

ANNEX VII ORGANISATION REQUIREMENTS FOR AIRCREW (PART-ORA)

CONTENTS

SUBPART GEN GENERAL REQUIREMENTS

SECTION I General

- ORA.GEN.105 Competent authority
- ORA.GEN.115 Application for an organisation certificate
- ORA.GEN.120 Means of compliance
- ORA.GEN.125 Terms of approval and privileges of an organisation
- ORA.GEN.130 Changes to organisations
- ORA.GEN.135 Continued validity
- ORA.GEN.140 Access
- ORA.GEN.150 Findings
- ORA.GEN.155 Immediate reaction to a safety problem
- ORA.GEN.160 Occurrence reporting

SECTION II Management

- ORA.GEN.200 Management system
- ORA.GEN.205 Contracted activities
- ORA.GEN.210 Personnel requirements
- ORA.GEN.215 Facility requirements
- ORA.GEN.220 Record-keeping

SUBPART ATO APPROVED TRAINING ORGANISATIONS

SECTION I General

- ORA.ATO.100 Scope
- ORA.ATO.105 Application
- ORA.ATO.110 Personnel requirements
- ORA.ATO.120 Record-keeping
- ORA.ATO.125 Training programme
- ORA.ATO.130 Training manual and operations manual
- ORA.ATO.135 Training aircraft and FSTDs
- ORA.ATO.140 Aerodromes and operating sites
- ORA.ATO.145 Pre-requisites for training
- ORA.ATO.150 Training in third countries

SECTION II Additional requirements for ATOs providing training for CPL, MPL and ATPL and the associated ratings and certificates

- ORA.ATO.210 Personnel requirements
- ORA.ATO.225 Training programme
- ORA.ATO.230 Training manual and operations manual

SECTION III Additional requirements for ATOS providing specific types of training

Chapter 1 Distance Learning Courses

- ORA.ATO.300 General
- ORA.ATO.305 Classroom instruction
- ORA.ATO.310 Instructors

Chapter 2 Zero Flight - Time Training

ORA.ATO.330 General
ORA.ATO.335 Full flight simulator

Chapter 3 Multi - crew pilot licence (MPL) course

ORA.ATO.350 General

Chapter 4 Flight training

ORA.ATO.355 Flight test training organisations

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
ORA.FSTD.105 Maintaining the FSTD qualification
ORA.FSTD.110 Modifications
ORA.FSTD.115 Installations
ORA.FSTD.120 Additional equipment

SECTION II Requirements for the qualification of FSTDs

ORA.FSTD.200 Application for FSTD qualification
ORA.FSTD.205 Certification specifications for FSTDs
ORA.FSTD.210 Qualification basis
ORA.FSTD.225 Duration and continued validity
ORA.FSTD.230 Changes to the qualified FSTD
ORA.FSTD.235 Transferability of an FSTD qualification
ORA.FSTD.240 Record-keeping

SUBPART AeMCAERO-MEDICAL CENTRES

SECTION I General

ORA.AeMC.105 Scope
ORA.AeMC.115 Application
ORA.AeMC.135 Continued validity

SECTION II Management

ORA.AeMC.200 Management system
ORA.AeMC.210 Personnel requirements
ORA.AeMC.215 Facility requirements
ORA.AeMC.220 Record-keeping

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 national aviation authority exercising oversight over:
- (1) organisations subject to a certification obligation shall be Maldives Civil Aviation Authority (MCAA).
 - (2) FSTDs shall be MCAA:
 - (i) for FSTDs:
 - located outside the territory of the Republic of Maldives, or,
 - located within the territory of the Republic of Maldives and operated by organisations having their principal place of business located in a third country,
 - (ii) for FSTDs located within the territory of the Republic of Maldives and operated by organisations having their principal place of business in the Republic of Maldives, the authority shall be MCAA.
- (b) When the FSTD located outside the Republic of Maldives is operated by an organisation certified by a MCAA, the MCAA shall qualify this 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 MCAA, taking into account the applicable requirements of Regulations and Implementing Rules.
- (b) Applicants for an initial certificate shall provide MCAA with documentation demonstrating how they will comply with the requirements established in Regulations and Implementing Rules. Such documentation shall include a procedure describing how changes not requiring prior approval will be managed and notified to MCAA.

