



Council of the  
European Union

Brussels, 22 March 2019  
(OR. en)

7814/19  
ADD 1

AVIATION 65  
DELECT 90

#### COVER NOTE

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From:	Secretary-General of the European Commission, signed by Mr Jordi AYET PUIGARNAU, Director
date of receipt:	12 March 2019
To:	Mr Jeppe TRANHOLM-MIKKELSEN, Secretary-General of the Council of the European Union

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No. Cion doc.:	C(2019) 1845 final - Annex
Subject:	ANNEX to the COMMISSION DELEGATED REGULATION amending Regulation (EU) No 748/2012 as regards the inclusion of risk-based compliance verification in Annex I and the implementation of requirements for environmental protection

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Delegations will find attached document C(2019) 1845 final - Annex.

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Encl.: C(2019) 1845 final - Annex



Brussels, 12.3.2019  
C(2019) 1845 final

ANNEX

ANNEX

*to the*

**COMMISSION DELEGATED REGULATION**

**amending Regulation (EU) No 748/2012 as regards the inclusion of risk-based compliance verification in Annex I and the implementation of requirements for environmental protection**

## ANNEX

Annex I (Part-21) to Regulation (EU) No 748/2012 is amended as follows:

(1) the table of contents is replaced by the following:

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(2) point 21.A.14 is amended as follows:

(a) point (a) is replaced by the following:

"(a) An applicant for a type-certificate or restricted type-certificate shall demonstrate its capability by holding a design organisation approval, issued by the Agency in accordance with Subpart J.";

(b) point (c) is replaced by the following:

"(c) By way of derogation from point (a), an applicant may demonstrate its capability by obtaining the Agency's acceptance of its certification programme established in accordance with point 21.A.15(b), where the product to be certified is:

1. an ELA1 aircraft; or
2. an engine or propeller installed in ELA1 aircraft.";

(3) point 21.A.15 is amended as follows:

(a) points (b), (c) and (d) are replaced by the following:

"(b) An application for a type-certificate or restricted type-certificate shall include, as a minimum, preliminary descriptive data of the product, the intended use of the product and the kind of operations for which certification is requested. In addition, it shall include, or be supplemented after the initial application, a certification programme for the demonstration of compliance in accordance with point 21.A.20, consisting of:

1. a detailed description of the type design, including all the configurations to be certified;
2. the proposed operating characteristics and limitations;
3. the intended use of the product and the kind of operations for which certification is requested;
4. a proposal for the initial type-certification basis, operational suitability data certification basis and environmental protection requirements, prepared in accordance with the requirements and options specified in points 21.B.80, 21.B.82 and 21.B.85;

5. a proposal for a breakdown of the certification programme into meaningful groups of compliance demonstration activities and data, including a proposal for the means of compliance and related compliance documents;
  6. a proposal for the assessment of the meaningful groups of compliance demonstration activities and data, addressing the likelihood of an unidentified non-compliance with the type-certification basis, operational suitability data certification basis or environmental protection requirements and the potential impact of that non-compliance on product safety or environmental protection. The proposed assessment shall take into account at least the elements set out in subpoints (1) to (4) of point 21.B.100(a). Based on this assessment, the application shall include a proposal for the Agency's involvement in the verification of the compliance demonstration activities and data; and
  7. a project schedule including major milestones.
- (c) After its initial submission to the Agency, the certification programme shall be updated by the applicant when there are changes to the certification project affecting any of the points 1 to 7 of point (b).
- (d) An application for a type-certificate or restricted type-certificate for an aircraft shall include, or be supplemented after the initial application, an application supplement for approval of the operational suitability data.";
- (b) the following points (e) and (f) are added:
- "(e) An application for a type-certificate or restricted type-certificate for a large aeroplane or a large rotorcraft shall be valid for five years and an application for any other type-certificate or restricted type-certificate shall be valid for three years, unless the applicant demonstrates at the time of application that its product requires a longer time period to demonstrate and declare compliance and the Agency agrees to that longer time period.
- (f) In the case where a type-certificate or restricted type-certificate has not been issued, or it is evident that it will not be issued, within the time limit provided for in point (e), the applicant may:
1. submit a new application and comply with the type-certification basis, operational suitability data certification basis and environmental protection requirements, as established and notified by the Agency in accordance with points 21.B.80, 21.B.82 and 21.B.85 for the date of the new application; or
  2. apply for an extension of the time period provided for in point (e) and propose a new date for the issuance of the type-certificate or restricted type-certificate. In that case, the applicant shall comply with the type-certification basis, operational suitability data certification basis and environmental protection requirements, as established and notified by the Agency in accordance with points 21.B.80, 21.B.82 and 21.B.85 for a date to be

selected by the applicant. However, that date shall not precede the new date proposed by the applicant for the issuance of the type-certificate or restricted type-certificate by more than five years for an application for a type-certificate or restricted type-certificate for a large aeroplane or a large rotorcraft, and by more than three years for an application for any other type-certificate or restricted type certificate.";

- (4) point 21.A.16A is deleted;
- (5) point 21.A.16B is deleted;
- (6) point 21.A.17A is deleted;
- (7) point 21.A.17B is deleted;
- (8) point 21.A.18 is deleted;
- (9) points 21.A.20 and 21.A.21 are replaced by the following:

**"21.A.20 Demonstration of compliance with the type certification basis, operational suitability data certification basis and environmental protection requirements**

- (a) Following the acceptance of the certification programme by the Agency, the applicant shall demonstrate compliance with the type certification basis, operational suitability data certification basis and environmental protection requirements, as established and notified to the applicant by the Agency in accordance with points 21.B.80, 21.B.82, 21.B.85, and shall provide the Agency with the means by which such compliance has been demonstrated.
- (b) The applicant shall report to the Agency any difficulty or event encountered during the process of demonstration of compliance that may have an appreciable effect on the risk assessment under point 21.A.15(b)(6) or on the certification programme, or may otherwise necessitate a change to the level of involvement of the Agency previously notified to the applicant in accordance with point 21.B.100(c).
- (c) The applicant shall record justifications of compliance within the compliance documents as referred to in the certification programme.
- (d) After completion of all demonstrations of compliance in accordance with the certification programme, including any inspections and tests in accordance with point

21.A.33, and after all flight tests in accordance with point 21.A.35, the applicant shall declare that:

1. it has demonstrated compliance with the type-certification basis, operational suitability data certification basis and environmental protection requirements, as established and notified by the Agency, following the certification programme as accepted by the Agency; and
  2. no feature or characteristic has been identified that may make the product unsafe for the uses for which certification is requested.
- (e) The applicant shall submit to the Agency the declaration of compliance provided for in point (d). Where the applicant holds an appropriate design organisation approval, the declaration of compliance shall be made in accordance with Subpart J and submitted to the Agency.

