

## ANNEX TO ED DECISION 2023/014/R

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

#### Issue 2, Amendment 16

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

- deleted text is struck through;
- new or amended text is highlighted in blue;
- an ellipsis '[...]' indicates that the rest of the text is unchanged.

#### Note to the reader

In amended, and in particular in existing (that is, unchanged) text, 'Agency' is used interchangeably with 'EASA'. The interchangeable use of these two terms is more apparent in the consolidated versions. Therefore, please note that both terms refer to the 'European Union Aviation Safety Agency (EASA)'.



## **ANNEX I (PART 21)**

[...]



### SECTION A — TECHNICAL REQUIREMENTS

### **SUBPART A — GENERAL PROVISIONS**

## 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 (RTCs), 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 European technical standard order (ETSO) 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,
   ETSO design data, and repair design data;
- 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 AMC1 21.A.433(b).

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

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

## GM1 21.A.5 Repair designs and record keeping

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

### 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 auxilliary power unit (APU) European technical standard order (ETSO) 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.

## SUBPART F — PRODUCTION WITHOUT PRODUCTION ORGANISATION APPROVAL

### AMC1 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 competent authority that coordination is satisfactory.

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

- (a) the responsibilities of a DO 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) the responsibilities and procedures of the PO for receiving, managing and using the applicable design data provided by the DO;
- (c) the responsibilities and procedures of the PO for developing, where applicable, its own manufacturing data in compliance with the applicable design data package;
- (d) the responsibilities of the PO to assist the DO 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) the scope of the arrangements covering Subpart F requirements, in particular, points 21.A.126(a)(4), 21.A.129(d), and 21.A.3A, and any associated GM or AMC;
- (f) the responsibilities of the PO, in the case of products prior to type certification, to assist a DO 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) the procedures to deal adequately with production deviations and non-conforming parts;



- the means to achieve adequate configuration control of manufactured parts, to enable the PO to make the final determination and identification for conformity or airworthiness release and eligibility status;
- (i) the identification of responsible persons who control the above; and
- (j) the acknowledgment by the holder of the TC/STC/repair or change approval/ETSO authorisation that the approved design data that is provided, controlled and modified in accordance with the arrangement 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. This is acceptable, provided that an effective link between the DAH and the PO can be maintained to satisfy the intent of point 21.A.122.

When the DO and the PO are two separate legal entities, a direct delivery authorisation 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 direct delivery authorisation, specific permissions may be granted (see AMC 21.A.4).

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

#### **LINK BETWEEN DESIGN AND PRODUCTION**

In accordance with AMC1 No 1 to 21.A.122 the person producing or intending to produce under Part 21 Subpart F should demonstrate to the authority that it has entered into an arrangement with the design organisation. The arrangement must be documented irrespective of whether the two organisations are separate legal entities or not.

The documented arrangement must facilitate the person producing or intending to produce under Part 21 Subpart F to demonstrate compliance with the requirement of 21.A.122 by means of written documents agreed.

In the case where the design organisation and the person producing or intending to produce under Part 21 Subpart F are part of the same legal entity these interfaces may be demonstrated by company procedures accepted by the competent authority.

In all other cases to define such a design/production interface the following sample format is offered:

Arrangement Sample Form

ARRANGEMENT in accordance with 21.A.122		
The undersigned agree on the following commitments:	Relevant interface procedures	
The design organisation [NAME] takes responsibility to: 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.) to the person producing under Part 21 Subpart F [NAME] provide visible statement(s) of approved design data.		



The person producing under Part 21 Subpart F [Nassist the design organisation [Name] in dealing matter and for required actions			
assist the design organisation [NAME] in case certification in demonstrating compliance w			
develop, where applicable, its own manufacturing airworthiness data package.	ng data in compliance with the		
The design organisation [NAME] and the person Subpart F [NAME] take joint responsibility to: deal adequately with production deviations accordance with the applicable procedures the manufacturer producing under Part 21 S	and non-conforming parts ir of the design organisation and		
achieve adequate configuration control of man manufacturer producing under Part 21 S determination and identification for conform	Subpart F to make the fina		
The scope of production covered by this arrange LIST]	ment is detailed in [DOCUMEN	T REFERENCE/ATTACHED	
[When the design organisation is not the same le Subpart F]	egal entity as the manufacturer	producing under Part 21	
Transfer of approved design data: The TC/STC/ETSO authorisation holder [NAME] a controlled and modified in accordance with the a authority and therefore the parts and appliances condition for safe operation may be released cer approved design data and is in a condition for sa [When the design organisation is not the same less Subpart F]	arrangement are recognised as manufactured in accordance vitifying that the item was manufe operation.	approved by the competent vith these data and found in a factured in conformity to	
Direct Delivery Authorisation:  This acknowledgment includes also [OR does not include] the general agreement for direct delivery to end users in order to guarantee continued airworthiness control of the released parts and appliances.			
For the [NAME of the design organisation/DOA holder]		rson producing under Part 21	
Date: Signature: xx.xx.xxxx	Date: xx.xx.xxxx	Signature:	
([NAME in block letter	rs])	([NAME in block letters])	

### Instructions for completion:

Title: The title of the relevant document must clearly indicate that it serves the purpose of a design/production interface arrangement in accordance with 21.A.122.

Commitment: The document must include the basic commitments between the design organisation and the manufacturer producing under Part 21 Subpart F as addressed in AMC 21.A.4 and AMC No-1 to-21.A.122.

Relevant Procedures: Identify an entry point into the documentary system of the organisations with respect to the implementation of the arrangement (for example a contract, quality plan, handbooks, common applicable procedures, working plans etc.).





Scope of arrangement: The scope of arrangement must state by means of a list or reference to relevant documents those products, parts or appliances that are covered by the arrangement.

Transfer of approved design data: Identify the relevant procedures for the transfer of the applicable design data required by 21.A.122 and AMC-No-1-to-21.A.122 from the design organisation to the person producing under Part 21 Subpart F. The means by which the design organisation advises the person producing under Part 21 Subpart F whether such data is approved or not approved must also be identified (ref. 21.A.4 / AMC 21.A.4).

Direct Delivery Authorisation: Where the design organisation and the person producing under Part 21 Subpart F are separate legal entities the arrangement must clearly identify whether authorisation for direct delivery to end users is permitted or not.

Where any intermediate production/design organisation is involved in the chain between the original design organisation and the person producing under Part 21 Subpart F, evidence must be available that this intermediate organisation has received authority from the design organisation to grant Direct Delivery Authorisation.

Signature: AMC-No-1 to-21.A.122 requests the identification of the responsible persons/offices who control the commitments laid down in the arrangement. Therefore the basic document must be signed mutually by the authorised representatives of the design organisation and the manufacturer producing under Part 21 Subpart F in this regard.



#### SUBPART G — PRODUCTION ORGANISATION APPROVAL

## AMC-ELA No 1 to 21.A.131 Scope

The AMC-ELA in this Subpart provide acceptable means of compliance for the issuance of a production organisation approval for organisations that produce

- aeroplanes that are within the scope of CS-LSA, CS-VLA and CS-23 level 1;
- sailplanes or powered sailplanes that are within the scope of CS-22; or
- balloons, hot-air airships and gas airships that are ELA2 aircraft,

that are not classified as complex motor-powered aircraft, as well as products or parts used on these products.

## GM-ELA No 1 to 21.A.131 Scope — General applicability of AMC-ELA and the use of AMC-ELA as a baseline outside its scope

The AMC indicated with 'AMC-ELA' and the GM related to them (as indicated with 'GM-ELA'), provide an alternative set of AMC and GM to the other available AMC and GM.

The AMC-ELA provide acceptable means to meet the requirements for small, non-complex organisations that produce aircraft as specified in AMC-ELA No 1 to 21.A.131.

If the AMC ELA are not applicable (for instance for small, non-complex organisations that produce other low risk products that are outside the scope of AMC ELA No 1 to 21.A.131, e.g. light rotorcraft, CS-23 Level 2, etc.), the applicant is not obliged to use any other available AMC. Switching to those other available AMC will not necessarily provide a means of compliance that is proportionate. Since AMC are a means, but not the only means, of showing compliance, applicants and approval holders can also propose alternative means of compliance. These alternative means can use the AMC ELA as a baseline, and complement them by additional or more stringent controls, processes or methods. This allows a gradual increase in the level of detail of the established procedures and the thoroughness of the implemented tools for POA approval. This enables the introduction of a proportionate approach that is commensurate with the kind of product and its associated risk or its production process risks, as a function of the complexity of the organisations and the risk and performance of the product. Using the AMC ELA as a baseline for POA outside the applicability of the AMC ELA is therefore considered to be an appropriate starting point.

Complementary elements need to be detailed, documented and recorded to a level at which the occurrence of repetitive non-conformities is mitigated. Applicants and approval holders need to demonstrate to the competent authority in such cases that those additional means meet the requirements that are appropriate for the products being produced.



## GM-ELA No 2 to 21.A.131 Scope – AMC-ELA as a complete, self-contained set of AMC

The AMC-ELA provide an alternative, complete and self-contained set of AMC. Applicants or POA holders that manufacture products or parts within the scope of AMC-ELA can use AMC-ELA instead of the existing AMC to Subpart G.

The AMC-ELA in full determine the acceptable means of compliance with Subpart G. The applicant should implement each of the means defined here on an individual basis. If the specific characteristics of the organisation render individual elements of AMC-ELA impracticable or not applicable, alternative means with a specific resolution should be agreed with the competent authority. A justification needs to be developed to show that the means that are applied meet the requirements of Part-21. A trustful relationship between the typically very compact team of the applicant and the competent authority should be developed. The applicant is strongly encouraged to ask the relevant contact person at the competent authority for mutual clarification of any questionable item, if there is any doubt.

