**Subpart**  **GEN. GENERAL REQUIREMENT’S**

**Section** **I.** **General**

 **ARA. GEN. 105 Definition’s and Abbreviation’s**

 For the purposes of this Part and of Part - ORA, the following definitions apply :

**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.** “ Alternative means of compliance ” - are those that propose an alternative to an existing AMC or those that propose new means to establish compliance with Regulation ( EC ) No 216 / 2008 and its Implementing Rules for which no associated AMC have been adopted by the Agency ;

**3.** “ Approved Training Organization “ *( ATO )* - means an organization qualified for the issue or continuation of an approval to provide training for pilot licences and associated ratings and certificates ;

**4.** “ Basic Instrument Training Device model “ *( BITD model )* - means a defined hardware and software combination, which has obtained a BITD qualification ;

**5.** “ Certification Specifications “ *( CS )* - are technical standards adopted by the Agency indicating means to show compliance with the Basic Regulation and its Implementing Rules and which can be used by organization for the purpose of certification ;

**6.** “ Flight Instructor “ *( FI )* - means an instructor with the privileges to provide training in an aircraft, in accordance with Part - FCL ;

**7.** “ 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 )* ;

**8.** “ FSTD qualification ” - means the level of technical ability of an FSTD as defined in the compliance document ;

**9.** “ FSTD user ” - means the organization or person requesting training, checking or testing through the use of an FSTD to an ATO ;

**10.** “ Grounding ” - means the formal prohibition of an aircraft to Take-off and the taking of such steps as are necessary to detain it ;

**11.** “ 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 the Basic Regulation, its Implementing Rules and AMC ;

**12.** “ ARO. RAMP ” - means the Subpart RAMP of Annex II to the Regulation on Air Operations ;

**13.** “ 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 ;

**14.** “ Part - ARA ” - means Annex VI to the Regulation on Civil Aviation Aircrew ;

**15.** “ Part - ORO ” - means Annex III to the Regulation on Air Operations ;

**16.** “ Part - CC ” - means Annex V to the Regulation on Civil Aviation Aircrew ;

**17.** “ Part - FCL ” - means Annex I to the Regulation on Civil Aviation Aircrew ;

**18.** “ Part - MED ” - means Annex IV to the Regulation on Civil Aviation Aircrew ;

**19.** “ Part - ORA ” - means Annex VII to the Regulation on Civil Aviation Aircrew ;

**20.** “ Principal place of business ” - means the head office or registered office of the organization within which the principal financial functions and operational control of the activities referred to in this Regulation are exercised ;

**21.** “ 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.

**22.** AeMC - Aero - Medical Centre ;

 AME - Aero -Medical Examiner ;

 AMEC - Aero -Medical Examiner Certificate ;

 GMP - General Medical Practitioner’s;

 QTG  - Qualification Test Guide ;

 MQTG  - Master Qualification Test Guide

 **ARA. 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.

 **ARA. 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 organizations 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 organization in accordance with ORA. GEN. 120 by analyzing the documentation provided and, if considered necessary, conducting an inspection of the organization ;

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 ;

3 ) inform other MS about alternative means of compliance that were accepted.

***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 organizations 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.

 **ARA. GEN. 125 Information to the Agency**

***a )*** The competent Authority shall without undue delay notify the Agency in case of any significant 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.

 **ARA. GEN. 135 Immediate reaction to a safety problem**

***a )*** Without prejudice to Directive 2003 / 42 / EC of the European Parliament and of the Council (1) the competent Authority shall implement a system to appropriately collect, analyze and disseminate safety information ;

***b )*** The Agency shall implement a system to appropriately analyze any relevant 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 organizations subject to Regulation ( EC ) No 216 / 2008 and its Implementing Rules ;

***c )*** Upon receiving the information referred to in ( a ) and ( 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 organizations 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.

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( 1 ) OJ L 167, 4. 7. 2003, p. 23.

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**Section**  **II.**  **Management**

 **ARA. 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 organization, means and methods to achieve compliance with Regulation ( EC ) No 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 and a safety risk management 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 including management system, 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 organization’s exercising activities in the territory of a Member State, but certified by 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 standardization.

 **ARA. GEN. 205 Allocation of tasks to qualified entities**

***a )*** Tasks related to the initial certification or continuing oversight of persons or organizations subject to Regulation ( EC ) No 216 / 2008 and its Implementing Rules shall be allocated by Member States only to qualified entities. When allocating tasks, the competent Authority shall ensure that it has :

( 1 ) a system in place to initially and continuously assess that the qualified entity complies with Annex V to Regulation ( EC ) No 216 / 2008. This system and the results of the assessments shall be documented ;

( 2 ) established a documented agreement with a the qualified entity, 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 and a safety risk management process required by ARA. GEN. 200 ( a ) ( 4 ) cover all certification or continuing oversight tasks performed on its behalf.

 **ARA. 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.

 **ARA. 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 authorization of its personnel ;

( 3 ) the allocation of tasks, covering the elements required by ARA. GEN. 205 as well as the details of tasks allocated ;

( 4 ) certification processes and continuing oversight of certified organizations ;

( 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 organization operating it ;

( 7 ) oversight of persons and organization’s exercising activities within the territory of the Member State, but overseen or certified by the competent Authority of another Member State or the Agency, as agreed between these Authorities ;

( 8 ) the evaluation and notification to the Agency of alternative means of compliance proposed by organizations 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 CR - EC No 216 / 2008 .

