

## ANNEX

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

1. 'Contents' is amended as follows:

i. The following points are deleted:

- '21.A.16A Certification specifications';
- '21.A.16B Special conditions';
- '21.A.17A Type-certification basis';
- '21.A.17B Operational suitability data certification basis';
- '21.A.18 Designation of applicable environmental protection requirements and certification specifications';
- '21.A.23 Issue of a restricted type-certificate';
- '21.A.103 Issue of approval';
- '21.A.437 Issue of a repair design approval'; and
- '21.B.70 Approval of changes to type-certificates'.

ii. The following points are inserted:

- '21.A.432C Application for a repair design approval';
- '21.B.70 Certification specifications';
- '21.B.75 Special conditions';
- '21.B.80 Type-certification basis for a type-certificate or restricted type-certificate';
- '21.B.82 Operational suitability data certification basis for an aircraft type certificate or restricted type-certificate';
- '21.B.85 Designation of applicable environmental protection requirements and certification specifications for a type-certificate and restricted type-certificate';
- '21.B.100 Level of involvement';
- '21.B.103 Issuance of a type-certificate or restricted type-certificate';
- '21.B.105 Type-certification basis, environmental protection requirements and operational suitability data certification basis for a major change to a type-certificate';
- '21.B.107 Issuance of an approval of a change to a type-certificate';
- '21.B.109 Type-certification basis, environmental protection requirements and operational suitability data certification basis for a supplemental type-certificate';
- '21.B.110 Issuance of a supplemental type-certificate';

- ‘21.B.113 Type-certification basis and environmental protection requirements for a major repair design approval’;
- ‘21.B.115 Issuance of a repair design approval’; and
- ‘21.B.117 Issuance of an ETSO authorisation’.

2. 21.A.14 is amended as follows:

i. (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.’; and

ii. (c) is replaced by the following:

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

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

3. 21.A.15 is amended as follows:

i. (a) is replaced by the following:

‘(a) An application for a type-certificate or restricted type-certificate shall be made in a form and manner established by the Agency.’

ii. (b) is 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 to include, a certification programme for compliance demonstrations in accordance with 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, where applicable, and environmental protection requirements, considering the requirements and options specified in 21.B.80, 21.B.82, and 21.B.85;

5. a proposal for a breakdown of the certification programme into compliance demonstration items, including references to their proposed means of compliance and related compliance documents;
  6. a proposal for the assessment of the proposed compliance demonstration items in respect of the likelihood of an unidentified non-compliance with the type-certification basis and the potential impact of this non-compliance on product safety or environmental protection, using the criteria of 21.B.100(a)(1)–(3), together with a proposal to the Agency for its level of involvement in the verification of those compliance demonstration items; and
  7. a project schedule including major milestones.’.
- iii. (c) is replaced by the following:
- ‘(c) After its initial submission to the Agency, the certification programme shall be kept updated, as necessary.’.
- iv. (d) is replaced by the following:
- ‘(d) An application for a type-certificate or restricted type-certificate for an aircraft shall include, or be supplemented after the initial application to include, an application supplement for approval of the operational suitability data, consisting of, as applicable:
1. the minimum syllabus of pilot type rating training, including determination of type rating;
  2. the definition of scope of the aircraft validation source data to support the objective qualification of simulators, associated to the pilot type rating training, or provisional data to support their interim qualification;
  3. the minimum syllabus of maintenance certifying staff type rating training, including determination of type rating;
  4. the determination of type or variant for cabin crew and type specific data for cabin crew;
  5. the master minimum equipment list; and
  6. other type-related operational suitability elements.’.
- v. The following new (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 effective for 5 years and an application for any other type-certificate shall be effective for 3 years, unless the applicant shows at the time of application that their product requires a longer period of time to demonstrate and declare compliance, and the Agency agrees to this longer 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 established under (e) above, the applicant may:

1. submit a new application and comply with the type-certification basis, operational suitability data certification basis, where applicable, and environmental protection requirements, as established and notified by the Agency in accordance with 21.B.80, 21.B.82 and 21.B.85 for the new application; or
2. apply for an extension of the original application and comply with the type-certification basis, operational suitability data certification basis, where applicable, and environmental protection requirements, as established and notified by the Agency in accordance with 21.B.80, 21.B.82 and 21.B.85 for an effective date to be selected by the applicant, but not before the date which precedes the new target date for the issuance of the type-certificate or restricted type-certificate by the time limit established under (e) above for the original application.’

