COMMISSION DELEGATED REGULATION (EU) 2022/201

of 10 December 2021

amending Regulation (EU) No 748/2012 as regards management systems and occurrence-reporting systems to be established by design and production organisations, as well as procedures applied by the Agency, and correcting that Regulation

THE EUROPEAN COMMISSION,

Having regard to the Treaty on the Functioning of the European Union,

Having regard to Regulation (EU) 2018/1139 of the European Parliament and of the Council of 4 July 2018 on common rules in the field of civil aviation and establishing a European Union Aviation Safety Agency, and amending Regulations (EC) No 2111/2005, (EC) No 1008/2008, (EU) No 996/2010, (EU) No 376/2014 and Directives 2014/30/EU and 2014/53/EU of the European Parliament and of the Council, and repealing Regulations (EC) No 552/2004 and (EC) No 216/2008 of the European Parliament and of the Council and Council Regulation (EEC) No 3922/91 ([1]), and in particular Article 19(1) and Article 62(13) thereof,

Whereas:

(1) Commission Regulation (EU) No 748/2012 ([2]) lays down the requirements for the design and production of civil aircraft as well as engines, propellers and parts to be installed therein.

(2) In accordance with point 3.1(b) of Annex II to Regulation (EU) 2018/1139, approved design and production organisations must, as appropriate for the type of activity undertaken and the size of the organisation, implement and maintain a management system, to ensure compliance with the essential requirements set out in that Annex, manage safety risks and aim for the continuous improvement of that system.

(3) Pursuant to Annex 19 'Safety Management' to the Convention on International Civil Aviation, signed in Chicago on 7 December 1944 (the 'Chicago Convention'), competent authorities are to require approved organisations that design and produce civil aircraft, as well as engines, propellers and parts to be installed therein, to implement a safety management system.

(4) Regulation (EU) No 748/2012 already requires approved design and production organisations to comply with some elements of the management system; however, this management system does not completely cover the Standards and Recommended Practices (SARPs) for such a safety management system established in Annex 19 to the Chicago Convention. Therefore, the missing elements of the management system should be added to the existing requirements.

(5) In order to ensure a proportionate implementation and consistency with the approach used for continuing airworthiness organisations operating in the general aviation domain, design and production organisations, for which an approval is not mandatory under Regulation (EU) No 748/2012, should not be required to comply with all the elements of the management system.

([1]) OJ L 212, 22.8.2018, p. 1.

([2]) Commission Regulation (EU) No 748/2012 of 3 August 2012 laying down implementing rules for the airworthiness and environmental certification of aircraft and related products, parts and appliances, as well as for the certification of design and production organisations (OJ L 224, 21.8.2012, p. 1).

(6) All organisations, including those that have their principal place of business outside the Union, when they design and produce products and parts in accordance with Regulation (EU) No 748/2012, are already required to establish a mandatory and voluntary occurrence-reporting system. However, Regulation (EU) No 748/2012 should be amended to ensure that that occurrence-reporting system is aligned with the principles of Regulation (EU) No 376/2014 of the European Parliament and of the Council ([3]).

(7) In addition, the requirements for the Agency with regard to the tasks related to design certification, oversight and enforcement should be amended.

(8) A sufficient transition period should be provided for approved design organisations to ensure their compliance with the new rules and procedures introduced by this Regulation.

(9) The measures provided for in this Regulation are based on Opinion No 04/2020 ([4]), issued by the Agency in accordance with Article 76(1) of Regulation (EU) 2018/1139.

(10) Regulation (EU) No 748/2012 should therefore be amended accordingly.

(11) Commission Delegated Regulation (EU) 2021/699 ([5]) introduced a requirement that any future holder of the type-certificate or restricted type-certificate for a large aeroplane is to ensure that the continuing structural integrity programme remains valid throughout the operational life of the aeroplane. In particular, point 21.A.101(h) was added in Annex I to Regulation (EU) No 748/2012 to the effect that certain future holders are to comply with certification specifications that provide at least an equivalent level of safety to points 26.300, 26.320 and 26.330 of Annex I to Commission Regulation (EU) 2015/640 ([6]). An error occurred by referring to point 26.320, which does not exist. Regulation (EU) No 748/2012 should therefore be corrected accordingly,

HAS ADOPTED THIS REGULATION:

Article 1

Regulation (EU) No 748/2012 is amended as follows:

(1) in Article 8, the following paragraph 4 is added:

'4. By way of derogation from points 21.B.433(d)(1) and (2) of Annex I (Part 21), a design organisation that holds a valid approval certificate issued in accordance with Annex I (Part 21) may correct, until 7 March 2025, any findings of non-compliance related to the Annex I requirements introduced by Commission Delegated Regulation (EU) 2022/201 (*).

Where after 7 March 2025, the organisation has not closed such findings, the approval certificate shall be revoked, limited or suspended in whole or in part.

(*) Commission Delegated Regulation (EU) 2022/201 of 10 December 2021 amending Regulation (EU) No 748/2012 as regards management systems and occurrence-reporting systems to be established by design and production organisations, as well as procedures applied by the Agency, and correcting that Regulation (OJ L 33, …, p. 7)';

(2) Annex I (Part 21) is amended in accordance with Annex I to this Regulation.

([3]) Regulation (EU) No 376/2014 of the European Parliament and of the Council of 3 April 2014 on the reporting, analysis and follow-up of occurrences in civil aviation, amending Regulation (EU) No 996/2010 of the European Parliament and of the Council and repealing Directive 2003/42/EC of the European Parliament and of the Council and Commission Regulations (EC) No 1321/2007 and (EC) No 1330/2007 (OJ L 122, 24.4.2014, p. 18).

([4]) https://www.easa.europa.eu/document-library/opinions

([5]) Commission Delegated Regulation (EU) 2021/699 of 21 December 2020 amending and correcting Regulation (EU) No 748/2012 as regards the instructions for continued airworthiness, the production of parts to be used during maintenance and the consideration of ageing aircraft aspects during certification (OJ L 145, 28.4.2021, p. 1).

([6]) Commission Regulation (EU) 2015/640 of 23 April 2015 on additional airworthiness specifications for a given type of operations and amending Regulation (EU) No 965/2012 (OJ L 106, 24.4.2015, p. 18).

Article 2

Annex I (Part 21) to Regulation (EU) No 748/2012 is corrected in accordance with Annex II to this Regulation.

Article 3

This Regulation shall enter into force on the twentieth day following that of its publication in the *Official Journal of the European Union*.

It shall apply from 7 March 2023, with the exception of Article 2 which shall apply from 7 March 2022.

This Regulation shall be binding in its entirety and directly applicable in all Member States.

Done at Brussels, 10 December 2021.

For the Commission
The President
Ursula VON DER LEYEN

ANNEX I

Annex I (Part 21) is amended as follows:

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

'*Contents*

(2) point 21.A.1 is replaced by the following:

'**21.A.1 Scope**

This Subpart establishes the general rights and obligations of the applicant for, and holder of, any certificate that has been issued or is to be issued in accordance with this Annex.';

(3) point 21.A.3A is replaced by the following:

'**21.A.3A Reporting system**

(a) Without prejudice to Regulation (EU) No 376/2014 of the European Parliament and of the Council (*) and its delegated and implementing acts, all natural or legal persons that have applied for or hold a type-certificate, restricted type-certificate, supplemental type-certificate, European Technical Standard Order (ETSO) authorisation, major repair design approval or any other relevant approval deemed to have been issued under this Regulation shall:

1. establish and maintain a system for collecting, investigating and analysing occurrence reports in order to identify adverse trends or to address deficiencies and to extract occurrences whose reporting is mandatory in accordance with point 3 and those which are reported voluntarily. When the principal place of business is located in a Member State, a single system may be established to meet the requirements of Regulation (EU) No 376/2014 of of the European Parliament and of the Council and its implementing acts and of Regulation (EU) 2018/1139 and its delegated and implementing acts. The reporting system shall include:

   (i) reports of and information related to failures, malfunctions, defects or other occurrences which cause or might cause adverse effects on the continuing airworthiness of the product, part or appliance covered by the type-certificate, restricted type-certificate, supplemental type-certificate, ETSO authorisation, major repair design approval or by any other relevant approval deemed to have been issued under this Regulation;

   (ii) errors, near misses and hazards that do not fall under point (i);

2. make available to known operators of the product, part or appliance and, on request, to any person authorised under other implementing or delegated acts the information about the system established in accordance with point 1, and on how to provide reports of and information related to failures, malfunctions, defects or other occurrences referred to in point 1(i);

3. report to the Agency any failure, malfunction, defect or other occurrence of which it is aware and is related to a product, part or appliance covered by the type-certificate, restricted type-certificate, supplemental type-certificate, ETSO authorisation, major repair design approval or by any other relevant approval deemed to have been issued under this Regulation, and which has resulted or may result in an unsafe condition.

