

▼ **M1***ANNEX VII***ORGANISATION REQUIREMENTS FOR AIRCREW****[PART-ORA]****SUBPART GEN*****GENERAL REQUIREMENTS******SECTION I******General*****ORA.GEN.105 Competent authority**

(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, if so 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

(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

(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.

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- (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).

ORA.GEN.125 Terms of approval and privileges of an organisation

A certified organisation shall comply with the scope and privileges defined in the terms of approval attached to the organisation's certificate.

ORA.GEN.130 Changes to organisations

- (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).

ORA.GEN.135 Continued validity

- (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.

▼ M1**ORA.GEN.140 Access**

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

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).

ORA.GEN.155 Immediate reaction to a safety problem

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.

▼ M14**ORA.GEN.160 Occurrence reporting**

- (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 Regulation (EU) No 748/2012, 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 Regulation (EU) No 376/2014 and the delegated and implementing acts adopted on the basis thereof, reports in accordance with point (c) shall:

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- (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.

▼ M1*SECTION II**Management***ORA.GEN.200 Management system**

- (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;

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- (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

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- (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.

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- (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.

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- (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.

▼ M1**ORA.GEN.205 Contracted activities**

- (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.

ORA.GEN.210 Personnel requirements

- (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.

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- (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

The organisation shall have facilities allowing the performance and management of all planned tasks and activities in accordance with the applicable requirements.

ORA.GEN.220 Record-keeping

- (a) The organisation shall establish a system of record-keeping that allows adequate storage and reliable traceability of all activities developed, covering in 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.

SUBPART ATO

APPROVED TRAINING ORGANISATIONS*SECTION I****General*****ORA.ATO.100 Scope**

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

ORA.ATO.105 Application

- (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;

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- (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).

ORA.ATO.110 Personnel requirements

- (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:

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- (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;

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- (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.

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- (d) Flight instructors and flight simulation training instructors shall hold the qualifications required by 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 for the type of training they provide.

▼ M1**ORA.ATO.120 Record-keeping****▼ M7**

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

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- (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

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- (c) information on the licences and associated ratings and certificates of the students, including the expiry dates of medical certificates and ratings.

ORA.ATO.125 Training programme

- (a) A training programme shall be developed for each type of course offered.

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- (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.

▼ M1**ORA.ATO.130 Training manual and operations manual**

- (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**▼ M11**

- (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.

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- (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

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- (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.

ORA.ATO.140 Aerodromes and operating sites

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.

▼ M2**ORA.ATO.145 Pre-requisites for training**

- (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.

▼ M1**ORA.ATO.150 Training in third countries**

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 skill test 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**

- (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.

▼ M1**ORA.ATO.225 Training programme**

- (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

- (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.

*SECTION III**Additional requirements for atos providing specific types of training***Chapter 1****Distance Learning Course****ORA.ATO.300 General**

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.

ORA.ATO.305 Classroom instruction

- (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.

ORA.ATO.310 Instructors

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**

- (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.

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- (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.

ORA.ATO.335 Full flight simulator

- (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 ORA.FSTD.205.

Chapter 3**Multi-crew pilot licence (MPL) courses****ORA.ATO.350 General**

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**

- (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**

- (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.

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- (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.

ORA.FSTD.105 Maintaining the FSTD qualification

- (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

- (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.

ORA.FSTD.115 Installations

- (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

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- (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.

ORA.FSTD.120 Additional equipment

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**

- (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 ORA.GEN.130 and ORA.FSTD.230.

ORA.FSTD.205 Certification specifications for FSTDs

- (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

- (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;

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- (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

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- (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 recategorised.

▼ M1**ORA.FSTD.225 Duration and continued validity**

- (a) ► **M18** 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;

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- (2) the competent authority being granted access to the organisation as defined in point ORA.GEN.140 to determine continued compliance with the relevant requirements of Regulation (EU) 2018/1139 and the implementing and delegated acts adopted on the basis thereof;

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- (3) the qualification certificate not being surrendered or revoked.

▼ M18

- (b) If the competent authority has extended the recurrent evaluation period for an FSTD in accordance with point ARA.FSTD.120(c) 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 ARA.FSTD.120(b)(1) 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.

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- (d) Upon surrender or revocation, the FSTD qualification certificate shall be returned to the competent authority.

ORA.FSTD.230 Changes to the qualified FSTD

- (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.

▼ M1

- (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 be notified 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.

ORA.FSTD.235 Transferability of an FSTD qualification

- (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

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.

SUBPART AeMC***AERO-MEDICAL CENTRES******SECTION 1******General*****▼ M18****ORA.AeMC.105 Scope**

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;

▼ M18

- (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.

▼ M1**ORA.AeMC.115 Application**

Applicants for an AeMC certificate shall:

- (a) comply with MED.D.005; and

▼ M18

- (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.

ORA.AeMC.120 AeMC certificate

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.

ORA.AeMC.135 Continued validity

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 MED.D.030 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.

ORA.AeMC.160 Reporting

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 MED.B.055(b) of Annex IV (Part-MED) and any health risk factors or trends identified during the aero-medical assessments.

▼ M1*SECTION II**Management***ORA.AeMC.200 Management system**

The AeMC shall establish and maintain a management system that includes the items addressed in ORA.GEN.200 and, in addition, processes:

▼ M18

- (a) for medical certification in compliance with Part-MED;
- (aa) to facilitate cooperation between the AMEs and other medical experts of the AeMC; and

▼ M1

- (b) to ensure medical confidentiality at all times.

⁽¹⁾ 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>).

▼ M18**ORA.AeMC.205 Contracted activities**

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.

ORA.AeMC.210 Personnel requirements

(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.

▼ M1**ORA.AeMC.215 Facility requirements**

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.

ORA.AeMC.220 Record-keeping

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.