ANNEX VII

ORGANIZATION REQUIREMENT's for AIRCREW

[PART - ORA]

GDCA of RA Yerevan May 2015

CR EU Nº 245 / 2014 of 13. 03. 2014

amending CR - EU Nº 1178 / 2011 of 3 November 2011 laying down technical requirements and administrative procedures related to civil aviation aircrew

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LIST OF EFFECTIVE PAGES

| Part - ORA | | TO PAGEE | EFFECTIVE DATE |
|-----------------------------------------------------------------------------------------------------------------------------------|----|-------------|-------------------|
| TITLE | 1 | 2 | 26-May-2015 |
| LIST of EFFECTIVE PAGE | 3 | 4 | 26-May-2015 |
| RECORD's of REVISION | 5 | 6 | 26-May-2015 |
| RECORD's of TEMPOPRARY REVISION | 7 | 8 | 26-May-2015 |
| TABLE of CONTENT | 9 | 10 | 26-May-2015 |
| | | | |
| SUBPART GEN - General Requirement's | 11 | 16 | 26-May-2015 |
| Section I. General | 11 | 14 | 26-May-2015 |
| Section II. Management | 15 | 16 | 22-December-2015 |
| SUBPART ATO - Approved Training Organizations | 17 | 26 | 26-May-2015 |
| Section I. General | 17 | 20 | 26-May-2015 |
| | 1/ | 20 | 20-1v1ay-2013 |
| Section II Additional Requirements for ATO's Providing Training for CPL, MPL and ATPL and the Associated Ratings and Certificates | 21 | 22 | 26-May-2015 |
| Section III Additional Requirements for ATO's Providing Specific Types of Training | 23 | 26 | 26-May-2015 |
| Chapter 1 - Distance Learning Course | 23 | 23 | 26-May-2015 |
| Chapter 2 - Zero Flight - Time Training (ZFTT) | 24 | 24 | 26-May-2015 |
| Chapter 3 - Multi - Crew Pilot Licence (MPL) Courses | 25 | 25 | 26-May-2015 |
| Chapter 4 - Flight Test Training | 26 | 26 | 26-May-2015 |
| | | | |
| SUBPART FSTD - Requirements for Organization's Operating FSTD's | 27 | 32 | 26-May-2015 |
| Section I. Requirement's for Organization's Operating FSTD's | 27 | 28 | 26-May-2015 |
| Section II. Requirement's for the Qualification of FSTD's | 29 | 32 | 26-May-2015 |
| | | | |
| SUBPART AeMC - Aero - Medical Centres (AeMC) | 33 | 36 | 26-May-2015 |
| Section I. General | 33 | 34 | 26-May-2015 |
| Section II. Management | 35 | 36 | 26-May-2015 |
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Table of Content

| List of Effective | Page | 3 |
|-------------------|---------------------------------------------------------------|------|
| Record of Revis | sion | 5 |
| - | 5 | 7 |
| | ıt | |
| SUBPART GEN | - General Requirement's | 11 |
| SECTION 1 | General | 11 |
| ORA. GEN. 105 | Competent Authority | 11 |
| ORA. GEN. 115 | Application for an Organization Certificate | 11 |
| ORA. GEN. 120 | Means of Compliance | 11 |
| ORA. GEN. 125 | Terms of approval and privileges of an organization | 11 |
| ORA. GEN. 130 | Changes to organizations | 12 |
| ORA. GEN. 135 | Continued validity | 12 |
| ORA. GEN. 140 | Access | 12 |
| ORA. GEN. 150 | Finding's | 12 |
| ORA. GEN. 155 | Immediate reaction to a safety problem | 13 |
| ORA. GEN. 160 | Occurrence reporting | 13 |
| SECTION II | Management | 15 |
| ORA. GEN. 200 | Management System | 15 |
| ORA. GEN. 205 | Contracted activities | 15 |
| ORA. GEN. 210 | Personnel requirements | 16 |
| ORA. GEN. 215 | Facility requirements | 16 |
| ORA. GEN. 220 | Record - keeping | . 16 |
| SUBPART ATO | - Approved Training Organization's | 17 |
| SECTION I | General | 17 |
| | Scope | |
| ORA. ATO. 105 | Application | . 17 |
| ORA. ATO. 110 | Personnel requirements | . 18 |
| ORA. ATO. 120 | Record - keeping | . 18 |
| ORA. ATO. 125 | Training programme | . 18 |
| ORA. ATO. 130 | Training Manual and Operation's Manual | 18 |
| ORA. ATO. 135 | Training aircraft and FSTD's | . 19 |
| ORA. ATO. 140 | Aerodromes and operating sites | 19 |
| ORA. ATO. 145 | Pre-requisites for training | 19 |
| ORA. ATO. 150 | Training in third countries | . 19 |
| SECTION II | Additional Requirements for ATO's Providing Training for CPL, | |
| | and ATPL and the Associated Ratings and Certificates | |
| | Personnel requirement's | |
| ORA. ATO. 225 | Training programme | 21 |
| ORA. ATO. 230 | Training Manual and Operation's Manual | 21 |

