (non-exhaustive list):
  - (i) national airworthiness requirements based on which the aircraft CoA was issued;
  - (ii) aircraft similarities to a certified variant;
  - (iii) aircraft with a satisfactory in-service experience as training aircraft;
  - (iv) simple and conventional aircraft design;
  - (v) aircraft that does not have hazardous design features or details, judging by experience; and
  - (vi) operable aircraft systems, equipment, and appliances that do not require exceptional skills or strength.
- (2) Additional assessment by a qualified instructor

To support the evaluation process performed by the competent authority and provide the competent authority with sufficient data related to the aircraft in question, after the positive initial assessment by the competent authority as per point (1), an instructor who is qualified in accordance with Part-FCL and nominated by the HT of the DTO should show through an evaluation report that the aircraft is appropriately equipped and suitable for the training courses provided. That evaluation report should consider all of the following criteria:

- (i) the aircraft should be safely controllable and manoeuvrable under all anticipated operating conditions, including after failure of one or more propulsion systems;
- (ii) the aircraft should allow for a smooth transition from one flight phase to another without requiring exceptional piloting skills, alertness, strength, or workload under any probable operating conditions;
- (iii) the aircraft should have sufficient stability to ensure that the demands made on the pilot are not excessive, considering the phase and duration of flight; and
- (iv) the assessment should take into account control forces, flight deck environment, pilot workload, and other human factors (HF) considerations, depending on the phase and duration of flight.

Subject to a positive evaluation report as per point (2), the competent authority should issue the authorisation.



## **DTO.GEN.250 Aerodromes and operating sites**

Regulation (EU) 2018/1119

- (a) When providing flight training on an aircraft, a DTO shall only use aerodromes or operating sites that have the appropriate facilities and characteristics to allow training of the relevant manoeuvres, taking into account the training provided and the category and type of aircraft used.
- (b) When a DTO uses more than one aerodrome to provide any of the training specified in point DTO.GEN.110(a)(1) and (2), it shall:
  - (1) for each additional aerodrome, designate a deputy head of training, who shall be responsible for the tasks referred to in point <a href="DTO.GEN.210(a)(2)(i)">DTO.GEN.210(a)(2)(i)</a> to (iii) on that aerodrome; and
  - (2) ensure the availability of sufficient resources to safely operate on all aerodromes, in compliance with the requirements of this Annex (Part-DTO).

## **AMC1 DTO.GEN.250 Aerodromes and operating sites**

ED Decision 2018/009/R

#### **GENERAL**

- (a) Except in the case of balloons, the base aerodrome or operating site and any other aerodromes or operating sites at which flight training is being conducted should have at least the following facilities:
  - (1) at least one runway or final approach and take-off area (FATO) that allows training aircraft to make a normal take-off or landing within the performance limits of all the aircraft used for the training flights at that aerodrome or operating site;
  - (2) a wind direction indicator that is visible at ground level from the ends of each runway or at the appropriate holding points;
  - (3) adequate runway electrical lighting, if used for night training;
  - (4) an air traffic service (ATS), except for uncontrolled aerodromes or operating sites where the training requirements may be satisfied safely by another acceptable means of communication.
- (b) In addition to (a), for helicopters, training sites should be available for:
  - (1) confined area operation training;
  - (2) simulated engine-off autorotation; and
  - (3) sloping ground operation.
- (c) In the case of balloons, the take-off sites used by the DTO should allow a normal take-off and clearing of all obstacles in the take-off flight path by at least 50 ft.
- (d) By way of derogation from paragraphs (a) to (c) above, for training that needs to take place in a specific environment (training for mountain rating, training on seaplanes), the training sites used should have the characteristics and facilities that are necessary to ensure a safe conduct of the training.