## GM-ELA No 3 to 21.A.131 Scope - Applicable design data

GM 21.A.131 applies.

# GM-ELA No 4 to 21.A.131 Scope - Explanation of terms used in AMC-ELA

'A method needs to be practised'.

When AMC-ELA applies the principle that 'a method needs to be practised', it means that the applicant can show what is actually done in order to comply with a requirement in a practical but systematic way. The applicant is not expected to have an excessively detailed documented procedure. As a baseline, documented procedures for such 'practised methods' can be limited to a declaration of the principles that are considered within the practised method. For example, a declaration such as 'Document control is ensured by the workflow management as part of the IT-based Document Management System (DMS)', may be provided. This is acceptable when evidence is provided by work results, by the demonstration of satisfactory conduct during surveillance activities, or by similar means. When the actions that are continuously performed show that they do not satisfy the needs of the AMC, a more detailed and documented procedure may need to be implemented to rectify the situation.

#### 'Delegation of tasks and responsibilities'

AMC ELA differentiates between the delegation of tasks and the delegation of responsibilities. For small and simple organisations, the delegation of responsibilities to specific and separate organisational positions can create overly burdensome administrative processes that do not reflect the operational reality. The AMC-ELA accepts that tasks can be delegated, while the responsibility formally remains with the delegator. This can increase efficiency, and it offers the possibility for the applicant to simplify procedures. A typical example is when the accountable manager delegates tasks, while keeping the responsibility associated with these tasks. If this situation is identified with respect



to the individual requirements, this may significantly reduce the effort required for documentation, and it allows streamlined methods to be practised.

#### 'Consolidated team'

AMC-ELA makes reference to companies working in a 'consolidated team', mainly in relation to coordination between the design and production activities. Companies are considered to be working in consolidated teams if the following criteria apply:

- Even when a consolidated team spans across different legal entities, it acts as one organisation;
- A consolidated team is expected to work within one consolidated setup, and under one management, so that a free flow of information is inherently ensured;
- In a consolidated team, functions are not duplicated, so the same person(s) takes care of both the production and design aspects of any one function;
- Responsibilities are defined at the level of the person or the position, not at the level of the legal entity;
- Within consolidated teams, adequate coordination is expected to be present through 'practised methods', without any further written definitions of responsibilities beyond those elements that are explicitly described within AMC-ELA.

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

The link between design and production is appropriately arranged when the organisation responsible for production and the one responsible for design both work within one consolidated team. The following documented arrangement may be used between the production organisation and the applicant for, or the holder of, a type design, in order to record their respective responsibilities.

#### **ARRANGEMENT**

in accordance with AMC-ELA No 1 to 21.A.133(c)

#### The undersigned agree on the following commitments:

The design organisation [NAME] takes responsibility for

- assuring the 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.) to the production organisation approval holder [NAME];
- providing visible statement(s) of approved design data.

The production organisation approval holder [NAME] takes responsibility for

- assisting the design organisation [NAME] in dealing with continuing airworthiness matters and for required actions;
- assisting the design organisation [NAME], with products prior to type certification, in demonstrating products' compliance with the certification specifications;
- developing, where applicable, its own manufacturing data in compliance with the airworthiness data package.

The design organisation [NAME] and the POA holder [NAME] take joint responsibility for



- dealing adequately with production deviations and non-conforming parts in accordance with the applicable procedures of the design organisation and the production organisation approval holder;
   achieving adequate configuration control of manufactured parts to enable the POA holder to make the
- final determination and identification for conformity.

The scope of production that is covered by this arrangement is detailed in the POE

[If the design organisation is not the same legal entity as the production organisation approval holder]

### Transfer of approved design data:

The TC/STC/ETSO holder [NAME] acknowledges that the approved design data provided, controlled and modified in accordance with this arrangement are recognised as having been approved by the competent authority, and that therefore, the parts and appliances manufactured in accordance with these data and found to be in a condition for safe operation may be released, certifying that the item was manufactured in conformity to approved design data and is in a condition for safe operation.

[If the design organisation is not the same legal entity as the production organisation approval holder]

#### **Direct Delivery Authorisation:**

This acknowledgment also includes [OR does not include] the general agreement for direct delivery to end users in order to guarantee continued airworthiness control of the released parts and appliances.

users in order to guarantee continued airworthiness control of the released parts and appliances.				
For the [NAME of the design organisation/DOA holder]		For the [NAME of the POA holder]		
Date:	Signature:	Date:	Signature:	
<del>xx.xx.xxx</del>		<del>xx.xx.xxx</del>		
	[NAME in block letters]		[NAME in block letters]	

## AMC-ELA No 2 to 21.A.133(c) Eligibility – Link between design and production

If the approval is held or is applied for by a different entity, and the work is not performed by one consolidated team, an arrangement in accordance with AMC-ELA No 1 to 21.A.133(c) is not sufficient. The roles and responsibilities for the coordination between the design and production staff (in both directions) need to be established. This may be achieved, for example, by simple flow chart definitions supported by strong, self-explanatory forms, or by task descriptions of responsible functions in the organisation, or by equivalent means. IT-based enterprise resource planning (ERP) systems can be used to ensure and to demonstrate that there is a correct flow of information on the basis of defined and visible workflows with assigned roles and release gates, without any further need for written definitions. Further means with a comparable effect are possible. Internal and external audits can verify that the coordination functions properly.

## AMC1 21.A.134 Application

#### **APPLICATION FORM**

An applicant for a POA should complete and submit to the competent authority an EASA Form 50 (see below).



The completed form, an outline of the production organisation exposition, and details of the proposed terms of approval should be forwarded to the competent authority.

EASA Form 50  Application for a Part 21 production organisation approval				
Competent authority  of an EU Member State or  EASA				
1. Registered name and address of the organisation:				
2. Trade name (if different):				
3. Location(s) for which the approval is applied for:				
4. Brief summary of the proposed activities at the addre	esses listed in Block 3:			
a) General:				
b) Scope of approval:				
c) Nature of privileges:				
5. Description of organisation:				
6. Links/arrangements with design approval holder(s)/design organisation(s) where different from 1.:				
7. Approximate number of staff engaged or intended to be engaged in the activities:				
8. Position and name of the accountable manager:				
Date	Signature of the accountable manager			

EASA Form 50



- Block 1: The name of the organisation should be entered as stated in the register of the National Companies Registration Office. For the initial application, a copy of the entry in the register of the National Companies Registration Office should be provided to the competent authority.
- Block 2: State the trade name by which the organisation is known to the public if it is different from the information given in Block 1. The logo of the organisation may be used in this block.
- Block 3: State all the locations for which the approval is applied for. Only those locations should be stated that are directly under the control of the legal entity stated in Block 1.
- Block 4: This block should include further details of the activities under the approval for the addresses indicated in Block 3 The 'General' block must include overall information, while the 'Scope of approval' block should address the scope of work and the products/categories following the principles laid down in GM 21.A.151. The 'Nature of privileges' block should indicate the requested privileges as defined in points 21.A.163(b)-(e). For an application for renewal, state 'not applicable'.
- Block 5: This block should provide a summary of the organisation with reference to the outline of the production organisation exposition, including the organisational structure, functions and responsibilities. The nomination of the responsible managers in accordance with point 21.A.145(c)(2) should be included as far as possible. For an application for renewal, state 'not applicable'.
- Block 6: The information entered here is essential for the evaluation of the eligibility of the application. Therefore, special attention should be given concerning the completion of this block, either directly or by reference to supporting documentation, in relation to the requirements of points 21.A.133(b) and (c) and the AMC to 21.A.133(b) and (c).
- Block 7: The information to be entered here should reflect the number of staff, or in the case of an initial approval, the intended number of staff for the complete set of activities that are to be covered by the approval, and it should also therefore include any associated administrative staff.
- Block 8: State the position and name of the accountable manager.

### GM 21.A.134 Application - Application form and manner

EASA Form 50 (see <u>AMC 21.B.220(c)</u>) should be obtained from the competent authority, and completed by the accountable manager of the organisation.

The completed form, an outline of the production organisation exposition, and details of the proposed terms of approval are to be forwarded to the competent authority.

### GM-ELA No 1 to 21.A.134 Scope - Application

GM 21.A.134 applies.

## AMC1 21.A.139(c)(2) Production management system

**ORGANISATION AND 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.145(c)(2).
- (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). Its composition can be adapted to its needs, considering point 21.A.245(c)(2) 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 competent authority'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(d)(2)(ii)(b)(1)(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

The production organisation is required by point 21.A.139(d) to demonstrate that it has established and maintains a quality 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 system should have, among other requirements, procedures to adequately carry out the assessment and surveillance of suppliers.

The use of other parties (OPs), 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 OPs.

The purpose of using an OP 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 system) to be delegated to another organisation under controlled conditions.

The use of OPs 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 an OP for the purpose of assessing and/or surveying a 'POA's supplier.

