

## ***European Aviation Safety Agency***

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**DECISION N° 2010/016/R  
OF THE EXECUTIVE DIRECTOR OF THE EUROPEAN AVIATION SAFETY AGENCY**

**OF 16 DECEMBER 2010**

**amending the Annex to Decision No. 2003/01/RM of the Executive Director of  
the Agency of 17 October 2003**

**on**

**Acceptable Means of Compliance and Guidance Material for the airworthiness  
and environmental certification of aircraft and related products, parts and  
appliances, as well as for the certification of design and production  
organisations**

**(«AMC and GM to Part-21»)**

***'Extended Range Operations with Two-Engined Aeroplanes ETOPS Certification  
and Operation'***,

***'Systematic review and transposition of existing FAA TSO standards for parts  
and appliances into EASA ETSO'***

**And**

***'Other party supplier control'***

THE EXECUTIVE DIRECTOR OF THE EUROPEAN AVIATION SAFETY AGENCY,

Having regard to the Regulation (EC) No 216/2008 of the European Parliament and of the Council of 20 February 2008 on common rules in the field of civil aviation and establishing a European Aviation Safety Agency, and repealing Council Directive 91/670/EEC, Regulation (EC) No 1592/2002 and Directive 2004/36/EC<sup>1</sup> (hereinafter 'The Basic Regulation'), and in particular Articles 18(c), 38(3)(a) and (e) thereof,

Having regard to the Commission Regulation (EC) No 1702/2003 of 24 September 2003 laying down implementing rules for the airworthiness and environmental certification of aircraft and related products, parts and appliances, as well as for the certification of design and production organisations<sup>2</sup>,

<sup>1</sup> OJ L 79, 19.03.2008, p. 1.

<sup>2</sup> OJ L 243, 27.9.2003, p. 6. Regulation as last amended by Regulation (EC) No 1194/2009 of 30 November 2009 (OJ L 321, 8.12.2009, p. 5).

Whereas:

- (1) The Agency shall, pursuant to Article 18 of the Basic Regulation, issue Certification Specifications, including Airworthiness Codes and Acceptable Means of Compliance, as well as guidance material for the application of the Basic Regulation and its Implementing Rules.
- (2) The Agency is obliged, pursuant to Article 19 of the Basic Regulation, to reflect the state of the art and the best practices in the fields concerned and to update the Certification Specifications taking into account the worldwide aircraft experience in service, and scientific and technical progress.
- (3) The Agency, pursuant to Article 52(1)(c) of the Basic Regulation and articles 5(3) and 6 of the Rulemaking Procedure<sup>3</sup>, has widely consulted interested parties on the matters that are subject of this Decision and has provided thereafter a written response to the comments received<sup>4</sup>.
- (4) Rulemaking task MDM.001 aimed at providing an improved set of requirements containing guidance for both holders of type-certificate and operators to support ETOPS.
- (5) Chapter 21A.3(a) of Part-21 already requires certificate and approval holders to have a 'System for Collection, Investigation and Analysis of Data'. However, there are no associated existing Acceptable Means of Compliance (AMC) detailing how this process is expected to be put in place. For this reason, the Agency has decided to create a new AMC explaining what is expected in the case of ETOPS significance occurrences.
- (6) Rulemaking task ETSO.007 proposes introduction of new ETSO specifications that are, where possible, technically similar to the existing Federal Aviation Administration (FAA) TSO.
- (7) These new ETSO standards require statements regarding environmental categories and design assurance levels for complex hardware. The standard form for the Declaration of Design and Performance does not show these new requirements. For this reason, the Agency has decided to amend the current standard form provided in the AMC&GM to Part-21 and include the new requirements.
- (8) Rulemaking task 21.042 aimed at providing criteria for holders of a Production Organisation Approval (POA) for supplier surveillance and assessment by a party other than the POA holder.
- (9) The Agency therefore decided to create new AMC's that the POA holder can use for supplier surveillance and assessment by a party other than the POA holder. These AMC provide criteria for the POA holder to show that, while the POA holder retains full responsibility, a party other than the POA holder performs supplier surveillance and assessment activities.