(b) Without prejudice to Regulation (EU) No 376/2014 of the European Parliament and of the Council and its delegated and implementing acts, any natural or legal person that holds or has applied for a production organisation approval certificate under Subpart G of this Section, or that produces a product, part or appliance under Subpart F of this Section, shall:

1. establish and maintain a system for collecting and assessing occurrence reports, including reports on errors, near misses and hazards, in order to identify adverse trends or to address deficiencies and extract occurrences whose reporting is mandatory in accordance with points 2 and 3 and those which are reported voluntarily. For organisations that have their principal place of business in a Member State, a single system may be established to meet the requirements of Regulation (EU) No 376/2014 of the European Parliament and of the Council and its implementing acts and of Regulation (EU) 2018/1139 and its delegated and implementing acts;

2. report to the responsible design approval holder all the cases where products, parts or appliances have been released by the production organisation and possible deviations from the applicable design data have been subsequently identified, and investigate with the design approval holder to identify those deviations which could lead to an unsafe condition;

3. report to the competent authority of the Member State responsible in accordance with point 21.1 and the Agency the deviations that have been identified in accordance with point 21.A.3A(b)2 and which could lead to an unsafe condition;

4. if the production organisation acts as a supplier to another production organisation, also report to that other organisation all the cases where it has released products, parts or appliances to that organisation and possible deviations from the applicable design data have been subsequently identified.

(c) Without prejudice to Regulation (EU) No 376/2014 of the European Parliament and of the Council and its delegated and implementing acts, any natural or legal person, when reporting in accordance with points (a)(3), (b)(2), (b)(3) and (b)(4), shall appropriately protect the confidentiality of the person who reports and of the person(s) mentioned in the report.

(d) Without prejudice to Regulation (EU) No 376/2014 of the European Parliament and of the Council and its delegated and implementing acts, any natural or legal person shall make the reports referred to in points (a)(3) and (b)(3) in a form and manner established by the Agency or the competent authority, respectively, and dispatch them as soon as practicable and in any case not later than 72 hours after the natural or legal person has identified that the occurrence may lead to a possible unsafe condition, unless exceptional circumstances prevent this.

(e) Without prejudice to Regulation (EU) No 376/2014 of the European Parliament and of the Council and its delegated and implementing acts, if an occurrence reported under point (a)(3) or under point (b)(3) results from a deficiency in the design or a production deficiency, the holder of the type-certificate, restricted type-certificate, supplemental type-certificate, major repair design approval, ETSO authorisation or any other relevant approval deemed to have been issued under this Regulation, or the production organisation as appropriate, shall investigate the reason for the deficiency and report to the competent authority of the Member State responsible in accordance with point 21.1 and to the Agency the results of its investigation and any action it intends to take or proposes to be taken to correct that deficiency.

(f) If the competent authority finds that action is required to correct the deficiency, the holder of the type-certificate, restricted type-certificate, supplemental type-certificate, major repair design approval, ETSO authorisation or any other relevant approval deemed to have been issued under this Regulation, or the production organisation as appropriate, shall submit the relevant data to the competent authority upon its request.

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(*) Regulation (EU) No 376/2014 of the European Parliament and of the Council of 3 April 2014 on the reporting, analysis and follow-up of occurrences in civil aviation, amending Regulation (EU) No 996/2010 of the European Parliament and of the Council and repealing Directive 2003/42/EC of the European Parliament and of the Council and Commission Regulations (EC) No 1321/2007 and (EC) No 1330/2007 (OJ L 122, 24.4.2014, p. 18).';

(4) point 21.A.5 is replaced by the following:

'**21.A.5 Record-keeping**

All natural or legal persons that hold or have applied for a type-certificate, restricted type-certificate, supplemental type-certificate, ETSO authorisation, design or repair approval, permit to fly, production organisation approval certificate or letter of agreement under this Regulation shall:

(a) when they design a product, part or appliance or changes or repairs thereto, establish a record-keeping system and maintain the relevant design information/data; that information/data shall be made available to the Agency in order to provide the information/data that is necessary to ensure the continued airworthiness of the product, part or appliance, the continued validity of the operational suitability data, and compliance with the applicable environmental protection requirements;

(b) when they produce a product, part or appliance, record the details of the production process relevant to the conformity of the product, part or appliances with the applicable design data, and the requirements imposed on their partners and suppliers, and make that data available to their competent authority in order to provide the information that is necessary to ensure the continuing airworthiness of the product, part or appliance;

(c) with regard to permits to fly:

1. maintain the documents that are produced to establish and justify the flight conditions, and make them available to the Agency and to their competent authority of the Member State in order to provide the information that is necessary to ensure the continued airworthiness of the aircraft;

2. when they issue a permit to fly under the privilege of approved organisations, maintain the documents associated with it, including inspection records and documents that support the approval of the flight conditions and the issuance of the permit to fly itself, and make them available to the Agency and to their competent authority of the Member State responsible for the oversight of the organisation in order to provide the information that is necessary to ensure the continued airworthiness of the aircraft;

(d) retain records of the competence and qualifications, referred to in points 21.A.139(c), 21.A.145(b), 21.A.145(c), 21.A.239(c), 21.A.245(a) or 21.A.245(e)(1), of the personnel that are involved in the following functions:

1. design or production;

2. independent monitoring of the compliance of the organisation with the relevant requirements;

3. safety management;

(e) retain records of the authorisation of personnel, when they employ personnel that:

1. exercise the privileges of the approved organisation pursuant to points 21.A.163 and/or 21.A.263, as appropriate;

2. carry out the independent function to monitor the compliance of the organisation with the relevant requirements pursuant to points 21.A.139(e) and/or 21.A.239(e), as appropriate;

3. carry out the independent verification function of the demonstration of compliance pursuant to point 21. A.239(d)(2).';

(5) the following point 21.A.9 is inserted:

'**21.A.9 Access and investigation**

Any natural or legal person that holds or has applied for a type-certificate, restricted type-certificate, supplemental type-certificate, ETSO authorisation, design change or repair approval, certificate of airworthiness, noise certificate, permit to fly, design organisation approval, production organisation approval certificate or letter of agreement under this Regulation, shall:

(a) grant the competent authority access to any facility, product, part and appliance, document, record, data, process, procedure or to any other material in order to review any report, make any inspection, or perform or witness any flight and ground test, as necessary, in order to verify the initial and continued compliance of the organisation with the applicable requirements of Regulation (EU) 2018/1139 and its delegated and implementing acts.;

(b) make arrangements to ensure the competent authority has access, as provided for in point (a), also in respect of the natural or legal person's partners, suppliers and subcontractors.';

(6) in point 21.A.44, point (a) is replaced by the following:

