

Annex V to ED Decision 2025/002/R

'AMC and GM to Part-ORA — Issue 1, Amendment 8'

The text of the amendment is arranged to show deleted, new and unchanged text as follows:

- deleted text is ~~struck through~~;
- new or amended text is highlighted in blue;
- an ellipsis '[...]' indicates that the rest of the text is unchanged.

Note to the reader

In amended, and in particular in existing (that is, unchanged) text, 'Agency' is used interchangeably with 'EASA'. The interchangeable use of these two terms is more apparent in the consolidated versions. Therefore, please note that both terms refer to the 'European Union Aviation Safety Agency (EASA)'.

The Annex to Decision 2012/017/R of the Executive Director of the Agency of 19 April 2012 is amended as follows:

AMC1 ORA.GEN.160 Occurrence reporting system

GENERAL

- (a) In addition to occurrence reporting in accordance with Regulation (EU) No 376/2014, the organisation should report all occurrences defined in AMC 20-8, ~~and as required by the applicable national rules implementing Directive 2003/43/EC² 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.~~

Rationale

RMT.0587

The Directive referred to in this AMC was repealed by Regulation (EU) No 376/2014, hence the text is revised, and the reference is updated. Additionally, since the obligation to report volcanic ash encounter is mandatory as per Regulation (EU) 2015/1018, point (b) of this AMC is obsolete and can be deleted.

AMC1~~2~~ ORA.GEN.200(a)(5) Management system

COMPLEX ORGANISATIONS – ORGANISATION'S SAFETY MANAGEMENT MANUAL

[...]

Rationale

RMT.0587

Based on a Member State's input, it was detected that there are two AMC that have the reference 'AMC1 ORA.GEN.200(a)(5)'. The latter one, placed after GM1 ORA.GEN.200(a)(5) and addressing a complex organisation's safety management manual, needs to be renamed to 'AMC2 ORA.GEN.200(a)(5)'.

GM1 ORA.ATO.110(d) Personnel requirements

- (a) Before allowing an FI that is experienced as specified in point FCL.905.FI(h)(3) to supervise SPIC flights during an IR training course, the ATO should consider at least the following factors:
- (1) the experience of the FI;
 - (2) the experience of the student pilot;
 - (3) the nature and complexity of the SPIC flight to be performed;
 - (4) the complexity and characteristics of the training aircraft; and

(5) the prevailing weather conditions.

(b) The ATO should identify the hazards related to the SPIC supervision and apply appropriate mitigation measures to reduce the associated risks.

Rationale

RMT.0678

See NPA 2020-14, page 63.

After a further internal review, the phrase 'or FSTD' in point (a)(4) is deleted since SPIC flights are not conducted in FSTDs.

AMC2 ORA.ATO.125 Training programme

[...]

(b) Variants

(1) Familiarisation ~~training~~: Where an aeroplane type rating also includes variants of the same aircraft type requiring familiarisation ~~training~~, the additional familiarisation ~~elements training~~ may be included in the theoretical knowledge training of the initial type rating course. ~~Flight training should be conducted on a single variant within the type.~~

[...]

Rationale

RMT.0587

Based on input received from a Member State, the text of point (b)(1) of AMC2 ORA.ATO.125 is updated for the following reasons:

- Familiarisation is not training but self-study, hence the text is revised to no longer refer to 'familiarisation training'.
- Since familiarisation solely consists of self-study, it cannot include flight training. Hence, the second sentence in point (b)(1) does not make sense and is removed.

AMC1 ORA.ATO.135 Training aircraft and FSTDs

[...]

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

(1) aircraft suitably equipped to simulate instrument meteorological conditions (IMC) and for the instrument flight training required. For flight training and testing for the instrument rating and the ~~basic instrument rating (BIR)~~ ~~en-route instrument rating (EIR)~~, an adequate number of IFR certificated aircraft should be available;

[...]

