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ANNEXES 1 to 7

ANNEXES

to the proposal for a

Regulation of the European Parliament and of the Council

establishing a Union certification system for aviation security screening equipment

{SWD(2016) 259 final}
{SWD(2016) 261 final}

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Annex I

PERFORMANCE REQUIREMENTS

The performance requirements which must be fulfilled are the following:

performance requirements as laid down in the Regulation (EU) No 300/2008 of the European Parliament and of the Council[1] and its supplementing and implementing acts.

[1] Regulation (EU) No 300/2008 of the European Parliament and of the Council of 11 March 2008 on common rules in the field of civil aviation security and repealing Regulation (EC) No 2320/2002 (OJ L 97, 9.4.2008, p. 72)

Annex II

EU CERTIFICATE OF CONFORMITY

1. GENERAL DESCRIPTION

The certificate of conformity shall be established in a maximum format A4 (210 × 297 mm) or a folder of maximum format A4. The hard copy may be replaced by an electronic file.

EU CERTIFICATE OF CONFORMITY

The undersigned [..... (*Full name and position*)]

hereby certifies that the equipment:

0.1. Make (Trade name of manufacturer): ....

0.2. Type: ....

0.3 Configuration: ....

0.4 Commercial name: ....

0.5. Equipment category: ....

0.6. Name and address of manufacturer: .....

0.7. Location of the equipment identification number: .....

0.8. Name and address of the manufacturer's representative (if any): .....

0.9. Equipment identification number: .....

conforms in all respects to the type described in approval (..... *EU type-approval certificate number including extension number if any*) issued on (..... *date of issue*) and can be permanently made available or put into service in the Member States.

(Place) (Date): …….. (Signature):.....

Annex III

EU TYPE-APPROVAL MARK

1. The EU type-approval number shall consist of five sections as follows: In all cases, the sections shall be separated by the '*' character.

Section 1: The lower case letter 'e' followed by the distinguishing number of the Member State issuing the EU type-approval:

1 for Germany; 2 for France; 3 for Italy; 4 for the Netherlands; 5 for Sweden; 6 for Belgium; 7 for Hungary; 8 for the Czech Republic; 9 for Spain; 11 for the United Kingdom; 12 for Austria; 13 for Luxembourg; 17 for Finland; 18 for Denmark; 19 for Romania; 20 for Poland; 21 for Portugal; 23 for Greece; 24 for Ireland; 25 for Croatia; 26 for Slovenia; 27 for Slovakia; 29 for Estonia; 32 for Latvia; 34 for Bulgaria; 36 for Lithuania; 49 for Cyprus; 50 for Malta.

Section 2: The number of the base directive or regulation.

Section 3: The identification number or letter of the latest performance requirement applicable to that equipment and against which the approval is granted

Section 4: A four-digit sequential number (with leading zeroes as applicable) to denote the base EU type-approval number. The sequence shall start from 0001.

Section 5: A two-digit sequential number (with leading zeros if applicable) to denote the extension. The sequence shall start from 00 for each base approval number.

2. Example of a third type-approval (which as yet no extension) issued by France to Commission Regulation (EU) 185/2010:

e2*185/2010*ETD1*0003*00

Annex IV

COMMON TESTING METHODOLOGIES FOR THE PURPOSE OF TYPE-APPROVAL OF AVIATION SECURITY SCREENING EQUIPMENT

The common testing methodologies to be applied for the tests referred to in Article 8 are the Common Testing Methodologies (CTMs) developed in the framework of the Common Evaluation Process (CEP) approved by the European Civil Aviation Conference (ECAC).