**21.A.21 Requirements for the issuance of a type certificate or restricted type certificate**

- (a) In order to be issued a product type certificate or, when the aircraft does not meet the essential requirements of Annex II to Regulation (EU) 2018/1139 an aircraft restricted type certificate, the applicant shall:
1. demonstrate its capability in accordance with point 21.A.14;
  2. comply with point 21.A.20;
  3. demonstrate that the engine and propeller, if installed in the aircraft:
    - (A) have a type-certificate issued or determined in accordance with this Regulation; or
    - (B) have been demonstrated to be in compliance with the aircraft type-certification basis established and the environmental protection requirements designated and notified by the Agency as necessary to ensure the safe flight of the aircraft.
- (b) By derogation from point (a)(2), at the applicant's request included in the declaration referred to in point 21.A.20(d), the applicant is entitled to have the aircraft type-certificate or restricted type-certificate issued before the applicant has demonstrated compliance with the operational suitability data certification basis, provided that the applicant demonstrates such compliance before the date at which those data are to be actually used.";

(10) point 21.A.23 is deleted;

(11) in point 21.A.31(a), point 4 is replaced by the following:



"4. any other data allowing by comparison the determination of the airworthiness and, if relevant, the environmental characteristics of later products of the same type.";

(12) point 21.A.33 is replaced by the following:

"21.A.33           **Inspections and tests**

- (a) (Reserved)
- (b) Before each test is undertaken during the demonstration of compliance required by point 21.A.20, the applicant shall have verified:
  - 1. for the test specimen, that:
    - (i) the materials and processes adequately conform to the specifications for the proposed type design;
    - (ii) the parts of the products adequately conform to the drawings in the proposed type design; and
    - (iii) the manufacturing processes, construction and assembly adequately conform to those specified in the proposed type design; and
  - 2. for the test and measuring equipment to be used for the test, that those are adequate for the test and appropriately calibrated.
- (c) On the basis of the verifications carried out in accordance with point (b), the applicant shall issue a statement of conformity listing any potential non-conformity, together with a justification that this will not affect the test results, and shall allow the Agency to make an inspection it considers necessary to check the validity of that statement.
- (d) The applicant shall allow the Agency to:
  - 1. review any data and information related to the demonstration of compliance ; and
  - 2. witness or carry out any test or inspection conducted for the purpose of the demonstration of compliance.
- (e) For all the tests and inspections witnessed or carried out by the Agency in accordance with point (d)(2):
  - 1. the applicant shall submit to the Agency a statement of conformity provided for in point (c); and
  - 2. no change that affects the validity of the statement of conformity shall be made to the test specimen, or the test and measuring equipment, between the time the statement of conformity provided for in point (c) was issued and the time the test specimen is presented to the Agency for test.";

(13) point 21.A.41 is replaced by the following:

**"21.A.41           Type-certificate**

The type-certificate and restricted type-certificate shall include the type design, the operating limitations, the type-certificate data sheet for airworthiness and emissions, the applicable type-certification basis and environmental protection requirements with which the Agency records compliance, and any other conditions or limitations prescribed for the product in the applicable certification specifications and environmental protection requirements. The aircraft type-certificate and restricted type-certificate shall include in addition the applicable operational suitability data certification basis, the operational suitability data and the type-certificate data sheet for noise. The aircraft type-certificate and restricted type-certificate data sheet shall include the record of CO<sub>2</sub> emissions compliance and the engine type-certificate data sheet shall include the record of exhaust emissions compliance.";

(14) point 21.A.91 is replaced by the following:

**"21.A.91           Classification of changes to a type-certificate**

Changes to a type-certificate are classified as minor and major. A ‘minor change’ has no appreciable effect on the mass, balance, structural strength, reliability, operational characteristics, operational suitability data, or other characteristics affecting the airworthiness of the product or its environmental characteristics. Without prejudice to point 21.A.19, all other changes are ‘major changes’ under this Subpart. Major and minor changes shall be approved in accordance with points 21.A.95 or 21.A.97, as appropriate, and shall be adequately identified.”

(15) point 21.A.93 is replaced by the following:

**"21.A.93           Application**

- (a) An application for approval of a change to a type-certificate shall be made in a form and manner established by the Agency.
- (b) An application shall include, or be supplemented after the initial application, a certification programme for the demonstration of compliance in accordance with point 21.A.20, consisting of:
  - 1. a description of the change identifying:
    - (i) the configuration(s) of the product in the type certificate upon which the change is to be made;
    - (ii) all areas of the product in the type-certificate, including the approved manuals, that are changed or affected by the change; and

- (iii) when the change affects the operational suitability data, any necessary changes to the operational suitability data;
  2. an identification of any reinvestigations necessary to demonstrate compliance of the change and areas affected by the change with the type-certification basis, operational suitability data certification basis and environmental protection requirements; and
  3. for a major change to a type-certificate:
    - (i) a proposal for the initial type-certification basis, operational suitability data certification basis and environmental protection requirements, prepared in accordance with the requirements and options specified in point 21.A.101;
    - (ii) a proposal for a breakdown of the certification programme into meaningful groups of compliance demonstration activities and data, including a proposal for the means of compliance and related compliance documents;
    - (iii) a proposal for the assessment of the meaningful groups of compliance demonstration activities and data, addressing the likelihood of an unidentified non-compliance with the type-certification basis, operational suitability data certification basis or environmental protection requirements and the potential impact of that non-compliance on product safety or environmental protection. The proposed assessment shall take into account at least the elements set out in subpoints (1)–(4) of point 21.B.100(a). Based on this assessment, the application shall include a proposal for the Agency's involvement in the verification of the compliance demonstration activities and data; and
    - (iv) a project schedule including major milestones.
- (c) An application for a change to a type-certificate of a large aeroplane or a large rotorcraft shall be valid for five years and an application for a change to any other type-certificate shall be valid for three years. In the case where the change has not been approved, or it is evident that it will not be approved, within the time limit provided for in this point, the applicant may:
  1. submit a new application for a change to the type-certificate and comply with the type-certification basis, operational suitability data certification basis and environmental protection requirements, as established by the Agency in accordance with point 21.A.101 and notified in accordance with point 21.B.105 for the date of the new application; or
  2. apply for an extension of the time period provided for in the first sentence of point (c) for the original application and propose a new date for the issuance of the approval. In that case, the applicant shall comply with the type-certification basis, operational suitability data certification basis and environmental protection requirements, as established by the Agency in accordance with point 21.A.101 and notified in accordance with point 21.B.105, for a date to be selected by the

applicant. However, that date shall not precede the new date proposed by the applicant for the issuance of the approval by more than five years for an application for a type-certificate or restricted type-certificate for a large aeroplane or a large rotorcraft, and by more than three years for an application for any other type-certificate or restricted type certificate.";

(16) points 21.A.95, 21.A.97 and 21.A.101 are replaced by the following:

**"21.A.95 Requirements for approval of a minor change**

- (a) Minor changes to a type-certificate shall be classified and approved by:
  - 1. the Agency; or
  - 2. an approved design organisation within the scope of its privileges provided for in points (1) and (2) of point 21.A.263(c), as recorded in the terms of approval.
- (b) A minor change to a type-certificate shall only be approved:
  - 1. when it has been demonstrated that the change and areas affected by the change comply with the type-certification basis and the environmental protection requirements incorporated by reference in the type-certificate;
  - 2. in the case of a change affecting the operational suitability data, when it has been demonstrated that the necessary changes to the operational suitability data comply with the operational suitability data certification basis incorporated by reference in the type-certificate;
  - 3. when compliance with the type-certification basis that applies in accordance with point (1) has been declared and the justifications of compliance have been recorded in the compliance documents; and
  - 4. when no feature or characteristic has been identified that may make the product unsafe for the uses for which certification is requested.
- (c) By derogation from point (1) in point (b), certification specifications which became applicable after those incorporated by reference in the type-certificate can be used for approval of a minor change, provided they do not affect the demonstration of compliance.
- (d) By derogation from point (a), at the applicant's request included in the declaration referred to in point 21.A.20(d), a minor change to an aircraft type-certificate may be approved before compliance with the operational suitability data certification basis has been demonstrated, provided that the applicant demonstrates such compliance before the date at which those data are actually used.
- (e) The applicant shall submit to the Agency the substantiation data for the change and a statement that compliance has been demonstrated in accordance with point (b).
- (f) An approval of a minor change to a type-certificate shall be limited to the specific configuration(s) in the type-certificate to which the change relates.

21.A.97            **Requirements for approval of a major change**

- (a) Major changes to a type-certificate shall be classified and approved by:
  - 1. the Agency; or
  - 2. an approved design organisation within the scope of its privileges provided for in points (1) and (8) of point 21.A.263(c), as recorded in the terms of approval.
- (b) A major change to a type-certificate shall only be approved:
  - 1. when it has been demonstrated that the change and areas affected by the change comply with the type-certification basis and environmental protection requirements, as established by the Agency in accordance with point 21.A.101;
  - 2. in the case of a change affecting the operational suitability data, when it has been demonstrated that the necessary changes to the operational suitability data meet the operational suitability data certification basis, as established by the Agency in accordance with point 21.A.101; and
  - 3. when compliance with points (1) and (2) has been demonstrated in accordance with point 21.A.20, as applicable to the change.
- (c) By derogation from points (2) and (3) of point (b), at the applicant's request included in the declaration referred to in point 21.A.20(d), a major change to an aircraft type-certificate may be approved before compliance with the operational suitability data certification basis has been demonstrated, provided that the applicant demonstrates such compliance before the date at which those data are actually used.
- (d) An approval of a major change to a type-certificate shall be limited to the specific configuration(s) in the type-certificate to which the change relates.

21.A.101            **Type-certification basis, operational suitability data certification basis and environmental protection requirements for a major change to a type-certificate**

- (a) A major change to a type-certificate and areas affected by the change shall comply with either the certification specifications applicable to the changed product on the date of the application for the change or certification specifications which became applicable after that date in accordance with point (f) below. The validity of the application shall be determined in accordance with point 21.A.93(c). In addition, the changed product shall comply with the environmental protection requirements designated by the Agency in accordance with point 21.B.85.
- (b) By derogation from point (a), an earlier amendment to a certification specification referred to in point (a) and to any other certification specification which is directly related may be used in any of the following situations, unless the earlier amendment became applicable before the date at which the corresponding certification specifications incorporated by reference in the type-certificate became applicable:
  - 1. a change that the Agency finds not to be significant. In determining whether a specific change is significant, the Agency shall consider the change in the context

of all previous relevant design changes and all related revisions to the applicable certification specifications incorporated by reference in the type-certificate for the product. Changes meeting one of the following criteria shall automatically be considered significant:

- (i) the general configuration or the principles of construction are not retained;
  - (ii) the assumptions used for certification of the product to be changed do not remain valid;
2. each area, system, part or appliance that the Agency finds not affected by the change;
  3. each area, system, part or appliance that is affected by the change for which the Agency finds that compliance with the certification specifications referred to in point (a) does not contribute materially to the level of safety of the changed product or is impractical.
- (c) By derogation from point (a), in the case of a change to an aircraft other than a rotorcraft of 2 722 kg (6 000 lb) or less maximum weight, or to a non-turbine rotorcraft of 1 361 kg (3 000 lb) or less maximum weight, the change and areas affected by the change shall comply with the type-certification basis incorporated by reference in the type-certificate. However, if the Agency finds that the change is significant in an area, the Agency may require that the change and areas affected by the change comply with an amendment to a certification specification of the type-certification basis incorporated by reference in the type-certificate and with any other certification specification which is directly related, unless the Agency also finds that compliance with that amendment does not contribute materially to the level of safety of the changed product or is impractical.
- (d) If the Agency finds that the certification specifications applicable on the date of the application for the change do not provide adequate standards with respect to the proposed change, the change and areas affected by the change shall also comply with any special conditions, and amendments to those special conditions, prescribed by the Agency in accordance with point 21.B.75, to provide a level of safety equivalent to that established by the certification specifications applicable on the date of the application for the change.
- (e) By derogation from points (a), (b) and (c), the change and areas affected by the change may comply with an alternative to a certification specification designated by the Agency if proposed by the applicant, provided that the Agency finds that the alternative provides a level of safety which is:
1. in the case of a type-certificate:
    - (i) equivalent to that of the certification specifications designated by the Agency under (a), (b) or (c) above; or
    - (ii) compliant with the essential requirements of Annex II to Regulation (EU) [2018/1139](#);

2. in the case of a restricted type-certificate, adequate with regard to the intended use.

- (f) If an applicant chooses to comply with a certification specification set out in an amendment that becomes applicable after submitting the application for a change to a type-certificate, the change and areas affected by the change shall also comply with any other certification specification which is directly related.
- (g) When the application for a change to a type-certificate for an aircraft includes, or is supplemented after the initial application to include, changes to the operational suitability data, the operational suitability data certification basis shall be established in accordance with points (a)–(f).";

(17) point 21.A.103 is deleted;

(18) points 21.A.111 and 21.A.112A are replaced by the following:

**"21.A.111        Scope**

This Subpart establishes the procedure for the approval of major changes to the type-certificate under supplemental type-certificate procedures, and establishes the rights and obligations of the applicants for, and holders of, those certificates. In this Subpart, the references to type-certificates include type-certificates and restricted type-certificates.