HAS DECIDED:

#### Article 1

The Annex 'Acceptable Means of Compliance and Guidance Material to be used in the airworthiness certification of products, parts and appliances and the approval of

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<sup>3</sup> Management Board Decision concerning the procedure to be applied by the Agency for the issuing of opinions, certification specifications and guidance material (Rulemaking Procedure), EASA MB/08/07, 13.6.2007.

<sup>4</sup> See NPA 2008-01 & CRD 2008-01, NPA 2009-11 & CRD 2009-11 and NPA 2010-01 & CRD 2010-01 available at [http://www.easa.europa.eu/ws\\_prod/r/r\\_archives.php](http://www.easa.europa.eu/ws_prod/r/r_archives.php).

16/12/2010

organisations involved in their design or manufacture' to Decision ED/2003/01/RM of the Executive Director of the Agency of 17 October 2003 is hereby amended as provided in Annex 1 to this decision.

Article 2

This decision shall enter into force on 23 December 2010. It shall be published in the Official Publication of the Agency.

Done in Cologne, on 16 December 2010.

P. GOUDOU

## Annex 1 to ED Decision 2010/016/R

The Annex 'Acceptable Means of Compliance and Guidance Material to be used in the airworthiness certification of products, parts and appliances and the approval of organisations involved in their design or manufacture' to Decision ED/2003/01/RM of the Executive Director of the Agency of 17 October 2003 is hereby amended as follows:

The text of amendments is arranged to show deleted text or new text as shown below:

1. Text to be deleted is shown with a ~~strike through~~.
2. New text to be inserted is highlighted with grey shading.
3. ... Indicates that remaining text is unchanged in front of or following the reflected amendment.

The title of AMC to 21A.3(a) is amended as follows:

**AMC No 1 to 21A.3(a)**

A new AMC No 2 to 21A.3(a) is added as follows:

**AMC No 2 to 21A.3(a) Collection, investigation and analysis of data related to ETOPS significant occurrences**

- (1) Holders of a type-certificate, restricted type-certificate, supplemental type-certificate or any other relevant approval deemed to have been issued under Part-21 and which includes extended range operation with two-engined aeroplane (ETOPS) capability should implement a specific tracking, reporting and resolution system for ETOPS significant occurrences, suitable to ensure the initial and continued fleet compliance with the applicable ETOPS reliability objectives. This system should be part of the system for collection, investigation and analysis of data required by 21.A.3(a).  
Appropriate coordination should exist between Engine TC holder, propeller TC holder and APU ETSO approval holder with the aircraft TC holder to ensure compliance with the ETOPS reliability objectives.
- (2) For tracking, reporting and resolution of ETOPS significant occurrences refer to EASA AMC 20-6.

The GM No. 2 to 21A.139(a) is amended as follows:

**GM No. 2 to 21A.139(a)**

**Quality System – Conformity of supplied parts or appliances**

The POA holder is responsible for determining and applying acceptance standards for physical condition, configuration status and conformity of supplied products, parts or appliances, whether to be used in production or delivered to customers as spare parts. This responsibility also includes BFE (Buyer Furnished Equipment) items.

To discharge this responsibility the quality system needs an organisational structure and procedures to adequately control external suppliers. Elements of the quality system for the control of suppliers may be performed by other parties provided that the conditions of AMC No. 1 or No. 2 to 21A.139(b)(1)(ii) are met.

Control can be based upon use of the following techniques (as appropriate to the system or product orientation necessary to ensure conformity).

- qualification and auditing of supplier's quality system,
- ....

The following new AMC No. 1 to 21A.139(b)(1)(ii) is introduced:

#### **AMC No. 1 to 21A.139(b)(1)(ii)**

**Vendor and sub-contractor assessment, audit and control – Production Organisation Approval (POA) holder using documented arrangements with other parties for assessment and surveillance of a supplier.**

#### **1 General**

##### Note

*For the purpose of this AMC, vendors and sub-contractors are hereafter referred to as "suppliers", regardless of whether or not they hold a POA and audit and control is hereafter referred to as "surveillance".*

The production organisation is required by Part-21 to demonstrate that it has established and maintains a quality system that enables the organisation to ensure that each item produced conforms to the applicable design data and is in a condition for safe operation. To discharge this responsibility, the quality system should have, among other requirements, procedures to adequately carry out the assessment and surveillance of suppliers.

