

**CAA Decision to adopt AMC and GM for UK Reg (EU) No. 748/2012  
pursuant to Article 76(3) UK Reg (EU) 2018/1139**

**DECISION No. 40**

**Publication date: 5 July 2024**

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**Decision amending Acceptable Means of Compliance (AMC) and Guidance Material (GM) for  
UK Reg (EU) No. 748/2012 (UK Initial Airworthiness Regulation)**

**Background**

Statutory Instrument (SI) 2023 No. 588, The Aviation Safety (Amendment) Regulations 2023, laid before Parliament on 30 May 2023, amended and consolidated UK Regulation (EU) No. 748/2012 as regards the introduction of safety management systems (SMS) in Part 21 organisations and effective occurrence reporting.

CAA UK-EU Transition Decision No. 1 adopted a form of AMC and GM as means by which the requirements in assimilated law UK Regulation (EU) No. 748/2012 could be met.

By this Decision, the CAA is amending and consolidating the AMC and GM to the relevant parts of Part 21 to UK Regulation (EU) No. 748/2012 to support the regulation changes which came into force on 1st July 2024.

**Decision**

1. The CAA, under Article 76(3) of UK Regulation (EU) 2018/1139, has decided to adopt the AMC and GM for UK Regulation (EU) 748/2012 attached at Schedule 1.

This Decision will remain in force unless revoked or amended by the CAA.



Rob Bishton  
For the Civil Aviation Authority and the United Kingdom

Date of Decision: 5<sup>th</sup> July 2024

Date of Decision Coming into force: 5<sup>th</sup> July 2024

**Schedule 1 - Changes to associated AMC and GM – applicable from 1st July 2024.**

**Includes the Acceptable Means of Compliance (AMC) and Guidance Material (GM) documents referenced below.**

The text of the amendment is arranged to show deleted text, new or amended text as shown below:

- (a) ~~Text to be deleted is shown struck through;~~
- (b) New text is highlighted in grey;
- (c) ~~Text to be deleted is shown struck through~~ followed by the replacement text which is highlighted in grey.

See attached schedule.

# Acceptable Means of Compliance (AMC) and Guidance Material (GM) to Annex I (Part-21) to UK UK Regulation (EU) No 748/2012

## Key

The text of the amendment is arranged to show deleted text, new or amended text as shown below:

- (a) New text is highlighted in grey;
- (b) Text to be deleted is shown struck through and in red followed by the replacement text which is highlighted in grey. E.g. '~~Deleted text~~'
- (c) an ellipsis '[...]' indicates that the rest of the text is unchanged.

Please note that this document does not contain all AMC and GM within Part 21. Any AMC and GM within Part 21 that are not included in this document, are not being amended in these changes.

# ANNEX I (PART 21)

## GM1 Annex I Definitions

For the purpose of the Acceptable Means of Compliance (AMC) and Guidance Material (GM) to Annex I (Part 21) to UK Regulation (EU) No 748/2012, the following definitions apply:

Term	Definition
Audit	<p>A systematic, independent, and documented process for obtaining evidence and objectively evaluating it to determine the extent to which the requirements are complied with.</p> <p><i>Note: audits may include inspections.</i></p>
Assessment	<p>In the context of management system performance monitoring, continuous improvement, and oversight, it refers to a planned and documented activity that is performed by competent personnel to evaluate and analyse the achieved level of performance and maturity in relation to the organisation's policy and objectives.</p> <p>Note: an assessment focuses on desirable outcomes and the overall performance, looking at the organisation as a whole. The main objective of the assessment is to identify the strengths and weaknesses to drive continual improvement.</p> <p><i>Remark: for 'risk assessment', please refer to the definition below.</i></p>
Certificate	<p>Any certificate, approval, licence, authorisation, attestation or other document that is issued as the outcome of the certification process, which attests compliance with the applicable requirements.</p>
Competency	<p>A combination of individual skills, practical and theoretical knowledge, attitude, training, and experience.</p>
Correction	<p>The elimination of a detected non-compliance.</p>
Corrective action	<p>The action to eliminate or mitigate the root cause(s) to prevent the recurrence of existing detected non-compliance, or of any other undesirable condition or situation. Proper determination of the root cause(s) is crucial for defining effective corrective action to prevent reoccurrence.</p>

Error	<p>A person's action or inaction that may lead to deviations from the accepted procedures or regulations.</p> <p><i>Note: errors are often associated with occasions when a planned sequence of mental or physical activities either fails to achieve its intended outcome, or is not appropriate with regard to the intended outcome, and when results cannot be attributed purely to chance.</i></p>
Fatigue	<p>A physiological state of reduced mental or physical performance capability, resulting from sleep loss or extended wakefulness, circadian phase, or workload (mental and/or physical activity), which can impair a person's alertness and ability to safely perform their tasks.</p>
Hazard	<p>A condition or an object with the potential to cause, or contribute to, an aircraft incident or accident.</p>
Human factors (HF)	<p>Anything that affects human performance, which means principles that apply to aeronautical activities, and which seek safe interface between the human and other system components by proper consideration of human performance (ref. ICAO Doc 10151 — Human Performance (HP) Manual for Regulators).</p>
Human performance (HP)	<p>Human capabilities and limitations that have an impact on the safety and efficiency of aeronautical activities (ref. ICAO Doc 10151 — Human Performance (HP) Manual for Regulators).</p>
Inspection	<p>In the context of compliance monitoring and oversight, it refers to an independent and documented conformity evaluation by observation and judgement, which is accompanied, as appropriate, by measurements, testing or gauging, in order to verify compliance with the applicable requirements.</p> <p><i>Note: inspection may be part of an audit (e.g. product audit), but may also be conducted outside the normal audit plan; for example, to verify the closure of a particular finding.</i></p> <p>In the context of an approved production organisation, this may refer to an activity necessary to confirm the conformance of a part, product, or appliance manufactured to design data and condition for safe operation. Depending on criticality, an inspection may be required to be carried out independently (such as confirmation of correct connections to control surfaces in the case of installation/disturbance) or within the production process (operator inspections).</p>
'Just culture'	<p>A culture in which front-line operators or other persons are not punished for actions, omissions or decisions taken by them that are commensurate with their experience and training, but in which gross negligence, wilful violations and destructive acts are not tolerated (Ref. Article 2 of UK Regulation (EU) No 376/2014).</p>

Near miss	An event in which an occurrence to be mandatorily reported according to UK Regulation (EU) No 376/2014 was narrowly averted or avoided. Example: a staff member, on rechecking their work at the end of a task, realises that one work card step was not properly carried out.
Organisational factor	A condition that affects the effectiveness of safety risk controls, and is related to the culture, policies, processes, resources, and the workplace of an organisation.
Oversight planning cycle	The time frame within which the areas of the approval and the processes that are identified through a risk assessment should be reviewed by the CAA by means of audits and inspections.
Oversight programme	The detailed oversight schedule that defines the number of audits and other activities, including the scope and duration of each activity, as well as the details of product audits and locations, as appropriate, to be performed by the CAA, and to the time frame for performing each activity.
Preventive action	The action to eliminate the cause of potential non-compliance, or any other undesirable potential situation.
Person	A person should be interpreted in accordance with the Interpretation Act 1978 and includes a natural or legal person(s), an organisation(s), a single person or a group of persons. The AMC and GM provides further guidance where the intended meaning of a person should be understood in its plural form, i.e. a group of persons.
Risk assessment	An evaluation that is based on engineering and operational judgement and/or analysis methods in order to establish whether the achieved or perceived risk is acceptable or tolerable.
Safety culture	An enduring set of values, norms, attitudes, and practices within an organisation, which is concerned with minimising the exposure of the workforce and the general public to dangerous or hazardous conditions. In a positive safety culture, a shared concern for, commitment to, and accountability for, safety is promoted.
Safety risk	The predicted probability and severity of the consequences or outcomes of a hazard (ICAO Document 9859 Safety Management Manual).

Safety training	<p>Dedicated training to support safety management policies and processes, including HF training.</p> <p><i>Note 1: the main objective of the safety training programme is to ensure that personnel at all levels of the organisation maintain their competency to fulfil their roles safely. Safety training should, in particular, consider the safety knowledge that is derived from hazard identification and risk management processes, and foster a positive safety culture.</i></p> <p><i>Note 2: safety management training refers to specific training for the staff that are involved in safety management functions in accordance with points 21.A.139(c) and 21.A.239(c) of Part 21.</i></p>
Surveillance	The CAA activities through which the CAA proactively verifies through inspections and audits that aviation, licence, certificate, authorisation or approval holders continue to meet the established requirements and function at the level of competency and safety required by the CAA.
Working days	The days between, and including, Monday and Friday, except public holidays.

## GM2 Annex I Abbreviations

For the purpose of the AMC and GM to Part 21, the following abbreviations apply:

AFM	Aircraft Flight Manual
AMC	Acceptable Means of Compliance
APU	Auxiliary Power Unit
CMR	Certification Maintenance Requirement
CofA	Certificate of Airworthiness
CRI	Certification Review Item
CS	Certification Specification
CS-CCD	Certification Specifications for Cabin Crew Data
CS-FCD	Certification Specifications for Operational Suitability Data (OSD) Flight Crew Data
CS-GEN-MMEL	Certification Specifications for Generic Master Minimum Equipment List
CS-MMEL	Certification Specifications for Master Minimum Equipment List

CS-MCSD	Certification Specifications for Maintenance Certifying Staff Data
CS-SIMD	Certification Specifications for Simulator Data
DAH	Design Approval Holder
DO	Design Organisation
DOA	Design Organisation Approval
EDTO	Extended Diversion Time Operation
ELOS	Equivalent Level of Safety
ESF	Equivalent Safety Finding
UKTSO	United Kingdom Technical Standard Order
FOD	Foreign Object Damage
HDO	Head of the Design Organisation
ICAO	International Civil Aviation Organization
ICA	Instructions for Continued Airworthiness
OSD	Operational Suitability Data
PAH	Production Approval Holder
PO	Production Organisation
POA	Production Organisation Approval
POATL	Production Organisation Approval Team Leader
POE	Production Organisation Exposition
GM	Guidance Material
MoC	Means of Compliance
RCofA	Restricted Certificate of Airworthiness
RTC	Restricted Type Certificate
SC	Special Condition



SMS	Safety Management System
STC	Supplemental Type Certificate
TC	Type Certificate
TCDS	Type Certificate Data Sheet

## SECTION A — TECHNICAL REQUIREMENTS

### SUBPART A — GENERAL PROVISIONS

#### GM1 21.A.3A Failures, malfunctions and defects

##### LINK BETWEEN POINT 21.A.3A AND UK REGULATION (EU) No 376/2014

UK Regulation (EU) No 376/2014 lays down requirements on the reporting, analysis and follow-up of occurrences in civil aviation. Compliance with point 21.A.3A of Part 21 does not exempt organisations from compliance with UK Regulation (EU) No 376/2014. For each category of reporter, UK Regulation (EU) 2015/1018 defines the nature of items to be mandatorily reported. UK Regulation (EU) No 376/2014 considers voluntary reporting of other occurrences that are perceived by the reporter as a threat to aviation safety and cause or might cause adverse effects on continuing airworthiness. These other occurrences include, but are not limited to errors, near misses and hazards.

Point 21.A.3A lays down requirements for the mandatory reporting of events to the CAA in view of performing the necessary activities linked to the continued airworthiness of aircraft, parts, and appliances. For Part 21 design organisations (DOs) and production organisations (POs), the reportability criteria (i.e. a potential unsafe condition) are the same as the ones laid down by UK Regulation (EU) No 376/2014.

Furthermore, compliance with UK Regulation (EU) No 376/2014 does not exempt organisations compliance with point 21.A.3A. However, this should not give rise to two parallel reporting systems, and point 21.A.3A and UK Regulation (EU) No 376/2014 should be seen as complementary in that

These reporting obligations may be discharged using one reporting channel.

In addition, any natural or legal person that has more than one role subject to the obligation to report may discharge all those obligations through a single report. Organisations are encouraged to properly describe this in their organisation manual, to address cases in which the responsibilities are discharged on behalf of the organisation.

## AMC1 21.A.3A(a) Failures, malfunctions and defects

### COLLECTION, INVESTIGATION, AND ANALYSIS OF EVENTS

In the context of the following AMC and GM to point 21.A.3A, the term ‘event’ refers to any failure, malfunction, defect, error, near miss, hazard identification, incident, accident, or other occurrence that is subject to a reporting system.

The ‘collection’, ‘investigation’, and ‘analysis’ functions of the system means:

- to analyse events and related available information;
- to identify adverse trends;
- to investigate the associated root cause(s); and
- to determine any necessary corrective action.

It should also allow the determination of reportable occurrences as required by point 21.A.3A(b)(1).

In addition, for parts whose failure could lead to an unsafe condition, the ‘analysis’ function of the system should ensure that reports and information sent, or available, to the design approval holder (DAH) are fully investigated so that the exact nature of any event and its effect on continuing airworthiness is understood. This may then result in changes to the design and/or to the instructions for continued airworthiness (ICA), and/or in establishing a mitigation plan to prevent or minimise the possibility of such occurrences in the future, as necessary. The ‘analysis’ is not limited to those occurrences that require the involvement of the CAA under point 21.A.3A(c)(1).

## GM 21.A.3A(a) The system for collection, investigation and analysis of data GM1

### 21.A.3A(a) Failures, malfunctions and defects

#### GENERAL – SYSTEM FOR COLLECTION, INVESTIGATION AND ANALYSIS OF DATA

~~In the context of this requirement the word ‘Collection’ means the setting up of systems and procedures which will enable relevant malfunctions, failures and defects to be properly reported when they occur.~~

The term ‘collection’ means the setting up of systems and procedures that will enable relevant failures, malfunctions, and defects, or other occurrences, to be properly collected when they occur.

As the collection system needs to accept reports that originate outside the organisation (from operators, maintenance organisations, suppliers, etc.), it is necessary to inform possible reporters of the existence of the system and of the appropriate means to introduce reports into it. This does not presume that direct access to the system is to be granted if other mechanisms are more appropriate.

The collection system should also ensure the collection, through an internal reporting scheme, of internal errors, near misses, and hazards that are perceived by the reporter as an actual or potential aviation safety risk.

Considerations for the collection of information related to events should include the following:

- the analysis of failure rates;
- the early rejection of parts from service; and
- comparison with the certification assumptions.

**INTERNAL SAFETY REPORTING SCHEME**

An internal safety reporting scheme is part of the overall system for collecting occurrence data as per point 21.A.3A(a). The objective of this GM is to provide specific guidance on internal safety reporting only.

- (a) The overall objectives of an internal safety reporting scheme are:
  - to collect information that is reported by the organisation staff; and
  - to use that reported information to improve the safety of operations,in conjunction with the safety management elements that are defined in points 21.A.139 and 21.A.239. Each internal safety reporting scheme should include provisions for confidentiality and enable and encourage free and frank reporting of events, as those listed in points 21.A.3A(a). This is facilitated by establishing a ‘just culture’.
- (b) The specific objectives of the scheme are to:
  - (1) enable an assessment of the safety implications of each relevant event that is reported, including previous similar events, so that any necessary action can be initiated; and
  - (2) ensure that lessons from relevant events are shared so that other persons and parts of the organisation may learn from them.
- (c) The scheme is an essential part of the overall management system and should be complementary to routine procedures and ‘control’ systems; it is not intended to duplicate or supersede any of them. The scheme is a tool to identify those instances in which routine procedures have failed or may fail.
- (d) All safety-related reports should be retained for an appropriate period as defined by the organisation, as the significance of such reports may only become obvious later.
- (e) The collection and analysis of timely, appropriate, and accurate data will allow the organisation to react to the information that it receives and to take necessary action.

~~AMC No 1 to 21.A.3A(a) Collection, investigation and analysis of data related to Flammability Reduction Means (FRM) reliability~~ AMC2 21.A.3A(a) Failures, malfunctions and defects

**COLLECTION, INVESTIGATION, AND ANALYSIS OF DATA RELATED TO FLAMMABILITY REDUCTION MEANS (FRM) RELIABILITY**

[Title change only, no change to text]

AMC No 2 to 21.A.3A(a) Reporting system

## COLLECTION, INVESTIGATION, AND ANALYSIS OF DATA RELATED TO ETOPS - SIGNIFICANT OCCURRENCES

AMC3 21.A.3A(a) Failures, malfunctions and defects

### COLLECTION, INVESTIGATION, AND ANALYSIS OF DATA RELATED TO ETOPS - SIGNIFICANT OCCURRENCES

[Title change only, no change to text]

## GM2 21.A.3A Failures, malfunctions and defects

### GENERAL

In the context of points 21.A.3A, the phrase ‘any other relevant approval deemed to have been issued under this Regulation’ refers to ‘grandfathered’ design approvals under Part 21, as defined in Article 3 of UK Regulation (EU) No 748/2012.

## GM 21.A.3A(b) Occurrence reporting

For occurrence reporting, refer to the latest edition of AMC 20-8 (see AMC 20 document).

## GM1 21.A.3A(a) and (c) Failures, malfunctions and defects

### EVENTS REPORTED VOLUNTARILY TO THE ORGANISATION

A natural or a legal person (including organisations that are not approved by the CAA) may voluntarily report to an organisation any event that is perceived by that person as posing an actual or potential hazard to aviation safety.

Voluntary reports may be originated by:

- (a) persons that are not listed in Article 4(6) of UK Regulation (EU) No 376/2014; or
- (b) persons that are listed in Article 4(6) of UK Regulation (EU) No 376/2014, even though such events are not included in UK Regulation (EU) 2015/1018; or
- (c) an organisation, if such organisation cannot determine whether the event should be mandatorily reported.

### A scenario of voluntary reporting

A production staff member in a production organisation is reporting to their production organisation a perceived design issue that is not covered by UK Regulation (EU) 2015/1018. The production organisation should make an assessment of the voluntary report and if it assesses that the reported event ‘may involve an actual or potential aviation safety risk’, then it would fall under the mandatory reporting classification reportable to the TC holder, the CAA, etc., as per point 21.A.3A a) ‘Failures, malfunctions and defects’. If the production organisation cannot determine whether a safety risk exists (due to lack of competence, lack of data, etc.), it should voluntarily report the event to the TC holder / Design Approval Holder using the processes identified in the DO/PO arrangement established to meet points 21.A.4 and 21.A.133 b) and c) for further assessment.

## AMC 21.A.3A(b)(2) Reporting to the CAA Failures, malfunctions and defects

### REPORTING TO THE CAA

Within the overall limit of 72 hours the degree of urgency for submission of a report should be determined by the level of hazard judged to have resulted from the occurrence.

Where an occurrence is judged by the person identifying the possible unsafe condition to have resulted in an immediate and particularly significant hazard the CAA expects to be advised immediately and by the fastest possible means (telephone, fax, email, telex, etc.) of whatever details are available at that time. This initial report must be followed up by a full written report within 72 hours. A typical example would be an uncontained engine failure resulting in damage to aircraft primary structure.

Where the occurrence is judged to have resulted in a less immediate and less significant hazard, report submission may be delayed up to the maximum of three days in order to provide more details.

Within the overall limit of 72 hours, the degree of urgency for submitting a report should be determined by the level of risk that is judged to have resulted from the occurrence.

If an occurrence is judged by the organisation that identified the possible unsafe condition to have resulted in an immediate and particularly significant hazard, the CAA should be advised immediately and by the fastest possible means (telephone, fax, email, telex, etc.) of whatever details are available at that time. This initial report must be followed up with a full written report within 72 hours. An example would be an uncontained engine failure that results in damage to the aircraft primary structure.

In all other cases, the submission of the report may be delayed up to a maximum of 72 hours after determining the possible unsafe condition, to provide more details.

## GM1 21.A.3A(b) Failures, malfunctions and defects

### REPORTING TO THE CAA — GENERAL

- (a) The reference to 'occurrence of which it is aware' implies that the organisation identifies the event as one that falls into the category of occurrences to be reported — usually when the organisation determines that the event is reportable. The 72-hour period starts when the possible unsafe condition is identified.
- (b) UK Regulation (EU) 2015/1018 lays down a generic 'list classifying occurrence in civil aviation to be mandatorily reported'. This list should not be understood as being an exhaustive collection of all the issues that may pose a significant risk to aviation safety and, therefore, reporting should not be limited to the items that are listed in that Regulation.
- (c) AMC-20 provides further details on occurrence reporting (AMC 20-8).
- (d) Point 21.A.3A(b) requires the reporting of occurrences that may result in an unsafe condition. GM 21.A.3B(b) 'Determination of an unsafe condition' could be used to assist in that determination.

**FOLLOW-UP TO, AND CLOSURE OF, REPORTED OCCURRENCES**

- (a) The organisation should transmit the following information to the CAA within 30 days from the date of the initial notification of the occurrence to the CAA:
- (1) the latest position of the design organisation (DO) as to whether an unsafe condition is confirmed;
  - (2) the results of the analysis and of the first investigation — including the cause(s) of the occurrence, if known; and
  - (3) the measures it has taken, intends to take, or proposes to be taken, including:
    - (i) containment measures that have already been defined by the reporting organisation and put in place (if any); and
    - (iii) in the case of reports made by the DO, for unsafe conditions, a risk assessment supporting that the product can be operated safely (see GM 21.A.3B(d)(4)) until the corrective action is defined and implemented, or that immediate mitigation measures need to be implemented until a more refined risk assessment can be provided.

Organisations are encouraged to provide a complete analysis and follow-up as soon as available and, no later than 3 months after the occurrence notification. It is recognised that analysing an occurrence may take longer than 3 months, especially if the investigation is complex or where the services of a special investigator are required.

The requirements for follow-up are not intended to jeopardise the quality and thoroughness of an occurrence analysis. It may be detrimental to safety if the analysis is completed in a rush within the encouraged 3-month period without properly establishing the root cause(s), making a risk assessment, and determining whether remedial action is required.

The design approval holder (DAH) and the production approval holder (PAH) should cooperate, as necessary, to ensure that any corrective action can be implemented. In addition, affected organisations are expected to cooperate under their respective regulatory framework from the reporting of an occurrence until its closure, to ensure complete results.

The final (close-out) report should include:

- the final DAH position as to whether an unsafe condition exists;
- the results of the occurrence analysis and of the final investigation, including the cause(s) of the occurrence;
- any corrective and preventive action by the reporting organisation; and
- in the case of reports made by the DO, a risk assessment supporting that those corrective and preventive measures allow the product to be operated safely (see GM 21.A.3B(d)(4)).

- (iv) Notwithstanding point (a), when the organisation identifies that no unsafe condition exists as a result of its analysis of a voluntarily reported occurrence, it can delay further communication to the CAA up to the issuance of the final report and report the occurrence as closed upon issue. In such cases, no follow-up report should be submitted. The final report to the CAA should include confirmation and justification that no unsafe condition exists. The organisation is requested to provide information on the cause(s) of the occurrence and on any corrective

or preventive action that was taken by the organisation.

This way of reporting should not be understood as an accepted deviation from the requirements of Part 21. If at any stage during the investigation, the organisation identifies that a possible unsafe condition exists, this should be communicated to the CAA via a mandatory report within 72 hours.

## AMC1 21.A.5 Record-keeping

### GENERAL

- (a) The record-keeping system should ensure that all the records that are required by point 21.A.5 are accessible within a reasonable time. Those records should be organised in a manner that ensures their traceability and retrievability throughout the required retention period.
- (b) The records should remain legible throughout the required retention period and be protected against damage, alteration, and tampering.
- (c) The format of the records should be specified in the organisation's procedures.
- (d) The organisation should ensure that copies of all the documents and supporting information that are developed:
  - (1) under the privileges that are defined under points 21.A.163 and 21.A.263; or
  - (2) for type certificates (TCs), restricted type certificates (RTC), supplemental type certificates (STCs), major changes, and major repairs that are not issued under the privileges that are defined under point 21.A.263, are retained throughout the operational life of the product or part.
- (e) The retention period starts when the record is created or when it is last amended.

If the organisation transfers a certificate or a letter of agreement to another natural or legal person, the records related to the certificate or to the letter of agreement should be transferred to the new holder.

## GM1 21.A.5 Record-keeping

### GENERAL

For organisations that hold or have applied for a type certificate (TC), restricted type certificate (RTC), supplemental type certificate (STC), a United Kingdom technical standard order (UKTSO) authorisation, a change to the TC approval, a repair design approval, a permit to fly, a production organisation approval (POA), or a letter of agreement under Part 21, the relevant design information/data includes at least the following, as applicable:

- design data such as type design data, as defined in point 21.A.31, and changes to that data, UKTSO design data, and repair design data;

For Design Organisations (DOs), the relevant records include at least:

- drawings and test reports, including inspection records for the product tested;
- the certification programme, including related certification basis data (certification review items (CRIs), special conditions (SCs), equivalent safety findings (ESFs)); and
- compliance demonstration data.

For repair designs, the record-keeping requirement of point 21.A.5 applies to the data described in AMC 21.A.433(a)d.

For production organisations (POs), the relevant records include at least:

- conformity justification data; and
- conformity attestation data (e.g. CAA Form 1 or CAA Form 52).

### AMC1 21.A.5(a) and 21.A.433(b) Repair design and record-keeping

- (a) The relevant substantiation data related to a new major repair design and record-keeping should include:
- (1) identification of the damage and of the source of the report;
  - (2) the major repair design approval sheet that identifies the applicable specifications and the references of the justifications;
  - (3) the repair drawing and/or instructions, and the scheme identifier;
  - (4) any correspondence with the holder of the type certificate (TC), supplemental type certificate (STC), or auxiliary power unit (APU) United Kingdom technical standard order (UKTSO) authorisation, if their advice on the design was sought;
  - (5) the structural justification (static strength, fatigue, damage tolerance, flutter, etc.) or references to that data;
  - (6) the effect on the aircraft, engines and/or systems (performance, flight handling, etc., as appropriate);
  - (7) the effect on the maintenance programme;
  - (8) the effect on the airworthiness limitations, the flight manual, and the operating manual;
  - (9) any change in the weight and moment; and
  - (10) any special test requirements.
- (b) The relevant minor repair documentation includes points (a)(1) and (a)(3). Other elements of point (a) may be included, where necessary. If the repair is outside the approved data, a justification for the classification is required.
- (c) Special consideration should be given to repairs that impose subsequent limitations on the part, product or appliance (e.g. engine turbine segments that may only be repaired a finite number of times, the number of repaired turbine blades per set, the oversizing of fastener holes, etc.).
- (d) Special consideration should also be given to life-limited parts and critical parts, notably with the involvement of the TC or STC holder, when deemed necessary under point 21.A.433(a)(4).



- (e) Repairs to engines or to APU critical parts would normally be accepted only with the involvement of the TC holder.

## GM1 21.A.5(a) and (b) Record-keeping

### RECORDING AND ARCHIVING SYSTEM

The main objective of record-keeping in design organisations (DOs) and production organisations (POs) is to ensure the retrievability of data that is required for the continued airworthiness of in-service products.

In addition, records within the design environment are essential to ensure proper control of the configuration of the type design and of its compliance with the certification basis.

In the production environment, records are also required, to ensure that products or parts are in conformity with the applicable data throughout the manufacturing cycle. In addition, certain records of milestones are needed, to subsequently provide objective evidence that all the prescribed stages of the production process have been satisfactorily completed.

Therefore, the approved DO or PO (or a natural or legal person that is demonstrating their design capability through an agreement on alternative procedures or through the acceptance of the organisation's certification programme, or a natural or legal person that produces products and parts under Part 21, Subpart F) are required to implement a system for the compilation and retention of records during all stages of design or production, which covers short-term and long-term records as appropriate to the nature of the product and its processes.