'(a) undertake the obligations laid down in points 21.A.3A, 21.A.3B, 21.A.4, 21.A.5, 21.A.6, 21.A.7, 21.A.9, 21. A.62 and 21.A.65, and, for this purpose, shall continue to meet the qualification requirements for eligibility under point 21.A.13;';

(7) point 21.A.47 is replaced by the following:

'**21.A.47 Transferability**

The transfer of a type-certificate or a restricted type-certificate or an ETSO authorisation for an auxiliary power unit may only be made to a natural or legal person that is able to undertake the obligations laid down in point 21.A.44, and, for this purpose, has demonstrated its capability in accordance with point 21.A.14.';

(8) in point 21.A.109, point (a) is replaced by the following:

'(a) undertake the obligations laid down in points 21.A.4, 21.A.5, 21.A.6, 21.A.7, 21.A.9 and 21.A.108;';

(9) in point 21.A.118A(a), point (1) is replaced by the following:

'1. laid down in points 21.A.3A, 21.A.3B, 21.A.4, 21.A.5, 21.A.6, 21.A.7, 21.A.9 and 21.A.120B;';

(10) the following point 21.A.124A is inserted:

'**21.A.124A Means of compliance**

(a) An organisation may use any alternative means of compliance to establish compliance with this Regulation.

(b) If an organisation wishes to use an alternative means of compliance, it shall, prior to using it, provide the competent authority with a full description. The description shall include any revisions to manuals or procedures that may be relevant, as well as an explanation indicating how compliance with this Regulation is achieved.

The organisation may use those alternative means of compliance subject to prior approval from the competent authority.';

(11) in point 21.A.125A, the title is replaced by the following:

'**21.A.125A Issuance of a letter of agreement**'

(12) point 21.A.125B is replaced by the following:

'**21.A.125B Findings and observations**

(a) After receipt of the notification of findings in accordance with point 21.B.125, the holder of a letter of agreement shall:

1. identify the root cause(s) of, and contributing factor(s) to, the non-compliance;

2. define a corrective action plan;

3. demonstrate the implementation of the corrective action to the satisfaction of the competent authority.

(b) The actions referred to in point (a) shall be performed within the period agreed with that competent authority in accordance with point 21.B.125.

(c) The observations received in accordance with point 21.B.125(e) shall be given due consideration by the holder of the letter of agreement. The organisation shall record the decisions taken in respect of those observations.';

(13) point 21.A.125C is replaced by the following:

'**21.A.125C Duration and continued validity**

(a) The letter of agreement shall be issued for a limited period of time that in any case shall not exceed 1 year. It shall remain valid subject to the organisation's compliance with all the following conditions:

1. the production organisation continues to comply with the applicable requirements of this Annex;

2. the production organisation or any of its partners, suppliers or subcontractors acknowledges that the competent authority may carry out investigations in accordance with point 21.A.9;

3. the production organisation is able to provide the competent authority with evidence showing that it maintains satisfactory control of the manufacture of products, parts and appliances under the letter of agreement;

4. the letter of agreement has not been revoked by the competent authority under point 21.B.65, has not been surrendered by the production organisation, and its duration has not expired.

(b) Upon surrender, revocation or expiry, the letter of agreement shall be returned to the competent authority.';

(14) point 21.A.126(b) is amended as follows:

(a) point (5) is replaced by the following:

'5. materials and parts that are withheld because of deviations from type design or production specifications, and that are to be considered for installation in the finished product, are subjected to an approved engineering and manufacturing review procedure. Those materials and parts that have been found in that procedure to be serviceable shall be properly identified and reinspected if it is necessary to be reworked or repaired. Materials and parts rejected in that procedure shall be marked and disposed of to ensure that they are not incorporated in the final product.';

(b) point (6) is deleted;

(15) point 21.A.129 is amended as follows:

(a) the title is replaced by the following:

'**21.A.129 Obligations of the production organisation**';

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

'(e) comply with Subpart A of this Section.';

(c) point (f) is deleted;

(16) the following point 21.A.134A is inserted:

'**21.A.134A Means of compliance**

(a) An organisation may use any alternative means of compliance to establish compliance with this Regulation.

(b) If an organisation wishes to use an alternative means of compliance, it shall, prior to using it, provide the competent authority with a full description. The description shall include any revisions to manuals or procedures that may be relevant, as well as an explanation indicating how compliance with this Regulation is achieved.

The organisation may use those alternative means of compliance subject to prior approval from the competent authority..';

(17) in point 21.A.135, the title is replaced by the following:

'**21.A.135 Issuance of production organisation approval**'

(18) point 21.A.139 is replaced by the following:

'**21.A.139 Production management system**

(a) The production organisation shall establish, implement and maintain a production management system that includes a safety management element and a quality management element, with clearly defined accountability and lines of responsibility throughout the organisation.

(b) The production management system shall:

1. correspond to the size of the organisation, and to the nature and complexity of its activities, taking into account the hazards and associated risks inherent in those activities;

2. be established, implemented and maintained under the direct accountability of a single manager appointed pursuant to point 21.A.145(c)(1).

(c) As part of the safety management element of the production management system, the production organisation shall:

1. establish, implement and maintain a safety policy and the corresponding related safety objectives;
2. appoint key safety personnel in accordance with point 21.A.145(c)(2);
3. establish, implement and maintain a safety risk management process to identify safety hazards entailed by its aviation activities, evaluate them and manage associated risks, including taking actions to mitigate the risks and verify their effectiveness;
4. establish, implement and maintain a safety assurance process that includes:
   (i) the measurement and monitoring of the organisation's safety performance;
   (ii) the management of changes in accordance with point 21.A.147;
   (iii) the principles for the continuous improvement of the safety management element;
5. promote safety in the organisation through:
   (i) training and education;
   (ii) communication;
6. establish an occurrence reporting system in accordance with point 21.A.3A in order to contribute to the continuous improvement of safety.

(d) As part of the quality management element of the production management system, the production organisation shall:

1. ensure that each product, part or appliance produced by the organisation or by its partners, or supplied from or subcontracted to outside parties, conforms to the applicable design data and is in condition for safe operation, thus enabling the exercise of the privileges set out in point 21.A.163;
2. establish, implement and maintain, as appropriate, within the scope of the approval, control procedures for:
   (i) document issue, approval or change;
   (ii) vendor and subcontractor assessment audit and control;
   (iii) verifying that incoming products, parts, materials and equipment, including items supplied new or used by buyers of products, are as specified in the applicable design data;
   (iv) identification and traceability;
   (v) manufacturing processes;
   (vi) inspection and testing, including production flight tests;
   (vii) the calibration of tools, jigs, and test equipment;
   (viii) non-conforming item control;
   (ix) airworthiness coordination with the applicant for, or holder of, the design approval;
   (x) the completion and retention of records;
   (xi) the competence and qualifications of personnel;
   (xii) the issue of airworthiness release documents;
   (xiii) handling, storage and packing;
   (xiv) internal quality audits and the resulting corrective actions;
   (xv) work within the terms of approval performed at any location other than the approved facilities;
   (xvi) work performed after the completion of production but prior to delivery, to maintain the aircraft in a condition for safe operation;
   (xvii) the issue of a permit to fly and approval of the associated flight conditions;
3. include specific provisions in the control procedures for any critical parts.

(e) The production organisation shall establish, as part of the production management system, an independent monitoring function to verify compliance of the organisation with the relevant requirements of this Annex as well as compliance with and adequacy of the production management system. Monitoring shall include feedback to the person or group of persons referred to in point 21.A.145(c)(2) and to the manager referred to in point 21.A.145(c)(1) to ensure, where necessary, the implementation of corrective action.

