

EN

EN

EN



COMMISSION OF THE EUROPEAN COMMUNITIES

Brussels, ...
C

Draft

COMMISSION REGULATION (EU) No .../..

of [...]

on Authority Requirements and Organisation Requirements

(Text with EEA relevance)

Draft

COMMISSION REGULATION (EU) No .../..

of [...]

on Authority Requirements and Organisation Requirements

THE COMMISSION OF THE EUROPEAN UNION,

Having regard to the Treaty establishing the European Union,

Having regard to Regulation (EC) No 216/2008 of the European Parliament and of the Council of 20 February 2008 on common rules in the field of civil aviation and establishing a European Aviation Safety Agency, and repealing Council Directive 91/670/EEC, Regulation (EC) No 1592/2002 and Directive 2004/36/EC¹, amended by Regulation (EC) No 1108/2009 of the European Parliament and of the Council of 21 October 2009² and in particular Article 7, 8, 10, and 15 thereof.

Whereas:

- (1) Regulation (EC) No 216/2008 establishes common Essential Requirements to provide for a high uniform level of civil aviation safety and environmental protection; it requires the Commission to adopt the necessary Implementing Rules to ensure their uniform application; it establishes the 'European Aviation Safety Agency' (hereinafter referred to as the 'Agency') to assist the Commission in the development of such Implementing Rules.
- (2) Articles 7 and 8 of Regulation (EC) No 216/2008 mandate the Commission to adopt common technical requirements and administrative procedures for civil aviation air crew and air operations to ensure compliance with the Essential Requirements laid down in Annexes III, IV and Vb of that Regulation.
- (3) Articles 10 and 15 of Regulation (EC) No 216/2008 further mandate the Commission to adopt common measures in relation to oversight and enforcement and the establishment of an information network between the Commission, the Agency and national aviation authorities.
- (4) In order to ensure a smooth transition and a high level of civil aviation safety in the European Union, Implementing Rules should reflect the state of the art, including best practices, and scientific and technical progress in the field of pilot training and air operations. Accordingly, technical requirements and administrative procedures agreed under the auspices of the International Civil Aviation Organisation (hereinafter referred to as "ICAO") and the European Joint Aviation Authorities (hereinafter referred to as "JAA"), as well as existing European and national rules, should be considered.
- (5) With a view to ensuring uniformity in the application of common requirements, it is essential that common standards be applied by the competent authorities and, where

¹ OJ L 79, 13.3.2008, p.1.

² OJ L 309, 24.11.2009, p. 51.

applicable, the Agency when assessing compliance with these requirements; the Agency should develop Acceptable Means of Compliance and Guidance Material to facilitate the necessary regulatory uniformity.

- (6) It is necessary to provide sufficient time for the aeronautical industry and Member State administrations to adapt to the new regulatory framework, in accordance with Article 70 of Regulation (EC) No 216/2008, and to recognise the validity of certificates issued before the entry into force of this Regulation under certain conditions, in accordance with Article 69 of that Regulation.
- (7) The measures provided by this Regulation are based on the Opinion issued by the Agency in accordance with Articles 17 and 19 of the Basic Regulation.
- (8) The measures provided for in this Regulation are in accordance with the Opinion of the European Aviation Safety Agency Committee established by Article 65 of the Basic Regulation,

HAS ADOPTED THIS REGULATION:

Article 1

Objective and scope

1. This Regulation establishes:
 - (a) requirements for the administration and management system to be fulfilled by the Agency and Member States for the implementation and enforcement of Regulation (EC) No 216/2008 and its Implementing Rules regarding civil aviation air crew;
 - (b) common technical requirements for the administration and management system and the conditions for issuing, maintaining, amending, limiting, suspending or revoking certificates of pilot training organisations and of aero-medical centres involved in the qualification of civil aviation air crew;
 - (c) the requirements for the certification of flight simulation training devices and for the administration and management system of organisations operating and using those devices.

Article 2

Definitions

For the purpose of this Regulation the definitions in Annex I shall apply.

Article 3

Safety planning

1. The Member States and the Agency shall establish aviation safety plans aimed at maintaining a high level of safety.
2. In the context of drawing up their plans, Member States and the Agency shall exchange any information available and cooperate in deciding any specific actions required to maintain the high level of safety.

Article 4

Oversight capabilities

1. Member States shall designate one or more entities as the competent authority within that Member State with allocated responsibilities for the certification and oversight of persons and organisations subject to Regulation (EC) No 216/2008 and its Implementing Rules.
2. If a Member State designates more than one entity as competent authority:
 - (a) the areas of competence of each competent authority shall be clearly defined in terms of responsibilities and geographic limitation.
 - (b) coordination shall be established between those entities to ensure effective oversight of all organisations and persons subject to Regulation No (EC) 216/2008 and its Implementing Rules within their respective remits.
3. Member States shall ensure that the competent authority(ies) has(ve) the necessary capability to ensure the oversight of all persons and organisations covered by their oversight programme, including sufficient resources to fulfil the requirements of this Regulation.
4. Member States shall ensure that competent authority personnel do not perform oversight activities when there is evidence that this could result directly or indirectly in a conflict of interest, in particular when relating to family or financial interest.
5. Personnel authorised by the competent authority to carry out certification and/or oversight tasks shall be empowered to perform at least the following functions/tasks:
 - (a) examine the records, data, procedures and any other material relevant to the execution of the certification and/or oversight task;
 - (b) take copies of or extracts from such records, data, procedures and other material;
 - (c) ask for an oral explanation on site;
 - (d) enter relevant premises, operating sites or means of transport;
 - (e) perform audits, inspections, including ramp inspections and unannounced inspections; and
 - (f) take enforcement measures as appropriate.

Such functions/tasks shall be carried out in compliance with the legal provisions of the relevant Member State.

Article 5

Flexibility provisions

1. When applying Article 14(1) of Regulation (EC) No 216/2008, the notification provided by the Member State shall include at least :
 - (a) a description of the safety problem;
 - (b) the affected requirements of Regulation (EC) No 216/2008 and its Implementing Rules
 - (c) the identification of the product, part, appliance, person or organisation concerned;

- (d) the identification of the affected activity;
 - (e) the measure required and its justification;
 - (f) the time limit for compliance with the measure required; and
 - (g) the date or period of applicability of the measure.
2. When applying Article 14(4) of Regulation (EC) No 216/2008, the notification sent by the Member State shall include at least:
- (a) the affected requirements of Regulation (EC) No 216/2008 and its Implementing Rules;
 - (b) the reason for granting the exemption;
 - (c) the identification of the product, part, appliance, person or organisation to which the exemption applies;
 - (d) the type of operation or the activity concerned;
 - (e) the date or period of applicability of the exemption;
 - (f) a reference to previous similar exemptions, if any; and
 - (g) evidence demonstrating that the level of safety is not adversely affected, including, if applicable, a description of the related mitigation measures.
3. When applying Article 14(6) of Regulation (EC) No 216/2008, the notification sent by the Member State shall include at least:
- (a) the requirements for which the Member State intends to grant a derogation;
 - (b) the reason for granting the derogation;
 - (c) the identification of the product, part, appliance, person or organisation to which the derogation applies;
 - (d) the conditions that the Member State has put in place to ensure that an equivalent level of protection is achieved; and
 - (e) evidence demonstrating that an equivalent level of protection is ensured.
4. When granting an exemption in accordance with Article 18(d) of Regulation (EC) No 216/2008, the notification sent by the Agency shall include at least:
- (a) the requirement for which the exemption is granted;
 - (b) the reason for granting the exemption;
 - (c) the identification of the product, part, appliance, person or organisation to which the exemption applies;
 - (d) the date or period of applicability of the exemption; and
 - (e) evidence demonstrating that the level of safety is not adversely affected, including, if applicable, a description of the related mitigation measures.

Article 6

Pilot training organisations

1. Pilot training organisations shall be certified in accordance with the provisions of Annex II to this Regulation.
2. Pilot training organisations holding JAR-compliant training organisation approval certificates issued or recognised by a Member State before 8 April 2012 shall be deemed to hold a certificate issued in accordance with this Regulation.

In such case the privileges of these organisations shall be limited to those included in the approval issued by the Member State.

3. Member States shall replace these certificates with certificates complying with the format laid down in Annex II no later than 8 April 2015.

Article 7

Flight simulation training devices

1. Flight simulation training devices (FSTDs) used for pilot training, with the exception of developmental FSTDs used for flight test training, shall be qualified in accordance with the provisions of Annex III.
2. JAR-compliant FSTD qualification certificates issued or recognised before 8 April 2012 shall be deemed to have been issued in accordance with this Regulation.
3. Member States shall replace these qualification certificates with qualification certificates complying with the format laid down in Annex II no later than 8 April 2015.

Article 8

Aero-medical centres

1. Certificates for aero-medical centres shall be issued in accordance with the provisions of Annex III.
2. JAR-compliant aero-medical centre approvals issued or recognised by a Member State before 8 April 2012 shall be deemed to have been issued in accordance with this Regulation.

Member States shall replace these approvals with certificates complying with the format laid down in Annex II no later than 8 April 2017.

Article 9

Transitional measures

1. Within a maximum period of 12 months from the entry into force of this Regulation, Member States' competent authorities shall transfer to the Agency all records related to the oversight of organisations for which the Agency is the competent authority in accordance with Article 21(1)(b) of Regulation (EC) No 216/2008.