The management of such information is subject to the appropriately documented procedures in the management system that is required by points 21.A.139 and 21.A.239 or to the manual/procedures that are required by points 21.A.14(b), 21.A.125A(b), or 21.A.602B(b)(2), as appropriate. This also applies in case of demonstrating the design capability through the acceptance of the certification programme under point 21.A.14(c).

All forms of recording media are acceptable (paper, film, magnetic, etc.), including the use of electronic records\*, provided that they can meet the required duration for archiving under the given conditions and that the continued readability of the records is ensured.

The related procedures are required to:

- identify the records to be kept;
- describe the organisation of, and responsibility for, the archiving system (its location, compilation, format) and the conditions for access to the information (e.g. by product, subject, etc.);
- control access to the data and provide effective protection from deterioration or accidental damage, alteration, and tampering;
- ensure the continued readability of the records;
- demonstrate to the CAA the proper functioning of the record system; and

- define an archiving period for each type of data as follows:
  - production data that supports the conformity of a product, part, or appliance is kept for not less than 3 years from the issue date of the related statement of conformity or authorised release certificate; and
  - design data, including data that supports the compliance of a product, part, or appliance with the certification basis (see GM1 21.A.5), as well as data that is considered essential for continuing airworthiness, is kept throughout the operational life of the product, part, or appliance; such continued airworthiness data may include, but are not limited to, in-service occurrence reports and mandatory continuing-airworthiness information;
- for organisations that are approved according to Part 21, Subparts G and J and organisations that demonstrate their design capability through an agreement on alternative procedures or acceptance of their certification programme by the CAA, ensure that the recording and record-keeping systems that are used by the partners, suppliers, and subcontractors meet the record-keeping objectives with the same level of confidence as they do for their own system; in each case, it should be defined who should retain the data record (organisation, partner, supplier, or subcontractor), as well as the method of surveillance of the recording/record-keeping system of the partners, suppliers, or subcontractors; and
- for natural or legal persons that produce items under Part 21, Section A, Subpart F, the data on supplied parts may be retained by the supplier if the supplier has a system that is agreed by the CAA under Part 21, Section A, Subpart F; in each case, the PO is required to define the archiving period and satisfy itself and the CAA that the recording media are acceptable.

\*Related to electronic records, the following definitions apply:

- electronic record: electronic or digital data that is created, generated, sent, communicated, received, or stored by electronic means;
- electronic data: it is typically in the form of documentation that is statically stored in a computer file that is not modifiable (e.g. pdf of a scanned document with wet ink signatures); and
- digital data: it is typically in the form of computer-generated bytes of information that is stored in a computer workable file (e.g. MS Word file, MS Excel file, 3D CAD file).

## AMC1 21.A.5 (d) & (e) Record-keeping

### RECORD OF STAFF INVOLVED IN DESIGN OR PRODUCTION

- (a) The following should be the minimum information to be recorded for each person that exercises the privileges of an organisation that is approved according to Part 21, Subparts G and J, or according to points 21.A.163 or 21.A.263, or that carries out the independent monitoring of compliance and adequacy according to points 21.A.139(e) and 21.A.239(e), or that carries out the independent verification function of demonstration of compliance pursuant to point 21.A.239(d)(2):
- (a) name;
  - (b) date of birth;

- (c) basic training received and standard attained;
  - (d) specific training received and standard attained;
  - (e) continuation training received (if appropriate);
  - (f) experience gained;
  - (g) scope of the authorisation;
  - (h) date of first issue of the authorisation;
  - (i) expiry date of the authorisation (if appropriate);
  - (j) identification number of the authorisation (or equivalent means to identify the link between the authorisation and the staff member that holds the authorisation); and (k) changes to the data.
- (b) The record may be kept in any format and should be controlled through an internal procedure of the organisation. That procedure is part of the management system.
  - (c) The staff member should be given reasonable access, on request, to their own records as per UK Regulation (EU) 2016/679.
  - (d) A design organisation (DO) or production organisation (PO) should keep the record for at least 3 years after the staff member is no longer employed by the organisation or has changed their position in the organisation, or after the withdrawal of the authorisation, whichever occurs sooner.
  - (e) Records of authorisation of the production staff are to be archived for at least 3 years after the staff member is no longer employed by the organisation or as soon as the authorisation is withdrawn. This staff member is any person that has an activity that is essential for ensuring:
    - the conformity to applicable design data, or
    - a condition for the safe operation of a product, part, or appliance.

## GM1 21.A.8 Access and investigations

### ARRANGEMENTS

The arrangements made by the applicant for, or holder of, a type certificate (TC), restricted type certificate (RTC), supplemental type certificate (STC), a United Kingdom technical standard order (UKTSO) authorisation, a major repair design approval, a permit to fly, a design organisation approval (DOA), a production organisation approval (POA), or a letter of agreement under Part 21 are required to allow the CAA to make investigations that include the complete organisation, including its partners, subcontractors, and suppliers, whether they are in the State of the applicant or not.

The investigations may include audits, enquiries, questions, discussions, and explanations, monitoring, witnessing, inspections, checks, as well as flight and ground tests and inspections of completed products, parts, or appliances that are either designed or produced.

In order to maintain its confidence in the standards that are achieved by the organisation, the CAA may make an investigation into a sample product, part, or appliance and of its associated records, reports, and certifications.

The arrangements are required to enable the organisation to assist the CAA and cooperate with it in conducting the investigation during the initial assessment and the subsequent surveillance to maintain the approval.

'Cooperation in conducting the investigation' means that the CAA has been granted full and free access to the facilities and to any information relevant to demonstrating compliance with the Part 21 requirements, and has been provided assistance, as necessary.

'Assistance to the CAA' includes all the appropriate means regarding the facilities of the organisation, to allow the CAA to conduct the investigation, such as meeting rooms, offices, personnel support, records, documentation, computer data, and communication facilities, all properly and promptly made available, as necessary.

The CAA seeks to have an open relationship with the organisation, and suitable liaison staff are required to be nominated to facilitate this, including one or more suitable representatives to accompany CAA staff during visits, not only at the organisation's own facilities, but also at subcontractors, partners, or suppliers.

### AMC 21.A.20(c) Compliance documentation

[...]

3. Each compliance document should be unequivocally identified by its reference and issue date. The various issues of a document should be controlled and comply with point 21.A.55 21.A.5.

## SUBPART F — PRODUCTION WITHOUT PRODUCTION ORGANISATION APPROVAL

### AMC 21.A.122 Eligibility — Link between design and production

#### LINK BETWEEN DESIGN AND PRODUCTION

An 'arrangement' is considered suitable if it is documented and satisfies the CAA that ~~co-~~ ~~ordination~~ coordination is satisfactory.

To achieve satisfactory ~~coordination~~ coordination, the documented arrangements must at least define the following aspects, irrespective of whether the design organisation (DO) and the ~~organisation~~ person producing or intending to produce under Part 21, Subpart F are separate legal entities or not:

- (a) 1. The responsibilities of a ~~DO~~ design organisation which assure correct and timely transfer of up-to-date applicable design data (e.g., drawings, material specifications, dimensional data, processes, surface treatments, shipping conditions, quality requirements, etc.);
- (b) 2. The responsibilities and procedures of the ~~production organisation (PO)~~ manufacturer for receiving, managing, and using the applicable design data provided by the ~~DO~~ design organisation;

- (c) ~~3.~~ The responsibilities and procedures of the ~~PO manufacturer~~ for developing, where applicable, its own manufacturing data in compliance with the applicable design data package;
- (d) ~~4.~~ The responsibilities of the ~~PO manufacturer~~ to assist the ~~DO design organisation~~ in dealing with continuing airworthiness matters and for required actions (e.g., traceability of parts in case of direct delivery to users, retrofitting of modifications, traceability of processes' outputs and approved deviations for individual parts as applicable, technical information and assistance, etc.);
- (e) ~~5.~~ The scope of the arrangements covering Subpart F requirements, in particular, ~~points 21.A.126(a)(4), 21.A.129(d), and (f) 21.A.3A,~~ and any associated GM or AMC;
- (f) ~~6.~~ The responsibilities of the ~~PO manufacturer~~, in the case of products prior to type certification, to assist a ~~DO design organisation~~ in demonstrating compliance with the CS (access and suitability of production and test facilities for manufacturing and testing of prototype models and test specimen);
- (g) ~~7.~~ The procedures to deal adequately with production deviations and non-conforming parts;
- (h) ~~8.~~ The means to achieve adequate configuration control of manufactured parts, to enable the ~~PO manufacturer~~ to make the final determination and identification for conformity or airworthiness release and eligibility status;
- (i) ~~9.~~ ~~The identification of responsible persons/offices who that controls control the above; and.~~
- (j) ~~10.~~ The acknowledgment by the holder of the TC/STC/repair or change approval/UKTSO authorisation that the approved design data that is provided, controlled and modified in accordance with the arrangement ~~are~~ is recognised as approved.

In many cases, the person producing or intending to produce under Part 21, Subpart F may receive the approved design data through an intermediate ~~PO production organisation~~. This is acceptable, provided that an effective link between the design approval holder (DAH) and the ~~PO production organisation~~ can be maintained to satisfy the intent of point 21.A.122.

When the ~~DO design organisation~~ and the ~~PO manufacturer~~ are two separate legal entities, a ~~DDirect Ddelivery Aauthorisation~~ should be available for direct delivery to end users in order to guarantee continued airworthiness control of the released parts and appliances.

Where there is no general agreement for a ~~DDirect Ddelivery Aauthorisation~~, specific permissions may be granted (see AMC 21.A.4).

## AMC2 No 2 to 21.A.122 Eligibility – Link between design and production

[...]

<b>ARRANGEMENT</b> in accordance with 21.A.122	
<b>The undersigned agree on the following commitments:</b>	<b>Relevant interface procedures</b>
[...] As per current form	
For the <i>[NAME of the design organisation/DOA holder]</i> <i>{DOA/ADOA number}</i>  <b>Date:</b> <b>Signature:</b>  XX.XX.XXXX [NAME in block letters]	For the <i>[NAME of the person producing under Part 21 Subpart F [POA holder] {POA number}]</i>  <b>Date:</b> <b>Signature:</b>  XX.XX.XXXX [NAME in block letters]

## GM 21.A.124(a) Application – Application form

### APPLICATION FORM

CAA Form 60 (see AMC 21.B.120(c)(1)) should be obtained from the CAA and completed by the applicant.

An application may be accepted from:

- An individual applying on his or her own behalf, or
- In the case of an organisation, an individual with the authority to make agreements on behalf of the organisation.

The completed form should be forwarded to the CAA.

## AMC1 21.A.124A(b) and 21.A.134A(b) Means of compliance

### DESCRIPTION SUPPORTING THE ALTERNATIVE MEANS OF COMPLIANCE

- (a) The description of the alternative means of compliance (AltMoC) should include:
- (1) a summary of the AltMoC;
  - (2) the content of the AltMoC;
  - (3) a statement that compliance with the regulation is achieved; and
  - (4) in support of that statement, an assessment that demonstrates that the AltMoC reaches an acceptable level of safety, taking into account the level of safety that is achieved by

the corresponding CAA AMC.

- (b) All these elements that describe the AltMoC are an integral part of the management system records, in accordance with point 21.A.5.

## GM1 21.A.124A and 21.A.134A Means of compliance

### GENERAL

- (a) Acceptable means of compliance (AMC), as referred to in Article 76(3) of UK Regulation (EU) 2018/1139, are a tool to standardise the demonstration of compliance with, and facilitate the verification activities of the CAA in relation to, that Regulation and regulations made under it. AMC are published by the CAA to achieve those objectives.
- (b) If an organisation wishes to use other means to comply with UK Regulation (EU) 2018/1139 and the regulation made under it, which are different from the AMC that are published by the CAA, that organisation may need to demonstrate compliance by using alternative means of compliance (AltMoC) that are established:
- (1) by the CAA (see GM1 21.B.115 and GM1 21.B.215); or
  - (2) by that organisation and approved by the CAA (see point (c)).

An AltMoC does not allow deviation from UK Regulation (EU) 2018/1139 and regulations made under it.

- (c) AltMoC that are established by an organisation and approved by the CAA.

An organisation that wishes to use a different means of compliance to the one published by the CAA can propose an AltMoC to the CAA and use it only once the CAA approves it. In that case, the organisation is responsible for demonstrating how that AltMoC establishes compliance with the regulation.

The approval of an AltMoC is granted to the organisation by the CAA on an individual basis and is restricted to that specific organisation. Other organisations that wish to use the same AltMoC should go through the AltMoC process (i.e. demonstrate how that AltMoC establishes compliance with the regulation) and obtain individual approval from the CAA.

## GM2 21.A.124A and 21.A.134A Means of compliance

### WHEN AN ALTERNATIVE MEANS OF COMPLIANCE IS NEEDED

When there is no CAA AMC to a certain point of a regulation, the means of compliance (MoC) that are proposed by the organisation to that point do not need to go through the AltMoC process. It is the responsibility of the CAA to verify that compliance with the regulation is achieved. However, in certain cases, the organisation may propose, and the CAA may agree, to have such MoC go through the AltMoC process.

When there is a CAA AMC, the AltMoC process is needed in the following cases (non-exhaustive list):

- an AltMoC to the regulation is technically different to the AMC that is published by the CAA;
- and
- a Form is significantly different from the one that is included in the CAA AMC.

*Note: a Form that is required by regulation cannot be modified.*

An example of issues that are not considered to require the AltMoC process include, but are not limited to:

- incorporating a CAA AMC into the organisational structure, organisational processes, or standard operating procedures of an organisation with different wording and terminology that are customised to the organisation's environment if it does not change the intent of the AMC and its associated level of safety.

## GM1 21.A.125B(a), 21.A.158(a) and 21.A.258(a) Findings and observations

### ROOT CAUSE ANALYSIS

- (a) It is important that the analysis does not primarily focus on establishing who or what caused the non-compliance, but on why it was caused. Establishing the root cause(s) of non-compliance often requires an overarching view of the events and circumstances that led to it, to identify all the possible systemic and contributing factors (human factors (HF), regulatory, organisational, technical factors, etc.) in addition to the direct factors.
- (b) A narrow focus on single events or failures, or the use of a simple, linear model, such as a fault tree, to identify the chain of events that led to the non-compliance, may not properly reflect the complexity of the issue, and therefore, there is a risk that important factors that must be considered to prevent reoccurrence will be ignored.

Such an inappropriate or partial root cause analysis often leads to applying 'quick fixes' that only address the symptoms of the non-compliance. A peer review of the results of the root cause analysis may increase its reliability and objectivity.

## AMC1 21.A.125B(a)(3), 21.A.158(a)(3) and 21.A.258(a)(3) Findings and observations

### FINDING-RELATED CORRECTIVE-ACTION PLAN AND IMPLEMENTATION

After receipt of notification of findings, the organisation should identify and define the action for all findings, to address the effects of the non-compliance, as well as its root cause(s) and contributing factor(s).

Depending on the issues identified, the organisation may need to take immediate corrective action.

The corrective action plan, in response to CAA findings, should:

- include the correction of the issue, corrective and preventive action, as well as the planning to implement them; and
- be timely submitted to the CAA for acceptance before it is effectively implemented.

After receiving the CAA's acceptance of the corrective action plan, the organisation should implement the associated action.

Within the agreed period, the organisation should inform the CAA that the corrective action plan has been implemented and should send the associated pieces of evidence, on request from the CAA.



#### **DUE CONSIDERATION TO OBSERVATIONS**

For each observation that is notified by the CAA, the organisation should analyse the related issues and determine when action is needed.

The handling of the observations may follow a process similar to the handling of the findings by the organisation.

The organisation should record the analysis and the related outputs, such as action taken, or the reasons why no action was taken.

### **GM1 21.A.126(b)(5) Production inspection system — ~~Engineering and manufacturing review procedure~~**

#### **ENGINEERING AND MANUFACTURING REVIEW PROCEDURE**

- 1.(a) The procedure should permit to record the deviation, to present it to the design approval holder (DAH) ~~Design holder~~ under the provisions of point 21.A.122, and to record the results of the review and actions taken consequently as regards the part/product.
- 2.(b) Any unintentional deviation from the manufacturing/inspection data should be recorded and handled in accordance with Part 21, Section A, Subpart D or E as changes to the approved design.

### **GM ~~21.A.126(b)(6) Production inspection system — Recording and record keeping~~**

1. — ~~Records within a production environment satisfy two purposes. Firstly, they should, during the production process to ensure that products, parts, or appliances are in conformity with the controlling data throughout the manufacturing cycle. Secondly, certain records of milestone events are needed to subsequently provide objective evidence that all prescribed stages of the production process have been satisfactorily completed and that compliance with the applicable design data has been achieved.~~

~~Therefore, the person producing under Part 21 Subpart F should implement a system for the compilation and retention of records during all stages of manufacture, covering short-term and long-term records appropriate to the nature of the product and its production processes.~~

~~The management of such information should be subject to appropriate documented procedures in the Manual required by 21.A.125A(b).~~

~~All forms of recording media are acceptable (paper, film, magnetic ...) provided they can meet the required duration for archiving under the conditions provided.~~

2. — ~~The related procedures should:~~
  - 2.1 — ~~Identify records to be kept.~~

- ~~2.2 Describe the organisation of and responsibility for the archiving system (location, compilation, format) and conditions for access to the information (e.g., by product, subject).~~
- ~~2.3 Control access and provide effective protection from deterioration or accidental damage.~~
- ~~2.4 Ensure continued readability of the records.~~
- ~~2.5 Demonstrate to the competent authority proper functioning of the records system.~~
- ~~2.6 Clearly identify the persons involved in conformity determination.~~
- ~~2.7 Define an archiving period for each type of data taking into account importance in relation to conformity determination subject to the following:~~
- ~~a) Data which supports conformity of a product, part, or appliance should be kept for not less than three years from the issue date of the related Statement of Conformity or Authorised Release Certificate.~~
  - ~~b) Data considered essential for continuing airworthiness should be kept throughout the operational life of the product, part or appliance.~~
- ~~2.8 Data related to supplied parts may be retained by the supplier if the supplier has a system agreed under Part 21 Section A Subpart F by the competent authority. The manufacturer should, in each case, define the archiving period and satisfy himself or herself and the competent authority that the recording media are acceptable.~~

## SUBPART G — PRODUCTION ORGANISATION APPROVAL

### GM No 2 to 21.A.158(a) Examples of level one findings

Examples of level one findings are non-compliances with any of the following points, that could affect the safety of the aircraft:

~~21.A.139, 21.A.145, , 21.A.148, 21.A.151, 21.A.163, 21.A.165(b), (c), (d), (e), (f) and (g).~~

~~It should be anticipated that a non-compliance with these points is only considered a level one finding when objective evidence has been found that this finding is an uncontrolled non-compliance that could affect the safety of the aircraft.~~

~~In addition, the failure to arrange for investigations under 21.A.157, in particular to obtain access to facilities, after denial of one written request should be classified as a level one finding.~~

## AMC-ELA No 1 to 21.A.133(c) Eligibility – Link between design and production

[...]

ARRANGEMENT in accordance with AMC-ELA No 1 to 21.A.133(c)			
The undersigned agree on the following commitments:		Relevant interface procedures	
[...] As per current form			
For the [NAME of the design organisation/DOA holder] {DOA/ADOA number}		For the [NAME of the person producing under Part 21 Subpart F [POA holder] {POA number}]	
<b>Date:</b>	<b>Signature:</b>	<b>Date:</b>	<b>Signature:</b>
xx.xx.xxxx		xx.xx.xxxx	
[NAME in block letters]		[NAME in block letters]	

## AMC1 21.A.139(a) Production management system

### ORGANISATION AND ACCOUNTABILITY

- (a) The production management system should encompass safety by including as part of the safety management element of the production management system a safety manager and a safety review board in the organisational structure. The functions of the safety manager are defined in AMC1 21.A.145(c)(2) and (4).
- (b) Safety review board
- (1) The safety review board (the 'board'), sometimes referred to as 'high-level safety committee', considers matters of strategic safety in support of the safety accountability of the accountable manager.
  - (2) The board should be normally chaired by the accountable manager and be generally composed of the person or group of persons nominated under point 21.A.145(c)(2) and (4). Its composition can be adapted to its needs, considering point 21.A.145(c)(2).
  - (3) The board should monitor:
    - (i) the organisation's safety performance against its safety policy and objectives;
    - (ii) whether any safety action is taken in a timely manner; and
    - (iii) the effectiveness of the organisation's management system processes.
  - (4) The board may also be tasked with:
    - (i) reviewing the results of compliance monitoring; and
    - (ii) monitoring the implementation of any related corrective and preventive action.
- (c) The board should ensure that appropriate resources are allocated to achieve the established safety objectives.

- (d) Notwithstanding point (a), if justified by the size of the organisation and the nature and complexity of its activities, and subject to a risk assessment and/or mitigation measures, as well as the CAA's agreement, the organisation may not need to establish a board. In that case, the tasks that are normally allocated to the board should be allocated to the safety manager.

## AMC1 21.A.139(c) Production management system

### SAFETY MANAGEMENT ELEMENT

Demonstration of compliance with the international industry standard SM-0001 'Implementing a Safety Management System in Design, Manufacturing and Maintenance Organisations', Issue B, 31 March 2022, is a means to support demonstration of compliance with the safety management element of the production management system.

## GM1 21.A.139(c) Production management system

### SAFETY MANAGEMENT ELEMENT

Safety management seeks to proactively identify hazards and mitigate the related safety risks before they result in aviation accidents and incidents. Safety management enables an organisation to manage its activities in a more systematic and focused manner. When an organisation has a clear understanding of its role in, and contribution to, aviation safety, this enables the organisation to prioritise safety risks and more effectively manage its resources for optimal results.

Safety should not be considered the responsibility of a single person or a limited group of people in the organisation. A safety culture should be developed throughout the organisation, which involves all the personnel as active contributors to the safety of the final product, part, or appliance (see AMC1 21.A.139(c)(1)).

The principles of the requirements in points 21.A.3A, 21.A.5, 21.A.139, 21.A.145, and 21.A.147, and the related AMC constitute the CAA production management system framework for aviation safety management. This framework addresses the core elements of the International Civil Aviation Organization (ICAO) safety management system (SMS) framework that is defined in ICAO Annex 19, Appendix 2, and facilitates the introduction of the additional safety management element.

This approach is intended to encourage organisations to embed safety management and risk-based decision-making into all their activities, instead of superimposing another system onto their existing management system and governance structure. In addition, if the organisation holds multiple organisation certificates that are issued under UK Regulation (EU) 2018/1139, it may choose to implement a single management system to cover all of its activities. An integrated management system may be used not only to capture multiple management system requirements resulting from UK Regulation (EU) 2018/1139, but also to cover for other regulatory provisions requiring compliance with ICAO Annex 19 or for other business management systems, such as security, occupational health, and environmental management systems. Integration will remove duplication and exploit synergies by managing safety risks across multiple activities. Organisations may determine the best means to structure their management systems to suit their business and organisational needs.

It is important to recognise that safety management will be a continuous activity, as hazards, risks, as well as the effectiveness of safety risk mitigations, will change over time.

The safety management capability of an organisation should be commensurate with the safety risks to be managed, which can be at the product, part, and appliance level or at the organisational level.

The risks that are inherent in a complex structure require a robust safety risk management process (e.g. a complex supply chain may induce hazards that are complex to mitigate, or the rate of production, when stretched to the limit, may require more efficient safety barriers).

As a consequence, scalability and suitability of the safety management element should be a function of the inherent safety risk capability of the organisation. For instance, for organisations with a lower risk level:

- (a) the risk assessment model that is used may be very simple in cases in which the identified hazards are easy to mitigate;
- (b) expert judgement might be sufficient to measure the efficiency of safety barriers;
- (c) the collection of data, safety information, and occurrences might be very limited;
- (d) there might be no need for software or tools to manage the SMS; and (e) the communication policy might be limited.

## AMC1 21.A.139(c)(1) Production management system

### SAFETY POLICY & OBJECTIVES

- (a) The safety policy should:
  - (1) reflect organisational commitments regarding safety, and its proactive and systematic management, including the promotion of a positive safety culture;
  - (2) include internal reporting principles by fostering the reporting of organisational threats as well as events, as defined in AMC3 21.A.3A(a);
  - (3) be endorsed by the accountable manager (AM);
  - (4) be communicated, with visible endorsement, throughout the organisation; and
  - (5) be periodically reviewed to ensure that it remains relevant and appropriate to the organisation.
- (b) The safety policy should include the commitment:
  - (1) to comply with all the applicable legislation, meet all the applicable requirements, and adopt practices to improve safety standards;
  - (2) to provide the necessary resources for the implementation of the safety policy;
  - (3) to apply human factors (HF) principles;
  - (4) to enforce safety as a primary responsibility of all managers; and
  - (5) to apply 'just culture' principles and, in particular, not to make available or use the information on occurrences:
    - (i) to attribute blame or liability to personnel for action, omissions, or decisions that are commensurate with their experience and training; or
    - (ii) for any purpose other than the improvement of aviation safety.
- (c) Senior management should continuously promote the safety policy to all personnel, demonstrate their commitment to it, and provide the necessary human and financial resources

for its implementation.

- (d) Taking due account of its safety policy, the organisation should define safety objectives. The safety objectives should:
- (1) form the basis for safety performance monitoring and measurement;
  - (2) reflect the organisation's commitment to maintaining or continuously improving the overall effectiveness of safety management;
  - (3) be communicated throughout the organisation; and
  - (4) be periodically reviewed to ensure that they remain relevant and appropriate to the organisation.

### GM1 21.A.139(c)(1) Production management system

#### **SAFETY POLICY**

The safety policy is the means for the organisation to state its intention to maintain and, where practicable, to improve the safety levels of all its activities, and to minimise its contribution to the risk of an aircraft accident or serious incident occurring, as far as reasonably practicable. The safety policy reflects the management's commitment to safety and the organisation's philosophy of safety management. It is the foundation on which the organisation's management system is built and serves as a reminder of 'how we do business here'. The creation of a positive safety culture begins with issuing a clear, unequivocal policy statement.

The commitment to apply 'just culture' principles forms the basis for the organisation's internal rules that describe how 'just culture' principles are guaranteed and implemented.

UK Regulation (EU) No 376/2014 defines the 'just culture' principles to be applied (refer, in particular, to Article 16(11) of that Regulation).

### GM1 21.A.139(c)(2) Production management system

#### **SAFETY ACTION GROUP**

- (a) Depending on the size of the organisation and the nature and complexity of its activities, a safety action group may be established as a standing group or as an ad hoc group to assist, or act on behalf of, the safety manager or the safety review board.
- (b) More than one safety action group may be established, depending on the scope of the task and the specific expertise that is required.

- (c) The safety action group usually reports to, and takes strategic direction from, the safety review board, and may be composed of managers, supervisors, and personnel from operational areas.
- (d) The safety action group may be tasked with or assist in the following:
  - (1) monitoring safety performance;
  - (2) defining action to control risks to an acceptable level;
  - (3) assessing the impact of organisational changes on safety;
  - (4) ensuring that safety action is implemented within the agreed timescales; and
  - (5) reviewing the effectiveness of previous safety action and safety promotion.

