Draft Annex

to draft Commission Delegated Regulation (EU) .../... amending Commission Regulation (EU) No 748/2012 as regards the establishment of safety management systems for design and production organisations as well as the establishment of procedures for the Agency when it carries out its tasks and responsibilities as regards the issuance, maintenance, amendment, suspension and revocation of design certificates, design approvals and design authorisations

ANNEX I

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

((1)	the 'Contents'	are replaced by	y the following:

'Contents

- 21.1 Competent authority
- 21.2 Scope

SECTION A — TECHNICAL REQUIREMENTS

SUBPART A — GENERAL PROVISIONS

- 21.A.1 Scope
- 21.A.2 Undertaking by another person than the applicant for, or holder of, a certificate
- 21.A.3A Reporting system
- 21.A.3B Airworthiness directives
- 21.A.4 Coordination between design and production
- 21.A.5 Record-keeping
- 21.A.6 Manuals
- 21.A.7 Instructions for continued airworthiness
- 21.A.9 Access and investigation

SUBPART B — TYPE-CERTIFICATES AND RESTRICTED TYPE-CERTIFICATES

- 21.A.11 Scope
- 21.A.13 Eligibility
- 21.A.14 Demonstration of capability
- 21.A.15 Application
- 21.A.19 Changes requiring a new type-certificate
- 21.A.20 Demonstration of compliance with the type-certification basis, operational suitability data certification basis and environmental protection requirements
- 21.A.21 Requirements for the issuance of a type-certificate or restricted type-certificate
- 21.A.31 Type design
- 21.A.33 Inspections and tests
- 21.A.35 Flight tests
- 21.A.41 Type-certificate
- 21.A.44 Obligations of the holder
- 21.A.47 Transferability
- 21.A.51 Duration and continued validity

- 21.A.62 Availability of operational suitability data
- 21.A.65 Continuing structural integrity for aeroplanes structures

(SUBPART C — NOT APPLICABLE)

SUBPART D — CHANGES TO TYPE-CERTIFICATES AND RESTRICTED TYPE-CERTIFICATES

- 21.A.90A Scope
- 21A.90B Standard changes
- 21.A.90C Stand-alone changes to the Instructions for Continued Airworthiness
- 21.A.91 Classification of changes in type design
- 21.A.92 Eligibility
- 21.A.93 Application
- 21.A.95 Requirements for approval of a minor change
- 21.A.97 Requirements for approval of a major change
- 21.A.101 Type-certification basis, operational suitability data certification basis and environmental protection requirements for a major change to a type-certificate
- 21.A.108 Availability of operational suitability data
- 21.A.109 Obligations and EPA marking

SUBPART E — SUPPLEMENTAL TYPE-CERTIFICATES

- 21.A.111 Scope
- 21.A.112A Eligibility
- 21.A.112B Demonstration of capability
- 21.A.113 Application for a supplemental type-certificate
- 21.A.115 Requirements for approval of major changes in the form of a supplemental type-certificate
- 21.A.116 Transferability
- 21.A.117 Changes to that part of a product covered by a supplemental type-certificate
- 21.A.118A Obligations and EPA marking
- 21.A.118B Duration and continued validity
- 21.A.120B Availability of operational suitability data

SUBPART F — PRODUCTION WITHOUT PRODUCTION ORGANISATION APPROVAL

- 21.A.121 Scope
- 21.A.122 Eligibility
- 21.A.124 Application
- 21.A.124A Alternative means of compliance