ORA.GEN.120 Means of compliance

- (a) Alternative means of compliance to the AMC adopted by the MCAA may be used by an organisation to establish compliance with Regulations and Implementing Rules.
- (b) When an organisation wishes to use an alternative means of compliance, it shall, prior to implementing it, provide MCAA 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 Regulations and Implementing Rules are met.

The organisation may implement these alternative means of compliance subject to prior approval by MCAA 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 MCAA.
- (b) For any changes requiring prior approval in accordance with Regulations and Implementing Rules, the organisation shall apply for and obtain an approval issued by MCAA. The application shall be submitted before any such change takes place, in order to enable MCAA to determine continued compliance with Regulations and Implementing Rules and to amend, if necessary, the organisation certificate and related terms of approval attached to it.

The organisation shall provide MCAA with any relevant documentation.

The change shall only be implemented upon receipt of formal approval by MCAA in accordance with ARA.GEN.330.

The organisation shall operate under the conditions prescribed by MCAA during such changes, as applicable.

- (c) All changes not requiring prior approval shall be managed and notified to MCAA as defined in the procedure approved by MCAA 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 Regulations and Implementing Rules, taking into account the provisions related to the handling of findings as specified under ORA.GEN.150;
 - (2) MCAA being granted access to the organisation as defined in ORA.GEN.140 to determine continued compliance with the relevant requirements of Regulations and Implementing Rules; and
 - (3) the certificate not being surrendered or revoked.
- (b) Upon revocation or surrender the certificate shall be returned to MCAA without delay.

ORA.GEN.140 Access

For the purpose of determining compliance with the relevant requirements of Regulations and 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) MCAA as 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 MCAA 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 any safety measures mandated by MCAA in accordance with ARA.GEN.135(c); including airworthiness directives.

ORA.GEN.160 Occurrence reporting

- (a) The organisation shall report to MCAA, and to any other organisation required by the State of the operator to be informed, any accident, serious incident and occurrence as defined in Regulations (MCAR 12).
- (b) Without prejudice to paragraph (a) the organisation shall report to MCAA and to the organisation responsible for the design 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 MCAR 21 or other irregular circumstance that has or may have endangered the safe operation of the aircraft and that has not resulted in an accident or serious incident.
- (c) Without prejudice to Regulations (MCAR 12), the reports referred in paragraphs (a) and (b) shall be made in a form and manner established by MCAA and shall contain all pertinent information about the condition known to the organisation.
- (d) Reports shall be made as soon as practicable, but in any case within 72 hours of the organisation identifying the condition to which the report relates, unless exceptional circumstances prevent this.
- (e) Where relevant, the organisation shall produce a follow-up report to provide details of actions it intends to take to prevent similar occurrences in the future, as soon as these actions have been identified. This report shall be produced in a form and manner established by MCAA.

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;
 - (5) documentation of all management system key processes, including a process for making personnel aware of their responsibilities and the procedure for amending this documentation;
 - (6) a function to monitor compliance of the organisation with the relevant requirements. Compliance monitoring shall include a feedback system of findings to the accountable manager to ensure effective implementation of corrective actions as necessary; and
 - (7) any additional requirements that are prescribed in the relevant subparts of this Part or other applicable Parts.
- (b) The management system shall correspond to the size of the organisation and the nature and complexity of its activities, taking into account the hazards and associated risks inherent in these activities.

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 MCAA 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.
- (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 MCAA 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 MCAA 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:
- (1) ensuring that the training provided is in compliance with Part-FCL and, in the case of flight test training, that the relevant requirements of Part-21 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 Part-FCL for the type of training that they are providing.

ORA.ATO.120 Record-keeping

The following records shall be kept for a period of at least 3 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.