## AMC1 DTO.GEN.250(b) Aerodromes and operating sites

ED Decision 2018/009/R

# SUFFICIENT RESOURCES OF A DTO THAT PROVIDES TRAINING FOR AEROPLANES OR HELICOPTERS AT MORE THAN ONE AERODROME OR OPERATING SITE

- (a) Deputy heads of training should meet the same qualification requirements as set out in AMC1 DTO.GEN.210(a)(2) for the head of training (HT).
- (b) The DTO should have the necessary number of instructors (point <u>DTO.GEN.210(d)</u> and <u>(e)</u>) as well as the necessary number of training aircraft (point <u>DTO.GEN.240</u>) in place to ensure proper training at all aerodromes and operating sites.
- (c) At each aerodrome or operating site of the DTO, the DTO should have in place the facilities (point <u>DTO.GEN.215</u>) as appropriate for the type of training carried outat each aerodrome or operating site.

## DTO.GEN.260 Theoretical knowledge instruction

Regulation (EU) 2018/1119

- (a) When providing theoretical knowledge instruction, a DTO may use on-site instruction or distance learning.
- (b) A DTO shall monitor and record the progress of any student undergoing theoretical knowledge instruction.

### DTO.GEN.270 Annual internal review and annual activity report

Regulation (EU) 2018/1119

A DTO shall take the following steps:

- (a) conduct an annual internal review of the tasks and responsibilities specified in point <a href="https://doi.org/10.1001/journal.com/">DTO.GEN.210</a> and establish a report on that review;
- (b) establish an annual activity report;
- (c) submit the report on the annual internal review and the annual activity report to the competent authority by the date determined by the competent authority.

# AMC1 DTO.GEN.270(a) Annual internal review and annual activity report

ED Decision 2018/009/R

#### **ANNUAL INTERNAL REVIEW**

The annual internal review should consist of a comprehensive assessment whether the DTO effectively carries out the tasks and responsibilities pursuant to point <u>DTO.GEN.210</u>. Specific emphasis should be given to the following:

- (a) availability of sufficient resources;
- (b) conduct of training in accordance with the requirements of Part-FCL and Part-DTO, with the DTO training programme(s) and with the DTO's safety policy;
- (c) random checks of training records and course completion certificates issued by the DTO;
- (d) assessment of the training programme(s) for its (their) adequacy and currency;



- (e) training aircraft including their documents and maintenance records;
- (f) aerodromes and operating sites, including associated facilities;
- (g) evaluation of both adequacy and effectiveness of the follow-up, corrective and, as applicable, remedial action taken after non-compliances that have been detected internally or that have been subject to findings as per point <a href="DTO.GEN.150">DTO.GEN.150</a>;
- (h) assessment of the safety policy including its means and methods as defined in AMC1 DTO.GEN.210 for its adequacy and currency;
- (i) assessment of the effectiveness of the implementation of the mitigation measures, as foreseen in the DTO's safety policy.

# AMC1 DTO.GEN.270(b) Annual internal review and annual activity report

ED Decision 2018/009/R

#### **ANNUAL ACTIVITY REPORT**

- (a) With regard to the past calendar year, the annual activity report should contain at least lists of:
  - (1) all training courses and refresher trainings actually provided;
  - (2) names of all flight, synthetic flight and theoretical knowledge instructors involved in the provision of training, including, in the case of DTOs for aeroplanes, helicopters and sailplanes, information on the aerodromes and operating sites of the DTO where it has mainly been providing training;
  - (3) number of students per training course;
  - (4) all training aircraft and FSTDs used, including registration marks and FSTD qualification letter codes (as applicable), including, with regard to each aircraft, information on:
    - (i) the training courses for which the aircraft has been used; and
    - (ii) the aerodromes of the DTO where the aircraft has been mainly used;
  - (5) all occurrences, accidents and incidents that occurred during the training courses; and
  - (6) any other information that is deemed relevant by the DTO.

# AMC1 DTO.GEN.270(c) Annual internal review and annual activity report

ED Decision 2018/009/R

#### SUBMISSION OF ANNUAL INTERNAL REVIEW AND ANNUAL ACTIVITY REPORT TO THE COMPETENT AUTHORITY

The annual internal review and the annual activity report for each past calendar year should be submitted to the competent authority within a time frame agreed between the DTO and the competent authority.



