

**AMC and GM to Annex VII ORGANISATION REQUIREMENTS FOR AIRCREW
(PART-ORA)**

SUBPART GEN – GENERAL REQUIREMENTS

SECTION I - GENERAL

GM1 ORA.GEN.005

The following provides a list of acronyms used throughout this Annex:

(A)	aeroplane
(H)	helicopter
ACAS	airborne collision avoidance system
AD	airworthiness directive
AIS	aeronautical information service
AM	accountable manager
AMC	Acceptable Means of Compliance
ARA	authority requirements for aircrew
ATA	Air Transport Association
ATC	air traffic control
ATO	approved training organisation
ATPL	airline transport pilot licence
BITD	basic instrument training device
BPL	balloon pilot licence
CBT	computer-based training
CFI	chief flying instructor
CM	compliance monitoring
CMP	compliance monitoring programme
CMS	compliance monitoring system
COP	code of practice
CRM	crew resource management
CS-FSTD(A)	Certification Specifications for aeroplane flight simulation training devices
CS-FSTD(H)	Certification Specifications for helicopter flight simulation training devices
CTKI	chief theoretical knowledge instructor
DG	dangerous goods
EC	European Community
ERP	emergency response plan
ETOPS	extended range operations with twin-engined aeroplanes
FATO	final approach and take-off area

FFS	full flight simulator
FMGC	flight management and guidance computer
FMS	flight management system
FNPT	flight navigation and procedures trainer
FSTD	flight simulation training device
FTD	flight training device
FTE	full-time equivalent
FTI	flight test instructor
GM	Guidance Material
GMP	general medical practitioner
HEMS	helicopter emergency medical service
HHO	helicopter hoist operation
HT	head of training
IFR	instrument flight rules
IMC	instrument meteorological conditions
IOS	instructor operation station
IR	Implementing Rule
LAPL	light aircraft pilot licence
LIFUS	line flying under supervision
LVO	low visibility operation
MCC	multi-crew cooperation
MMEL	master minimum equipment list
MPA	multi-pilot aeroplane
MPL	multi-crew pilot licence
NVIS	night vision imaging system
OPC	operator proficiency check
ORA	organisation requirements for aircrew
OSD	operational suitability data
OTD	other training device
PBN	performance-based navigation
PF	pilot flying
PIC	pilot-in-command
PPL	private pilot licence
QTG	qualification test guide
SMM	safety management manual
SOP	standard operating procedure
SPL	sailplane pilot licence
TAWS	terrain awareness warning system
TRE	type rating examiner
TRI	type rating instructor

VDR	validation data roadmap
ZFTT	zero flight-time training

AMC1 ORA.GEN.120(a) Means of compliance

DEMONSTRATION OF COMPLIANCE

In order to demonstrate that the Implementing Rules are met, a risk assessment should be completed and documented. The result of this risk assessment should demonstrate that an equivalent level of safety to that established by the Acceptable Means of Compliance (AMC) adopted by the Agency is reached.

AMC1 ORA.GEN.125 Terms of approval and privileges of an organisation

MANAGEMENT SYSTEM DOCUMENTATION

The management system documentation should contain the privileges and detailed scope of activities for which the organisation is certified, as relevant to the applicable requirements. The scope of activities defined in the management system documentation should be consistent with the terms of approval.

AMC1 ORA.GEN.130 Changes to organisations

APPLICATION TIME FRAMES

- (a) The application for the amendment of an organisation certificate should be submitted at least 30 days before the date of the intended changes.
- (b) In the case of a planned change of a nominated person, the organisation should inform the competent authority at least 10 days before the date of the proposed change.
- (c) Unforeseen changes should be notified at the earliest opportunity, in order to enable the competent authority to determine continued compliance with the applicable requirements and to amend, if necessary, the organisation certificate and related terms of approval.

GM1 ORA.GEN.130(a) Changes to organisations

GENERAL

- (a) Typical examples of changes that may affect the certificate or the terms of approval are listed below:
 - (1) the name of the organisation;
 - (2) the organisation's principal place of business;
 - (3) the organisation's scope of activities;
 - (4) additional locations of the organisation;
 - (5) the accountable manager;
 - (6) any of the persons referred to in ORA.GEN.210 (a) and (b);
 - (7) the organisation's documentation as required by this Part, safety policy and procedures;
 - (8) the facilities.