Rationale

RMT.0587

The AMC text still contains a reference to the EIR which, in that context, can be replaced by a reference to the BIR.

AMC1 ORA.ATO.210 Personnel requirements

[...]

(c) In the case of an ATO offering integrated courses, the head of training (HT), the chief flying instructor (CFI) and the chief theoretical-knowledge instructor (CTKI) should be employed full-time or part-time, depending upon the scope of training offered. **The three positions of HT, CFI, and CTKI should not be combined but should be filled by three persons.**

(d) In **all other the cases** of an ATO offering only one of the following:

~~(1) — modular courses,~~

~~(2) — type rating courses, and~~

~~(3) — theoretical knowledge instruction,~~

the positions of HT, CFI and CTKI may be combined and filled by one or two persons with extensive experience in the training conducted by the training organisation, full-time or part-time, depending upon the scope of training offered, **provided that the organisation has demonstrated to the competent authority the adequacy of such personnel set-up for its organisation (point ORA.GEN.200(b)).**

Rationale

RMT.0587

Recurring queries that EASA received from Member States showed interpretation and implementation issues with regard to point (d) of AMC1 ORA.ATO.210. The list in that point is ambiguous (with the term 'one of the following' in the introductory phrase and the word 'and' at the end of point (d)(2)), contains general terms which can be interpreted differently ('modular courses'), and does not address cases where ATOs provide training courses which are not listed (e.g. class rating training, instructor training).

After reviewing the case, EASA concluded that the best option would be to revise that AMC to no longer include such an ambiguous list and to leave more flexibility to the competent authorities, when approving ATOs. In any case, point ORA.GEN.200(b) applies, requiring ATOs to set up a management system with appropriate staffing, as required to perform all intended activities in a safe manner. In this context, it is up to an ATO to demonstrate to the competent authority that safe and rule-compliant training can be ensured with a particular personnel setting.

For this reason, the AMC text is revised. The proposal was already presented to the Aircrew TeB during a meeting on 1 February 2023. During that meeting, many Aircrew TeB members showed support for such a revision of point (d) of that AMC. Based on one comment received during that Aircrew TeB meeting, also point (c) is revised to better clarify that, in the case of integrated courses, indeed three individual persons are required to fill the three positions of HT, CFI, and CTKI.

AMC1 ORA.ATO.230(b) Training manual and operations manual

[...]

(d) Personnel training

- (5) **proficiency** checks to verify that training personnel is proficient with regard to all internal ATO standards, processes and procedures;

[...]

Rationale

RMT.0587

On request by Member States, the text in point (d)(5) is amended to clarify the purpose of (proficiency) checks in terms of this AMC, which are not meant to refer to proficiency checks for revalidation or renewal of pilot ratings.

After an internal review prior to the publication of the ED Decision, text is added to further improve the clarity of the new wording.

AMC1 ORA.ATO.300 General

[...]

(b) [...]

- (6) measurement criteria to determine whether a student has satisfactorily completed the appropriate elements of the course to a standard that, in the judgement of the HT, or **CTKI CGI**, will enable them to be entered for the Part-FCL theoretical examinations with a good prospect of success;

Rationale

RMT.0587

Based on input from a stakeholder, it is proposed to replace the term 'CGI' with the term 'CTKI'. The term CGI refers to 'chief ground instructor', as used in JAR-FCL. In Part-FCL, the term chief theoretical knowledge instructor (CTKI) is used.