| SECTION III Add | litional Requirements for ATO Providing Specific Types of Training. | 23 |
|----------------------------------|---------------------------------------------------------------------|----|
| Chapter 1 - Distant | ce Learning Course | 23 |
| ORA. ATO. 305 | General | 23 |
| Chapter 2 - Zero | Flight - Time Training (ZFTT) | 24 |
| ORA. ATO. 330 | General | 24 |
| | - | |
| - | <i>i - Crew Pilot Licence (MPL) Courses</i> | |
| | <i>Test Training</i> | |
| | | |
| UKA. AIU. 355 F | Ight Test Training Organizations | 20 |
| SUBPART FSTD | - Requirements for Organization's Operating FSTD's | |
| | and the Qualification of FSTD's | 27 |
| SECTION I R | Requirement's for Organization's Operating FSTD's | 27 |
| | General | |
| | Maintaining the FSTD qualification | |
| ORA. FSTD. 110 | Modification | |
| ORA. FSTD. 115 | Installation's | |
| ORA. FSTD. 120 | Additional equipment | |
| | Requirement's for the Qualification of FSTD's | |
| | Application for FSTD qualification | |
| | Certification specifications for FSTD's | |
| ORA. FSTD. 210 | Qualification basis | |
| ORA. FSTD. 225 ORA. FSTD. 230 | Duration and continued validity Changes to the qualified FSTD | |
| ORA. FSTD. 230 ORA. FSTD. 235 | Transferability of an FSTD qualification | |
| ORA. FSTD. 235 ORA. FSTD. 240 | Record - keeping | |
| | - Aero-Medical Centres | |
| | eneral | |
| ORA. AeMC. 105 | | |
| | Application | |
| | Continued validity | |
| SECTION II N | Aanagement | 35 |
| ORA. AeMC. 200 | Management system | 35 |
| | Personnel requirements | |
| ORA. AeMC. 215 | Facility requirements | 35 |
| ORA. AeMC. 220 | Record - keeping | 35 |

Annex VII PART - ORA

ORGANIZATION REQUIREMENTS for AIRCREW

SUBPART GEN. GENERAL REQUIREMENTS

Section I. General

ORA. GEN. 105 Competent Authority

a) For the purpose of this Part, the GDCA of RA exercising oversight over :

- 1) organizations and FSTD's subject to a certification obligation shall be :
 - for organizations and FSTD's having their principal place of business in a Republic
 - of Armenia, the Authority designated that by GDCA of RA.

ORA. GEN. 115 Application for an Organization Certificate

a) The application for an Organization Certificate or an amendment to an existing certificate shall be made in a form and manner established by the GDCA, taking into account the applicable requirements according of CR-EC N^o 216/2008 and its Implementing Rules; *b*) Applicants for an initial certificate shall provide the GDCA with documentation demonstrating how they will comply with the requirements according in CR-EC N^o 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 GDCA.