2. Certification process initiated before 8 April 2012 by a Member State concerning an organisation for which the Agency is the competent authority in accordance with Article 21(1)(b) of Regulation (EC) No 216/2008 shall be finalised by that Member State in coordination with the Agency. The Agency shall assume all its responsibilities as competent authority concerning such organisation after the issuance of the certificate.
3. Applicants for an organisation certificate under this Regulation having submitted their application before 8 April 2012 and not having been issued such a certificate before that date shall show compliance with the provisions of this Regulation before the certificate is issued.

Article 10

Entry into force

1. This Regulation shall enter into force on the 20th day following its publication in the Official Journal of the European Union and shall become applicable as from 8 April 2012.
2. By way of derogation from paragraph 1 Member States may elect not to apply:
 - (a) the provisions of Annex II and Annex III to this Regulation to JAR-compliant approved training organisations and aero-medical centres until no later than 8 October 2013;
 - (b) the provisions of Annex II and III to this Regulation to training organisations providing training only for the light aircraft pilot licence, private pilot licence, balloon pilot licence or sailplane pilot licence until no later than 8 April 2015;
 - (c) the provisions of Annex II and III to this Regulation to training organisations providing training for flight test ratings in accordance with FCL.820 until no later than 8 April 2015;
 - (d) the provisions of OR.GEN.200 (a)(3) to FSTD certificate holders, not being an approved training organisation and not holding an air operator certificate until no later than 8 April 2014.
3. When a Member State makes use of the provisions of paragraph 2, it shall notify the Commission and the Agency. This notification shall describe the reasons and the duration for such derogation as well as the programme for implementation containing actions envisaged and related timing.

This Regulation shall be binding in its entirety and directly applicable in all Member States.

Done at Brussels, XXXX.

For the Commission
[...]
The President

ANNEX I TO IMPLEMENTING REGULATION

DEFINITIONS FOR TERMS USED IN THIS REGULATION

1. 'Acceptable Means of Compliance (AMC)' are non-binding standards adopted by the Agency to illustrate means to establish compliance with the Basic Regulation and its Implementing Rules;
2. 'Aero-medical Centre (AeMC)' means an organisation qualified for the issue or continuation of an approval to issue medical certificates, including initial class 1 medical certificates;
3. 'Air crew' means flight crew and cabin crew;
4. 'Alternative means of compliance' are those that propose an alternative to an existing Acceptable Means of Compliance or those that propose new means to establish compliance with Regulation (EC) No 216/2008 and its Implementing Rules for which no associated Acceptable Means of Compliance have been adopted by the Agency;
5. 'Approved training organisation (ATO)' means an organisation qualified for the issue or continuation of an approval to provide training for pilot licences and associated ratings and certificates.
6. 'Basic instrument training device model (BITD model)' means a defined hardware and software combination, which has obtained a BITD qualification;
7. 'Cabin crew (CC) member' means an appropriately qualified crew member, other than a flight crew or technical crew member, who is assigned by an operator to perform duties related to the safety of passengers and flight during operations;
8. 'Flight instructor (FI)' means an instructor with the privileges to provide training in an aircraft, in accordance with Part-FCL;
9. 'Flight simulation training device (FSTD)' means a training device which is:
 - (a) in the case of aeroplanes, a full flight simulator (FFS), a flight training device (FTD), a flight and navigation procedures trainer (FNPT), or a basic instrument training device (BITD);
 - (b) in the case of helicopters, a full flight simulator (FFS), a flight training device (FTD) or a flight and navigation procedures trainer (FNPT);
10. 'FSTD qualification' means the level of technical ability of an FSTD as defined in the compliance document;
11. 'FSTD user' means the organisation or person requesting training, checking or testing through the use of an FSTD to an ATO;
12. 'Grounding' means the formal prohibition of an aircraft to take-off and the taking of such steps as are necessary to detain it;
13. 'Guidance Material (GM)' means non-binding material developed by the Agency that helps to illustrate the meaning of a requirement or specification and is used to support the interpretation of regulations and Acceptable Means of Compliance;
14. 'JAR' means Joint Aviation Requirements;
15. 'JAR-compliant certificate' means a certificate issued or recognised, in accordance with the national legislation reflecting JAR and procedures, by a Member State having

implemented the relevant JAR and having been recommended for mutual recognition within the Joint Aviation Authorities' system in relation to such JAR;

16. 'AR.RAMP' means the Subpart RAMP of Annex II to the Regulation on Air Operations.
17. 'Other training device (OTD)' means an aid used for pilot training other than an FSTD that provides for training where a complete flight deck or cockpit environment is not necessary;
18. 'Part-AR' means Annex II to this Regulation;
19. 'Part-CAT' means Annex IV to the Regulation on Air Operations;
20. 'Part-CC' means Annex V to the Regulation on Civil Aviation Air Crew;
21. 'Part-FCL' means Annex I to the Regulation on Civil Aviation Air Crew;
22. 'Part-OR' means Annex III to this Regulation;
23. 'Principal place of business' means the head office or registered office of the organisation within which the principal financial functions and operational control of the activities referred to in this Regulation are exercised;
24. 'Qualification test guide (QTG)' means a document designed to demonstrate that the performance and handling qualities of an FSTD represent those of the aircraft, class of aeroplane or type of helicopter, simulated within prescribed limits and that all applicable requirements have been met. The QTG includes both the data of the aircraft, class of aeroplane or type of helicopter and FSTD data used to support the validation.

ANNEX II TO IMPLEMENTING REGULATION

PART AUTHORITY REQUIREMENTS (AR)

SUBPART GEN - GENERAL REQUIREMENTS

SECTION I - GENERAL

AR.GEN.115 Oversight documentation

The competent authority shall provide all legislative acts, standards, rules, technical publications and related documents to relevant personnel in order to allow them to perform their tasks and to discharge their responsibilities.

AR.GEN.120 Means of compliance

- (a) The Agency shall develop Acceptable Means of Compliance (AMC) that may be used to establish compliance with Regulation (EC) No 216/2008 and its Implementing Rules. When the AMC are complied with, the related requirements of the Implementing Rules are met.
- (b) Alternative means of compliance may be used to establish compliance with the Implementing Rules.
- (c) The competent authority shall establish a system to consistently evaluate that all alternative means of compliance used by itself or by organisations and persons under its oversight allow the establishment of compliance with Regulation (EC) No 216/2008 and its Implementing Rules.
- (d) The competent authority shall evaluate all alternative means of compliance proposed by an organisation in accordance with OR.GEN.120 by analysing the documentation provided and, if considered necessary, conducting an inspection of the organisation.

When the competent authority finds that the alternative means of compliance are in accordance with the Implementing Rules, it shall without undue delay:

- (1) notify the applicant that the alternative means of compliance may be implemented and, if applicable, amend the approval or certificate of the applicant accordingly; and
 - (2) notify the Agency of their content, including copies of all relevant documentation.
- (e) When the competent authority itself uses alternative means of compliance to achieve compliance with Regulation (EC) No 216/2008 and its Implementing Rules it shall:
 - (1) make them available to all organisations and persons under its oversight; and
 - (2) without undue delay notify the Agency.

The competent authority shall provide the Agency with a full description of the alternative means of compliance, including any revisions to procedures that may be relevant, as well as an assessment demonstrating that the Implementing Rules are met.

AR.GEN.125 Information to the Agency

- (a) The competent authority shall without undue delay notify the Agency in case of any problems with the implementation of Regulation (EC) No 216/2008 and its Implementing Rules.
- (b) The competent authority shall provide the Agency with safety-significant information stemming from the occurrence reports it has received.

AR.GEN.135 Immediate reaction to a safety problem

- (a) Without prejudice to Directive 2003/42/EC³ the competent authority shall implement a system to appropriately collect, analyse and disseminate safety information.
- (b) The Agency shall implement a system to appropriately analyse any safety information received and without undue delay provide to Member States and the Commission any information, including recommendations or corrective actions to be taken, necessary for them to react in a timely manner to a safety problem involving products, parts, appliances, persons or organisations subject to Regulation (EC) No 216/2008 and its Implementing Rules.
- (c) Upon receiving the information referred to in (b), the competent authority shall take adequate measures to address the safety problem.
- (d) Measures taken under (c) shall immediately be notified to all persons or organisations which need to comply with them under Regulation (EC) No 216/2008 and its Implementing Rules. The competent authority shall also notify those measures to the Agency and, when combined action is required, the other Member States concerned.

³ Directive 2003/42/EC of the European Parliament and of the Council of 13 June 2003 on occurrence reporting in civil aviation, *OJ L 167, 4.7.2003, p. 23–36*.

SECTION II - MANAGEMENT

AR.GEN.200 Management system

- (a) The competent authority shall establish and maintain a management system, including as a minimum:
- (1) documented policies and procedures to describe its organisation, means and methods to achieve compliance with Regulation (EC) 216/2008 and its Implementing Rules. The procedures shall be kept up-to-date and serve as the basic working documents within that competent authority for all related tasks;
 - (2) a sufficient number of personnel to perform its tasks and discharge its responsibilities. Such personnel shall be qualified to perform their allocated tasks and have the necessary knowledge, experience, initial and recurrent training to ensure continuing competence. A system shall be in place to plan the availability of personnel, in order to ensure the proper completion of all tasks;
 - (3) adequate facilities and office accommodation to perform the allocated tasks;
 - (4) a function to monitor compliance of the management system with the relevant requirements and adequacy of the procedures including the establishment of an internal audit process. Compliance monitoring shall include a feedback system of audit findings to the senior management of the competent authority to ensure implementation of corrective actions as necessary; and
 - (5) a person or group of persons, ultimately responsible to the senior management of the competent authority for the compliance monitoring function.
- (b) The competent authority shall, for each field of activity, appoint one or more persons with the overall responsibility for the management of the relevant task(s).
- (c) The competent authority shall establish procedures for participation in a mutual exchange of all necessary information and assistance with other competent authorities concerned including on all findings raised and follow-up actions taken as a result of oversight of persons and organisations exercising activities in the territory of a Member State, but certified by or making declarations to the competent authority of another Member State or the Agency.
- (d) A copy of the procedures related to the management system and their amendments shall be made available to the Agency for the purpose of standardisation.

