ENAC Ente Nazionale per l'Aviazione Civile	**FSTD Organisation Compliance Checklist** **EU Regulation 1178/2011 as amended by EU Reg. 290/2012**
Operator Identification:	
Specific Items: **S** = Satisfactory **RMK** = Remarks **U** = Unsatisfactory **N/A** = Not Applicable	Date / Ref.

Reference		AMC & GM	How it is achieved	Specific Items
ORA.GEN.115	**Application for an organisation certificate** *(a) The application for an organisation certificate or an amendment to an existing certificate shall be made in a form and manner established by the competent authority, taking into account the applicable requirements of Regulation (EC) No 216/2008 and its Implementing Rules.* *(b) Applicants for an initial certificate shall provide the competent authority with documentation demonstrating how they will comply with the requirements established in Regulation (EC) No 216/2008 and its Implementing Rules. Such documentation shall include a procedure describing how changes not requiring prior approval will be managed and notified to the competent authority.*	(SEE ORA.FSTD.200) AMC1 ORA.FSTD.115		
ORA.GEN.120	**Means of compliance** *(a) Alternative means of compliance to the AMC adopted by the Agency may be used by an organisation to establish compliance with Regulation (EC) No 216/2008 and its Implementing Rules.* *(b) When an organisation wishes to use an alternative means of compliance, it shall, prior to implementing it, provide the competent authority with a full description of the alternative means of compliance. The description shall include any revisions to manuals or procedures that may be relevant, as well as an assessment demonstrating that Regulation (EC) No 216/2008 and its Implementing Rules are met.* *The organisation may implement these alternative means of compliance subject to prior approval by the competent authority and upon receipt of the notification as prescribed in ARA.GEN.120(d).*	AMC1 ORA.GEN.120(a)		
ORA.GEN.125	**Terms of approval and privileges of an organisation** A certified organisation shall comply with the scope and privileges defined in the terms of approval attached to the organisation's certificate.	AMC1 ORA.GEN.125		

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ORA.GEN.130	**Changes to organisations** *(a) Any change affecting:* *(1) the scope of the certificate or the terms of approval of an organisation; or* *(2) any of the elements of the organisation's management system as required in ORA.GEN.200(a)(1) and (a)(2),* *shall require prior approval by the competent authority.* *(b) For any changes requiring prior approval in accordance with Regulation (EC) No 216/2008 and its Implementing Rules, the organisation shall apply for and obtain an approval issued by the competent authority. The application shall be submitted before any such change takes place, in order to enable the competent authority to determine continued compliance with Regulation (EC) No 216/2008 and its Implementing Rules and to amend, if necessary, the organisation certificate and related terms of approval attached to it.* *The organisation shall provide the competent authority with any relevant documentation.* *The change shall only be implemented upon receipt of formal approval by the competent authority in accordance with ARA.GEN.330.* *The organisation shall operate under the conditions prescribed by the competent authority during such changes, as applicable.* *(c) All changes not requiring prior approval shall be managed and notified to the competent authority as defined in the procedure approved by the competent authority in accordance with ARA.GEN.310(c).*	AMC1 ORA.GEN.130, GM1 ORA.GEN.130(a), GM2 ORA.GEN.130(a)		
ORA.GEN.135	**Continued validity** (a) The organisation's certificate shall remain valid subject to: (1) the organisation remaining in compliance with the relevant requirements of Regulation (EC) No 216/2008 and its Implementing Rules, taking into account the provisions related to the handling of findings as specified under ORA.GEN.150; (2) the competent authority being granted access to the organisation as defined in ORA.GEN.140 to determine continued compliance with the relevant requirements of Regulation (EC) No 216/2008 and its Implementing Rules; and (3) the certificate not being surrendered or revoked. (b) Upon revocation or surrender the certificate shall be returned to the competent authority without delay.	- -		

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ORA.GEN.140	**Access** *For the purpose of determining compliance with the relevant requirements of Regulation (EC) No 216/2008 and its Implementing Rules, the organisation shall grant access to any facility, aircraft, document, records, data, procedures or any other material relevant to its activity subject to certification, whether it is contracted or not, to any person authorised by:* *(a) the competent authority defined in ORA.GEN.105; or* *(b) the authority acting under the provisions of ARA.GEN.300(d), ARA.GEN.300(e) or ARO.RAMP*	- -		
ORA.GEN.150	**Findings** *After receipt of notification of findings, the organisation shall:* *(a) identify the root cause of the non-compliance;* *(b) define a corrective action plan; and* *(c) demonstrate corrective action implementation to the satisfaction of the competent authority within a period agreed with that authority as defined in ARA.GEN.350(d).*	AMC1 ORA.GEN.150(b), GM1 ORA.GEN.150		
ORA.GEN.155	**Immediate reaction to a safety problem** *The organisation shall implement:* *(a) any safety measures mandated by the competent authority in accordance with ARA.GEN.135(c); and* *(b) any relevant mandatory safety information issued by the Agency, including airworthiness directives*	- -		