## AMC1 21.A.139(c)(3) and (4) Production management system

### SAFETY MANAGEMENT KEY PROCESSES

- (a) Hazard identification processes
  - (1) Hazard identification should be based on a combination of reactive and proactive methods.
  - (2) The organisation should focus in particular on hazards that may generate nonconformity of a product, part, or appliance that is produced.
- (b) Safety risk management processes
  - (1) The organisation should develop and maintain a safety risk management process that ensures a reactive, proactive, and predictive approach composed of the following elements:
    - (i) analysis (e.g. in terms of the probability or likelihood as well as severity of the consequences of hazards and occurrences);
    - (ii) assessment (in terms of tolerability); and
    - (iii) control (in terms of mitigation) of risks to an acceptable level.
  - (2) The organisation should specify, within the risk management process, who has the authority to make decisions, considering point (b)(1) of this AMC.
  - (3) For each individual organisation approval certificate held, the risks for each approval should be clearly identified and understood by the Safety Manager.
- (c) Regardless of the approval status of the subcontracted organisations, the production organisation (PO) is responsible for ensuring that hazard identification and risk management activities are performed on subcontracted activities, as required by point 21.A.139(d)(2)(ii), as well as for the monitoring of their compliance and adequacy, as required by point 21.A.139(e).
- (d) Internal investigation
  - (1) In line with 'just culture' as part of the safety policy, the organisation should define how to investigate events such as errors or near misses, in order to understand not only what happened, but also how it happened, as well as to prevent or reduce the probability and/or the consequences of any future recurrence.

The outcomes of these investigations should where relevant be incorporated into

future iterations of the safety risk management process and the safety assurance process.

- (2) The scope of internal investigations should extend beyond the scope of the occurrences that are required to be reported to the CAA in accordance with point 21.A.3A.

(e) Safety performance monitoring and measurement

- (1) The organisation should define the processes through which the safety performance of the organisation is verified against the safety policy and the safety objectives.

- (2) This process may include, as appropriate to the size, nature, and complexity of the organisation, the following elements:

- (i) safety reporting that also addresses the status of compliance with the applicable requirements;

- (ii) safety reviews, including trend reviews, which should be conducted during the introduction and deployment of new products, parts, or new equipment/technologies, the implementation of new or changed procedures, or in cases of organisational changes that may have an impact on safety;

- (iii) safety audits that focus on the integrity of the organisation's management system, and that periodically assess the status of safety risk controls;

- (iv) safety surveys that examine particular elements or procedures of a specific area, such as the following:

- (A) the problem areas identified;

- (B) bottlenecks in the daily production management activities;

- (C) the perceptions and opinions of the production management personnel; and

- (D) any areas of dissent or confusion; and

- (v) other indicators relevant to safety performance.

(f) Management of change

Changes to the production management system may pose new hazards or decrease the effectiveness of existing safety risk controls. The organisation should manage any safety risks that are related to change in that organisation. The management of change should be a documented process to identify external or internal change that may have an adverse effect on safety. The management of change should use the organisation's existing processes for hazard identification, risk assessment, and risk mitigation.

(g) Continuous improvement

The organisation should continuously seek to improve its safety performance and the effectiveness of its production management system. Continuous improvement may be achieved through review of the following elements:

- (1) compliance monitoring and audits;

- (2) assessments, including assessments of the effectiveness of the safety culture and of the management system, to assess in particular the effectiveness of the safety risk management processes;



- (3) staff surveys, including safety culture surveys, that can provide useful feedback on how engaged the staff are in the production management system;
- (4) the monitoring of events and their recurrence;
- (5) the evaluation of the safety performance indicators as well as reviews of all the available safety performance information; and
- (6) the identification of lessons learned.

## AMC1 21.A.139(c)(4)(ii) Production management system

### MANAGEMENT OF CHANGE

This AMC provides a means to consider organisational changes for their potential impact on safety. Organisational changes should also be evaluated for their significance, as required by point 21.A.147. In addition, necessary changes should be introduced into the production organisation exposition (POE), as per point 21.A.143(c). The production management system should be designed such that all the above points are taken into account.

- (a) Organisational changes should be proactively considered for their safety implications. The magnitude of a change, its safety criticality, and its potential impact on human performance (HP) should be assessed in any process for the management of change. Certain non-complex organisational changes may not require additional assessment.
- (b) Special consideration, including human factors (HF) issues, should be given to the transition period during which the change becomes effective.
- (c) During the process for the management of change, relevant previous risk assessments and existing hazards should be reviewed for their possible effects.

## GM1 21.A.139(c)(4)(ii) Production management system

### MANAGEMENT OF CHANGE

Unless properly managed, changes in the organisational structure, facilities, scope of work, personnel, documentation, policies and procedures, etc. may result in inadvertently creating new hazards, which may expose the organisation to new or greater risks. Effective organisations seek to improve their processes, while being conscious of the fact that changes may expose the organisation to potential hazards and risks if they are not properly and effectively managed.

The process for the management of change typically provides principles and a structured framework for managing all aspects of change. The disciplined implementation of management of change may maximise the effectiveness of change, engage staff, and minimise the risks that are inherent in change.

Change may have the potential to raise new HF issues, or to exacerbate existing ones. For example, changes in computer systems, equipment, technology, personnel changes (including changes in management personnel), procedures, the organisation of work, or work processes are likely to affect performance.

Effective management of change is supported by the following elements:

- (a) the implementation of a process for hazard identification/risk analysis and assessment for major operational changes, major organisational changes, changes in key personnel, and changes that may affect the way in which production management is carried out;
- (b) the identification of changes that may have a considerable impact on:
  - (1) resources (material and human);
  - (2) management direction (policies, processes, procedures, training); and
  - (3) management control;
- (c) safety cases/risk assessments that are aviation-safety-focused; and
- (d) the involvement of key stakeholders in the process for the management of change, as appropriate.

### GM1 21.A.139(c)(5) Production management system

#### SAFETY PROMOTION

- (a) Safety training, combined with safety communication and information sharing, is part of safety promotion.
- (b) Safety promotion activities support the following:
  - (1) the organisation's policies, encouraging a positive safety culture, thus creating an environment that is favourable to the achievement of the organisation's safety objectives;
  - (2) organisational lessons learned; and
  - (3) the implementation of an effective safety reporting scheme and the development of a 'just culture'.
- (c) Depending on the particular safety issue, safety promotion may also constitute or complement risk mitigation action.

### AMC1 21.A.139(c)(5)(i) Production management system

#### SAFETY TRAINING

- (a) The production management staff, as described in points 21.A.145(c)(1) and (2), should receive initial and recurring safety training, as appropriate to their responsibilities, including in safety management principles and the associated safety objectives, to ensure their continued competency.
- (b) The organisation should identify the category of other staff to which safety training should be provided, and define the initial and recurrent training programmes, including appropriate timelines.
- (c) Adequate records of the safety training that is provided should be kept in accordance with point 21.A.5.

## GM1 21.A.139(c)(5)(i) Production management system

### SAFETY TRAINING

- (a) The main purpose of the safety training programme is:
- (1) to support safety management policies and processes; and
  - (2) to ensure that personnel at all levels of the organisation develop and maintain their competency to fulfil their safety roles.
- (b) Each organisation may adapt its syllabus to its own needs. Typically, depending on the targeted staff, to contribute to a positive safety culture, the following items may be included:
- (1) the organisational roles and responsibilities related to safety, including the hazard identification and risk management processes;
  - (2) the safety objectives and the associated safety performance indicators;
  - (3) human factors (HF) principles, including human performance (HP) and limitations;
  - (4) legislation, where applicable;
  - (5) safety reporting systems and investigations; and
  - (6) safety issues.
- (c) The purpose of the recurrent safety training is:
- (1) primarily to ensure that staff are kept abreast notably of changes to safety management system (SMS) principles, processes, and procedures; and
  - (2) also to share feedback on safety issues that are relevant to the organisation or lessons learned.
- (d) The training staff should have sufficient knowledge and experience to teach the topics at the required level, as well as the skills to influence attitudes and behaviours.

## AMC1 21.A.139(c)(5)(ii) Production management system

### SAFETY COMMUNICATION

- (a) The organisation should establish communication to the staff, as appropriate to their safety responsibilities, regarding safety matters, which:
- (1) ensures awareness of safety management activities;
  - (2) conveys safety-critical information, especially related to assessed risks and analysed hazards;
  - (3) explains why particular action is taken; and
  - (4) explains why safety procedures are established or changed.
- (b) The appropriate nominated post holders, as detailed in the production organisation exposition, should hold or direct regular meetings with staff, during which information, action, and procedures are discussed, and these may be used to communicate safety matters.

## GM No 1 to AMC1 21.A.139(d) (a) Quality System Production management system

### QUALITY MANAGEMENT ELEMENT

The quality management element is an organisational structure, included in the production management system, with responsibilities, procedures, processes, and resources which that implement a management function to determine and enforce quality principles.

The quality management element should be documented in such a way that the documentation can be made easily available to personnel who need to use the material for performing their normal duties, in particular:

- procedures, instructions, data to cover the issues of point 21.A.139(d)(2)(b)(1) are available in a written form;
- distribution of relevant procedures to offices/persons is made in a controlled manner;
- procedures which identify persons responsible for the prescribed actions are established; and
- the updating process is clearly described.

The manager responsible for ensuring that the quality management element is implemented and maintained should be identified.

The CAA will verify on the basis of the exposition and by appropriate investigations that the production organisation (PO) has established and can maintain their documented quality management element.

## GM1 No 2 to 21.A.139(d)(1) (a) Quality System — Conformity of supplied parts of appliances Production management system

### CONFORMITY OF SUPPLIED PARTS OR APPLIANCES

The production organisation approval (POA) holder is responsible for determining and applying acceptance standards for physical condition, configuration status and conformity of supplied products, parts or appliances, whether to be used in production or delivered to customers as spare parts. This responsibility also includes BFE (Buyer Furnished Equipment) items.

To discharge this responsibility the quality management element needs an organisational structure and procedures to adequately control suppliers. Elements of the quality management element for the control of suppliers may be performed by other parties provided that the conditions of AMC No 1 21.A.139(d)(2)(ii) or AMC No 2 21.A.139(d)(2)(ii) (b)(1)(ii) are met.

Control can be based upon use of the following techniques (as appropriate to the system or product orientation necessary to ensure conformity):

- qualification and auditing of the supplier's quality management element of the production management system;
- evaluation of the supplier's capability in performing all the manufacturing activities, inspections and tests necessary to establish the conformity of parts or appliances to the type design;
- first article inspection inspections, including destruction, if necessary, to verify that the article

conforms to the applicable data for a new production line or a new supplier;

- incoming inspections and tests of supplied parts or appliances that can be satisfactorily inspected on receipt;
- identification of incoming documentation and data relevant to the showing of conformity to be included in the certification documents;
- a vendor rating system which gives confidence in the performance and reliability of this supplier; and
- any additional work, tests or inspection which may be needed for parts or appliances which are to be delivered as spare parts and which are not subjected to the checks normally provided by subsequent production or inspection stages.

The POA holder may rely on the results of inspections/inspection/tests performed by the supplier if it can establish that:

- the personnel responsible in charge of for these tasks satisfy the competency standards of the POA quality management element of the production management system;
- quality measurements are clearly identified; and
- the records or reports showing evidence of conformity are available for review and audit.

The POA holder retains direct responsibility for inspections/tests that are performed either at its own facilities or at the supplier's facilities.

The control of suppliers holding a POA for the parts or appliances to be supplied can be reduced to a level at which a satisfactory interface between the two quality management element can be demonstrated. Thus, for the purpose of showing conformity, a POA holder can rely upon documentation for parts or appliances, which is released under a suppliers in accordance with the supplier's privileges that are defined in point 21.A.163-privileges.

A supplier who does not hold a POA is considered as to be a sub-contract/subcontractor under the direct control of the POA quality management element of the production management system.

The POA holder retains direct responsibility for inspections/tests carried out either at its own facilities or at supplier's facilities.

## GM2 21.A.139(d)(1) Production management system

### QUALITY MANAGEMENT ELEMENT — PARTNER AND SUBCONTRACTOR ARRANGEMENTS

When defining the arrangements between the production organisation (PO) and its partners and subcontractors, both elements of the production management system should be taken into account, i.e. the safety management element and the quality management element. The following guidance should therefore be considered applicable to both elements.

- When the PO subcontracts activities, the arrangements should consider the safety risk management process that is part of the PO's safety management element (see point 21.A.139(c)(3)). When the subcontractor does not have a safety management element, the subcontractor should be integrated into the safety management element of the PO; when the subcontractor has implemented a safety management system (such as for design organisation approval (DOA) or production organisation approval (POA)), the two safety management

systems, i.e. of the PO and of the subcontractor, should be harmonised.

- (b) Depending on the complexity and criticality of those arrangements, the following elements within the arrangements should be addressed:
- (1) coordination and interfaces between all the parties involved;
  - (2) applicable procedures;
  - (3) safety culture, including internal safety reporting schemes (see point 21.A.3A);
  - (4) communication between all the parties involved, including reporting, regular meetings, and feedback channels;
  - (5) allocation of tasks, of clear accountability, and of responsibilities; and
  - (6) the qualifications and competency of key personnel with reference to point 21.A.145.
- (c) The safety risk management should focus on the need to exchange safety data and safety information that are deemed significant for the determination of relevant risks in terms of likelihood, severity, impact, and acceptability, such as, wherever appropriate, but not limited to the following:
- (1) (at product level) failure, malfunction, defect, or other occurrences, non-conformity or outcome of the compliance monitoring function, quality escape, process failure, foreign object damage (FOD), deviation (e.g. calibration of tools), component failure analysis, in-service event, etc.;
  - (2) (at documentation level) key processes (e.g. airworthiness directives, production documentation, production processes); and
  - (3) (at organisational level) organisational changes, disruptive events, resources' issues, human performance (HP) issues.
- (d) Regular communication should be ensured between all the parties involved, to discuss work progress, risk mitigation measures, changes to the arrangements, as well as any other significant issues.

## AMC1 GM 21.A.139(d)(2)(b)(1) Quality system — Elements of the quality system- Production management system

### PRODUCTION MANAGEMENT SYSTEM - ELEMENTS OF THE QUALITY MANAGEMENT ELEMENT

- (1). The control procedures covering the elements of point 21.A.139(d)(2)(b)(1) should document the standards to which the production organisation intends to work.
- (2). An organisation having a quality management element designed to meet a recognised Standard such as ISO 9001 (relevant to the scope of approval being requested) should expand it to include at least the following additional topics, as appropriate, in order to demonstrate compliance with the requirements of Part 21 ~~Subpart G~~:
  - Mandatory and voluntary Occurrence Reporting, as required by points 21.A.3A and 21.A.139(c), and continued airworthiness as required by point 21.A.165(i);
  - Control of work occasionally performed (outside the POA facility by POA personnel);

- ~~Co-ordination~~ coordination with the applicant for, or holder of, an approved design, as required by points 21.A.133(b) and (c) and 21.A.165(k);
  - Issue of certifications within the scope of approval for the privileges of point 21.A.163;
  - Incorporation of airworthiness data in production and inspection data, as required in points 21.A.133(b) and (c) and 21.A.145(b);
    - ~~W~~When applicable, ground test and/or production flight test of products in accordance with procedures defined by the applicant for, or holder of, the design approval;
    - ~~P~~Procedures for traceability including a definition of clear criteria of which items need such traceability; Traceability is defined as a means of establishing the origin of an article by reference to historical records for the purpose of providing evidence of conformity; and
    - ~~P~~Personnel training and qualification procedures especially for certifying staff, as required in point 21.A.145(d).
- (3) An organisation having a quality management element of the production management system designed to meet a recognised aerospace quality standard will still need to ensure compliance with all the requirements of ~~Subpart G~~ of Part 21. In all cases, the CAA will still need to be satisfied that compliance with Part 21 ~~Subpart G~~ is established.

**AMC No 1 to 21.A.139(b)(1)(ii) Vendor and sub-contractor assessment, audit and control – Production Organisation Approval (POA) holder using documented arrangements with other parties for assessment and surveillance of a supplier.**

**AMC1 to 21.A.139(d)(2)(ii) Production management system**

**VENDOR AND SUBCONTRACTOR ASSESSMENT, AUDIT AND CONTROL — PRODUCTION ORGANISATION APPROVAL HOLDER THAT USES DOCUMENTED ARRANGEMENTS WITH OTHER PARTIES FOR THE ASSESSMENT AND SURVEILLANCE OF A SUPPLIER**

(1) General

*Note:*

*For the purpose of this AMC, vendors and sub-contractors are hereafter referred to as ‘suppliers’, regardless of whether or not they hold a POA and audit and control is hereafter referred to as ‘surveillance’.*

The production organisation is required by Part 21 point 21.A.139(d) to demonstrate that it has established and maintains a quality management element system that enables the organisation to ensure that each item produced conforms to the applicable design data and is in a condition for safe operation. To discharge this responsibility, the quality management element system should have, among other requirements, procedures to adequately carry out the assessment and surveillance of suppliers.

The use of other parties, such as a consulting firm or quality assurance company, for supplier assessment and surveillance does not exempt the production organisation approval (POA) holder from its obligations under point 21.A.165. The supplier assessment and surveillance, corrective action and follow-up activity conducted at any of its supplier’s facilities may be performed by other parties.

The purpose of using the other party cannot be to replace the assessment, audit and control of the POA Holder. It is to allow an element (i.e. the assessment of the quality management element system) to be delegated to another organisation under controlled conditions.

The use of other parties to perform supplier assessments and surveillance should be part of the production organisation quality system and fulfil the conditions of this AMC.

This AMC is applicable to a method whereby a POA holder has a documented arrangement with the other party for the purpose of assessing and/or surveying a POA’s supplier.

2) Approval by the competent authority Intentionally left blank

~~Implementing or changing procedures for using OP for supplier assessment and surveillance is a significant change to the quality system and requires approval in accordance with 21.A.147.~~

3) Conditions and criteria for the use of other parties to perform supplier assessment and

(a) The POA holder should include the use of other parties for supplier assessment and surveillance in the POA holders’ quality management element of the production management system to demonstrate compliance with the applicable requirements of Part 21.

(b) The procedures that are required for using other parties for supplier assessment and surveillance should be consistent with other procedures of the POA holders’ quality system.



(c) The procedures of the POA holder that uses OP other parties to perform supplier assessment and surveillance should include the following:

- (1) Identification of the other party that will conduct the supplier assessment and surveillance.
- (2) A listing of suppliers under surveillance by the other party. This listing should be maintained by the POA holder and made available to the CAA upon request.
- (3) The method used by the POA holder to evaluate and monitor the other party. The method should include the following as a minimum:
  - (i) Verification that standards and checklists used by the other party are acceptable for the applicable scope.
  - (ii) Verification that the OP other party is appropriately qualified and have has sufficient knowledge, experience, and training to perform their its allocated tasks.
  - (iii) Verification that the frequency with which the other party carry out surveillance frequency of the suppliers is commensurate with the complexity of the product and with the surveillance frequency established by the POA holder's suppliers control programme.
  - (iv) Verification that the assessment and surveillance of the suppliers suppliers' assessment and surveillance is including on-site surveillance activities that are conducted on-site by the OP other party; and.
  - (v) Verification that the OP other party has access to the applicable proprietary data to the level of detail necessary to survey suppliers functions.

Where the POA holder uses an OP other party accredited by a signatory to the European cooperation for Accreditation (EA) Multilateral Agreement and working works in accordance with an aviation standard (e.g. EN 9104 series of requirements) that describes requirements for the other party assessment and surveillance by the other party, the items (ii) and (iv) shall be deemed to be complied with.

- (4) A definition that states to what scope extent the OP other party will conduct surveillance of the suppliers surveillance on behalf of the POA holder. If the OP other party partly replaces surveillance by the POA holder in part, the POA holder should identify the functions that will continue to be surveyed by the POA holder.
  - (5) The procedures used by the other party OP to notify the POA holder of any non-conformities that is discovered at the supplier's facility, and of the corrective action and follow-up.
- (d) The POA should make arrangements that allow the CAA to make investigation investigations in accordance with point 21.A.157 21.A.8, to include other party OP activities.

~~AMC2 No 2 to 21.A.139(d)(2)(ii)(b)(1)(iii)~~ Production management system  
Vendor and sub-contractor assessment, audit and control – Production  
Organisation Approval (POA) holder using other party supplier certification

**VENDOR AND SUBCONTRACTOR ASSESSMENT, AUDIT, AND CONTROL — PRODUCTION ORGANISATION  
APPROVAL HOLDER THAT USES OTHER PARTIES SUPPLIER CERTIFICATION**

(1). General

*Note:*

*For the purpose of this AMC, vendors and sub-contractors are hereafter referred to as 'suppliers', regardless of whether or not they hold a POA and audit and control is hereafter referred to as 'surveillance'.*

Other party supplier certification is a method whereby a supplier contracts with an appropriately recognised or accredited party other party for the purpose of obtaining a certification from that other party. Certification indicates that the supplier has satisfactorily demonstrated to meet that it meets the applicable standard on a continuing basis. Other party OP certification results in placing the supplier on the other party OP list of certified organisations, or in the supplier receiving a certificate identifying the requirements that have been met. Periodic follow-up evaluations are conducted by the other party OP to verify continued compliance with the requirements of the applicable standard.

The production organisation is required by ~~Part 21~~ point 21.A.139(d) to demonstrate that it has established and maintains a quality management element that enables the organisation to ensure that each item produced conforms to the applicable design data and is in a condition for safe operation. To discharge this responsibility, the quality system should have, among other requirements, procedures to adequately carry out the assessment and surveillance of suppliers.

The assessment and surveillance of suppliers by the other party OP should be deemed to satisfy the requirements of point 21.A.139(d)(1)(ii) when the conditions of this AMC are satisfied. The assessment and surveillance of suppliers by other parties OP as part of supplier certification does not exempt the production organisation approval (POA) holder from its obligations under point 21.A.165. The supplier assessment and surveillance, corrective action and follow-up activity conducted at any of its supplier's facilities may be performed by the other party.

The purpose of using the OP other party cannot be to replace the assessment, audit and control of the POA Hholder. It is to allow an element (i.e. the assessment of the quality management element) to be delegated to another organisation under controlled conditions.

The use of suppliers that are certified by other parties OP in accordance with this AMC should be part of a production organisation quality management element.

- (2): ~~Approval by the competent authority intentionally left blank.~~  
~~Implementing or changing procedures for using suppliers that are certified by an OP is a significant change to the quality system and requires approval in accordance with 21.A.147.~~
- (3): Conditions and criteria for using supplier certification for ~~the~~ supplier assessment and surveillance

- (a) The POA holder should include the use of supplier certification for the supplier assessment and surveillance in the POA holder's quality management element to demonstrate compliance with the applicable requirements of Part 21.
- (b) The procedures that are Procedures required for use of supplier certification for the supplier assessment and surveillance should be consistent with the other procedures of the POA holders' quality management element.
- (c) The procedures Procedures of the POA holder that uses supplier certification for the supplier assessment and surveillance should include the following:
- (1) A listing Listing of the other party OP that has have certified or will certify suppliers and will conduct supplier assessment and surveillance or the scheme under which the accreditation of the other party OP is controlled. This listing should be maintained by the POA holder and made available to the CAA upon request.
  - (2) A listing of the certified suppliers that are under surveillance by the other party OP and that are used by the POA holder. This listing should be maintained by the POA holder and made available to the CAA upon request.
  - (3) The method used by the POA holder to evaluate and monitor the certification process of any other party OP certification body or other party OP certification scheme used. This applies not only to new suppliers, but also to any decision by the POA holder to rely on other party OP certification of current suppliers. The method should include the following as a minimum:
    - (i) ~~V~~verification that certification standards and checklists are acceptable and applied to the applicable scope;
    - (ii) ~~V~~verification that the other party OP is appropriately qualified and has sufficient knowledge, experience and training to perform its allocated tasks;
    - (iii) ~~V~~verification that the frequency with which the other party OP carries out surveillance frequency of the suppliers is commensurate with the complexity of the product and with the surveillance frequency established by the POA holder's suppliers control programme;
    - (iv) ~~V~~verification that the surveillance of the suppliers' surveillance is including on-site surveillance activities that are conducted on-site by the other party OP;
    - (v) ~~V~~verification that the surveillance report will be made available to the CAA upon request;
    - (vi) ~~V~~verification that the other party OP continues to be recognised or accredited; and.
    - (vii) ~~V~~verification that the other party OP has access to the applicable proprietary data to the level of detail necessary to survey the suppliers' suppliers functions.

Where the POA holder uses the other party OP accredited by a signatory to the European cooperation for Accreditation (EA) Multilateral Agreement and

working works in accordance with an aviation standard (e.g. EN 9104 series of requirements) that describes the requirements for the other party OP certification, the items (ii), (iv), and (v) shall should be deemed to be complied with.:

- (4) A definition that states to what scope extent the other party OP will conduct suppliers supplier surveillance on behalf of the POA holder. If the other party OP partly replaces surveillance by the POA holder in part, the POA holder should identify the functions that will continue to be surveyed by the POA holder.
  - (5) The pProcedures that ensure that the POA is aware of the loss of an existing certification.
  - (6) The pProcedures that ensure that the POA holder is aware of any non-conformities and has access to detailed information of on these any non-conformities.
  - (7) The pProcedures to evaluate the consequences of non-conformities and take appropriate actions.
- (d) The POA should make arrangements that allow the CAA to make investigation investigations in accordance with point 21.A.8, 21.A.157 to include other party OP activities.

## GM1 21.A.139(d)(2)(ii) Production management system

### ASSESSMENT, AUDIT, AND CONTROL OF VENDOR AND SUBCONTRACTOR

For the purposes of AMC1 21.A.139(d)(2)(ii) and AMC2 21.A.139(d)(2)(ii), vendors and subcontractors are referred to as 'suppliers', whether they hold production organisation approvals (POAs) or not; audit and control are hereinafter referred to as 'surveillance'. Implementing or significantly changing procedures to use the other party OP for supplier assessment and surveillance is a significant change to the quality management element, and it requires approval in accordance with point 21.A.147.

## AMC1 21.A.139(d)(2)(xiv) and 21.A.139(e) Production management system

### INDEPENDENT MONITORING FUNCTION

- (a) The independent monitoring function should ensure that:
- (1) the activities of the production organisation (PO) are monitored for their compliance with the applicable requirements and with any additional requirements as established by the organisation, and that those activities are properly performed under the supervision of the nominated persons that are referred to in point 21.A.145(c)(2) and (4); furthermore, compliance with, and the adequacy of, the production management system should be monitored;
  - (2) all subcontracted production activities are monitored for compliance and adequacy with the applicable arrangements;

- (3) an objective review of the complete set of production-management-related activities is provided through independent monitoring activities, such as audits, inspections, reviews;
  - (4) the independence of the monitoring activities is established by always ensuring that those activities and inspections are performed by staff that are not involved in the function, procedure, or products that they monitor, and that are independent from the operating managers of the function(s) being monitored; however, this should not exclude support by domain experts during monitoring;
  - (5) a monitoring plan is established to show when and how often the activities that are required by Part 21 will be audited;
  - (6) the monitoring cycle should not exceed the applicable oversight planning cycle that is established according to point 21.B.222; the determination of the monitoring plan should consider at least the following aspects:
    - (i) the criticality of the items checked; and
    - (ii) the safety performance of the organisation, including any previous findings and root causes;
  - (7) when non-compliance is found, the root cause(s) and contributing factor(s) are identified, and corrective action is defined and followed up;
  - (8) feedback is provided to the management of the PO; and
  - (9) the above elements perform the planned continuing and systematic evaluations or audits of the factors that affect the conformity (and, where required, the safe operation) of the products, parts, or appliances to the applicable design; this evaluation should include all the elements of the production management system to demonstrate compliance with Part 21.
- (b) The staff performing an independent monitoring function should have access to all the parts of the PO and, as necessary, to any subcontracted organisations.

### **GM No 1 to 21.A.139(b)(2) Quality System – Independent quality assurance function**

The quality assurance function which is part of the organisation is required to be independent from the functions being monitored. This required independence relates to the lines of reporting, authority and access within the organisation and assumes an ability to work without technical reliance on the monitored functions.