(f) If the production organisation holds one or more additional organisation certificates within the scope of Regulation (EU) 2018/1139, the production management system may be integrated with that required under the additional certificate(s) held.';

(19) point 21.A.143 is amended as follows:

(a) the title is replaced by the following:

'**21.A.143 Production organisation exposition**';

(b) point (a) is amended as follows:

(i) the introductory phrase is replaced by the following:

'(a) The production organisation shall establish and maintain a production organisation exposition (POE) that provides directly or by cross reference the following information related to the production management system as described in point 21.A.139:';

(ii) point (11) is replaced by the following:

'11. a description of the production management system, the policy, processes and procedures as provided for in point 21.A.139(c);';

(iii) point (12) is replaced by the following:

'12. a list of the outside parties referred to in point 21.A.139(d)(1);';

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

'(b) The initial issue of the POE shall be approved by the competent authority.';

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

'(c) The POE shall be amended as necessary so that it remains an up-to-date description of the organisation. Copies of any amendments shall be supplied to the competent authority.';

(20) point 21.A.145 is replaced by the following:

'**21.A.145 Resources**

The production organisation shall demonstrate that:

(a) the facilities, working conditions, equipment and tools, processes and associated materials, number and competence of staff, and the general organisation are adequate to discharge its obligations under point 21.A.165;

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

1. the production organisation holds all data it needs to determine conformity with the applicable design data. Such data may originate from the Agency and from the holder of, or applicant for, the type-certificate, restricted type-certificate or design approval, and may include any exemption granted from the environmental protection requirements;

2. the production organisation has established a procedure to ensure that the airworthiness and environmental protection data are correctly incorporated in its production data;

3. such data are kept up to date and made available to all personnel that need access to such data to perform their duties;

(c) with regard to management and staff:

1. an accountable manager has been appointed by the production organisation with the authority to ensure that, within the organisation, all production is performed to the required standards and that the production organisation is continuously in compliance with the requirements of the production management system referred to in point 21.A.139, and the data and procedures identified in the POE referred to in point 21.A.143;

2. a person or group of persons has/have been nominated by the accountable manager to ensure that the organisation is in compliance with the requirements of this Annex, and are identified, together with the extent of their authority; such person or group of persons shall be responsible to the accountable manager and have direct access to him. The person or group of persons shall have the appropriate knowledge, background and experience to discharge their responsibilities;

3. staff at all levels have been given the 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 protection data matters;

(d) with regard to certifying staff authorised by the production organisation to sign the documents issued under point 21.A.163 within the scope of the terms of approval:

1. they have the appropriate knowledge, background (including other functions in the organisation) and experience to discharge their allocated responsibilities;

2. they are provided with evidence of the scope of their authorisation.';

(21) point 21.A.147 is replaced by the following:

'**21.A.147 Changes in the production management system**

After the issue of a production organisation approval certificate, each change in the production management system that is significant for the demonstration of conformity or the airworthiness and environmental protection characteristics of the product, part or appliance, shall be approved by the competent authority before being implemented. The production organisation shall submit an application for approval to the competent authority demonstrating that it will continue to comply with this Annex.';

(22) point 21.A.157 is deleted;

(23) point 21.A.158 is replaced by the following:

'**21.A.158 Findings and observations**

(a) After receipt of the notification of findings in accordance with point 21.B.225, the holder of the production organisation approval certificate shall:

1. identify the root cause(s) of, and contributing factor(s) to, the non-compliance;

2. define a corrective action plan;

3. demonstrate the implementation of the corrective action to the satisfaction of the competent authority.

(b) The actions referred to in point (a) shall be performed within the period agreed with that competent authority in accordance with point 21.B.225.

(c) The observations received in accordance with 21.B.225(e) shall be given due consideration by the holder of the production organisation approval certificate. The organisation shall record the decisions taken in respect of those observations.';

(24) point 21.A.159 is replaced by the following:

'**21.A.159 Duration and continued validity**

(a) A production organisation approval certificate shall be issued for an unlimited period of time. It shall remain valid subject to the production organisation's compliance with all the following conditions:

1. the production organisation continues to comply with the applicable requirements of Regulation (EU) 2018/1139 and its delegated and implementing acts;

2. the competent authority is permitted by the production organisation or by any of its partners, suppliers or subcontractors to perform the investigations in accordance with point 21.A.9;

3. the production organisation is able to provide the competent authority with evidence showing that it maintains satisfactory control of the manufacture of products, parts and appliances under the approval;

4. the production organisation approval certificate has not been revoked by the competent authority under point 21.B.65, or surrendered by the production organisation.

(b) Upon surrender or revocation, the production organisation approval certificate shall be returned to the competent authority.';

(25) point 21.A.165 is amended as follows:

(a) points (d) to (h) are replaced by the following:

'(d) provide assistance to the holder of the type-certificate or other design approval in dealing with any continuing airworthiness actions that are related to the products, parts or appliances that have been produced;

(e) where, under its terms of approval, the holder of a production organisation approval intends to issue a certificate of release to service, determine, prior to issuing the certificate, that each completed aircraft has been subjected to necessary maintenance and is in condition for safe operation;

(f) where applicable, under the privilege set out in point 21.A.163(e), determine the conditions under which a permit to fly can be issued;

(g) where applicable, under the privilege set out in point 21.A.163(e), establish compliance with points 21.A.711(c) and (e) before issuing an aircraft with a permit to fly;

(h) comply with Subpart A of this Section.';

(b) points (i), (j) and (k) are deleted;

(26) point 21.A.180 is deleted;

(27) point 21.A.181(a) is amended as follows:

(a) the introductory phrase is replaced by the following:

'(a) An airworthiness certificate shall be issued for an unlimited period of time. It shall remain valid subject to compliance with all the following conditions:';

(b) point (1) is replaced by the following:

'1. the aircraft continues to comply with the applicable type design and continued airworthiness requirements; and';

(c) point (4) is replaced by the following:

'4. the certificate has not been revoked by the competent authority under point 21.B.65, or surrendered by the certificate holder.';

(28) point 21.A.210 is deleted;

(29) point 21.A.211(a) is amended as follows:

(a) the introductory phrase is replaced by the following:

'(a) A noise certificate shall be issued for an unlimited period of time. It shall remain valid subject to compliance with all the following conditions:';

(b) point (a)(1) is replaced by the following:

'1. the aircraft continues to comply with the applicable type design and continued airworthiness requirements; and';

(c) point (4) is replaced by the following:

'(4) the certificate has not been revoked by the competent authority under point 21.B.65, or surrendered by the certificate holder.';

(30) point 21.A.239 is replaced by the following:

'**21.A.239 Design management system**

(a) The design organisation shall establish, implement and maintain a design management system that includes a safety management element and a design assurance element with clearly defined accountability and lines of responsibility throughout the organisation.

(b) The design management system shall:

1. correspond to the size of the organisation and to the nature and complexity of its activities, taking into account the hazards and associated risks inherent in those activities;

2. be established, implemented and maintained under the accountability of a single manager appointed pursuant to point 21.A.245(a).

(c) As part of the safety management element of the design management system, the design organisation shall:

1. establish, implement and maintain a safety policy and the corresponding related safety objectives;

2. appoint key safety personnel in accordance with point 21.A.245(b);

3. establish, implement and maintain a safety risk management process that includes the identification of aviation safety hazards entailed by its activities, their evaluation and the management of the associated risks, including taking actions to mitigate the risks and verify their effectiveness;

4. establish, implement and maintain a safety assurance process that includes:

(i) the measurement and monitoring of the organisation's safety performance;

(ii) the management of changes in accordance with points 21.A.243(c) and 21.A.247;

(iii) the principles for the continuous improvement of the safety management element;

5. promote safety in the organisation through:

(i) training and education;

(ii) communication;

6. establish an occurrence reporting system in accordance with point 21.A.3A in order to contribute to continuous improvement of safety.