ORA. GEN. 120 Means of Compliance

a) Alternative means of compliance to the AMC adopted by the GDCA of RA may be used by an organization;

b) When an organization wishes to use an alternative means of compliance, it shall, prior to implementing it, provide the GDCA with a full description of the alternative means of compliance. The description shall include any revisions to manuals or procedures that may be relevant. The organization may implement these alternative means of compliance subject to prior approval by the GDCA and upon receipt of the notification as prescribed in ARA. GEN. 120 (d).

ORA. GEN. 125 Terms of Approval and Privileges of an Organization

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

ORA. GEN. 130 Changes to Organizations

a) Any change affecting :

- 1) the scope of the certificate or the terms of approval of an organization; or
- 2) any of the elements of the organization's management system as required in

ORA. GEN. 200 (a) (1) and (a) (2), shall require prior approval by the GDCA. **b**) For any changes requiring prior approval in accordance with CR-EC N^o 216/2008 and its Implementing Rules, the organization shall apply for and obtain an approval issued by the GDCA. The application shall be submitted before any such change takes place, in order to enable the GDCA to determine continued compliance with CR-EC N^o 216/2008 and its Implementing Rules and to amend, if necessary, the organization certificate and related terms of approval attached to it. The organization shall provide the GDCA with any relevant documentation.

The change shall only be implemented upon receipt of formal approval by the GDCA in accordance with ARA. GEN. 330. The organization shall operate under the conditions prescribed by the GDCA during such changes, as applicable;

c) All changes not requiring prior approval shall be managed and notified to the GDCA as defined in the procedure approved by the GDCA of RA in accordance with ARA. GEN. 310(c).

ORA. GEN. 135 Continued Validity

a) The organization's certificate shall remain valid subject to:

- 1) the organization remaining in compliance with the relevant requirements, taking into account the provisions related to the handling of findings as specified under ORA. GEN. 150;
- 2) the GDCA being granted access to the organization as defined in ORA.GEN.140 to determine continued compliance with the relevant requirements; and

3) the certificate not being surrendered or revoked.

b) Upon revocation or surrender the certificate shall be returned to the GDCA of RA without delay.

ORA. GEN. 140 Access

For the purpose of determining compliance with the relevant requirements, the organization 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 authorized by :

a) the GDCA (Competent Authority) defined in ORA. GEN. 105; or
b) the GDCA of RA acting under the provisions of ARA. GEN. 300 (d), ARA. GEN. 300 (e) or ARO. RAMP.

ORA. GEN. 150 Finding's

After receipt of notification of findings, the organization 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 GDCA of RA within a period agreed with that authority as defined in ARA. GEN. 350 (d).

ORA. GEN. 155 Immediate Reaction to a Safety Problem

The organization shall implement :

- a) any safety measures mandated by the GDCA of RA in accordance with ARA. GEN. 135
 (c);
- **b**) any relevant mandatory safety information issued by the GDCA of RA, any mandatory safety information issued by other sources including airworthiness directives.

ORA. GEN. 160 Occurrence Reporting

a) The organization shall report to the GDCA of RA, and to any other organization required by the State of the Operator to be informed, any accident, serious incident and occurrence as defined in relevant regulation, according in CR-EU N^o 996/2010 of the European Parliament and of the Council and Directive 2003/42/EC of the European Parliament and of the Council;

b) Without prejudice to paragraph (*a*) the organization shall report to the GDCA of RA and to the organization 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 CR-EU N⁰ 748/2012 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, the reports referred in paragraphs (a) and (b) shall be made in a form and manner established by the GDCA of RA and contain all pertinent information about the condition known to the organization;

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

e) Where relevant, the organization 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 GDCA of RA.

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Section II. Management

ORA. GEN. 200 Management System

a) The organization shall establish, implement and maintain a management system that includes :

- 1) clearly defined lines of responsibility and accountability throughout the organization, including a direct safety accountability of the Accountable Manager;
- 2) a description of the overall philosophies and principles of the organization with regard to safety, referred to as the safety policy;
- 3) the identification of aviation safety hazards entailed by the activities of the organization, 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 organization 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 organization and the nature and complexity of its activities, taking into account the hazards and associated risks inherent in these activities.

c) Notwithstanding point (a), in an organization 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 organizational review, to be performed at least once every calendar year. The GDCA shall be notified about the results of this review by the organization without undue delay.