***b )*** The competent Authority shall maintain a list of all organization certificates, FSTD qualification certificates and personnel licences, certificates and attestations it 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* subject to applicable data protection law.

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**Section**  **III**. **Oversight, Certification and Enforcement**

***a )*** The GDCA of RA shall verify :

1 ) compliance with the requirements applicable to organizations or persons prior to the issue of an organization certificate, approval, FSTD qualification certificate or personnel licence, certificate, rating, or attestation, as applicable ;

2 ) continued compliance with the applicable requirements of organizations 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 ARA. 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 organizations concerned with the results of safety oversight activity ;

3 ) be based on audits and inspections, including ramp and unannounced inspections ;

4 ) provide the competent authority with the evidence needed in case further action is required, including the measures foreseen by ARA. GEN. 350 and ARA. GEN. 355.

***c )*** The scope of oversight defined in ( a ) and ( b ) shall take into account the results of past oversight activities and the safety priorities ;

***d )*** Without prejudice to the competences of the Member States and to their obligations as set out in ARO. RAMP, the scope of the oversight of activities performed in the territory of a Member State by persons or organizations established or residing in another Member State shall be determined on the basis of the safety priorities, as well as of past oversight activities ;

***e )*** Where the activity of a person or organization involves more than one Member State or the Agency, the competent Authority responsible for the oversight under ( a ) may agree to have oversight tasks performed by the competent authority(ies) of the Member State(s) where the activity takes place or by the Agency. Any person or organization 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.

 **ARA. GEN. 305 Oversight Programme**

***a )*** The GDCA shall establish and maintain an oversight programme covering the oversight activities required by ARA. GEN. 300 and by ARO. RAMP ;

***b )*** For organizations certified by the competent Authority and FSTD qualification certificate holders, the oversight programme shall be developed taking into account the specific nature of the organization, the complexity of its activities, the results of past certification and / or oversight activities and shall be based on the assessment of associated risks. 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 organizations 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 organization 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 organization has demonstrated an effective identification of aviation safety hazards and management of associated risks ;

2 ) the organization has continuously demonstrated under ORA. GEN. 130 that it has full control over all changes ;

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 GDCA as defined in ARA. 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 organization 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 organization 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.

 **ARA. GEN. 310 Initial Certification Procedure – Organization’s**

***a )*** Upon receiving an application for the initial issue of a certificate for an organization, the competent Authority shall verify the organization’s compliance with the applicable requirements ;

***b )*** When satisfied that the organization is in compliance with the applicable requirements, the competent Authority shall issue the certificate(s), as established in Appendixes III and V to this Part. The certificate(s) shall be issued for an unlimited duration. The privileges and scope of the activities that the organization is approved to conduct shall be specified in the terms of approval attached to the certificate(s) ;

***c )*** To enable an organization to implement changes without prior competent Authority approval in accordance with ORA. GEN. 130, the competent Authority shall approve the procedure submitted by the organization defining the scope of such changes and describing how such changes will be managed and notified.

 **ARA. GEN. 315 Procedure for Issue, Revalidation, Renewal or change of**

 **Licences, Rating’s, Certificates or Attestations – Person’s**

***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.

 **ARA. GEN. 330 Changes – Organization’s**

***a )*** Upon receiving an application for a change that requires prior approval, the competent authority shall verify the organization’s compliance with the applicable requirements before issuing the approval.

The competent Authority shall prescribe the conditions under which the organization may operate during the change, unless the competent authority determines that the organization’s certificate needs to be suspended. When satisfied that the organization is in compliance with the applicable requirements, the competent Authority shall approve the change ;

***b )*** Without prejudice to any additional enforcement measures, when the organization implements changes requiring prior approval without having received competent Authority approval as defined in (a), the competent Authority shall suspend, limit or revoke the organization’s certificate ;

***c )*** For changes not requiring prior approval, the competent Authority shall assess the information provided in the notification sent by the organization in accordance with ORA. GEN. 130 to verify compliance with the applicable requirements. In case of any non-compliance, the competent Authority shall :

1 ) notify the organization about the non-compliance and request further changes ;

2 ) in case of level 1 or level 2 findings, act in accordance with ARA. GEN. 350.

 **ARA. GEN. 350 Findings and corrective actions – Organization’s**

***a )*** The competent Authority for oversight in accordance with ARA. GEN. 300 ( a ) shall have a system to analyze findings for their safety significance ;

***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 organization’s procedures and manuals or with the terms of an approval or certificate which lowers safety or seriously hazards flight safety.

The *Level* ***1*** findings shall include :

1 ) failure to give the competent authority access to the organization’s facilities as defined in ORA. GEN. 140 during normal operating hours and after two written requests ;

2 ) obtaining or maintaining the validity of the organization certificate by falsification of submitted documentary evidence;

3 ) evidence of malpractice or fraudulent use of the organization 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 organization’s procedures and manuals or with the terms of an approval or certificate which could lower safety or 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 organization 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 organization ;

2 ) In the case of *Level* ***2***  findings, the competent Authority shall :

( i ) grant the organization 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 organization and, if the assessment concludes that they are sufficient to address the non-compliance(s), accept these.

3 ) Where an organization 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 ) ;*

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 ARA. GEN. 300 ( d ) identifies any non-compliance with the applicable requirements of Regulation ( EC ) No 216 / 2008 and its Implementing Rules by an organization 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.

 **ARA. GEN. 355 Finding’s and enforcement measures – Person’s**

***a )*** If, during oversight or by any other means, evidence is found by the competent Authority responsible for oversight in accordance with ARA. 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 organization 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 ARA. 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.

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