21.A.125A	Issue of a letter of agreement
21.A.125B	Findings and observations
21.A.125C	Duration and continued validity
21.A.126	Production inspection system
21.A.127	Tests: aircraft
21.A.128	Tests: engines and propellers
21.A.129	Obligations of the production organisation
21.A.130	Statement of conformity
SUBPART	G — PRODUCTION ORGANISATION APPROVAL
21.A.131	Scope
21.A.133	Eligibility
21.A.134	Application
21.A.134A	Alternative means of compliance
21.A.135	Issue of production organisation approval
21.A.139	Production management system
21.A.143	Production organisation exposition
21.A.145	Resources
21.A.147	Changes to the production management system
21.A.148	Changes of location
21.A.149	Transferability
21.A.151	Terms of approval
21.A.153	Changes to the terms of approval
21.A.158	Findings and observations
21.A.159	Duration and continued validity
21.A.163	Privileges
21.A.165	Obligations of the holder
	H — CERTIFICATES OF AIRWORTHINESS AND RESTRICTED ATES OF AIRWORTHINESS
21.A.171	Scope
21.A.172	Eligibility
21.A.173	Classification
21.A.174	Application
21.A.175	Language
21.A.177	Amendment or modification

21.A.179 Transferability and reissuance within Member States

21.A.101	Duration and continued variatty
21.A.182	Aircraft identification
SUBPART	I — NOISE CERTIFICATES
21.A.201	Scope
21.A.203	Eligibility
21.A.204	Application
21.A.207	Amendment or modification
21.A.209	Transferability and reissuance within Member States
21.A.211	Duration and continued validity
SUBPART	J — DESIGN ORGANISATION APPROVAL
21.A.231	Scope
21.A.233	Eligibility
21.A.234	Application
21.A.235	Issue of design organisation approval
21.A.239	Design management system
21.A.243	Handbook
21.A.245	Resources
21.A.247	Changes to the design management system
21.A.249	Transferability
21.A.251	Terms of approval
21.A.253	Changes to the terms of approval
21.A.258	Findings and observations
21.A.259	Duration and continued validity
21.A.263	Privileges
21.A.265	Obligations of the holder
SUBPART	K — PARTS AND APPLIANCES
21.A.301	Scope
21.A.303	Compliance with applicable requirements
21.A.305	Approval of parts and appliances
21.A.307	Release of parts and appliances for installation
(SUBPART	Γ L — NOT APPLICABLE)
SUBPART	M — REPAIRS
21.A.431A	Scope
21A.431B	Standard repairs

21.A.432B	Demonstration of capability
21.A.432C	Application for a repair design approval
21.A.433	Requirements for approval of a repair design
21.A.435	Classification and approval of repair designs
21.A.439	Production of repair parts
21.A.441	Repair embodiment
21.A.443	Limitations
21.A.445	Unrepaired damage
21.A.451	Obligations and EPA marking
(SUBPART	Γ N — NOT APPLICABLE)
SUBPART AUTHORI	O — EUROPEAN TECHNICAL STANDARD ORDER SATIONS
21.A.601	Scope
21.A.602A	Eligibility
21.A.602B	Demonstration of capability
21.A.603	Application
21.A.604	ETSO authorisation for an auxiliary power unit (APU)
21.A.605	Data requirements
21.A.606	Requirements for issuance of an ETSO authorisation
21.A.607	ETSO authorisation privileges
21.A.608	Declaration of design and performance (DDP)
21.A.609	Obligations of holders of ETSO authorisations
21.A.610	Approval for deviation
21.A.611	Design changes
21.A.619	Duration and continued validity
21.A.621	Transferability
SUBPART	P — PERMIT TO FLY
21.A.701	Scope
21.A.703	Eligibility
21.A.707	Application for permit to fly
21.A.708	Flight conditions
21.A.709	Application for approval of flight conditions
21.A.710	Approval of flight conditions
21.A.711	Issue of a permit to fly