**21.A.112A       Eligibility**

Any natural or legal person that has demonstrated, or is in the process of demonstrating, its capability in accordance with point 21.A.112B may apply for a supplemental type-certificate in accordance with the conditions laid down in this Subpart.";

(19) point 21.A.112B is amended as follows:

(a) point (a) is replaced by the following:

"(a) An applicant for a supplemental type-certificate shall demonstrate its capability by holding a design organisation approval, issued by the Agency in accordance with Subpart J.";

(b) point (c) is replaced by the following:

"(c) By way of derogation from point (a), in the case of products referred to in point 21.A.14(c), an applicant may demonstrate its capability by obtaining the Agency's acceptance of its certification programme established in accordance with point 21.A.93(b).";

(20) point 21.A.113 is amended as follows:

(a) point (b) is replaced by the following:

"(b) When applying for a supplemental type-certificate, the applicant shall:

(i) include in the application the information required by point 21.A.93(b);

(ii) specify whether the certification data has been or will be prepared completely by the applicant or on the basis of an arrangement with the owner of the type-certification data.";

(b) the following point (c) is added:

"(c) Point 21.A.93(c) applies to the requirements for the time limits of the application effectivity as well as the requirements related to the need to update the type-certification basis, operational suitability data certification basis and environmental protection requirements, when the change has not been approved or it is evident that it will not be approved within the time limit established.";

(21) point 21.A.114 is deleted;

(22) point 21.A.115 is replaced by the following:

**"21.A.115 Requirements for approval of major changes in the form of a supplemental type-certificate**

(a) Supplemental type certificates shall be issued by:

1. the Agency; or
2. an approved design organisation within the scope of its privileges provided for in points (1) and (9) of point 21.A.263(c), as recorded in the terms of approval.

(b) A supplemental type-certificate shall only be issued when:

1. the applicant has demonstrated its capability in accordance with point 21.A.112B;
2. it has been demonstrated that the change to a type-certificate and areas affected by the change comply with the type-certification basis and the environmental protection requirements, as established by the Agency in accordance with point 21.A.101;
3. in the case of a supplemental type-certificate affecting the operational suitability data, it has been demonstrated that the necessary changes to the operational suitability data meet the operational suitability data certification basis, as established by the Agency in accordance with point 21.A.101;
4. compliance with points (2) and (3) has been demonstrated in accordance with point 21.A.20, as applicable to the change; and



5. in case the applicant has specified that it provided certification data on the basis of an arrangement with the owner of the type-certification data in accordance with point 21.A.113(b):

- (i) the type-certificate holder has indicated that it has no technical objection to the information submitted under point 21.A.93; and
- (ii) the type-certificate holder has agreed to collaborate with the supplemental type-certificate holder to ensure discharge of all obligations for continued airworthiness of the changed product through compliance with points 21.A.44 and 21.A.118A.

(c) By derogation from points (3) and (4) of point (b), at the applicant's request included in the declaration referred to in point 21.A.20(d), the applicant is entitled to have a supplemental type-certificate for an aircraft issued before the applicant has demonstrated compliance with the operational suitability data certification basis, provided that the applicant demonstrates such compliance before the date at which those data are to be actually used.

(d) A supplemental type-certificate shall be limited to the specific configuration(s) in the type-certificate to which the related major change relates.";

(23) in point 21.A.130, point (b) is replaced by the following:

"(b) A statement of conformity shall include all of the below:

1. for each product, part or appliance, a statement that the product, part or appliance conforms to the approved design data and is in condition for safe operation;
2. for each aircraft, a statement that the aircraft has been ground- and flight-checked in accordance with point 21.A.127(a);
3. for each engine, or variable pitch propeller, a statement that the engine or variable pitch propeller has been subjected by the manufacturer to a final functional test in accordance with point 21.A.128;
4. additionally, in the case of environmental requirements:
  - (i) a statement that the completed engine is in compliance with the applicable engine exhaust emissions requirements on the date of manufacture of the engine, and;
  - (ii) a statement that the completed aeroplane is in compliance with the applicable CO<sub>2</sub> emissions requirements on the date its first certificate of airworthiness is issued.";

(24) in point 21.A.145, points (b) and (c) are replaced by the following:

"(b) with regard to all necessary airworthiness and environmental data:

1. the production organisation is in receipt of such data from the Agency, and from the holder of, or applicant for, the type-certificate, restricted type-certificate or design approval, including any exemption granted against the CO<sub>2</sub> production cut-off requirements, to determine conformity with the applicable design data;
2. the production organisation has established a procedure to ensure that airworthiness and environmental data are correctly incorporated in its production data and,
3. such data are kept up to date and made available to all personnel who need access to such data to perform their duties.

(c) with regard to management and staff:

1. a manager has been nominated by the production organisation, and is accountable to the competent authority. His or her responsibilities within the organisation shall consist of ensuring that all production is performed to the required standards and that the production organisation is continuously in compliance with the data and procedures identified in the exposition referred to in point 21.A.143;
2. a person or group of persons have been nominated by the production organisation to ensure that the organisation is in compliance with the requirements of this Annex (Part 21), and are identified, together with the extent of their authority. Such person(s) shall act under the direct authority of the accountable manager referred to in point (1). The person(s) nominated shall be able to show the appropriate knowledge, background and experience to discharge their responsibilities;
3. staff at all levels have been given appropriate authority to be able to discharge their allocated responsibilities and that there is full and effective coordination within the production organisation in respect of airworthiness and environmental data matters.";

(25) in point 21.A.147, point (a) is replaced by the following:

"(a) After the issue of a production organisation approval, each change to the approved production organisation that is significant to the showing of conformity or to the

airworthiness and environmental characteristics of the product, part or appliance, particularly changes to the quality system, shall be approved by the competent authority. An application for approval shall be submitted in writing to the competent authority and the organisation shall demonstrate to the competent authority, before implementing the change, that it complies with this Subpart.";

(26) in point 21.A.174, point (b) is replaced by the following:

“(b) Each application for a certificate of airworthiness or restricted certificate of airworthiness shall include:

1. the class of airworthiness certificate applied for;
2. with regard to new aircraft:
  - (i) a statement of conformity:
    - issued under point 21.A.163(b); or
    - issued under point 21.A.130 and validated by the competent authority; or
    - for an imported aircraft, a statement signed by the exporting authority that the aircraft conforms to a design approved by the Agency;
  - (ii) a weight and balance report with a loading schedule and;
  - (iii) the flight manual, when required by the applicable certification specifications for the particular aircraft.
3. with regard to used aircraft:
  - (i) originating from a Member State, an airworthiness review certificate issued in accordance with Part-M;
  - (ii) originating from a non-Member State:
    - a statement by the competent authority of the State where the aircraft is, or was, registered, reflecting the airworthiness status of the aircraft on its register at the time of transfer;
    - a weight and balance report with a loading schedule;

- the flight manual when such material is required by the applicable airworthiness code for the particular aircraft;
- historical records to establish the production, modification, and maintenance standard of the aircraft, including all limitations associated with a restricted certificate of airworthiness under point 21.B.327;
- a recommendation for the issue of a certificate of airworthiness or restricted certificate of airworthiness and an airworthiness review certificate following an airworthiness review in accordance with Part-M; and
- the date on which the first certificate of airworthiness was issued and, if the standards of Annex 16 Volume III apply, the CO2 metric value data.";