4. 21.A.16A is deleted.

5. 21.A.16B is deleted.

6. 21.A.17A is deleted.

7. 21.A.17B is deleted.

8. 21.A.18 is deleted.

9. 21.A.20 is 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) The applicant shall demonstrate, following the certification programme under 21.A.15(b) as accepted by the Agency, compliance with the type-certification basis, operational suitability data certification basis, where applicable, and environmental protection requirements, as established and notified by the Agency in accordance with 21.B.80, 21.B.82, 21.B.85, as applicable, 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 compliance demonstration process that may have an appreciable effect on the risk assessment under 21.A.15(b)(6) or 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 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 compliance demonstrations in accordance with the certification programme and the inspections and tests in accordance with 21.A.33 and, where applicable, 21.A.35, the applicant shall declare that:
  - 1. it has demonstrated compliance with the type-certification basis, operational suitability data certification basis, where applicable, 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 under (d) above. Where the applicant holds an appropriate design organisation approval, the declaration of (d) shall be made in accordance with Subpart J and submitted to the Agency.’

10. 21.A.21 is replaced by the following:

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

- (a) To obtain from the Agency a product type-certificate or, when the aircraft does not meet the essential requirements of Annex I to Regulation (EC) No 216/2008, an aircraft restricted type-certificate, the applicant shall:
  - 1. demonstrate its capability in accordance with 21.A.14;
  - 2. demonstrate compliance with 21.A.20;
  - 3. demonstrate that:
    - (i) in the case of an aircraft type-certificate, the engine and propeller, if installed in the aircraft, have a type-certificate issued or determined in accordance with this Regulation; or
    - (ii) in the case of an aircraft restricted type-certificate, 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 shown to be in compliance with the certification specifications designated and notified by the Agency as necessary to ensure the safe flight of the aircraft.
- (b) By derogation from (a)(2) above, the applicant may request in the declaration referred to in 21.A.20(d) that the aircraft type-certificate is issued before the applicant has demonstrated compliance with the applicable operational suitability data certification basis, subject to the applicant’s demonstration of compliance with the operational

suitability data certification basis before the operational suitability data must actually be used.’

11. 21.A.23 is deleted.

12. 21.A.33 is replaced by the following:

**‘21.A.33 Inspections and tests**

- (a) (Reserved)
- (b) Before each test is undertaken during the compliance demonstrations required by 21.A.20, the applicant shall have determined:
  - 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) After completion of the conformity determinations under (b) above, the applicant shall issue a statement of conformity listing any potential nonconformity, 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 compliance demonstration; and
  - 2. witness or carry out any test or inspection conducted for the purpose of compliance demonstration.
- (e) For all the tests and inspections conducted or witnessed by the Agency under (d)(2) above:
  - 1. the applicant shall submit to the Agency a statement of conformity as required under (c) above; 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 under (c) above was issued and the time the test specimen is presented to the Agency for test.’

13. 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 by the Agency. In addition, the aircraft type-certificate and restricted type-certificate shall both include the applicable operational suitability data certification basis, the operational suitability data and the type-certificate data sheet for noise. The engine type-certificate data sheet shall include the record of emission compliance.’