The use of Other Parties (OP), such as a consulting firm or quality assurance company, for supplier assessment and surveillance does not exempt the POA holder from its obligations under 21A.165. The supplier assessment and surveillance, corrective action and follow-up activity conducted at any of its supplier's facilities may be performed by OP.

The purpose of using an OP cannot be to replace the assessment, audit and control of the POA Holder. It is to allow an element (i.e. the assessment of the quality system) to be delegated to another organisation under controlled conditions.

The use of OP to perform supplier assessments and surveillance should be part of the production organisation quality system and fulfil the conditions of this AMC.

This AMC is applicable to a method whereby a POA holder has a documented arrangement with OP for the purpose of assessing and/or surveying a POA's supplier.

#### **2 Approval by the Competent Authority.**

Implementing or changing procedures for using OP for supplier assessment and surveillance is a significant change to the quality system and requires approval in accordance with 21A.147.

#### **3 Conditions and criteria for the use of OP to perform supplier assessment and surveillance.**

- The POA holder should include the use of OP for supplier assessment and surveillance in the POA holders' quality system to demonstrate compliance with the applicable requirements of Part-21.
- Procedures required for using OP for supplier assessment and surveillance should be consistent with other procedures of the POA holders' quality system.
- Procedures of the POA holder that uses OP to perform supplier assessment and surveillance should include the following:

- (1) Identification of the OP that will conduct supplier assessment and surveillance.

- (2) A listing of suppliers under surveillance by the OP. This listing should be maintained by the POA holder and made available to the Competent Authority upon request.
- (3) The method used by the POA holder to evaluate and monitor the OP. The method should include the following as a minimum:
  - (i) Verification that standards and checklists used by the OP are acceptable for the applicable scope.
  - (ii) Verification that the OP is appropriately qualified and have sufficient knowledge, experience and training to perform their allocated tasks.
  - (iii) Verification that the OP surveillance frequency of the suppliers is commensurate with the complexity of the product and with the surveillance frequency established by the POA holder's suppliers control programme.
  - (iv) Verification that the suppliers' assessment and surveillance is conducted on-site by the OP.
  - (v) Verification that the OP has access to applicable proprietary data to the level of detail necessary to survey suppliers functions.

Where the POA holder uses an OP accredited by a signatory to the European cooperation for Accreditation (EA) Multilateral Agreement and working in accordance with an aviation standard (e.g. EN 9104 series of requirements) that describes requirements for the other party assessment and surveillance, the items (ii) and (iv) shall be deemed to be complied with.

- (4) A definition to what scope the OP will conduct suppliers surveillance on behalf of the POA holder. If the OP replaces surveillance in part, the POA holder should identify the functions that will continue to be surveyed by the POA holder.
- (5) The procedures used by the OP to notify the POA holder of nonconformities discovered at the suppliers facility, corrective action and follow-up.

(d) The POA should make arrangements that allow the Competent Authority to make investigation in accordance with 21A.157 to include OP activities.

The following new AMC No. 2 to 21A.139(b)(1)(ii) is introduced:

### **AMC No. 2 to 21A.139(b)(1)(ii)**

#### **Vendor and sub-contractor assessment, audit and control - Production Organisation Approval (POA) holder using other party supplier certification**

##### **1 General**

###### Note

*For the purpose of this AMC, vendors and sub-contractors are hereafter referred to as "suppliers", regardless of whether or not they hold a POA and audit and control is hereafter referred to as "surveillance".*

Other party supplier certification is a method whereby a supplier contracts with an appropriately recognised or accredited Other Party (OP) for the purpose of obtaining a certification from that OP. Certification indicates that the supplier has satisfactorily demonstrated to meet the applicable standard on a continuing basis. OP certification results in placing the supplier on the OP list of certified organisations, or in the supplier receiving a certificate identifying the requirements that have been met. Periodic follow-up evaluations are conducted by the OP to verify continued compliance with the requirements of the applicable standard.

