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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.

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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.

ORA.GEN.160 Occurrence reporting

(a) The organisation shall report to the competent authority, and to any other organisation required by the State of the operator to be informed, any accident, serious incident and occurrence as defined in Regulation (EU) No 996/2010 of the European Parliament and of the Council [1] and Directive 2003/42/EC of the European Parliament and of the Council [2].

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(b) Without prejudice to paragraph (a) the organisation shall report to the competent authority and to the organisation responsible for the design of the aircraft any incident, malfunction, technical defect, exceeding of technical limitations and any occurrence that would highlight inaccurate, incomplete or ambiguous information contained in the operational suitability data established in accordance with Commission Regulation (EU) No 748/2012 [3] or other irregular circumstance that has or may have endangered the safe operation of the aircraft and that has not resulted in an accident or serious incident.

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(c) Without prejudice to Regulation (EU) No 996/2010, Directive 2003/42/EC, Commission Regulation (EC) No 1321/2007 [4] and Commission Regulation (EC) No 1330/2007 [5], the reports referred in paragraphs (a) and (b) shall be made in a form and manner established by the competent authority and contain all pertinent information about the condition known to the organisation.

(d) Reports shall be made as soon as practicable, but in any case within 72 hours of the organisation identifying the condition to which the report relates, unless exceptional circumstances prevent this.

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[1] OJ L 295, 12.11.2010, p. 35.
[2] OJ L 167, 4.7.2003, p. 23.
[3] OJ L 224, 21.8.2012, p. 1.
[4] OJ L 294, 13.11.2007, p. 3.
[5] OJ L 295, 14.11.2007, p. 7.

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(e) Where relevant, the organisation shall produce a follow-up report to provide details of actions it intends to take to prevent similar occurrences in the future, as soon as these actions have been identified. This report shall be produced in a form and manner established by the competent authority.

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.

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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.

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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.

(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.

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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 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

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(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.