14. In 21.A.91, ‘operational suitability data’ is replaced by ‘operational suitability’.

15. 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 to include, a certification programme for compliance demonstrations in accordance with 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 applicable type-certification basis, operational suitability data certification basis, where applicable, 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, where applicable, and environmental protection requirements, considering the requirements and options specified in 21.A.101;

- (ii) a proposal for a breakdown of the certification programme into compliance demonstration items, including a proposal for their means of compliance and related compliance documents;
  - (iii) a proposal for the assessment of the proposed compliance demonstration items in respect of the likelihood of an unidentified non-compliance with the type-certification basis and the potential impact of this non-compliance on product safety or environmental protection, using the criteria of 21.B.100(a)(1)–(3), together with a proposal to the Agency for its level of involvement in the investigation of those compliance demonstration items; 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 is effective for 5 years, and an application for a change to any other type-certificate is effective for 3 years. In a case where the change has not been approved, or it is evident that it will not be approved, within the time limit established under 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, where applicable, and environmental protection requirements, established by the Agency in accordance with 21.A.101 and notified in accordance with 21.B.105 to be applicable to the new application for a change; or
  2. apply for an extension of the original application and comply with the type-certification basis, operational suitability data certification basis, where applicable, and environmental protection requirements, established by the Agency in accordance with 21.A.101 and notified in accordance with 21.B.105 for an effective date to be selected by the applicant, but not before the date which precedes the new target date for the issuance of the approval by the time limit established under this point for the original application.’

16. 21.A.95 is 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:
  1. either by the Agency; or
  2. by an approved design organisation within the scope of its 21.A.263(c)(1) and (2) privileges, 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 unless specifications



of later effective amendments are elected by the applicant that do not affect the compliance demonstration;

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 applicable operational suitability data certification basis incorporated by reference in the type-certificate unless specifications of later effective amendments are elected by the applicant that do not affect the compliance demonstration;
  3. when compliance with the applicable type-certification basis of (b)(1) above 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 (b)(2) above, a minor change to an aircraft type-certificate may be approved before compliance with the applicable operational suitability data certification basis has been demonstrated, subject to demonstrating compliance before the operational suitability data must actually be used.
- (d) The applicant shall submit to the Agency the substantiation data for the change and a statement that compliance has been demonstrated in accordance with (b) above.
- (e) An approval of a minor change to a type-certificate is limited to that or those specific configurations in the type-certificate upon which the change is made.’

17. 21.A.97 is replaced by the following:

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

- (a) Major changes to a type-certificate shall be classified and approved:
1. either by the Agency; or
  2. by an approved design organisation within the scope of its 21.A.263(c)(1) and (8) privileges, 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 applicable type-certification basis and environmental protection requirements established by the Agency in accordance with 21.A.101 and notified in accordance with 21.B.105, as applicable;
  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 applicable operational suitability data certification basis established in accordance with 21.A.101; and
  3. when compliance with (1) and (2) above has been demonstrated in accordance with 21.A.20, as applicable to the change.

- (c) By derogation from (b)(2) and (3) above, a major change to an aircraft type-certificate may be approved before compliance with the applicable operational suitability data certification basis has been demonstrated, subject to demonstrating compliance before the operational suitability data must actually be used.
- (d) An approval of a major change to a type-certificate is limited to that or those specific configurations in the type-certificate upon which the change is made.'

18. 21.A.101 is replaced by the following:

**'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 the certification specifications, applicable to the changed product, in effect on the date of the application for the change unless compliance with certification specifications of later effective amendments is elected by the applicant or required under (f) below and 21.A.93(b). In addition, the changed product shall comply with the applicable environmental protection requirements designated by the Agency in accordance with 21.B.85.
- (b) By derogation from (a) above, the change and areas affected by the change may comply with an earlier amendment to the certification specifications referred to in (a), and to any other certification specification the Agency finds directly related. However, those earlier amended certification specifications may not precede the corresponding certification specifications incorporated by reference in the type-certificate. An earlier amendment of the certification specifications may be used for any of the following:
  - 1. A change that the Agency finds not to be significant. In determining whether a specific change is significant, the Agency considers 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 are automatically 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 (a) above does not contribute materially to the level of safety of the changed product or is impractical.
- (c) By derogation from (a) above, 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 designate compliance with an amendment to the type-certification basis incorporated by reference in the type-certificate in effect on the date of the application and with any certification specification that the Agency finds directly related unless the Agency also finds that compliance with that amendment or certification specification 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 in effect 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 under the provisions of point 21.B.75, to provide a level of safety equivalent to that established by the certification specifications in effect on the date of the application for the change.
- (e) If any alternative to a certification specification designated by the Agency under (a), (b) or (c) is proposed by the applicant, then this alternative shall provide a level of safety:
  - (i) in the case of a type-certificate:
    - (A) equivalent to that of the certification specifications designated by the Agency under (a), (b) or (c) above; or
    - (B) equivalent to that of the essential requirements of Annex I to Regulation (EC) No 216/2008; or
  - (ii) in the case of a restricted type-certificate, adequate with regard to the intended use.
- (f) If an applicant elects to comply with an applicable certification specification at an amendment that becomes effective 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 that the Agency finds 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 (a)–(f) above.’