## GM1 No 2 to 21.A.139(f)(b)(2) Production management system Quality System — Adequacy of procedures and monitoring function

### ADEQUACY OF THE PRODUCTION MANAGEMENT SYSTEM

Adequacy of the production management system procedures means that the production organisation management system, through the use of the procedures as set forth defined, is capable of meeting the conformity objectives that are identified in point 21.A.139(d)(1)(a).

The quality assurance function to ensure the above should perform planned continuing and systematic evaluations or audits of factors that affect the conformity (and, where required, safe operation) of the products, parts or appliances to the applicable design. This evaluation should include all elements of the quality system in order to demonstrate compliance with Part 21 Subpart G.

## GM1 21.A.143 Exposition — Production Organisation Exposition

### PRODUCTION ORGANISATION EXPOSITION (POE) - GENERAL

- (a) The purpose of the production organisation exposition (POE) is to set forth state in a concise document documented format the organisational relationships, responsibilities, terms of reference, and the CAA, procedures, means and methods of the organisation.

The information to be provided is specified in point 21.A.143(a). Where this information is documented and integrated in manuals, procedures and instruction instructions, the POE should provide a summary of the information and an appropriate cross-reference.

- (b) Point 21.A.143(b) requires that the initial issue of the POE is approved by the CAA. Revisions of the POE are subject to the process that is described in point (c) below. The competent authority requires the POE to be an accurate definition and description of the production organisation. The document does not require approval in itself, but it will be considered as such by virtue of the approval of the organisation.

- (c) When changes to the organisation occur, according to point 21.A.143(c), the POE is required to be kept up to date. This should be done as per a procedure, that is laid down in the POE. If the changes are significant, the organisation should not amend the POE before the CAA approves the change in accordance with point 21.A.147. Significant changes to the organisation (as defined in GM 21.A.147(a)) should be approved by the competent authority prior to update of the POE.

When an organisation is approved against any other implementing rule containing a requirement for an exposition, a supplement covering the differences may suffice to meet the requirements of Part 21 Subpart G except that the supplement should have an index identifying where those parts missing from the supplement are covered. Those items then formally become part of the POE. In any combined documents the POE should be easily identifiable.

**CONTENT OF THE PRODUCTION ORGANISATION EXPOSITION**

- (a) All staff should be familiar with those production organisation exposition (POE) parts that are relevant to their tasks.
- (b) A paragraph in the POE should provide a description of the organisation, as well as the safety policy and the corresponding objectives, as required by point 21.A.139(c)(1).
- (c) The POE should include a statement, signed by the accountable manager (and countersigned by the Chief Executive, if different), which confirms that the POE and any associated manuals are complied with at all times.

This statement should read as follows, or embrace the intent of the following text:

*'This exposition defines the organisation and the procedures upon which the CAA's production organisation approval (POA) is based.*

*These procedures are approved by the undersigned, and must be complied with, as applicable, to ensure that all production activities are performed on time and to an approved standard.*

*It is understood that the approval of the production organisation (PO) is based on the organisation's continuous compliance with the applicable requirements of Part 21, and with the organisation's procedures that are described in this exposition. The CAA is entitled to limit, suspend, or revoke the approval if the organisation fails to fulfil the obligations that are imposed by Part 21, or any conditions according to which the approval was issued.*

Signed .....

Dated .....

Accountable manager and ..... (quote the position of the signatory) Chief Executive.....

For and on behalf of ..... (quote the organisation's name)'

The statement should be reissued at the earliest opportunity when the accountable manager or Chief Executive changes.

- (d) The POE should include the description of the internal safety reporting scheme that is required by point 21.A.3A and should include voluntary reporting as outlined in UK Regulation (EU) No 376/2014 and GM1 21.A.3A(a) and (c).
- (e) The POE should include the safety management procedures (including identification of safety hazards, evaluation, and associated risks management), safety assurance procedures, and safety promotion processes.
- (f) If the organisation holds one or more additional organisation certificates within the scope of UK Regulation (EU) 2018/1139 and the regulation made under it that are adopted on the basis thereof, so that the organisation is required to establish another exposition, the organisation may combine the documents by producing a separate manual or supplement that covers the differences between the POE and the other exposition. In that case, the manual or supplement should identify where in the other exposition the remaining information on the production

organisation (PO) is covered. That remaining information then formally becomes part of the exposition.

- (g) The organisation may document its safety policy, safety objectives, and all the safety management system key processes (as required by point 21.A.139(c)) in a separate manual (e.g. a safety management manual or management system manual) or in its POE. Organisations that hold multiple organisation approvals, which are issued under UK Regulation (EU) 2018/1139 and the regulation made under it that are adopted on the basis thereof, may prefer to have a separate manual to avoid duplication.

## AMC1 21.A.145(a) Approval Requirements

### RESOURCES - EQUIPMENT AND TOOLS

The organisation's equipment and tools should enable all the specified tasks to be accomplished in a repeatable manner without any detrimental effects. The calibration control of the equipment and tools that affect the dimensions and values of products should demonstrate compliance with, and be traceable to, national or international standards.

## AMC2 21.A.145(a) Approval Requirements

### RESOURCES - STAFF NUMBER AND COMPETENCY

- (a) Sufficient personnel means that, for each function, according to the nature of the work and the production rate, the organisation has a sufficient number of qualified staff to accomplish all the specified manufacturing tasks and to attest the conformity of such tasks. The number of staff should be such that the relevant airworthiness considerations may be applied in all areas without any undue pressure.
- (b) The organisation should have a system in place to plan the availability of staff to ensure that the organisation has sufficient appropriately qualified staff to plan, perform, supervise, inspect, and monitor the organisation's activities in accordance with the organisation's terms of approval.
- (c) The organisation should establish and control the competency of the staff that is involved in activities of the organisation, as detailed in the organisation's terms of approval, in accordance with documented procedures. In addition to the necessary expertise that is related to the job function, the competency of the staff should include an understanding of safety management and human factors (HF) principles, which is appropriate to the staff member's function and responsibilities in the organisation.
- (d) An evaluation of the competence of personnel is performed as part of the quality management element of the production management system. This should include, where appropriate, verification that specific qualification standards have been implemented, for example NDT, welding, etc. Training should be organised to establish and maintain the competence levels determined by the organisation to be necessary.
- (e) To assist in the assessment of competency and to perform the analysis of the training needs, job (job family) descriptions are recommended, which should contain sufficient criteria to enable the required competency assessment throughout the duration of the employment/contract.



- (f) The organisation should develop a procedure that describes the process for assessing the competency of the staff. The procedure should specify:
- (1) the staff that are responsible for that process;
  - (2) the means and methods for the initial assessment;
  - (3) the means and methods for the continuous control of the competency of the personnel, including feedback on their performance;
  - (4) the action to be taken if the assessment is not satisfactory; and
  - (5) how to record assessment results.
- (g) Adequate initial and recurrent training should be provided in relation to the job function to ensure that staff remain competent. That training should be adapted based on experience that is gained within the organisation (for safety training, refer also to AMC1 21.A.139(c)(5)(i)).
- (h) The organisation should record the training that is provided as described in point (g).

## GM1 21.A.145(a) Approval Requirements

### RESOURCES - FACILITIES

A facility is a working area where the working conditions and the environment are controlled as appropriate in respect of: cleanliness, temperature, humidity, ventilation, lighting, space/access, noise, and air pollution.

~~Equipment and tools should be such as to enable all specified tasks to be accomplished in a repeatable manner without detrimental effect. Calibration control of equipment and tools which affect critical dimensions and values should demonstrate compliance with, and be traceable to, national or international standards.~~

~~Sufficient personnel means that the organisation has for each function according to the nature of the work and the production rate, a sufficient quantity of qualified personnel to accomplish all specified manufacturing tasks and to attest the conformity. Their number should be such that airworthiness consideration may be applied in all areas without undue pressure.~~

~~An evaluation of the competence of personnel is performed as part of the quality system. This should include, where appropriate, verification that specific qualification standards have been implemented, for example NDT, welding, etc. Training should be organised to establish and maintain the personal competence levels determined by the organisation to be necessary.~~

## GM1 21.A.145(b)(2) Approval Requirements —~~Airworthiness and environmental protection, production/quality data procedures~~

### RESOURCES - PRODUCTION DATA

- 1 When a production organisation approval (POA) holder ~~or~~ an applicant for a POA is developing its own manufacturing data, such as computer-based data, from the design data package that is delivered by a design organisation, procedures are required to demonstrate the ~~right~~ correct transcription of the original design data.

- 2 Procedures are required to define the manner in which airworthiness and environmental protection, noise, fuel venting, and exhaust emissions data is used to issue and update the production/quality data, which determines the conformity of products, parts, and appliances. The procedure should also define the traceability of such data to each individual product, part, or appliance for the purpose of certifying their condition for safe operation and of issuing a Statement of Conformity or CAA Form 1.

## AMC1 21.A.145(c)(1) Approval Requirements

### RESOURCES - ACCOUNTABLE MANAGER

- (a) The accountable manager (AM) should:
- (1) have sufficient knowledge and authority to be able to respond to the CAA regarding major issues concerning the production organisation approval (POA), and to carry out any necessary improvements;
  - (2) promote the safety policies and objectives that are specified in AMC1 21.A.139(c)(1); and
  - (3) demonstrate a Part 21 understanding that is sufficient to discharge the relevant responsibilities.
- (b) The production organisation exposition (POE) that is submitted in accordance with point 21.A.143 should show that the AM has the direct or functional responsibility for all the departments of the organisation which are involved in the POA. If any of those departments are functionally linked, the AM still has the ultimate responsibility for compliance of the PO with Part 21.

## GM1 21.A.145(c)(1) Approval Requirements – Accountable manager

### RESOURCES - ACCOUNTABLE MANAGER

'Accountable manager' refers to means the manager that who is responsible, and has corporate authority for ensuring that all production work is carried out to the required standard. This function may be performed carried out by the Chief Executive or by another person in the organisation, nominated by him or her the Chief Executive to fulfil the function, provided that the his or her position and authority of that person in the organisation permits allows that person to discharge the associated attached responsibilities.

The manager is responsible for ensuring that all necessary resources are available and properly used in order to produce under the production approval in accordance with Part 21, Section A, Subpart G.

The manager needs to have sufficient knowledge and authority to enable him or her to respond to the competent authority regarding major issues of the production approval and implement necessary improvements.

The manager needs to be able to demonstrate that he or she is fully aware of and supports the quality policy and maintains adequate li with the quality manager.

**RESOURCES – NOMINATED MANAGERS**

- (a) The person or group of persons nominated in accordance with point 21.A.145(c)(2) and (4) should represent the management structure of the organisation and be responsible for all the functions as specified in Part 21, Subpart G ~~Section A Subpart G~~. It therefore follows that, ~~depending~~ Depending on the size of the ~~Part 21 Section A Subpart G~~ approved production organisation (PO), the functions may be subdivided under individual managers (and in fact may be further subdivided) or combined in a variety of ways.
- (b) The organisation should nominate a person or a group of persons that are responsible for:
- (1) the independent monitoring function as defined in point 21.A.139(c); and
  - (2) ensuring the establishment, implementation and maintenance of effective safety risk management processes as defined in point 21.A.139(c)(3).
- (c) If more than one person is designated for the management of the independent monitoring function, the AM should identify a unique focal point, typically known as the ‘quality manager’.
- (d) If more than one person is designated to establish, implement and maintain effective safety risk management processes as defined in point 21.A.139(c)(3), the AM should identify a ‘safety manager’ as the unique focal point.
- (e) ~~The competent authority requires the~~ Each nominated ~~managers~~ manager ~~to~~ should be identified and their credentials submitted on an ~~CAA Form 4~~ (see EASA Form 4 for Production Organisations on the CAA website under: <http://easa.europa.eu/certification/applicationforms.php>) to the CAA in a form and manner established by the CAA, as a significant change ~~in orders~~ so that they may be seen to be appropriate in terms of their relevant knowledge and satisfactory experience related to the nature of the production activities as performed by the ~~Part 21 Section A Subpart G~~ approved PO organisation.
- (f) The responsibilities and the ~~duties~~ tasks of each individual manager ~~are required to~~ should be clearly defined, ~~in order to prevent uncertainties about the relations, within the organisation. In the case of organisation structures where staff members are responsible to more than one person, as for instance in matrix and project organisations, responsibilities of the managers should be defined~~ in such a way that all the responsibilities are covered.
- (g) Where a ~~Part 21 Section A Subpart G~~ approved PO organisation chooses to appoint managers for all or for any combination of the functions that are identified in Part 21 ~~functions~~ because of the size of the undertaking, it is necessary that those managers should ultimately report ultimately to the accountable manager. When ~~in cases where~~ a manager does not directly report to the accountable manager, ~~he or she~~ that manager should have a formally established direct access to the accountable manager formally established.
- (h) The independent monitoring function should be independent from other functions. As such, the quality manager should not be at the same time one of the other persons that are referred to in point 21.A.145(c)(2) and (4), except for the safety manager. If the same person is designated to manage both the independent monitoring function and safety-management-

related processes and tasks, the accountable manager, in order to discharge their safety accountability, should ensure that sufficient resources are allocated to both functions, taking into account the size of the organisation, and the nature and complexity of its activities.

(i) Quality manager

The role of the quality manager should be to ensure that:

- (1) the activities of the organisation are monitored for compliance with the applicable requirements and any additional requirements as established by the organisation, and that those activities are performed properly under the supervision of the nominated persons that are referred to in point 21.A.145(c)(2) and (4);
- (2) an audit plan is properly implemented, maintained, and continually reviewed and improved; and
- (3) corrections and corrective action are requested, as necessary.

(j) Safety manager

Depending on the size of the organisation and the nature and complexity of its activities, the safety manager may be assisted by additional safety personnel in performing all the safety management tasks defined in AMC1 21.A.139(c)(2) production management system.

If the safety manager is the nominated post holder for more than one organisation approval certificate, within an integrated management system, they are to ensure the relevant risks, specific to each approval, are identified and mitigated as appropriate.

The role of the safety manager should be:

- (1) to facilitate hazard identification, as well as risk assessment and management;
  - (2) to monitor the implementation of action taken to mitigate risks, as listed in the safety action plan, unless action follow-up is addressed by the independent monitoring function;
  - (3) to provide periodic reports on safety performance to the safety review board (the functions of the safety review board are defined in AMC1 21.A.139(c)(2));
  - (4) to ensure the maintenance of safety management documentation;
  - (5) to ensure that there is safety training available, and that it meets acceptable standards;
  - (6) to provide advice on safety matters; and
  - (7) to ensure the initiation and follow-up of internal investigations of occurrences.
- (k) Subject to a risk assessment and the CAA agreement, with due regard to the size of the organisation, and the nature and complexity of its activities, the functions of the quality manager and the safety manager may be performed by the accountable manager, provided that the accountable manager has demonstrated the related level of competency.

~~One such manager, normally known as the quality manager is responsible for monitoring the organisation's compliance with Part 21 Section A Subpart G and requesting remedial action as~~

necessary by the other managers or the accountable manager as appropriate. He or she should have a direct access to the accountable manager.

## AMC2 21.A.145(c)(2) and (4) Approval Requirements

### RESOURCES – MANAGEMENT STAFF COMPETENCIES

- (a) The organisation should provide initial and recurrent training to the persons or group of persons that are nominated in accordance with point 21.A.145(c)(2) and (4), which is adequate to their job function and ensures that their continued competency is maintained throughout the duration of their employment/contract.
- (b) All prospective members of the production management staff and staff that are nominated in accordance with point 21.A.145(c)(2) and (4) should:
  - (1) be assessed for their competency, qualifications, and capabilities that are related to their intended duties;
  - (2) be able to demonstrate their knowledge of, and compliance with, the production management organisation procedures that are applicable to their job function; and
  - (3) be able to demonstrate an understanding of the safety management principles, as well as human factors (HF) issues and human performance (HP) issues that are related to their tasks.
- (c) The quality manager should be able to demonstrate relevant knowledge, background, and appropriate experience that are related to the activities of the organisation, including knowledge of, and experience in, independent system monitoring.
- (d) The competency of the person that assumes (or the persons that assume) the function of the safety manager should include, but not be limited to, the following:
  - (1) knowledge of the International Civil Aviation Organization (ICAO) standards and CAA requirements for safety management;
  - (2) an understanding of management systems, including compliance monitoring systems;
  - (3) an understanding of risk management;
  - (4) an understanding of safety investigation techniques;
  - (5) an understanding of HF, including HP and limitations;
  - (6) an understanding of a positive safety culture and of its promotion; and
  - (7) operational experience related to the activities of the organisation.

## AMC1 21.A.145(d)(1) Approval Requirements – Certifying staff

### RESOURCES – CERTIFYING STAFF

1. (a) Certifying Staff should be nominated by the production organisation to ensure that each of their products, parts, and/or appliances qualify/qualifies for a statements of Conformity or a

- Release Certificates. The position and number of certifying staff positions and numbers are to be appropriate to the complexity of the product and the production rate.
- 2.(b) The qualifications of certifying staff should be based on their knowledge, background and experience and on a specific training (or testing) that is established by the organisation to ensure that it is appropriate to the product, part, or appliance to be released.
  - (c) Training should be given to certifying staff to develop a satisfactory level of knowledge of product/part specifications, the organisation's procedures, production management systems (including compliance monitoring), aviation legislation, and the associated regulations AMC and GM that are relevant to their particular role. Training should include on-the-job training, as relevant.
  - (d) For that purpose, in addition to the general training policy, the organisation should define its own standards for training, including pre-qualification standards, for personnel to be identified as certifying staff.
5. Training policy is part of the Quality System and its appropriateness forms part of investigation by the competent authority within the organisation approval process and subsequent surveillance of persons proposed by managers.
  6. The training must be updated in response to experience gained and changes in technology.
  - 7.(e) A feedback system to ascertain that the required standards are being maintained must be put in place to ensure the continuing compliance of personnel with authorisation requirements.
  - 8.(f) For the release of products, parts, or appliances, the responsibilities to issue statements of conformity or release certificates (CAA Form 1) or permit to fly, including the approval of flight conditions, are allocated to the certifying staff that is identified in point 21.A.145(d)(2).
  9. The competent authority holds the right to reject those personnel, appointed by the organisation, if found to have inappropriate experience or not to otherwise comply with its requirements.

## GM1 21.A.145(d)(1) Approval Requirements

Where the CAA finds personnel appointed by the organisation to have inappropriate experience or not to be compliant with the requirements, then a finding against the training and authorisation process will be raised. As part of the organisations response, a determination of the appropriate corrective action should be submitted.

## AMC 21.A.145(d)(2) Approval requirements – Record of certifying staff

1. The following is the minimum information to be recorded in respect of each certifying person:
  - (a) Name
  - (b) Date of Birth
  - (c) Basic Training and standard attained
  - (d) Specific Training and standard attained
  - (e) If appropriate – Continuation Training

- (f) — Experience
  - (g) — Scope of the authorisation
  - (h) — Date of first issue of the authorisation
  - (i) — If appropriate — expiry date of the authorisation
  - (j) — Identification Number of the authorisation
2. — The record may be kept in any format and must be controlled by an internal procedure of the organisation. This procedure forms part of the quality system.
  3. — Persons authorised to access the system must be maintained at a minimum to ensure that records cannot be altered in an unauthorised manner and that confidential records cannot become accessible to unauthorised persons.
  4. — The certifying person must be given reasonable access on request to his or her own records.
  5. — Under the provision of 21.A.157 the competent authority has a right of access to the data held in such a system.
  6. — The organisation must keep the record for at least two years after the certifying person has ceased employment with the organisation or withdrawal of the authorisation, whichever is the sooner.

## AMC1 21.A.145(d)(2)(3) Approval requirements — Evidence of authorisation

### RESOURCES - EVIDENCE OF AUTHORISATION

- 1.(a) The certifying staff should be provided with evidence of their authorisation. This should be done through an internal authorisation document. That document ~~must~~ should be in a style that makes its scope clear to the certifying staff and any entitled authorised person that ~~who~~ may require to examine the authorisation. It should include the privileges that are granted to the certifying staff and the category of products upon which they may exercise those privileges. Where codes are used to define the scope, an interpretation document should be readily available.
- 2.(b) Certifying staff are not required to carry the authorisation document at all times, but they should be able to make it available within a reasonable time following a request from an entitled authorised person. ~~Authorised persons,~~ which includes the CAA.

## AMC1 21.A.147 Changes to the approved production organisation

### CHANGES IN THE PRODUCTION MANAGEMENT SYSTEM - APPLICATION FOR APPROVAL OF SIGNIFICANT CHANGES OR VARIATIONS IN THE SCOPE OR TERMS OF A PRODUCTION ORGANISATION APPROVAL

- (a) An application for approval of significant changes or variations in the scope or terms of a production organisation approval (POA) should be submitted in writing to the CAA. The production organisation (PO) should demonstrate to the CAA, on the basis of the submission of any proposed changes to the production organisation exposition (POE), and before the

implementation of the changes, that it will continue to comply with Part 21 after the implementation.

- (b) The approved PO should submit to the CAA an application for any significant change(s), or for a variation in the scope or terms of its POA, using a CAA Form 51 (AMC1 21.B.240).

## GM1 21.A.147(a) Changes to the approved production organisation Significant changes

### CHANGES IN THE PRODUCTION MANAGEMENT SYSTEM - SIGNIFICANT CHANGES

1-Changes to be approved by the CAA include:

- Significant changes to the production capacity or methods;
- Changes in the organisation's structure, especially those parts of the organisation in charge of the safety management element or the quality management element of the organisation's production management system; quality and safety;
- a change of the accountable manager or of any other person that is nominated under point 21.A.145(c)(2) and (4);
- Changes in the production or quality management systems that may have an important impact on the conformity, or airworthiness of any each product, part, or appliance, including in the reporting lines between the personnel that are nominated in accordance with point 21.A.145(c)(2) and (4) and the accountable manager; and.
- Changes in the placement or control of significant sub-contracted subcontracted work or supplied parts.

2-To ensure that changes do not result in non-compliance with Part 21, Section A Subpart G it is in the interest of both the CAA and the approval holder to establish a relationship and exchange information that will permit the necessary evaluation work to be conducted before the implementation of a change. This relationship should also permit agreement on the need for variation of the terms of approval (refer to point 21.A.143(a)(9)).

3- Where a change of name or ownership results in the issue of a new approval, the investigation will normally take account of the CAA's knowledge and information from the preceding approval.

4- Changes of location are addressed in point 21.A.148, and changes of ownership in point 21.A.149, and the change of scope of the approval in point 21.A.153.

## GM1 21.A.149 and 21.A.249 Transferability

### GENERAL

Transfer of approval would normally only be agreed in cases where the ownership changes but the organisation itself remains effectively unchanged. For example:

An acceptable transfer situation could be a change of company name (supported by the appropriate certificate from the National Companies Registration Office or equivalent) but with no changes to site address, facilities, type of work, staff, accountable manager or person nominated under 21.A.145.



Alternatively, in the event of receivership (bankruptcy, insolvency or other equivalent legal process) there may be good technical justification for continuation of the approval provided that the company continues to function in a satisfactory manner in accordance with their POE. It is likely that at a later stage the approval might be voluntarily surrendered or the organisation transferred to new owners in which case the former paragraphs apply. If it does not continue to operate satisfactorily then the CAA could suspend or revoke the approval under 21.B.245.

In order for the CAA to agree to a transfer of approval, it will normally prescribe it as a condition in accordance with 21.A.147(b) that the obligations and responsibilities of the former organisation should be transferred to the new organisation, otherwise transfer is not possible and application for a new approval will be required.

A transfer of approval to another production or design organisation is, by default, excluded by points 21.A.149 or 21.A.249 respectively. These points only allow it exceptionally if it is a direct consequence of a transfer of ownership in an approved production or design organisation, which is then considered a significant change to the existing approval (to which point 21.A.147 or 21.A.247 applies).

As a consequence, and in order to apply this exception, the production or design organisation has to demonstrate to the CAA the existence of a change in ownership which resulted in the fact that a different legal entity is now conducting the approved production or design functions while remaining effectively unchanged.

An example of such an exception is a change of ownership that leads to a re-registration of the organisation (supported by the appropriate certificate from Companies House or equivalent).

In order to demonstrate that the organisation remains effectively unchanged, the organisation needs to demonstrate that there are no changes affecting the initial demonstration of compliance of the organisation with Subpart G or Subpart J. If, for instance, the change of ownership would, in addition, lead to a change of address, facilities, type of work, staff, accountable manager or persons nominated under points 21.A.145 or 21.A.245, then it is not an acceptable transfer situation; the exception does not apply in this case. A new investigation by the CAA would be necessary. The new organisation would have to apply for its own approval. In such a case where the organisation applies for a new approval, the demonstration of compliance in accordance with points 21.A.135 or 21.A.235 may be limited to the demonstration that the changes in the organisation comply with the Subpart G or Subpart J requirements, while referring for the rest to the compliance demonstration of the previous approval holder.

A pure name change, where the ownership does not change, does not require a transfer of the approval. In this case, the natural or legal person that holds the approval remains the same. However, as a consequence of the name change, the approval document needs to be amended to reflect the new company name. This is a significant change, to which point 21.A.147 or 21.A.247 applies.

Another example of a transfer of ownership, which may be exceptionally accepted under points 21.A.149 or 21.A.249, may be the event of insolvency or another equivalent legal process. In this case, there is no change to the production or design organisation, except that the custodial responsibility for its property, including its tangible and intangible assets and rights, is transferred to a receiver or insolvency administrator. The insolvency administrator may aim to continue the business of the same organisation.

## AMC 21.A.153 Changes to the terms of approval - Application for a change to the terms of approval

CAA Form 51 (see AMC1 No 1-21.B.240) must be obtained from the CAA and completed in accordance with the procedures of the production organisation exposition (POE).

The information entered on the form is the minimum required by the CAA to assess the need for change of the production organisation approval.

The completed form and an outline of the changed POE, and details of the proposed change to POA terms of approval must be forwarded to the CAA.

## AMC-ELA No 1 to 21.A.153 Changes to the terms of approval — Application for a change to the terms of approval

CAA Form 51 (see AMC1 No 1-21.B.240) should be obtained from the CAA and completed in accordance with the instructions provided by the CAA. The information entered on the form is needed by the CAA in order to assess whether the production organisation approval (POA) is to be amended. The completed form should be forwarded to the CAA. The applicant and the CAA can agree on whether the assessment for a change in approval can be completed via a desktop audit or through a surveillance audit.

## GM1 21.A.139, 21.A.157, 21.A.239, 21.A.257, 21.B.120, 21.B.140, 21.B.220, 21.B.235 and 21.B.240 The use of information and communication technologies (ICT) for performing remote audits

[...]

## GM 21.A.157 Investigations — Arrangements

The arrangements made by the applicant for, or holder of an approval under Part 21 Section A Subpart G should allow the competent authority to make investigations that include the complete production organisation including partners, sub-contractors and suppliers, whether they are in the State of the applicant or not.

The investigation may include; audits, enquiries, questions, discussions and explanations, monitoring, witnessing, inspections, checks, flight and ground tests and inspection of completed products, parts or appliances produced under the POA.

In order to maintain its confidence in the standards achieved by a POA holder or applicant the competent authority may make an investigation of a sample product part or appliance and its associated records, reports and certifications.

The arrangements should enable the organisation to give positive assistance to the competent authority and co-operate in performing the investigation during both initial assessment and for the subsequent surveillance to maintain the POA.

Co-operation in performing investigation means that the competent authority has been given full and free access to the facilities and to any information relevant to demonstrate compliance to Part 21 Section A Subpart G requirements, and assistance (personnel support, records, reports, computer data, etc., as necessary).