- (2) Reserved
- (3) Conditions and criteria for the use of OPs to perform supplier assessment and surveillance
  - (a) The POA holder should include the use of OPs for supplier assessment and surveillance in the POA holders' quality system to demonstrate compliance with the applicable requirements of Part 21.
  - (b) The procedures that are required for using OPs 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 OPs to perform supplier assessment and surveillance should include the following:
    - (1) Identification of the OP that will conduct the supplier assessment and surveillance.
    - (2) A listing of suppliers under surveillance by the OP. This listing should be maintained by the POA holder and made available to the competent authority upon request.
    - (3) The method used by the POA holder to evaluate and monitor the OP. The method should include the following as a minimum:
      - (i) verification that standards and checklists used by the OP are acceptable for the applicable scope;
      - (ii) verification that the OP is appropriately qualified and has sufficient knowledge, experience, and training to perform it's its allocated tasks;
      - (iii) verification that the frequency with which the OP carry out surveillance 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 is including on-site surveillance activities that are conducted by the OP; and
      - (v) verification that the OP has access to the applicable proprietary data to the level of detail necessary to survey suppliers functions.

Where the POA holder uses an OP accredited by a signatory to the European cooperation for Accreditation (EA) Multilateral Agreement and works in accordance with an aviation standard (e.g. EN 9104 series of requirements) that



- describes requirements for the assessment and surveillance by the other party, items (ii) and (iv) shall be deemed to be complied with.
- (4) A definition that states to what extend the OP will conduct surveillance of the suppliers on behalf of the POA holder. If the OP partly replaces surveillance by the POA holder, the POA holder should identify the functions that will continue to be surveyed by the POA holder.
- (5) The procedures used by the OP to notify the POA holder of any non-conformity 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 competent authority to make investigations in accordance with point 21.A.9 to include OP activities.

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

## ADEQUACY OF THE PRODUCTION MANAGEMENT SYSTEMPROCEDURES AND OF THE MONITORING FUNCTION

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

## AMC1 21.A.143(a)(1) Production organisation exposition

#### 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 senior company manager, 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 competent authority'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 competent authority\* is

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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)
Senior company manager
For and on behalf of(quote the organisation's name)'

\*Where 'competent authority' is stated, please insert the actual name of the approving competent-authority organisation or administration that grants the POA.

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

- (d) The POE should include the description of the internal safety reporting scheme that is required by point 21.A.3A(b)(1)(a)(1)(ii).
- (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 Regulation (EU) 2018/1139 and the delegated and implementing acts 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 Regulation (EU) 2018/1139 and the delegated and implementing acts that are adopted on the basis thereof, may prefer to have a separate manual to avoid duplication.

## **GM1 21.A.145(b)(2) Resources**

#### **PRODUCTION DATA**

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 correct transcription of the original design data.



Procedures are required to define the manner in which airworthiness, noise, fuel venting, and exhaust emissions and environmental protection 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 EASA Form 1.

### AMC1 21.A.145(c)(2) Resources

#### **NOMINATED MANAGERS**

[...]

(k) Subject to a risk assessment and the competent authority's agreement, with due regard to the size of the organisation, and the nature and complexity of its activities, the functions of the compliance monitoring 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.

## GM1 21.A.147 Changes to the production management system

#### SIGNIFICANT CHANGES

Changes to be approved by the competent authority include:

- significant changes to the production capacity or methods;
- changes in the organisation<sup>'</sup>'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);
- changes in the production management system that may have an important impact on the conformity or airworthiness of any product, part, or appliance, including in the reporting lines between the personnel that is nominated in accordance with point 21.A.145(c)(2) and the accountable manager; and
- changes in the placement or control of significant subcontracted work or supplied parts.

To ensure that changes do not result in non-compliance with Part 21, it is in the interest of both the competent authority 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)).



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

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

### GM-ELA No 1 to 21.A.148 Changes of location

A change of location of the major place of activities to a different geographic location, city, airfield or similar is deemed to be of significance, and is treated in line with <u>GM-ELA No 1 to 21.A.147</u>.

No other changes related to the location of the company, including a relocation within one building, or to a neighbouring building on the same premises, or similar, are considered to be of significance, as long as the parameters that are critical to the environment, infrastructure or equipment remain the same, and are under the responsibility of the accountable manager (AM). Any other alterations will be addressed during the subsequent periodical authority oversight.

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

EASA Form 51 (see <u>AMC1 21.A.147</u>) should be obtained from the competent authority and completed in accordance with the instructions provided by the competent authority. The information entered on the form is needed by the competent authority in order to assess whether the production organisation approval (POA) is to be amended. The completed form should be forwarded to the competent authority. The applicant and the competent authority 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.159(a)(3) Duration and continued validity Evidence of a lack of satisfactory control

#### SATISFACTORY CONTROL OF THE MANUFACTURE

The following are examples of lack of satisfactory control A positive finding by the competent authority of:

- 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 competencye 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.

## AMC-ELA No 1 to 21.A.163(c) Privileges to issue authorised release certificates

Block 12 on any issued EASA Form 1 is filled with the following statement:

'ELIGIBLE ONLY FOR INSTALLATION ON AIRCRAFT THAT ARE NOT CLASSIFIED AS COMPLEX MOTOR POWERED AIRCRAFT, AND THAT ARE EITHER AEROPLANES WITHIN THE SCOPE OF CS LSA, CS VLA OR CS-23 LEVEL 1, OR SAILPLANES OR POWERED SAILPLANES WITHIN THE SCOPE OF CS-22, OR BALLOONS, HOT AIR AIRSHIPS OR GAS AIRSHIPS THAT ARE ELA2 AIRCRAFT.'

## AMC-ELA No 1 to 21.A.165(a);(b) Obligations of the holder - Basic working document

The organisation should ensure that its personnel have access to, and are familiar with, the parts of the organisation's procedures that are applicable to their activities. This may be done, for example, by providing information to the personnel when updates of the documentation become available, or by making the changed documentation available at a location where the information is accessible to all the affected personnel.

Staff members of the production organisation who are involved in the production of products under the POA should be able to demonstrate their awareness of the information that is provided within the POE and the company manual. This can be achieved by any suitable means, and it does not necessarily require training sessions to be provided. Regular internal monitoring should be used to internally verify that the relevant staff members are aware of the relevant definitions.

The organisation should systematically conduct monitoring for compliance with this documentation. This monitoring can be via auditing, structured experience exchanges, regular quality meetings, brainstorming or lessons-learned sessions, project reviews at appropriate phases of the development, or other similar means.

## GM-ELA No 1 to 21.A.165(c) Obligations of the holder

GM No 1 to 21.A.165(c) is applicable.



GM No 2 to 21.A.165(c) is applicable.

GM No 3 to 21.A.165(c) is applicable.

GM No 4 to 21.A.165(c) is applicable.



#### SUBPART J — DESIGN ORGANISATION APPROVAL

### AMC-ELA No 1 to 21.A.231 Scope

The AMC-ELA in this Subpart provides acceptable means of compliance for a design organisation approval for organisations that design:

- aeroplanes that are within the scope of CS-LSA, CS-VLA and CS-23 level 1;
- sailplanes or powered sailplanes that are within the scope of CS-22; or
- balloons, hot-air airships and gas airships that are ELA2 aircraft,

that are not classified as complex motor-powered aircraft, as well as products or articles that are used on these types of aircraft.

## GM-ELA No 1 to 21.A.231 Scope

The AMC indicated with 'AMC-ELA' and the GM related to them (as indicated with 'GM-ELA') provide an alternative set of AMC and GM to the other available AMC and GM.

The AMC-ELA provide acceptable means to meet the requirements of Subpart J for small, non-complex organisations that make designs for aircraft as specified in AMC-ELA No 1 to 21.A.231.

If the AMC-ELA are not applicable (for instance, for small, non-complex organisations that make designs for other low-risk products outside the scope of AMC-ELA No 1 to 21.A.231, e.g. light rotorcraft, CS 23 Level 2, etc.), the applicant is not obliged to use any other available AMC. Switching to those other available AMC will not necessarily provide a means of compliance that is proportionate. Since AMC are a means, but not the only means of showing compliance, applicants and approval holders can also propose alternative means of compliance. These alternative means may use the AMC ELA as a baseline, and complement them with additional or more stringent controls, processes or methods. This allows a gradual increase in the level of detail of the established procedures and the thoroughness of the implemented tools for DOA approval. This enables the introduction of a proportionate approach that is commensurate with the kind of product and its associated risk as a function of the complexity of the organisation and the risk and performance of the product. The use of AMC-ELA as a baseline for DOA outside the applicability of that AMC-ELA is therefore considered to be an appropriate starting point.

Complementing elements need to be detailed, documented and recorded to a level where the occurrence of any repetitive non-conformities is mitigated. Applicants and approval holders need to demonstrate to the competent authority in such cases that those additional means meet the requirements that are appropriate for the complexity of these designs.

## GM-ELA No 2 to 21.A.231 Scope - AMC-ELA as a complete, self-contained set of AMC

The AMC-ELA provide an alternative, complete and self-contained set of AMC. Small, non-complex organisations that design products or articles within the scope of AMC-ELA can use AMC-ELA instead of the existing AMC to Subpart J.



The AMC-ELA in full determine the acceptable means of compliance with Subpart J. The applicant should implement each of the means defined here on an individual basis. If the specific characteristics of the organisation render individual elements of the AMC-ELA impracticable or not applicable, alternative means with specific resolutions should be agreed with the competent authority. A justification needs to be developed that shows that the means applied meet the requirements of Part-21. A trustful relationship between the typically very compact team of the applicant and the competent authority should be developed. The applicant is strongly encouraged to ask the relevant contact person at the competent authority for mutual clarification of any questionable item, if there is any doubt.