# GM1 DTO.GEN.270(c) Annual internal review and annual activity report

ED Decision 2018/009/R

#### SUBMISSION OF ANNUAL INTERNAL REVIEW AND ANNUAL ACTIVITY REPORT TO THE COMPETENT AUTHORITY

It is recommended that the competent authority and the DTO agree on the regular time frames; for example, to agree that the annual internal review and annual activity report for the past calendar year should be submitted during the first quarter of each year.



### **APPENDIX TO ANNEX VIII**

Ap	pendix 1 to Annex VIII (Part-DTO)
	Regulation (EU) 2020/35:
I	CLARATION
	suant to Commission Regulation (EU) No 1178/2011
	Initial declaration
	Notification of changes (1) – DTO reference number:
1.	Declared training organisation (DTO)
	Name:
2.	Place(s) of business
	Contact dataile (adduces whose areail) of the DTO's principal place of hydrogen
2	Contact details (address, phone, email) of the DTO's principal place of business:
3.	Personnel
	Name and contact details (address, phone, email) of the DTO's representative:
	Name and contact details (address, phone, email) of the DTO's head of training and, if applicable, of the DTO's deputy head(s) of training:
4.	Training scope
	List of all training provided:
	List of all training programmes used to provide the training (documents to be attached to this declaration)
	or, in the case referred to in point DTO.GEN.230(d) of Annex VIII (Part-DTO) to Regulation (EU) No
	1178/2011, the reference to all approved training manuals used to provide the training:
5.	Training aircraft and FSTDs
	List of aircraft used for the training:
	List of qualified FSTDs used for the training (if applicable, including letter code as indicated on the
	qualification certificate):
6.	Aerodrome(s) and the operating site(s)
	Contact details (address, phone, email) of all aerodromes and operating sites used by the DTO to provide
	the training:
7.	Date of intended commencement of training:
8.	Application for approval of examiner standardisation courses and refresher seminars (if applicable)
	☐ The DTO hereby applies for approval of the above-mentioned training programme(s) for examiner
	courses for sailplanes or balloons in accordance with points DTO.GEN.110(b) and DTO.GEN.230(c) of
	Annex VIII (Part-DTO) to Regulation (EU) No 1178/2011.
9.	Statement
	The DTO has developed a safety policy in accordance with Annex VIII (Part-DTO) to Commission
	Regulation (EU) No 1178/2011, and in particular with point DTO.GEN.210(a)(1)(ii) thereof, and will apply
	that policy during all training activities covered by the declaration.
	The DTO complies and will, during all training activities covered by the declaration, continue to comply
	with the essential requirements set out in Annex IV to Regulation (EU) 2018/1139, with the requirements

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<sup>&</sup>lt;sup>1</sup> In the case of changes, only point 1 and those fields containing changes need to be completed.



of Annex I (Part-FCL) and Annex VIII (Part-DTO) to <u>Commission Regulation (EU) No 1178/2011</u>, and with the requirements of Annex III (Part-BFCL) to <u>Commission Regulation (EU) 2018/395</u> and Annex III (Part-SFCL) to <u>Commission Implementing Regulation (EU) 2018/1976</u>.

We confirm that all information contained in this declaration, including its annexes (if applicable), is complete and correct.

Name, date and signature of the representative of the DTO

Name, date and signature of the head of training of the DTO



## COMMISSION DELEGATED REGULATION (EU) 2020/723

Commission Delegated Regulation (EU) 2020/723

of 4 March 2020

laying down detailed rules with regard to the acceptance of third-country certification of pilots and amending Regulation (EU) No 1178/2011

Regulation (EU) 2020/723

#### 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 Regulations (EC) No 552/2004 and (EC) No 216/2008 of the European Parliament and of the Council and Council Regulation (EEC) No 3922/91¹, and in particular Article 68(3) thereof,