Annex V

MODEL

[EXTENSION OF] [REFUSAL OF] [WITHDRAWAL OF]

EU TYPE-APPROVAL CERTIFICATE

Maximum format: A4 (210 × 297 mm)

EU AVIATION SECURITY SCREENING EQUIPMENT

Stamp of approval authority

With regard to Regulation…

[EU type-approval number:]

[Reason for extension][Reason for refusal][Reason for withdrawal]:

[EU type-approval extension number]

SECTION I

0.1. Make (trade name of manufacturer):

0.2. Type:

0.2.1. Configuration:

0.2.2. Commercial name(s)[2]:

0.3. Means of identification of type and configuration, if marked on the aviation screening equipment:

0.3.1. Location of the marking/s:

0.4. Category of equipment[3] :

[2] If not available at the time of granting the type-approval, this item shall be completed at the latest when the equipment is introduced on the market.

[3] As defined in the Commission Regulation (EU) No 185/2010 of 4 March 2010 laying down detailed measures for the implementation of the common basic standards on aviation security

0.5. Name and address of manufacturer

0.6. Name(s) and address(es) of assembly plant(s):

0.7. Name and address of the manufacturer's representative (if any):

SECTION II

The undersigned hereby certifies the accuracy of the manufacturer's description in the attached information document of the aviation security screening equipment described above ((a) sample(s) having been selected by the EU type-approval authority and submitted by the manufacturer as prototype(s) of the equipment type) and that the attached test results are applicable to the equipment type and configuration.

[the following section does not apply in case of extension or revision of EU type approval certificate:

1. The equipment type meets/does not meet (1) the performance requirements of [all the relevant regulatory acts in Annex I to this Regulation]

2. The approval is granted/refused/withdrawn (1)].

(Place) (Signature) (Date)

Attachments:

Information package.

Test results

Name(s) and specimen(s) of the signature(s) of the person(s) authorised to sign certificates of conformity and a statement of their position in the approval authority.

ANNEX VI

CONFORMITY OF PRODUCTION PROCEDURES

Conformity of production procedures include inseparably the assessment of quality management systems, referred to below as 'initial assessment' and verification by the approval authority and product-related controls, referred to as 'production conformity arrangements'.

1. **Initial assessment**

1.1. The approval authority of a Member State shall verify the existence of satisfactory arrangements and procedures for ensuring effective control so that produced equipment conforms to the approved type.

1.2. Guidance for conducting assessments may be found in the relevant harmonised standards Guidelines for quality and/or environmental management systems auditing.

1.3. The approval authority issuing the EU type-approval certificate shall verify the arrangements and procedures referred to in point 1.1

1.3.1. The initial assessment and/or verification of production conformity arrangements shall be carried out by the approval authority granting the approval or an appointed body acting on behalf of the approval authority.

1.3.1.1. When considering the extent of the initial assessment to be carried out, the approval authority may take account of available information relating to the manufacturer's certification described in point 1.3.3, which has not been taken into account or recognised under that point.

1.3.2. The initial assessment and/or verification of production conformity arrangements may also be carried out by the approval authority of another Member State or the appointed body designated for this purpose by the approval authority.

1.3.2.1. In such a case, the approval authority of the other Member State shall prepare a statement of compliance outlining the areas and production facilities it has covered as relevant to the equipment to be type-approved and to the regulatory acts according to which this equipment is to be type-approved.

1.3.2.2. On receiving an application for a compliance statement from the approval authority of a Member State which issued an EU type-approval certificate, the approval authority of another Member State shall send without delay the statement of compliance or advise that it is not in a position to provide such a statement.

1.3.2.3. The statement of compliance shall include at least the following:

(a) Group or company

(b) Particular organisation

(c) Plants/Sites (e.g. Equipment Plant 1 (United Kingdom))

(d) Equipment (e.g. ETD)

(e) Documents examined (e.g. Company and site quality manual and procedures)

(f) Date of the assessment (e.g. Audit conducted from 18 to 30.5.2009)

(g) Planned monitoring visit (e.g. October 2010)

1.3.3. The approval authority shall also accept the manufacturer's certification to harmonised standard EN ISO 9001:2008 or an equivalent harmonised standard as satisfying the initial assessment requirements of point 1. The manufacturer shall provide details of the certification and undertake to inform the approval authority of any revisions to its validity or scope.