(27) point 21.A.231 is replaced by the following:

**"21.A.231        Scope**

This Subpart establishes the procedure for the approval of design organisations and rules governing the rights and obligations of applicants for, and holders of, such approvals. In this Subpart, the references to type-certificates include type-certificates and restricted type-certificates.";

(28) point 21.A.251 is replaced by the following:

**"21.A.251        Terms of approval**

The terms of approval shall identify the types of design work, the categories of products, parts and appliances for which the design organisation holds a design organisation approval, and the functions and duties that the organisation is approved to perform with regard to the airworthiness, operational suitability and environmental characteristics of the products. For design organisation approvals covering type-certification or European Technical Standard Order (ETSO) authorisation for auxiliary power units (APUs), the terms of approval shall contain in addition the list of products or APUs. Those terms shall be issued as part of a design organisation approval."

(29) point 21.A.258 is amended as follows:

(a) point (a) is replaced by the following:

"(a) When, during the investigations referred to in points 21.A.257 and 21.B.100, objective evidence is found demonstrating non-compliance of the holder of a

design organisation approval with the applicable requirements of this Annex, the finding shall be classified as follows:

1. a 'level 1' finding is any non-compliance with the requirements of this Annex that may lead to uncontrolled non-compliances with applicable requirements and affect the safety of the aircraft;
2. a 'level 2' finding is any non-compliance with the requirements of this Annex that is not classified as a 'level 1' finding;

(b) points (c) and (d) are replaced by the following:

"(c) After receipt of notification of findings under the applicable administrative procedures established by the Agency:

1. in the case of a 'level 1' finding, the holder of a design organisation approval shall demonstrate to the satisfaction of the Agency that it has taken adequate corrective action within a period of no more than 21 working days after written confirmation of the finding;
2. in the case of a 'level 2' findings, the holder of a design organisation approval shall demonstrate to the satisfaction of the Agency that it has taken adequate corrective action within a time period set by the Agency which is appropriate to the nature of the finding and is initially no longer than three months. The Agency may extend that initial time period where it considers that the nature of the finding allows such extension and where the applicant has submitted a corrective action plan which the Agency finds satisfactory; and
3. a 'level 3' finding shall not require immediate action by the holder of a design organisation approval.

(d) In cases of 'level 1' or 'level 2' findings, the design organisation approval may be subject to a partial or full suspension or revocation under the applicable administrative procedures established by the Agency. In that case, the holder of a design organisation approval shall provide confirmation of receipt of the notice of suspension or revocation of the design organisation approval in a timely manner.";

(30) point 21.A.263 is replaced by the following:

"21.A.263       **Privileges**

(a) (Reserved)

(b) (Reserved)

(c) A holder of a design organisation approval shall be entitled, within the scope of its terms of approval, as established by the Agency, and under the relevant procedures of the design assurance system:

1. to classify changes to a type-certificate or to a supplemental type-certificate and repair designs as ‘major’ or ‘minor’;
2. to approve minor changes to a type-certificate or to a supplemental type-certificate and minor repair designs;
3. (Reserved);
4. (Reserved);
5. to approve certain major repair designs under Subpart M to products or auxiliary power units (APUs);
6. to approve for certain aircraft the flight conditions under which a permit to fly can be issued in accordance with point 21.A.710(a)(2), except for permits to fly to be issued for the purpose of point 21.A.701(a)(15);
7. to issue a permit to fly in accordance with point 21.A.711(b) for an aircraft it has designed or modified, or for which it has approved, in accordance with point 21.A.263(c)(6), the flight conditions under which the permit to fly can be issued, and where the holder of a design organisation approval itself:
  - (i) controls the configuration of the aircraft, and
  - (ii) attests conformity with the design conditions approved for the flight;
8. to approve certain major changes to a type-certificate under Subpart D; and
9. to issue certain supplemental type-certificates under Subpart E and approve certain major changes to those certificates.";

(31) point 21.A.265 is replaced by the following:

**"21.A.265 Obligations of the holder**

The holder of a design organisation approval shall, within the scope of its terms of approval, as established by the Agency:

- (a) maintain the handbook required under point 21.A.243 in conformity with the design assurance system;
- (b) ensure that this handbook or the relevant procedures included by cross-reference are used as a basic working document within the organisation;
- (c) determine that the design of products, or changes or repairs thereto comply with the applicable specifications and requirements and have no unsafe features;
- (d) provide the Agency with statements and associated documentation confirming compliance with point (c), except for approval processes carried out in accordance with point 21.A.263(c);

- (e) provide to the Agency data and information related to the actions required under point 21.A.3B;
- (f) determine, in accordance with point 21.A.263(c)(6), the flight conditions under which a permit to fly can be issued;
- (g) establish, in accordance with point 21.A.263(c)(7), compliance with points (b) and (e) of point 21.A.711 before issuing a permit to fly to an aircraft;
- (h) designate data and information issued under the authority of the approved design organisation within the scope of its terms of approval as established by the Agency with the following statement: 'The technical content of this document is approved under the authority of the DOA ref. EASA. 21J.[XXXX]'. '";

(32) point 21.A.431A is amended as follows:

- (a) point (a) is replaced by the following:

"(a) This Subpart establishes the procedure for the approval of a repair design of a product, part or appliance and establishes the rights and obligations of the applicants for, and holders of, those approvals.";
- (b) points (c) and (d) are replaced by the following:

"(c) A 'repair' means the elimination of damage and/or restoration to an airworthy condition following the initial release to service by the manufacturer of any product, part or appliance.

(d) The elimination of damage by replacement of parts or appliances without the necessity for design activity shall be considered as a maintenance task and shall therefore require no approval under this Annex.";
- (c) the following point (f) is added:

"(f) In this Subpart, the references to type-certificates include type-certificates and restricted type-certificates.";

(33) point 21.A.432B is amended as follows:

- (a) point (a) is replaced by the following:

"(a) An applicant for approval of a major repair design shall demonstrate its capability by holding a design organisation approval, issued by the Agency in accordance with Subpart J.";
- (b) point (c) is replaced by the following:

"(c) By way of derogation from point (a), in the case of products referred to in point 21.A.14(c), an applicant may demonstrate its capability by obtaining the Agency's acceptance of its certification programme established in accordance with point 21.A.432C(b).";

(34) the following point 21.A.432C is inserted:

**"21.A.432C Application for a repair design approval**

- (a) An application for a repair design approval shall be made in a form and manner established by the Agency.
- (b) An application for a major repair design approval shall include, or be supplemented after the initial application, a certification programme containing:
  - 1. a description of the damage and repair design identifying the configuration of the type design upon which the repair is made;
  - 2. an identification of all areas of the type design and the approved manuals that are changed or affected by the repair design;
  - 3. an identification of any reinvestigations necessary to demonstrate compliance of the repair design and areas affected by the repair design with the type-certification basis incorporated by reference in, as applicable, either the type-certificate, the supplemental type-certificate or the APU ETSO authorisation;
  - 4. any proposed amendments to the type-certification basis incorporated by reference in, as applicable, either the type-certificate, the supplemental type-certificate or the APU ETSO authorisation;
  - 5. a proposal for a breakdown of the certification programme into meaningful groups of compliance demonstration activities and data, including the means and process proposed to be followed to demonstrate compliance with point 21.A.433(a)(1) and references to related compliance documents;
  - 6. a proposal for the assessment of the meaningful groups of compliance demonstration activities and data, addressing the likelihood of an unidentified non-compliance with the type-certification basis and the potential impact of that non-compliance on product safety. The proposed assessment shall take into account at least the elements set out in subpoints (1)–(4) of point 21.B.100(a). Based on this assessment, the application shall include a proposal for the Agency's involvement in the verification of the compliance demonstration activities and data; and
  - 7. the specification whether the certification data is prepared completely by the applicant or on the basis of an arrangement with the owner of the type-certification data.";



(35) points 21.A.433 and 21.A.435 are replaced by the following:

**"21.A.433 Requirements for approval of a repair design**

(a) A repair design shall only be approved:

1. when it has been demonstrated, following the certification programme referred to in point 21.A.432C(b), that the repair design complies with the type-certification basis incorporated by reference in, as applicable, either the type-certificate, the supplemental type-certificate or the APU ETSO authorisation, as well as with any amendments established and notified by the Agency in accordance with point 21.B.450;
2. when compliance with the type-certification basis that applies in accordance with point (a)(1) has been declared and the justifications of compliance have been recorded in the compliance documents;
3. when no feature or characteristic has been identified that may make the product unsafe for the uses for which certification is requested; and
4. where the applicant has specified that it provided certification data on the basis of an arrangement with the owner of the type-certification data in accordance with point 21.A.432C(b)(7):
  - (i) when the holder has indicated that it has no technical objection to the information submitted under point (a)(2); and
  - (ii) when the holder has agreed to collaborate with the repair design approval holder to ensure discharge of all obligations for continued airworthiness of the changed product through compliance with point 21.A.451.

(b) The applicant shall submit to the Agency the declaration referred to in point (a)(2) and, on request by the Agency, all necessary substantiation data.

**21.A.435 Classification and approval of repair designs**

- (a) A repair design shall be classified as either 'major' or 'minor' in accordance with the criteria set out in point 21.A.91 for a change to the type-certificate.
- (b) A repair design shall be classified and approved by:
1. the Agency; or
  2. an approved design organisation within the scope of its privileges provided for in points (1), (2) and (5) of point 21.A.263(c), as recorded in the terms of approval.";

(36) point 21.A.437 is deleted;

(37) points 21.A.604, 21.A.605 and 21.A.606 are replaced by the following:

#### "21.A.604      **ETSO authorisation for an auxiliary power unit (APU)**

With regard to an ETSO authorisation for an APU:

- (a) by way of derogation from points 21.A.603, 21.A.610 and 21.A.615, the following points shall apply: points 21.A.15, 21.A.20, 21.A.21, 21.A.31, 21.A.33, 21.A.44, 21.B.75 and 21.B.80. However, an ETSO authorisation shall be issued in accordance with point 21.A.606 instead of a type-certificate;
- (b) by way of derogation from point 21.A.611, the requirements of Subpart D shall apply to the approval of design changes by the APU ETSO authorisation holder and the requirements of Subpart E shall apply to the approval of design changes by other applicants. Where the requirements of Subpart E apply, a separate ETSO authorisation shall be issued instead of a supplemental type certificate; and
- (c) the requirements of Subpart M shall apply to the approval of repair designs.

#### 21.A.605      **Data requirements**

- (a) The applicant shall submit to the Agency the following documents:
  - 1. a certification programme for the ETSO authorisation, setting out the means to demonstrate compliance with point 21.A.606(b);
  - 2. a statement of compliance certifying that the applicant has met the requirements of this Subpart;
  - 3. a declaration of design and performance (DDP), stating that the applicant has demonstrated that the article complies with the applicable ETSO in accordance with the certification programme;
  - 4. a copy of the technical data required in the applicable ETSO;
  - 5. the exposition, or a reference to the exposition, referred to in point 21.A.143 for the purpose of obtaining an appropriate production organisation approval under Subpart G or the manual, or a reference to the manual, referred to in point 21.A.125A(b) for the purpose of manufacturing under Subpart F without production organisation approval;
  - 6. for an APU, the handbook, or a reference to the handbook, referred to in point 21.A.243 for the purpose of obtaining an appropriate design organisation approval under Subpart J;
  - 7. for all other articles, the procedures, or a reference to the procedures, referred to in point 21.A.602B(b)(2);
- (b) The applicant shall report to the Agency any difficulty or event encountered during the approval process that may significantly impact the ETSO authorisation."

#### 21.A.606      **Requirements for the issuance of an ETSO authorisation**

In order to be issued an ETSO authorisation, the applicant shall:

- (a) demonstrate its capability in accordance with point 21.A.602B;
- (b) demonstrate that the article complies with the technical conditions of the applicable ETSO or with deviations therefrom approved in accordance with point 21.A.610, if any;
- (c) comply with the requirements of this Subpart; and
- (d) declare that no feature or characteristic has been identified that may make the article unsafe for the uses for which certification is requested.";

(38) in point 21.A.701, point (16) is added:

"16. flying an aircraft for troubleshooting purposes or to check the functioning of one or more systems, parts or appliances after maintenance.";

(39) in point 21.B.5, point (a) is replaced by the following:

"(a) This Section establishes the procedure for the competent authority, when exercising its tasks and responsibilities concerned with the issuance, maintenance, amendment, suspension and revocation of certificates, approvals and authorisations referred to in this Annex I."

(40) Subpart B of Section B is replaced by the following:

## "SUBPART B — TYPE-CERTIFICATES AND RESTRICTED TYPE-CERTIFICATES

### 21.B.70 **Certification specifications**

The Agency, in accordance with Article 76 (3) of Regulation (EU) 2018/1139, shall issue certification specifications and other detailed specifications, including certification specifications for airworthiness, operational suitability data and environmental protection, that competent authorities, organisations and personnel may use to demonstrate compliance of products, parts and appliances with the relevant essential requirements set out in Annexes II, IV and V to that Regulation, as well as with those for environmental protection set out in Article 9(2) and Annex III of that Regulation. Such specifications shall be sufficiently detailed and specific to indicate to applicants the conditions under which certificates are to be issued, amended or supplemented.