(d) As part of the design assurance element of the design management system, the design organisation shall:

1. establish, implement and maintain a system for the control and supervision of the design, and of design changes and repairs, of products, parts and appliances covered by the terms of approval; that system shall:

(i) include an airworthiness function responsible for ensuring that the design of products, parts and appliances, or the design changes and repairs, comply with the applicable type-certification basis, the applicable operational suitability data certification basis and the environmental protection requirements;

(ii) ensure that the design organisation properly discharges its responsibilities in accordance with this Annex and with the terms of approval issued under point 21.A.251;

2. establish, implement and maintain an independent verification function on the basis of which the design organisation demonstrates compliance with the applicable airworthiness, operational suitability data and environmental protection requirements;

3. specify the manner in which the design management system accounts for the acceptability of the parts or appliances that are designed or the tasks that are performed by its partners or subcontractors according to the methods which are the subject of written procedures.

(e) The design organisation shall establish, as part of the design management system, an independent monitoring function to verify compliance of the organisation with the relevant requirements of this Annex as well as the compliance with and adequacy of the design management system. Monitoring shall include feedback to the person or the group of persons referred to in point 21.A.245(b) and to the manager referred to in point 21.A.245(a) to ensure, where necessary, the implementation of corrective action.

(f) If the design organisation holds one or more additional organisation certificates within the scope of Regulation (EU) 2018/1139, the design management system may be integrated with that required under the additional certificate(s).';

(31) point 21.A.243 is replaced by the following:

'**21.A.243 Handbook**

(a) As part of the design management system, the design organisation shall create and furnish to the Agency a handbook that describes, directly or by cross reference, the organisation, its relevant policies, processes and procedures, the type of design work, and the categories of products, parts and appliances for which the design organisation holds a design organisation approval, as identified in the terms of approval issued in accordance with point 21.A.251 and, where relevant, the interfaces with and the control of its partners or subcontractors.

If flight tests are to be conducted, a flight test operations manual that defines the organisation's policies and procedures in relation to flight tests shall also be created and furnished to the Agency. The flight test operations manual shall include:

1. a description of the organisation's processes for flight tests, including its involvement in the process for issuing a permit to fly;

2. crewing policy, including composition, competency, currency and flight time limitations, in accordance with Appendix XII, where applicable;

3. procedures for the carriage of persons other than the crew members and for flight test training, where applicable;

4. a policy for the risk and safety management and associated methodologies;

5. procedures to identify the instruments and equipment to be carried on board;

6. a list of documents that need to be produced for the flight test.

(b) Where any parts or appliances or any changes to the products are designed by partner organisations or subcontractors, the handbook shall include a statement of how the design organisation is able to demonstrate, for all parts and appliances, the compliance in accordance with point 21.A.239(d)(2), and shall contain, directly or by cross reference, descriptions of and information on the design activities and the organisation of those partner organisations or subcontractors, as necessary to establish the statement.

(c) The handbook shall be amended as necessary to remain an up-to-date description of the organisation, and copies of the amendments shall be provided to the Agency.

(d) The design organisation shall establish and maintain a statement of the qualifications and experience of the management staff and of other persons in the organisation that are responsible for making decisions that affect airworthiness, operational suitability data and environmental protection matters. It shall submit that statement to the competent authority';

(32) point 21.A.245 is replaced by the following:

'**21.A.245 Resources**

(a) The organisation shall appoint a head of the design organisation with the authority to ensure that, within the organisation, all design activities are performed to the required standards and that the design organisation is continuously in compliance with the requirements of the design management system referred to in point 21.A.239 and the procedures specified in the handbook referred to in point 21.A.243.

(b) The head of the design organisation shall nominate and specify the extent of authority of:

1. a chief of the airworthiness function;

2. a chief of the independent monitoring function;

3. depending on the size of the organisation and the nature and complexity of its activities, any other person or group of persons that are required to ensure that the organisation complies with the requirements of this Annex.

(c) By way of derogation from point 21.A.245(b)(1), the airworthiness function referred to in point 21.A.239(d)(1)(i) may be performed under the direct supervision of the head of the design organisation in either of the following cases:

1. where the scope of activities of/of work of the design organisation, as identified in the terms of approval issued under point 21.A.251, is limited to minor changes and/or minor repairs;

2. for a limited period of time when the design organisation does not have a nominated chief of the airworthiness function and the exercise of that function under the direct supervision of the head of the design organisation is commensurate with the scope and level of the organisation's activities.

(d) The person or group of persons nominated pursuant to point (b) shall:

1. be answerable to the head of the design organisation and have direct access to them;

2. have the appropriate knowledge, background and experience to discharge their responsibilities.

(e) The design organisation shall ensure that:

1. the staff in all technical departments are of sufficient numbers and experience and have been given the appropriate authority to be able to discharge their allocated responsibilities and the facilities, equipment and accommodation that are adequate to enable the staff to fulfil the airworthiness, operational suitability data and environmental protection requirements as regards the product;

2. there is full and efficient coordination between the departments and within the departments in respect of airworthiness, operational suitability data and environmental protection matters.';

(33) point 21.A.247 is replaced by the following:

'**21.A.247 Changes in the design management system**

After the issue of a design organisation approval, each change to the design management system that is significant to the demonstration of compliance or to the airworthiness, operational suitability and environmental protection of the product, part or appliance shall be approved by the Agency before being implemented. The design organisation shall submit to the Agency an application for approval demonstrating, on the basis of the proposed changes to the handbook, that it will continue to comply with this Annex.';

(34) point 21.A.257 is deleted;

(35) point 21.A.258 is replaced by the following:

'**21.A.258 Findings and observations**

(a) After the receipt of the notification of findings in accordance with point 21.B.433, the holder of the design organisation approval shall:

1. identify the root cause(s) of, and contributing factor(s) to, the non-compliance;

2. establish a corrective action plan;

3. demonstrate the implementation of the corrective action to the satisfaction of the Agency.

(b) The actions referred to in point (a) shall be performed within the period agreed by the Agency in accordance with point 21.B.433.

(c) The observations received in accordance with point 21.B.433(e) shall be given due consideration by the holder of the design organisation approval. The organisation shall record the decisions taken in respect of those observations.';

(36) point 21.A.259 is replaced by the following:

'**21.A.259 Duration and continued validity**

(a) A design organisation approval shall be issued for an unlimited period of time. It shall remain valid subject to the design organisation's compliance with all the following conditions:

1. the design organisation continues to comply with Regulation (EU) 2018/1139 and its delegated and implementing acts; taking into account the provisions of point 21.B.433 of this Annex related to the handling of findings;

2. the holder of the design organisation approval or any of its partners or subcontractors acknowledge that the competent authority may carry out investigations in accordance with point 21.A.9;

3. the design organisation is able to provide the Agency with evidence showing that the design management system of the organisation maintains satisfactory control and supervision of the design of products, repairs and changes thereto under the approval;

4. the certificate has not been revoked by the Agency under point 21.B.65, or surrendered by the design organisation.