Assistance to the competent authority includes all appropriate means associated with the facilities of the production organisation to allow the competent authority to perform these investigations, such as the availability of a meeting room, office and personnel support, documentation and data, and communication facilities, all properly and promptly available as necessary.

The competent authority seeks to have an open relationship with the organisation and suitable liaison personnel should be nominated to facilitate this, including suitable representative(s) to accompany competent authority staff during visits not only at the organisations own facilities but also at subcontractors, partners or suppliers.

### **GM-ELA No 1 to 21.A.157 Investigations – Arrangements**

The production organisation is encouraged to coordinate with the competent authority on any investigations that focus on issues that could result in unsafe conditions.

The production organisation grants to the competent authority full and free access to the facilities and to any information that is relevant to demonstrate the conformity of the product to the approved type design, and it provides assistance (personnel support, records, reports, computer data, etc., as necessary) to the competent authority during the investigation.

In this context, assistance to the competent authority includes providing all the appropriate means that are necessary to allow the competent authority to perform these investigations, such as making available a meeting room, office and personnel support, documentation and data, and communication facilities, which should all be properly and promptly made available as necessary.

### **GM No 2 to 21.A.158(a) Examples of level one findings**

Examples of level one findings are non-compliances with any of the following points, that could affect the safety of the aircraft:

21.A.139, 21.A.145, 21.A.147, 21.A.148, 21.A.151, 21.A.163, 21.A.165(b), (c), (d), (e), (f) and (g).

It should be anticipated that a non-compliance with these points is only considered a level one finding when objective evidence has been found that this finding is an uncontrolled non-compliance that could affect the safety of the aircraft.

In addition, the failure to arrange for investigations under 21.A.157, in particular to obtain access to facilities, after denial of one written request should be classified as a level one finding.

### **GM1 21.A.159(a)(3) Duration and continued validity**

#### **SATISFACTORY CONTROL OF THE MANUFACTURE**

The following are examples of lack of satisfactory control:

1. an uncontrolled non-compliance with type design data affecting the airworthiness of product part or appliance
2. an incident/accident identified as caused by POA holder
3. non-compliance with the POE and its associated procedures which could affect conformity of manufactured items to design data
4. insufficient competency of certifying staff
5. insufficient resources in respect of facilities, tools and equipment
6. insufficient means to ensure good production work standards
7. a lack of effective and timely response to prevent a recurrence of any of point 1 to 6.

### **GM 21.A.165(d) and (h) Obligations of the holder – Recording and archiving system**

Records within a production environment satisfy two purposes. Firstly, they are required, during the production process to ensure that products, parts, or appliances are in conformity with the controlling data throughout the manufacturing cycle. Secondly, certain records of milestone events are needed to subsequently provide objective evidence that all prescribed stages of the production process have been satisfactorily completed and that compliance with the applicable design data has been achieved.

Therefore, the approved production organisation should implement a system for the compilation and retention of records during all stages of manufacture, covering short term and long term records appropriate to the nature of the product and its production processes.

The management of such information should be subject to appropriate procedures in the quality System required by 21.A.139.

All forms of recording media acceptable (paper, film, magnetic, ...) provided they can meet the required duration for archiving under the conditions provided:

The related organisation procedures should:

- Identify records to be kept.
- Describe the organisation of and responsibility for the archiving system (location, compilation, format) and conditions for access to the information (e.g., by product, subject).
- Control access and provide effective protection from deterioration or accidental damage.
- Ensure continued readability of the records.
- Demonstrate to the CAA proper functioning of the records system.
- Clearly identify the persons involved in conformity determination.
- Define an archiving period for each type of data taking into account importance in relation to conformity determination subject to the following:

- a) ~~Data which supports conformity of a product, part, or appliance should be kept for not less than three years from the issue date of the related Statement of Conformity or Authorised Release Certificate.~~
  - b) ~~Data considered essential for continuing airworthiness should be kept throughout the operational life of the product, part or appliance.~~
- ~~— Ensure that the recording and record-keeping system used by the partners, supplier and subcontractors meet the objective of conformity of the product, part or appliance with the same level of confidence as for their own manufacture. They should define in each case who is to retain the record data (organisation or partner, supplier or sub-contractor). They should also define method for surveillance of the recording/record-keeping system of the partners, suppliers or sub-contractors.~~

## ANNEX I (PART 21)

### SUBPART J — DESIGN ORGANISATION APPROVAL

#### AMC1 21.A.239(a) Design management system

##### SAFETY ACCOUNTABILITY

- (a) The management system should encompass safety by including a safety manager and a safety review board in the organisational structure. The functions of the safety manager are defined in AMC1 21.A.245(b).
- (b) Safety review board
  - (1) The safety review board (the 'board'), sometimes referred to as 'high-level safety committee', considers matters of strategic safety in support of the safety accountability of the head of the design organisation (HDO).
  - (2) The board should be normally chaired by the HDO and be generally composed of the person or group of persons nominated under point 21.A.245(b). Its composition can be adapted to its needs, considering point 21.A.245(b).
  - (3) The board should monitor:
    - (i) the organisation's safety performance against its safety policy and objectives;
    - (ii) whether any safety action is taken in a timely manner; and
    - (iii) the effectiveness of the organisation's management system processes.
  - (4) The board may also be tasked with:
    - (i) reviewing the results of compliance monitoring; and
    - (ii) monitoring the implementation of related corrective and preventive action.

- (c) The board should ensure that appropriate resources are allocated to achieve the established safety objectives.
- (d) Notwithstanding point (a), if justified by the size of the organisation and the nature and complexity of its activities, and subject to a risk assessment and/or mitigation measures, as well as the CAA's agreement, the organisation may not need to establish a board. In that case, the tasks that are normally allocated to the board should be allocated to the safety manager.

## AMC-ELA No 1 to 21.A.239(a) Design assurance system – Definition

[...]

## AMC1 21.A.239(c) Design management system

### SAFETY MANAGEMENT ELEMENT

Demonstration of compliance with the international industry standard SM-0001 'Implementing a Safety Management System in Design, Manufacturing and Maintenance Organisations', Issue B, 31 March 2022, is a means to support demonstration of compliance with the safety management element of the design management system.

## GM1 21.A.239(c) Design management system

### SAFETY MANAGEMENT ELEMENT

Safety management seeks to proactively identify hazards and mitigate the related safety risks before they result in aviation accidents and incidents. Safety management enables an organisation to manage its activities in a more systematic and focused manner. When an organisation has a clear understanding of its role in, and contribution to, aviation safety, this enables the organisation to prioritise safety risks and more effectively manage its resources for optimal results.

Safety should not be considered the responsibility of a single person or a limited group of people in the organisation. A safety culture should be developed throughout the organisation, which involves all the personnel as active contributors to the safety of the final product, part, or appliance, (see AMC1 21.A.239(c)(1)).

The principles of the requirements in points 21.A.3A, 21.A.5, 21.A.239, 21.A.245, and 21.A.247, and the related AMC constitute the design management system framework for aviation safety management. This framework addresses the core elements of the International Civil Aviation Organization (ICAO) safety management system (SMS) framework that is defined in ICAO Annex 19, Appendix 2, and facilitates the introduction of the additional safety management element.

This approach is intended to encourage organisations to embed safety management and risk-based decision-making into all their activities, instead of superimposing another system onto their existing management system and governance structure. In addition, if the organisation holds multiple organisation certificates that are issued under UK Regulation (EU) 2018/1139, it may choose to

implement a single management system to cover all of its activities. An integrated management system may be used not only to capture multiple management system requirements resulting from UK Regulation (EU) 2018/1139, but also to cover for other regulatory provisions requiring compliance

with ICAO Annex 19 or for other business management systems, such as security, occupational health,

and environmental management systems. Integration will remove duplication and exploit synergies by managing safety risks across multiple activities. Organisations may determine the best means to structure their management systems to suit their business and organisational needs.

It is important to recognise that safety management will be a continuous activity, as hazards, risks, as well as the effectiveness of safety risk mitigations, will change over time.

The safety management capability of an organisation should be commensurate with the safety risks to be managed, which can be at the product, part, and appliance level or at the organisational level.

The risks that are inherent in a complex structure require a robust safety risk management process (e.g. complex interfaces with different partners that participate in the design of a product may pose hazards that are complex to mitigate).

As a consequence, scalability and suitability of the safety management element should be a function of the inherent safety risk capability of the organisation. For instance, for organisations with a lower risk level:

- (a) the risk assessment model that is used may be very simple in cases in which the identified hazards are easy to mitigate;
- (b) expert judgement might be sufficient to measure the efficiency of safety barriers;
- (c) the collection of data, safety information, and occurrences might be very limited;
- (d) there might be no need for software or tools to manage the SMS; and (e) the communication policy might be limited.

## AMC1 21.A.239(c)(1) Design management system

### SAFETY POLICY & OBJECTIVES

- (a) The safety policy should:
  - (1) reflect organisational commitments regarding safety, and its proactive and systematic management, including the promotion of a positive safety culture;
  - (2) include internal reporting principles by fostering the reporting of organisational threats as well as events, as defined in AMC3 21.A.3A(a);
  - (3) be endorsed by the head of the design organisation (HDO);
  - (4) be communicated, with visible endorsement, throughout the organisation; and
  - (5) be periodically reviewed to ensure that it remains relevant and appropriate to the organisation.
- (b) The safety policy should include the commitment:
  - (1) to comply with all the applicable legislation, meet all the applicable requirements, and adopt practices to improve safety standards;
  - (2) to provide the necessary resources for the implementation of the safety policy;
  - (3) to apply human factors (HF) principles;
  - (4) to enforce safety as a primary responsibility of all managers; and
  - (5) to apply 'just culture' principles and, in particular, not to make available or use the information on occurrences:

- (i) to attribute blame or liability to personnel for actions, omissions, or decisions that are commensurate with their experience and training; or
  - (ii) for any purpose other than the improvement of aviation safety.
- (c) Senior management should continuously promote the safety policy to all personnel, demonstrate their commitment to it, and provide the necessary human and financial resources for its implementation.
- (d) Taking due account of its safety policy, the organisation should define safety objectives. The safety objectives should:
  - (1) form the basis for safety performance monitoring and measurement;
  - (2) reflect the organisation's commitment to maintaining and continuously improving the overall effectiveness of safety management;
  - (3) be communicated throughout the organisation; and
  - (4) be periodically reviewed to ensure that they remain relevant and appropriate to the organisation.

## GM1 21.A.239(c)(1) Design management system

### SAFETY POLICY

The safety policy is the means for the organisation to state its intention to maintain and, where practicable, to improve the safety levels of all its activities, and to minimise its contribution to the risk of an aircraft accident or serious incident occurring, as far as reasonably practicable. The safety policy reflects the management's commitment to safety and the organisation's philosophy of safety management. It is the foundation on which the organisation's management system is built and serves as a reminder of 'how we do business here'. The creation of a positive safety culture begins with issuing a clear, unequivocal policy statement.

The commitment to apply 'just culture' principles forms the basis for the organisation's internal rules that describe how 'just culture' principles are guaranteed and implemented.

UK Regulation (EU) No 376/2014 defines the 'just culture' principles to be applied (refer, in particular, to Article 16(11) of that Regulation).



**SAFETY ACTION GROUP**

- (a) Depending on the size of the organisation and the nature and complexity of its activities, a safety action group may be established as a standing group or as an ad hoc group to assist, or act on behalf of, the safety manager or the safety review board.
- (b) More than one safety action group may be established, depending on the scope of the task and the specific expertise that is required.
- (c) The safety action group usually reports to, and takes strategic direction from, the safety review board, and may be composed of managers, supervisors, and personnel from operational areas.
- (d) The safety action group may be tasked with or assist in the following:
  - (1) monitoring safety performance;
  - (2) defining action to control risks to an acceptable level;
  - (3) assessing the impact of organisational changes on safety;
  - (4) ensuring that safety action is implemented within the agreed timescales; and
  - (5) reviewing the effectiveness of previous safety action and safety promotion.

**SAFETY MANAGEMENT KEY PROCESSES**

- (a) Hazard identification processes
  - (1) Hazard identification should be based on a combination of reactive and proactive methods.
  - (2) The organisation should focus in particular on hazards that may result from non-compliance or errors in the design of a product, part, or appliance.
- (b) Safety risk management processes
  - (1) The organisation should develop and maintain a safety risk management process that ensures a reactive, proactive, and predictive approach composed of the following elements:
    - (i) analysis (e.g. in terms of the probability or likelihood as well as severity of the consequences of hazards and occurrences);
    - (ii) assessment (in terms of tolerability); and
    - (iii) control (in terms of mitigation) of risks to an acceptable level.
  - (2) The organisation should specify, within the risk management process, who has the authority to make decisions, considering point (b)(1) of this AMC.
  - (3) For each individual organisation approval certificate held, the risks for each approval should be clearly identified and understood by the Safety Manager.

(c) Regardless of the approval status of the subcontracted organisations, the design organisation (DO) is responsible for ensuring that hazard identification and risk management activities are performed on subcontracted activities, as required by point 21.A.239(d)(3), as well as for the monitoring of their compliance and adequacy, as required by point 21.A.239(e).

(d) Internal investigation

(1) In line with 'just culture' as part of the safety policy, the organisation should define how to investigate events such as errors or near misses, in order to understand not only what happened, but also how it happened, as well as to prevent or reduce the probability and/or the consequences of any future recurrence.

(2) The scope of internal investigations should extend beyond the scope of the occurrences that are required to be investigated in accordance with point 21.A.3A.

(e) Safety performance monitoring and measurement

(1) The organisation should define the processes through which the safety performance of the organisation is verified against the safety policy and the safety objectives.

(2) This process may include, as appropriate to the size, nature, and complexity of the organisation, the following elements:

(i) safety reporting that also addresses the status of compliance with the applicable requirements;

(ii) safety reviews, including trend reviews, which should be conducted during the introduction of new technologies, the implementation of new or changed procedures, or in cases of organisational changes that may have an impact on safety;

(iii) safety audits that focus on the integrity of the organisation's management system, and that periodically assess the status of safety risk controls;

(iv) safety surveys that examine particular elements or procedures of a specific area, such as the following:

(A) the problem areas identified;

(B) bottlenecks in the daily design management activities,

(C) the perceptions and opinions of the design management personnel; and

(D) any areas of dissent or confusion; and

(v) other indicators relevant to safety performance.

(f) Management of change

Changes to the design management system may pose new hazards or decrease the effectiveness of existing safety risk controls. The organisation should manage any safety risks that are related to change in that organisation. The management of change should be a documented process to identify external or internal change that may have an adverse effect on safety. The management of change should use the organisation's existing processes for hazard identification, risk assessment, and risk mitigation.

(g) **Continuous improvement**

The organisation should continuously seek to improve its safety performance and the effectiveness of its design management system. Continuous improvement may be achieved through review of the following elements:

- (1) compliance monitoring and audits;
- (2) assessments, including assessments of the effectiveness of the safety culture and of the management system, to assess in particular the effectiveness of the safety risk management processes;
- (3) staff surveys, including safety culture surveys, that can provide useful feedback on how engaged the staff are in the design management system;
- (4) the monitoring of events and their recurrence;
- (5) the evaluation of the safety performance indicators as well as reviews of all the available safety performance information; and
- (6) the identification of lessons learned.

## AMC1 21.A.239(c)(4)(ii) Design management system

### MANAGEMENT OF CHANGE

This AMC provides a means to consider organisational changes for their potential impact on safety. Organisational changes should also be evaluated for their significance, as required by point 21.A.247. In addition, necessary changes should be introduced into the handbook, as per point 21.A.243(c). The design management system should be designed such that all the above points are taken into account.

- (a) Organisational changes should be proactively considered for their safety implications. The magnitude of a change, its safety criticality, and its potential impact on human performance (HP) should be assessed in any process for the management of change. Certain non-complex organisational changes may not require additional assessment.
- (b) Special consideration, including human factors (HF) issues, should be given to the transition period during which the change becomes effective.
- (c) During the process for the management of change, relevant previous risk assessments and existing hazards should be reviewed for their possible effects.

## GM1 21.A.239(c)(4)(ii) Design management system

### MANAGEMENT OF CHANGE

Unless properly managed, changes in the organisational structure, facilities, scope of work, personnel, documentation, policies and procedures, etc. may result in inadvertently creating new hazards, which may expose the organisation to new or greater risks. Effective organisations seek to improve their processes, while being conscious of the fact that changes may expose the organisation to potential hazards and risks if they are not properly and effectively managed.

The process for the management of change typically provides principles and a structured framework for managing all aspects of changes. The disciplined implementation of management of change may

maximise the effectiveness of change, engage staff, and minimise the risks that are inherent in change.

Change may have the potential to raise new HF issues, or to exacerbate existing ones. For example, changes in computer systems, equipment, technology, personnel changes (including changes in management personnel), procedures, the organisation of work, or work processes are likely to affect performance.

Effective management of change is supported by the following elements:

(a) the implementation of a process for hazard identification/risk analysis and assessment for major operational changes, major organisational changes, changes in key personnel, and changes that may affect the way in which design management is carried out; (b) the identification of changes that may have a considerable impact on:

- (1) resources (material and human);
- (2) management direction (policies, processes, procedures, training); and
- (3) management control;

(b) safety cases/risk assessments that are aviation-safety focused; and

(c) the involvement of key stakeholders in the process for the management of change, as appropriate.

## GM1 21.A.239(c)(5) Design management system

### SAFETY PROMOTION

- (a) Safety training, combined with safety communication and information sharing, is part of safety promotion.
- (b) Safety promotion activities support the following:
  - (1) the organisation's policies, encouraging a positive safety culture, thus creating an environment that is favourable to the achievement of the organisation's safety objectives;
  - (2) organisational lessons learned; and
  - (3) the implementation of an effective safety reporting scheme and the development of a 'just culture'.
- (c) Depending on the particular safety issue, safety promotion may also constitute or complement risk mitigation action.

## AMC1 21.A.239(c)(5)(i) Design management system

### SAFETY TRAINING

- (a) The design management staff, as described in points 21.A.245(a) and (b), should receive initial and recurring safety training, as appropriate to their responsibilities, including in safety management principles and the associated safety objectives, to ensure their continued competency.
- (b) The organisation should identify the category of other staff to which safety training should be provided, and define the initial and recurrent training programmes, including appropriate timelines.

- (c) Adequate records of the safety training that is provided should be kept in accordance with point 21.A.5.

## GM1 21.A.239(c)(5)(i) Design management system

### SAFETY TRAINING

- (a) The main purpose of the safety training programme is:
- (1) to support safety management policies and processes; and
  - (2) to ensure that personnel at all levels of the organisation develop and maintain their competency to fulfil their safety roles.
- (b) Each organisation may adapt its syllabus to its own needs. Typically, depending on the targeted staff, to contribute to a positive safety culture, the following items may be included:
- (1) the organisational roles and responsibilities related to safety, including the hazard identification and risk management processes;
  - (2) the safety objectives and the associated safety performance indicators;
  - (3) human factors (HF) principles, including human performance (HP) and limitations;
  - (4) legislation, where applicable;
  - (5) safety reporting systems and investigations; and
  - (6) safety issues.
- (c) The purpose of the recurrent safety training is:
- (1) primarily to ensure that staff are kept abreast notably of changes to safety management system (SMS) principles, processes, and procedures; and
  - (2) also to share feedback on safety issues that are relevant to the organisation or lessons learned.
- (d) The training staff should have sufficient knowledge and experience to teach the topics at the required level, as well as the skills to influence attitudes and behaviours.

## AMC1 21.A.239(c)(5)(ii) Design management system

### SAFETY COMMUNICATION

- (a) The organisation should establish communication to the staff, as appropriate to their safety responsibilities, regarding safety matters, which:
- (1) ensures awareness of safety management activities;
  - (2) conveys safety-critical information, especially related to assessed risks and analysed hazards;
  - (3) explains why particular action is taken; and
  - (4) explains why safety procedures are established or changed.

The appropriate nominated post holders, as detailed in the handbook, should hold or direct regular meetings with staff, during which information, action, and procedures are discussed, and these may be used to communicate safety matters.

**DESIGN ASSURANCE ELEMENT**

(a) 1. Purpose

This GM outlines some basic principles and objectives of 21.A.239(a) the design assurance element.

(b) 2. Definitions

2.(1) The design assurance element ~~includes system~~ is the organisational structure, responsibilities, procedures, and resources to ensure the proper functioning of the design organisation.

2.(2) ~~The design~~ 'Design assurance' refers to ~~means all those~~ planned and systematic actions necessary to provide adequate confidence that the organisation has the capability to:

— ~~to~~ design products or parts in accordance with the applicable type certification basis, the operational suitability data (OSD) certification basis, CS and the environmental protection requirements,;

— ~~to~~ demonstrate and verify the compliance with these type certification basis, the OSD certification basis, CS and the environmental protection requirements,; and — ~~to~~ demonstrate to the Agency the CAA that is compliance.

2.(3) ~~The~~ 'Type Investigation' ~~means~~ refers to the tasks of the organisation in support of the type certificate (TC), supplemental type certificate (STC), or other design approval processes necessary to demonstrate, and verify, and ~~to~~ maintain compliance with the applicable type certification basis, OSD certification basis, CS and environmental protection requirements.

3. Design Assurance

~~The complete process, starting with the CS and environmental protection requirements and product specifications and culminating with the issuing of a type certificate, is shown in the diagram on Figure 1. This identifies the relationship between the design, the Type Investigation and design assurance processes.~~

Effective design assurance demands a continuing evaluation of factors that affect the adequacy of the design for intended applications, in particular that the product, or part, complies with applicable CS and environmental protection requirements and will continue to comply after any change.

Two main aspects should therefore be considered:

- How the planned and systematic actions are defined and implemented, from the very beginning of design activities up to continued airworthiness activities;
- How these actions are regularly evaluated and corrective actions implemented as necessary.

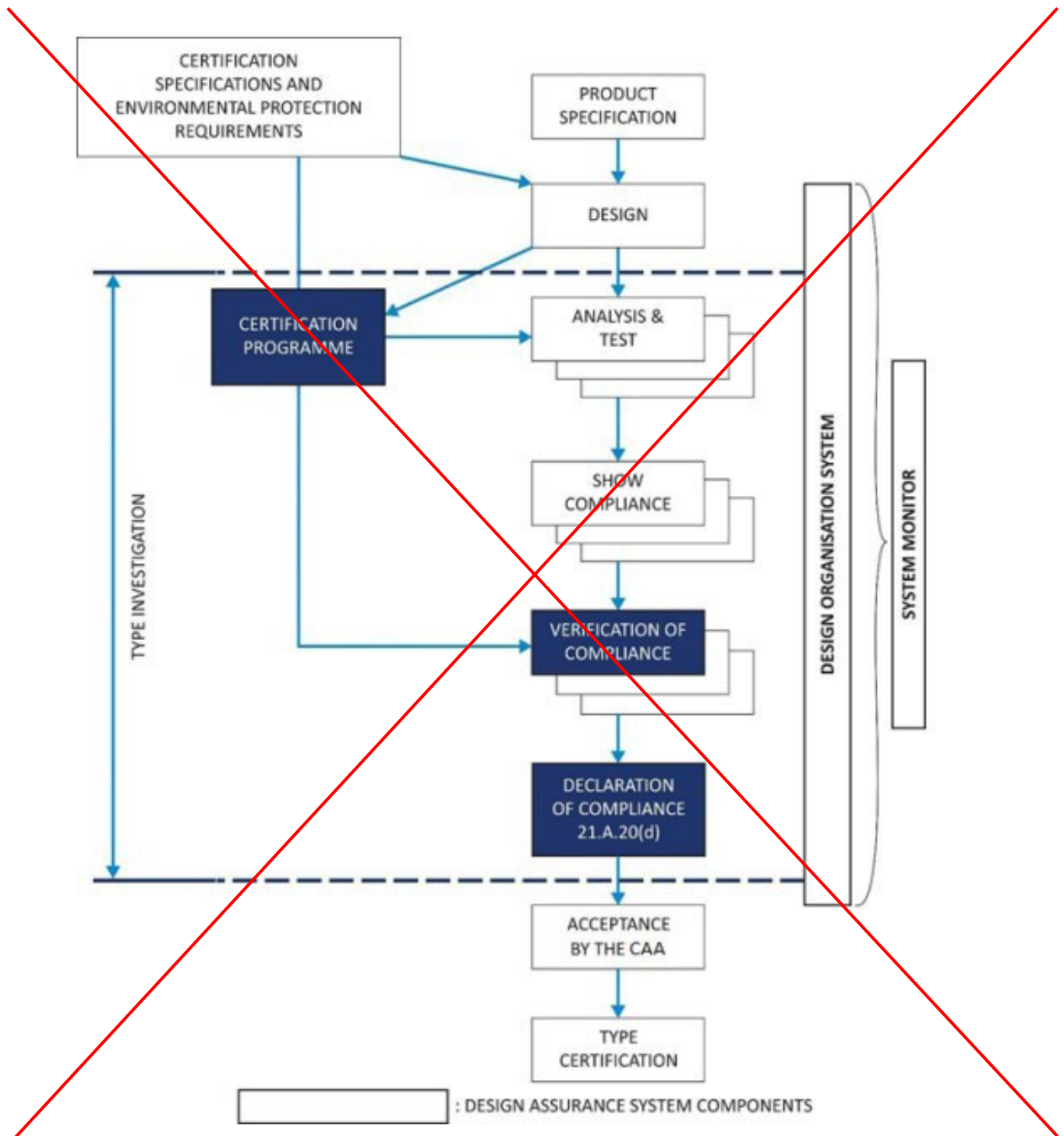


Figure 1 — RELATIONSHIPS BETWEEN DESIGN, DESIGN ASSURANCE AND TYPE INVESTIGATION

### 3.1—Planned and Systematic Actions

For design organisations carrying out Type Investigation of products, the planned and systematic actions should cover the following tasks and procedures should be defined accordingly:

#### 3.1.1 General

- a. ~~To issue or, where applicable, supplement or amend the handbook in accordance with 21.A.243, in particular to indicate the initiation of design activities on a product.~~
- b. ~~To assure that all instructions of the Handbook are adhered to.~~
- c. ~~To conduct Type Investigation.~~
- d. ~~To nominate staff as 'compliance verification engineers' responsible to approve compliance documents as defined in paragraph 3.1.3.~~
- e. ~~To nominate personnel belonging to the Office of Airworthiness responsible as defined in paragraph 3.1.4.~~
- f. ~~In the case of an applicant for a supplemental type certificate, to obtain the agreement of the type certificate holder for the proposed supplemental type certificate to the extent defined in 21.A.115.~~
- g. ~~To ensure full and complete liaison between the type design organisation and related organisations having responsibility for products manufactured to the type certificate.~~
- h. ~~To provide the assurance to the CAA that prototype models and test specimens adequately conform to the type design (see 21.A.33(b)(1)).~~

#### 3.1.2 Chief Executive and Head of design organisation (or his or her Deputy)

- a. ~~The Chief Executive should provide the necessary resources for the proper functioning of the design organisation.~~
- b. ~~The Head of the design organisation, or an authorised representative, should sign a declaration of compliance (see 21.A.20(d) and 21.A.97(a)(3)) with the applicable CS and environmental protection requirements after verification of satisfactory completion of the Type Investigation. In accordance with 21.A.20(e) and 21.A.97(a)(4), his or her signature on the declaration of compliance confirms that the procedures as specified in the handbook have been followed (see also GM 21.A.265(b)).~~
- c. ~~The functions of Chief Executive and Head of the design organisation may be performed by the same person.~~

#### 3.1.3 Compliance Verification

- a. ~~Approval by signing of all compliance documents, including test programmes and data, necessary for the verification of compliance with the applicable CS and environmental protection requirements as defined in the certification programme.~~



- b. — Approval of the technical content (completeness, technical accuracy...), including any subsequent revisions, of the manuals approved by the CAA (Aircraft Flight Manual, the Airworthiness Limitations section of the Instructions for Continued Airworthiness and the Certification Maintenance Requirements (CMR) document, where applicable).