AMC1 ORA.FSTD.225(b)(4) Duration and continued validity

~~The assigned person should have experience in FSTDs and training. The person may have FSTD experience or training experience with an education in FSTD evaluation procedures only, provided the other element of expertise is available within the organisation and a procedure for undertaking the annual review and reporting to the competent authority is documented within the compliance monitoring function.~~

EXPERIENCE OF THE ASSIGNED PERSON OR GROUP OF PERSONS

- (a) A person or a group of persons assigned in accordance with point ORA.FSTD.225(b) should:
- (1) be qualified in flight simulation hardware, software, computer modelling or equivalent with sufficient technical knowledge and experience to understand and analyse objective test results, and assess that the FSTD complies with the applicable certification specifications;
 - (2) be qualified to assess the performance, handling and features of the FSTD, hold or have held an instructor certificate and meet either of the following:
 - (i) hold(s) or has (have) held a type/class rating on the aircraft being simulated; or
 - (ii) is (are) assisted by an instructor that holds or has held a rating as specified in point (2)(i), with sufficient flying experience in that type/class to support the evaluation team;
 - (3) have been involved at least in an initial evaluation or one recurrent evaluation carried out by a competent authority within the past 36 months.
- (b) The organisation that operates the FSTD should maintain the list of assigned person(s) qualified to perform the task.

Rationale*RMT.0587 (ex-RMT.0196)*

The purpose of the amendments to AMC1 ORA.FSTD.225(b) is to explain the expected qualification and experience of the EEP person/team within the organisation that operates the FSTD. In general, the revision follows the principles established for the composition of the evaluation team responsible for FSTD evaluation at competent authority level (AMC4 ARA.FSTD.100(a)(1)). The AMC establishes that usually the EEP person is, or the EEP team is usually composed of:

- (1) an FSTD technical expert who is qualified to understand and analyse the FSTD objective test results and assess that the FSTD complies with the applicable certification specifications; and
- (2) a flight crew training expert who holds or has held an instructor certificate and holds or has held a type/class rating on the aircraft being simulated. If the flight crew training expert is not type-/class-rated on the aircraft being simulated, they should be supported by a pilot who is an instructor and holds or has held a rating for the aircraft being simulated and have flying experience in that type/class of aircraft.

Depending on the complexity of the FSTD, the roles of the FSTD technical expert and the flight crew training expert could be performed by one person who satisfies the criteria above.

Furthermore, the EEP person or group of persons is (are) expected to have experience in evaluation carried out by a competent authority in the past 36 months. This is to facilitate that the person(s) responsible for the EEP has (have) current knowledge and practical experience of how to perform an evaluation for FSTD under EEP, based on their experience in evaluations performed by a competent authority.

Point (b) of this AMC is included based on the same text proposed in NPA 2020-15.

When presenting the draft for that AMC to the FSTD focal points from national competent authorities of the Member States, a comment was raised on the need to have a second pilot in the case of simulation of complex motor-powered aircraft. That comment is addressed in GM2 ORA.FSTD.225(b).

AMC2 ORA.FSTD.225(b) Duration and continued validity**EXTENDED RECURRENT EVALUATION PERIOD — ORGANISATION'S DOCUMENTATION**

- (a) For the purpose of extending the recurrent evaluation period of an FSTD, the organisation that operates the FSTD should provide the following to the competent authority:
- (1) a declaration that the organisation that operates the FSTD fulfils the criteria of point ARA.FSTD.120(c)(1);
 - (2) the procedures in accordance with point ARA.FSTD.120(c)(4);
 - (3) the qualification and experience of the person(s) assigned in accordance with point ORA.FSTD.225(b);
 - (4) the FSTD performance evaluation metrics developed in accordance with AMC2 ORA.FSTD.100 for the previous 2 years;
 - (5) the evaluation reports together with the follow-up reports for the previous 2 years.
- (b) The assigned person or group of persons should provide a dossier with the same content as for a recurrent evaluation for information to the competent authority 14 days before performing the tasks under point ORA.FSTD.225(b).
- Note:* Further guidance on the content of the dossier for a recurrent evaluation can be found in GM3 ORA.FSTD.100, point(d).
- (c) The assigned person or group of persons should prepare a report following the objective, functions and subjective testing with results, including any items identified during the conduct of the tasks described in point ORA.FSTD.225(b). The report should be submitted to the competent authority within the period specified in point ORA.FSTD.225(b).