AR.GEN.205 Allocation of tasks

- (a) When allocating a task related to the initial certification or continuing oversight of persons or organisations subject to Regulation (EC) No 216/2008 and its Implementing Rules to a natural or legal person, the competent authority shall ensure that it has:
- (1) a system in place to initially and continuously assess their:
 - (i) adequate technical competence;
 - (ii) adequate facilities and equipment;
 - (iii) absence from conflict of interest; and
 - (iv) compliance with the criteria defined in Annex V to Regulation (EC) No 216/2008, where relevant.

This system and the results of the assessments shall be documented;

- (2) established a documented agreement with the natural or legal person, approved by both parties at the appropriate management level, which clearly defines:
 - (i) the tasks to be performed;
 - (ii) the declarations, reports and records to be provided;
 - (iii) the technical conditions to be met in performing such tasks;
 - (iv) the related liability coverage; and
 - (v) the protection given to information acquired in carrying out such tasks.
- (b) The competent authority shall ensure that the internal audit process required by AR.GEN.200 (a)(4) covers all certification or continuing oversight tasks performed on its behalf.

AR.GEN.210 Changes in the management system

- (a) The competent authority shall have a system in place to identify changes that affect its capability to perform its tasks and discharge its responsibilities as defined in Regulation (EC) No 216/2008 and its Implementing Rules. This system shall enable it to take action as appropriate to ensure that its management system remains adequate and effective.
- (b) The competent authority shall update its management system to reflect any change to Regulation (EC) No 216/2008 and its Implementing Rules in a timely manner, so as to ensure effective implementation.
- (c) The competent authority shall notify the Agency of changes affecting its capability to perform its tasks and discharge its responsibilities as defined in Regulation (EC) No 216/2008 and its Implementing Rules.

AR.GEN.220 Record-keeping

- (a) The competent authority shall establish a system of record-keeping providing for adequate storage, accessibility and reliable traceability of:
 - (1) the management system's documented policies and procedures;
 - (2) training, qualification and authorisation of its personnel;
 - (3) the allocation of tasks, covering the elements required by AR.GEN.205 as well as the details of tasks allocated;
 - (4) certification processes and continuing oversight of certified organisations;
 - (5) processes for issuing personnel licences, ratings, certificates and attestations and for the continuing oversight of the holders of those licences, ratings, certificates and attestations;
 - (6) processes for issuing FSTD qualification certificates and for the continuing oversight of the FSTD and of the organisation operating it;
 - (7) oversight of persons and organisations exercising activities within the territory of the Member State, but overseen or certified by the competent authority of another Member State, as agreed between these authorities;
 - (8) the evaluation and notification to the Agency of alternative means of compliance proposed by organisations and the assessment of alternative means of compliance used by the competent authority itself;

- (9) findings, corrective actions and date of action closure;
 - (10) enforcement measures taken;
 - (11) safety information and follow-up measures; and
 - (12) the use of flexibility provisions in accordance with Article 14 of Regulation (EC) No 216/2008;
- (b) The competent authority shall maintain a list of all organisation certificates, FSTD qualification certificates and personnel licences, certificates and attestations issued.
- (c) All records shall be kept for the minimum period specified in this Regulation. In the absence of such indication, records shall be kept for a minimum period of 5 years.

SECTION III - OVERSIGHT, CERTIFICATION AND ENFORCEMENT

AR.GEN.300 Oversight

- (a) The competent authority shall verify:
 - (1) compliance with the requirements applicable to organisations or persons prior to the issue of an organisation certificate, approval, FSTD qualification certificate or personnel licence, certificate, rating, or attestation, as applicable;
 - (2) continued compliance with the applicable requirements of organisations it has certified, of persons and of FSTD qualification certificate holders;
 - (3) implementation of appropriate safety measures mandated by the competent authority as defined in AR.GEN.135 (c) and (d).
- (b) This verification shall:
 - (1) be supported by documentation specifically intended to provide personnel responsible for safety oversight with guidance to perform their functions;
 - (2) provide the persons and organisations concerned with the results of safety oversight activity;
 - (3) be based on audits and inspections, including ramp and unannounced inspections; and
 - (4) provide the competent authority with the evidence needed in case further action is required, including the measures foreseen by AR.GEN.350 and AR.GEN.355.
- (c) The scope of oversight defined in (a) and (b) above shall be determined on the basis of the results of past oversight activities and of the safety priorities identified in the safety plan.
- (d) Without prejudice to the competences of the Member States and to their obligations as set out in AR.RAMP, the scope of the oversight of activities performed in the territory of a Member State by persons or organisations established or residing in another Member State shall be determined on the basis of the safety priorities identified in the safety plan, as well as of past oversight activities.
- (e) Where the activity of a person or organisation involves more than one Member State or the Agency, the competent authority responsible for the oversight under (a) may agree to have part of that oversight performed locally by the competent authority(ies) of the Member State(s) where the activity takes place or by the Agency. Any person or organisation subject to such agreement shall be informed of its existence and of its scope.
- (f) The competent authority shall collect and process any information deemed useful for oversight, including for ramp and unannounced inspections.

AR.GEN.305 Oversight programme

- (a) The competent authority shall establish and maintain an oversight programme covering the oversight activities required by AR.GEN.300 and by AR.RAMP.
- (b) For organisations certified by the competent authority and FSTD qualification certificate holders, the oversight programme shall be developed taking into account the specific nature of the organisation, the complexity of its activities and the results of past certification and/or oversight activities. It shall include within each oversight planning cycle:

- (1) audits and inspections, including ramp and unannounced inspections as appropriate; and
 - (2) meetings convened between the accountable manager and the competent authority to ensure both remain informed of significant issues.
- (c) For organisations certified by the competent authority and FSTD qualification certificate holders an oversight planning cycle not exceeding 24 months shall be applied.

The oversight planning cycle may be reduced if there is evidence that the safety performance of the organisation or the FTSD qualification certificate holder has decreased.

The oversight planning cycle may be extended to a maximum of 36 months if the competent authority has established that, during the previous 24 months:

- (1) the organisation has demonstrated an effective identification of aviation safety hazards and management of associated risks;
- (2) no major changes occurred in the management system of the organisation or its activity;
- (3) no level 1 findings have been issued; and
- (4) all corrective actions have been implemented within the time period accepted or extended by the competent authority as defined in AR.GEN.350 (d)(2).

The oversight planning cycle may be further extended to a maximum of 48 months if, in addition to the above, the organisation has established, and the competent authority has approved, an effective continuous reporting system to the competent authority on the safety performance and regulatory compliance of the organisation itself.

- (d) For persons holding a licence, certificate, rating, or attestation issued by the competent authority the oversight programme shall include inspections, including unannounced inspections, as appropriate.
- (e) The oversight programme shall include records of the dates when audits, inspections and meetings are due and when such audits, inspections and meetings have been carried out.

AR.GEN.310 Initial certification procedure – organisations

- (a) Upon receiving an application for the initial issue of a certificate for an organisation, the competent authority shall verify the organisation's compliance with the applicable requirements.
- (b) When satisfied that the organisation is in compliance with the applicable requirements, the competent authority shall issue the certificate(s), as established in Appendix III and Appendix IV to this Part. The certificate(s) shall be issued for an unlimited duration. The privileges and scope of the activities that the organisation is approved to conduct shall be specified in the terms of approval attached to the certificate(s).
- (c) To enable an organisation to implement changes without prior competent authority approval in accordance with OR.GEN.130, the competent authority shall approve the procedure submitted by the organisation defining the scope of such changes and describing how such changes will be managed and notified.

AR.GEN.315 Procedure for issue, revalidation, renewal or change of licences, ratings, certificates or attestations - persons

- (a) Upon receiving an application for the issue, revalidation, renewal or change of a personal licence, rating, certificate or attestation and any supporting documentation, the competent authority shall verify whether the applicant meets the applicable requirements.
- (b) When satisfied that the applicant meets the applicable requirements, the competent authority shall issue, revalidate, renew or change the licence, certificate, rating, or attestation.

AR.GEN.330 Changes – organisations

- (a) Upon receiving an application for a change that requires prior approval, the competent authority shall verify the organisation's compliance with the applicable requirements before issuing the approval.

The competent authority shall prescribe the conditions under which the organisation may operate during the change, unless the competent authority determines that the organisation's certificate needs to be suspended.

When satisfied that the organisation is in compliance with the applicable requirements, the competent authority shall approve the change.