19. 21.A.103 is deleted.

20. In 21.A.111, the following is added:

‘In this Subpart, the references to type-certificates include type-certificates and restricted type-certificates.’

21. 21.A.112A is replaced by the following:

‘Any natural or legal person that has demonstrated, or is in the process of demonstrating, its capability under 21.A.112B shall be eligible as an applicant for a supplemental type-certificate under the conditions laid down in this Subpart.’

22. 21.A.112B is amended as follows:

i. (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.’; and

ii. (c) is replaced by the following:

‘(c) By way of derogation from (a) above, in the case of products defined in 21.A.14(c), an applicant may demonstrate its capability through acceptance by the Agency of a certification programme established in accordance with 21.A.93(b).’.

23. 21.A.113 is amended as follows:

i. (b) is replaced by the following:

‘(b) An application for a supplemental type-certificate shall include the information required by 21.A.93(b). In addition, such an application shall include a justification that the information on which those elements are based is adequate either from the applicant’s own resources, or through an arrangement with the type-certificate holder.’; and

ii. (c) is added as follows:

‘(c) 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, where applicable, and environmental protection requirements, when the change has not been approved or it is evident that it will not be approved within the applicable time limit established, are those specified in 21.A.93(c).’.

24. 21.A.114 is deleted.

25. 21.A.115 is replaced by the following:

**‘21.A.115 Requirements for the issuance of a supplemental type-certificate**

(a) Supplemental type certificates shall be issued:

1. either by the Agency; or
2. by an approved design organisation within the scope of its 21.A.263(c)(1) and (9) privileges, 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 21.A.112B;
  2. it has been demonstrated that the change to a type-certificate and areas affected by the change comply with the applicable type-certification basis and the environmental protection requirements established by the Agency in accordance with 21.A.101 and notified in accordance with 21.B.109, as applicable;
  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 applicable operational suitability data certification basis established by the Agency in accordance with 21.A.101 and notified in accordance with 21.B.109, as applicable;
  4. compliance with (b)(2) and (3) has been demonstrated in accordance with 21.A.20, as applicable to the change; and
  5. where under 21.A.113(b), the applicant has entered into an arrangement with the type-certificate holder:
    - (i) the type-certificate holder has advised that it has no technical objection to the information submitted under 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 21.A.44 and 21.A.118A.
- (c) By derogation from (b)(3) and (4) above, a supplemental type-certificate for an aircraft may be issued before compliance with the applicable operational suitability data certification basis has been demonstrated, subject to demonstrating compliance before the operational suitability data must actually be used.
- (d) A supplemental type-certificate is limited to that or those specific configurations in the type-certificate upon which the related major change is made.’

26. In 21.A.231, the following is added:

‘In this Subpart, the references to type-certificates include type-certificates and restricted type-certificates.’

27. 21.A.258 is amended as follows:

i. (a) is replaced by the following:

‘(a) When, during the investigations referred to in 21.A.257 and 21.B.100, objective evidence is found showing non-compliance of the holder of a design organisation approval with the applicable requirements of this Annex I (Part-21), the finding shall be classified as follows:

1. a 'level 1' finding is any non-compliance with this Annex I (Part-21) that may lead to uncontrolled non-compliances with applicable requirements and affect the safety of the aircraft; and
2. a 'level 2' finding is any non-compliance with this Annex I (Part-21) that is not classified as 'level 1'.

ii. (c) is 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 corrective action to the satisfaction of the Agency within a period of no more than 21 working days after written confirmation of the finding;
2. in the case of 'level 2' findings, the corrective-action period granted by the Agency shall be appropriate to the nature of the finding but in any case, it shall initially not be more than 3 months. In certain circumstances and subject to the nature of the finding, the Agency may extend the 3-month period subject to the provision of a satisfactory corrective-action plan agreed by the Agency; and
3. a 'level 3' finding shall not require immediate action by the holder of a design organisation approval.'

iii. (d) is replaced by the following:

'(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. 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.'