ORA. GEN. 205 Contracted activities

a) Contracted activities include all activities within the organization's scope of approval that are performed by another organization either itself certified to carry out such activity or if not certified, working under the contracting organization's approval. The organization 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 organization contracts any part of its activity to an organization that is not itself certified in accordance with this Part to carry out such activity, the contracted organization shall work under the approval of the contracting organization. The contracting organization shall ensure that the GDCA of RA is given access to the contracted organization, to determine continued compliance with the applicable requirements.

ORA. GEN. 210 Personnel Requirements

a) The organization 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 organization, with the responsibility of ensuring that the organization remains in compliance with the applicable requirements. Such person(s) shall be ultimately responsible to the Accountable Manager;

c) The organization shall have sufficient qualified personnel for the planned tasks and activities to be performed in accordance with the applicable requirements;

d) The organization shall maintain appropriate experience, qualification and training records to show compliance with paragraph (c);

e) The organization 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 organization 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 organization 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 organization'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 organizations 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 Organization (*ATO*) shall provide the GDCA of RA with :

- 1) the following information:
 - (i) name and address of the training organization;
 - (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 (*FSTD's*) that the training organization intends to use, if applicable;
 - (vii) the type of training that the training organization wishes to provide and the corresponding training programme; *and*
- 2) the Operations and Training Manuals.

b) Flight Test Training Organizations.

Notwithstanding (a)(1)(iv) and (v), training organizations 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 Head of Training 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 Operation's 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 ARM - OPS (Part - ORO).

ORA. ATO. 135 Training Aircraft and FSTD's

All ATO's, EXCEPT those PROVIDING FLIGHT TEST TRAINING

a) The ATO shall use an adequate fleet of training aircraft or FSTD's appropriate to the courses of training provided;

b) The ATO shall only provide training in FSTD's when it demonstrates to the GDCA:

- 1) the adequacy between the FSTD specifications and the related training programme;
- 2) that the FSTD's used comply with the relevant requirements of Part FCL;
- 3) in the case of Full Flight Simulators (*FFS's*), 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.

The fleet should include, as appropriate to the courses of training :

1) aircraft suitably equipped to simulate Instrument Meteorological Conditions (IMC) and for the Instrument Flight Training required. For flight training and testing for the Instrument Rating and the En-route Instrument Rating (EIR), an adequate number of IFR - Certificated aircraft should be available.

d) <u>Flight Test Training Organizations</u>. 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 -Medical, Part - FCL, and, if applicable, as defined in the mandatory part of the operational suitability data established in accordance with CR-EU N° 748/2012;
b) In the case of ATO's providing Flight Test Training, the students shall meet all the pre - requisites for training established in accordance with CR-EU N° 748/2012.

ORA. ATO. 150 Training in Third Countries - (reserved)

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

Section II. Additional Requirements for ATO's Providing Training for CPL, MPL and ATPL and the Associated Ratings and Certificates

ORA. ATO. 210 Personnel Requirement's

a) <u>Head of Training</u> (HT).

Except in the case of ATO's 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) <u>Chief Flight Instructor</u> (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 standardization 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) <u>Chief Theoretical Knowledge Instructor</u> (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 standardization 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 <u>Training Manual</u> 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 <u>Operations Manual</u> 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 ATO's Providing Specific Types of Training

<u>Chapter 1</u> - <u>Distance Learning Course</u>

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.

<u>Chapter 2</u> - <u>Zero Flight - Time Training</u>

ORA. ATO. 330 General

a) Approval for Zero Flight - Time Training (*ZFTT*), as specified in Part - FCL, shall only be given to ATO's that also have the privileges to conduct commercial air transport operations or ATO's 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 (FFS)

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.

<u>Chapter 3</u> - <u>Multi-Crew Pilot Licence (MPL) Courses</u>

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 operation's or a specific arrangement with a commercial air transport Operator.