21.A.432A Eligibility

21.A.713	Changes		
21.A.715	Language		
21.A.719	Transferability		
21.A.723	Duration and continued validity		
21.A.725	Renewal of permit to fly		
21.A.727	Obligations of the holder of a permit to fly		
SUBPART	Q — IDENTIFICATION OF PRODUCTS, PARTS AND APPLIANCES		
21.A.801	Identification of products		
21.A.803	Handling of identification data		
21.A.804	Identification of parts and appliances		
21.A.805	Identification of critical parts		
21.A.807	Identification of ETSO articles		
SECTION	B — PROCEDURES FOR COMPETENT AUTHORITIES		
SUBPART	A — GENERAL PROVISIONS		
21.B.10	Oversight documentation		
21.B.15	Information to the Agency		
21.B.20	Immediate reaction to a safety problem		
21.B.25	Management system		
21.B.30	Allocation of tasks to qualified entities		
21.B.35	Changes to the management system		
21.B.40	Resolution of disputes		
21.B.55	Record-keeping		
21.B.65	Suspension, limitation and revocation		
SUBPART	${\tt BTYPE-CERTIFICATES}~{\tt AND}~{\tt RESTRICTED}~{\tt TYPE-CERTIFICATES}$		
21.B.70	Certification specifications		
21.B.75	Special conditions		
21.B.80	Type-certification basis for a type-certificate or a restricted type-certificate		
21.B.82	Operational suitability data certification basis for an aircraft type certificate or a restricted type-certificate		
21.B.85	Designation of applicable environmental protection requirements and certification specifications for a type-certificate or a restricted type-certificate		
21.B.100	Level of involvement		
21.B.103	Issue of a type-certificate or a restricted type-certificate		
(SUBPART C — NOT APPLICABLE)			

SUBPART D — CHANGES TO TYPE-CERTIFICATES AND RESTRICTED TYPE-CERTIFICATES

- 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 Issue of an approval of a change to a type-certificate

SUBPART E — SUPPLEMENTAL TYPE-CERTIFICATES

- 21.B.109 Type-certification basis, environmental protection requirements and operational suitability data certification basis for a supplemental type-certificate
- 21.B.111 Issue of a supplemental type-certificate

SUBPART F — PRODUCTION WITHOUT PRODUCTION ORGANISATION APPROVAL

- 21.B.115 Alternative means of compliance
- 21.B.120 Initial certification procedure
- 21.B.125 Findings and corrective actions; observations
- 21.B.135 Maintenance of the letter of agreement
- 21.B.140 Amendment of a letter of agreement

SUBPART G — PRODUCTION ORGANISATION APPROVAL

- 21.B.215 Alternative means of compliance
- 21.B.220 Initial certification procedure
- 21.B.221 Oversight principles
- 21.B.222 Oversight programme
- 21.B.225 Findings and corrective actions; observations
- 21.B.240 Changes to the production management system

SUBPART H — CERTIFICATES OF AIRWORTHINESS AND RESTRICTED CERTIFICATES OF AIRWORTHINESS

- 21.B.320 Investigation
- 21.B.325 Issue of airworthiness certificate
- 21.B.326 Certificate of airworthiness
- 21.B.327 Restricted certificate of airworthiness

SUBPART I — NOISE CERTIFICATES

- 21.B.420 Investigation
- 21.B.425 Issue of noise certificates

SUBPART J — DESIGN ORGANISATION APPROVAL

- 21.B.430 Initial certification procedure
- 21.B.431 Oversight principles

21.B.432 Oversight programme

21.B.433 Findings and corrective actions; observations

21.B.435 Changes to the design management system

SUBPART K — PARTS AND APPLIANCES

(SUBPART L — NOT APPLICABLE)

SUBPART M — REPAIRS

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

21.B.453 Issue of a repair design approval

(SUBPART N — NOT APPLICABLE)

SUBPART O — EUROPEAN TECHNICAL STANDARD ORDER AUTHORISATIONS

21.B.480 Issue of an ETSO authorisation

SUBPART P — PERMIT TO FLY

21.B.520 Investigation

21.B.525 Issue of a permit to fly

SUBPART Q — IDENTIFICATION OF PRODUCTS, PARTS AND APPLIANCES

Appendices

Appendix I — EASA Form 1 — Authorised Release Certificate

Appendix II – EASA Form 15a and 15c – Airworthiness Review Certificate

Appendix III — EASA Form 20a — Permit to Fly

Appendix IV — EASA Form 20b — Permit to Fly (issued by approved organisations)