#### 3.1.4 Office of Airworthiness

- a. — Liaison between the design organisation and the CAA with respect to all aspects of the certification programme.
- b. — Ensuring that a handbook is prepared and updated as required in 21.A.243.
- c. — Co-operation with the CAA in developing procedures to be used for the type certification process.
- d. — Issuing of guidelines for documenting compliance.
- e. — Co-operation in issuing guidelines for the preparation of the manuals required by the applicable implementing rules, Service Bulletins, drawings, specifications, and standards.
- f. — Ensuring procurement and distribution of applicable CS and environmental protection requirements and other specifications.
- g. — Co-operating with the CAA in proposing the type certification basis
- h. — Interpretation of CS and environmental protection requirements and requesting decisions of the CAA in case of doubt.
- i. — Advising of all departments of the design organisation in all questions regarding airworthiness, operational suitability, environmental protection approvals and certification.
- j. — Preparation of the certification programme and co-ordination of all tasks related to Type Investigation in concurrence with the CAA
- k. — Regular reporting to the CAA about Type Investigation progress and announcement of scheduled tests in due time.
- l. — Ensuring co-operation in preparing inspection and test programmes needed for demonstration of compliance.
- m. — Establishing the compliance checklist and updating for changes.
- n. — Checking that all compliance documents are prepared as necessary to demonstrate compliance with all CS and environmental protection requirements, as well as for completeness, and signing for release of the documents.
- o. — Checking the required type design definition documents described in 21.A.31 and ensuring that they are provided to the CAA for approval when required.

- ~~p. Preparation, if necessary, of a draft for a type-certificate data sheet and/or type-certificate data sheet modification.~~
- ~~q. Providing verification to the head of the design organisation that all activities required for Type Investigation have been properly completed.~~
- ~~r. Approving the classification of changes in accordance with 21.A.91 and granting the approval for minor changes in accordance with 21.A.95(b).~~
- ~~s. Monitoring of significant events on other aeronautical products as far as relevant to determine their effect on airworthiness or operational suitability of products being designed by the design organisation.~~
- ~~t. Ensuring co-operation in preparing Service Bulletins and the Structural Repair Manual, and subsequent revisions, with special attention being given to the manner in which the contents affect airworthiness and environmental protection and granting the approval on behalf of the CAA.~~
- ~~u. Ensuring the initiation of activities as a response to a failure (accident/incident/in-service occurrence) evaluation and complaints from the operation and providing of information to the CAA in case of airworthiness or operational suitability impairment (continuing airworthiness and continued operational suitability).~~
- ~~v. Advising the CAA with regard to the issue of airworthiness directives in general based on Service Bulletins.~~
- ~~w. Ensuring that the manuals approved by the CAA, including any subsequent revisions (the Aircraft Flight Manual, MMEL, the Airworthiness Limitations section of the Instructions for Continued Airworthiness and the Certification Maintenance Requirements (CMR) document, where applicable) are checked to determine that they meet the respective requirements, and that they are provided to the CAA for approval.~~

### 3.1.5 Maintenance and Operating Instructions

- ~~(a) Ensuring the preparation and update of all maintenance and operating/installation instructions (including instructions for continued airworthiness and service bulletins) needed to maintain airworthiness (continuing airworthiness) in accordance with the relevant CSs. For that purpose, the applicant should:
 
  - ~~— establish the list of all documents it produces to comply with CS 2X.1581 and with the Appendix referred to in CS 2X.1529, CS-E 20/25 or CS-P 30/40;~~
  - ~~— establish a system to collect in-service experience to be used for the improvement of the instructions;~~
  - ~~— define its procedures and the organisation to produce and issue these documents, under the obligation of point 21.A.265(h); the procedures should cover:~~~~

- ~~— preparation, including the format and language (available industrial standards can be referred to and used);~~
- ~~— proofreading (checking for clarity, readability, typos, etc.);~~
- ~~— verification of technical consistency with the corresponding approved change(s), repair(s) or approved data, including the effectivity, description, effects on airworthiness and environmental protection, especially when limitations are changed;~~
- ~~— verification of feasibility in practical applications when relevant and feasible; and~~
- ~~— responsibilities and authorised signatories.~~

*Note:* The compliance verification, as described in 3.1.3(b) of this GM, applies to the manuals approved by the CAA (aircraft flight manual, the Airworthiness Limitations section of the Instructions for Continued Airworthiness (ICA) and the Certification Maintenance Requirements (CMR) document, where applicable). For the other ICA or other maintenance instructions, the procedure required by 3.1.5(a) provides a sufficient level of verification and does not require specific compliance verification unless, in line with 21.A.90C, additional work to demonstrate compliance is required. In this case, where additional showing of compliance is required, points 21.A.91 to 21.A.109 apply and then the independent checking function of the showings of compliance as per 21.239(b) applies.

- ~~(b) In accordance with 21.A.57, 21.A.61, 21.A.107, 21.A.119, 21.A.120A and 21.A.449, ensuring that these documents are provided to all affected operators and all involved authorities.~~

### 3.1.6 Operational Suitability Data

- ~~(a) Ensuring the preparation and update of all OSD in accordance with the relevant CSs. For that purpose, the applicant should:
 
  - ~~— establish the list of all the documents it produces to comply with CSM MEL or CS-GEN-MMEL, CS-FCD, CS-CCD, CS-SIMD and CS-MCSD, as applicable;~~
  - ~~— define its procedures and the organisation to produce and issue these documents under the obligation of point 21.A.265(h); these procedures should cover the aspects described in 3.1.5(a) above.~~~~
- ~~(b) In accordance with points 21.A.6 and 21.A.7, ensuring that these documents are provided to all affected operators and training organisations and all involved authorities.~~

3.2 Continued effectiveness of the design assurance system. The organisation should establish the means by which the continuing evaluation (system monitoring) of the design assurance system will be performed in order to ensure that it remains effective.

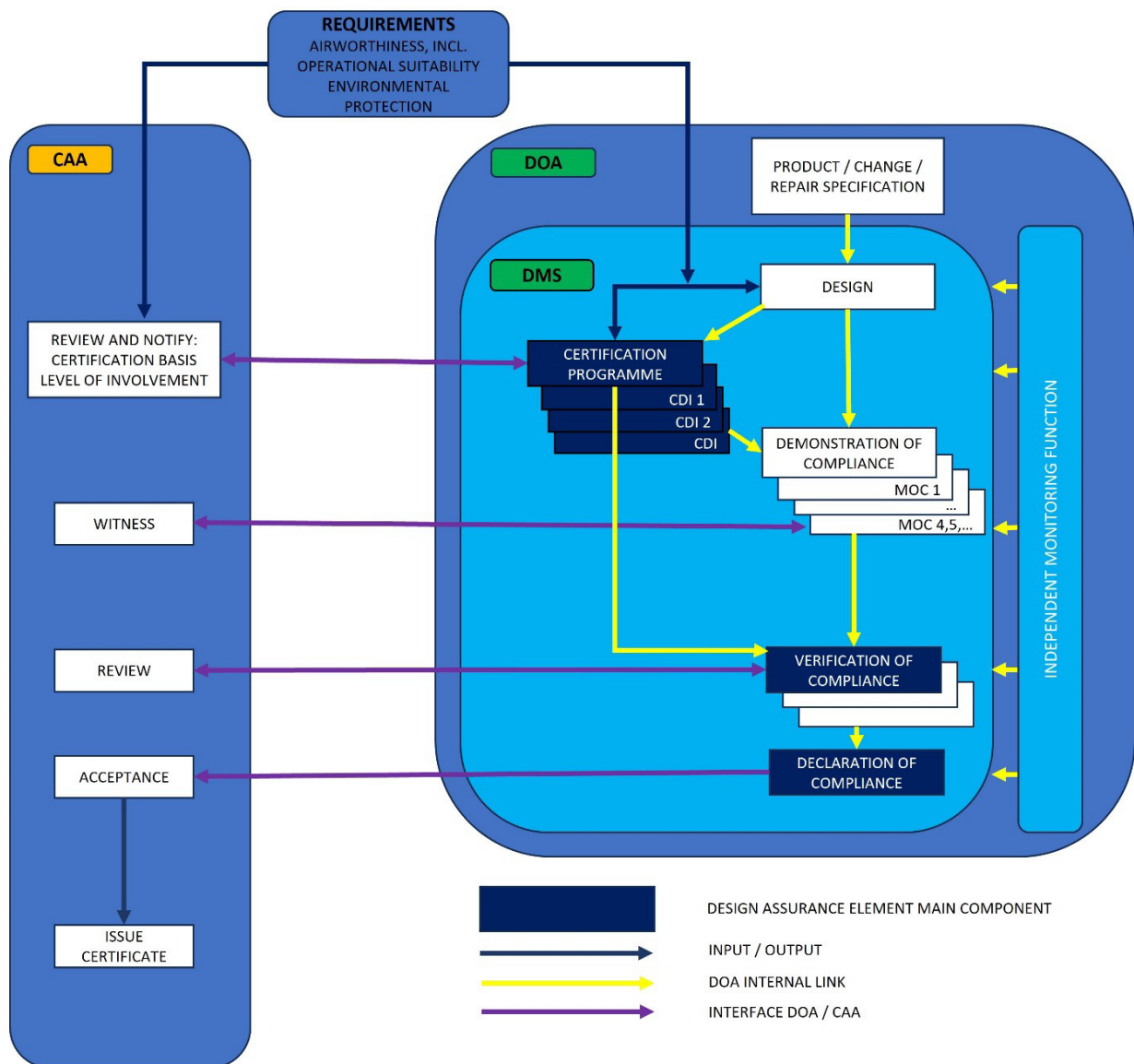
**DESIGN ASSURANCE ELEMENT**

- (a) Intentionally left blank
- (b) Intentionally left blank
- (c) Design assurance element

The complete design process, starting with the type certification basis, operational suitability data (OSD) certification basis, as well as environmental protection requirements and product specifications, and culminating with the issuing of a type certificate (TC), is shown in Figure 1, which identifies the relationships between the design, the certification, and the design assurance processes.

Effective design assurance requires a continuing evaluation of all the factors that affect the adequacy of the design for the intended applications. In particular, it should be ensured that the product or part complies with the applicable type certification basis, OSD certification basis, and environmental protection requirements, and that it will continue to comply after any change to the TC or any repair.

Planned and systematic tasks should therefore be defined and performed from the very beginning of the design activities up to the continued-airworthiness activities.



**Figure 1 — RELATIONSHIPS' CONCEPT IN DESIGN AND CERTIFICATION**

**(1) Planned and systematic tasks**

For design organisations that carry out the certification process of products, their planned and systematic tasks should cover the following, and the related procedures should be defined accordingly.

**(i) General**

- (A) Issue or, where applicable, supplement, or amend the handbook in accordance with point 21.A.243, in particular to indicate the initiation of design activities on a product.
- (B) Assure that all the instructions of the handbook are adhered to.
- (C) Conduct the certification process.

- (D) Nominate staff as 'compliance verification engineers' that are responsible for approving compliance documents as defined in point (c)(1)(iii).
- (E) Nominate staff that belong to the Office of Airworthiness and are responsible as defined in point (c)(1)(iv).
- (F) In the case of an applicant for an STC, obtain the agreement of the TC holder for the proposed supplemental type certificate (STC) to the extent that is defined in point 21.A.115.
- (G) Ensure that there is full and complete liaison between the design organisation and the related organisations that have responsibility for the products and parts that are manufactured according to the type design.
- (H) Provide assurance to the CAA that any prototype models and test specimens adequately conform to the type design (see point 21.A.33(c)).

(ii) Head of the design organisation (or deputy)

The head of the design organisation (HDO), or an authorised representative, should sign a declaration of compliance (see points 21.A.20(d) and 21.A.97(b)(3)) with the applicable type certification basis, OSD certification basis, and environmental protection requirements after verifying the satisfactory completion of the certification process. In accordance with point 21.A.20(e), the signature of the HDO on the declaration of compliance confirms that the procedures as specified in the handbook have been followed (see also GM 21.A.265(b)).

(iii) Compliance verification

- (A) Approval through the signing of all the compliance documents, including test programmes and data that are necessary for the verification of compliance with the applicable type certification basis, OSD certification basis and environmental protection requirements, as defined in the certification programme.
- (B) Approval of the technical content (completeness, technical accuracy, etc.), including any subsequent revisions of the manuals to be approved by the CAA (aircraft flight manual (AFM), airworthiness limitations section of the instructions for continued airworthiness (ICA), and certification maintenance requirements (CMRs) document, where applicable).

(iv) Airworthiness function

The airworthiness function is commonly performed by the Office of Airworthiness and should cover the following tasks as relevant\*:

- (A) liaison between the design organisation (DO) and the CAA with respect to all aspects of the certification programme;

- (B) ensuring that a handbook and the flight test operations manual, when relevant, are prepared and updated as required by point 21.A.243;
- (C) cooperation with the CAA in developing procedures to be used for the type certification process;
- (D) issuing of guidelines for documenting compliance;
- (E) cooperation in issuing guidelines for the preparation of the manuals that are required by the applicable requirements, service bulletins (SBs), drawings, specifications, and standards;
- (F) ensuring procurement and distribution of the applicable type certification basis, OSD certification basis, as well as environmental protection requirements and other specifications;
- (G) cooperating with the CAA in proposing the type certification basis, OSD certification basis, and environmental protection requirements;
- (H) the interpretation of the type certification basis, OSD certification basis, and environmental protection requirements, and requesting the CAA to take decisions in case of doubt;
- (I) advising all the departments of the DO on any question regarding airworthiness, operational suitability, environmental protection approvals, and certification;
- (J) the preparation of the certification programme, including a proposal for CAA involvement in the verification of compliance demonstration activities and data, and coordination of all the tasks related to the certification process in agreement with the CAA;
- (K) regular reporting to the CAA about the progress of the certification process, including any difficulty or event that may necessitate a change of the previously notified CAA level of involvement, and announcing scheduled activities (e.g. tests) in due time;
- (L) ensuring cooperation in preparing the inspection and test programmes needed for demonstration of compliance;
- (M) establishing the compliance checklist and updating it with any changes;
- (N) checking that all the compliance documents that are necessary to demonstrate compliance with the type certification basis, OSD certification basis, and environmental protection requirements are prepared and complete, and signing the documents for release;
- (O) checking the required type design definition documents that are described in point 21.A.31 and ensuring that they are provided to the CAA for approval when required;
- (P) preparation, if necessary, of a draft of a type certification data sheet (TCDS) and/or a modification to a TCDS;

- (Q) providing verification to the HDO that all the activities that are required for the certification process have been properly completed;
- (R) managing the exercise of the DO privileges in accordance with point 21.A.263(c);
- (S) monitoring significant events on other aeronautical products, as far as they are relevant, to determine their effect on the airworthiness or operational suitability of the products that are designed by the DO;
- (T) ensuring that there is cooperation in preparing Service Bulletins (SB) and the structural repair manual, and any subsequent revisions, with special attention to the manner in which the contents affect airworthiness and environmental protection, and granting the approval on behalf of the CAA;
- (U) ensuring the initiation of activities in response to a failure (accident/incident/in-service occurrence) evaluation and to complaints from the operation, and providing information to the CAA if airworthiness or operational suitability are impaired (continuing airworthiness and continued operational suitability);
- (V) advising the CAA on the issuing of airworthiness directives in general based on SBs; and
- (W) ensuring that the manuals that are approved by the CAA, including any subsequent revisions, (AFM, airworthiness limitations section of the ICA, and CMR document, where applicable) are checked, to determine whether they meet their respective requirements, and that they are provided to the CAA for approval.

\* Some of the above tasks may be carried out through a different organisational function.

- (v) Maintenance and operating instructions
  - (A) Ensuring the preparation and updating of all the maintenance and operating instructions (including ICA and SBs) that are needed to maintain airworthiness (i.e. continuing airworthiness) in accordance with the relevant certification specifications (CSs). For that purpose, the applicant should:
    - (a) establish the list of all the documents they produce to comply with CS 2X.1581 (CS 23.2620) and with the Appendix that is referred to in CS 2X.1529, CS-E 20/25, or CS-P 30/40, or CS 23.2625;
    - (b) establish a system to collect in-service experience to be used for the improvement of the instructions; and
    - (c) define the procedures and the organisation for producing and issuing those documents, taking into account the obligation of point 21.A.265(h); those procedures should cover the following elements:



- (1) preparation, including format and language (available industrial standards can be referred to and used);
- (2) proofreading (checking for clarity, readability, typos, etc.);
- (3) verification of technical consistency with the corresponding approved change(s), repair(s), or approved data, including effectivity, description, effects on airworthiness and environmental protection, especially when limitations are changed;
- (4) verification of feasibility in practical applications, when relevant and feasible; and
- (5) responsibilities and authorised signatories.

Note: Compliance verification, as described in point (c)(1)(iii) of this AMC, applies to the manuals that are approved by the CAA (AFM, airworthiness limitations section of the ICA, and CMR document, where applicable); for the other ICA or other maintenance instructions, the procedure that is required by (c)(1)(v) of this AMC provides a sufficient level of verification and does not require specific compliance verification unless, as per point 21.A.90C, additional work to demonstrate compliance is required; in that case, where additional compliance demonstration is required, points 21.A.91 to 21.A.109, as well as the independent checking function of compliance demonstration as per point 21.A.239(b), apply.

- (B) In accordance with points 21.A.6 and 21.A.7 and, where applicable, point 21.A.609, ensuring that those documents are made available as per point 21.A.7(b).

(vi) Operational suitability data

- (A) Ensuring the preparation and updating of all OSD in accordance with the relevant CSs. For that purpose, the applicant should:
  - (a) establish the list of all the documents that they produce to comply with CS-MMEL or CS-GEN-MMEL, CS-FCD, CS-CCD, CS-SIMD, and CS-MCSD, as applicable; and
  - (b) define the procedures and the organisation for producing and issuing those documents, taking into account the obligation of point 21.A.265(h); those procedures should cover the aspects that are described in (c)(1)(v)(A).
- (B) In accordance with points 21.A.6, 21.A.62, 21.A.108, and 21.A.120B, ensuring that those documents are provided to all the affected operators and training organisations, as well as to all the authorities involved.

## AMC2 ~~GM No 2 to 21.A.239(d)(a)~~ Design management system ~~Design assurance system for minor changes to type design or minor repairs to products~~

### DESIGN ASSURANCE ELEMENT FOR MINOR CHANGES TO TYPE DESIGN OR MINOR REPAIRS TO PRODUCTS

#### (a) ~~1~~ Purpose

This ~~GM~~AMC outlines some basic principles and objectives in order to comply with ~~21.A.239(a)~~ the design assurance element for organisations designing only minor changes to type design or minor repairs to products.

#### (b) ~~2~~ Design assurance element of the design management system.

The design assurance element of the design management system should include the following:

- an organisational structure to:
  - to control the design;
  - to demonstrate compliance with the applicable type certification basis, operational suitability data (OSD) certification basis, CS and environmental protection requirements;
  - to independently check demonstrations of compliance;
  - to liaise with the Agency the CAA;
  - to continuously evaluate the design organisation; and
  - to control ~~sub-contractors~~ subcontractors; and
- procedures and responsibilities associated with the functions listed above, taking due account of Part 21 requirements applicable to design and approval of minor changes to type design or minor repairs to products.

## AMC ~~21.A.239(a)(3)~~ Design assurance system – Independent system monitoring

The system monitoring function required by ~~21.A.239(a)(3)~~ may be undertaken by the existing quality assurance organisation when the design organisation is part of a larger organisation.

## AMC1 ~~21.A.239(d)(2) (b)~~ Design management assurance system – Independent checking function of the demonstration of compliance

### INDEPENDENT VERIFICATION FUNCTION OF THE DEMONSTRATION OF COMPLIANCE

- (a) ~~1~~. The independent ~~verification~~checking function of the demonstration of compliance should consist of the verification by a person that did not ~~creating~~create the compliance data. Such a person may work in conjunction with the individuals that ~~who~~ prepare compliance data.
- (b) ~~2~~. The verification should be shown by signing compliance documents, including test programmes and data.

- (c) ~~3~~. For a product, there is normally only one compliance verification engineer that is nominated for each relevant subject. A procedure should cover the non-availability of nominated persons and their replacement, when necessary.
- (d) ~~4~~. For STC cases, when compliance statement and associated documentation are produced by the TC holder, and when ~~this~~ these data ~~is~~ are approved under the system of the authority of TC holder, then the STC applicant does not need to provide, within its own DOA, the independent verification ~~checking~~ function that is required in point 21.A.239(d)(2)(b) for ~~these~~ that data.

## GM1 21.A.239(d)(3)(c) Design management system Design

### DESIGN ASSURANCE ELEMENT — PARTNERS AND SUBCONTRACTORS

In meeting the requirements of point 21.A.239(d)(3), the applicant for a design organisation approval under Subpart J may adopt the following policy:

- (a) ~~1~~. The satisfactory integration of the ~~Partner/Sub-contractor~~ partner and / or subcontractor and applicant's design assurance element of the design management system ~~should be~~ is demonstrated for the activities that are covered under the applicant's terms of approval.
- (b) ~~2~~. In the event that a ~~Partner/Sub-contractor~~ partner and subcontractor holds a design organisation approval (DOA), then in accordance with point 21.A.239(d)(3)(c), the applicant may take this into account in demonstrating the effectiveness of ~~that~~ this integrated system.
- (c) ~~3~~. When any ~~Partner/Sub-contractor~~ partner and subcontractor does not hold a DOA, then the applicant will need to establish to its own satisfaction and the satisfaction of ~~the Agency~~ the CAA, the adequacy of that partner's/~~sub-contractor's~~ subcontractor's design assurance element of the design management system in accordance with point 21.A.243(b).

## GM2 21.A.239(d)(3) Design management system

### DESIGN ASSURANCE ELEMENT — PARTNER AND SUBCONTRACTOR ARRANGEMENTS

When defining the arrangements between the design organisation (DO) and its partners and / or subcontractors, both elements of the design management system should be taken into account, i.e. the safety management element and the design assurance element. The following guidance should therefore be considered applicable to both elements.

- (a) When the DO subcontracts activities, the arrangements should consider the safety risk management process that is part of its safety management element (see point 21.A.239(c)(3)). When the subcontractor does not have a safety management element, the subcontractor should be integrated into the safety management element of the DO; when the subcontractor has implemented a safety management system (such as for design organisation approval (DOA) or production organisation approval (POA)), the two safety management systems, i.e. of the DO and of the subcontractor, should be harmonised.
- (b) Depending on the complexity and criticality of those arrangements, the following elements within the arrangements should be addressed:

- (1) coordination and interfaces between all the parties involved;
  - (2) applicable procedures;
  - (3) safety culture, including internal safety reporting scheme (see point 21.A.3A).
  - (4) communication between all the parties involved, including reporting, regular meetings, and feedback channels;
  - (5) allocation of tasks, of clear accountability, and of responsibilities; and
  - (6) the qualifications and competency of key personnel with reference to point 21.A.245.
- (c) The safety risk management should focus on the needs to exchange safety data and safety information that are deemed significant for the determination of relevant risks in terms of likelihood, severity, impact, and acceptability, such as, wherever appropriate, but not limited to the following:
- (1) (at product level) failure, malfunction, defect, or other occurrences, non-conformity or outcome of the compliance monitoring function, component failure analysis, in-service event, etc.;
  - (2) (at documentation level) key processes (e.g. airworthiness directives, design and certification documentation, design processes); and
  - (3) (at organisation level) changes, disruptive events, resources' issues, human performance (HP) issues.
- (d) Regular communication should be ensured between all the parties involved, to discuss work progress, risk mitigation measures, changes to the arrangements, as well as any other significant issues.

## AMC1 21.A.239(e) Design management system

### INDEPENDENT MONITORING FUNCTION

- (a) The independent monitoring function should ensure that:
- (1) the activities of the design organisation (DO) are monitored for their compliance with the applicable requirements and with any additional requirements as established by the organisation, and that those activities are properly performed under the supervision of the nominated persons that are referred to in point 21.A.245(b); furthermore, compliance with, and the adequacy of, the design management system should be monitored;
  - (2) all subcontracted design activities are monitored for adequacy and compliance with the applicable arrangements;
  - (3) an objective review of the complete set of design-management-related activities is provided through independent monitoring activities, such as audits, inspections, reviews, including product and project samples as defined by the handbook procedures;
  - (4) the independence of the monitoring activities is established by always ensuring that those activities and inspections are performed by staff that are not involved in the function, procedure, or products that they monitor, and that are independent from the

operating managers of the function(s) being monitored; however, this should not exclude support by domain experts during monitoring;

- (5) a monitoring plan is established to show when and how often the activities that are required by Part 21 will be audited;
  - (6) the monitoring cycle should not exceed the applicable oversight planning cycle that is established according to point 21.B.432; the determination of the monitoring plan should consider at least the following aspects:
    - the criticality of the items checked; and
    - the safety performance of the organisation, including any previous findings and root causes;
  - (7) when non-compliance is found, the root cause(s) and contributing factor(s) are identified, and corrective action is defined and followed up; and
  - (8) feedback is provided to the management of the DO.
- (b) The independent monitoring function that is required by point 21.A.239(e) may be undertaken by the existing quality assurance organisation if the DO is part of a larger organisation.
- (c) The staff performing an independent monitoring function should have access to all the parts of the DO and, as necessary, to any subcontracted organisations.

## AMC1 21.A.243(a) Data

### HANDBOOK --GENERAL

- (a) All personnel should be familiar with those parts of the handbook that are relevant to their tasks.
- (b) The handbook should provide the following information for each product that is covered by the design organisation approval (DOA):
- (1) A description of the tasks that which can be performed under the approval, according to the following classification:
    - (i) ~~a. General areas, like subsonic turbojet aeroplanes, turbopropeller turboprop aeroplanes, small aeroplanes, rotorcraft., etc.;~~
    - (ii) ~~b. Technologies handled by the organisation (composite, wood or metallic construction, electronic systems, etc.);~~
    - (iii) ~~c. A list of types and models for which the design approval has been granted and for which privileges may be exercised, supported by a brief description for each product.;~~  
and
    - (iv) ~~d. For repair design, classification and (if appropriate) approval activities, it is necessary to specify the scope of activity in terms of structures, systems, engines, etc.~~
  - (2) A general description of the organisation, its main departments, their functions and the names of those in charge; a description of the line management and of the functional relationships between the various departments.