The production organisation is required by Part-21 to demonstrate that it has established and maintains a quality system that enables the organisation to ensure that each item produced conforms to the applicable design data and is in a condition for safe operation. To discharge this responsibility, the quality system should have, among other requirements, procedures to adequately carry out the assessment and surveillance of suppliers.

The assessment and surveillance of suppliers by an OP should be deemed to satisfy the requirements of 21A.139(b)(1)(ii) when the conditions of this AMC are satisfied. The assessment and surveillance of suppliers by OP as part of supplier certification does not exempt the POA holder from its obligations under 21A.165. The supplier assessment and surveillance, corrective action and follow-up activity conducted at any of its supplier's facilities may be performed by OP.

The purpose of using an OP cannot be to replace the assessment, audit and control of the POA Holder. It is to allow an element (i.e. the assessment of the quality system) to be delegated to another organisation under controlled conditions.

The use of suppliers that are certified by OP in accordance with this AMC should be part of a production organisation quality system.

##### **2 Approval by the Competent Authority.**

Implementing or changing procedures for using suppliers that are certified by an OP is a significant change to the quality system and requires approval in accordance with 21A.147.

##### **3 Conditions and criteria for using supplier certification for the supplier assessment and surveillance.**

- (a) The POA holder should include the use of supplier certification for the supplier assessment and surveillance in the POA holder's quality system to demonstrate compliance with the applicable requirements of Part-21.
- (b) Procedures required for use of supplier certification for the supplier assessment and surveillance should be consistent with other procedures of the POA holders' quality system.

(c) Procedures of the POA holder that uses supplier certification for the supplier assessment and surveillance should include the following:

- (1) Listing of the OP that has certified or will certify suppliers and will conduct supplier assessment and surveillance or the scheme under which the accreditation of the OP is controlled. This listing should be maintained by the POA holder and made available to the Competent Authority upon request.
- (2) A listing of the certified suppliers under surveillance by the OP and used by the POA holder. This listing should be maintained by the POA holder and made available to the Competent Authority upon request.
- (3) The method used by the POA holder to evaluate and monitor the certification process of any OP certification body or OP certification scheme used. This applies not only to new suppliers, but also to any decision by the POA holder to rely on OP certification of current suppliers. The method should include the following as a minimum:
  - (i) Verification that certification standards and checklists are acceptable and applied to the applicable scope.
  - (ii) Verification that the OP is appropriately qualified and has sufficient knowledge, experience and training to perform its allocated tasks.
  - (iii) Verification that the OP surveillance frequency of the suppliers is commensurate with the complexity of the product and with the surveillance frequency established by the POA holder's suppliers control programme.
  - (iv) Verification that the suppliers' surveillance is conducted on-site by the OP.
  - (v) Verification that the surveillance report will be made available to the Competent Authority upon request.
  - (vi) Verification that the OP continues to be recognised or accredited.
  - (vii) Verification that the OP has access to applicable proprietary data to the level of detail necessary to survey suppliers functions.

Where the POA holder uses an OP accredited by a signatory to the European cooperation for Accreditation (EA) Multilateral Agreement and working in accordance with an aviation standard (e.g. EN 9104 series of requirements) that describes requirements for the OP certification, the items (ii), (iv) and (v) shall be deemed to be complied with.

- (4) A definition to what scope the OP will conduct suppliers surveillance on behalf of the POA holder. If the OP replaces surveillance in part, the POA holder should identify the functions that will continue to be surveyed by the POA holder.
- (5) Procedures that ensure that the POA is aware of the loss of an existing certification.
- (6) Procedures that ensure that the POA holder is aware of nonconformities and has access to detailed information of these nonconformities.
- (7) Procedures to evaluate the consequences of nonconformities and take appropriate actions.

(d) The POA should make arrangements that allow the Competent Authority to make investigation in accordance with 21A.157 to include OP activities



The AMC 21A.608 is amended as follows:

### Declaration of Design and Performance

STANDARD FORM

DDP No. ....