- (b) Prior approval by the competent authority is required for any changes to the organisation's procedure describing how changes not requiring prior approval will be managed and notified to the competent authority.
- (c) Changes requiring prior approval may only be implemented upon receipt of formal approval by the competent authority.

GM2 ORA.GEN.130(a) Changes to organisations

CHANGE OF NAME OF THE ORGANISATION

A change of name requires the organisation to submit a new application as a matter of urgency.

Where this is the only change to report, the new application can be accompanied by a copy of the documentation previously submitted to the competent authority under the previous name, as a means of demonstrating how the organisation complies with the applicable requirements.

AMC1 ORA.GEN.150(b) Findings

GENERAL

The corrective action plan defined by the organisation should address the effects of the non-conformity, as well as its root-cause.

GM1 ORA.GEN.150 Findings

GENERAL

- (a) Corrective action is the action to eliminate or mitigate the root cause(s) and prevent recurrence of an existing detected non-compliance or other undesirable condition or situation.
- (b) Proper determination of the root cause is crucial for defining effective corrective actions.

AMC1 ORA.GEN.160 Occurrence reporting

GENERAL

- (a) The organisation should report all occurrences defined in AMC 20-8, and as required by the applicable national rules implementing Directive 2003/43/EC¹ on occurrence reporting in civil aviation.
- (b) In addition to the reports required by AMC 20-8 and Directive 2003/43/EC, the organisation should report volcanic ash clouds encountered during flight.

¹ 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

AMC1 ORA.GEN.200(a)(1);(2);(3);(5) Management system

NON-COMPLEX ORGANISATIONS - GENERAL

- (a) Safety risk management may be performed using hazard checklists or similar risk management tools or processes, which are integrated into the activities of the organisation.
- (b) The organisation should manage safety risks related to a change. The management of change should be a documented process to identify external and internal change that may have an adverse effect on safety. It should make use of the organisation's existing hazard identification, risk assessment and mitigation processes.
- (c) The organisation should identify a person who fulfils the role of safety manager and who is responsible for coordinating the safety management system. This person may be the accountable manager or a person with an operational role in the organisation.
- (d) Within the organisation, responsibilities should be identified for hazard identification, risk assessment and mitigation.
- (e) The safety policy should include a commitment to improve towards the highest safety standards, comply with all applicable legal requirements, meet all applicable standards, consider best practices and provide appropriate resources.
- (f) The organisation should, in cooperation with other stakeholders, develop, coordinate and maintain an emergency response plan (ERP) that ensures orderly and safe transition from normal to emergency operations and return to normal operations. The ERP should provide the actions to be taken by the organisation or specified individuals in an emergency and reflect the size, nature and complexity of the activities performed by the organisation.

AMC1 ORA.GEN.200(a)(1) Management system

COMPLEX ORGANISATIONS - ORGANISATION AND ACCOUNTABILITIES

The management system of an organisation should encompass safety by including a safety manager and a safety review board in the organisational structure.

- (a) Safety manager
 - (1) The safety manager should act as the focal point and be responsible for the development, administration and maintenance of an effective safety management system.
 - (2) The functions of the safety manager should be to:
 - (i) facilitate hazard identification, risk analysis and management;
 - (ii) monitor the implementation of actions taken to mitigate risks, as listed in the safety action plan;
 - (iii) provide periodic reports on safety performance;
 - (iv) ensure maintenance of safety management documentation;
 - (v) ensure that there is safety management training available and that it meets acceptable standards;
 - (vi) provide advice on safety matters; and

- (vii) ensure initiation and follow-up of internal occurrence / accident investigations.
- (b) Safety review board
 - (1) The Safety review board should be a high level committee that considers matters of strategic safety in support of the accountable manager's safety accountability.
 - (2) The board should be chaired by the accountable manager and be composed of heads of functional areas.
 - (3) The safety review board should monitor:
 - (i) safety performance against the safety policy and objectives;
 - (ii) that any safety action is taken in a timely manner; and
 - (iii) the effectiveness of the organisation's safety management processes.
- (c) The safety review board should ensure that appropriate resources are allocated to achieve the established safety performance.
- (d) The safety manager or any other relevant person may attend, as appropriate, safety review board meetings. He/she may communicate to the accountable manager all information, as necessary, to allow decision making based on safety data.