#### Whereas:

- (1) With the adoption of Regulation (EU) 2018/1139 and in particular its Article 68, the Commission is now empowered to adopt delegated acts with regard to the acceptance of certificates and other documentation attesting compliance with civil aviation rules issued in accordance with the laws of a third country, whilst ensuring an equivalent level of safety to that provided for in Regulation (EU) 2018/1139.
- (2) The main objective of this Regulation is to bring the current legal framework into line with Regulation (EU) 2018/1139 and therefore the content of Article 8, Annex III and related provisions of Commission Regulation (EU) No 1178/2011<sup>2</sup> concerning the acceptance of third country certificates should be transferred into a delegated act. Furthermore, those provisions should now also include rules on acceptance of third-country sailplanes and balloons certificates.
- (3) Regulation (EU) No 1178/2011 lists conditions for the acceptance of licences from third countries. Under certain conditions, a pilot licence issued by a third country may currently be accepted by Member States or the holder of such a third country licence can obtain credit when applying for a licence in accordance with Regulation (EU) No 1178/2011. Such credit is currently determined based on a recommendation from an approved training organisation.
- (4) The rules applicable to training organisations providing training for certain non-commercial pilot licences and ratings have been simplified and the declared training organisation ('DTO') has been introduced, pursuant to <a href="Commission Regulation">Commission Regulation</a> (EU) 2018/1119<sup>3</sup>. Therefore, the rules concerning the acceptance of licences from third countries should be updated in order to permit

<sup>&</sup>lt;sup>1</sup> OJ L 212, 22.8.2018, p. 1.

<sup>-</sup>

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).

Commission Regulation (EU) 2018/1119 of 31 July 2018 amending Regulation (EU) No 1178/2011 as regards declared training organisations (OJ L 204, 13.8.2018, p. 13).



- DTOs to give credit to holders of third country licences who apply for a licence issued under the Union legal framework.
- (5) Article 8 of <u>Regulation (EU) No 1178/2011</u> as well Annex III to that Regulation, currently containing requirements for the acceptance of licences from third countries, should therefore be deleted,

HAS ADOPTED THIS REGULATION:



#### SECTION 1 — GENERAL PROVISIONS

#### Article 1 — Scope

Regulation (EU) 2020/723

This Regulation lays down the detailed rules for the conditions for the acceptance of pilot licences and associated ratings, privileges or certificates, as well as associated medical certificates issued in accordance with laws of third countries.

#### Article 2 — Definitions

Regulation (EU) 2020/723

- The definitions contained in <u>Regulation (EU) No 1178/2011</u>, <u>Commission Regulation (EU) 2018/395<sup>1</sup></u> and <u>Commission Implementing Regulation (EU) 2018/1976<sup>2</sup></u> shall apply for the purposes of this Regulation.
- 2. In addition, for the purposes of this Regulation, 'manufacturer flights' means the flights referred to in Article 6(3) of Commission Regulation (EU) No 965/2012<sup>3</sup>.

## <u>Article 3 — Acceptance of licences from third countries</u>

Regulation (EU) 2020/723

Without prejudice to international agreements concluded between the Union and a third country in accordance with point (a) of Article 68(1) of Regulation (EU) 2018/1139, Member States may:

- in accordance with Section 2 of this Regulation accept pilot licences and associated ratings, privileges or certificates, as well as associated medical certificates issued in accordance with laws of third countries;
- (b) in accordance with <a href="Article 3">Article 3</a> of <a href="Regulation">Regulation</a> (EU) 2018/395</a> or Article 3a of <a href="Implementing Regulation">Implementing Regulation</a> (EU) 2018/1976, as applicable, issue equivalent licences to applicants who already hold an equivalent licence, rating, privilege or certificate issued in accordance with Annex 1 to the Convention on International Civil Aviation, signed on 7 December 1944 in Chicago ('the Chicago Convention') by a third country, provided that those applicants comply with the requirements of Section 3 and taking account of any credit based on a recommendation from an approved training organisation or a declared training organisation;
- (c) give full credits as regards the requirements to undergo a training course prior to undertaking the theoretical knowledge examinations and the skill test to holders of an airline transport pilots licence ('ATPL') issued by or on behalf of a third country in accordance with Annex 1 to the Chicago Convention provided that those holders 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 Regulation (EU) No 1178/2011 and provided that the third country licence contains a valid type rating for the aircraft to be used for the ATPL skill test;