(b) Upon surrender or revocation, the certificate shall be returned to the Agency.';

(37) in point 21.A.263(c), the introductory phrase is replaced by the following:

'(c) The holder of a design organisation approval shall be entitled, within the scope of its terms of approval issued under point 21.A.251 and under the relevant procedures of the design management system:';

(38) point 21.A.265 is amended as follows:

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

'(c) determine that the design of the products, or of the changes or repairs thereto, complies with the applicable type-certification basis, operational suitability data certification basis, and the environmental protection requirements, and have no unsafe features;';

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

'(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]";'

(c) the following point (i) is inserted:

'(i) comply with Subpart A of this Section.';

(39) point 21.A.451 is amended as follows:

(a) point (a)(1)(i) is replaced by the following:

'(i) laid down in points 21.A.3A, 21.A.3B, 21.A.4, 21.A.5, 21.A.6, 21.A.7, 21.A.9, 21.A.439, 21.A.441 and 21.A.443;';

(b) point (b)(1) is replaced by the following:

'1. undertake the obligations laid down in points 21.A.4, 21.A.5 and 21.A.7;';

(40) in point 21.A.604, point (a) is replaced by the following:

'(a) by way of derogation from points 21.A.9, 21.A.603, 21.A.610 and 21.A.621, 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.A.47, 21.B.75 and 21.B.80. However, an ETSO authorisation shall be issued in accordance with point 21.A.606 instead of the type-certificate;';

(41) point 21.A.609 is amended as follows:

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

'(b) prepare and maintain, for each model of each article for which an ETSO authorisation has been issued, an updated set of complete technical data and records in accordance with point 21.A.5;';

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

'(f) comply with points 21.A.3A, 21.A.3B, 21.A.4 and 21.A.9;';

(42) point 21.A.615 is deleted;

(43) point 21.A.619 is replaced by the following:

'**21.A.619 Duration and continued validity**

(a) An ETSO authorisation shall be issued for an unlimited period of time. It shall remain valid subject to compliance with all the following conditions:

1. the conditions set when the ETSO authorisation was granted continue to be observed by the applicant;
2. the obligations specified in point 21.A.609 continue to be discharged by the ETSO authorisation holder;
3. the holder of the ETSO authorisation or any of its partners, suppliers or subcontractors acknowledge that the competent authority may carry out investigations in accordance with point 21.A.9;
4. it has been proved that the ETSO article does not give rise to unacceptable hazards in service;
5. the ETSO authorisation has not been revoked by the Agency under point 21.B.65, or surrendered by its holder.

(b) Upon surrender or revocation, the ETSO authorisation shall be returned to the Agency.';

(44) point 21.A.705 is deleted;

(45) in point 21.A.711, the title is replaced by the following:

'**21.A.711 Issuance of a permit to fly**';

(46) point 21.A.721 is deleted;

(47) in point 21.A.723, point (a) is replaced by the following:

'(a) A permit to fly shall be issued for a maximum period of 12 months and shall remain valid subject to compliance with all the following conditions:

1. the organisation continues to comply with the conditions and restrictions associated with the permit to fly as set out in point 21.A.711(e);
2. the holder or any of its partners, suppliers or subcontractors acknowledge that the competent authority may carry out investigations in accordance with point 21.A.9;
3. the permit to fly has not been revoked by the competent authority under point 21.B.65, or surrendered by its holder;
4. the aircraft remains on the same register.';

(48) point 21.A.729 is deleted;

(49) in point 21.B.103, the title is replaced by the following:

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

(50) in point 21.B.107, the title is replaced by the following:

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

(51) in point 21.B.111, the title is replaced by the following:

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

(52) point 21.B.150 is deleted;

(53) point 21.B.260 is deleted;

(54) in point 21.B.425, the title is replaced by the following:

'**21.B.425 Issuance of noise certificates**';

(55) in point 21.B.453, the title is replaced by the following:

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

(56) points 21.B.430 and 21.B.445 are deleted;

(57) in Section B, Subpart J is replaced by the following::

'**SUBPART J – DESIGN ORGANISATION APPROVAL**

21.B.430 Initial certification procedure

(a) Upon receiving an application for the initial issue of a design organisation approval, the competent authority shall verify the applicant's compliance with the applicable requirements,

(b) A meeting with the head of the design organisation shall be convened at least once during the investigation for initial certification to ensure that this person understands their role and accountability.

(c) The competent authority shall record all the findings issued, closure actions as well as recommendations for the issue of the design organisation approval.

(d) The competent authority shall confirm to the applicant in writing all the findings raised during the verification. For initial certification, all findings must be corrected to the satisfaction of the competent authority before the design organisation approval can be issued.

(e) When satisfied that the applicant complies with the applicable requirements, the competent authority shall issue the design organisation approval.

(f) The certificate reference number shall be included in the design organisation approval in a manner specified by the Agency.

(g) The certificate shall be issued for an unlimited period of time. The privileges and the scope of the activities that the design organisation is approved to perform, including any limitations as applicable, shall be specified in the terms of approval attached to the design organisation approval.

21.B.431 Oversight principles

The competent authority shall verify whether certified organisations continue to comply with the applicable requirements

(a) The verification shall:

1. be supported by documentation specifically intended to provide personnel responsible for oversight with guidance to perform their functions;

2. provide the organisations concerned with the results of oversight activities;

3. be based on assessments, audits, inspections and, if needed, unannounced inspections;

4. provide the competent authority with the evidence needed in case further action is required, including the measures provided for in point 21.B.433.

(b) The competent authority shall establish the scope of the oversight set out in point (a) taking into account the results of past oversight activities and the safety priorities.

(c) The competent authority shall collect and process any information deemed necessary for performing oversight activities.

21.B.432 Oversight programme

(a) The competent authority shall establish and maintain an oversight programme covering the oversight activities required to comply with point 21.B.431(a).

(b) The oversight programme shall take into account the specific nature of the organisation, the complexity of its activities, the results of past certification or oversight activities, or both, and it shall be based on the assessment of the associated risks. It shall include, within each oversight planning cycle:

1. assessments, audits and inspections, including, where appropriate:

(i) management system assessments and process audits;

(ii) product audits of a relevant sample of the design and certification of the products, parts and appliances that are within the scope of work of the organisation;

(iii) sampling of the work performed;

(iv) unannounced inspections;

2. meetings convened between the head of the design organisation and the competent authority to ensure that both parties remain informed of all significant issues.

(c) The oversight planning cycle shall not exceed 24 months.

(d) Notwithstanding point (c), the oversight planning cycle may be extended to 36 months if the competent authority has established that during the previous 24 months:

1. the organisation has demonstrated that it can effectively identify aviation safety hazards and manage the associated risks;

2. the organisation has continuously demonstrated compliance with point 21.A.247 and has full control over all changes to the design management system;

3. no level 1 findings have been issued;

4. all corrective actions have been implemented within the time period that was accepted or extended by the competent authority as provided for in point 21.B.433(d).

Notwithstanding point (c), the oversight planning cycle may be further extended to a maximum of 48 months if, in addition to the conditions laid down in points (d)(1) to (d)(4), the organisation has established, and the competent authority has approved, an effective continuous system for reporting to the competent authority on the safety performance and regulatory compliance of the organisation itself.

(e) The oversight planning cycle may be reduced if there is evidence that the safety performance of the organisation has decreased.

(f) The oversight programme shall include records of the dates when assessments, audits, inspections and meetings are due, and when assessments, audits, inspections and meetings have been effectively carried out.

(g) At the completion of each oversight planning cycle, the competent authority shall issue a recommendation report on the continuation of the approval, reflecting the results of the oversight.

21.B.433 Findings and corrective actions; observations

(a) The competent authority shall have a system in place to analyse findings for their safety significance.

(b) A level 1 finding shall be issued by the competent authority when a non-compliance is detected with the applicable requirements of Regulation (EU) 2018/1139 and its delegated and implementing acts, with the organisation's procedures and manuals, or with the design organisation's certificate including the terms of approval, which may lead to uncontrolled non-compliances and to a potential unsafe condition.

The level 1 findings shall also include:

1. any failure to grant the competent authority access to the organisation's facilities referred to in point 21.A.9 during normal operating hours and after two written requests;

2. obtaining the design organisation approval or maintaining its validity by falsification of the submitted documentary evidence;

3. any evidence of malpractice or fraudulent use of the design organisation approval;

4. failure to appoint a head of the design organisation pursuant to point 21.A.245(a).

(c) A level 2 finding shall be issued by the competent authority when any non-compliance is detected with the applicable requirements of Regulation (EU) 2018/1139 and its delegated and implementing acts, with the organisation's procedures and manuals, or with the certificate including the terms of approval, which is not classified as a level 1 finding.