ORA.ATO.125 Training programme

- (a) A training programme shall be developed for each type of course offered.
- (b) The training programme shall comply with the requirements of Part-FCL and, in the case of flight test training, the relevant requirements of Part-21.

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

- (a) The ATO shall use an adequate fleet of training aircraft or FSTDs appropriate to the courses of training provided.
- (b) The ATO shall only provide training in FSTDs when it demonstrates to MCAA:
 - (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.

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.

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-MED, Part-FCL, and, if applicable, as defined in the data established in accordance with MCAR-21.
- (b) In the case of ATOs providing flight test training, the students shall meet all the pre-requisites for training established in MCAR-21.

ORA.ATO.150 Training in third countries

When the ATO is approved to provide training for the instrument rating (IR) in third countries; the training programme shall include acclimatisation flying before the IR skill test is taken.

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.

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, such 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 Courses

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.
- (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) course

RA.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 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 MCAA 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.

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 MCAA in advance of any major changes to determine if the tests carried out are satisfactory. MCAA will 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
 - (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 MCAA 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 MCAA:
 - (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 MCAA 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 MCAA shall issue, Certification Specifications as standard means to show compliance of FSTDs with the Essential Requirements.
- (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 MCAA that are effective on the date of the application for the initial qualification;
 - (2) the aircraft validation data defined by the data as approved under MCAR-21, if applicable; and
 - (3) any special conditions prescribed by MCAA 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.

ORA.FSTD.225 Duration and continued validity

- (a) The full flight simulator (FFS), flight training device (FTD) or flight and navigation procedures trainer (FNPT) qualification shall remain valid subject to:
 - (1) the FSTD and the operating organisation remaining in compliance with the applicable requirements;
 - (2) MCAA being granted access to the organisation as defined in ORA.GEN.140 to determine continued compliance with the relevant requirements of Regulations and Implementing Rules; and
 - (3) the qualification certificate not being surrendered or revoked.
- (b) The period of 12 months established in ARA.FSTD.120 (b)(1) may be extended up to a maximum of 36 months, in the following circumstances:
 - (1) the FSTD has been subject to an initial and at least one recurrent evaluation that has established its compliance with the qualification basis;
 - (2) the FSTD qualification certificate holder has a satisfactory record of successful regulatory FSTD evaluations during the previous 36 months;
 - (3) MCAA performs a formal audit of the compliance monitoring system defined in ORA.GEN.200 (a)(6) of the organisation every 12 months; and
 - (4) an assigned person of the organisation with adequate experience reviews the regular reruns of the qualification test guide (QTG) and conducts the relevant functions and subjective tests every 12 months and sends a report of the results to MCAA.
- (c) A BITD qualification shall remain valid subject to regular evaluation for compliance with the applicable qualification basis by MCAA in accordance with ARA.FSTD.120.
- (d) Upon surrender or revocation, the FSTD qualification certificate shall be returned to MCAA.

ORA.FSTD.230 Changes to the qualified FSTD

- (a) The holder of an FSTD qualification certificate shall inform MCAA 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 MCAA 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 MCAA 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 MCAA.

MCAA 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, MCAA shall be notified and suitable controls established for the period during which the FSTD is inactive.

The organisation shall agree with MCAA 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 MCAA in advance in order to agree upon a plan of transfer of the FSTD.
- (b) MCAA 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 I General

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 issue medical certificates, including initial class 1 medical certificates.

ORA.AeMC.115 Application

Applicants for an AeMC certificate shall:

- (a) comply with MED.D.005; and
- (b) in addition to the documentation for the approval of an organisation required in ORA.GEN.115, provide details of clinical attachments to or liaison with designated hospitals or medical institutes for the purpose of specialist medical examinations.

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:

- (a) complying with MED.D.030;and
- (b) ensuring their continued experience by performing an adequate number of class 1 medical examinations every year.

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:

- (a) for medical certification in compliance with Part-MED; and
- (b) to ensure medical confidentiality at all times.

ORA.AeMC.210 Personnel requirements

- (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.

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.’