Appendix V — EASA Form 24 — Restricted Certificate of Airworthiness

Appendix VI — EASA Form 25 — Certificate of Airworthiness

Appendix VII — EASA Form 45 — Noise Certificate

Appendix VIII — EASA Form 52 — Aircraft Statement of Conformity

Appendix IX — EASA Form 53 — Certificate of Release to Service

Appendix X — EASA Form 55 — Production Organisation Approval Certificate

Appendix XI — EASA Form 65 — Letter of Agreement for production without production organisation approval

Appendix XII — Categories of flight tests and associated flight test crew qualification.';

(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 (¹) 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. The occurrence-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 typecertificate, 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 associated implementing or delegated acts the information about the system established in accordance with point (a)(1), and on how to provide reports of and information related to failures, malfunctions, defects or other occurrences referred to in point (a)(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,

⁽¹) 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).

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 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, or that produces a product, part or appliance under Subpart F, 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;
 - 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 according to point 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 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 reporter and of the person(s) mentioned in the report.
- (d) Without prejudice to Regulation (EU) No 376/2014 and its delegated and implementing acts, any natural or legal person shall make the reports defined in points (a)(3) and (b)(3) in a form and manner established by the competent authority, 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 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.';

(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; this 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 work 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 this 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;
 - 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 of the personnel that are involved in the design or the production and in the independent function to monitor the compliance of the organisation with the relevant requirements, and in safety management if requested by points 21.A.139(c), 21.A.145(c), 21.A.239(c), 21.A.245(a), 21.A.145(b) or 21.A.245(e)(1);
- (e) retain records of the authorisation of personnel when they employ personnel that:
 - 1. exercise the privileges of the approved organisation according to points 21.A.163 or 21.A.263:
 - 2. carry out the independent function to monitor the compliance of the organisation with the relevant requirements according to points 21.A.139(e) and 21.A.239(e);
 - 3. carry out the independent verification function of the demonstration of compliance according to 21A.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 determine the initial and continued compliance of the organisation with the applicable requirements of this Annex;
- (b) make arrangements to ensure the competent authority has access, as described 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.14;';

(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 APU 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 according to 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, point (a)(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 Alternative means of compliance

- (a) Alternative means of compliance to the acceptable means of compliance (AMC) adopted by the Agency may be used by an organisation to establish compliance with Regulation (EU) 2018/1139 and its delegated and implementing acts.
- (b) If a production organisation wishes to use an alternative means of compliance, it shall, prior to using it, provide the competent authority with a full description of that alternative means of compliance. The description shall include any revisions to manuals or procedures that may be relevant, as well as an assessment that demonstrates compliance with Regulation (EU) 2018/1139 and its delegated and implementing acts.

The production organisation may use these alternative means of compliance subject to prior approval by the competent authority, and upon receipt of the notification as provided for in point 21.B.115.';

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

'21.A.125B Findings and observations

- (a) After receipt of the notification of findings according to 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 defined by the competent authority as defined in point 21.B.125.
- (c) The observations received in accordance with 21.B.125(d) shall be given due consideration by the holder of the letter of agreement. The organisation shall record the decisions taken in respect of these observations.';

(12) 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 and 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 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 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.';
- (13) in point 21.A.126, point (b)(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 determined by this procedure to be serviceable shall be properly identified and reinspected if it is necessary to be reworked or repaired. Materials and parts rejected by this procedure shall be marked and disposed of to ensure that they are not incorporated in the final product.';
- (14) in point 21.A.126, point (b)(6) is deleted;

(15) the title of point 21.A.129 is replaced by the following:

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

- (16) in point 21.A.129, point (e) is replaced by the following:
 - '(e) comply with Subpart A of this Section;';
- (17) in point 21.A.129, point (f) is deleted;
- (18) the following point 21.A.134A is inserted:

'21.A.134A Alternative means of compliance

- (a) Alternative means of compliance to the acceptable means of compliance (AMC) adopted by the Agency may be used by a production organisation to establish compliance with Regulation (EU) 2018/1139 and its delegated and implementing acts.
- (b) If a production organisation wishes to use an alternative means of compliance, it shall, prior to using it, provide the competent authority with a full description of that alternative means of compliance. The description shall include any revisions to manuals or procedures that may be relevant, as well as an assessment that demonstrates compliance with Regulation (EU) 2018/1139 and its delegated and implementing acts.