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ORA.GEN160	**Occurrence reporting** *(a) The organisation shall report to the competent authority, and to any other organisation required by the State of the operator to be informed, any accident, serious incident and occurrence as defined in Regulation (EU) No 996/2010 of the European Parliament and of the Council (1) and Directive 2003/42/EC of the European Parliament and of the Council.* *(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 data established in accordance with Part-21 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, Directive 2003/42/EC, Commission Regulation (EC) No 1321/2007 (3) and Commission Regulation (EC) No 1330/2007 (4), 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 actions have been identified. This report shall be produced in a form and manner established by the competent authority*	AMC1 ORA.GEN.160		

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ORA.GEN.200	**Management system** *(a) The organisation shall establish, implement and maintain a management system that includes:* *(1) clearly defined lines of responsibility and accountability throughout the organisation, including a direct safety accountability of the accountable manager;* *(2) a description of the overall philosophies and principles of the organisation with regard to safety, referred to as the safety policy;* *(3) the identification of aviation safety hazards entailed by the activities of the organisation, their evaluation and the management of associated risks, including taking actions to mitigate the risk and verify their effectiveness;* *(4) maintaining personnel trained and competent to perform their tasks;* *(5) documentation of all management system key processes, including a process for making personnel aware of their responsibilities and the procedure for amending this documentation;* *(6) a function to monitor compliance of the organisation with the relevant requirements. Compliance monitoring shall include a feedback system of findings to the accountable manager to ensure effective implementation of corrective actions as necessary; and* *(7) any additional requirements that are prescribed in the relevant subparts of this Part or other applicable Parts.* *(b) The management system shall correspond to the size of the organisation and the nature and complexity of its activities, taking into account the hazards and associated risks inherent in these activities.*	AMC1 ORA.GEN.200(a)(1); (2);(3);(5), AMC1 ORA.GEN.200(a)(1); GM1 ORA.GEN.200(a)(1); GM2 ORA.GEN.200(a)(1); AMC1 ORA.GEN.200(a)(2); GM1 ORA.GEN.200(a)(2); AMC1 ORA.GEN.200(a)(3); GM1 ORA.GEN.200(a)(3); AMC1 ORA.GEN.200(a)(4); GM1 ORA.GEN.200(a)(4); AMC1 ORA.GEN.200(a)(5); GM1 ORA.GEN.200(a)(5); AMC1 ORA.GEN.200(a)(5); AMC1 ORA.GEN.200(a)(6); GM1 ORA.GEN.200(a)(6); GM3 ORA.GEN.200(a)(6); AMC1 ORA.GEN.200(b); AMC1 ORA.GEN.205; GM1 ORA.GEN.205; AMC2 ORA.GEN.215; GM1 ORA.GEN.220(b) AMC1 ORA.GEN.220(b)		
ORA.GEN.205	**Contracted activities** *(a) Contracted activities include all activities within the organisation's scope of approval that are performed by another organisation either itself certified to carry out such activity or if not certified, working under the contracting organisation's approval. The organisation shall ensure that when contracting or purchasing any part of its activity, the contracted or purchased service or product conforms to the applicable requirements.* *(b) When the certified organisation contracts any part of its activity to an organisation that is not itself certified in accordance with this Part to carry out such activity, the contracted organisation shall work under the approval of the contracting organisation. The contracting organisation shall ensure that the competent authority is given access to the contracted organisation, to determine continued compliance with the applicable requirements.*	AMC1 ORA.GEN.205, GM1 ORA.GEN.205		

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ORA.GEN.210	**Personnel requirements** (a) The organisation shall appoint an accountable manager, who has the authority for ensuring that all activities can be financed and carried out in accordance with the applicable requirements. The accountable manager shall be responsible for establishing and maintaining an effective management system. (b) A person or group of persons shall be nominated by the organisation, with the responsibility of ensuring that the organisation remains in compliance with the applicable requirements. Such person(s) shall be ultimately responsible to the accountable manager. (c) The organisation shall have sufficient qualified personnel for the planned tasks and activities to be performed in accordance with the applicable requirements. (d) The organisation shall maintain appropriate experience, qualification and training records to show compliance with paragraph (c). (e) The organisation shall ensure that all personnel are aware of the rules and procedures relevant to the exercise of their duties.	- -		
ORA.GEN.215	**Facility requirements** *The organisation shall have facilities allowing the performance and management of all planned tasks and activities in accordance with the applicable requirements.*	- -		
ORA.GEN.220	**Record-keeping** *(a) The organisation shall establish a system of record–keeping that allows adequate storage and reliable traceability of all activities developed, covering in particular all the elements indicated in ORA.GEN.200.* *(b) The format of the records shall be specified in the organisation's procedures.* *(c) Records shall be stored in a manner that ensures protection from damage, alteration and theft.*	AMC1 ORA.GEN.220(b), GM1 ORA.GEN.220(b)		