28. 21.A.263 is replaced by the following:

'(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 21.A.710(a)(2), except for permits to fly to be issued for the purpose of 21.A.701(a)(15);
7. to issue a permit to fly in accordance with 21.A.710(b) for an aircraft it has designed or modified, or for which it has approved the 21.A.263(c)(6) conditions under which the permit to fly can be issued, and when 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.'

29. 21.A.265 is amended as follows:

- i. (a) is replaced by the following:

'(a) maintain the handbook required under 21.A.243 in conformity with the design assurance system;'
- ii. (c) is replaced by the following:

'(c) determine that the design of products, or changes or repairs thereto, as applicable, comply with the applicable specifications and requirements and have no unsafe features;'
- iii. (d) is replaced by the following:

'(d) provide the Agency with statements and associated documentation confirming compliance with (c) above except for approval processes under the 21.A.263(c) privileges.';
- iv. (e) is replaced by the following:

'(e) provide to the Agency data and information related to the actions required under 21.A.3B;'
- v. (f) is replaced by the following:

'(f) where applicable, determine under the 21.A.263(c)(6) privilege the flight conditions under which a permit to fly can be issued;'
- vi. (g) is replaced by the following:

‘(g) where applicable, establish under the 21.A.263(c)(7) privilege compliance with 21.A.711(b) and (e) before issuing a permit to fly to an aircraft.’ and

vii. a new (h) is added:

‘issue data and information containing the following statement: ‘The technical content of this document is approved under the authority of the DOA ref. EASA. 21J.[XXXX].’.’.

30. 21.A.431A is amended as follows:

i. (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.’;

ii. (c) is 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.’;

iii. (d) is replaced by the following:

‘(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 I (Part-21).’; and

iv. the following (f) is added:

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

31. 21.A.432B is amended as follows:

i. (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.’; and

ii. (c) is replaced by the following:

‘(c) By way of derogation from (a), in the case of products defined in 21.A.14(c), an applicant may demonstrate its capability through acceptance by the Agency of a certification programme established in accordance with 21.A.432C(b).’.



32. The following new 21.A.432C is inserted after 21.A.432B:

**‘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 to include, 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 reinvestigations and justifications;
  - 3. an identification of any reinvestigations necessary to demonstrate compliance of the repair design and areas affected by the repair design with the applicable type-certification basis;
  - 4. any proposed amendments to the type-certification basis or environmental protection requirements incorporated by reference in the type-certificate or supplemental type-certificate or auxiliary power unit (APU) ETSO authorisation, as applicable;
  - 5. the means and process proposed to be followed to demonstrate compliance with 21.A.433(a)(1);
  - 6. a proposal for the assessment of the proposed compliance demonstration items in respect of the likelihood of an unidentified non-compliance with the type-certification basis and the potential impact of this non-compliance on product safety, using the criteria of 21.B.100(a)(1)–(3), together with a proposal to the Agency for its level of involvement in the verification of those compliance demonstration items.’ and
  - 7. where the applicant is not the type-certificate, supplemental type-certificate, or APU ETSO authorisation holder, as applicable, a justification that the information on which those identifications are based is adequate either from the applicant’s own resources, or through an arrangement with the type-certificate, supplemental type-certificate or APU ETSO authorisation holder.’.