GM1 ORA.GEN.200(a)(1) Management system

SAFETY MANAGER

- (a) Depending on the size of the organisation and the nature and complexity of its activities, the safety manager may be assisted by additional safety personnel for the performance of all safety management related tasks.
- (b) Regardless of the organisational set-up it is important that the safety manager remains the unique focal point as regards the development, administration and maintenance of the organisation's safety management system.

GM2 ORA.GEN.200(a)(1) Management system

COMPLEX ORGANISATIONS - SAFETY ACTION GROUP

- (a) A safety action group may be established as a standing group or as an ad-hoc group to assist or act on behalf of the safety review board.
- (b) More than one safety action group may be established depending on the scope of the task and specific expertise required.
- (c) The safety action group should report to and take strategic direction from the safety review board and should be comprised of managers, supervisors and personnel from operational areas.
- (d) The safety action group should:
 - (1) monitor operational safety;
 - (2) resolve identified risks;
 - (3) assess the impact on safety of operational changes; and
 - (4) ensure that safety actions are implemented within agreed timescales.
- (e) The safety action group should review the effectiveness of previous safety recommendations and safety promotion.

AMC1 ORA.GEN.200(a)(2) Management system

COMPLEX ORGANISATIONS - SAFETY POLICY

- (a) The safety policy should:
 - (1) be endorsed by the accountable manager;
 - (2) reflect organisational commitments regarding safety and its proactive and systematic management;
 - (3) be communicated, with visible endorsement, throughout the organisation; and
 - (4) include safety reporting principles.
- (b) The safety policy should include a commitment:
 - (1) to improve towards the highest safety standards;
 - (2) to comply with all applicable legislation, meet all applicable standards and consider best practices;
 - (3) to provide appropriate resources;
 - (4) to enforce safety as one primary responsibility of all managers; and
 - (5) not to blame someone for reporting something which would not have been otherwise detected.
- (c) Senior management should:
 - (1) continually promote the safety policy to all personnel and demonstrate their commitment to it;
 - (2) provide necessary human and financial resources for its implementation; and
 - (3) establish safety objectives and performance standards.

GM1 ORA.GEN.200(a)(2) Management system

SAFETY POLICY

The safety policy is the means whereby the organisation states its intention to maintain and, where practicable, improve safety levels in all its activities and to minimise its contribution to the risk of an aircraft accident as far as is reasonably practicable.

The safety policy should state that the purpose of safety reporting and internal investigations is to improve safety, not to apportion blame to individuals.

AMC1 ORA.GEN.200(a)(3) Management system

COMPLEX ORGANISATIONS - SAFETY RISK MANAGEMENT

- (a) Hazard identification processes
 - (1) Reactive and proactive schemes for hazard identification should be the formal means of collecting, recording, analysing, acting on and generating feedback about hazards and the associated risks that affect the safety of the operational activities of the organisation.
 - (2) All reporting systems, including confidential reporting schemes, should include an effective feedback process.
- (b) Risk assessment and mitigation processes
 - (1) A formal risk management process should be developed and maintained that ensures analysis (in terms of likelihood and severity of occurrence), assessment

(in terms of tolerability) and control (in terms of mitigation) of risks to an acceptable level.

- (2) The levels of management who have the authority to make decisions regarding the tolerability of safety risks, in accordance with (b)(1), should be specified.

(c) Internal safety investigation

- (1) The scope of internal safety investigations should extend beyond the scope of occurrences required to be reported to the competent authority.

(d) Safety performance monitoring and measurement

- (1) Safety performance monitoring and measurement should be the process by which the safety performance of the organisation is verified in comparison to the safety policy and objectives.
- (2) This process should include:
 - (i) safety reporting;
 - (ii) safety studies, that is, rather large analyses encompassing broad safety concerns;
 - (iii) safety reviews including trends reviews, which would be conducted during introduction and deployment of new technologies, change or implementation of procedures, or in situations of structural change in operations;
 - (iv) safety audits focussing on the integrity of the organisation's management system, and periodically assessing the status of safety risk controls; and
 - (v) safety surveys, examining particular elements or procedures of a specific operation, such as problem areas or bottlenecks in daily operations, perceptions and opinions of operational personnel and areas of dissent or confusion.