<sup>&</sup>lt;sup>1</sup> Commission Regulation (EU) 2018/395 of 13 March 2018 laying down detailed rules for the operation of balloons pursuant to Regulation (EC) No 216/2008 of the European Parliament and of the Council (OJ L 71, 14.3.2018, p. 10).

Commission Implementing Regulation (EU) 2018/1976 of 14 December 2018 laying down detailed rules for the operation of sailplanes pursuant to Regulation (EU) 2018/1139 of the European Parliament and of the Council (OJ L 326, 20.12.2018, p. 64).

Commission Regulation (EU) No 965/2012 of 5 October 2012 laying down technical requirements and administrative procedures related to air operations pursuant to Regulation (EC) No 216/2008 of the European Parliament and of the Council (OJ L 296, 25.10.2012, p. 1).



(d) issue aeroplane or helicopter type ratings to holders of licences issued in accordance with <a href="Regulation">Regulation (EU) No 1178/2011</a> that comply with the requirements established by a third country for the issue of such ratings; those ratings shall be restricted to aircraft registered in that third country, but this restriction may be removed when the pilot complies with the requirements in <a href="Article 10">Article 10</a> to this Regulation.



#### SECTION 2 — VALIDATION OF LICENCES

### Article 4 — General provisions for validation of licences

Regulation (EU) 2020/723

- 1. A competent authority of a Member State may validate a pilot licence issued by a third country in compliance with the requirements of Annex 1 to the Chicago Convention.
- 2. For the purposes of the provisions set out in this Regulation, the competent authority of the Member State shall be the following:
  - (a) for pilots residing within the territory of the Union a competent authority of the Member State of a place where a pilot resides or is established;
  - (b) for pilots not residing in the territory of the Union a competent authority of the Member State where the operator for which they are flying or intend to fly has its principal place of business, or where the aircraft on which they are flying or intend to fly is registered.
- 3. The validation of a licence shall have a validity period, which does not exceed one year, and its privileges shall only be exercised as long as the licence remains valid.
  - The competent authority that validated the licence may extend the validity only once and only by a maximum of one year, if during the validity period the pilot has applied for a licence in accordance with Annex I (Part-FCL) to <a href="Regulation (EU) No 1178/2011">Regulation (EU) No 1178/2011</a> or is undergoing training for the issuance of such a licence. In that last case, the extension shall cover the period of time necessary for the licence to be issued in accordance with Annex I (Part-FCL) to <a href="Regulation (EU) No 1178/2011">Regulation (EU) No 1178/2011</a>.
- 4. The holders of a licence validated by a Member State shall exercise their privileges in accordance with the requirements stated in Annex I (Part-FCL) to Regulation (EU) No 1178/2011.

# <u>Article 5 — Pilot licences for commercial air transport and other</u> commercial activities

Regulation (EU) 2020/723

For the validation of pilot licences for commercial air transport and other commercial activities, the holders shall comply with the following requirements, as applicable, for the privileges sought:

- (a) complete, as a skill test, the type or class rating revalidation requirements of Annex I (Part-FCL) to Regulation (EU) No 1178/2011, as relevant to the privileges of the licence held;
- (b) demonstrate knowledge of the relevant parts of the operational requirements and Annex I (Part-FCL) to Regulation (EU) No 1178/2011;
- (c) demonstrate language proficiency in accordance with Point FCL.055 of Annex I (Part-FCL) to Regulation (EU) No 1178/2011;
- (d) hold a valid Class 1 medical certificate, issued in accordance with Annex IV (Part-MED) to Regulation (EU) No 1178/2011;
- (e) in the case of aeroplanes, in addition to the requirements in points (a) to (d), comply with the experience requirements set out in table 1 in the <u>Annex</u> to this Regulation;
- (f) in the case of helicopters, in addition to the requirements in points (a) to (d), comply with the experience requirements set out in table 2 in the <u>Annex</u> to this Regulation.