2. Production conformity arrangements

2.1. The approval authority of a Member State shall verify the existence of adequate arrangements and documented control plans, to be agreed with the manufacturer for each approval, to carry out at specified intervals those tests or associated checks necessary to verify continued conformity with the approved type including any relevant physical tests specified in the regulatory acts.

2.2. The holder of an EU type-approval certificate shall, in particular:

2.2.1. ensure the existence and application of procedures for effective control of the conformity of products with the approved type and configuration;

2.2.2. have access to the testing, or other appropriate, equipment necessary for checking the conformity with each approved type and configuration;

2.2.3. ensure that test or check results data are recorded and that any annex document related to the test results remain available for a period to be determined in agreement with the approval authority. That period shall not exceed 10 years;

2.2.4. analyse the results of each type of test or check, in order to verify and ensure the stability of the product characteristics, making allowance for variation of an industrial production;

2.2.5. ensure that, for each type and configuration of aviation security screening equipment, at least the correctly built specifications in relation to the approval and the information required for certificates of conformity in Annex II is verified;

2.2.6. ensure that any set of samples or test pieces giving evidence of non-conformity in the type of test or check in question, give rise to a further sampling and test or check. All the necessary steps shall be taken to restore conformity of the corresponding production.

3. Continued verification arrangements

3.1. The authority which has issued an EU type-approval certificate may at any time verify the conformity control methods applied in each production facility.

3.1.1. The normal arrangements shall be to monitor the continued effectiveness of the procedures laid down in Sections 1 and 2 (initial assessment and product conformity arrangements).

3.1.1.1. Surveillance activities carried out by notified technical services shall be accepted as satisfying the requirements of point 3.1.1 with regard to the procedures established at initial assessment.

3.1.1.2. The normal frequency of verifications by the approval authority (other than those referred to in point 3.1.1.1) shall be such as to ensure that the relevant controls applied in accordance with Sections 1 and 2 are reviewed over a period consistent with the climate of trust established by the approval authority.

3.2. At every review, records of tests or checks and records of production shall be made available to the inspector; in particular, records of those tests or checks documented as required in point 2.2.

3.3. The inspector may select samples at random to be tested in the manufacturer's laboratory or in the facilities of the technical service. In such a case only physical test shall be carried out. The minimum number of samples may be determined according to the results of the manufacturer's own verification.

3.4. Where the level of control appears unsatisfactory, or when it seems necessary to verify the validity of the tests carried out in accordance with point 3.2, the inspector shall select samples to be sent to a technical service to perform physical tests.

3.5. Where unsatisfactory results are found during an inspection or a monitoring review, the approval authority shall ensure that all necessary steps are taken to restore conformity of production as rapidly as possible.

Annex VII

STANDARDS WITH WHICH TECHNICAL SERVICES HAVE TO COMPLY

1. The standards to be complied with by the technical services for activities related to EU type-approval testing are the following:

1.1. Category A (tests performed in own facilities): the relevant harmonised standards on the general requirements for the competence of testing and calibration laboratories. A technical service designated for category A activities may carry out or supervise the tests in the facilities of a manufacturer or of a third party.

1.2. Category B (supervising of tests performed in the manufacturer's facilities or in the facilities of a third party): the relevant harmonised standards on the general criteria for the operation of various types of bodies performing inspection. Before performing or supervising any test in the facilities of a manufacturer or of a third party, the technical service shall check that the tests facilities and measurement devices comply with the appropriate requirements of the standard referred to in point 1.1.

2. The standards to be complied with by the technical services for activities related to Conformity of Production verification are the following:

2.1. Category C (procedure for the Initial Assessment and surveillance audits of the manufacturer's quality management system): the relevant harmonised standards on the requirements for bodies providing audit and certification of management systems.

2.2. Category D (inspection or testing of production samples or supervision thereof): the relevant harmonised standards on the general criteria for the operation of various types of bodies performing inspection.