(e) The management of change

The organisation should manage safety risks related to a change. The management of change should be a documented process to identify external and internal change that may have an adverse effect on safety. It should make use of the organisation's existing hazard identification, risk assessment and mitigation processes.

(f) Continuous improvement

The organisation should continuously seek to improve its safety performance. Continuous improvement should be achieved through:

- (1) proactive and reactive evaluations of facilities, equipment, documentation and procedures through safety audits and surveys;
- (2) proactive evaluation of individuals' performance to verify the fulfilment of their safety responsibilities; and
- (3) reactive evaluations in order to verify the effectiveness of the system for control and mitigation of risk.

(g) The emergency response plan (ERP)

- (1) An ERP should be established that provides the actions to be taken by the organisation or specified individuals in an emergency. The ERP should reflect the size, nature and complexity of the activities performed by the organisation.
- (2) The ERP should ensure:
 - (i) an orderly and safe transition from normal to emergency operations;

- (ii) safe continuation of operations or return to normal operations as soon as practicable; and
- (iii) coordination with the emergency response plans of other organisations, where appropriate.

GM1 ORA.GEN.200(a)(3) Management system

INTERNAL OCCURRENCE REPORTING SCHEME

- (a) The overall purpose of the scheme is to use reported information to improve the level of safety performance of the organisation and not to attribute blame.
- (b) The objectives of the scheme are to:
 - (1) enable an assessment to be made of the safety implications of each relevant incident and accident, including previous similar occurrences, so that any necessary action can be initiated; and
 - (2) ensure that knowledge of relevant incidents and accidents is disseminated, so that other persons and organisations may learn from them.
- (c) The scheme is an essential part of the overall monitoring function and it is complementary to the normal day-to-day procedures and 'control' systems and is not intended to duplicate or supersede any of them. The scheme is a tool to identify those instances where routine procedures have failed.
- (d) All occurrence reports judged reportable by the person submitting the report should be retained as the significance of such reports may only become obvious at a later date.

AMC1 ORA.GEN.200(a)(4) Management system

TRAINING AND COMMUNICATION ON SAFETY

- (a) Training
 - (1) All personnel should receive safety training as appropriate for their safety responsibilities.
 - (2) Adequate records of all safety training provided should be kept.
- (b) Communication
 - (1) The organisation should establish communication about safety matters that:
 - (i) ensures that all personnel are aware of the safety management activities as appropriate for their safety responsibilities;
 - (ii) conveys safety critical information, especially relating to assessed risks and analysed hazards;
 - (iii) explains why particular actions are taken; and
 - (iv) explains why safety procedures are introduced or changed.
 - (2) Regular meetings with personnel where information, actions and procedures are discussed may be used to communicate safety matters.

GM1 ORA.GEN.200(a)(4) Management system

TRAINING AND COMMUNICATION ON SAFETY

The safety training programme may consist of self-instruction via a media (newsletters, flight safety magazines), class-room training, e-learning or similar training provided by training service providers.

AMC1 ORA.GEN.200(a)(5) Management system

ORGANISATION'S MANAGEMENT SYSTEM DOCUMENTATION

- (a) The organisation's management system documentation should at least include the following information:
 - (1) a statement signed by the accountable manager to confirm that the organisation will continuously work in accordance with the applicable requirements and the organisation's documentation as required by this Part;
 - (2) the organisation's scope of activities;
 - (3) the titles and names of persons referred to in ORA.GEN.210 (a) and (b);
 - (4) an organisation chart showing the lines of responsibility between the persons referred to in ORA.GEN.210;
 - (5) a general description and location of the facilities referred to in ORA.GEN.215;
 - (6) procedures specifying how the organisation ensures compliance with the applicable requirements;
 - (7) the amendment procedure for the organisation's management system documentation.
- (b) The organisation's management system documentation may be included in a separate manual or in (one of) the manual(s) as required by the applicable Subpart(s). A cross reference should be included.