Rationale*RMT.0587 (ex-RMT.0196)*

Point (a) of this AMC provides an overview of the documentation which the organisation that operates the FSTD needs to provide to the competent authority prior to its decision to extend the recurrent evaluation period. Based on the assessment of these documents, the competent authority may take the decision to extend, or not, the recurrent evaluation period of the FSTD. Point (a)(4) envisages that the organisation should provide FSTD performance metrics which give information on the usage and performance of the FSTD. Such metrics are currently envisaged in AMC2 ORA.FSTD.100. Evaluation reports with follow-up reports are included in point (a)(5) due to the fact that in some cases (FSTD located in third countries), such reports are not always easily accessible by the competent authority.

Point (b) of this AMC envisages that the organisation should send a dossier, whose scope is already defined in GM3 ORA.FSTD.100. The rationale for this is that the competent authority is informed about the status of the FSTD at each recurrent 12-month period and before the organisation performs the EEP tasks.

Point (c) of this AMC clarifies that the assigned person or group of persons should prepare and submit a report to the authority following the completion of the EEP tasks.

The text was consulted with the FSTD focal points from national competent authorities of the Member States on 10 June 2024. No changes were proposed as a result of this consultation.

GM1 ORA.FSTD.225(b) Duration and continued validity**INDEPENDENCE OF THE ASSIGNED PERSON(S)**

An effective compliance monitoring function is necessary to support the implementation of the extended evaluation period. It is essential that an appropriate level of independence be maintained, and the tasks referred to in point ORA.FSTD.225(b) should not be undertaken by a person that, within the previous 12-month recurrent period, was involved in the tasks referred to in point ORA.FSTD.105(b) for the relevant FSTD being evaluated.

Rationale*RMT.0587 (ex-RMT.0196)*

That new GM explains the expected level of independence of the person(s) who is (are) assigned to perform the EEP tasks. The independence is considered essential to ensure that the EEP person(s) is (are) 'not checking their own work'. Therefore, the GM recommends that the tasks under the EEP should not be undertaken by the person(s) who maintains (maintain) the FSTD, and more concretely, who analyses (analyse) and evaluates (evaluate) the FSTD MQTG results (both objective tests and functions and subjective tests).

The text was consulted with the FSTD focal points from national competent authorities of the Member States on 10 June 2024. No changes were proposed following that consultation.

GM2 ORA.FSTD.225(b) Duration and continued validity**PROCESS TO CONDUCT THE FUNCTIONS AND SUBJECTIVE TESTS**

When conducting the functions and subjective tests, especially for a complex motor-powered aircraft, the assigned person or group of persons, when being qualified in accordance with point (a)(2)(i) of AMC1 ORA.FSTD.225(b), should be supported by a pilot who holds or has held a rating on the same or similar type as the aircraft being simulated.

Rationale*RMT.0587 (ex-RMT.0196)*

After consultations with the FSTD focal points from national competent authorities of the Member States on 10 June 2024, this GM is added to clarify that a supporting pilot is recommended when running the functions and subjective tests, mainly for a complex motor-powered aircraft. The reasoning is that the supporting pilot shares the related workload in performing the functions and subjective testing.

Furthermore, it clarifies that such a supporting pilot is only needed when the assigned person(s) is (are) qualified in accordance with point (a)(2)(i) of AMC1 ORA.FSTD.225(b). Otherwise, when the assigned person(s) is (are) not type/class rated on the aircraft being simulated, they are supported by an instructor that holds or has held a type/class rating on the aircraft being simulated (according to AMC1 ORA.FSTD.225(b), point (2)(a)(ii)). Therefore, in such cases there is no need for a supporting pilot.

As regards the qualification of the supporting pilot, it is deemed relevant that the supporting pilot is rated on a similar type as the aircraft being simulated and not necessarily on the same type of the aircraft being simulated. The reason is that the assigned person already has this qualification.