(d) When a finding is detected during oversight or by any other means, the competent authority shall, without prejudice to any additional action required by Regulation (EU) 2018/1139 and its delegated and implementing acts, communicate in writing the finding to the organisation and request corrective action to address the non-compliance(s) identified. Where a level 1 finding directly relates to a product, the competent authority shall inform the competent authority of the Member State in which the aircraft is registered.

1. If there are any level 1 findings, the competent authority shall:

(i) grant the organisation a corrective action implementation period that is appropriate to the nature of the finding and that in any case shall not be more than 21 working days. That period shall commence from the date of the written communication of the finding to the organisation requesting corrective action to address the non-compliance(s) identified;

(ii) assess the corrective action plan and implementation plan proposed by the organisation, and if it concludes that they are sufficient to address the non-compliance(s), accept them;

(iii) if the organisation fails to submit an acceptable corrective action plan, or fails to perform the corrective action within the time period accepted by the competent authority, take immediate and appropriate action to prohibit or limit the activities of the organisation involved and, if appropriate, take action to revoke the design organisation approval or to limit or suspend it in whole or in part, depending upon the extent of the level 1 finding, until successful corrective action has been taken by the organisation.

2. If there are any level 2 findings, the competent authority shall:

(i) grant the organisation a corrective action implementation period that is appropriate to the nature of the finding, and that in any case shall initially not be more than 3 months. That period shall commence from the date of the written communication of the finding requesting corrective action. At the end of this period, and subject to the nature of the finding, the competent authority may extend the 3-month period provided that a corrective action plan has been agreed by the competent authority;

(ii) assess the corrective action and the implementation plan proposed by the organisation, and if it concludes that they are sufficient to address the non-compliance(s), accept them;

(iii) if the organisation fails to submit an acceptable corrective action plan, or fails to perform the corrective action within the time period accepted or extended by the competent authority, the finding shall be raised to level 1 and action shall be taken as laid down in point (d)(1).

(e) The competent authority may issue observations for any of the following cases not requiring level 1 or level 2 findings:

1. for any item whose performance has been assessed to be ineffective;

2. when it has been identified that an item has the potential to cause a non-compliance under points (b) or (c);

3. when suggestions or improvements are of interest for the overall safety performance of the organisation.

The observations issued under this point shall be communicated in writing to the organisation and recorded by the competent authority.

21.B.435 Changes in the design management system

(a) Upon receiving an application for a significant change to the design management system, the competent authority shall verify the organisation's compliance with the applicable requirements of Regulation (EU) 2018/1139 and its delegated and implementing acts, before issuing the approval.

(b) The competent authority shall establish the conditions under which the organisation may operate during the change unless the competent authority determines that the design organisation approval needs to be suspended.

(c) When it is satisfied that the organisation complies with the applicable requirements of Regulation (EU) 2018/1139 and its delegated and implementing acts, the competent authority shall approve the change.

(d) Without prejudice to any additional enforcement measures, if the organisation implements a significant change to the design management system without having received the approval of the competent authority pursuant to point (c), the competent authority shall consider the need to suspend, limit or revoke the organisation's certificate.

(e) For non-significant changes to the design management system, the competent authority shall include the review of such changes in its continuing oversight in accordance with the principles set forth in point 21.B.431. If any non-compliance is found, the competent authority shall notify the organisation, request further changes and act in accordance with point 21.B.433.';

(58) in point 21.B.453, the title is replaced by the following

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

(59) in point 21.B.480, the title is replace by the following:

'**21.B.480 Issuance of an ETSO authorisation**';

(60) Appendix VIII is replaced by the following:

'Appendix VIII

Aircraft statement of conformity – EASA Form 52

AIRCRAFT STATEMENT OF CONFORMITY		
1. State of manufacture	2. [MEMBER STATE] ([1]) A Member of the European Union ([2])	3. Statement ref. no:
4. Organisation		
5. Aircraft type	6. Type-certificate ref. nos:	
7. Aircraft registration or mark	8. Production organisation identification no:	
9. Engine/propeller details ([3])		
10. Modifications and/or service bulletins ([3])		
11. Airworthiness directives		
12. Concessions		
13. Exemptions, waivers or derogations ([3])		
14. Remarks		
15. Certificate of airworthiness		
16. Additional requirements		
17. Statement of conformity It is hereby certified that the aircraft conforms fully to the type-certified design and to the items in blocks 9, 10, 11, 12 and 13. The aircraft is in a condition for safe operation. The aircraft has been satisfactorily tested in flight.		
18. Signed	19. Name	20. Date (d/m/y)
21. Production organisation approval reference		

EASA Form 52 – Issue 3

([1]) Or "EASA", if EASA is the competent authority.

([2]) Delete for non-EU Member States or EASA.

([3]) Delete as applicable.

Instructions for the use of the "Aircraft statement of conformity – EASA Form 52"

1. PURPOSE AND SCOPE

1.1. The use of the aircraft statement of conformity issued by a production organisation that produces under Part 21 Section A Subpart F is described in point 21.A.130 and in the related acceptable means of compliance (AMC).

1.2. The purpose of the aircraft statement of conformity (EASA Form 52) issued under Part 21 Section A Subpart G is to enable the holder of an appropriate production organisation approval certificate to exercise the privilege to obtain an individual aircraft certificate of airworthiness and, if requested, a certificate of noise from the competent authority of the Member State of registry.

2. GENERAL

2.1. The statement of conformity must comply with the model, including the block numbers and the location of each block. The size of each block may, however, be varied to suit the individual application, but not to the extent that would render the statement of conformity unrecognisable. If in doubt, consult the competent authority.

2.2. The statement of conformity must be either preprinted or computer generated, but in either case, the printing of lines and characters must be clear and legible. Preprinted wording is permitted in accordance with the attached model, but no other certification statements are permitted.

2.3. The completion of the statement may be either machine/computer printed or handwritten, using block letters to allow for easy reading. English, and where relevant, one or more of the official language(s) of the issuing Member State, are acceptable.

2.4. A copy of the statement and all the referenced attachments are to be retained by the approved production organisation.

3. COMPLETION OF THE STATEMENT OF CONFORMITY BY THE ORIGINATOR

3.1. There must be an entry in all blocks to render the document a valid statement.

3.2. A statement of conformity may not be issued to the competent authority of the Member State of registry unless the design of the aircraft and its installed products are approved.

3.3. The information required in blocks 9, 10, 11, 12, 13 and 14 may be by reference to separate identified documents held on file by the production organisation, unless the competent authority agrees otherwise.

3.4. This statement of conformity is not intended to include those items of equipment that may be required to be fitted in order to satisfy the applicable operational rules. However, some of those individual items may be included in block 10 or in the approved type design. Operators are therefore reminded of their responsibility to ensure compliance with the applicable operational rules for their own particular operations.

Block 1 Enter the name of the State of manufacture.

Block 2 The competent authority that issues the statement of conformity under its authority.

Block 3 A unique serial number must be preprinted in this block for statement control and traceability purposes. An exception is in the case of a computer-generated document: the number need not be preprinted where the computer is programmed to produce and print a unique number.

Block 4 The full name and the address of the location of the organisation that issues the statement. This block may be preprinted. Logos, etc., are permitted if the logo, etc., can be contained within the block.