GM1 ORA.GEN.200(a)(5) Management system

ORGANISATION'S MANAGEMENT SYSTEM DOCUMENTATION

- (a) It is not required to duplicate information in several manuals. The information may be contained in any of the organisation manuals (e.g. operations manual, training manual), which may also be combined.
- (b) The organisation may also choose to document some of the information required to be documented in separate documents (e.g. procedures). In this case, it should ensure that manuals contain adequate references to any document kept separately. Any such documents are then to be considered an integral part of the organisation's management system documentation.

AMC1 ORA.GEN.200(a)(5) Management system

COMPLEX ORGANISATIONS – ORGANISATION'S SAFETY MANAGEMENT MANUAL

- (a) The safety management manual (SMM) should be the key instrument for communicating the approach to safety for the whole of the organisation. The SMM should document all aspects of safety management, including the safety policy, objectives, procedures and individual safety responsibilities.
- (b) The contents of the safety management manual should include all of the following:
 - (1) scope of the safety management system;
 - (2) safety policy and objectives;
 - (3) safety accountability of the accountable manager;
 - (4) safety responsibilities of key safety personnel;
 - (5) documentation control procedures;
 - (6) hazard identification and risk management schemes;
 - (7) safety action planning;
 - (8) safety performance monitoring;
 - (9) incident investigation and reporting;
 - (10) emergency response planning;
 - (11) management of change (including organisational changes with regard to safety responsibilities);
 - (12) safety promotion.
- (c) The SMM may be contained in (one of) the manual(s) of the organisation.

AMC1 ORA.GEN.200(a)(6) Management system

COMPLIANCE MONITORING - GENERAL

- (a) Compliance monitoring

The implementation and use of a compliance monitoring function should enable the organisation to monitor compliance with the relevant requirements of this Part and other applicable Parts.

 - (1) The organisation should specify the basic structure of the compliance monitoring function applicable to the activities conducted.
 - (2) The compliance monitoring function should be structured according to the size of the organisation and the complexity of the activities to be monitored.
- (b) Organisations should monitor compliance with the procedures they have designed to ensure safe activities. In doing so, they should as a minimum, and where appropriate, monitor:
 - (1) privileges of the organisation;
 - (2) manuals, logs, and records;
 - (3) training standards;
 - (4) management system procedures and manuals.
- (c) Organisational set up
 - (1) To ensure that the organisation continues to meet the requirements of this Part and other applicable Parts, the accountable manager should designate a

compliance monitoring manager. The role of the compliance monitoring manager is to ensure that the activities of the organisation are monitored for compliance with the applicable regulatory requirements, and any additional requirements as established by the organisation, and that these activities are being carried out properly under the supervision of the relevant head of functional area.

- (2) The compliance monitoring manager should be responsible for ensuring that the compliance monitoring programme is properly implemented, maintained and continually reviewed and improved.
 - (3) The compliance monitoring manager should:
 - (i) have direct access to the accountable manager;
 - (ii) not be one of the other persons referred to in ORA.GEN.210 (b);
 - (iii) be able to demonstrate relevant knowledge, background and appropriate experience related to the activities of the organisation; including knowledge and experience in compliance monitoring; and
 - (iv) have access to all parts of the organisation, and as necessary, any contracted organisation.
 - (4) In the case of a non-complex organisation, this task may be exercised by the accountable manager provided he/she has demonstrated having the related competence as defined in (c)(3)(iii).
 - (5) In the case the same person acts as compliance monitoring manager and as safety manager, the accountable manager, with regards to his/her direct accountability for safety, should ensure that sufficient resources are allocated to both functions, taking into account the size of the organisation and the nature and complexity of its activities.
 - (6) The independence of the compliance monitoring function should be established by ensuring that audits and inspections are carried out by personnel not responsible for the function, procedure or products being audited.
- (d) Compliance monitoring documentation
- (1) Relevant documentation should include the relevant part(s) of the organisation's management system documentation.
 - (2) In addition, relevant documentation should also include the following:
 - (i) terminology;
 - (ii) specified activity standards;
 - (iii) a description of the organisation;
 - (iv) the allocation of duties and responsibilities;
 - (v) procedures to ensure regulatory compliance;
 - (vi) the compliance monitoring programme, reflecting:
 - (A) schedule of the monitoring programme;
 - (B) audit procedures;
 - (C) reporting procedures;
 - (D) follow-up and corrective action procedures; and
 - (E) recording system.
 - (vii) the training syllabus referred to in (e)(2);
 - (viii) document control.