<u>Chapter 4</u> - <u>Flight Test Training</u>

ORA. ATO. 355 Flight Test Training Organizations

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 requirement's of Part - 21 are met; and

2) a specific arrangement exists between the ATO and the Part - 21 organization that employ's, 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 ORGANIZATION'S OPERATING FSTD's and the QUALIFICATION of FSTD's

Section I. Requirement's for Organization's Operating FSTD's

ORA. FSTD. 100 General

a) The applicant for an FSTD qualification certificate shall demonstrate to the competent GDCA 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 :

or

1) in the terms of the ATO certificate;

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 analyzed 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 FSTD's 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 organization shall prepare amendments for any affected validation tests. The organization shall Test the FSTD to the new criteria;

c) The organization shall inform the GDCA in advance of any major changes to determine if the tests carried out are satisfactory. The GDCA 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;

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 GDCA to ensure that it does not adversely affect the quality of training.

Section II. Requirement's for the Qualification of FSTD's

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 GDCA of RA:

1) in the case of Basic Instrument Training Devices (BITD's), by the BITD manufacturer;

2) in all other cases, by the organization 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 FSTD's

a) The GDCA of RA shall issue Certification Specifications, in accordance with European Regulation Article 19 of CR-EC N^o 216/2008, Certification Specifications as standard means to show compliance of FSTD's with the Essential Requirements of Annex III to CR-EC N^o 216/2008;

b) Such Certification Specification's 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 GDCA of RA that are effective on the date of the application for the initial qualification;
- 2) the aircraft validation data defined by the mandatory part of the operational suitability data as approved under CR-EU N^o 748/2012, if applicable; *and*
- 3) any special conditions prescribed by the competent Authority if the related Certification Specifications do not contain adequate or appropriate standards for the FSTD because the FSTD has novel or different features to those upon which the applicable Certification Specifications are based.

b) The qualification basis shall be applicable for future recurrent qualifications of the FSTD, unless it is re-categorized.

and

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 organization remaining in compliance with the applicable Requirement's ;
- 2) the competent Authority being granted access to the organization as defined in ORA. GEN. 140 to determine continued compliance according with the relevant requirements of CR-EC $N^{\circ} 216/2008$ and its 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) the competent Authority performs a formal audit of the compliance monitoring system defined in ORA. GEN. 200(a)(6) of the organization every 12 months;
- 4) an assigned person of the organization 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 the GDCA.

c) A BITD qualification shall remain valid subject to regular evaluation for compliance with the applicable qualification basis by the GDCA in accordance with ARA. FSTD. 120;

d) Upon surrender or revocation, the FSTD qualification certificate shall be returned to the GDCA of RA.

ORA. FSTD. 230 Changes to the Qualified FSTD

a) The holder of an FSTD qualification certificate shall inform the GDCA of any proposed changes to the FSTD, such as:

- 1) major modification's;
- 2) relocation of the FSTD;
- 3) any de-activation of the FSTD.

b) In case of an upgrade of the FSTD qualification level, the organization shall apply to the competent Authority for an upgrade evaluation. The organization 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 organization shall inform the GDCA before the planned activity along with a schedule of related events. Prior to returning the FSTD to service at the new location, the organization 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 GDCA. The GDCA 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 organization plans to remove an FSTD from active status for prolonged periods, the GDCA shall be notified and suitable controls established for the period during which the FSTD is inactive.

The organization shall agree with the GDCA a plan for the de-activation, any storage and reactivation 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 organization operating an FSTD, the new organization shall inform the GDCA in advance in order to agree upon a plan of transfer of the FSTD;

b) The GDCA 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 organization 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.

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SUBPART AeMC. AERO - MEDICAL CENTRES

Section I. General

ORA. AeMC. 105 Scope

This Subpart establishes the additional requirements to be met by an organization 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;

b) In addition to the documentation for the approval of an organization 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 organization :

a) Complying with MED. D. 030;

b) Ensuring their continued experience by performing an adequate number of Class 1 Medical Examination's every year.

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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;
 - 2) have on staff an adequate number of fully qualified AME's 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;
 b) Keep all medical records in a way that ensures that medical confidentiality is respected at all

times.

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