- (b) Without prejudice to any additional enforcement measures, when the organisation implements changes requiring prior approval without having received competent authority approval as defined in (a), the competent authority shall suspend, limit or revoke the organisation's certificate.
- (c) For changes not requiring prior approval, the competent authority shall assess the information provided in the notification sent by the organisation in accordance with OR.GEN.130 to verify compliance with the applicable requirements. In case of any non-compliance, the competent authority shall:
 - (1) notify the organisation about the non-compliance and request further changes; and
 - (2) in case of level 1 or level 2 findings, act in accordance with AR.GEN.350.

AR.GEN.350 Findings and corrective actions

- (a) The competent authority for oversight in accordance with AR.GEN.300 (a) shall have a system to analyse findings for their safety significance as part of the safety plan.
- (b) A level 1 finding shall be issued by the competent Authority when any significant non-compliance is detected with the applicable requirements of Regulation (EC) No 216/2008 and its Implementing Rules, with the organisation's procedures and manuals or with the terms of an approval or certificate which lowers safety or seriously hazards flight safety.

In addition, the following shall be considered level 1 findings:

- (1) failure to give the competent authority access to the organisation's facilities as defined in OR.GEN.140 during normal operating hours and after two written requests;
 - (2) obtaining or maintaining the validity of the organisation certificate by falsification of submitted documentary evidence;
 - (3) evidence of malpractice or fraudulent use of the organisation certificate; and
 - (4) the lack of an accountable manager.
- (c) A level 2 finding shall be issued by the competent Authority when any non-compliance is detected with the applicable requirements of Regulation (EC) No 216/2008 and its Implementing Rules, with the organisation's procedures and manuals or with the terms of an approval or certificate which could lower safety or possibly hazard flight safety.
 - (d) When a finding is detected during oversight or by any other means, the competent authority shall, without prejudice to any additional action required by Regulation (EC) No 216/2008 and its Implementing Rules, communicate the finding to the organisation in writing and request corrective action to address the non-compliance(s) identified. Where relevant, the competent authority shall inform the State in which the aircraft is registered.
 - (1) In the case of level 1 findings the competent authority shall take immediate and appropriate action to prohibit or limit activities, and if appropriate, it shall take action to revoke the certificate or specific approval or to limit or suspend it in whole or in part, depending upon the extent of the level 1 finding, until successful corrective action has been taken by the organisation.
 - (2) In the case of level 2 findings, the competent authority shall:
 - (i) grant the organisation a corrective action implementation period appropriate to the nature of the finding that in any case initially shall not be more than 3 months. At the end of this period, and subject to the nature of the finding, the competent authority may extend the 3 month period subject to a satisfactory corrective action plan agreed by the competent authority; and
 - (ii) assess the corrective action and implementation plan proposed by the organisation and, if the assessment concludes that they are sufficient to address the non-compliance(s), accept these.
 - (3) Where an organisation fails to submit an acceptable corrective action plan, or to perform the corrective action within the time period accepted or extended by the competent authority, the finding shall be raised to a level 1 finding and action taken as laid down in (d)(1) above.

- (4) The competent authority shall record all findings it has raised or that have been communicated to it and, where applicable, the enforcement measures it has applied, as well as all corrective actions and date of action closure for findings.
- (e) Without prejudice to any additional enforcement measures, when the authority of a Member State acting under the provisions of AR.GEN.300 (d) identifies any non-compliance with the applicable requirements of Regulation (EC) No 216/2008 and its Implementing Rules by an organisation certified by the competent authority of another Member State or the Agency, it shall inform that competent authority and provide an indication of the level of finding.

AR.GEN.355 Enforcement measures - persons

- (a) If, during oversight or by any other means, evidence is found by the competent authority responsible for oversight in accordance with AR.GEN.300 (a) that shows a non-compliance with the applicable requirements by a person holding a licence, certificate, rating or attestation issued in accordance with Regulation (EC) No 216/2008 and its Implementing Rules, the competent authority shall raise a finding, record it and communicate it in writing to the licence, certificate, rating or attestation holder.
- (b) When such finding is raised, the competent authority shall carry out an investigation. If the finding is confirmed, it shall:
 - (1) limit, suspend or revoke the licence, certificate, rating or attestation as applicable, when a safety issue has been identified; and
 - (2) take any further enforcement measures necessary to prevent the continuation of the non-compliance.
- (c) Where applicable, the competent authority shall inform the person or organisation that issued the medical certificate or attestation.
- (d) Without prejudice to any additional enforcement measures, when the authority of a Member State acting under the provisions of AR.GEN.300 (d) finds evidence showing a non-compliance with the applicable requirements by a person holding a licence, certificate, rating or attestation issued by the competent authority of any other Member State, it shall inform that competent authority.
- (e) If, during oversight or by any other means, evidence is found showing a non-compliance with the applicable requirements by a person subject to the requirements laid down in Regulation (EC) No 216/2008 and its Implementing Rules and not holding a licence, certificate, rating or attestation issued in accordance with that Regulation and its Implementing Rules, the competent authority that identified the non-compliance shall take any enforcement measures necessary to prevent the continuation of that non-compliance.

ANNEX II TO IMPLEMENTING REGULATION

PART AUTHORITY REQUIREMENTS (AR)

SUBPART FCL - SPECIFIC REQUIREMENTS RELATING TO FLIGHT CREW LICENSING

SECTION I – GENERAL

AR.FCL.120 Record-keeping

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

SECTION II - LICENCES, RATINGS AND CERTIFICATES

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

- (a) Issue of licences and ratings. The competent authority shall issue a pilot licence and associated ratings, using the form as established in Appendix I to this Part.
- (b) Issue of instructor and examiner certificates. The competent authority shall issue an instructor or examiner certificate as:
 - (1) an endorsement of the relevant privileges in the pilot licence as established in Appendix I to this Part; or
 - (2) a separate document, in a form and manner specified by the competent authority.
- (c) Endorsement of licence by examiners. Before specifically authorising certain examiners to revalidate or renew ratings or certificates, the competent authority shall develop appropriate procedures.

AR.FCL.205 Monitoring of examiners

- (a) The competent authority shall develop an oversight programme to monitor the conduct and performance of examiners taking into account:
 - (1) the number of examiners it has certified; and
 - (2) the number of examiners certified by other competent authorities exercising their privileges within the territory where the competent authority exercises oversight.
- (b) The competent authority shall have a sufficient number of inspectors to implement the oversight programme.
- (c) The competent authority shall maintain a list of examiners it has certified and of examiners certified by other competent authorities exercising their privileges in its territory and to which the competent authority has provided a briefing in accordance with FCL.1015 (c)(2). The list shall state the privileges of the examiners and be published and kept updated by the competent authority.
- (d) The competent authority shall develop procedures to designate examiners for the conduct of skill tests for the issue of a multi-crew pilot licence (MPL) or airline transport pilot licence (ATPL).

AR.FCL.210 Information for examiners

The competent authority may provide examiners it has certified and examiners certified by other competent authorities exercising their privileges in their territory with safety criteria to be observed when skill tests and proficiency checks are conducted in an aircraft.

AR.FCL.215 Validity period

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

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

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

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

- (a) The competent authority shall limit, suspend or revoke as applicable a pilot licence and associated ratings or certificates in accordance with AR.GEN.315 in, but not limited to, the following circumstances:
 - (1) obtaining the pilot licence, rating or certificate by falsification of submitted documentary evidence;
 - (2) falsification of the logbook and licence or certificate records;
 - (3) the licence holder no longer complies with the applicable requirements of Part-FCL;
 - (4) exercising the privileges of a licence, rating or certificate when adversely affected by alcohol or drugs;
 - (5) non-compliance with the applicable operational requirements;
 - (6) evidence of malpractice or fraudulent use of the certificate; or
 - (7) unacceptable performance in any phase of the flight examiner's duties or responsibilities.
- (b) If, during the investigation following an accident or incident in which the licence holder was involved while exercising the privileges of his/her licence, rating or certificate, there is evidence that pilot competence may be a causal factor for the accident or incident, the

competent authority may suspend the licence, rating or certificate pending the results of the investigation.

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

SECTION III - THEORETICAL KNOWLEDGE EXAMINATIONS

AR.FCL.300 Examination procedures

- (a) The competent authority shall put in place the necessary arrangements and procedures to allow applicants to undergo theoretical knowledge examinations in accordance with the applicable requirements of Part-FCL.
- (b) In the case of the ATPL, MPL, commercial pilot licence (CPL), and instrument ratings, those procedures shall comply with all of the following:
 - (1) Examinations shall be done in written or computer-based form.
 - (2) Questions for an examination shall be selected by the competent authority, according to a common method which allows coverage of the entire syllabus in each subject, from the European Central Question Bank (ECQB). The ECQB is a database of multiple choice questions held by the Agency.
 - (3) The examination in communications may be provided separately from those in other subjects. An applicant who has previously passed one or both of the examinations in visual flight rules (VFR) and instrument flight rules (IFR) communications shall not be re-examined in the relevant sections.
- (c) The competent authority shall inform applicants of the languages available for examinations.
- (d) The competent authority shall establish appropriate procedures to ensure the integrity of the examinations.
- (e) If the competent authority finds that the applicant is not complying with the examination procedures during the examination, this shall be assessed with a view to failing the applicant, either in the examination of a single subject or in the examination as a whole.
- (f) The competent authority shall ban applicants who are proven to be cheating from taking any further examination for a period of at least 12 months from the date of the examination in which they were found cheating.