(e) Training

- (1) Correct and thorough training is essential to optimise compliance in every organisation. In order to achieve significant outcomes of such training, the organisation should ensure that all personnel understand the objectives as laid down in the organisation's management system documentation.
- (2) Those responsible for managing the compliance monitoring function should receive training on this task. Such training should cover the requirements of compliance monitoring, manuals and procedures related to the task, audit techniques, reporting and recording.
- (3) Time should be provided to train all personnel involved in compliance management and for briefing the remainder of the personnel.
- (4) The allocation of time and resources should be governed by the volume and complexity of the activities concerned.

GM1 ORA.GEN.200(a)(6) Management system

COMPLIANCE MONITORING - GENERAL

- (a) The organisational set-up of the compliance monitoring function should reflect the size of the organisation and the nature and complexity of its activities. The compliance monitoring manager may perform all audits and inspections himself/herself or appoint one or more auditors by choosing personnel having the related competence as defined in AMC1 ORA.GEN.200(a)(6) point (c)(3)(iii), either from within or outside the organisation.
- (b) Regardless of the option chosen it must be ensured that the independence of the audit function is not affected, in particular in cases where those performing the audit or inspection are also responsible for other functions within the organisation.
- (c) In case external personnel are used to perform compliance audits or inspections:
 - (1) any such audits or inspections are performed under the responsibility of the compliance monitoring manager; and
 - (2) the organisation remains responsible to ensure that the external personnel has relevant knowledge, background and experience as appropriate to the activities being audited or inspected; including knowledge and experience in compliance monitoring.
- (d) The organisation retains the ultimate responsibility for the effectiveness of the compliance monitoring function in particular for the effective implementation and follow-up of all corrective actions.

GM2 ORA.GEN.200(a)(6) Management system

COMPLEX ORGANISATIONS - COMPLIANCE MONITORING PROGRAMME FOR ATOs

- (a) Typical subject areas for compliance monitoring audits and inspections for approved training organisations (ATOs) should be the following:
 - (1) facilities;
 - (2) actual flight and ground training;
 - (3) technical standards.
- (b) ATOs should monitor compliance with the training and operations manuals they have designed to ensure safe and efficient training. In doing so, they should, where appropriate, additionally monitor the following:
 - (1) training procedures;

- (2) flight safety;
- (3) flight and duty time limitations, rest requirements and scheduling;
- (4) aircraft maintenance/operations interface.

GM3 ORA.GEN.200(a)(6) Management system

AUDIT AND INSPECTION

- (a) 'Audit' means a systematic, independent and documented process for obtaining evidence and evaluating it objectively to determine the extent to which requirements are complied with.
- (b) 'Inspection' means an independent documented conformity evaluation by observation and judgement accompanied as appropriate by measurement, testing or gauging, in order to verify compliance with applicable requirements.

AMC1 ORA.GEN.200(b) Management system

SIZE, NATURE AND COMPLEXITY OF THE ACTIVITY

- (a) An organisation should be considered as complex when it has a workforce of more than 20 full time equivalents (FTEs) involved in the activity subject to Regulation (EC) No 216/2008² and its Implementing Rules.
- (b) Organisations with up to 20 full time equivalents (FTEs) involved in the activity subject to Regulation (EC) No 216/2008 and its Implementing Rules, may also be considered complex based on an assessment of the following factors:
 - (1) in terms of complexity, the extent and scope of contracted activities subject to the approval;
 - (2) in terms of risk criteria, whether any of the following are present:
 - (i) operations requiring the following specific approvals: performance-based navigation (PBN), low visibility operation (LVO), extended range operations with two-engined aeroplanes (ETOPS), helicopter hoist operation (HHO), helicopter emergency medical service (HEMS), night vision imaging system (NVIS) and dangerous goods (DG);
 - (ii) different types of aircraft used;
 - (iii) the environment (offshore, mountainous area etc.);
- (c) Regardless of the criteria mentioned in (a) and (b), the following organisations should always be considered as non-complex:
 - (1) Approved Training Organisations (ATOs) only providing training for the light aircraft pilot licence (LAPL), private pilot licence (PPL), sailplane pilot licence (SPL) or balloon pilot licence (BPL) and the associated ratings and certificates;
 - (2) Aero-Medical Centres (AeMCs).