## GM-ELA No 3 to 21.A.231 Scope - Explanation of terms used in AMC-ELA

#### 'A method needs to be practised'

When the AMC-ELA uses the term 'a method needs to be practised', it means that the applicant can show what is actually done in order to comply with a requirement in a practical and systematic way. The applicant is not expected to have an excessively detailed documented procedure. As a baseline, documented procedures for such 'practised methods' can be limited to a 'declaration' of the principles that are considered within the practised method that refers to the system used. For example, a declaration such as 'Document control is ensured by workflow management as part of the IT-based Document Management System (DMS)' may be provided. This is acceptable when evidence is provided by work results, by demonstration of actual behaviour during surveillance activities, or by similar means. When the actual behaviour continuously shows that it does not satisfy the needs of the requirements, a more detailed documented procedure may need to be implemented to rectify the situation.

#### **Delegation of tasks and responsibilities**

AMC-ELA differentiates between the delegation of tasks, and the delegation of responsibilities. For small and simple organisations, the delegation of responsibilities to specific and separate organisational positions can create overly burdensome administrative processes that do not reflect the operational reality.

The AMC-ELA accepts that tasks can be delegated, while the responsibility formally stays with the delegator. This can increase efficiency, and it offers the possibility to simplify procedures. A typical example is when the head of the design organisation (HDO) delegates tasks, while keeping the responsibility associated with this task.

If this situation is identified with respect to the individual requirements, this may significantly reduce the effort required for documentation, and it allows streamlined methods to be practised.

### AMC-ELA No 1 to 21.A.234 Application

EASA Form 80 should be obtained from the EASA website and completed by the head of the design organisation (HDO). The completed form should be submitted to EASA, accompanied by a copy of the company's registration.



## AMC1 21.A.243(a) 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 can be performed under the approval, according to the following classification:
    - (i) general areas, like subsonic turbojet aeroplanes, turboprop aeroplanes, small aeroplanes, rotorcraft, etc.;
    - (ii) technologies handled by the organisation (composite, wood or metallic construction, electronic systems, etc.);
    - (iii) 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) 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 management system, together with a chart indicating the functional and hierarchical relationship of the design management system to the management and to other parts of the organisation; also the chains of responsibilities within the design management system, and the control of the work of all partners and 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) the procedures followed and forms used in the 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, and the environmental protection requirements, including specific requirements for import by importing authorities;



- (ii) the procedures for classifying design changes as 'major' or 'minor' and for the approval of minor changes;
- the procedures for classifying and approving unintentional deviations from the applicable design data occurring in production (concessions or non-conformity);
   and
- (iv) 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 cooperation with the production organisation when dealing with any continuing airworthiness action that 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 of the organisation of current changes in engineering drawings, specifications, and design management procedures.
- (8) A description of the recording system for:
  - (i) the type design, including relevant design information, drawings and test reports, including inspection records of test specimens;
  - (ii) the means of compliance; and
  - (iii) the compliance documentation (compliance checklist, 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 reports of problems that 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)).
- (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) (Reserved).
- (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) (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 management system will be performed in order to ensure that it remains effective.
- (16) A description of the procedures for the establishment and control of the OSD (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)(1).
- (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 senior company manager, 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 EASA'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. EASA 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)
Senior company manager
For and on behalf of(quote the organisation's name)

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

(c) 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 Regulation (EU) 2018/1139 and the delegated and implementing acts that are adopted on the basis thereof, may prefer to have a separate manual to avoid duplication.



## **GM1 21.A.243(d) Handbook**

#### STATEMENT OF QUALIFICATIONS AND EXPERIENCE

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:

- the senior company managerchief executive officer (CEO) (see AMC1 21.A.239(d), point (c)(1)(ii), AMC1 21.A.245(a), GM1 21.A.249, GM 21.A.265(b));
- the other management staff:
  - the head of the design organisation (HDO) (see points 21.A.239(b)(2) and 21.A.245(a));
  - the chief of the airworthiness function (see point 21.A.245(b)(1));
  - the chief of the independent monitoring function (see point 21.A.245(b)(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
- the staff 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(c)(2));and
  - staff 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)).

A statement of the qualifications and experience of the senior company manager GEO 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).

## 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 competent authority 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.

NOTE: When the HDO has no direct control on the resources necessary for the proper functioning of the design organisation, then a senior company manager should provide these resources. To confirm such commitment, the senior company manager should sign, along with the HDO, the binding statement (see AMC1 21.A.243(a), point (b)(20) and GM 21.A.265(b)).

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

The following changes are considered to be significant:

- Changes in ownership:
  - relocation of the major place of activity to a different geographic location, city, airfield or similar. Relocation within one building, or to a neighbouring building on the same premises, or a similar move, does not require prior approval, as long as there is no negative effect on the interface with or the access to the related production organisation;
- Changes in the scope of approval;
- Changes in the nomination of, or the allocation of responsibilities to, the HDO, the HoΛ, or the ISM; or
- Changes in the parts of the organisation that contribute directly to the airworthiness, operational suitability or environmental protection functions, such as changes to the principles or to the procedures related to:
  - type certification;
  - the classification of changes and repairs as 'major' or 'minor';
  - the handling of major changes and major repairs;
  - the approval of the design of minor changes and minor repairs;
  - the issue of information and instructions under the DOA privileges;
  - the approval of minor revisions to the aircraft flight manual;
  - the approval of the designs of major repairs;
  - continued airworthiness or continued operational suitability; or
  - configuration control if airworthiness, operational suitability or environmental protection is affected.



Significant changes require EASA approval prior to their implementation. The organisation should submit the application for approval of a significant change to the DOA, using EASA Form 82, to EASA sufficiently ahead of time, stating the nature of any significant change, and supported by a draft of the updated version of the DOH, so that the required extent of the investigation can be agreed upon and conducted in a reasonable way. The focus of the assessment is the continued ability to comply with the provisions of Subpart J.

Any other changes to the approved organisation do not require prior EASA approval, and will be addressed as part of the regular DOA surveillance.

To ensure that changes do not result in non-compliance with the applicable requirements of Subpart J, it is in the interest of both EASA and the approval holder to establish a relationship and to exchange data during the implementation of a change. As part of this relationship, the company should consider informing EASA sufficiently ahead of the next regular surveillance activity of any non significant changes.

## GM1 21.A.249 Transferability

#### **GENERAL**

- 1. Transfer of the approval would normally only be agreed in cases where the organisation itself remains substantially unchanged.
- 2. An acceptable transfer situation could be for example 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 or senior company manager Chief Executive. However, if the same legal entity were to relocate to new premises with a new senior company manager Chief Executive and/or new departmental heads, then a substantial investigation by EASA the Agency would be necessary such that the change would be classified as a re-approval.
- 3. In the event of receivership there may be good technical justification for continuation of the approval provided that the company continues to function in a satisfactory manner. It is likely that at a later stage the approval might be surrendered by the receiver or transferred to another legal entity in which case the former paragraphs apply.

## GM-ELA No 1 to 21.A.251 Terms of approval

The terms of approval are stated on the certificate issued by EASA. The certificate states the
scope of work and the products, changes or repairs to them, with the appropriate limitations
for which the approval has been granted. For a design organisation approval (DOA) that covers
a type certification, the list of product types covered by the design assurance system (DAS) is
included.



- 2. A change to the terms of approval in accordance with point <u>21.A.253</u> will lead to an amendment of the certificate of approval.
- The certificate of approval references the design organisation handbook (DOH), which has been
  provided in accordance with point <u>21.A.243</u>. This handbook defines the tasks that may be
  performed under the approval.
- 4. Scopes of work are defined, for example, by 'small aeroplanes', 'VLA', 'LSA', 'Balloons', 'Airships', etc. If the product within the framework defined in <u>AMC-ELA No 1 to 21.A.231</u> is a subset of that term (for example, not for all small aeroplanes), corresponding limitations are incorporated into the terms of approval for the product category. Technologies are quoted in the scope of work when they are considered by EASA to be limitations for the DOA.
- 5. For repair design activities, the certificate of approval states the scope of work, along with the appropriate limitations for which the approval has been granted.

### AMC-ELA No 1 to 21.A.253 Changes to the terms of approval

An application for an approval of changes to the terms of approval should be filed by the applicant using EASA Form 82.

# AMC-ELA1 to 21.A.263 Privileges and AMC-ELA1 to 21.A.265(h) Obligations of the holder

(a) The privilege to classify minor/major changes and repairs is granted in accordance with 21.A.263(c)(1) on the basis of the application of the method defined in response to AMC-ELA No 2 to 21.A.239(a).

The defined method should cover the following points:

- the identification of changes to a type design or repairs, including the applicable requirements as per the type certification data sheet (TCDS);
- the classification of changes as major if additional work is required to demonstrate compliance with the applicable requirements;
- the classification of changes as minor if no additional work is required to demonstrate compliance with the applicable requirements;
- the recording of the classification, and documented justification of the classification, for those cases that are not straightforward;
- approval of the classification by the authorised signatories.

It is acceptable to use the same classification process for repairs as for changes. Nevertheless, <u>GM 21.A.435(a)</u> should be taken into consideration when classifying repairs.



(b) The privilege to approve minor changes and minor repairs is granted together with the privilege of classification, on the basis of the application of the method defined in response to AMC-ELA No 2 to 21.A.239(a).