# <u>Article 6 — Pilot licences for non-commercial activities with an</u> instrument rating

Regulation (EU) 2020/723

For the validation of private pilot licences with an instrument rating, or Commercial Pilot Licences ('CPL') and Airline Transport Pilot Licences ('ATPL') with an instrument rating where the pilot intends only to exercise private pilot privileges, holders shall comply with all of the following requirements:

- (a) complete the skill test for instrument rating and the type or class ratings relevant to the privileges of the licence held, in accordance with <a href="Appendix 7">Appendix 7</a> and <a href="Appendix 9">Appendix 9</a> of Annex I (Part-FCL) to <a href="Regulation (EU) No 1178/2011">Regulation (EU) No 1178/2011</a>;
- (b) demonstrate knowledge of Air Law, Aeronautical Weather Codes, Flight Planning and Performance (IR) and Human Performance;
- (c) demonstrate language proficiency in accordance with <u>FCL.055</u> of Annex I (Part-FCL) to <u>Regulation (EU) No 1178/2011</u>;
- (d) hold at least a valid Class 2 medical certificate issued in accordance with Annex 1 to the Chicago Convention;
- (e) have a minimum experience of at least 100 hours of instrument flight time as pilot in command ('PIC') in the relevant category of aircraft.

# <u>Article 7 — Pilot licences for non-commercial activities without an</u> instrument rating

Regulation (EU) 2020/723

For the validation of private pilot licences, or CPL and ATPL licences without an instrument rating where the pilot intends only to exercise private pilot privileges, holders shall comply with all of the following requirements:

- (a) demonstrate knowledge of Air Law and Human Performance;
- (b) pass the private pilot licence ('PPL') skill test as set out in point <u>FCL.235</u> of Annex I (Part-FCL) to <u>Regulation (EU) No 1178/2011</u>;
- (c) fulfil the relevant requirements of Subpart H of Annex I (Part-FCL) to Regulation (EU) No 1178/2011, for the issuance of a type or class rating as relevant to the privileges of the licence held;
- (d) hold at least a Class 2 medical certificate issued in accordance with Annex 1 to the Chicago Convention;
- (e) demonstrate language proficiency in accordance with <u>FCL.055</u> of Annex I (Part-FCL) to <u>Regulation (EU) No 1178/2011</u>;
- (f) have a minimum experience of at least 100 hours as pilot in the relevant category of aircraft.