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ORA.FSTD.100	**General (Management System)** *(a) The applicant for an FSTD qualification certificate shall demonstrate to the competent authority that it has established a management system in accordance with ORA.GEN Section II. This demonstration shall ensure that the applicant has, directly or through contract, the capability to maintain the performance, functions and other characteristics specified for the FSTD's qualification level and to control the installation of the FSTD.* *(b) If the applicant is the holder of a qualification certificate issued in accordance with this Part, the FSTD specifications shall be detailed:* *(1) in the terms of the ATO certificate; or* *(2) in the case of an AOC holder, in the training manual.*	AMC1 ORA.FSTD.100, AMC2 ORA.FSTD.100, AMC3 ORA.FSTD.100, GM1 ORA.FSTD.100, GM2 ORA.FSTD.100		
ORA.FSTD.105	**Maintaining the FSTD qualification** *(a) In order to maintain the qualification of the FSTD, an FSTD qualification certificate holder shall run the complete set of tests contained within the master qualification test guide (MQTG) and functions and subjective tests progressively over a 12-month period.* *(b) The results shall be dated, marked as analysed and evaluated, and retained in accordance with ORA.FSTD.240, in order to demonstrate that the FSTD standards are being maintained.* *(c) A configuration control system shall be established to ensure the continued integrity of the hardware and software of the qualified FSTD.*	AMC1 FSTD(A).300 (9) (ii)		

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ORA.FSTD.110	**Modifications** *(a) The holder of an FSTD qualification certificate shall establish and maintain a system to identify, assess and incorporate any important modifications into the 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.*	AMC1 ORA.FSTD.110, GM1 ORA.FSTD.110		
ORA.FSTD.115	**Installations** *(a) The holder of an FSTD qualification certificate shall ensure that:* *(1) the FSTD is housed in a suitable environment that supports safe and reliable operation;* *(2) all FSTD occupants and maintenance personnel are briefed on FSTD safety to ensure that they are aware of all safety equipment and procedures in the FSTD in case of an emergency; 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.*	AMC1 ORA.FSTD.115, GM1 ORA.FSTD.115		
ORA.FSTD.120	**Additional equipment** *Where additional equipment has been added to the FSTD, even though not required for qualification, it shall be assessed by the competent authority to ensure that it does not adversely affect the quality of training.*	- -		

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ORA.FSTD.200	**Application for FSTD qualification** *(a) The application for an FSTD qualification certificate shall be made in a form and manner established by the 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 ORA.GEN.130 and ORA.FSTD.230.*	AMC1 ORA.FSTD.200		
ORA.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.*	- -		
ORA.FSTD.210	**Qualification basis** *(a) The qualification basis for the issuance of an FSTD qualification certificate shall consist of:* *(1) the applicable Certification Specifications established by the Agency that are effective on the date of the application for the initial qualification;* *(2) the aircraft validation data defined by the data 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.*	- -		

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ORA.FSTD.225	**ORA.FSTD.225 Duration and continued validity** (a) The FSTD qualification certificate shall remain valid subject to the following conditions: (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 point ORA.GEN.140 to determine continued compliance with the relevant requirements of Regulation (EU) 2018/1139 and the implementing and delegated acts adopted on the basis thereof ; and (3) the qualification certificate not being surrendered or revoked. (b) If the competent authority has extended the recurrent evaluation period for an FSTD in accordance with point ARA.FSTD.120(c) of Annex VI (Part-ARA), the organisation shall assign a person or group of persons with adequate experience who shall do all of the following within a period of 60 days before and 30 days after the start of each recurrent 12-month period in accordance with point ARA.FSTD.120 (b)(1) of Annex VI: (1) review the regular reruns of the complete tests in the master QTG; (2) conduct the relevant functions and subjective tests; (3) send a report of the results to the competent authority. (c) A BITD qualification shall remain valid subject to regular evaluation for compliance with the applicable qualification basis by the competent authority in accordance with point ARA.FSTD.120 of Annex VI.	AMC1 ORA.FSTD.225(b)(4)		

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ORA.FSTD.230	**Changes to the qualified FSTD** *(a) The holder of an FSTD qualification certificate 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.*	AMC1 ORA.FSTD.230(b)		
ORA.FSTD.235	**Transferability of an FSTD qualification** *(a) When there is a change of the organisation operating an FSTD, the new organisation shall inform the competent authority in advance in order to agree upon a plan of transfer of the FSTD.* *(b) The competent authority may perform an evaluation in accordance with the original qualification basis of the FSTD.* *(c) When the FSTD no longer complies with its initial qualification basis, the organisation shall apply for a new FSTD qualification certificate.*	- -		

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ORA.FSTD.240	**Record-keeping** *The holder of an FSTD qualification certificate shall keep records of:* *(a) all documents describing and proving the initial qualification basis and level of the FSTD for the duration of the FSTD's lifetime; and* *(b) any recurrent documents and reports related to each FSTD and to compliance monitoring activities for a period of at least 5 years.*	AMC1 ORA.GEN.220(b) AMC1 ORA.FSTD.240		

REMARKS

Date ..... Position ..... Signature .....