Block 5	The aircraft type in full as specified in the type-certificate and its associated data sheet.
Block 6	The type-certificate reference numbers and issue for the subject aircraft.
Block 7	If the aircraft is registered, then this mark will be the registration mark. If the aircraft is not registered, then this will be the mark that is accepted by the competent authority of the Member State and, if applicable, by the competent authority of a third country.
Block 8	The identification number assigned by the production organisation for control and traceability and product support purposes. This is sometimes referred to as a "production organisation serial number" or "constructor's number".
Block 9	The engine type and the propeller type(s) in full as specified in the relevant type-certificate and its associated data sheet. Their production organisation identification number and the associated location must also be stated.
Block 10	Approved design changes to the aircraft definition.
Block 11	A listing of all the applicable airworthiness directives (or equivalent) and a declaration of compliance, together with a description of the method of compliance of the subject individual aircraft, including products and installed parts, appliances and equipment. Any future compliance requirement time must be stated.
Block 12	Approved unintentional deviations from the approved type design, sometimes referred to as "concessions", "divergences" or "non-conformances".
Block 13	Only agreed exemptions, waivers or derogations may be included here.
Block 14	Remarks. Any statement, information, particular data or limitation which may affect the airworthiness of the subject aircraft. If there is no such information or data, state "NONE".
Block 15	Enter "certificate of airworthiness", or "restricted certificate of airworthiness", as requested.
Block 16	Additional requirements such as those notified by an importing country must be noted in this block.
Block 17	The validity of the statement of conformity is subject to the full completion of all the blocks on the form. A copy of the flight test report, together with any recorded defects and rectification details, must be kept on file by the production organisation approval certificate holder. The report must be signed as satisfactory by the appropriate certifying staff and a flight crew member, e.g. the test pilot or the flight test engineer. The flight tests performed are those defined under the control of the quality management element of the production system, as established by point 21.A.139, in particular point 21.A.139(d)(1)(vi), to ensure that the aircraft conforms to the applicable design data, and is in condition for safe operation. The listing of items provided (or made available) to satisfy the aspects of this statement that relate to the safe operation of the aircraft must be kept on file by the production organisation approval certificate holder.
Block 18	The statement of conformity may be signed by the person that is authorised to do so by the production approval holder in accordance with point 21.A.145(d). A rubber stamp signature must not be used.
Block 19	The name of the person that signs the statement must be typed or printed in a legible form.
Block 20	The date on which the statement of conformity is signed must be given.
Block 21	The competent authority approval reference must be quoted.'

(61) Appendix X is replaced by the following:

'Appendix X

Production organisation approval certificate – EASA Form 55

Production organisation approval certificates referred to in Subpart G of Annex I (Part 21)

[MEMBER STATE] ([1])

A Member of the European Union ([2])

PRODUCTION ORGANISATION APPROVAL CERTIFICATE

Reference: [MEMBER STATE CODE ([1])].21G.XXXX

Pursuant to Regulation (EU) 2018/1139 of the European Parliament and of the Council and to Commission Regulation (EU) No 748/2012, for the time being in force and subject to the conditions specified below, the [COMPETENT AUTHORITY OF THE MEMBER STATE] hereby certifies:

[COMPANY NAME AND ADDRESS]

as a production organisation in compliance with Annex I (Part 21) Section A of Regulation (EU) No 748/2012, is approved to produce products, parts and appliances listed in the attached approval schedule and issue the related certificates using the above references.

CONDITIONS:

1. This approval is limited to that specified in the enclosed terms of approval.
2. This approval is subject to compliance with the procedures specified in the approved production organisation exposition.
3. This approval is valid while the approved production organisation remains in compliance with Annex I (Part 21) to Regulation (EU) No 748/2012.
4. Subject to compliance with the foregoing conditions, this approval shall remain valid for an unlimited period of time unless it has previously been surrendered, superseded, suspended or revoked.

Date of original issue:……

Date of this revision:……

Revision No:……

Signed:……

For the competent authority: [COMPETENTAUTHORITY IDENTIFICATION ([1])]

EASA Form 55a – Issue 3

([1]) Or "EASA", if EASA is the competent authority.

([2]) Delete for non-EU Member States.

[MEMBER STATE] ([1]) A Member of the European Union ([2])	**Terms of approval**	TA: [MEMBER STATE CODE ([1])].21G.XXXX

This document is part of the production organisation approval number [MEMBER STATE CODE ([1])].21G.XXXX issued to:

Company name:

Section 1. **SCOPE OF WORK:**

PRODUCTION OF	PRODUCTS/CATEGORIES

For details and limitations, refer to the Production Organisation Exposition, Section xxx

Section 2. **LOCATIONS:**

Section 3. **PRIVILEGES:**

The production organisation is entitled to exercise, within its terms of approval and in accordance with the procedures of its Production Organisation Exposition, the privileges laid down in point 21.A.163, subject to the following:

[keep only applicable text]

Prior to the approval of the design of the product, the EASA Form 1 may be issued only for conformity purposes.

A statement of conformity may not be issued for a non-approved aircraft.

Maintenance may be performed, until compliance with the maintenance regulations is required, in accordance with the Production Organisation Exposition Section xxx

Permits to fly may be issued in accordance with the Production Organisation Exposition Section yyy

Date of original issue:	Signed:
Date of this revision:	
Revision No:	For [COMPETENT AUTHORITY IDENTIFICATION ([1])]

EASA Form 55b – Issue 3

([1]) Or "EASA", if EASA is the competent authority.

([2]) Delete for non-EU Member States.'

(62) Appendix XI is replaced by the following:

'Appendix XI

Letter of agreement for production without a production organisation approval – EASA Form 65

Letter of agreement referred to in Subpart F of Annex I (Part 21)

[MEMBER STATE] ([1])

A Member of the European Union ([2])

LETTER OF AGREEMENT FOR PRODUCTION WITHOUT A PRODUCTION ORGANISATION APPROVAL

[NAME OF THE APPLICANT]

[TRADE NAME (if different from the name of the applicant)]

[FULL POSTAL ADDRESS OF THE APPLICANT]

Date (Day, Month, Year)

Reference: [MEMBER STATE CODE ([2])].21F.XXXX

Dear Mr/Ms [Name of the Applicant],

Your production inspection system has been evaluated and found to be in compliance with Section A, Subpart A and Subpart F of Annex I (Part 21) to Commission Regulation (EU) No 748/2012.

Therefore, subject to the conditions specified below, we agree that the showing of conformity of the products, parts and appliances mentioned below may be done under Section A, Subpart F of Annex I (Part 21) to Regulation (EU) No 748/2012.

No of Units	**P/N**	**S/N**
AIRCRAFT		
PARTS		

The following conditions are applicable to this letter of agreement:

(1) It is valid while [Company Name] remains in compliance with Section A, Subpart A and Subpart F of Annex I (Part 21) to Regulation (EU) No 748/2012.

(2) It requires compliance with the procedures specified in [Company Name] manual ref./issue date .....

(3) It terminates on .....

(4) The statement of conformity issued by [Company Name] under point 21.A.130 of Regulation (EU) No 748/2012 shall be validated by the issuing authority of this letter of agreement in accordance with the procedure ..... of the referenced manual.

(5) [Company Name] shall notify the issuing authority of this letter of agreement immediately of any changes to the production inspection system that may affect the inspection, conformity or airworthiness of the products and parts listed in this letter.

For the competent authority: [COMPETENT AUTHORITY IDENTIFICATION ([1])([2])]

Date and signature

EASA Form 65 – Issue 3

([1]) Or "EASA", if EASA is the competent authority.

([2]) Delete for non-EU Member States.'.

ANNEX II

In Annex I (Part 21), point 21.A.101, point (h) is replaced by the following:

'(h) For large aeroplanes subject to point 26.300 of Annex I to Commission Regulation (EU) 2015/640 (*), the applicant shall comply with certification specifications that provide at least an equivalent level of safety to points 26.300 and 26.330 of Annex I to Regulation (EU) 2015/640, except for applicants for supplemental type-certificates who are not required to take into account point 26.303.

(*) Commission Regulation (EU) 2015/640 of 23 April 2015 on additional airworthiness specifications for a given type of operations and amending Regulation (EU) No 965/2012 (OJ L 106, 24.4.2015, p. 18).'.