# <u>Article 8 — Validation of pilot licences for specific tasks of limited</u> duration

- 1. Notwithstanding the provisions of the Articles above, in the case of manufacturer flights, a competent authority of a Member State may accept a licence issued in accordance with Annex 1 to the Chicago Convention by a third country for a maximum of 12 months for specific tasks of limited duration, such as instruction flights for initial entry into service, demonstration, ferry or test flights, provided that the applicant complies with the following requirements:
  - (a) holds an appropriate licence and medical certificate and associated ratings or qualifications issued in accordance with Annex 1 to the Chicago Convention;
  - (b) is employed, directly or indirectly, by an aircraft manufacturer or by an aviation authority.
  - In this case, the privileges of the holder shall be limited by the competent authority to performing flight instruction and testing for initial issue of type ratings, the supervision of initial line flying by the operators' pilots, delivery or ferry flights, initial line flying, flight demonstrations or test flights, as appropriate to the tasks foreseen under this paragraph.
- 2. By way of derogation from Articles 4 to 7, a competent authority of a Member States may, for competition flights or display flights of limited duration, validate a licence issued by a third country allowing the holder to exercise the privileges of a PPL as specified in Annex I (Part-FCL) to Regulation (EU) No 1178/2011, a Balloon Pilot Licence (BPL) as specified in Annex III (Part-BFCL) to Regulation (EU) 2018/395 or an Sailplane Pilot Licence (SPL) as specified in Annex III (Part-SFCL) to Implementing Regulation (EU) 2018/1976, provided that all of the following requirements are complied with:
  - (a) prior to the event, the organiser of the competition or display flights provides the competent authority with adequate evidence on how it will ensure that the pilot will be familiarised with the relevant safety information and manage any risk associated with the flights;
  - (b) the applicant holds an appropriate licence and medical certificate and associated ratings or qualifications issued in accordance with Annex 1 to the Chicago Convention.
- 3. By way of derogation from the provisions of Articles 4 to 7, a competent authority of a Member State may validate a licence which is equivalent to one of those referred to in paragraph 2 and issued in compliance with the requirements of Annex 1 to the Chicago Convention by a third country for a maximum of 28 days per calendar year for specific non-commercial tasks, provided that the applicant complies with all of the following requirements:
  - (a) holds an appropriate licence and medical certificate and associated ratings or qualifications issued in accordance with Annex 1 to the Chicago Convention;
  - (b) has completed at least one acclimatisation flight with a qualified instructor prior to carrying out the specific tasks of limited duration.



#### SECTION 3 — CONVERSION OF LICENCES

#### Article 9 — Conditions for conversion of licences

- The competent authority of a Member State may convert a licence for the relevant aircraft category into a PPL in accordance with Annex I (Part-FCL) to Regulation (EU) No 1178/2011 with a single-pilot class or type rating, a BPL in accordance with Annex III (Part-BFCL) to Regulation (EU) 2018/395 or an SPL in accordance with Annex III (Part-SFCL) to Implementing Regulation (EU) 2018/1976, where the original licence is issued in compliance with the requirements of Annex 1 to the Chicago Convention by a third country and the licence is, alternatively:
  - (a) an equivalent licence to the licences referred to in paragraph 1;
  - (b) a CPL or an ATPL.
- 2. The holder of the licence to be converted shall comply with the following minimum requirements for the relevant aircraft category:
  - (a) pass a written examination in Air Law and Human Performance;
  - (b) pass the PPL, BPL or SPL skill test, as relevant, in accordance with Annex I (Part-FCL) to Regulation (EU) No 1178/2011, Annex III (Part-BFCL) to Regulation (EU) 2018/395 or Annex III (Part-SFCL) to Implementing Regulation (EU) 2018/1976;
  - (c) fulfil the requirements for the issue of the relevant class or type rating, in accordance with Subpart H;
  - (d) hold a medical certificate, as required and issued in accordance with Annex IV (Part-MED) to Regulation (EU) No 1178/2011;
  - (e) demonstrate language proficiency in accordance with <u>FCL.055</u> of Annex I (Part-FCL) to Regulation (EU) No 1178/2011;
  - (f) have completed at least 100 hours of flight time as a pilot.



#### SECTION 4 — ACCEPTANCE OF CLASS AND TYPE RATINGS

#### Article 10 — Conditions for acceptance of class and type ratings

Regulation (EU) 2020/723

A valid class or type rating contained in a licence issued by a third country may be inserted in a licence issued in accordance with Annex I (Part-FCL) to Regulation (EU) No 1178/2011, provided that the applicant:

- (a) complies with the experience requirements and the prerequisites for the issue of the applicable type or class rating in accordance with Part-FCL;
- (b) passes the relevant skill test for the issue of the applicable type or class rating in accordance with Part-FCL;
- (c) is in current flying practice;
- (d) has no less than:
  - (i) for aeroplane class ratings, 100 hours of flight experience as a pilot in that class;
  - (ii) for aeroplane type ratings, 500 hours of flight experience as a pilot in that type;
  - (iii) for single-engine helicopters with a maximum certificated take-off mass of up to 3 175 kg, 100 hours of flight experience as a pilot in that type;
  - (iv) for all other helicopters, 350 hours of flight experience as a pilot in that type.