The defined method should cover the following points:

- the identification of whether additional work is required to demonstrate compliance with the applicable requirements;
- determination of the required compliance documentation and the verification by following the same workflow as the one applied for the initial design and certification;
- approving the repair under the DOA privileges by using a formalised approach. This may be, for example, defined by an adequately structured form that provides:
  - adequate identification of the change;
  - the identification of the applicable requirements;
  - reference to compliance documents;
  - the identification of the effects on limitations and approved documentation (if any);
  - evidence that independent checking has been conducted;
  - the date and evidence of the approval given by the relevant nominated staff.
- identification of the authorised signatories for the approval of minor changes and minor repairs;
- a statement that the design of minor changes/repairs is conducted using the same provisions as those defined for the design work during the initial design and certification. It is acceptable to use the same approval process for minor repairs as the one used for minor changes.
- (c) Instructions required by the certification specifications, such as the maintenance manual, the MMEL, etc., are usually prepared within the type investigation process to comply with the certification requirements. These documents are covered by the type investigation process. The generation and publication of information or instructions related to continued airworthiness, including updates to the above-mentioned ICA and MMEL and to any related design activity, are handled according to the same principles as any type design, change design or repair design activity/documentation if no separate method/process as per GM 21.A.265(h) is defined. The DOH should state how documents under this obligation are issued and distributed to the aircraft owner and to other interested parties. Using the change/repair process would be the simplest way for small companies to do this.
- (d) The approval of minor revisions to the AFM and its supplements should contain the following statement: 'The technical content of this document is approved under the authority of the DOA, ref.: EASA.21J.[XXXX]. Such a change is treated as a change to the type certificate, as the AFM is formally a part of the type certificate, and it is consequently classified on the basis of the application of the method defined in response to AMC-ELA No 2 to 21.A.239(a), and identified as being related to a 'minor' design change. Administrative revisions to the AFM are also expected to be classified as 'minor'. The following revisions to the AFM are defined as 'minor' revisions:



- 1. editorial revisions or corrections to the AFM;
- changes to parts of the AFM that are not required to be approved by EASA;
- 3. changes to limitations or procedures that are achieved without altering or exceeding the certification data;
- 4. conversions of units of measurement that were previously approved by the FAA or by EASA, and that are added to the AFM in a previously approved manner;
- 5. the addition of aircraft serial numbers to an existing AFM if the aircraft configuration, as related to the AFM, is identical to the configuration of the aircraft already in that AFM;
- 6. the removal of references to aircraft serial numbers that are no longer applicable to that AFM;
- 7. the translation of an EASA-approved AFM into the language of the State of Design or the State of Registration;
- 8. AFM revisions as part of minor changes to a type design.
- (e) In order to be granted a privilege to approve flight conditions (FC) and to issue PtFs, the design organisation should have in place an adequate FTOM in accordance with AMC ELA No 2 to 21.A.243 that is limited to the products designed and produced by the company, and over which the company has full configuration control. Authorised signatories shall be defined within the FTOM, or its equivalent.

In such a case, the FTOM (or another document) should contain a defined method that addresses the following points if the (FC) are approved under the DOA privileges:

- FC that must be complied with to safely perform a flight must be determined in accordance with point <u>21.A.708</u>;
- management of the aircraft configuration, including the handling of changes to the aircraft configuration operated under a PtF;
- the documentation of substantiations of flight conditions;
- approval under the privilege using EASA Form 18A defined in AMC 21.A.263(c)(6), and the definition of the authorised signatories.

For a PtF that is issued under the privilege, a method should be defined that addresses the following points:

- how conformity with the approved conditions is established, documented and attested;
- the issue of the PtF under the DOA privilege (form), and the authorised signatories;
- the interface with the local authority for the flight.

Further guidance is provided in AMC 21.A.263(c)(6) and (c)(7), as well as in the GM and AMC related to Subpart P.



## **AMC1 21.A.263(c)(1) Privileges**

PROCEDURE FOR THE CLASSIFICATION OF CHANGES TO A TYPE CERTIFICATE (TC) OR TO A SUPPLEMENTAL TYPE CERTIFICATE (STC), AND OF REPAIR DESIGNS AS 'MINOR' OR 'MAJOR'

#### 1. INTENT

This AMC provides the means to develop a procedure for the classification of changes to a TC, APU ETSO or to that part of the product covered by an STC, and repair designs.

Each design organisation approval (DOA) applicant should develop its own internal classification procedure following this AMC in order to obtain the associated privilege under 21.A.263(c)(1).

2. PROCEDURE FOR THE CLASSIFICATION OF CHANGES TO A TC, APU ETSO, OR TO THAT PART OF THE PRODUCT COVERED BY AN STC, AND REPAIR DESIGNS

#### 2.1 Content

The procedure should address the following points:

- the identification of changes to a TC, APU ETSO or to that part of the product covered by an STC, and repair designs;
- classification;
- justification of the classification;
- acceptance of the classification by authorised signatories; and
- supervision of changes to a TC, APU ETSO or to that part of the product covered by an STC, and repair designs initiated by subcontractors.
- 2.2 Identification of changes to a TC, APU ETSO or to that part of the product covered by an STC, and repair designs

The procedure should indicate how the following are identified:

- items (consisting of areas, systems, parts, or appliances) to be affected by the change or repair following the definitions provided in paragraph 3.9 of GM 21.A.101;
- airworthiness directives which have, or might have, an impact on any of the identified items affected by the change or repair;
- other constituents of the TC and of the pre-existing change(s) to the TC as applicable to the affected items (for instance, operating limitations, OSD constituents, manuals see also point 21.A.90A and the associated GM) to be affected by the change or repair;
- the existing type-certification basis of the affected items containing, as applicable, the certification specifications, special conditions, deviations from the applicable certification specifications and the equivalent level of safety findings incorporated by reference in the TC of the product to be changed;
- the existing OSD certification basis;



- the definition of the change or repair to the affected items and to the other affected constituents of the TC and of the pre-existing change(s) to the TC, if applicable, in accordance with the provisions of points 21.A.31 and 21.A.91;
- the certification basis of the change or repair determined in accordance with point 21.A.101 with the support of GM 21.A.101 (point 21.A.433 for repairs); this might lead to preclassification of the change as 'major significant' as per the associated definitions (see point 2.3 below).

The procedure should request the applicant to record a justification that the information, on which those identifications are based, is adequate. This may be done either by using the DOA holder's own resources, or through an arrangement with the TC holder, or any other design approval holder as relevant.

The procedure should address cases where the pre-existing configuration of the type design is the result of multiple changes or repairs applied to the same areas, systems, parts, equipment or appliances.

#### 2.3 Classification

The procedure should show how the effects on airworthiness, operational suitability and environmental protection are analysed, from the very beginning, by reference to the specific applicable requirements of the affected items.

If no specific CSs or environmental protection requirements are applicable to the affected items, the above review should be carried out at the level of the part or system where the affected items are integrated and where specific CSs or environmental protection requirements are applicable.

For changes to a TC, the criteria used for the classification should be in compliance with point 21.A.91 and follow the guidelines provided in GM 21.A.91.

For repairs, the criteria used for the classification should be in compliance with point 21.A.435 and follow the guidelines provided in GM 21.A.435(a).

The procedure should define provisions to contact EASA in case of doubts regarding the classification.

The procedure should take into consideration that a change to a TC may have been found to be significant according to point 21.A.101 and following the definitions provided in GM 21.A.101. Therefore, it is already preclassified at the stage of the determination of the certification basis (see point 2.2 above).

#### 2.4 Justification of the classification

All decisions on the classification of changes to a TC, APU ETSO or to that part of the product covered by an STC, and repair designs classified as 'major' or 'minor' should be recorded, and, for those which are not straightforward, also justified according to the procedure and criteria in point 2.3 above. These records should be easily accessible to EASA for sample checking.

2.5 Acceptance of the classification by the authorised signatories



All classifications of changes to a TC, APU ETSO or to that part of the product covered by an STC, and repair designs should be accepted by an appropriately authorised signatory, belonging to the airworthiness function, as explained in AMC1 21.A.239(d).or tasked by the office of airworthiness, as explained in GM No 1 to 21.A.239(a)(3.1.4)(r).

The procedure should indicate the authorised signatories for the various products listed in the terms of approval.

For those changes or repairs that are handled by subcontractors, as described under point 2.6, a description should be provided of how the DOA holder manages its classification responsibility.

The final classification may be:

- major changes significant to a TC;
- major changes not significant to a TC or major repairs;
- minor changes to a TC or minor repairs where additional work is necessary to demonstrate compliance with the certification basis, the operational suitability data certification basis, where applicable, and the environmental protection requirements; or
- minor changes to a TC or minor repairs requiring no further demonstration of compliance.

The procedure should indicate how the above four classes of changes/repairs are identified, taking into consideration the requirements laid down in point 21.A.31.

2.6 Supervision of changes to a TC, APU ETSO or to that part of the product covered by an STC, and repair designs initiated by subcontractors

The procedure should indicate, directly or by cross reference to written procedures, how changes to a TC, or to that part of the product covered by an STC, and repair designs may be initiated and classified by subcontractors, and are controlled and supervised by the DOA holder, taking into consideration the requirements laid down in point 21.A.239(d)(3) and its associated guidance material.21.A.239(c) and the associated GM 21.A.239(c).

## AMC1 21.A.263(c)(2) Privileges

PROCEDURE FOR THE APPROVAL OF MINOR CHANGES AND MINOR REPAIRS TO A TYPE CERTIFICATE (TC), AN AUXILIARY POWER UNIT EUROPEAN TECHNICAL STANDARD ORDER (APU ETSO) OR A SUPPLEMENTAL TYPE CERTIFICATE (STC)

#### 1. INTENT

This AMC provides the means to develop a procedure for the approval of minor changes to a TC, APU ETSO or to that part of the product covered by an STC, and minor repairs.



Each design organisation approval (DOA) applicant should develop its own internal procedures following this AMC in order to obtain the associated privilege under 21.A.263(c)(2).

