

## **Management System Changes to Initial Airworthiness Regulation 748\_2012 mandated by Commission Delegated Regulation (EU) 2022\_201 (10 Dec 2021)**

Sofema Aviation Services (SAS) [www.sassofia.com](http://www.sassofia.com) considers in details the forthcoming changes, their applicability, and regulatory obligations

### **Introduction - Commission Delegated Regulation (EU) 2022\_201**

Applies to management systems and occurrence-reporting systems to be established by design and production organisations.

Ref also EASA Basic Regulation (EU) 2018/1139 and (EU) No 376/2014

- 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.
- ICAO Annex 19 'Safety Management' requires 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.
- 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.

### **Proportionality**

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.

## **Concerning Type Certificates**

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

## **Embodiment of Requirements & Changes**

- 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.

## **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:

- 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;
- 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:

- Establish, implement and maintain a safety policy and the corresponding related safety objectives;

- Appoint key safety personnel in accordance with point 21.A.145(c)(2);
- 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;
- Establish, implement and maintain a safety assurance process that includes:
  - The measurement and monitoring of the organisation's safety performance;
  - The management of changes in accordance with point 21.A.147;
  - The principles for the continuous improvement of the safety management element.
- Promote safety in the organisation through:
  - Training and education;
  - Communication;
- Establish an occurrence reporting system in accordance with point 21.A.3A in order to contribute to the continuous improvement of safety.
- As part of the quality management element of the production management system, the production organisation shall:
  - 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;
  - Establish, implement and maintain, as appropriate, within the scope of the approval, control procedures for:
    - Document issue, approval or change;
    - Vendor and subcontractor assessment audit and control;
    - Verifying those incoming products, parts, materials and equipment, including items supplied new or used by buyers of products, are as specified in the applicable design data;
    - Identification and traceability;
    - Manufacturing processes;
    - Inspection and testing, including production flight tests;
    - The calibration of tools, jigs, and test equipment;
    - Non-conforming item control;
    - Airworthiness coordination with the applicant for, or holder of, the design approval;
    - The completion and retention of records;
    - The competence and qualifications of personnel;
    - The issue of airworthiness release documents;
    - Handling, storage and packing;
    - Internal quality audits and the resulting corrective actions;

- Work within the terms of approval performed at any location other than the approved facilities;
  - Work performed after the completion of production but prior to delivery, to maintain the aircraft in a condition for safe operation;
  - The issue of a permit to fly and approval of the associated flight conditions;
- Include specific provisions in the control procedures for any critical parts.
- 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.
- 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.';

#### **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:

- 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;
- 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:

- Establish, implement and maintain a safety policy and the corresponding related safety objectives;
- Appoint key safety personnel in accordance with point 21.A.245(b);

- 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;
- Establish, implement and maintain a safety assurance process that includes:
  - The measurement and monitoring of the organisation's safety performance;
  - The management of changes in accordance with points 21.A.243(c) and 21.A.247;
  - The principles for the continuous improvement of the safety management element;
- Promote safety in the organisation through:
  - Training and education;
  - Communication;
- 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:

- 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:
  - 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;
  - 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;
- 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;
- 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).’;

#### **Reporting System (21.A.3A)**

(a)holders of 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:

- 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 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:
  - 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;
  - Errors, near misses and hazards that do not fall under point (i);
- 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);

- 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) holders of or 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:

- 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;
- 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;
- 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;
- 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) Shall appropriately protect the confidentiality of the person who reports and of the person(s) mentioned in the report.
- (d) Report within 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) 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.

### **Next Steps**

Sofema Aviation Services & Sofema Online provide training compliant with EASA related to Part 21 and CS 25 - Please see [www.sassofia.com](http://www.sassofia.com) or [www.sofemaonline.com](http://www.sofemaonline.com) for additional questions or information please email [team@sassofia.com](mailto:team@sassofia.com)