### 21.B.75 **Special conditions**

- (a) The Agency shall prescribe special detailed technical specifications, named 'special conditions', for a product if the related certification specifications do not contain adequate or appropriate safety standards for the product because:

1. the product has novel or unusual design features relative to the design practices on which the applicable certification specifications are based;
  2. the intended use of the product is unconventional; or
  3. experience from other similar products in service or products having similar design features or newly identified hazards have shown that unsafe conditions may develop.
- (b) Special conditions contain such safety standards as the Agency finds necessary in order to establish a level of safety equivalent to that of the applicable certification specifications.

#### **21.B.80 Type-certification basis for a type-certificate or restricted type-certificate**

The Agency shall establish the type certification basis and notify it to the applicant for a type-certificate or restricted type-certificate. The type certification basis shall consist of:

- (a) the certification specifications for airworthiness designated by the Agency from those applicable to the product at the date of application for that certificate, unless:
1. the applicant chooses to comply, or is required to comply in accordance with point 21.A.15(f), with certification specifications which became applicable after the date of the application; If an applicant chooses to comply with a certification specification which became applicable after the date of the application, the Agency shall include in the type-certification basis any other certification specification that is directly related; or
  2. the Agency accepts any alternative to a designated certification specification that cannot be complied with, for which compensating factors have been found that provide an equivalent level of safety; or
  3. the Agency accepts or prescribes other means that:
    - (i) in the case of a type-certificate, demonstrate compliance with the essential requirements of Annex II to Regulation (EU) 2018/1139; or
    - (ii) in the case of a restricted type-certificate, provide a level of safety adequate with regard to the intended use; and
- (b) any special condition prescribed by the Agency in accordance with point 21.B.75(a).

#### **21.B.82 Operational suitability data certification basis for an aircraft type-certificate or restricted type-certificate**

The Agency shall establish the operational suitability data certification basis and notify it to the applicant for an aircraft type-certificate or restricted type-certificate. The operational suitability data certification basis shall consist of:

- (a) the certification specifications for operational suitability data designated by the Agency out of those applicable to the aircraft at the date of the application or at the date of the application supplement for operational suitability data, whichever date is later, unless:
  - 1. the applicant chooses to comply, or in accordance with point 21.A.15(f) is required to comply with certification specifications which became applicable after the date of the application; If an applicant chooses to comply with a certification specification which became applicable after the date of the application, the Agency shall include in the type-certification basis any other certification specification that is directly related; or
  - 2. the Agency accepts or prescribes alternative means to demonstrate compliance with the relevant essential requirements of Annexes II, IV and V to Regulation (EU) No 2018/1139 .
- (b) any special condition prescribed by the Agency in accordance with point 21.B.75(a).

**21.B.85 Designation of applicable environmental protection requirements and certification specifications for a type-certificate or restricted type-certificate**

- (a) The Agency shall designate and notify to the applicant for a type-certificate or restricted type-certificate for an aircraft, for a supplemental type-certificate or for a major change to a type-certificate or to a supplemental type-certificate, the applicable noise requirements established in Annex 16 to the Chicago Convention, Volume I, Part II, Chapter 1 and:
  - 1. for subsonic jet aeroplanes, in Chapters 2, 3, 4 and 14;
  - 2. for propeller-driven aeroplanes in Chapters 3, 4, 5, 6, 10, and 14;
  - 3. for helicopters, in Chapters 8 and 11;
  - 4. for supersonic aeroplanes, in Chapter 12; and
  - 5. for tilt rotors, in Chapter 13.
- (b) The Agency shall designate and notify to the applicant referred to in point (a) the applicable emission requirements for preventions of intentional fuel venting for aircraft established in Annex 16 to the Chicago Convention, Volume II, Part II, Chapter 1 and 2.
- (c) The Agency shall designate and notify to the applicant referred to in point (a) the applicable smoke, gaseous and particulate matter engine emission requirements established in Annex 16 to the Chicago Convention, Volume II, Part III, Chapter 1 and
  - 1. for smoke and gaseous emissions of turbojet and turbofan engines intended for propulsion only at subsonic speeds, in Chapter 2;

2. for smoke and gaseous emissions of turbojet and turbofan engines intended for propulsion at supersonic speeds, in Chapter 3; and
  3. for particulate matter emissions of turbojet and turbofan engines intended for propulsion only at subsonic speeds, in Chapter 4.
- (d) The Agency shall designate and notify to the applicant referred to in point (a) the applicable aeroplane CO<sub>2</sub> emission requirements established in Annex 16 to the Chicago Convention, Volume III, Part II, Chapter 1 and
1. for subsonic jet aeroplanes, in Chapter 2; and
  2. for subsonic propeller-driven aeroplanes, in Chapter 2.

#### 21.B.100 **Level of involvement**

- (a) The Agency shall determine its involvement in the verification of the compliance demonstration activities and data related to the application for a type-certificate, restricted type-certificate, major change approval, supplemental type certificate, major repair design approval or ETSO authorisation for APU. It shall do so on the basis of an assessment of meaningful groups of compliance demonstration activities and data of the certification programme. That assessment shall address:
- the likelihood of an unidentified non-compliance with the type-certification basis, operational suitability data certification basis or environmental protection requirements; and
  - the potential impact of that non-compliance on product safety or environmental protection,
- and consider at least the following elements:
1. novel or unusual features of the certification project, including operational, organisational and knowledge management aspects;
  2. complexity of the design and/or demonstration of compliance;
  3. criticality of the design or technology and the related safety and environmental risks, including those identified on similar designs; and
  4. performance and experience of the design organisation of the applicant in the domain concerned.
- (b) For the approval of a minor repair design, minor change or ETSO authorisation other than for APU, the Agency shall determine its involvement at the level of the entire certification project, taking into account any novel or unusual features, complexity of the design and/or demonstration of compliance, criticality of the design or technology, as well as the performance and experience of the applicant's design organisation.
- (c) The Agency shall notify its level of involvement to the applicant and it shall update its level of involvement when this is warranted by information which has an appreciable impact on the risk previously assessed pursuant to point (a) or (b).

The Agency shall notify the applicant about the change in the level of involvement.

**21.B.103 Issuance of a type-certificate or restricted type-certificate**

- (a) The Agency shall issue an aircraft, engine or propeller type-certificate or an aircraft restricted type-certificate, provided that:
1. the applicant has complied with point 21.A.21;
  2. the Agency, through verifications of the demonstration of compliance in accordance with its involvement determined pursuant to point 21.B.100, has not found any non-compliance with the type-certification basis, the operational suitability data certification basis where applicable in accordance with point 21.B.82, and the environmental protection requirements; and
  3. no feature or characteristic has been identified that may make the product unsafe for the uses for which the certification is requested.
- (b) By derogation from point (a), at the applicant's request included in the declaration referred to in point 21.A.20(d), the Agency may issue an aircraft type-certificate before compliance with the operational suitability data certification basis has been demonstrated, provided that the applicant demonstrates such compliance before the date at which those data are to be actually used.