- 2. PROCEDURE FOR THE APPROVAL OF MINOR CHANGES TO A TC, AN APU ETSO OR TO THAT PART OF THE PRODUCT COVERED BY AN STC, AND MINOR REPAIRS
  - 2.1 Content

The procedure should address the following points:

- compliance documentation;
- approval under the DOA privilege;
- authorised signatories; and
- supervision of minor changes to a TC, an APU ETSO or to that part of the product covered by an STC or minor repairs handled by subcontractors.
- 2.2 Compliance documentation

For those minor changes to a TC, an APU ETSO or to that part of the product covered by an STC, and minor repairs where additional work to demonstrate compliance with the applicable CSs and environmental protection requirements is necessary, compliance documentation should be established and independently verified as required by point 21.A.239(d)(2).checked as required by point 21.A.239(b).

The procedure should describe how the compliance documentation is produced and checked. For compliance documentation, see also AMC 21.A.20(c).

- 2.3 Approval under the DOA privilege
  - 2.3.1 For those minor changes to a TC, an APU ETSO or to that part of the product covered by an STC, and minor repairs where additional work to demonstrate compliance with the applicable CSs and environmental protection requirements is necessary, the procedure should define a document to formalise the approval under the DOA privilege.

This document should include at least:

- a brief description of the change or repair and the reasons for the change or repair;
- identification of the initial configuration of the affected area and other items (which determines the eligibility for installation of the change or repair into an aircraft);
- identification of the final configuration of the affected area, and of supplements to manuals and to OSD constituents;
- the applicable CSs or environmental protection requirements and methods of compliance;
- references to the compliance documents;
- the effects, if any, on the limitations and on the approved documentation;
- evidence of the independent checking function of the demonstration of compliance;



- evidence of the approval under the privilege of point 21.A.263(c)(2) by an authorised signatory; and
- the date of the approval.

For repairs, see AMC1 21.A.5 and AMC1 21.A.433(b). AMC 21.A.433(b) and 21.A.447.

2.3.2 For the other minor changes to a TC, APU ETSO or to that part of the product covered by an STC, and minor repairs, the procedure should define a means to identify the change or repair and the reasons for the change or repair, and to formalise its approval by the appropriate engineering authority under an authorised signatory. This function may be delegated by the Office of Airworthiness but should be controlled by the Office of Airworthiness, either directly or through appropriate procedures of the DOA holder's design assurance system.

#### 2.4 Authorised signatories

The persons authorised to sign for the approval under the privilege of point 21.A.263(c)(2) should be identified (name, signature and scope of authority) in appropriate documents that may be linked to the handbook.

2.5 Supervision of minor changes to a TC, APU ETSO or to that part of the product covered by an STC, and minor repairs handled by subcontractors

For the minor changes to a TC, APU ETSO or to that part of the product covered by an STC, and minor repairs described in 2.3.2 which are handled by subcontractors, the procedure should indicate, directly or by cross reference to written procedures, how these minor changes to a TC, APU ETSO or to that part of the product covered by an STC, and minor repairs are approved at the subcontractor level and the arrangements made for the control and supervision by the DOA holder.

## **AMC2 21.A.263(c)(2) Privileges**

ORGANISATIONS THAT DESIGN MINOR CHANGES TO A TYPE CERTIFICATE (TC), AN AUXILIARY POWER UNIT EUROPEAN TECHNICAL STANDARD ODER (APU ETSO) OR A SUPPLEMENTAL TYPE CERTIFICATE (STC) AND MINOR REPAIRS TO PRODUCTS: PROCEDURE FOR THE APPROVAL OF MINOR CHANGES TO A TC, AN APU ETSO OR MINOR REPAIRS

### 1. Content

The procedure should address the following points:

- compliance documentation;
- approval under the DOA privilege; and
- authorised signatories.



#### 2. Compliance documentation

For those minor changes to a TC, an APU ETSO or to that part of the product covered by an STC, and minor repairs where additional work to demonstrate compliance with the applicable CSs and environmental protection requirements is necessary, compliance documentation should be established and independently verified as required by point 21.A.239(d)(2). checked as required by point 21.A.239(b).

The procedure should describe how the compliance documentation is produced and checked. For compliance documentation, see also AMC 21.A.20(c).

### 3. Approval under the DOA privilege

3.1. For those minor changes to a TC, an APU ETSO or to that part of the product covered by an STC, and minor repairs where additional work to demonstrate compliance with the applicable CSs or environmental protection requirements is necessary, the procedure should define a document to formalise the approval under the DOA privilege.

This document should include at least:

- (a) a brief description of the change or the repair and the reason for change or repair;
- identification of the initial configuration of the affected area and other items (which determines the eligibility for installation of the change or repair into an aircraft);
- (c) identification of the final configuration of the affected area, and of supplements to manuals and to OSD constituents;
- (d) the applicable CSs or environmental protection requirements and methods of compliance;
- (e) references to the compliance documents;
- (f) the effects, if any, on the limitations and on the approved documentation;
- (g) evidence of the independent checking function of the demonstration of compliance;
- (h) evidence of the approval under the privilege of point 21.A.263(c)(2) by an authorised signatory; and
- (i) the date of the approval.

For repairs, see also AMC 21.A.433(b) and 21.A.447.

- 3.2. For the other minor changes to a TC, APU ETSO or to that part of the product covered by an STC, and minor repairs, the procedure should define a means to identify the change or repair and the reasons for the change or repair, and to formalise its approval by the appropriate engineering authority under an authorised signatory. This function should be controlled through appropriate procedures of the DOA holder's design assurance system.
- 4. Authorised signatories



The persons authorised to sign for the approval under the privilege of 21.A.263(c)(2) should be identified (name, signature and scope of authority) in appropriate documents that may be linked to the handbook.

## AMC-ELA No 1 to 21.A.265(a) Obligations of the holder – Administration of the design organisation handbook

The design organisation handbook (DOH) of the applicant should be in a language that will permit the best use of it by all the personnel who perform tasks for the design organisation. The DOH may be completely or partially integrated into the company's organisation manual. Refer also to <u>AMC-ELA No 1 to 21.A.243</u> for the required content.

## AMC-ELA No 1 to 21.A.265(b) Obligations of the holder – Use of the design organisation handbook as a basic working document

It is the responsibility of the HDO to ensure that the design organisation handbook (DOH) is used as a basic working document within the design organisation. In this sense, the HDO should include a statement to the DOH that the information provided within the DOH is binding.

The organisation should ensure that personnel have access to, and are familiar with, that part of the content of the DOH that covers their activities. This may be done, for example, by distributing the information that updates of the documentation are available, and by making the documentation available at a location where the information is accessible to all affected persons.

Staff at the design organisation who are involved in the demonstration of compliance of products under the DOA approval should be able to demonstrate their awareness of the definitions provided within the DOH. This can be achieved by any suitable means, and it does not necessarily require training sessions to be provided. Regular internal monitoring should be conducted to verify that the relevant staff members are aware of the relevant definitions.

Monitoring of compliance with this documentation should be done by systematic means. These means do not need to be limited to, or to even include auditing, but they can be accomplished by structured experience exchanges, regular quality meetings, brainstorming or lessons-learned sessions, project reviews at appropriate phases of the product development, or other similar means accepted by EASA.

## GM1 21.A.265(b) Obligations of the holder

**USE OF THE HANDBOOK** 



- The handbook should be signed by the senior company manager chief executive and the head of the design organisation and declared as a binding instruction for all personnel charged with the development and type investigation of products. This binding statement should be provided independently of the means chosen by the design organisation to document its processes and procedures.
- 2. All procedures referenced in the handbook are considered as parts of the handbook and therefore as basic working documents.

## AMC-ELA No 1 to 21.A.265(c) Obligations of the holder – Determination of compliance

The organisation should apply the methods detailed in <u>AMC-ELA No 2 to 21.A.239(a)</u> to determine whether the design of the product, or changes or repairs to them, comply with the applicable requirements, and to ensure that the design of the product contains no unsafe features.

## AMC-ELA No 1 to 21.A.265(e) Obligations of the holder - Providing information in response to airworthiness directives

The design organisation handbook (DOH) should contain a declaration to ensure that the proposal of appropriate corrective actions/required inspections is submitted to EASA in cases where EASA has issued airworthiness directives in response to potentially unsafe conditions of a product under the responsibility of the approved DO. In addition, the provisions in the DOH should ensure that following the approval by EASA of any proposals referred to under this point, the DO makes appropriate descriptions and procedures for the corrective actions/required inspections available to all known operators or owners of the product and, upon request, to any person that is required to comply with the airworthiness directive.

## AMC-ELA1 to 21.A.263 Privileges and AMC-ELA1 to 21.A.265(h) Obligations of the holder

(a) The privilege to classify minor/major changes and repairs is granted in accordance with 21.A.263(c)(1) on the basis of the application of the method defined in response to AMC-ELA No 2 to 21.A.239(a).

The defined method should cover the following points:

 the identification of changes to a type design or repairs, including the applicable requirements as per the type certification data sheet (TCDS);

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- the classification of changes as major if additional work is required to demonstrate compliance with the applicable requirements;
- the classification of changes as minor if no additional work is required to demonstrate compliance with the applicable requirements;
- the recording of the classification, and documented justification of the classification, for those cases that are not straightforward;
- approval of the classification by the authorised signatories.

It is acceptable to use the same classification process for repairs as for changes. Nevertheless, <u>GM 21.A.435(a)</u> should be taken into consideration when classifying repairs.

(b) The privilege to approve minor changes and minor repairs is granted together with the privilege of classification, on the basis of the application of the method defined in response to <u>AMC-ELA No 2 to 21.A.239(a)</u>.