ANNEX II TO IMPLEMENTING REGULATION

PART AUTHORITY REQUIREMENTS (AR)

SUBPART CC - SPECIFIC REQUIREMENTS RELATING TO CABIN CREW

SECTION I - CABIN CREW ATTESTATIONS

AR.CC.100 Procedures for cabin crew attestations

- (a) The competent authority shall establish procedures for the issue, record-keeping and oversight of cabin crew attestations in accordance with AR.GEN.315, AR.GEN.220 and AR.GEN.300.
- (b) Cabin crew attestations shall be issued using the format and specifications established in Appendix II to this Part.

AR.CC.105 Suspension or revocation of cabin crew attestations

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

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

SECTION II - ORGANISATIONS PROVIDING CABIN CREW TRAINING OR ISSUING CABIN CREW ATTESTATIONS

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

- (a) Before issuing an approval to a training organisation or a commercial air transport operator to provide cabin crew training, the competent authority shall verify that:
 - (1) the conduct, the syllabi and associated programmes of the training courses provided by the organisation comply with the relevant requirements of Part-CC and Part-OR;
 - (2) the training devices used by the organisation realistically represent the passenger compartment environment of the aircraft type(s) and the technical characteristics of the equipment to be operated by the cabin crew; and
 - (3) the trainers and instructors conducting the training sessions are suitably experienced and qualified in the training subject covered.
- (b) If a Member State decides, in accordance with Article 8(4) of Regulation (EC) No 216/2008, that organisations may be approved to issue cabin crew attestations, the competent authority shall only grant such approvals to organisations complying with the requirements in (a). Before granting such an approval, the competent authority shall:
 - (1) assess the capability and accountability of the organisation to perform the related tasks;
 - (2) ensure that the organisation has established documented procedures for the performance of the related tasks, including for the conduct of examination(s) by personnel who are qualified for this purpose and free from conflict of interest, and for the issue of cabin crew attestations in accordance with AR.GEN.315 and AR.CC.100(b); and
 - (3) require the organisation to provide information and documentation related to the cabin crew attestations it issues and their holders, as relevant for the competent authority to conduct its record-keeping, oversight and enforcement tasks.

ANNEX II TO IMPLEMENTING REGULATION

PART AUTHORITY REQUIREMENTS (AR)

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

SECTION I - GENERAL

AR.ATO.105 Oversight Programme

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

AR.ATO.120 Record-keeping

- (a) In addition to the records required in AR.GEN.220, the competent authority shall include in its system of record-keeping details of courses provided by the ATO, and if applicable, records relating to FSTDs used for training.
- (b) The competent authority shall keep and update a list of the qualified FSTDs under its supervision, the dates when evaluations are due and when such evaluations were carried out.

ANNEX II TO IMPLEMENTING REGULATION

PART AUTHORITY REQUIREMENTS (AR)

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

SECTION I - GENERAL

AR.FSTD.100 Initial evaluation procedure

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

AR.FSTD.110 Issue of an FSTD qualification certificate

Except for the case of BITDs, when satisfied that the FSTD and the organisation operating it, are in compliance with the applicable requirements, the competent authority shall issue the FSTD qualification certificate, using the form as established in Appendix IV to this Part.

AR.FSTD.120 Continuation of an FSTD qualification

- (a) The competent authority shall conduct recurrent evaluations of the FSTD in accordance with the procedures detailed in AR.FSTD.100. These evaluations shall take place:

- (1) every year, in the case of a full flight simulator (FFS), flight training device (FTD) or flight and navigation procedures trainer (FNPT);
 - (2) every 3 years, in the case of a BITD.
- (b) The competent authority shall continuously monitor the organisation operating the FSTD to verify that:
- (1) the complete set of tests in the MQTG is rerun progressively every year between each recurrent evaluation;
 - (2) the results of that evaluation continue to comply with the qualification standards and are dated and retained; and
 - (3) a configuration control system is in place to ensure the continued integrity of the hardware and software of the qualified FSTD.

AR.FSTD.130 Changes

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

AR.FSTD.135 Findings and corrective actions - FSTD qualification certificate

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

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

ANNEX II TO IMPLEMENTING REGULATION

PART AUTHORITY REQUIREMENTS (AR)

SUBPART AeMC - SPECIFIC REQUIREMENTS RELATING TO AERO-MEDICAL CENTRES (AeMCs)

SECTION I - GENERAL

AR.AeMC.110 Initial certification procedure

The certification procedure for an AeMC shall follow the provisions laid down in AR.GEN.310, except that upon receiving an application for the issue of the approval for an AeMC, the competent authority shall conduct an audit of the organisation before issuing a certificate.

AR.AeMC.150 Findings and corrective actions - AeMC

Without prejudice to AR.GEN.350, level 1 findings include, but are not limited to, the following:

- (a) failure to nominate a head of the AeMC;
- (b) failure to ensure medical confidentiality of aero-medical records; and
- (c) failure to provide the competent authority with the medical and statistical data for oversight purposes.

ANNEX II TO IMPLEMENTING REGULATION

PART AUTHORITY REQUIREMENTS (AR)

SUBPART MED - SPECIFIC REQUIREMENTS RELATING TO AERO-MEDICAL CERTIFICATION

SECTION I - GENERAL

AR.MED.120 Medical assessors

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

- (a) postgraduate work experience in medicine of at least 5 years;
- (b) specific knowledge and experience in aviation medicine; and
- (c) specific training in medical certification.

AR.MED.125 Referral to the licensing authority

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

- (a) the medical assessor or medical staff of the competent authority shall evaluate the relevant medical documentation and request further medical documentation, examinations and tests where necessary; and
- (b) the medical assessor shall determine the applicant's fitness for the issue of a medical certificate with one or more limitation(s) as necessary.

AR.MED.130 Medical certificate format

The format of the medical certificate shall be in accordance with Appendix VI to this Part.

AR.MED.135 Aero-medical forms

The competent authority shall use forms for:

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

AR.MED.145 GMP notification to the competent authority

The competent authority shall establish a notification process for general medical practitioners (GMPs) to ensure that the GMP is aware of the medical requirements laid down in MED.B.095.

AR.MED.150 Record-keeping

- (a) In addition to the records required in AR.GEN.220, the competent authority shall include in its system of record-keeping details of aero-medical examinations and assessments submitted by AMEs, AeMCs or GMPs.
- (b) All aero-medical records of licence holders shall be kept for a minimum period of 10 years after the expiry of their last medical certificate.

- (c) Aero-medical records shall be made available after written consent of the applicant/licence holder and only to:
- (1) an AeMC, AME or GMP for the purpose of completion of an aero-medical assessment;
 - (2) a medical review board that may be established by the competent authority for secondary review of borderline cases;
 - (3) relevant medical specialists for the purpose of completion of an aero-medical assessment;
 - (4) the medical assessor of the competent authority of another Member State for the purpose of cooperative oversight;
 - (5) the applicant/licence holder concerned upon their written request; and
 - (6) after disidentification of the applicant/licence holder to the Agency for standardisation purposes.

SECTION II– AERO-MEDICAL EXAMINERS (AMEs)

AR.MED.200 Procedure for the issue of an AME certificate

- (a) The certification procedure for an AME shall follow the provisions laid down in AR.GEN.315. Before issuing the certificate, the competent authority shall have evidence that the AME practice is fully equipped to perform aero-medical examinations within the scope of the AME certificate applied for.
- (b) The competent authority shall establish the format of the AME certificate. It shall contain as a minimum:
- (1) first name, last name and title of the holder;
 - (2) competent authority issuing the certificate
 - (3) AME number;
 - (4) privileges and scope of the activity;
 - (5) address of the AME's practice;
 - (6) date of the issue of the AME certificate; and
 - (7) expiry date of the AME certificate.

AR.MED.240 General medical practitioners (GMPs) acting as AMEs

- (a) The competent authority of a Member State shall notify the Agency and competent authorities of other Member States if aero-medical examinations for the LAPL can be carried out on its territory by GMPs.
- (b) The competent authority of such Member State shall maintain a list of all GMPs acting as AMEs on their territory. This list shall be disclosed to other Member States and the Agency upon request.

AR.MED.245 Continuing oversight of AMEs and GMPs

When developing the continuing oversight programme referred to in AR.GEN.305, the competent authority shall take into account the number of AMEs and GMPs exercising their privileges within the territory where the competent authority exercises oversight.

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

- (a) The competent authority shall limit, suspend or revoke an AME certificate in cases where:
 - (1) the AME no longer complies with applicable requirements;
 - (2) failure to meet the criteria for certification or continuing certification;
 - (3) deficiency of aero-medical record-keeping or submission of incorrect data or information;
 - (4) falsification of medical records, certificates or documentation;
 - (5) concealment of facts appertaining to an application for, or holder of, a medical certificate or false or fraudulent statements or representations to the competent authority;
 - (6) failure to correct findings from audit of the AME practice; and
 - (7) at the request of the certified AME.
- (b) The certificate of an AME shall be automatically revoked in either of the following circumstances:
 - (1) revocation of medical licence to practice; or
 - (2) removal from the Medical Register.

AR.MED.255 Enforcement measures

If, during oversight or by any other means, evidence is found showing a non-compliance of an AeMC, an AME or a GMP, the licensing authority shall review the medical certificates issued by that AeMC, AME or GMP and may render them invalid where required to ensure flight safety.