Finally, adding it in the GM ensures that this arrangement is considered when determining the EEP team, but there are also other possible arrangements in organising the EEP team as per AMC1 ORA.FSTD.225(b).

Subpart AeMC — Aero-medical Centres

SECTION I — GENERAL

GM1 ORA.AeMC.105 Scope

It is recommended that AeMCs provide support to regional AME peer groups in order to enhance professional expertise.

Rationale

RMT.0287

In the previous update of Part-MED, EASA recommended the creation of AME peer groups to mitigate the risk of working in isolation. Discussions during the MEG meeting revealed the fact that such AME peer groups have not been created in most of the Member States. The MEG members considered that the AeMCs should play a role in supporting such support groups. In reaction to the feedback received during the MEG meeting, the rulemaking group considered that the development of GM would be beneficial to demonstrate the role of the AeMC in the development of the regional AME peer groups.

In this context, and following the comments mentioned above, this new GM was created.

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 and of supporting specialist consultants, and a list of medical and technical facilities for initial class 1 and class 3 aero-medical examinations, as applicable according to the scope of the AeMC approval and of supporting specialist consultants.
- ~~(b) The AeMC should provide details of clinical attachments to hospitals, medical institutions and/or specialists.~~
- (b) Medical staff should be sufficient to perform the standard required medical examinations to be performed within the organisation of the AeMC.
- (c) The standard required medical examinations should at least encompass the following specialities: ophthalmology including colour vision, otorhinolaryngology, cardiology and mental health.
- (d) Contracted activities with designated hospitals or medical institutes for the purpose of additional specialist medical examinations include clinical attachments or liaison with hospitals, medical institutions and/or specialists.

Rationale

RMT.0287

The standardisation experience and the discussions in the MEG highlighted the fact that many organisations when applying for AeMCs do not have sufficient medical experts on staff to cover the

standard medical examinations required to be performed within the organisation. Furthermore, these organisations do not have proper documentation for contracted activities.

In this context, and following the discussions mentioned above, this AMC is updated and extended to provide clear information regarding the intention and meaning of the initial documentation to be provided when applying for an AeMC certification.

AMC1 ORA.AeMC.135 Continued validity

EXPERIENCE

- (a) A total of ~~A~~ at least 200 class 1, class 3 or equivalent military aero-medical examinations and assessments should be performed at ~~an~~ the AeMC every year.
- (b) In Member States where the number of aero-medical examinations and assessments mentioned in ~~point~~ (a) cannot be reached due to a low number of professional pilots or ATCOs, a proportionate number, as defined by the competent authority, of class 1 or class 3 aero-medical examinations and assessments should be performed.
- (c) In these cases, the continued ~~ing~~ experience of the ~~head-of~~ AMEs in an the AeMC ~~and aero-medical examiners on staff should~~ may 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, class 3 or equivalent military medical certificates.
- (d) Aero-medical research including publication in peer-reviewed journals may also be accepted as contributing to the continued experience of the AMEs in ~~head-of, and aero-medical examiners at,~~ an AeMC.

Rationale

RMT.0287

In the context of ORA.AeMC requirements and AMC/GM being applicable also to AeMCs performing class 3 medical examinations, the rulemaking group proposed to update the text to add the reference to class 3.

SECTION II — MANAGEMENT

AMC1 ORA.AeMC.200 Management system

- (a) In order to maintain personnel trained and competent to perform their tasks as specified in ORA.GEN.200(a)(4), the management system should ensure that each AME performs a sufficient number of aero-medical examinations and assessments to meet the professional standards of an AeMC. The required activity of each AME should be specified in the management system.
- (b) The management system should encompass regular exchange of professional expertise including case analysis.

Rationale

RMT.0287

The standardisation experience revealed the fact that in many cases the AeMC management systems do not give proper consideration to the training and competence of personnel and the risk resulting from insufficient recurrent training. The discussions in the MEG identified the need to clarify the management system provisions regarding personnel training.