The organisation may use these alternative means of compliance subject to prior approval by the competent authority, and upon receipt of the notification as provided for in point 21.B.215.';

(19) 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 clear 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 these activities;
 - 2. be established under the direct accountability of a single manager nominated according 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 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 its safety performance;
 - (ii) the management of changes in accordance with points 21.A.143(b) and 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 according to point 21.A.3A in order to contribute to the aim of 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, and thus exercise the privileges as defined 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) the verification 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 function to monitor the compliance of the organisation with the relevant requirements and compliance with, and adequacy of, the production management system. This monitoring shall include a feedback system 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, as necessary, the implementation of corrective action.
- (f) If the production organisation holds other organisation certificate(s) issued on the basis of Regulation (EU) 2018/1139 and its delegated and implementing acts, it may integrate the production management system with the management system that is required for the issue of the other certificate(s).';
- (20) in point 21.A.143, the title is replaced by the following:

'21.A.143 Production organisation exposition';

- (21) in point 21.A.143, point (a) is replaced by the following:
 - '(a) The organisation shall establish a production organisation exposition that provides directly or by cross reference the following information related to the production management system as described in point 21.A.139:';
- (22) in point 21.A.143, point (a)(11) is replaced by the following:
 - '11. a description of the production management system, the policy, processes and procedures as required by point 21.A.139(b);';
- (23) in point 21.A.143, point (a)(12) is replaced by the following:

- '12. a list of those outside parties referred to in point 21.A.139(d)(1);';
- (24) 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 is in receipt of such data from the Agency and from the holder of, or applicant for, the type-certificate, restricted type-certificate or design approval, including any exemption granted against the environmental protection requirements, to determine conformity with the applicable design data;
 - 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 nominated 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 exposition 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 degree of their authority; such person or group of persons shall be responsible to the accountable manager and have direct access to them. 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.';
- (25) point 21.A.147 is replaced by the following:

'21.A.147 Changes to the production management system

After the issue of a production organisation approval certificate, each change to 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 to the competent authority for approval which demonstrates that that it will continue to comply with this Annex.';

- (26) point 21.A.157 is deleted;
- (27) point 21.A.158 is replaced by the following:

'21.A.158 Findings and observations

- (a) After receipt of the notification of findings according to 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 defined by the competent authority as defined in point 21.B.225.
- (c) The observations received in accordance with 21.B.225(d) 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.';
- (28) 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.';
- (29) in point 21.A.165, points (d) to (k) 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 intends to issue a certificate of release to service, determine that each completed aircraft has been subjected to necessary maintenance and is in condition for safe operation, prior to issuing the certificate;
 - (f) where applicable, under the privilege of point 21.A.163(e), determine the conditions under which a permit to fly can be issued;
 - (g) where applicable, under the privilege of point 21.A.163(e), establish compliance with points 21.A.711(c) and (e) before issuing an aircraft with a permit to fly;
 - (f) comply with Subpart A of this Section.';
- (30) point 21.A.180 is deleted;
- (31) in point 21.A.181, points (a) and (a)(1) are 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:
 - 1. the aircraft continues to comply with the applicable type design and continued airworthiness requirements; and';
- (32) in point 21.A.181, point (a)(4) is replaced by the following:
 - '4. the certificate is not revoked by the competent authority under point 21.B.65, or surrendered by the certificate holder.';
- (33) point 21.A.210 is deleted;
- (34) in point 21.A.211, points (a) and (a)(1) are 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:
 - 1. the aircraft continues to comply with the applicable type design and continued airworthiness requirements; and';
- (35) in point 21.A.211, point (a)(4) is replaced by the following:
 - '(4) the certificate is not revoked by the competent authority under point 21.B.65, or surrendered by the certificate holder.';
- (36) 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 clear 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 these activities:
 - 2. be established under the accountability of a single manager nominated according 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 its 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 according to point 21.A.3A in order to contribute to the aim of 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; this system shall:
 - (i) include an airworthiness function responsible for managing 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 it 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 of the demonstration of compliance on the basis of which the organisation declares compliance with the applicable airworthiness, operational suitability data and environmental protection requirements; and
 - 3. specify the manner in which the design assurance 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 subjects of written procedures.
- (e) The design organisation shall establish, as part of the design management system, an independent function to monitor its compliance with the relevant requirements as well as the compliance with, and adequacy of the design management system. This monitoring shall include a feedback system 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 corrective action, as necessary.
- (f) If the design organisation holds other organisation certificate(s) issued on the basis of Regulation (EU) 2018/1139 and its delegated and implementing acts, it may integrate the design management system into the management system that is required for the issue of the other certificate(s).';
- (37) 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 establish a handbook that describes, directly or by cross reference, the organisation, the

relevant policy, 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 be established. The flight test operations manual shall include:

- 1. a description of the organisation's processes for flight tests, including the flight test organisation's involvement into the issue process of a permit to fly;
- 2. crewing policy, including composition, competency, currency and flight time limitations, in accordance with Appendix XII to this Annex, where applicable;
- 3. procedures for the carriage of persons other than the crew members and for flight test training, when 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 give, for all parts and appliances, the assurance of compliance required by 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, furnish to the competent authority, 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.';
- (38) point 21.A.245 is replaced by the following:

'21.A.245 Resources

(a) The organisation shall nominate 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, together with the degree of their authority:
 - 1. a chief of the airworthiness function;
 - 2. a chief of the independent monitoring of compliance and adequacy function; and
 - 3. depending on the size of the organisation and on 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 (b)(1), the airworthiness function, as required by point 21.A.239(d)(1)(i), may be performed under the direct supervision of the head of the design organisation:
 - 1. when the scope 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; or
 - 2. for a limited period of time when the design organisation does not have a nominated chief of the airworthiness function and if it is commensurate with the scope and level of the organisation's activities.
- (d) The person or group of persons identified in point (b) shall:
 - 1. be responsible 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 number and experience of the staff in all technical departments are sufficient and they have been given the appropriate authority to be able to discharge their allocated responsibilities and these, together with the accommodation, facilities and equipment, 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.';
- (39) point 21.A.247 is replaced by the following:
 - '21.A.247 Changes to 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 submission of the proposed changes to the handbook, that it will continue to comply with this Annex.';

- (40) point 21.A.257 is deleted;
- (41) point 21.A.258 is replaced by the following:

'21.A.258 Findings and observations

- (a) After the receipt of the notification of findings according to 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. define 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 defined by the Agency as defined in point 21.B.433.
- (c) The observations received in accordance with point 21.B.433 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.';
- (42) 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 the applicable requirements of Regulation (EU) 2018/1139 and its delegated and implementing acts;
 - 2. the Agency is permitted by the holder of the design organisation approval or by any of its partners or subcontractors to perform the 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 is not 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.';
- (43) in point 21.A.263, the introductory phrase of point (c) 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:';
- (44) in point 21.A.265, point (c) is replaced by the following:
 - '(c) determine that the design of the products, or of the changes or repairs to them, complies with the applicable type-certification basis, operational suitability data certification basis, and the environmental protection requirements and have no unsafe features;';
- (45) in point 21.A.265, a new point (i) is inserted:
 - '(i) comply with Subpart A of this Annex.';
- (46) in point 21.A.451, 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;';
- (47) in point 21.A.451, 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; and';
- (48) 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;';
- (49) in point 21.A.609, 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;';
- (50) in point 21.A.609, point (f) is replaced by the following:
 - '(f) comply with points 21.A.3A, 21.A.3B, 21.A.4 and 21.A.9;';
- (51) point 21.A.615 is deleted;