ISSUE No. ....

- 1 Name and address of manufacturer.
- 2 Description and identification of article including:
  - Type No .....
  - Modification Standard
  - Master drawing record
  - Weight and overall dimensions
- 3 Specification reference, i.e., ETSO No. and Manufacturer's design specification.
- 4 The rated performance of the article directly or by reference to other documents.
- 5 Particulars of approvals held for the equipment.
- 6 Reference to qualification test report.
- 7 Service and Instruction Manual reference number.
- 8 Statement of compliance with **the** appropriate ETSO and any deviations therefrom.
- 9 A statement of the level of compliance with the ETSO in respect of the ability of the article to withstand various ambient conditions or to exhibit various properties.

The following are examples of information to be given under this heading depending on the nature of the article and the requirements of the ETSO.

- ~~a. Working and ultimate pressure or loads.~~
- ~~b. Limitations of voltage and frequency.~~
- ~~c. Time rating (e.g., continuous, intermittent) or duty cycle.~~
- ~~d. Limits of accuracy of measuring instruments.~~
- ~~e. Whether the equipment is "flameproof" (explosion-proof).~~
- ~~f. Whether the equipment is "fire-resistant".~~
- ~~g. The compass safe distance.~~
- ~~h. Level of radio interference.~~
- ~~j. Radio and audio frequency susceptibility.~~

- ~~k. — Degree of vibration which the equipment will withstand.~~
- ~~l. — Degree of acceleration and shock which the equipment will withstand.~~
- ~~m. — Degree of waterproofness or sealing of equipment.~~
- ~~n. — Ability to withstand sand and dust.~~
- ~~o. — Ability to resist salt spray and aircraft fluids.~~
- ~~p. — Fungus resistance.~~
- ~~q. — Temperature and altitude category.~~
- ~~r. — Humidity category.~~
- ~~s. — Any other known limitations which may limit the application in the aircraft e.g., restrictions in mounting attitude.~~

a. Environmental Qualification

- i. Temperature and Altitude
- ii. Temperature Variation
- iii. Humidity
- iv. Operational Shocks and Crash Safety
- v. Vibration
- vi. Explosion Proofness
- vii. Waterproofness
- viii. Fluids Susceptibility
- ix. Sand and Dust
- x. Fungus Resistance
- xi. Salt Spray
- xii. Magnetic Effect
- xiii. Power Input
- xiv. Voltage Spike
- xv. Audio Frequency Conducted Susceptibility - Power Inputs
- xvi. Induced Signal Susceptibility
- xvii. Radio Frequency Susceptibility (Radiated and Conducted)
- xviii. Emission of Radio Frequency Energy
- xix. Lightning Induced Transient Susceptibility
- xx. Lightning Direct Effects
- xxi. Icing
- xxii. Electrostatic Discharge
- xxiii. Fire, Flammability

(NOTE: The manufacturer should list environmental categories for each of the sections of the issue of EUROCAE ED-14/RTCA DO-160 that was used to qualify the article.)

- b. For radio transmitters the transmitting frequency band, maximum transmitting power, and emission designator.
- c. Working and ultimate pressure or loads.

- d. Time rating (e.g., continuous, intermittent) or duty cycle.
- e. Limits of accuracy of measuring instruments.
- f. Any other known limitations which may limit the application in the aircraft e.g., restrictions in mounting attitude.

10 A statement of the software level(s) used or "None" if not applicable.

(NOTE: Software levels are those defined in the applicable issue of EUROCAE ED-12/RTCA document DO-178.)

11 A statement of design assurance level for complex hardware or a statement indicating whether complex hardware is embedded or not in the product.

(NOTE: Complex hardware design assurance levels are those defined in the applicable issue of EUROCAE ED-80/RTCA DO-254.)

~~44~~12 The declaration in this document is made under the authority of

.....(name of manufacturer)

(Manufacturer's name) cannot accept responsibility for equipment used outside the limiting conditions stated above without their agreement.

Date: .....Signed.....(Manufacturer's authorised representative)