#### Article 11 — Amendments to Regulation (EU) No 1178/2011

Regulation (EU) 2020/723

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

- (a) Article 8 is deleted;
- (b) Annex III is deleted.

## Article 12 — Entry into force and application

Reaulation (EU) 2020/723

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, 4 March 2020.

For the Commission

The President

Ursula VON DER LEYEN



## **ANNEX TO DELEGATED REGULATION (EU) 2020/723**

# Conditions for acceptance of licences issued by or on behalf of third countries

Table 1
Experience requirements for aeroplanes

Licence held	Total flying hours experience	Privileges	
(1)	(2)	(3)	
ATPL(A)	> 1 500 hours as PIC on multi-pilot aeroplanes	Commercial air transport in multi-pilot aeroplanes as PIC	(a)
ATPL(A) or CPL(A)/IR <sup>1</sup>	> 1 500 hours as PIC or co-pilot on multi-pilot aeroplanes according to operational requirements	Commercial air transport in multi-pilot aeroplanes as co-pilot	(b)
MPL	> 1 500 hours as co-pilot on multi-pilot aeroplanes according to operational requirements	Commercial air transport in multi-pilot aeroplanes as co-pilot	(ba)
CPL(A)/IR	> 1 000 hours as PIC in commercial air transport since gaining an IR	Commercial air transport in single-pilot aeroplanes as PIC	(c)
CPL(A)/IR	> 1 000 hours as PIC or as co-pilot in single-pilot aeroplanes according to operational requirements	Commercial air transport in single-pilot aeroplanes as co-pilot according to operational requirements	(d)
ATPL(A), CPL(A)/IR, CPL(A)	> 700 hours in aeroplanes, including 200 hours in the activity role for which acceptance is sought, and 50 hours in that role in the last 12 months	Exercise of privileges in aeroplanes in operations other than commercial air transport	(e)
CPL(A)	> 1 500 hours as PIC in commercial air transport including 500 hours on seaplane operations	Commercial air transport in single-pilot aeroplanes as PIC	(f)

CPL(A)/IR holders on multi-pilot aeroplanes shall have demonstrated ICAO ATPL(A) level knowledge before acceptance.



Table 2
Experience requirements for helicopters

Licence held	Total flying hours experience	Privileges	
(1)	(2)	(3)	
ATPL(H) valid IR	> 1 000 hours as PIC on multi-pilot helicopters	Commercial air transport in multi-pilot helicopters as PIC in VFR and IFR operations	(a)
ATPL(H) no IR privileges	> 1 000 hours as PIC on multi-pilot helicopters	Commercial air transport in multi-pilot helicopters as PIC in VFR operations	(b)
ATPL(H) valid IR	> 1 000 hours as pilot on multi-pilot helicopters	Commercial air transport in multi-pilot helicopters as co-pilot in VFR and IFR operations	(c)
ATPL(H) no IR privileges	> 1 000 hours as pilot on multi-pilot helicopters	Commercial air transport in multi-pilot helicopters as co-pilot in VFR operations	(d)
CPL(H)/IR <sup>1</sup>	> 1 000 hours as pilot on multi-pilot helicopters	Commercial air transport in multi-pilot helicopters as co-pilot	(e)
CPL(H)/IR	> 1 000 hours as PIC in commercial air transport since gaining an IR	Commercial air transport in single-pilot helicopters as PIC	(f)
ATPL(H) with or without IR privileges, CPL(H)/IR, CPL(H)	> 700 hours in helicopters other than those certificated under CS-27/29 or equivalent, including 200 hours in the activity role for which acceptance is sought, and 50 hours in that role in the last 12 months	Exercise of privileges in helicopters in operations other than commercial air transport	(g)

CPL(H)/IR holders on multi-pilot helicopters shall have demonstrated ICAO ATPL(H) level knowledge before acceptance.