- (3) A description of the assigned responsibilities and delegated authority of all parts of the organisation, which, taken together, constitute the organisation's design assurance management system, together with a chart indicating the functional and hierarchical relationship of the design assurance management system to the management and to other parts of the organisation; also the chains of responsibilities within the design assurance management system, and the control of the work of all partners and sub-contractors/subcontractors.
- (4) A general description of the way in which the organisation performs all the design functions in relation to airworthiness, operational suitability and environmental protection approvals, including:
- (i) a. The procedures followed and forms used in the Type Investigation certification process to ensure that the design of, or the change to the design of, the product, as applicable, is identified and documented, and complies with the applicable type certification basis, operational suitability data (OSD) certification basis, CS and the environmental protection requirements, including specific requirements for import by importing authorities;
  - (ii) b. The procedures for classifying design changes as 'major' or 'minor' and for the approval of minor changes.;
  - (iii) c. The procedures for classifying and approving unintentional deviations from the applicable approved design data occurring in production (concessions or non-conformity non-conformance's).; and
  - (iv) d. The procedure for classifying and obtaining approval for repairs.
- (5) A general description of the way in which the organisation performs its functions in relation to the continuing airworthiness and continued operational suitability of the product it designs, including co-operation/cooperation with the production organisation when dealing with any continuing airworthiness actions that are/is related to the production of the product, part, or appliance, as applicable.
- (6) A description of the human resources, facilities, and equipment, which constitutes the means for design, and, where appropriate, for ground and flight testing.
- (7) An outline of a system for controlling and informing the personnel/Staff of the organisation of current changes in engineering drawings, specifications, and design assurance management procedures.
- (8) A description of the recording system for:
- (i) a. The type design, including relevant design information, drawings and test reports, including inspection records of test specimens.;
  - (ii) b. The means of compliance.;
  - (iii) c. The compliance documentation (compliance checklist/check list, reports, etc. ...).
- (9) A description of the record-keeping system to comply with point 21.A.5
- (10) A description of the means by which the organisation collects, monitors, analyses and responds to problems that/which cause or might cause an adverse effect on the

airworthiness or operational suitability of its product, part, or appliance during design, production, and in service, in particular to comply with point 21.A.3A (see also AMC3 21.A.3A(a) and AMC1 21.A.239(d) and GM No 1 to 21.A.239(a), points 3.1.4(s) and (u)).

- (11) The names of the design organisation (DO)-authorised signatories. Nominated persons with specific responsibilities such as those mentioned in points 21.A.33 and 21.A.35 should be listed as well.
- (12) Intentionally left blank.
- (13) A clear definition of the tasks, competency, and areas of responsibility of the Office of Airworthiness.
- (14) A description of the procedures for the establishment and the control of the manuals and instructions for continued airworthiness (ICA) maintenance and operating instructions (see points 21.A.6, 21.A.7 and, where applicable, 21.A.609).
- (15) A description of the means by which the continuing evaluation (system monitoring) of the design assurance management system will be performed in order to ensure that it remains effective.
- (16) A description of the procedures for the establishment and the control of the OSD operational suitability data (see points 21.A.5, 21.A.62, 21.A.108, and 21.A.120B).
- (17) A description of the organisation's safety policy and objectives, as required by point 21.A.239(c)(1).
- (18) A description of the internal safety reporting scheme, as required by point 21.A.3A(a).
- (19) A description of the safety management procedures (including identification of safety hazards, evaluation, and associated risks management), safety assurance procedures, and safety promotion processes.
- (20) A statement, signed by the head of the design organisation (HDO) (and countersigned by the chief executive, if different), which confirms that the design management handbook and any associated manuals are complied with at all times.

This statement should read as follows, or embrace the intent of the following text:

*'This handbook defines the organisation and procedures upon which the CAA's DOA is based.*

*These procedures are approved by the undersigned, and must be complied with, as applicable, to ensure that all design activities are performed on time and to an approved standard.*

*It is understood that the approval of the DO is based on the organisation's continuous compliance with the applicable requirements of Part 21, and with the organisation's procedures that are described in this handbook. The CAA is entitled to limit, suspend, or revoke the approval if the organisation fails to fulfil the obligations that are imposed by Part 21, or any conditions according to which the approval was issued.*

Signed .....

Dated .....

HDO and .....(quote the position of the signatory)

Chief Executive

For and on behalf of .....(quote the organisation's name)'

The statement should be reissued at the earliest opportunity when the HDO or Chief Executive changes.

- (b) The organisation may document its safety policy, safety objectives, and all the safety management system key processes (as required by point 21.A.239(c)) in a separate manual (e.g. a safety management manual or management system manual) or in its handbook. Organisations that hold multiple organisation approvals, which are issued under UK Regulation (EU) 2018/1139 and the regulation made under it that are adopted on the basis thereof, may prefer to have a separate manual to avoid duplication.

## AMC2 21.A.243(a) Data Model content of handbook for organisations designing minor changes to type design or minor repairs to products

### TYPICAL CONTENT OF HANDBOOK FOR ORGANISATIONS THAT DESIGN MINOR CHANGES TO TYPE DESIGN OR MINOR REPAIRS TO PRODUCTS

The following is a typical table of contents for the handbook:

#### Part 1. Organisation

- 1.1 Objective of the handbook and binding statement
- 1.2 Responsible person for the administration of the handbook
- 1.3 Amendment procedure
- 1.4 List of effective pages
- 1.5 Distribution list
- 1.6 Presentation of the design organisation (DO) (including locations)
- 1.7 Scope of work (with identification of type and models of products)
- 1.8 Organisation charts
- 1.9 Human resources
- 1.10 Management staff
- 1.11 Certifying personnel (see AMC2 ~~to~~ 21.A.243(d), paragraph (b))
- 1.12 Independent system monitoring
- 1.13 Safety management system

#### Part 2. Procedures

- 2.1 Management of changes to type design and design of repairs:
  - configuration control,



- classification, and
  - approval of minor changes to type design and minor repairs
- 2.2 Control of design ~~sub-contractors~~ subcontractors
- 2.3 Collecting/Investigating of failures, malfunctions, and defects
- 2.4 ~~Co-ordination~~ Coordination with production
- 2.5 Documentation control
- in ~~relations~~ relation to with the changes and repairs, and
  - in relation to with failures/malfunctions and defects (i.e. ~~S~~services ~~B~~ulletins)
- 2.6 Record-keeping

## AMC1 21.A.243(d) Data

### HANDBOOK- STATEMENT OF QUALIFICATIONS AND EXPERIENCE

- (a) The following statements should be provided:
- (1) Other management staff as defined in GM1 21.A.243(d)
- For each nominated manager, the organisation should provide this data to the CAA to show that the nominated managers are suitable in terms of their relevant knowledge and satisfactory experience related to the nature of the design activities that are performed by the organisation.
- The nominated managers should be identified and their credentials submitted to the CAA in a form and manner as established by the CAA.
- (2) The staff that make decisions that affect airworthiness, operational suitability, and environmental protection.
- For that staff, no individual statements are required. The organisation should demonstrate that there is an internal authorisation system that allows it to select, train, maintain, and identify them for all the tasks for which they are needed.
- (b) The staff that are defined in point (a) should be identified in the handbook or linked to it. This, together with the corresponding procedures, should enable that staff to carry out the assigned tasks and to properly discharge the associated responsibilities.

## GM No ~~AMC2~~ to 21.A.243(d) Data requirements – Statement of the qualification and experience – Organisations that design minor changes to type designs or minor repairs to products

### HANDBOOK - STATEMENT OF THE QUALIFICATION AND EXPERIENCE — ORGANISATIONS THAT DESIGN MINOR CHANGES TO TYPE DESIGN OR MINOR REPAIRS TO PRODUCTS

For organisations that design minor changes to type design or minor repairs to products, the statement of the qualifications and experience that is required by point 21.A.243(d) should be addressed as follows:

(a) ~~1.~~ The nominated managers should be identified and their relevant knowledge and satisfactory experience related to the nature of the design activities that they perform should be demonstrated. For each nominated manager, the organisation should provide to the CAA evidence of competency, in a form and manner established by the CAA, ~~credentials submitted to on CAA Form 4 – DOA (see <http://easa.europa.eu/certification/application-forms.php>) in order~~ so that they may be ~~seen~~ considered to be appropriate in terms of relevant knowledge and satisfactory experience related to the nature of the design activities as performed by the organisation.

(b) ~~2.~~ The persons responsible ~~to~~for:

- ~~classify~~classifying changes to type designs or repairs (point 21.A.263(c)(1));
- ~~verify~~verifying compliance (point 21.A.239(b)(d)(2));
- ~~approve~~approving minor changes to type design and minor repairs (point 21.A.263(c)(2));  
and
- ~~issue~~issuing information or instructions (point 21.A.265(h)),

should be selected by the organisation in accordance with a procedure and criteria that are agreed ~~with~~ by the Agency the CAA.

## GM1 21.A.243(d) Data

### HANDBOOK - STATEMENT OF QUALIFICATIONS AND EXPERIENCE

#### 1. ~~—~~ Purpose

This GM provides guidelines on the following points:

- ~~Who are the persons covered by 21.A.243(d)?~~
- ~~What is requested from the applicant for these persons?~~

#### 2. ~~—~~ Who are the persons?

Three different types of functions are named or implicitly identified in the requirements of Part 21, Subpart J or in the associated AMC and GM, when using qualified and experienced personnel:

1. — the Chief Executive [(see GM No 1 to 21.A.239(a),

~~para. 3.1.2, AMC1 21.A.243(a), AMC2 21.A.245(a), GM 21.A.249, GM 21.A.265(b). As applicable, where the functions of Chief Executive and Head of the design organisation are performed by the same person, AMC1 21.A.239(d)(c)(1)(ii) and AMC1 21.A.245(a); †~~

2. the other management staff:

- the ~~H~~head of the design organisation (HDO) (see points AMC1 21.A.239(d), point (c)(1)(ii), 21.A.239(b)(2), 21.A.245(a) and ~~[see GM No 1 to 21.A.239(a), para.3.1.2, GM No 1 21.A.245, para.4.1, GM 21.A.265(b)]; †~~
- the ~~Chief of the Office of Airworthiness~~ Head of the airworthiness function, (see point 21.A.245(b)(1)); ~~or see [see GM No 1 to 21.A.245, para. 4.2]~~
- the ~~Chief head~~ of the independent monitoring function (see point 21.A.245(b)(2)); ~~of the design assurance system [see 21.A.239(a)(3) and AMC No 1 to 21.A.243(a), para.2]~~
- the safety manager (see GM1 21.A.239(c)(2), AMC1 21.A.239(c)(2) and AMC1 21.A.245(b), point (g)); and
- when a safety review board is established, the chairperson of that board, if different from the HDO (see AMC1 21.A.239(c)(2)); and

3.

the ~~staff personnel~~ making decisions affecting airworthiness, operational suitability, and environmental protection:

- compliance verification engineers (see AMC1 21.A.239(d), point (c)(1)(iii) and AMC1 21.A.239(d)(2)); ~~and [see GM No 1 to 21.A.239(a), para.3.1.3; AMC 21.A.239(b)]~~
- ~~staff personnel~~ of the Office of Airworthiness making decisions affecting airworthiness, operational suitability, and environmental protection, especially those that are linked with the 21.A.263 privileges (signing documents for release, approving classification of changes and repairs, and granting the approval of minor/major changes, supplemental type certificates (STCs) and minor/major repairs, granting the approval of service bulletins (SBs), and minor revisions to the aircraft flight manual) (see AMC1 21.A.239(d), point (c)(1)(iv)). ~~[see GM No 1 to 21.A.239(a), para. 3.1.4]~~

A statement of the qualifications and experience of the Chief Executive is not required. For the other two categories that are identified above, a statement of qualifications and experience should be provided (see AMC1 21.A.243(d) and AMC2 21.A.243(d) respectively).

3. — Kind of statement

3.1 — Chief Executive

~~The Chief Executive should provide the necessary resources for the proper functioning of the design organisation.~~

~~A statement of the qualification and experience of the Chief Executive is normally not required.~~

3.2 — Other management staff

~~The person or persons nominated should represent the management structure of the organisation and be responsible through the Head of design organisation to the Chief Executive for the execution of all functions as specified in Part 21, Subpart J. Depending~~

~~on the size of the organisation, the functions may be subdivided under individual managers.~~

~~The nominated managers should be identified and their credentials furnished to the CAA on CAA Form 4-DOA (see CAA website:~~

~~<http://easa.europa.eu/certification/application-forms.php>) in order that they may be seen to be appropriate in terms of relevant knowledge and satisfactory experience related to the nature of the design activities as performed by the organisation.~~

~~The responsibilities and the tasks of each individual manager should be clearly defined, in order to prevent uncertainties about the relations, within the organisation. Responsibilities of the managers should be defined in a way that all responsibilities are covered.~~

### ~~3.3 Personnel making decisions affecting airworthiness, operational suitability and environmental protection~~

~~For these personnel, no individual statement is required. The applicant should show to the CAA that there is a system to select, train, maintain and identify them for all tasks where they are necessary.~~

~~The following guidelines for such a system are proposed:~~

- ~~— These personnel should be identified in the handbook, or in a document linked to the handbook. This, and the corresponding procedures, should enable them to carry out the assigned tasks and to properly discharge associated responsibilities.~~
- ~~— The needs, in terms of quantity of these personnel to sustain the design activities, should be identified by the organisation.~~
- ~~— These personnel should be chosen on the basis of their knowledge, background and experience.~~
- ~~— When necessary, complementary training should be established, to ensure sufficient background and knowledge in the scope of their authorization. The minimum standards for new personnel to qualify in the functions should be established. The training should lead to a satisfactory level of knowledge of the procedures relevant for the particular role.~~
- ~~— Training policy forms part of the design assurance system and its appropriateness forms part of investigation by the CAA within the organisation approval process and subsequent surveillance of persons proposed by the organisation.~~
- ~~— This training should be adapted in response to experience gained within the organisation~~
- ~~— The organisation should maintain a record of these personnel which includes details of the scope of their authorisation. The personnel concerned should be provided with evidence of the scope of their authorisation.~~
- ~~— The following minimum information should be kept on record:
  - ~~a) Name~~
  - ~~b) Date of birth~~~~

- c) — Experience and training
- d) — Position in organisation
- e) — Scope of the authorisation
- f) — Date of first issue of the authorisation
- g) — If appropriate, date of expiry of the authorisation
- h) — Identification number of the authorisation.

The record may be kept in any format and should be controlled.

- Persons authorised to access the system should be maintained at a minimum to ensure that records cannot be altered in an unauthorised manner or that such confidential records do not become accessible to unauthorised persons.
- Personnel should be given access to their own record.
- Under the provision of 21.A.257 the CAA has a right of access to the data held in such a system.
- The organisation should keep the record for at least two years after a person has ceased employment with the organisation or withdrawal of the authorisation, whichever is the sooner.

## AMC1 21.A.245(a) Resources

### HEAD OF THE DESIGN ORGANISATION

- (a) The head of the design organisation (HDO) should:
- (1) have sufficient knowledge and authority to be able to respond to the CAA regarding major issues concerning the design organisation (DO) and the product design approval, and to carry out any necessary improvements;
  - (2) promote the safety policy that is specified in AMC1 21.A.239(c)(1); and
  - (3) demonstrate a Part 21 understanding that is sufficient to discharge the relevant responsibilities.
- (b) The handbook that is submitted in accordance with point 21.A.243 should show that the HDO has the direct or functional responsibility for all the departments of the organisation which are responsible for the design of the product. If the departments responsible for design are functionally linked, the HDO still has the ultimate responsibility for compliance of the DO with Part 21.

## AMC2 21.A.245(a) Resources

### CHIEF EXECUTIVE

- (a) The functions of Chief Executive and Head of the design organisation may be performed by the same person.
- (b) If the functions of Chief Executive and Head of design are not performed by the same person, the Chief Executive should provide the necessary resources for the proper functioning of the

design organisation. To confirm such commitment, the Chief Executive should sign, along with the HDO, the binding statement (see AMC1 21.A.243(a) paragraph (b)(20) and GM 21.A.265(b).

## AMC1 21.A.245(b) Resources

### NOMINATED MANAGERS

- (a) The person or group of persons nominated in accordance with point 21.A.245 should represent the management structure of the organisation and be responsible for all the functions as specified in Part 21, Subpart J.
- (b) The nominated managers should be identified (see GM1 21.A.243(d)).
- (c) The responsibilities and the duties of each individual manager should be defined.
- (d) The independent monitoring function should be independent from the design and airworthiness functions. As such, the head of independent monitoring should not be at the same time, one of the other persons that are referred to in point 21.A.245(b)(1) or (b)(3), except for the safety manager. If the same person is designated to manage both the independent monitoring function and safety-management-related processes and tasks, the head of the design organisation (HDO), in order to discharge their safety accountability, should ensure that sufficient resources are allocated to both functions, taking into account the size of the organisation, and the nature and complexity of its activities.

(e) **Head of airworthiness**

If more than one team, including their management, are designated for the airworthiness function as defined in point 21.A.239(d)(1)(i), the HDO should identify the person that acts as the unique focal point for the entire design organisation (DO), i.e. the 'head of airworthiness'.

The need to designate more than one team may be triggered by the specific scope and volume of activity of the DO. For example:

- managing several lines of products (separate airworthiness representatives per line of product); and
- division between initial and continued airworthiness activities.

The tasks for which the head of airworthiness should be responsible are presented in AMC1 21.A.239(d), point (c)(1)(iv).

(f) **Head of independent monitoring**

The role of the head of independent monitoring should be to ensure that:

- (1) the activities of the organisation are monitored for compliance with the applicable requirements and any additional requirements as established by the organisation, and that those activities are performed properly under the supervision of the nominated persons that are referred to in point 21.A.245(b);
- (2) an audit plan is properly implemented, maintained, and continually reviewed and improved; and
- (3) corrections and corrective action are requested, as necessary.

(g) **Safety manager**

If more than one person is designated to establish, implement and maintain effective safety management processes as defined in point 21.A.239(c)(2), the HDO should identify the 'safety manager' as the unique focal point.

Depending on the size of the organisation and the nature and complexity of its activities, the safety manager may be assisted by additional safety personnel in performing all the safety management tasks defined in AMC1 21.A.239(c)(2) Design management system.

If the safety manager is the nominated post holder for more than one organisation approval certificate, within an integrated management system, they are to ensure the relevant risks, specific to each approval, are identified and mitigated as appropriate.

The role of the safety manager should be:

- (1) to facilitate hazard identification, as well as risk assessment and management;
- (2) to monitor the implementation of action taken to mitigate risks, as listed in the safety action plan, unless action follow-up is addressed by the independent monitoring function;
- (3) to provide periodic reports on safety performance to the safety review board (the functions of the safety review board are defined in AMC1 21.A.239(c)(2));
- (4) to ensure the maintenance of safety management documentation;
- (5) to ensure that there is safety training available, and that it meets acceptable standards;
- (6) to provide advice on safety matters; and
- (7) to ensure the initiation and follow-up of internal investigations of occurrences.

## GM1 21.A.245(c)(2) Resources

### **DIRECT SUPERVISION OF THE AIRWORTHINESS FUNCTION BY THE HEAD OF THE DESIGN ORGANISATION**

To cope with unexpected circumstances, for a period of time, it is possible for the head of the design organisation (HDO) to directly supervise the airworthiness function activities. This period of time should be limited and should typically not exceed 6 months.

Such a situation should be discussed with the CAA and may be subject to certain limitations (e.g. only continued airworthiness activities may be allowed).

## AMC1 21.A.245(d) Resources

### **MANAGEMENT REPORTING LINES AND COMPETENCIES**

- (a) Managers that are nominated in accordance with point 21.A.245(b) should report directly to the HDO through either a hierarchical or a formal functional link.
- (b) All prospective members of the design management staff and staff that are nominated in accordance with point 21.A.245(b) should:

- (1) be assessed for their competency, qualifications, and capabilities that are related to their intended duties;
  - (2) be able to demonstrate their knowledge of, and compliance with, the design management organisation procedures that are applicable to their tasks; and
  - (3) be able to demonstrate an understanding of the safety management principles, as well as human factors (HF) issues and human performance (HP) issues that are related to their tasks.
- (c) The head of airworthiness should be able to demonstrate relevant knowledge, background, and appropriate experience that is related to the product certification and continued airworthiness, including knowledge of, and experience in, managing the design assurance element of the design management system.
- (d) The head of independent monitoring should be able to demonstrate relevant knowledge, background, and appropriate experience that are related to the activities of the organisation, including knowledge of, and experience in, independent system monitoring.
- (e) The competency of the person that assumes (or the persons that assume) the function of the safety manager should include, but not be limited to, the following:
- (1) knowledge of the International Civil Aviation Organization (ICAO) standards and CAA requirements for safety management;
  - (2) an understanding of management systems, including compliance monitoring systems;
  - (3) an understanding of risk management;
  - (4) an understanding of safety investigation techniques;
  - (5) an understanding of HF, including HP and limitations;
  - (6) an understanding of a positive safety culture and of its promotion; and
  - (7) operational experience related to the activities of the organisation.

## AMC1 21.A.245(e) Resources

### STAFF, FACILITIES, AND COORDINATION

(a) *General*

The handbook that is submitted in accordance with point 21.A.243 should show that sufficient skilled personnel are available, and that suitable technical and organisational provisions are made for carrying out the type investigation that is defined in GM1 21.A.239(d), point (b)(3).

(b) *Personnel*

The organisation should show that the personnel that is available to comply with point 21.A.245(e)(1) are able, based on their special qualifications and numbers, to provide assurance of the design or modification of a product, as well as of the compilation and verification of all the data that is needed to meet the applicable type certification basis, operational suitability data (OSD) certification basis, and environmental protection requirements, while taking into account the state of the art and new experience.



The organisation should have a system in place to plan the availability of staff to ensure that the organisation has sufficient appropriately qualified staff to plan, perform, supervise, inspect, and monitor the organisation's activities in accordance with the organisation's terms of approval.

(c) *Technical*

The organisation should have access to:

- (1) workshops and production facilities that are suitable for manufacturing prototype models and test specimens; and
- (2) accommodation and test facilities that are suitable for carrying out the tests and measurements that are needed to demonstrate compliance with the type certification basis, OSD certification basis, and environmental protection requirements; the test facilities may be subject to additional technical conditions that are related to the nature of the tests performed.

(d) *Organisation*

The handbook that is submitted in accordance with point 21.A.243 should show that:

- (1) the responsibilities for all the tasks that are related to the certification process are assigned in such a way that gaps in authority are excluded;
- (2) the responsibility for a number of tasks as in point (d)(1) may be assigned to one person, especially in cases of simple projects; and
- (3) coordination between technical departments and the persons in charge of the system monitoring that is required by point 21.A.239(e) is established:
  - (i) to ensure the quick and efficient reporting and resolution of difficulties that are encountered using the handbook and associated procedures;
  - (ii) to maintain the design management system; and
  - (iii) to optimise auditing activities.

(e) *Competency and training*

- (1) The organisation should establish and control the competency of the staff that is involved in the activities of the organisation, as detailed in the organisation's terms of approval, in accordance with documented procedures. In addition to the necessary expertise that is related to the job function, the competency of the staff should include an understanding of safety management and human factors (HF) principles, which is appropriate to the staff member's function and responsibilities in the organisation.
- (2) To assist in the assessment of competency and to perform the analysis of the training needs, job (job family) descriptions are recommended, which should contain sufficient criteria to enable the required competency assessment throughout the duration of the employment/contract.
- (3) The organisation should develop a procedure that describes the process for assessing the competency of the staff. The procedure should specify:

- (i) the staff that are responsible for that process;
  - (ii) the means and methods for the initial assessment;
  - (iii) the means and methods for the continuous control of the competency of the personnel, including feedback on their performance;
  - (iv) the action to be taken if the assessment is not satisfactory; and
  - (v) how to record assessment results.
- (4) Adequate initial and recurrent training should be provided in relation to the job function to ensure that staff remain competent. This training should be adapted based on experience that is gained within the organisation (for safety training, refer also to AMC1 21.A.239(c)(5)(i)).
- (5) The organisation should record the training that is provided as described in point (e)(4).

## GM No 1 to 21.A.245 Requirements for approval

See 21.A.245

- 1.—*General.* The data submitted in accordance with 21.A.243 should show that sufficient skilled personnel are available and suitable technical and organisational provisions have been made for carrying out the Type Investigation defined by GM No 1 to 21.A.239(a), paragraph 2.3.
- 2.—*Personnel.* The applicant should show that the personnel available to comply with 21.A.245(a) are, due to their special qualifications and number, able to provide assurance of the design or modification of a product, as well as the compilation and verification of all data needed to meet the applicable CS and environmental protection requirements while taking into account the present state of the art and new experience.
- 3.—*Technical.* The applicant should have access to:
  - a.—Workshops and production facilities which are suitable for manufacturing prototype models and test specimens.
  - b.—Accommodation and test facilities which are suitable for carrying out tests and measurements needed to demonstrate compliance with the CS and environmental protection requirements. The test facilities may be subjected to additional technical conditions related to the nature of tests performed.
- 4.—*Organisation.* The data submitted in accordance with 21.A.243 should show that:
  - 4.1—The Head of the design organisation for which an application for approval has been made, has the direct or functional responsibility for all departments of the organisation which are responsible for the design of the product. If the departments responsible for design are functionally linked, the Head of the design organisation still carries the ultimate responsibility for compliance of the organisation with Part 21 Subpart J.
  - 4.2—An Office of Airworthiness, or equivalent function, has been established and staffed on a permanent basis to act as the focal point for co-ordinating airworthiness, operational suitability and environmental protection matters (see GM No 1 to 21.A.239(a) paragraph

~~3.1.4); it reports directly to the Head of the design organisation or is integrated into an independent quality assurance organisation reporting to the Head of the design organisation.~~

~~4.3 [Reserved]~~

~~4.4 Responsibilities for all tasks related to Type Investigations are assigned in such a way that gaps in authority are excluded.~~

~~4.5 The responsibility for a number of tasks as in paragraph 4.4 may be assigned to one person especially in the case of simple projects.~~

~~4.6 Co-ordination between technical departments and the persons in charge of the system monitoring required by 21.A.239(a)(3) has been established:~~

~~a. to ensure quick and efficient reporting and resolution of difficulties encountered using the handbook and associated procedures~~

~~b. to maintain the design assurance system~~

~~c. to optimise auditing activities.~~

## **GM No 2 to 21.A.245 Requirements for approval – Organisations designing minor changes to type design or minor repairs to products**

The data submitted in accordance with 21.A.243 should show that:

- ~~1. The manager responsible for design has the direct or functional responsibility for all departments of the organisation which are involved in the design of minor changes to type design or minor repairs to products.~~
- ~~2. Person(s) have been nominated to liaise with the CAA and to co-ordinate airworthiness, operational suitability and environmental protection matters. Their position in the organisation should allow direct report to the manager responsible for design.~~
- ~~3. Responsibilities for all tasks related to the design and approval of minor changes to type design or minor repairs to products are assigned to ensure that all areas are covered~~
- ~~4. The responsibility for a number of tasks as in paragraph 3 may be assigned to one person especially in the case of simple projects.~~

## **GM1 21.A.247 Significant Changes in the design management system Significant changes to the design management system**

In addition to a change in ownership (see point 21.A.249), the following changes to the design assurance management system should be considered to be 'significant' ~~to~~for the demonstration of

compliance, or for the airworthiness, operational suitability, or environmental protection of the products:

(a) 1. Organisation

- Relocation to new premises (see also GM 21.A.249);
- A change in the industrial organisation (partnership, subcontractors, suppliers, design work sharing), unless it can be shown that the independent verification checking function of the demonstration of compliance is not affected;
- A change in the parts of the organisation that contribute directly to the airworthiness, operational suitability, or environmental protection (independent verification checking function, airworthiness function office of airworthiness (or equivalent));
- A change to the independent monitoring principles of compliance and adequacy (see point 21.A.239(e)(a)(3)).