SECTION III - MEDICAL CERTIFICATION

AR.MED.315 Review of examination reports

The licensing authority shall:

- (a) review examination and assessment reports received from the AeMCs, AMEs and GMPs and inform them of any inconsistencies, mistakes or errors made in the assessment process; and
- (b) assist AMEs and AeMCs on their request regarding their decision on aero-medical fitness in contentious cases.

AR.MED.325 Secondary review procedure

The competent authority shall establish a procedure for the review of borderline and contentious cases with independent medical advisors, experienced in the practice of aviation medicine, to consider and advise on an applicant's fitness for medical certification.

APPENDIX I TO ANNEX II PART AUTHORITY REQUIREMENTS (AR)

FLIGHT CREW LICENCE

The flight crew licence issued by a Member State in accordance with Part-FCL shall conform to the following specifications:

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

Cover page

<p>Competent authority name and logo (English and any language(s) determined by the competent authority)</p> <p>EUROPEAN UNION (English only)</p> <p>FLIGHT CREW LICENCE (English and any language(s) determined by the competent authority)</p> <p>Issued in accordance with Part-FCL This licence complies with ICAO standards, except for the LAPL privileges (English and any language(s) determined by the competent authority)</p> <p>EASA Form 141 Issue 1</p>	<p>Requirements</p> <p>“European Union” to be deleted for non-EU Member States</p> <p>Size of each page shall be one eighth A4</p>
---	--

I	State of issue		Requirements
III	Licence number		Serial number of the licence will always commence with the UN country code of the State of licence issue followed by “.FCL.” .
IV	Last and first name of holder		
IVa	Date of birth (see instructions)		Standard date format is to be used, i.e. day/month/year in full (e.g., 21/01/1995)
XIV	Place of birth		
V	Address of holder: Street, town, area, postal code		
VI	Nationality		
VII	Signature of holder		
VIII	Issuing competent authority E.g. This CPL(A) has been issued on the basis of an ATPL issued by (third county)		
X	Signature of issuing officer and date		
XI	Seal or stamp of issuing competent authority		

II	Titles of licences, date of initial issue and country code	<p>Abbreviations used will be as used in Part-FCL (e.g. PPL(H), ATPL(A), etc.)</p> <p>Standard date format is to be used, i.e. day/month/year in full (e.g., 21/01/1995)</p>
IX	<p>Validity: The privileges of the licence shall be exercised only if the holder has a valid medical certificate for the required privilege.</p> <p>.....</p> <p>A document containing a photo shall be carried for the purposes of identification of the licence holder.</p>	<p>This document is not specified, but a passport would suffice when outside the State of licence issue.</p>
XII	<p>Radiotelephony privileges: The holder of this licence has demonstrated competence to operate R/T equipment on board aircraft in (specify the language(s)).</p>	
XIII	<p>Remarks:</p> <p>Language Proficiency: (language(s) / level / validity date)</p>	<p>All additional licensing information required and privileges established by ICAO, EC or EU Directives/ Regulations to be entered here.</p> <p>Language proficiency endorsement(s), level and validity date shall be included.</p> <p>In case of LAPL: LAPL not issued in accordance with ICAO standards</p>

Abbreviations used in this licence		
		e.g. ATPL (airline transport pilot licence), CPL (commercial pilot licence), IR (instrument rating), R/T (radio telephony), MEP (multi-engine piston aeroplanes), FI (flight instructor), TRE (type rating examiner), etc.

APPENDIX II TO ANNEX II PART AUTHORITY REQUIREMENTS (AR)

STANDARD EASA FORMAT FOR CABIN CREW ATTESTATIONS

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

<p style="text-align: center;">1. CABIN CREW ATTESTATION Issued in accordance with Part-CC</p> <p>2. Reference number:</p> <p>3. State of issue:</p> <p>4. Full name of holder:</p> <p>5. Date and place of birth:</p> <p>6. Nationality:</p> <p>7. Signature of holder:</p> <p>8. Competent authority:</p> <p>9. Issuing body: <i>Official seal, Stamp or Logo</i></p> <p>10. Signature of issuing officer:</p> <p>11. Date of issue:</p> <p>12. The holder may ,only exercise the privileges to act as cabin crew on aircraft engaged in commercial air transport operations if he/she complies with the requirements in Part-CC for continuous fitness and valid aircraft type qualifications.</p> <p>EASA Form 142 Issue 1</p>

1. CABIN CREW ATTESTATION

Issued in accordance with Part-CC

2. Reference number:

3. State of issue:

4. Full name of holder:

5. Date and place of birth:

6. Nationality:

7. Signature of holder:

8. Competent authority:

9. Issuing body:

Official seal, Stamp or Logo

10. Signature of issuing officer:

11. Date of issue:

12. The holder may ,only exercise the privileges to act as cabin crew on aircraft engaged in commercial air transport operations if he/she complies with the requirements in Part-CC for continuous fitness and valid aircraft type qualifications.

EASA Form 142 Issue 1

Instructions:

- (a) The cabin crew attestation shall include all items specified in EASA Form 142 in accordance with items 1 - 12 below.
- (b) Size shall be one-eighth A4 and the material used shall prevent or readily show any alterations or erasures.
- (c) The document shall be printed in English and such other languages as the competent authority deems appropriate.
- (d) The document shall be issued by the competent authority or by an organisation approved to issue cabin crew attestations. In that latter case reference to the approval by the competent authority of the Member State shall be stated.
- (e) The cabin crew attestation is recognised in all Member States and it is not necessary to exchange the document when working in another Member State.

Item 1: The title “CABIN CREW ATTESTATION” and the reference to Part-CC

Item 2: Attestation reference number shall commence with the UN country code of the Member State followed by at least the 2 last numbers of the year of issue and an individual reference/number according to a code established by the competent authority (e.g. BE-08-xxxx).

Item 3: The Member State where the cabin crew attestation was issued.

Item 4: The full name (surname and first name) stated in the official identity document of the holder.

Items 5 and 6: Date and place of birth as well as nationality as stated in the official identity document of the holder.

Item 7: The signature of the holder.

Item 8: Identification details of the competent authority of the Member State where the attestation is issued shall be entered and shall provide the full name of the competent authority, postal address, official seal, and logo if applicable.

Item 9: If the competent authority is the issuing body, the term ‘competent authority’ and official seal or stamp shall be entered.

In the case of an approved organisation, identification details shall be entered and shall at least provide the full name of the organisation, postal address and if applicable, the logo and:

- (a) in the case of a commercial air transport operator, the air operator certificate (AOC) number and detailed reference to the approvals by the competent authority to provide cabin crew training and to issue attestations; or
- (b) in the case of an approved training organisation, the reference number of the relevant approval by the competent authority.

Item 10: The signature of the officer acting on behalf of the issuing body.

Item 11: Standard date format shall be used: i.e. day/month/year in full (e.g. 22/02/2008).

Item 12: The same sentence in English and its full and precise translation into such other languages as the competent authority deems appropriate.

APPENDIX III TO ANNEX II PART AUTHORITY REQUIREMENTS (AR)

CERTIFICATE FOR APPROVED TRAINING ORGANISATIONS (ATOs)

European Union *
Competent Authority

APPROVED TRAINING ORGANISATION CERTIFICATE

[CERTIFICATE NUMBER/REFERENCE]

Pursuant to Commission Regulation (EU) No XXX/XXXX and subject to the conditions specified below, the [Competent Authority] hereby certifies

[NAME OF THE TRAINING ORGANISATION]

[ADDRESS OF THE TRAINING ORGANISATION]

as a Part-OR certified training organisation with the privilege to provide Part-FCL training courses, including the use of FSTDs, as listed in the attached training course approval.

CONDITIONS:

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

This certificate is valid whilst the approved organisation remains in compliance with Part-OR, Part-FCL and other applicable regulations.

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

Date of issue:

Signed:

[Competent Authority]

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

EASA FORM 143 Issue 1 - page 1/2

APPROVED TRAINING ORGANISATION CERTIFICATE

TRAINING COURSE APPROVAL

Attachment to ATO Certificate Number:

[CERTIFICATE NUMBER/REFERENCE]

[NAME OF THE TRAINING ORGANISATION]

has obtained the privilege to provide and conduct the following Part-FCL training courses and to use the following FSTDs:

Training course	Used FSTD(s), including letter code ⁽¹⁾

⁽¹⁾ as indicated on the qualification certificate

This training course approval is valid as long as:

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

Date of issue:

Signed: [Competent Authority]

For the Member State/EASA

EASA FORM 143 Issue 1 - page 2/2

APPENDIX IV TO ANNEX II PART AUTHORITY REQUIREMENTS (AR)

FLIGHT SIMULATION TRAINING DEVICE QUALIFICATION CERTIFICATE

Introduction

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

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

European Union *
Competent Authority

FLIGHT SIMULATION TRAINING DEVICE QUALIFICATION CERTIFICATE

REFERENCE:

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

FSTD [TYPE AND LETTER CODE]
located at [ADDRESS OF THE ORGANISATION]

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

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

Date of issue:.....

Signed:.....