(52) 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 required 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 competent authority is permitted by the holder of the ETSO authorisation or by any of its partners, suppliers or subcontractors to perform the 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.;
- (53) point 21.A.705 is deleted;
- (54) point 21.A.721 is deleted;
- (55) 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 of point 21.A.711(e) associated with the permit to fly;
 - 2. the competent authority is permitted by the holder or by any of its partners, suppliers or subcontractors to perform the 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.';
- (56) points 21.B.430 and 21.B.445 are deleted;
- (57) the following points 21.B.430, 21.B.431, 21.B.432, 21.B.433 and 21.B.435 are added:

'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, taking into account the oversight principles laid down in points 21.B.431(b) and (d).
- (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 organisation is approved to conduct, 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 the continued compliance with the applicable requirements of the organisations that it has certified.

- (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 defined in points (a) and (b) 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 that covering the oversight activities required by 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 and/or oversight activities, 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, as 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 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) An oversight planning cycle that does not exceed 24 months shall be applied.
- (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 it 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 defined in point 21.B.433.

Notwithstanding point (c), the oversight planning cycle may be further extended to a maximum of 48 months if, in addition to the conditions provided in points (1) to (4) above, 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 as defined in point 21.A.3A.

The level 1 finding shall also include:

- 1. any failure to grant the competent authority access to the organisation's facilities as defined 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. the lack of a head of the design organisation designated according to 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. If 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. The 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 and implementation plan proposed by the organisation, and if the assessment 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, the competent authority may take immediate and appropriate action to prohibit or limit the activities of the organisation involved and, if appropriate, may 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. The 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. 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 implementation plan proposed by the organisation, and if the assessment 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) For those cases not requiring level 1 or level 2 findings, the competent authority may issue observations:
 - 1. for any item whose performance has been assessed to be ineffective; or
 - 2. when it has been identified that an item has the potential to cause a non-compliance under points (b) or (c); or

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 to 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 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, 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.';

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)				
4. Organisation					
5. Aircraft Type		6. Type-certificate ref. Nos:			
7. Aircraft Registration	7. Aircraft Registration Or Mark		8. Production Organisation Identification No:		
9. Engine/Propeller Details (³)					
10. Modifications and/or	10. Modifications and/or Service Bulletins (3)				
11. Airworthiness Direct	ives				
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 above 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 under 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 format, 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 should 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 these 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 should 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 defined 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 defined in the relevant type-certificate and its associated data sheet. Their production organisation identification number and the associated location should 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 should 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 should 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, should be kept on file by the production organisation approval certificate holder. The report should 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 should 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 should not be used.
- Block 19 The name of the person that signs the statement should be typed or printed in a legible form.
- Block 20 The date on which the statement of conformity is signed should be given.
- Block 21 The competent authority approval reference should be quoted.';

(58) 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 Commission 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, and
- 2. This approval is subject to compliance with the procedures specified in the approved production organisation exposition, and
- 3. This approval is valid while the approved production organisation remains in compliance with Annex I (Part 21) to Commission 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)]
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 CODE (1)].21G.XXXX issued to:	production organ	nisation approv	al number [MEMBER STATE	
Company name:				
Section 1. SCOPE OF WORK:				
PRODUCTION OF	,	PRODUCTS/CATEGORIES		
For datails and limitations, refer to	the Production (Propriention Ev	position Section vvv	
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 no	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 [COMPETI IDENTIFICAT	ENT AUTHORITY	

EASA Form 55b — Issue 3

- (1) Or 'EASA', if EASA is the competent authority.
- (²) Delete for non-EU Member States.'

(59) 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 Commission 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 Commission 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 the provisions of point 21.A.130 of the above-mentioned Regulation 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.