(b) 2. Responsibilities

- Change of the management personnel staff:
  - the Head of the design organisation (HDO) (see point 21.A.245(a)) (GM No 1 to 21.A.239(a), para. 3.1.2; GM No 1 to 21.A.245, para. 4.1; GM 21.A.265(b));
  - the head of Office of Airworthiness (see point 21.A.245(b)) (GM No 1 to 21.A.245, para. 4.2); and
  - the head of independent monitoring of compliance and adequacy of the design management assurance system (see point 21.A.245(b)(2)) (21.A.239(a)(3) and AMC No 1 to 21.A.243(a), para. 2); and
  - the safety manager (see point 21.A.239(c)(2)).
- Reporting lines between the personnel that is nominated in accordance with point 21.A.245(b) and the HDO.
- ~~New distribution~~ Allocation of responsibilities that affecting safety, airworthiness, operational suitability, or environmental protection.;
- ~~For organisations designing minor changes to type design or minor repairs to products, change of the persons identified in GM No 2 to 21.A.243(d).~~

(c) 3. Procedures

Change to the principles of procedures related to:

- the type certification;
- the classification of changes and repairs as 'major' or 'minor' (see point 21.A.263(c)(1));
- the ~~treatment~~ handling of major changes and major repairs;
- the approval of the design of minor changes and minor repairs (see point 21.A.263(c)(2));
- the approval of the design of certain major repairs (see point 21.A.435(b) or 21.A.263(c)(5));

- the approval of the conditions under which a permit to fly can be issued (see point 21.A.263(c)(6));
- the issue of a permit to fly (see point 21.A.263(c)(7));
- the approval of certain major changes to a type certificate (TC) (see point 21.A.263(c)(8));
- the approval of certain supplemental type certificates (STCs) (see point 21.A.263(c)(9));
- the approval of certain major changes to certain STCs supplemental type certificates; (see point 21.A.263(c)(9));
- continued airworthiness or continued operational suitability (see point 21.A.3B);
- the configuration control, when airworthiness, operational suitability, or environmental protection is affected;
- the acceptability of design tasks that are undertaken by partners or subcontractors (see point 21.A.239(d)(3)(e));
- the issue of data and information under the obligation of point 21.A.265(h); and — the safety risk management process (see point 21.A.239(c)(3)).

(d) ~~4~~ Resources

- A substantial ~~Substantial~~ reduction in the number and/or experience of personnel ~~staff~~ (see point 21.A.245(e) ~~(d)~~ (1)).

## GM-ELA No 1 to 21.A.247 Changes in design management assurance system

[...]

## GM-ELA No 1 to 21.A.257 Investigations – Arrangements

Investigations by the CAA may include enquiries, questions, discussions, explanations and inspections of products that are developed under the scope of approval of the DOA.

The design organisation should assist the CAA in its investigations by providing appropriate means to allow EASA to perform these inspections and audits, such as meeting rooms and office support.

If design partners or subcontractors fulfil nominated functions within the DO, for example as CVEs, the organisation should coordinate access to the subcontractor, when it is explicitly requested by the CAA on a specific subject.

Any failure to allow the CAA access to facilities to conduct investigations will be classified as a level 1 finding.

## GM 21.A.257(a) Investigations

~~Arrangements that allow the CAA to make investigations include the complete design organisation including partners, sub-contractors and suppliers, whether they are in the State of the applicant or not, assisting and co-operating with the CAA in performing inspections and audits conducted during initial assessment and subsequent surveillance.~~

~~Assistance to the CAA includes all appropriate means associated with the facilities of the design organisation to allow the CAA to perform these inspections and audits, such as a meeting room and office support.~~

## AMC 21.A.263(c)(6) Procedure for the approval of the conditions for issuing a permit to fly

[...]

CAA Form 18A

[...]

S

[~~strikethrough what is not applicable~~]

10a. Approved under the authority of DOA UK.21J.xyz [when privilege of 21.A.263(c)(6) applies]

10b. Submitted under the authority of DOA UK.21J. xyz [when privilege of 21.A.263(c)(6) does not apply]

[...]

## AMC-ELA No 1 to 21.A.263 Privileges and AMC-ELA No 1 to 21.A.265(h) Obligations of the holder

[...]

(d) The approval of minor revisions to the AFM and its supplements should contain the following statement: 'Revision No [YY] to AFM (or supplement) ref. [ZZ] is approved under the authority of DOA ref. UK. 21J. [XXXX]'. [...]

## SUBPART P — PERMIT TO FLY

### GM 21.A.705 CAA

An aircraft registered in a Member State is under the responsibility of this Member State regarding continuing airworthiness aspects. Consequently, any permit to fly under Part 21 is issued by that Member State, including any cases in which the aircraft will fly in another State. The permit to fly contains all the conditions and restrictions to ensure safe flight, but other airspace and operational rules remain within the competence of the authority of the State where the flight will take place. The applicant is also therefore required to ensure compliance with the relevant regulations of that State.

# SECTION B — PROCEDURES FOR THE CAA

## SUBPART A — GENERAL PROVISIONS

### GM1 21.B.6 Immediate reaction to a safety problem

#### SAFETY INFORMATION AND RECOMMENDED CONTENT FOR SAFETY ANALYSES

Safety information that stems from occurrence reports means a conclusive safety analysis that summarises individual occurrence data and provides an in-depth analysis of a safety issue, and that may be relevant for the CAA's safety action planning. A conclusive safety analysis should contain the following:

- (a) a detailed description of the safety issue, including the scenario in which the safety issue takes place; and
- (b) an indication of the stakeholders that are affected by the safety issue, including types of operations and organisations;

and, as appropriate:

- (c) a risk assessment that establishes the severity and probability of all the possible consequences of the safety issue;
- (d) information about the existing safety barriers that the aviation system has in place to prevent the likely consequences of the safety issue from occurring;
- (e) any mitigating action that is already in place or developed to deal with the safety issue;
- (f) recommendations for future action to control the risk; and
- (g) any other element that the CAA considers essential to properly assess the safety issue.

### GM 21.B.20 Responsibility for implementation

Each certificate or approval in accordance with Part 21 Section A Subparts F, G, H, I and P will normally be issued and controlled by the CAA. Therefore, to ensure consistency between the competent authorities of the Member States in issuing certificates and approvals, implementation of Part 21 should be based on the following three principles:

- a) — The establishment and maintenance of an effective organisation and corresponding processes by all competent authorities.
- b) — The operation of all competent authorities in accordance with Part 21 and its Acceptable Means of Compliance (AMC) and guidance material (GM).

As a result the responsibility for implementation comprises of the two main objectives:

- a) — To ensure that certificates and approvals are only granted to applicants that comply with the requirements of Part 21; and



- b) — To ensure sufficient visibility of the processes to give the CAA and the other Member States the necessary confidence in the certificates or approvals granted.

### AMC 21.B.30(a) Documented procedures

The various elements of the organisation for the related Part 21 activities must be documented in order to establish a reference source for the establishment and maintenance of this organisation. The documented procedures must be established in a way that it will facilitate its use. They must be clearly identified, kept up to date and made readily available to all the personnel involved in the relevant activities.

The documented procedures must cover, as a minimum, the following aspects:

- a) — policy and objectives,
- b) — organisation structure,
- c) — responsibilities and attached authority,
- d) — procedures and processes,
- e) — internal and external interfaces,
- f) — internal control procedures,
- g) — training of personnel,
- h) — cross references to associated documents,
- i) — assistance from other competent authorities or the CAA (where required).

Except for smaller competent authorities, it is likely that the information is held in more than one document or series of documents, and suitable cross reference information must be provided. For example, organisational structure and job descriptions are not usually in the same documentation as the detailed working procedures. In such cases it is recommended that the documented procedures include an index of cross references to all such other related information, and the related documentation must be readily available when required.

### AMC1 21.B.55(a) Record-keeping

#### GENERAL

- (a) The record-keeping system should ensure that all the records are accessible within a reasonable time whenever they are needed. Those records should be organised in a manner that ensures their traceability and retrievability throughout the required retention period.
- (b) All the records that contain sensitive data on applicants or organisations should be stored in a secure manner with controlled access, to ensure their confidentiality.
- (c) The records should be kept in paper form, or in an electronic format, or a combination of both. Records that are stored on microfilm or optical discs are also acceptable. The records should remain legible and accessible throughout the required retention period. The retention period starts when the record is created.

- (d) Paper record systems should use robust material that can withstand normal handling and filing. Computer record systems should have at least one backup system that should be updated within 24 hours of any new entry. Computer record systems should include safeguards to prevent unauthorised personnel from altering the data.
- (e) All the computer hardware that is used to ensure the backup of data should be stored in a different location from the one that contains the working data and in an environment that ensures that the data remains in a good condition. When hardware or software changes take place, special care should be taken that all the necessary data continues to be accessible throughout at least the full period that is specified in point 21.B.55(d).

## AMC1 21.B.55(a)(1) and (a)(2) Record-keeping

### CAA MANAGEMENT SYSTEM

The records that are related to the CAA's management system should include, as a minimum, and as applicable:

- (a) the documented policies and procedures;
- (b) the personnel files of CAA personnel, with the supporting documents related to their training and qualifications;
- (c) the results of the CAA's internal audits and safety risk management processes, including audit findings, as well as any corrective, preventive, and risk mitigation action.
- (d)

## GM1 21.B.55 Record keeping for design approvals transferred to the CAA

Record keeping related to design approvals, for which the responsibility is transferred to the CAA, will remain initially with the CAA that has granted the approvals, at the disposal of the CAA. This GM specifies the administrative documents to be kept for the various kinds of design approvals. It does not repeat the requirements put on holders of design approvals to keep records (ref. 21.A.5, 21.A.105, 21.A.118A(a)(1), 21.A.447, 21.A.605)

[...]

## SUBPART F — PRODUCTION WITHOUT PRODUCTION ORGANISATION APPROVAL

## GM1 21.B.115 and 21.B.215 Means of compliance

### ALTERNATIVE MEANS OF COMPLIANCE — GENERAL

- (a) The CAA may establish alternative means to comply with the regulation, which are different from the AMC.
- (b) AltMoC used by an organisation under the CAA oversight, may be used by another organisation, only if processed in accordance with 21.B.115 or 21.B.215, and 21.A.124A or 21.A.134A.

- (c) AltMoC that are issued by the CAA may cover the following cases:
  - (1) AltMoC applied for and used by an organisation under the oversight of the CAA and made available to that organisation.
  - (2) AltMoC to be used by multiple organisations under the oversight of the CAA and made available to these organisations, whilst not discharging its own authority responsibilities.

## AMC1 21.B.115(b) and 21.B.215(b) Means of compliance

### PROCESSING THE ALTERNATIVE MEANS OF COMPLIANCE

To meet the objective of point (b) of points 21.B.115 and 21.B.215:

- (a) the CAA should establish the means to consistently evaluate over time that all the AltMoC that are used by itself or by organisations under its oversight allow for the establishment of compliance with the regulation;
- (b) if the CAA issues AltMoC for the organisations under its oversight, it should make them available to all relevant organisations;
- (c) the CAA should evaluate the AltMoC that is proposed by an organisation by analysing the documentation provided and, if considered necessary, by inspecting the organisation; when the CAA finds that the AltMoC is in accordance with the Regulation, it should:
  - (1) notify the applicant that the AltMoC is approved;
  - (2) indicate that this AltMoC may be implemented, and agree when the production organisation exposition (POE) is to be amended accordingly.
- (d) All these elements that describe the AltMoC are an integral part of the records to be kept, which are managed in accordance with point 21.B.55.

## AMC 21.B.120(e)(1) Evaluation of applications

[...]

## GM1 21.B.125(a) 21.B.125(b) and (c), 21.B.225(b) and (c) and 21.B.430(b) Findings and corrective actions; observations **Objective evidence**

### EVIDENCE

~~Objective~~ Evidence is a fact that which is, or can be, documented, based on observations, measurements, or tests that can be verified. ~~Objective~~ Evidence generally comes from the following:

- (a) documents or manuals;
- (b) examination of equipment/products; and
- (c) information from interview questions and from observations of an organisation's production activities, as applicable.

## GM1 21.B.125(b) and (c) Findings and corrective actions; observations

### EXAMPLES OF LEVEL 1 FINDINGS

Examples of level 1 findings are non-compliance with any of the following points, which may affect the safety of the aircraft:

- point 21.A.126;
- point 21.A.127;
- point 21.A.128; and
- point 21.A.129.

It should be anticipated that non-compliance with those points is only considered a level 1 finding if there is objective evidence that that finding is uncontrolled non-compliance that could affect the safety of the aircraft.

## GM1 21.B.125(b) and 21.B.225(b) Findings and corrective actions; observations

### SIGNIFICANT NON-COMPLIANCE

Significant non-compliance includes uncontrolled non-compliance with applicable design data, which is non-compliance that:

- (a) cannot be discovered through systematic analysis; or
- (b) prevents the identification of the affected products, parts, appliances, or material.

## AMC1 21.B.125(e) Findings and corrective actions

### NOTIFICATION OF FINDINGS

In the case of a level 1 finding, confirmation from the accountable manager should be obtained in a timely manner that they have taken note of the finding and its details.

A finding requires effective oversight by the CAA to monitor the timely completion of the corrective action. That oversight may include intermediate communication, such as letters, as necessary, to remind the approval holder to verify that the corrective action plan is followed.

## GM1 21.B.125(f) and 21.B.225(f) Findings and corrective actions; observations

### DIFFERENCE BETWEEN A 'LEVEL 2 FINDING' AND AN 'OBSERVATION'

- (a) 'Findings' are issued for non-compliance with the regulation, with the organisation's procedures and manuals, or with the certificate including the terms of approval, whereas 'observations' may be issued to an organisation that remains compliant with the regulation,

while additional input to the organisation may be considered for continuous improvement (see points (1), (2), and (3) of point 21.B.125(f)).

The CAA may decide to issue a 'level 2' finding when the 'observations' process is not managed correctly or is overlooked.

- (b) Examples to help differentiate between a 'level 2 finding' and an 'observation' are provided below, based on the requirements for the control and calibration of tools in accordance with point 21.A.139(d)(2)(vii).

#### Example of a 'level 2 finding':

The organisation could not demonstrate compliance with some elements of point 21.A.145(a) regarding the control register of the tools and equipment, as evidenced by the fact that:

- (a) some sampled tools that are physically available in the tool store were missing in the tool control register that is managed by the organisation; or
- (b) one tool was not correctly identified (e.g. incorrect part number or serial number) in the tool control register.

#### Examples of 'observations':

- (a) Accumulation of tools in the tool store, which have not been yet sent for calibration. This situation may have some consequences regarding the availability of tools and the operational capabilities during a peak of activities (ineffectiveness of the process).
- (b) The process for managing the tool control register through the dedicated software is not detailed enough (potential to cause a 'level 2 finding').
- (c) The colour of the 'unserviceable' tag of the tools may generate some confusion. The organisation should consider changing the colour of that unserviceable tag to better alert its staff to the particular status of the unserviceable tools (potential improvement).

### **AMC 21.B.130 Issue of the letter of agreement**

Unless otherwise agreed by the competent authority no production before the issue of the letter of agreement may be accepted under Part 21 Section A Subpart F.

### **GM 21.B.130(b) Issue of the letter of agreement**

The agreement should include or reference a pre-defined plan of inspection points established as part of the production inspection system and agreed with the competent authority to be used as a basis for the inspections described in 21.A.129 and 21.B.120(c)(5) and its associated CS and GM. The plan should clearly identify inspection point, places, inspection subjects (materials, process, tooling documentation, human resources, etc.), as well as the focal points and the method of communication between the manufacturer and the competent authority.

The competent authority should detail a method how it will assure itself that the manufacturer is working in accordance with the manual and the agreed inspection procedures during the validity

~~period of the agreement. For renewal of this validity period the procedure as defined in 21.B.140 should be used.~~

~~Any conditions under which the agreement will expire (such as termination date and/or number of units to produce), should be clearly stated in the letter of agreement.~~

### **GM 21.B.150(d) Record keeping — Traceability of release certificates**

The recordkeeping for those CAA Forms 52 and 1 that have been validated by the competent authority should allow verification of such validation by concerned parties including the recipients of the release certificates.

## SUBPART G — PRODUCTION ORGANISATION APPROVAL

### GM1 21.B.221(b)(3) Oversight principles

#### CONTINUED SURVEILLANCE

As a minimum the holder of a production organisation approval should be subject to continued surveillance activity by the CAA at least once every year.

### AMC No 1 to 21.B.230 Issue of the certificate

The CAA should base its decision to issue or amend a POA on the recommendation report (CAA Form 56, see GM No 2 to 21.B.220(c)) of the POAT submitted by the POA team leader. The CAA Form 56 includes a proposal by the POAT for the scope and terms of approval defining the products, parts and appliances for which the approval is to be granted, with appropriate limitations. When the CAA issues the approval a final controlled copy of an acceptable exposition for the organisation should have been supplied to the CAA. In some cases it may be accepted that some findings are not fully closed because corrective actions are still in progress. The CAA may decide according to the following principles: 1) Findings should be equivalent to level two, which do not need to be rectified as a matter of urgency within less than three months, and should normally not exceed three in number. 2) Corrective action plan, including timescales, should have been accepted and should not require an additional and specific follow-up audit by the CAA. A record should be kept by the CAA and should be brought to the attention of the CAA on request for standardisation purposes.

### GM-ELA No 1 to 21.B.230 Issue of certificate

The terms of approval, which identify the products or the categories of parts and appliances, or both, for which the holder is entitled to exercise their privileges, will be described by the competent authority using standard terms, as follows:

**Starts with selection of:**

**...continues with selection from:**

**...ends with:**

Manufacturing of

aeroplanes that are within the scope of CS-LSA, CS-VLA and CS-23 level 1, not classified as complex motor-powered aircraft,

where <company> holds the type design approval, including all related spare parts.

Manufacturing of engines used on

sailplanes or powered sailplanes that are within the scope of CS-22,

Manufacturing of propeller used on

balloons,

hot-air airships,

gas airships that comply with 3 % maximum static heaviness, non-vector thrust (except reverse thrust), conventional and simple design of structure, control system and ballonet system, and non-power-assisted controls,

The type and the model should not be listed within the terms of approval. They are provided within the company's manual (or the equivalent documentation).

Changes to the list of types and models are not, in themselves, considered to be changes in the scope of work, and they should be coordinated with the competent authority.

If the scope of work is related to a restricted type design in which the approval of the engine and/or the propeller is included in the aircraft type design, the work associated with these engines and/or propellers is included in the scope of work related to the aircraft. A separate scope related to the engine and/or the propeller is not required.

### **AMC ELA No 1 to 21.B.235 Continued surveillance**

The CAA should determine whether there is continued conformity to the type design by assessing:

1. the adherence of the company to the procedures laid out in the quality system that is referenced by the POE; and
2. a representative number of sample products at various stages of production.

Surveillance activities are:

1. planned activities to a schedule that are adequate for the size, product range and production rate of the company, so as to ensure that there is a complete review within 24 months. To obtain the required complete review of the production organisation within 24 months, all the relevant stages of production should be audited once within this 24 month period;
2. unplanned activities in response to unsafe situations that may be caused by a problem in the production organisation, and that are significant enough to require a detailed assessment that cannot be delayed until the next scheduled surveillance event.

### **GM ELA No 1 to 21.B.235 Continued surveillance**

A sampling plan in support of the planned surveillance activity could, for example, include:

1. a (part of the) product with the modification (or change) incorporated;
2. the installation, testing, or operation of a major part or system;
3. the accuracy and the generation of the flight test report data;
4. the accuracy and the generation of the weighing report data;
5. an engine test bed run;
6. the traceability of production records as defined from the type design;
7. the accuracy and the generation of the statement of conformity data, and the associated determination of safe operation;



- 8. ~~the accuracy and generation of the CAA Form 1 data. It is recommended that flexibility should be allowed in the sampling plan so as to:~~
- 9. ~~accommodate changes in the rate of production;~~
- 10. ~~make use of results from other samples;~~
- 11. ~~make use of results from other POA investigations;~~
- 12. ~~provide the maximum confidence to the national authorities.~~

## **GM 21.B.235(a)(4) Guide to the conduct of monitoring production standards.**

1. ~~21.B.235(a)(4) identifies a need for a sample investigation of products, parts or appliances, their associated conformity determinations and certifications made by a POA holder. For this to be performed effectively and efficiently, the CAA should integrate a sampling plan as part of the planning of the investigation and continued surveillance activities appropriate to the scope and size of the relevant applicant.~~

2. ~~The sampling plan could, for example, investigate:~~

- ~~— a modification (or change)~~
- ~~— the installation, testing, or operation of a major part or system~~
- ~~— the accuracy and generation of the Flight Test report data~~
- ~~— the accuracy and generation of the Weighing report data~~
- ~~— an engine test bed run~~
- ~~— records traceability~~
- ~~— the accuracy and generation of the Statement of Conformity data and the associated safe operation determination~~
- ~~— the accuracy and generation of CAA Form 1 data.~~

~~The sampling plan should be flexible so as to:~~

- ~~— accommodate changes in production rate~~
- ~~— make use of results from other samples~~
- ~~— make use of results from other POA investigations~~
- ~~— provide the maximum national authorities confidence~~

~~To be effective this product sample requires that the individual investigator(s):~~

- ~~— have a good practical knowledge of the product, part or appliance~~
- ~~— have a good practical knowledge of the manufacturing processes~~
- ~~— have an up to date knowledge of the manufacturers production programme~~
- ~~— use an appropriate and up to date sample plan and compliance check lists~~

- have a suitable recording system for the results
- have a properly operating feedback system to their national authorities organisation for POA and the manufacturer
- maintain an effective working relationship with the manufacturer and his staff
- be able to communicate effectively

### **GM 21.B.235(b) Maintenance of the POA – Work allocation within the competent authority**

After issue of the approval the competent authority should appoint a suitable member of its technical staff as the POATL to be in charge of the approval for the purpose of continued surveillance.

Where the POA holder facilities are located in more than one Member State the competent authority of the State of manufacture will liaise with the competent authorities of the various partners/members to ensure appropriate continued surveillance.

### **GM 21.B.235(b) and (c) Continued surveillance**

Continued surveillance consists of:

1. Planned continued surveillance, in which the total surveillance actions are split into several audits, which are carried out at planned intervals during the validity period of the production organisation approval. Within the continued surveillance one aspect may be audited once or several times depending upon its importance.
2. Unplanned POA reviews, which are specific additional investigation of a POA holder related to surveillance findings or external needs. The competent authority is responsible for deciding when a review is necessary taking into account changes in the scope of work, changes in personnel, reports on the organisation performance submitted by other CAA or national authorities teams, reports on the in service product.

### **AMC 21.B.235(c) Continuation of POA**

At the end of the 24 months continued surveillance cycle the POATL responsible for the POA should complete a CAA Form 56 (see GM No 2 to 21.B.220(c)) as a summary report for the continued surveillance including the recommendation for continuation of the POA as applicable. The CAA Form 56 should be countersigned by the person responsible within the competent authority for his acceptance. At this stage there is no limitation to the number of level two findings that may be open, provided they are within the time limits of the respective corrective action plans.

### **AMC1 No 1 to 21.B.240 Application for significant changes or variation of scope and terms of the POA** Changes in the production management system

#### **APPLICATION FOR SIGNIFICANT CHANGES OR VARIATION OF SCOPE OF TERMS OF THE POA**

The CAA must receive an application for significant changes or variation of scope and terms of the POA on a CAA Form 51 (see below) completed by the applicant.

**CAA Form 51**

**Application for significant changes or variation of the scope or terms of a Part 21 POA**

<b>United Kingdom</b>	
<b>CAA</b>	
1. Name and address of the POA holder:	
2. Approval reference number:	
3. Location(s)	
4. Brief summary of the proposed changes to the activities at the Item 3 addresses:	
(a) General:	
(b) Scope of approval:	
(c) Nature of privileges:	
5. Description of organisational changes:	

6. Position and name of the accountable manager or nominee:	
<hr/> Date	<hr/> Signature of the accountable manager (or nominee)

CAA Form 51

Block 1: The name must be entered as written on the current approval certificate. Where a change in the name is to be announced state the old name and address here, while using Block 5 for the information about the new name and address. The change of name and/or address must be supported by evidence, e.g. by a copy of the entry in the register of commerce.

Block 2: State the current approval reference number. UK Regulation (EU) 748/2012 Annex I - PART 21 September 2023 Page 727 Block 3: State the locations for which changes in the terms of approval are requested or state 'not applicable' if no change is to be anticipated here. Block 4: This Block should include further details for the variation of the scope of approval for the addresses indicated in

Block 3. The Block 'General' must include overall information for the change (including changes e.g. in workforce, facilities etc.), while the Block 'Scope of approval' must address the change in the scope of work and products/categories following the principles laid down in the GM 21.A.151. The Block 'nature of privileges' must indicate a change in the privileges as defined in 21.A.163(b)- (d). State 'not applicable' if no change is anticipated here.

Block 4: This Block should include further details for the variation of the scope of approval for the addresses indicated in Block 3. The Block 'General' must include overall information for the change (including changes e.g. in workforce, facilities etc.), while the Block 'Scope of approval' must address the change in the scope of work and products/categories following the principles laid down in the GM 21.A.151. The Block 'nature of privileges' must indicate a change in the privileges as defined in 21.A.163(b)- (d). State 'not applicable' if no change is anticipated here.

Block 5: This Block must state the changes to the organisation as defined in the current production organisation exposition, including changes the organisational structure, functions and responsibilities. This Block must therefore also be used to indicate a change in the accountable manager in accordance with 21.A.145(c)(1) or a change in the nomination of the responsible managers in accordance with 21.A.145(c)(2). A change in the nomination of responsible managers must be accompanied by the corresponding CAA Forms 4. State 'not applicable' if no change is anticipated here.

Block 6: State the position and name of the accountable manager here. Where there is a change in the nomination of the accountable manager, the information must refer to the nominee for this position. State 'not applicable' if no change is anticipated here.

In case of an application for a change of the accountable manager the CAA Form 51 must be signed by the new nominee for this position. In all other cases the CAA Form 51 must be signed by the accountable manager.

## **AMC-ELA No 1 to 21.B.245 Suspension and revocation of a production organisation approval CAA**

ORS9 Decision No. 1

If there is a level 1 finding and the CAA intends to limit the production organisation approval (POA), the CAA should not limit the possibility for the manufacturer to issue or release conformity certificates unless it is absolutely necessary to do so. In that case, the CAA may apply conditions for the issue or release of conformity certificates.

## **GM 21.B.245 Continued validity**

### **1. GENERAL**

Decisions on restriction, surrender, suspension or revocation of POA will always be actioned in such a way as to comply with any applicable national laws or regulations relating to appeal rights and the conduct of appeals, unless the decision has been taken by the CAA. In such case, the CAA appeal procedures will apply.

2. RESTRICTION is temporary withdrawal of some of the privileges of a POA under 21.A.163.

3. SURRENDER is a permanent cancellation of a production organisation approval by the CAA upon formal written request by the accountable manager of the organisation concerned. The organisation effectively relinquishes its rights and privileges granted under the approval and, after cancellation, may not make certifications invoking the approval and must remove all references to the approval from its company documentation.

4. SUSPENSION is temporary withdrawal of all the privileges of a production organisation approval under 21.A.163. The approval remains valid but no certifications invoking the approval may be made while the suspension is in force. Approval privileges may be re-instated when the circumstances causing the suspension are corrected and the organisation once again can demonstrate full compliance with the Requirements.

5. REVOCATION is a permanent and enforced cancellation of the whole of an approval by the CAA. All rights and privileges of the organisation under the approval are withdrawn and, after revocation, the organisation may not make any certifications or other statements invoking the approval and must remove all references to the approval from its company documentation.

## **AMC 21.B.245 Corrective action plan**

It is expected that any established POA holder will move quickly to re-establish compliance with Part 21 and not risk the possibility of approval suspension. Therefore, the corrective action period granted by the CAA must be appropriate to the nature of the finding but in any case initially must not be more than six months. In certain circumstances and subject to the nature of the finding the CAA can vary

~~the six months period subject to a satisfactory corrective action plan agreed by the CAA. Failure to comply within time scale agreed by the CAA means that provisional suspension of the POA in whole or in part must proceed.~~