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

EASA Form 145 Issue 1 – page 1/2

[competent authority]

FSTD QUALIFICATION CERTIFICATE: [Reference]

FSTD SPECIFICATIONS

- A. Type or variant of aircraft:
- B. FSTD qualification level:
- C. Primary reference document:
- D. Visual system:
- E. Motion system:
- F. Engine fit:
- G. Instrument fit:
- H. ACAS fit:
- I. Windshear:
- J. Additional capabilities:
- K. Restrictions or limitations:

L. Guidance information for training, testing and checking considerations	
CAT I	RVR m DH ft
CAT II	RVR m DH ft
CAT III (lowest minimum)	RVR m DH ft
LVTO RVR	m
Recency	
IFR-training / check	/
Type rating	
Proficiency checks	
Autocoupled approach	
Autoland / roll out guidance	/
ACAS I / II	/
Windshear warning system / predictive windshear	/
WX-radar	
HUD / HUGS	/
FANS	
GPWS/EGPWS	/

L. Guidance information for training, testing and checking considerations	
ETOPS capability	
GPS	
Other	

Date of issue:.....

Signed:.....

For the Member State/EASA

EASA Form 145 Issue 1 – page 2/2

APPENDIX V TO ANNEX II PART AUTHORITY REQUIREMENTS (AR)

CERTIFICATE FOR AERO-MEDICAL CENTRES (AeMCs)

European Union *
Competent Authority

AERO-MEDICAL CENTRE CERTIFICATE

REFERENCE:

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

[NAME OF THE ORGANISATION]

[ADDRESS OF THE ORGANISATION]

as a Part-OR certified Aero-medical centre with the privileges and the scope of activities as listed in the attached terms of approval.

CONDITIONS:

1. This certificate is limited to that specified in the scope of approval section of the approved organisation manual;
2. This certificate requires compliance with the procedures specified in the organisation documentation as required by Part-OR.
3. This certificate shall remain valid subject to compliance with the requirements of Part-OR unless it has been surrendered, superseded, suspended or revoked.

Date of issue.....Signed:.....

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

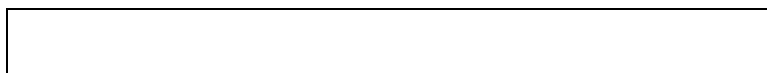
EASA Form 146 Issue 1

APPENDIX VI TO ANNEX II PART AUTHORITY REQUIREMENTS (AR)

STANDARD EASA MEDICAL CERTIFICATE FORMAT

The medical certificate shall conform to the following specifications:

- (a) Content
 - (1) State where the medical certificate has been issued (I),
 - (2) Class of medical certificate (II),
 - (3) Certificate number commencing with the UN country code of the issuing State of the licensing authority and followed by a code of numbers and/or letters in Arabic numerals and latin script (III),
 - (4) Name of holder (IV),
 - (5) Nationality of holder (VI),
 - (6) Date of birth of holder: (dd/mm/yyyy) (XIV),
 - (7) Signature of holder (VII)
 - (8) Limitation(s) (XIII)
 - (9) Expiry date of the medical certificate (IX) for:
 - Class 1 single pilot commercial operations carrying passengers,
 - Class 1 other commercial operations,
 - Class 2,
 - LAPL
 - (10) Date of medical examination
 - (11) Date of last electrocardiogram
 - (12) Date of last audiogram
 - (13) Date of issue and signature of the AME that issued the certificate (X). GMP and/or medical assessor may be added to this field if they have the competence to issue medical certificates under the national law of the Member State where the certificate is issued.
 - (14) Seal or stamp (XI)
- (b) Material: The paper or other material used shall prevent or readily show any alterations or erasures. Any entries or deletions to the form shall be clearly authorised by the licensing authority.
- (c) Language: Licences shall be written in the national language(s) and in English and such other languages as the licensing authority deems appropriate.
- (d) All dates on the medical certificate shall be written in a dd/mm/yyyy format.
- (e) A standard EASA medical certificate format is shown in this Appendix.



		LOGO	
		NAME OF COMPETENT AUTHORITY Class 1/2/LAPL NATIONAL LANGUAGE(S) MEDICAL CERTIFICATE	
		PERTAINING TO A FLIGHT CREW LICENCE	

I	National language(s)/ <i>Licensing authority</i>
III	National language(s)/Certificate number commencing with the <u>UN</u> country code of the State of the licensing authority and followed by a code of numbers and/or letters in Arabic numerals and in latin script
IV	National language(s)/ <i>Last and first name of holder:</i>
XIV	National language(s)/ <i>Date of birth: (dd/mm/yyyy)</i>
VI	National language(s)/ <i>Nationality:</i>
VII	National language(s)/ <i>Signature of holder:</i>
2	

XIII National language(s)/*Limitations*:

Code.

Description :

1.1.1.

X National language(s)/* *Date of issue*:

(dd/mm/yyyy)

Signature of issuing AME /(GMP)/(medical assessor)::

XI National language(s)/*Stamp*:

	IX Nat. lang(s)/ Expiry date of this certificate	Class 1 single pilot commercial operations carrying passengers (dd/mm/yyyy)		
		Class 1 (dd/mm/yyyy)		
		Class 2 (dd/mm/yyyy)		
		LAPL (dd/mm/yyyy)		
	Nat. lang(s)/Examination date: (dd/mm/yyyy)			
MED.A.020 Decrease in medical fitness (a) Licence holders shall not exercise the privileges of their licence and related ratings or certificates at any time when they: (1) are aware of any decrease in their medical fitness that might render them unable to safely exercise those privileges; (2) take or use any prescribed or non-prescribed medication that is likely to interfere with the safe exercise of the privileges of the applicable licence; or (3) receive any medical, surgical or other treatment that is likely to interfere with flight safety. (b) In addition, licence holders shall, without undue delay, seek aero-medical advice when they: (1) have undergone a surgical operation or invasive procedure; (2) have commenced the regular use of any medication; (3) have suffered any significant personal injury involving incapacity to function as a member of the flight crew; (4) have been suffering from any significant illness involving incapacity to function as a member of the flight crew; (5) are pregnant; (6) have been admitted to hospital or medical clinic; or (7) first require correcting lenses.				
4				

* Date of issue is the date the certificate is issued and signed

ANNEX III PART ORGANISATION REQUIREMENTS (OR)

SUBPART GEN – GENERAL REQUIREMENTS

SECTION I – GENERAL

OR.GEN.105 Competent authority

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; and
 - FSTDs located within the territory of the Member States and operated by organisations having their principle 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 in accordance with Article 4 of this Regulation where the organisation operating it has its principle place of business, or the Agency, if so requested by the Member State concerned.

OR.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.

OR.GEN.120 Means of compliance

- (a) Alternative means of compliance to those adopted by the Agency may be used by an organisation to establish compliance with Regulation (EC) No 216/2008 and its Implementing Rules.
- (b) When an organisation wishes to use an alternative means of compliance to the AMC adopted by the Agency to establish compliance with Regulation (EC) No 216/2008 and its Implementing Rules, 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 the 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 AR.GEN.120 (d).

OR.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.

OR.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 OR.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 AR.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 AR.GEN.310 (c).

OR.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 OR.GEN.150;
 - (2) the competent authority being granted access to the organisation as defined in OR.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.

OR.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 OR.GEN.105; or
- (b) the authority acting under the provisions of AR.GEN.300(d), AR.GEN.300(e) or AR.RAMP.

OR.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 AR.GEN.350 (d).

OR.GEN.155 Immediate reaction to a safety problem

The organisation shall implement:

- (a) any safety measures mandated by the competent authority in accordance with AR.GEN.135 (c); and
- (b) any relevant mandatory safety information issued by the Agency, including airworthiness directives and safety directives.

OR.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 996/2010⁴ and Directive 2003/42/EC⁵.
- (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, occurrence that would highlight inaccurate, incomplete or ambiguous information contained in operational suitability data 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 Regulation (EU) No 996/2010 and Directive 2003/42/EC, 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.
- (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

⁴ Regulation (EU) No 996/2010 of the European Parliament and of the Council of 20 October 2010 on the investigation and prevention of accidents and incidents in civil aviation and repealing Directive 94/56/EC Text with EEA relevance, *OJ L 295, 12.11.2010, p. 35–50*

⁵ Directive 2003/42/EC of the European Parliament and of the Council of 13 June 2003 on occurrence reporting in civil aviation, *OJ L 167, 4.7.2003, p. 23–36*

actions have been identified. This report shall be produced in a form and manner established by the competent authority.

SECTION II – MANAGEMENT

OR.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.

OR.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.

OR.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) The 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) above.
- (e) The organisation shall ensure that all personnel are aware of the rules and procedures relevant to the exercise of their duties.

OR.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.

OR.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 OR.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.

ANNEX III PART ORGANISATION REQUIREMENTS (OR)

SUBPART ATO – APPROVED TRAINING ORGANISATIONS

SECTION I – GENERAL

OR.ATO.100 Scope

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

OR.ATO.105 Application

- (a) Applicants for the issue of a certificate as an approved training organisation (ATO) shall provide the competent authority with:
- (1) the following information:
 - (i) name and address of the training organisation;
 - (ii) date of intended commencement of activity;
 - (iii) personal details and qualifications of the head of training (HT), the flight instructor(s), flight simulation training instructors and the theoretical knowledge instructor(s);
 - (iv) name(s) and address(es) of the aerodromes(s) and/or operating site(s) at which the training is to be conducted;
 - (v) list of aircraft to be used for training, including their group, class or type, registration, owners and category of the certificate of airworthiness, if applicable;
 - (vi) list of flight simulation training devices (FSTDs) that the training organisation intends to use, if applicable;
 - (vii) the type of training that the training organisation wishes to provide and the corresponding training programme; and
 - (2) the operations and training manuals.
- (b) Flight test training organisations. Notwithstanding (a)(1)(iv) and (v), training organisations providing flight test training shall only need to provide:
- (1) the name(s) and address(es) of the main aerodromes and/or operating site(s) at which the training is to be conducted; and
 - (2) a list of the types or categories of aircraft to be used for flight test training.
- (c) In the case of a change to the certificate, applicants shall provide the competent authority with the relevant parts of the information and documentation referred to in (a).