² 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/EC. *OJ L 79*, 19.3.2008, p. 1.

AMC1 ORA.GEN.205 Contracted activities

RESPONSIBILITY WHEN CONTRACTING ACTIVITIES

- (a) The organisation may decide to contract certain activities to external organisations.
- (b) A written agreement should exist between the organisation and the contracted organisation clearly defining the contracted activities and the applicable requirements.
- (c) The contracted safety related activities relevant to the agreement should be included in the organisation's safety management and compliance monitoring programmes.
- (d) The organisation should ensure that the contracted organisation has the necessary authorisation or approval when required, and commands the resources and competence to undertake the task.

GM1 ORA.GEN.205 Contracted activities

RESPONSIBILITY WHEN CONTRACTING ACTIVITIES

- (a) Regardless of the approval status of the contracted organisation, the contracting organisation is responsible to ensure that all contracted activities are subject to hazard identification and risk management as required by ORA.GEN.200 (a)(3) and to compliance monitoring as required by ORA.GEN.200 (a)(6).
- (b) When the contracted organisation is itself certified to carry out the contracted activities, the organisation's compliance monitoring should at least check that the approval effectively covers the contracted activities and that it is still valid.
- (c) If the organisation requires the contracted organisation to conduct an activity which exceeds the contracted organisation's terms of approval, this will be considered as the contracted organisation working under the approval of the contracting organisation.

AMC1 ORA.GEN.215 Facility requirements

ATOs PROVIDING TRAINING FOR THE CPL, MPL AND ATPL AND THE ASSOCIATED RATINGS AND CERTIFICATES

- (a) For ATOs providing flight training, the following flight operations accommodation should be available:
 - (1) an operations room with facilities to control flying operations;
 - (2) a flight planning room with the following facilities:
 - (i) appropriate current maps and charts;
 - (ii) current aeronautical information service (AIS) information;
 - (iii) current meteorological information;
 - (iv) communications to air traffic control (ATC) and the operations room;
 - (v) any other flight safety related material.
 - (3) adequate briefing rooms/cubicles of sufficient size and number;
 - (4) suitable offices for the supervisory personnel and room(s) to allow flight instructors to write reports on students, complete records and other related documentation;
 - (5) furnished crew-room(s) for instructors and students.

- (b) For ATOs providing theoretical knowledge training, the following facilities for theoretical knowledge instruction should be available:
- (1) adequate classroom accommodation for the current student population;
 - (2) suitable demonstration equipment to support the theoretical knowledge instruction;
 - (3) a radiotelephony training and testing facility;
 - (4) a reference library containing publications giving coverage of the syllabus;
 - (5) offices for the instructional personnel.

AMC2 ORA.GEN.215 Facility requirements

ATOs PROVIDING TRAINING FOR THE LAPL, PPL, SPL OR BPL AND THE ASSOCIATED RATINGS AND CERTIFICATES

- (a) The following flight operations accommodation should be available:
- (1) a flight planning room with the following facilities:
 - (i) appropriate current aviation maps and charts;
 - (ii) current AIS information;
 - (iii) current meteorological information;
 - (iv) communications to ATC (if applicable);
 - (v) any other flight safety related material.
 - (2) adequate briefing room(s)/cubicles of sufficient size and number;
 - (3) suitable office(s) to allow flight instructors to write reports on students, complete records and other related documentation;
 - (4) suitable rest areas for instructors and students, where appropriate to the training task;
 - (5) in the case of ATOs providing training for the BPL or LAPL(B) only, the flight operations accommodation listed in (a)(1) to (a)(4) may be replaced by other suitable facilities when operating outside aerodromes.
- (b) The following facilities for theoretical knowledge instruction should be available:
- (1) adequate classroom accommodation for the current student population;
 - (2) suitable demonstration equipment to support the theoretical knowledge instruction;
 - (3) suitable office(s) for the instructional personnel.
- (c) A single room may be sufficient to provide the functions listed in (a) and (b).