Consequently, the rulemaking group proposed to add a new AMC to ensure that personnel is and remains properly trained and competent.

GM2 ORA.AeMC.200 Management system

The assessment of the AeMC's management system by a national health authority may be a part of the AeMC's overall management system.

Rationale

RMT.0287

The standardisation experience and the discussions in the MEG highlighted the fact that in some cases AeMCs as health institutions are overseen also by national health authorities. In such cases a specific management system is assessed and approved by those health authorities; such approvals of parts of the management system that may be relevant for aviation may be credited during the certification and oversight processes by the competent authority certifying the respective AeMC.

Consequently, the rulemaking group proposed to add this GM to provide information to the AeMCs and competent authorities that certain areas of the management system could be credited where appropriate.

AMC1 ORA.AeMC.205(a) Contracted activities

In addition to the documentation for the approval of an organisation listed in AMC1 ORA.GEN.205, the AeMC should provide a written declaration of their subcontractor that contracted examinations or assessments will be performed on the basis of the requirements of Regulation (EU) No 1178/2011 and associated AMC and GM.

Rationale

RMT.0287

The implementation experience revealed during the standardisation inspections and the discussions in the MEG highlighted the need for regulatory material to clarify the contracted activities. As a result, the rulemaking group proposed implementing rules as well as AMC to clarify what part of the examinations must be undertaken inside and what can be outsourced by means of these contracted activities.

In this context, and following the discussions mentioned above, this AMC is added to provide clear information regarding the intention and meaning of the conditions related to the contracted activities outsourced by the AeMC.

AMC1 ORA.AeMC.210 Personnel requirements

GENERAL

- ~~(a) The An~~ An aero-medical examiner (AME) should have held ~~AME class 1~~ AME class 1 privileges, as applicable in accordance with the scope defined in the terms of approval attached to the AeMC's certificate ~~for at least 5 years~~ and have performed at least 200 aero-medical examinations and assessments for a class 1, class 3 or equivalent military 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.~~

Rationale

RMT.0287

The rulemaking group and the discussions in the MEG highlighted the importance of having properly trained and qualified head of AeMC making decisions on initial class 1 or class 3 aero-medical examinations and providing training for other AMEs. Consequently, the rulemaking group proposed to clarify the previous wording. Additionally, the group proposed to delete point (b) of this AMC as its content was added to ORA.AeMC.105.

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 equipment for:

(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; ~~and~~
 - (9) contrast sensitivity, including mesopic conditions with and without glare.
- (c) Hearing
- (1) pure-tone audiometer
- (d) Otorhinolaryngology (ENT)
- 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 through contracted activities ~~with a service provider~~:
- (1) clinical laboratory facilities; ~~and~~
 - (2) ultrasound of the abdomen;
 - (3) exercise ECG;
 - (4) 24-hour heart rhythm monitoring;
 - (5) 24-hour blood pressure monitoring; and
 - (6) mental health assessment including psychometric testing.

Rationale

RMT.0287

The rulemaking group and the discussions in the MEG highlighted the fact that certain equipment for cardiovascular evaluation is used occasionally and having it part of the standard equipment in an AeMC is a burden for the AeMCs in acquiring and maintaining such equipment while it may be readily available in specialised medical practices. Consequently, the rulemaking group proposed to move these pieces of equipment to point (f) of the AMC dedicated to facilities that may be arranged with a service provider as part of contracted activities. Additionally, the rulemaking group proposed to also add mental health assessment facilities including psychometric testing in point (f) as well considering the requirements for a comprehensive mental health assessment for class 1 initial examination added following the safety recommendation resulting from the GermanWings accident.

Furthermore, during the last round of consultation with the MEG, some of the members highlighted that mesopic contrast sensitivity is part of the comprehensive eye examination required for the initial class 1. Consequently, it was added to the list of facilities needed for ophthalmological examination.