OR.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.

OR.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.

OR.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.

OR.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-OR Subpart OPS.

OR.ATO.135 Training aircraft and FSTDs

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

OR.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.

OR.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 operational suitability data (OSD) established in accordance with Part-21.
- (b) In the case of ATOs providing flight test training, the students shall meet all the pre-requisites for training established in Part-21.

OR.ATO.150 Training in third countries

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

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

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

OR.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 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.

OR.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.

OR.ATO.230 Training manual and operations manual

- (a) The training manual shall state the standards, objectives and training goals for each phase of training that the students are required to comply with and shall address the following subjects:
- training plan,
 - briefing and air exercises,
 - flight training in an FSTD, if applicable,
 - theoretical knowledge instruction.
- (b) The operations manual shall provide relevant information to particular groups of personnel, as flight instructors, flight simulation training instructors, theoretical knowledge instructors, operations and maintenance personnel, and shall include general, technical, route and staff training information.

SECTION III – ADDITIONAL REQUIREMENTS FOR ATOs PROVIDING SPECIFIC TYPES OF TRAINING

Chapter 1 – Distance Learning Course

OR.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.

OR.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.

OR.ATO.310 Instructors

All instructors shall be fully familiar with the requirements of the distance learning course programme.

Chapter 2 – Zero Flight-Time Training

OR.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-OR Subpart OPS, has operational experience on the aeroplane type.

OR.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 OR.FSTD.205.

Chapter 3 – Multi-crew pilot licence (MPL) courses

OR.ATO.350 General

The privileges to conduct MPL integrated training courses and MPL instructor courses shall only be given to the ATO if it also has the privilege to conduct commercial air transport operations or a specific arrangement with a commercial air transport operator.

Chapter 4 – Flight test training

OR.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.

ANNEX III PART ORGANISATION REQUIREMENTS (OR)

SUBPART FSTD – REQUIREMENTS FOR ORGANISATIONS OPERATING FLIGHT SIMULATION TRAINING DEVICES (FSTDs) AND THE QUALIFICATION OF FSTDs

SECTION I – REQUIREMENTS FOR ORGANISATIONS OPERATING FSTDs

OR.FSTD.100 General

- (a) The applicant for an FSTD qualification shall demonstrate to the competent authority that it has established a management system in accordance with OR.GEN.200. 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 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.

OR.FSTD.105 Maintaining the FSTD qualification

- (a) In order to maintain the qualification of the FSTD, the complete set of tests contained within the master qualification test guide (MQTG) and functions and subjective tests shall be run progressively over a 12-month period.
- (b) The results shall be dated, marked as analysed and evaluated, and retained in accordance with OR.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.

OR.FSTD.110 Modifications

- (a) The holder of an FSTD qualification shall establish and maintain a system to identify, assess and incorporate any important modifications into the FSTDs it operates, especially:
 - (1) any aircraft modifications that are essential for training, testing and checking, whether or not enforced by an airworthiness directive; and
 - (2) any modification of an FSTD, including motion and visual systems, when essential for training, testing and checking, as in the case of data revisions.
- (b) Modifications of the FSTD hardware and software that affect handling, performance and systems operation or any major modifications of the motion or visual system shall be evaluated to determine the impact on the original qualification criteria. The organisation shall prepare amendments for any affected validation tests. The organisation shall test the FSTD to the new criteria.
- (c) The organisation shall inform the competent authority in advance of any major changes to determine if the tests carried out are satisfactory. The competent authority shall determine if a special evaluation of the FSTD is necessary prior to returning it to training following the modification.

OR.FSTD.115 Installations

- (a) The holder of an FSTD qualification 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.

OR.FSTD.120 Additional equipment

Where additional equipment has been added to the FSTD, even though not required for qualification, it shall be assessed by the competent authority to ensure that it does not adversely affect the quality of training.

SECTION II – REQUIREMENTS FOR THE QUALIFICATION OF FSTDs

OR.FSTD.200 Application for FSTD qualification

- (a) The application for an FSTD qualification shall be made in a form and manner established by the competent authority:
- (1) in the case of basic instrument training devices (BITDs), by the BITD manufacturer;
 - (2) in all other cases, by the organisation intending to operate the FSTD.
- (b) Applicants for an initial qualification shall provide the competent authority with documentation demonstrating how they will comply with the requirements established in this Regulation. Such documentation shall include the procedure established to ensure compliance with OR.GEN.130 and OR.FSTD.230.

OR.FSTD.205 Certification specifications for FSTDs

- (a) The Agency shall issue, in accordance with Article 19 of Regulation (EC) No 216/2008, Certification Specifications as standard means to show compliance of FSTDs with the Essential Requirements of Annex III to Regulation (EC) No 216/2008.
- (b) Such Certification Specifications shall be sufficiently detailed and specific to indicate to applicants the conditions under which qualifications will be issued.

OR.FSTD.210 Qualification basis

- (a) The qualification basis for the issuance of an FSTD qualification shall consist of:
- (1) the applicable Certification Specifications established by the Agency that are effective on the date of the application for the initial qualification;
 - (2) the aircraft validation data defined by the operational suitability data (OSD) as approved under Part-21, 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 recategorised.

OR.FSTD.215 Issue of an FSTD qualification certificate

The FSTD qualification certificate shall be issued by the competent authority when, after completion of an evaluation of the FSTD, the applicant has shown that the FSTD meets the applicable qualification basis in accordance with OR.FSTD.210 and the organisation operating the FSTD meets the applicable requirements to maintain the qualification of the FSTD in accordance with OR.FSTD.100.

OR.FSTD.220 Interim FSTD qualification

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

OR.FSTD.225 Duration and continued validity

- (a) The FFS, flight training device (FTD) or flight and navigation procedures trainer (FNPT) qualification shall be issued for an unlimited duration, and shall remain valid subject to:
 - (1) the FSTD and the operating organisation remaining in compliance with the applicable requirements;
 - (2) the competent authority being granted access to the organisation as defined in OR.GEN.140 to determine continued compliance with the relevant requirements of Regulation (EC) No 216/2008 and its Implementing Rules; and
 - (3) the FSTD being evaluated at recurrent 12 month periods for compliance with the applicable qualification basis. The start for each recurrent 12 month period is the date of the initial qualification. The FSTD recurrent evaluation shall take place within the 60 days prior to the end of this 12 month recurrent evaluation period; and
 - (4) the qualification not being surrendered or revoked.
- (b) This period of 12 months established in (a)(3) 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 operator has a satisfactory record of successful regulatory FSTD evaluations over a period of at least 3 years;
 - (3) the competent authority performs a formal audit of the compliance monitoring system defined in OR.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 the competent authority.

- (c) A BITD qualification shall be issued for an unlimited duration and shall remain valid subject to regular evaluation for compliance with the applicable qualification basis by the competent authority at the request of the organisation. This evaluation shall be made at periods not exceeding 36 months.
- (d) Upon surrender or revocation, the FSTD qualification certificate shall be returned to the competent authority.

OR.FSTD.230 Changes to the qualified FSTD

- (a) The holder of an FSTD qualification shall inform the competent authority of any proposed changes to the FSTD, such as:
 - (1) major modifications;
 - (2) relocation of the FSTD; and
 - (3) any de-activation of the FSTD.

(b) In case of an upgrade of the FSTD qualification level, the organisation shall apply to the competent authority for an upgrade evaluation. The organisation shall run all validation tests for the requested qualification level. Results from previous evaluations shall not be used to validate FSTD performance for the current upgrade.

(c) When an FSTD is moved to a new location, the organisation shall inform the competent authority before the planned activity along with a schedule of related events.

Prior to returning the FSTD to service at the new location, the organisation shall perform at least one third of the validation tests, and functions and subjective tests to ensure that the FSTD performance meets its original qualification standard. A copy of the test documentation shall be retained together with the FSTD records for review by the competent authority.

The competent authority may perform an evaluation of the FSTD after relocation. The evaluation shall be in accordance with the original qualification basis of the FSTD.

(d) If an organisation plans to remove an FSTD from active status for prolonged periods, the competent authority shall be notified and suitable controls established for the period during which the FSTD is inactive.

The organisation shall agree with the competent authority a plan for the de-activation, any storage and re-activation to ensure that the FSTD can be restored to active status at its original qualification level.

OR.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.

OR.FSTD.240 Record-keeping

The holder of an FSTD qualification 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.

ANNEX III PART ORGANISATION REQUIREMENTS (OR)

SUBPART AeMC – AERO-MEDICAL CENTRES

SECTION I – GENERAL

OR.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.

OR.AeMC.115 Application

Applicants for an AeMC certificate shall:

- (a) comply with MED.C.005; and
- (b) in addition to the documentation for the approval of an organisation required in OR.GEN.115, provide details of clinical attachments to hospitals or medical institutes.

OR.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.C.030; and
- (b) ensuring their continued experience by performing an adequate number of class 1 medical examinations every year.

SECTION II – MANAGEMENT

OR.AeMC.200 Management system

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

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

OR.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.

OR.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.

OR.AeMC.220 Record-keeping

In addition to the records required in OR.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.