AMC1 ORA.GEN.220(b) Record-keeping

GENERAL

- (a) The record-keeping system should ensure that all records are accessible whenever needed within a reasonable time. These records should be organised in a way that ensures traceability and retrievability throughout the required retention period.
- (b) Records should be kept in paper form or in electronic format or a combination of both. Records stored on microfilm or optical disc format are also acceptable. The

records should remain legible throughout the required retention period. The retention period starts when the record has been created or last amended.

- (c) Paper systems should use robust material which can withstand normal handling and filing. Computer systems should have at least one backup system which should be updated within 24 hours of any new entry. Computer systems should include safeguards against the ability of unauthorised personnel to alter the data.
- (d) All computer hardware used to ensure data backup should be stored in a different location from that containing the working data and in an environment that ensures they remain in good condition. When hardware or software changes take place, special care should be taken that all necessary data continues to be accessible at least through the full period specified in the relevant Subpart. In the absence of such indication, all records should be kept for a minimum period of 5 years.

GM1 ORA.GEN.220(b) Record-keeping

RECORDS

Microfilming or optical storage of records may be carried out at any time. The records should be as legible as the original record and remain so for the required retention period.

Subpart AeMC – Aero-medical Centres

SECTION I – GENERAL

AMC1 ORA.AeMC.115 Application

GENERAL

- (a) The documentation for the approval of an AeMC should include the names and qualifications of all medical staff, a list of medical and technical facilities for initial class 1 aero-medical examinations and of supporting specialist consultants.
- (b) The AeMC should provide details of clinical attachments to hospitals, medical institutions and/or specialists.

AMC1 ORA.AeMC.135 Continued validity

EXPERIENCE

- (a) At least 200 class 1 aero-medical examinations and assessments should be performed at the AeMC every year.
- (b) In Member States where the number of aero-medical examinations and assessments mentioned in (a) cannot be reached due a low number of professional pilots, a proportionate number of class 1 aero-medical examinations and assessments should be performed.
- (c) In these cases, the continuing experience of the head of the AeMC and aero-medical examiners on staff should also be ensured by them performing aero-medical examinations and assessments for:
 - (1) class 2 medical certificates as established in Part-MED; and/or
 - (2) third country class 1 medical certificates.
- (d) Aero-medical research including publication in peer reviewed journals may also be accepted as contributing to the continued experience of the head of, and aero-medical examiners at, an AeMC.

SECTION II – MANAGEMENT

GM1 ORA.AeMC.200 Management system

RESEARCH

If aero-medical research is conducted at an AeMC, its management system should include processes to conduct that research and publish the results.

AMC1 ORA.AeMC.210 Personnel requirements

GENERAL

- (a) The aero-medical examiner (AME) should have held class 1 privileges for at least 5 years and have performed at least 200 aero-medical examinations for a class 1 medical certificate before being nominated as head of an AeMC.
- (b) The AeMC may provide practical AME training for persons fully qualified and licensed in medicine.

AMC1 ORA.AeMC.215 Facility requirements

MEDICAL-TECHNICAL FACILITIES

The medical-technical facilities of an AeMC should consist of the equipment of a general medical practice and, in addition, of:

(a) Cardiology

Facilities to perform:

- (1) 12-lead resting ECG;
- (2) stress ECG;
- (3) 24-hour blood pressure monitoring; and
- (4) 24-hour heart rhythm monitoring.

(b) Ophthalmology

Facilities for the examination of:

- (1) near, intermediate and distant vision;
- (2) external eye, anatomy, media and funduscopy;
- (3) ocular motility;
- (4) binocular vision;
- (5) colour vision (anomaloscopy or equivalent);
- (6) visual fields;
- (7) refraction; and
- (8) heterophoria.

(c) Hearing

- (1) pure-tone audiometer

(d) Otorhinolaryngology

Facilities for the clinical examination of mouth and throat and:

- (1) otoscopy;
- (2) rhinoscopy;
- (3) tympanometry or equivalent; and
- (4) clinical assessment of vestibular system.

(e) Examination of pulmonary function

- (1) spirometry

(f) The following facilities should be available at the AeMC or arranged with a service provider:

- (1) clinical laboratory facilities; and
- (2) ultrasound of the abdomen.