(41) Subpart D of Section B is replaced by the following:

**"21.B.105 Type-certification basis, environmental protection requirements and operational suitability data certification basis for a major change to a type-certificate**

The Agency shall establish the applicable type-certification basis, the environmental protection requirements, and in the case of a change affecting the operational suitability data, the operational suitability data certification basis established in accordance with point 21.A.101 and notify them to the applicant for a major change to a type certificate.

**21.B.107 Issuance of an approval of a change to a type-certificate**

- (a) The Agency shall issue an approval of a change to a type-certificate provided that:
1. the applicant for an approval has complied with:
    - (i) point 21.A.95 for a minor change; or
    - (ii) point 21.A.97 for a major change;
  2. the Agency, through its verification of the demonstration of compliance in accordance with the level of its involvement determined pursuant to point (a) or (b) of point 21.B.100 has not found any non-compliance with the type-certification basis, operational suitability data certification basis where

applicable in accordance with point 21.B.82, and environmental protection requirements; and

3. no feature or characteristic has been identified that may make the product unsafe for the uses for which certification is requested.
- (b) In the case of a change affecting the operational suitability data, by derogation from points (1) and (2) of point (a), at the applicant's request included in the declaration referred to in point 21.A.20(d), the Agency may approve a change to an aircraft type-certificate before compliance with the operational suitability data certification basis has been demonstrated, provided that the applicant demonstrates such compliance before the date at which those data are to be actually used.
  - (c) The approval of the changes to the operational suitability data shall be included in the approval of the change to the type-certificate.
  - (d) The approval of a change to a type-certificate shall be limited to the specific configuration(s) in the type-certificate to which the change relates.";

(42) Subpart E of Section B is replaced by the following:

"In this Subpart, references to type-certificates include type-certificates and restricted type-certificates.

**21.B.109 Type-certification basis, environmental protection requirements and operational suitability data certification basis for a supplemental type-certificate**

The Agency shall establish the applicable type-certification basis, the environmental protection requirements and, in the case of a change affecting the operational suitability data, the operational suitability data certification basis established in accordance with point 21.A.101 and notify them to the applicant for a supplemental type-certificate.

**21.B.111 Issuance of a supplemental type-certificate**

- (a) The Agency shall issue a supplemental type-certificate, provided that:
  1. the applicant has complied with point 21.A.115(b);
  2. the Agency, through its verification of the demonstration of compliance in accordance with the level of involvement established pursuant to point 21.B.100(a), has not found any non-compliance with the type-certification basis, operational suitability data certification basis where applicable in accordance with point 21.B.82, and environmental protection requirements; and
  3. no feature or characteristic has been identified that may make the product unsafe for the uses for which certification is requested.



- (b) In the case of a supplemental type-certificate affecting the operational suitability data, by derogation from points (1) and (2) of point (a), at the applicant's request included in the declaration referred to in point 21.A.20(d), the Agency may issue a supplemental type-certificate before compliance with the operational suitability data certification basis has been demonstrated, provided that the applicant demonstrates such compliance before the date at which those data are to be actually used.
- (c) The approval of the changes to the operational suitability data shall be included in the supplemental type-certificate.
- (d) The supplemental type-certificate shall be limited to the specific configuration(s) in the type-certificate to which the related major change relates.";

(43) Point 21.B.326 is replaced by the following:

**"21.B.326 Certificate of airworthiness**

The competent authority of the Member State of registry shall issue a certificate of airworthiness for:

- (a) new aircraft:
  - 1. upon presentation of the documentation required by point 21.A.174(b)(2);
  - 2. where the competent authority of the Member State of registry is satisfied that the aircraft conforms to an approved design and is in a condition for safe operation; this may include inspections by the competent authority of the Member State of registry; and
  - 3. where the competent authority of the Member State of registry is satisfied that the aircraft is in compliance with the applicable CO<sub>2</sub> emissions requirements on the date on which the certificate of airworthiness is first issued.
- (b) used aircraft:
  - 1. upon presentation of the documentation required by point 21.A.174(b)(3) demonstrating that:
    - (i) the aircraft conforms to a type design approved under a type-certificate and any supplemental type-certificate, change or repair approved in accordance with this Annex I (Part 21) and;
    - (ii) the applicable airworthiness directives have been complied with and;
    - (iii) the aircraft has been inspected in accordance with the applicable provisions of Annex I (Part-M) to Regulation (EC) No 2042/2003 and;
    - (iv) the aircraft was in compliance with the applicable CO<sub>2</sub> emissions requirements on the date on which the certificate of airworthiness was first issued;

2. where the competent authority of the Member State of registry is satisfied that the aircraft conforms to an approved design and is in a condition for safe operation; this may include inspections by the competent authority of the Member State of registry and;
3. where the competent authority of the Member State of registry is satisfied that the aircraft was in compliance with the applicable CO<sub>2</sub> emissions requirements on the date on which the certificate of airworthiness was first issued."

(44) Subpart M of Section B is replaced by the following:

**"21.B.450 Type-certification basis and environmental protection requirements for a repair design approval**

The Agency shall designate any amendments to the type-certification basis incorporated by reference in, as applicable, either the type-certificate, the supplemental type-certificate or the APU ETSO authorisation, which the Agency considers necessary for maintaining a level of safety equal to that previously established and notify them to the applicant for a repair design.

**21.B.453 Issuance of a repair design approval**

- (a) The Agency shall issue an approval of a major repair design, provided that:
  1. the applicant has demonstrated its capability in accordance with point 21.A.432B;
  2. the applicant has complied with point 21.A.433;
  3. the Agency, through its verification of the demonstration of compliance in accordance with the level of involvement established pursuant to point 21.B.100(a), has not found any non-compliance with the type-certification basis and environmental protection requirements; and
  4. no feature or characteristic has been identified that may make the product unsafe for the uses for which certification is requested.
- (b) The Agency shall issue an approval of a minor repair design, provided that the applicant has complied with points (2) and (4) of point (a) and provided that the Agency, through its verifications of the demonstration of compliance in accordance with the level of involvement pursuant to point 21.B.100(b), has not found any non-compliance with the type-certification basis and environmental protection requirements.";

(45) Subpart O of Section B is replaced by the following:

**"21.B.480 Issuance of an ETSO authorisation**

The Agency shall issue an ETSO authorisation, provided that:

- (a) the applicant has complied with point 21.A.606;
- (b) the Agency, through its verifications of the demonstration of compliance in accordance with the level of involvement pursuant to point 21.B.100(b), has not found any non-compliance with the technical conditions of the applicable ETSO or with deviations therefrom approved in accordance with point 21.A.610, if any; and
- (c) no feature or characteristic has been identified that may make the article unsafe for the uses for which certification is requested."