33. 21.A.433 is 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 under 21.A.432C(b), where applicable, that the repair design complies with the type-certification basis incorporated by reference in the type-certificate or supplemental type-certificate or APU ETSO authorisation, as applicable, as well as with any

amendments established and notified, when applicable, by the Agency in accordance with 21.B.113;

2. when compliance with the applicable type-certification basis of (a)(1) above 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 under 21.A.432C(b)(7), an arrangement with the type certificate, supplemental type certificate or APU ETSO authorisation holder, as applicable, is in place:
  - (i) when the holder has advised that it has no technical objection to the information submitted under (a)(2) above; 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 21.A.451.

(b) The applicant shall submit to the Agency the declaration as per (a)(2) above and, on request, all necessary substantiation data.

34. 21.A.435 is replaced by the following:

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

- (a) A repair design may be ‘major’ or ‘minor’. The ‘major/minor’ classification shall be made in accordance with the criteria of 21.A.91 for a change to the type-certificate.
- (b) A repair design shall be classified and approved:
  1. either by the Agency; or
  2. by an approved design organisation within the scope of its 21.A.263(c)(1)(2) and (5) privileges, as recorded in the terms of approval.’

35. 21.A.437 is deleted.

36. 21.A.604 is 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) 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, shall apply by way of derogation from 21.A.603, 21.A.610 and 21.A.615 except that an ETSO authorisation shall be issued in accordance with 21.A.606 instead of a type-certificate;

- (b) Subpart D or Subpart E is applicable for the approval of design changes by way of derogation from 21.A.611 — when Subpart E is used, a separate ETSO authorisation shall be issued instead of a supplemental type certificate; and
- (c) Subpart M is applicable to the approval of repair designs.’

37. 21.A.605 is replaced by the following:

**‘21.A.605 Data requirements**

- (a) The applicant shall submit to the Agency the following documents:
  - 1. a certification programme for the ETSO authorisation, defining the means to demonstrate compliance with 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 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 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 21.A.243 for the purpose of obtaining an appropriate design organisation approval under Subpart J;
  - 7. for all other articles, the procedures referred to in 21.A.602B(b)(2) (or a reference to these procedures); and
  - 8. a proposal for the assessment of the proposed compliance demonstration items in respect of the likelihood of an unidentified non-compliance with the applicable ETSO and the potential impact of this non-compliance on article safety, using the criteria of 21.B.100(b), together with a proposal to the Agency for its level of involvement in the verification of those compliance demonstration items.’
- (b) The applicant shall report to the Agency any difficulty or event encountered during the approval process that may significantly impact the ETSO authorisation.’

38. 21.A.606 is replaced by the following:

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

To obtain an ETSO authorisation from the Agency, the applicant shall:

- (a) demonstrate its capability in accordance with 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 21.A.610, if any;
- (c) comply with 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.’

39. SECTION B, SUBPART B is amended as follows:

- i. ‘Administrative procedures established by the Agency shall apply.’ is deleted;
- ii. 21.B.70, 21.B.75, 21.B.80, 21.B.82, 21.B.85, 21.B.100 and 21.B.103 are added:

**21.B.70 Certification specifications**

The Agency shall issue certification specifications in accordance with Article 9 of Regulation (EC) No 216/2008, including certification specifications for airworthiness, operational suitability data and environmental protection, as the standard means to demonstrate compliance of products, parts and appliances with the relevant essential requirements of Annexes I, III and IV to Regulation (EC) No 216/2008 as well as with those for environmental protection of Article 6 of said Regulation. Such specifications shall be sufficiently detailed and specific to indicate to applicants the conditions under which certificates will 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 and notify to the applicant for a type-certificate or restricted type-certificate the type-certification basis which shall consist of:

- (a) the applicable certification specifications for airworthiness designated by the Agency from those effective on the date of application for that certificate unless:

1. compliance with certification specifications of later effective amendments is elected by the applicant or is required under 21.A.15 (f); if an applicant elects to comply with a certification specification of a later effective amendment, the Agency shall include in the type-certification basis any other certification specification that it finds 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 alternative means:
    - (i) in the case of a type-certificate, that will demonstrate compliance with the essential requirements of Annex I to Regulation (EC) No 216/2008; or
    - (ii) in the case of a restricted type-certificate, that will provide a level of safety adequate with regard to the intended use; and
- (b) any special condition prescribed by the Agency in accordance with 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 and notify to the applicant for an aircraft type-certificate or restricted type-certificate the operational suitability data certification basis which shall consist of:

- (a) the applicable certification specifications for operational suitability data designated by the Agency from those effective on the date of the application or application supplement for operational suitability data, whatever comes later unless:
  1. compliance with certification specifications of later effective amendments is elected by the applicant or is required under 21.A.15 (f); if an applicant elects to comply with a certification specification of a later effective amendment, the Agency shall include in the type-certification basis any other certification specification that it finds directly related; or
  2. the Agency accepts or prescribes alternative means to demonstrate compliance with the relevant essential requirements of Annexes I, III and IV to Regulation (EC) No 216/2008.
- (b) any special condition prescribed in accordance with 21.B.75(a).

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

- (a) The Agency shall designate and notify to the applicant for a type-certificate or restricted type-certificate for an aircraft, or for a supplemental type-certificate, or for a major change to a type-certificate (or to a supplemental type-certificate) the

applicable noise requirements in accordance with the provisions of ICAO Annex 16, Volume I, Part II, Chapter 1 and:

1. for subsonic jet aeroplanes, Chapters 2, 3, 4 and 14, as applicable;
  2. for propeller-driven aeroplanes, Chapters 3, 4, 5, 6, 10, and 14, as applicable;
  3. for helicopters, Chapters 8 and 11, as applicable;
  4. for supersonic aeroplanes, Chapter 12, as applicable; and
  5. for tilt rotors, Chapter 13, as applicable.
- (b) The Agency shall designate and notify to the applicant for a type-certificate or restricted type-certificate for an aircraft, or a type-certificate for an engine, or for a supplemental type certificate, or for a major change to a type-certificate (or to a supplemental type-certificate) the applicable emission requirements in accordance with the provisions of ICAO Annex 16, Volume II, Part II:
1. for prevention of intentional fuel venting, Chapter 2;
  2. for emissions of turbojet and turbofan engines intended for propulsion only at subsonic speeds, Chapter 2; and
  3. for emissions of turbojet and turbofan engines intended for propulsion only at supersonic speeds, Chapter 3.
- (c) The certification specifications for environmental protection issued in accordance with 21.B.70 provide for acceptable means to demonstrate compliance with the noise and emission requirements referred to in (a) and (b) above, respectively.

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

- (a) The Agency shall determine its level of involvement in compliance verification for the compliance demonstration items of the certification programme. This shall be done on the basis of an assessment of the proposed compliance demonstration items for the likelihood of an unidentified non-compliance with the type-certification basis in combination with the potential impact thereof on product safety or environment. In doing so, the Agency shall consider the characteristics of the design and/or compliance demonstration, taking into account but not limited to:
1. novel or unusual features of the certification project, including operational, organisational and knowledge management aspects;
  2. complexity of the design and/or compliance demonstration;
  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 a minor repair design, minor change or ETSO authorisation, the Agency shall establish its level of involvement at the level of the certification project, taking into account any novel or unusual features, complexity of the design and/or compliance demonstration, criticality of the design or technology, as well as the performance and experience of the applicant's design organisation.
- (c) The Agency shall notify to the applicant the Agency's level of involvement, update its level of involvement when this is warranted by receipt of information which has an appreciable impact on the risk previously assessed under (a) or (b), and notify the applicant accordingly.

**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 its verifications in accordance with 21.B.100, has not found any non-compliance with the applicable type-certification basis, the operational suitability data certification basis, where applicable, 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 certification is requested.
- (b) By derogation from (a) above, and at the applicant's request included in the declaration referred to in 21.A.20(d), an aircraft type-certificate may be issued before compliance with the applicable operational suitability data certification basis has been demonstrated, subject to the applicant's demonstration of compliance with the operational suitability data certification basis before the operational suitability data must actually be used.'; and

iii. The following is added:

'In addition, administrative procedures established by the Agency shall apply.'

40. Section B, Subpart D is amended as follows:

i. 21.B.105 and 21.B.107 are added:

**'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 and notify to the applicant for a major change to a type certificate 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 21.A.101.