The defined method should cover the following points:

- the identification of whether additional work is required to demonstrate compliance with the applicable requirements;
- determination of the required compliance documentation and the verification by following the same workflow as the one applied for the initial design and certification;
- approving the repair under the DOA privileges by using a formalised approach. This may be, for example, defined by an adequately structured form that provides:
  - adequate identification of the change;
  - the identification of the applicable requirements;
  - reference to compliance documents;
  - the identification of the effects on limitations and approved documentation (if any);
  - evidence that independent checking has been conducted;
  - the date and evidence of the approval given by the relevant nominated staff.
- identification of the authorised signatories for the approval of minor changes and minor repairs;
- a statement that the design of minor changes/repairs is conducted using the same provisions as those defined for the design work during the initial design and certification.
   It is acceptable to use the same approval process for minor repairs as the one used for minor changes.
- (c) Instructions required by the certification specifications, such as the maintenance manual, the MMEL, etc., are usually prepared within the type investigation process to comply with the certification requirements. These documents are covered by the type investigation process. The generation and publication of information or instructions related to continued airworthiness, including updates to the above mentioned ICA and MMEL and to any related design activity, are handled according to the same principles as any type design, change design or repair design activity/documentation if no separate method/process as per <u>GM 21.A.265(h)</u> is defined. The DOH should state how documents under this obligation are issued and distributed to the aircraft



owner and to other interested parties. Using the change/repair process would be the simplest way for small companies to do this.

- (d) The approval of minor revisions to the AFM and its supplements should contain the following statement: 'The technical content of this document is approved under the authority of the DOA, ref.: EASA.21J.[XXXX]. Such a change is treated as a change to the type certificate, as the AFM is formally a part of the type certificate, and it is consequently classified on the basis of the application of the method defined in response to AMC-ELA No 2 to 21.A.239(a), and identified as being related to a 'minor' design change. Administrative revisions to the AFM are also expected to be classified as 'minor'. The following revisions to the AFM are defined as 'minor' revisions:
  - 1. editorial revisions or corrections to the AFM;
  - 2. changes to parts of the AFM that are not required to be approved by EASA;
  - 3. changes to limitations or procedures that are achieved without altering or exceeding the certification data;
  - 4. conversions of units of measurement that were previously approved by the FAA or by EASA, and that are added to the AFM in a previously approved manner;
  - 5. the addition of aircraft serial numbers to an existing AFM if the aircraft configuration, as related to the AFM, is identical to the configuration of the aircraft already in that AFM;
  - 6. the removal of references to aircraft serial numbers that are no longer applicable to that AFM:
  - 7. the translation of an EASA-approved AFM into the language of the State of Design or the State of Registration:
  - 8. AFM revisions as part of minor changes to a type design.
- (e) In order to be granted a privilege to approve flight conditions (FC) and to issue PtFs, the design organisation should have in place an adequate FTOM in accordance with AMC ELA No 2 to 21.A.243 that is limited to the products designed and produced by the company, and over which the company has full configuration control. Authorised signatories shall be defined within the FTOM, or its equivalent.

In such a case, the FTOM (or another document) should contain a defined method that addresses the following points if the (FC) are approved under the DOA privileges:

- FC that must be complied with to safely perform a flight must be determined in accordance with point <u>21.A.708</u>;
- management of the aircraft configuration, including the handling of changes to the aircraft configuration operated under a PtF;
- the documentation of substantiations of flight conditions;
- approval under the privilege using EASA Form 18A defined in <u>AMC 21.A.263(c)(6)</u>, and the definition of the authorised signatories.

For a PtF that is issued under the privilege, a method should be defined that addresses the following points:



- how conformity with the approved conditions is established, documented and attested;
- the issue of the PtF under the DOA privilege (form), and the authorised signatories;
- the interface with the local authority for the flight.

Further guidance is provided in AMC 21.A.263(c)(6) and (c)(7), as well as in the GM and AMC related to Subpart P.

## (SUBPART L — NOT APPLICABLE)

[...]

### SUBPART M — REPAIRS

AMC1 21.A.433(ba) Requirements for approval of a repair designand 21.A.5 Repair design and record-keeping

#### **RECORD KEEPING**

- (a) 1. Relevant substantiation data associated with a new major repair design and record-keeping should include:
  - (1)a. the identification of the damage and the reporting source;
  - (2)b. the major repair design approval sheet identifying the applicable specifications and references of justifications;
  - (3) the repair drawing and/or instructions and scheme identifier;
  - (4)d. the correspondence with the holder of the type certificate (TC), supplemental type certificate (STC), or auxiliary power unit European technical standard order (APU ETSO) authorisation, if its advice on the design has been sought;
  - (5)e. the structural justification (static strength, fatigue, damage tolerance, flutter, etc.) or references to this data;
  - (6)f. the effect on the aircraft, engines and/or systems (performance, flight handling, etc., as appropriate);
  - (7)g. the effect on the maintenance programme;
  - (8) h. the effect on airworthiness limitations, the flight manual and the operating manual;
  - (9)i. any weight and moment changes; and
  - (10)<sub>j</sub>. special test requirements.
- (b)2. Relevant minor repair documentation includes paragraphs 1(a)(1) and (a)(3)(c). Other points of paragraph (a)1 may be included where necessary. If the repair is outside the approved data, a justification for the classification is required.



- (c)3. 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, oversizing of fastener holes, etc.).
- (d)4. 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 21.A.433(a)(4).
- (e)5. Repairs to engine or APU critical parts would normally only be accepted with the involvement of the TC holder.

## **SUBPART P — PERMIT TO FLY**

[...]



## SECTION B — PROCEDURES FOR COMPETENT AUTHORITIES

## SUBPART A — GENERAL PROVISIONS

## AMC1GM-21.B.25(a) Organisation Management system

### **GENERAL**

- (a) The competent authority designated by each Member State should have an organisation be organised in such a way that-:
  - a)(1) there is specific and effective management authority in the conduct of all relevant activities;
  - b)(2) the functions and processes described in the applicable requirements of Regulation (EU) 2018/1139 and its delegated and implementing acts, AMC, CSs, and GMPart 21 and its AMC and GM may be are properly implemented;
  - the competent authority's policy of the Member State policy, organisation and operating procedures for the implementation of the applicable requirements of Regulation (EU) 2018/1139 and its delegated and implementing acts, AMC, CSs, and GMPart 21 are properly documented and applied,
  - d)(4) all the competent authority's personnel who are of the Member State personnel involved in the related activities are provided with training where necessary;
  - e)(5) specific and effective provision is made for the communicatingon and interfacinge as necessary with the Agency EASA and the other competent authorities of the Member States,; and
  - f)(6) all the functions related to implementing the applicable requirements the implementation of Part 21 are adequately described and shown (Standardisation).
- (b) A general policy in respect of Part 21 the activities related to the applicable requirements of Regulation (EU) 2018/1139 and the delegated and implementing acts should be developed, sponsored promoted and implemented by the manager at the highest appropriate level, for example, the manager at the top of the functional area of the competent authority of the Member State that is responsible for such activities the related matters.
  - (1) Appropriate steps should be taken to ensure that the policy is known and understood by all the personnel staff involved, and all the necessary steps should be taken to implement and maintain the policy.
  - (2) The general policy Whilst satisfying also additional national regulatory responsibilities, the general policy should, in particular, take into account:
    - (a) the provisions of the Regulation (EU) 2018/1139 (EC) No 216/2008;
    - (b) the provisions of the applicable delegated and implementing acts, Part 21 and its AMC, CSs, and GM;



- (c) the needs of industry; and
- (d) the needs of EASA the Agency and of the competent authorityies of the Member States.
- (3) The policy should define specific objectives for the key elements of the competent authority organisation and processes for implementating on the related Part 21 activities, including the corresponding control procedures and the measurement of the achieved standard.

## GM1 21.B.25 Management system

#### **GENERAL – RELEVANT ACTIVITIES**

For the purpose of the AMC and GM to point 21.B.25, the activities referred to are those activities related to the certification and surveillance of design or production organisations.

## AMC2 21.B.25 Management system

### **ORGANISATIONAL STRUCTURE**

- (a) In deciding upon the required organisational structure, the competent authority should review:
  - (1) the number of certificates, approvals, authorisations and letters of agreements to be issued;
  - (2) the number, complexity and sizes of the Part 21 organisations under its oversight obligations;
  - (3) the possible use of qualified entities and of the resources of the competent authority of other Member States to fulfil the continuing oversight obligations;
  - (4) the complexity of the aviation industry, taking into consideration the diversity of the products and parts; and
  - (5) the potential growth of activities in the field of civil aviation.
- (b) The competent authority should retain effective control of the important surveillance functions and not delegate them in such a way that Part 21 organisations, in effect, regulate themselves in airworthiness matters.
- (c) The set-up of the organisational structure should ensure that the various tasks and obligations of the competent authority do not solely rely on individuals. The continuous and undisturbed fulfilment of these tasks and obligations of the competent authority should also be guaranteed in cases of illness, accidents or leave of individual employees.



## GM 21.B.25(b) Resources

The organisation for related Part 21 activities should be clearly defined within the general organisation of the competent authority of the Member State, with the hierarchical and functional links, and the names of the senior staff. Although final responsibility should be placed at the top of the functional area that is responsible for the related Part 21 activities as a whole, all subordinate levels of management should be suitably resourced and empowered to fulfil their delegated tasks.

The definition of an organisation for the implementation of related Part 21 activities should include the specification of

- a) a manager responsible for the specific Part 21 activity acting as internal and external focal point. The responsibility is best placed with the manager who is in control of the day to day functions concerning the specific Part 21 activity, although he may delegate specific tasks to other individuals;
- b) individual or group responsibilities, duties and associated reporting lines;
- c) the resources, human and material;
- d) the documented procedures to be operated in respect of the relevant Part 21 activities.