### **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
    - (i) of a minor change has complied with 21.A.95; or
    - (ii) of a major change has complied with 21.A.97;
  - 2. the Agency, through its verifications in accordance with 21.B.100(a) or (b), as applicable, has not found any non-compliance with the applicable type-certification basis, operational suitability data certification basis, where applicable, 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 (a)(1) and (2) above, and at the applicant's request included in the declaration referred to in 21.A.20(d), a change to an aircraft type-certificate may be approved before compliance with the applicable operational suitability data certification basis has been demonstrated, subject to the applicant's demonstration of compliance before the operational suitability data must actually be used.
- (c) The approval of the changes to the operational suitability data is included in the approval of the change to the type-certificate. However, the Agency shall use a separate classification and approval process for administering changes to operational suitability data.
- (d) The approval of a change to a type-certificate is limited to that or those specific configurations in the type-certificate upon which the related change is made.'; and

ii. The following is added:

'In addition, administrative procedures established by the Agency shall apply.'

#### 41. Section B, Subpart E is amended as follows:

i. The sentence 'Administrative procedures established by the Agency shall apply.' is replaced by the following:

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

ii. The following 21.B.109 and 21.B.110 are added:

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

The Agency shall establish and notify to the applicant for a supplemental type-certificate 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 21.A.101.

**21.B.110 Issuance of a supplemental type-certificate**

- (a) The Agency shall issue a supplemental type-certificate provided that:
  - 1. the applicant has complied with 21.A.115(b);
  - 2. the Agency, through its verifications in accordance with 21.B.100(a), has not found any non-compliance with the applicable type-certification basis, operational suitability data certification basis, where applicable, 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 (a)(1) and (2) above, and at the applicant's request included in the declaration referred to in 21.A.20(d), a supplemental type-certificate may be issued before compliance with the applicable operational suitability data certification basis has been demonstrated, subject to the applicant's demonstration of compliance with the operational suitability data certification basis before the operational suitability data must actually be used.
- (c) The approval of the changes to the operational suitability data is included in the supplemental type-certificate. However, the Agency shall use a separate classification and approval process for administering changes to operational suitability data.
- (d) The supplemental type-certificate is limited to that or those specific configurations in the type-certificate upon which the related major change is made.'; and

iii. The following is added:

'In addition, administrative procedures established by the Agency shall apply.'

42. Section B, Subpart M is amended as follows:

- i. The sentence 'Administrative procedures established by the Agency shall apply.' is deleted;
- ii. The following 21.B.113 and 21.B.115 are added:

**'21.B.113 Type-certification basis and environmental protection requirements for a repair design approval**

The Agency shall designate and notify to the applicant for a repair design any amendments to the type-certification basis incorporated by reference in the type-certificate or supplemental type-certificate or APU ETSO authorisation, as applicable,

which the Agency considers necessary for maintaining a level of safety equal to that previously established.

**21.B.115 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 21.A.432B;
  - 2. the applicant has complied with 21.A.433;
  - 3. the Agency, through its investigations in accordance with 21.B.100(a), has not found any non-compliance with the applicable 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 (a)(2) and (4) above, and that the Agency, through its investigations in accordance with 21.B.100(b), has not found any non-compliance with the applicable type-certification basis and environmental protection requirements.’; and

iii. The following is added:

‘In addition, administrative procedures established by the Agency shall apply.’.

43. Section B, Subpart O is amended as follows:

- i. The sentence ‘Administrative procedures established by the Agency shall apply.’ is deleted;
- ii. The following 21.B.117 is added:

**‘21.B.117 Issue of an ETSO authorisation**

The Agency shall issue an ETSO authorisation provided that:

- (a) the applicant has complied with 21.A.606; and
- (b) the Agency, through its verifications in accordance with 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 21.A.610, if any; and
- (c) no feature or characteristic has been identified that may make the product unsafe for the uses for which certification is requested.’; and

iii. The following is added:

‘In addition, administrative procedures established by the Agency shall apply.’.