The various tasks and responsibilities of the personnel involved in the related Part 21 activities should be clearly identified. The authority attached to the responsibilities should be enough to ensure that the activities will be performed correctly.

These responsibilities include among others:

- a) the management of the organisation
- b) the management of investigation teams
- c) the team leadership/membership
- d) the investigation and surveillance activities
- e) the administrative management of certificates and approvals, , including record keeping
- f) the external and internal interface activities including feedback to the Agency
- g) the control and distribution of documentation

The definition of the organisation should include means to ensure continued effectivity of the organisation. The means should provide for a regular assessment of the organisation and its related activities as well as a feedback system for the follow up of necessary corrective actions (e.g., through the implementation of a quality system, internal audit system, etc.).

## GM 21.B.25(c) Qualification and training

The competent authority of the Member State should ensure appropriate and adequate training of its personnel to meet the standard that is considered by the Agency necessary to perform the work. Arrangements should be made for initial and continuation training as required.

It is understood that the basic competence of the competent authority of the Member State staff is a matter of recruitment and normal management functions in selection of staff for particular duties.



Moreover, it is understood that the competent authority of the Member State provides training in the basic skills as required for those duties.

However, to avoid differences in understanding and interpretation, it is considered important that all personnel involved in Part 21 activities should be provided with further training specifically related to the relevant Part 21 activity up to the common Agency standard.

The competent authority of the Member State should provide training through its own training organisation with qualified trainers or through another qualified training source (e.g., training provided by other competent authorities, the Agency or qualified entities).

## AMC1 21.B.25(a)(1) Management system

## **DOCUMENTED POLICIES AND PROCEDURES**

- (a) The various elements of the organisation involved with the activities related to Regulation (EU) 2018/1139 and its delegated and implementing acts should be documented in order to establish a reference source for the establishment and maintenance of this organisation.
- (b) The documented procedures should be established in a way that facilitates their use. They should be clearly identified, kept up to date and made readily available to all the personnel involved in the related activities.
- (c) The documented procedures should cover, as a minimum, all of the following aspects:
  - (1) policies and objectives;
  - (2) the organisational structure;
  - (3) responsibilities and the associated authority;
  - (4) processes and procedures;
  - (5) internal and external interfaces;
  - (6) internal control procedures;
  - (7) the training of personnel;
  - (8) cross-references to associated documents; and
  - (9) assistance from other competent authorities or EASA (where required).
- (d) It is likely that the information may be held in more than one document or series of documents, and suitable cross-referencing should be provided. For example, the organisational structure and the job descriptions are not usually in the same documentation as the detailed working procedures. In such cases, it is recommended that the documented procedures should include an index of cross-references to all such other related information, and the related documentation should be readily available when required.



## GM1 21.B.25(a)(2) Management system

### SUFFICIENT PERSONNEL

- (a) This GM on the determination of the required personnel is limited to the performance of certification and oversight tasks, excluding any personnel who are required to perform tasks that are subject to any national regulatory requirements.
- (b) The elements to be considered when determining who are the required personnel and when planning their availability may be divided into quantitative and qualitative elements:
  - (1) Quantitative elements
    - (i) the estimated number of initial certificates to be issued;
    - (ii) the number of organisations to be certified by the competent authority;
    - (iii) the estimated number of subcontracted organisations used by certified organisations.
  - (2) Qualitative elements
    - (i) the size, nature, and complexity of the activities of certified organisations, taking into account:
      - (A) the privileges of each organisation;
      - (B) the types of approval and the scopes of approval;
      - (C) possible certification to industry standards;
      - (D) the number of personnel; and
      - (E) the organisational structure and the existence of subsidiaries;
    - (ii) the safety priorities identified;
    - (iii) the results of past oversight activities, including audits, inspections and reviews, in terms of risks and regulatory compliance, taking into account:
      - (A) the number and the levels of findings;
      - (B) the time frame for the implementation of corrective actions;
      - (C) the maturity of the management systems implemented by organisations, and their ability to effectively manage safety risks; and
    - (iv) the size and complexity of the Member States' aviation industry, and the potential growth of activities in the field of civil aviation, which may be an indication of the number of new applications, and changes to existing certificates to be expected.
- (c) Based on existing data from previous oversight planning cycles, and taking into account the situation within the Member State's aviation industry, the competent authority may estimate:
  - (1) the standard working time required for processing applications for new certificates, approvals, authorisations or letters of agreement;



- (2) the number of new certificates, approvals, authorisations or letters of agreement to be issued for each planning period; and
- (3) the number of changes to existing certificates, approvals, authorisations or letters of agreement to be processed for each planning period.
- (d) In line with the competent authority's oversight policy, the following planning data should be determined:
  - (1) the standard number of audits to be performed per oversight planning cycle;
  - (2) the standard duration of each audit;
  - (3) the standard working time for audit preparation, on-site audit, reporting, and follow-up per inspector;
  - (4) the standard number of unannounced inspections to be performed;
  - (6) the standard duration of inspections, including preparation, reporting, and follow-up per inspector; and
  - (7) the minimum number and the required qualifications of the inspectors for each audit/inspection.
- (e) The standard working time could be expressed either in working hours per inspector, or in working days per inspector. All planning calculations should, then, be based on the same units (working hours or days).
- (f) The use of a spreadsheet application is recommended to process the data defined under (c) and (d), to assist in determining the total number of working hours/days per oversight planning cycle required for certification, oversight and enforcement activities. This application could also serve as a basis for implementing a system for planning the availability of personnel.
- (g) The number of working hours/days per planning period for each qualified inspector that may be allocated for certification, oversight and enforcement activities should be determined, taking into account:
  - (1) purely administrative tasks not directly related to certification and oversight;
  - (2) training;
  - (3) participation in other projects;
  - (4) planned absences; and
  - (5) the need to include a reserve for unplanned tasks or unforeseeable events.
- (h) The determination of working time available for certification, oversight and enforcement activities should also consider, if applicable:
  - the use of qualified entities;
  - (2) cooperation with other competent authorities for approvals that involve more than one Member State; and
  - (3) oversight activities under a bilateral aviation safety agreement.



- (i) Based on the elements listed above, the competent authority should be able to:
  - (1) monitor the dates when audits and inspections are due, and when they were carried out;
  - (2) implement a system to plan the availability of personnel; and
  - (3) identify possible gaps between the number and the qualifications of personnel and the required volume of certification and oversight.

Care should be taken to keep planning data up to date in line with changes in the underlying planning assumptions, with a particular focus on risk-based oversight principles.

## AMC1 21.B.25(a)(3) Management system

### QUALIFICATIONS AND TRAINING — GENERAL

- (a) It is essential for the competent authority to have the full capability to adequately assess the compliance and performance of an organisation by ensuring that the whole range of activities is assessed by appropriately qualified personnel.
- (b) For each inspector, the competent authority should:
  - (1) define the competencies required to perform the allocated certification and oversight tasks;
  - (2) define the associated minimum qualifications that are required;
  - (3) establish initial and recurrent training programmes in order to maintain and to enhance the competency of inspectors at the level that is necessary to perform the allocated tasks; and
  - (4) ensure that the training provided meets the established standards, and is regularly reviewed and updated as necessary.
- (c) The competent authority should ensure that training is provided by qualified trainers with appropriate training skills.

## AMC2 21.B.25(a)(3) Management system

#### QUALIFICATIONS AND TRAINING — INSPECTORS

- (a) Competent authority inspectors should have:
  - practical experience and expertise in the application of aviation safety standards and safe operating practices;
  - (2) comprehensive knowledge of:
    - (i) relevant parts of Regulation (EU) 2018/1139 and its delegated and implementing acts and the related AMC, CSs and GM;
    - (ii) the competent authority's procedures;
    - (iii) the rights and obligations of an inspector;



- (iv) safety management systems based on the EU management system requirements and ICAO Annex 19, and compliance monitoring;
- (v) design or production standards, as applicable;
- (vi) design-related or production-related human factors and human performance principles, as appropriate;
- (3) training on auditing techniques and assessing and evaluating management systems and safety risk management processes;
- (4) 5 years of relevant work experience to be allowed to work without supervision as an inspector. This may include experience gained during training to obtain the qualifications described in point (a)(5) below; and
- (5) a relevant engineering degree with additional education. 'Relevant engineering degree' means an engineering degree from aeronautical, mechanical, electrical, electronic, avionics or other studies relevant to the design and production of aircraft/aircraft components.
- (b) In addition to technical competency, inspectors should have a high degree of integrity, be impartial in carrying out their tasks, be tactful, and have a good understanding of human nature.
- (c) A programme for recurrent training should be developed that ensures that the inspectors remain competent to perform their allocated tasks. As a general policy, it is not desirable for the inspectors to obtain technical qualifications from those entities that are under their direct regulatory oversight.

## AMC3 21.B.25(a)(3) Management system

#### **INITIAL AND RECURRENT TRAINING — INSPECTORS**

(a) Initial training programme

The initial training programme for inspectors should include, to an extent appropriate to their role, current knowledge, experience and skills in at least the following:

- (1) aviation legislation, organisation, and structure;
- (2) the Chicago Convention, the relevant ICAO Annexes and Documents;
- (3) Regulation (EU) No 376/2014 on the reporting, analysis and follow-up of occurrences in civil aviation;
- (4) overview of Regulation (EU) 2018/1139 and its delegated and implementing acts and the related AMC, CSs, and GM;
- (5) Regulation (EU) No 748/2012 as well as any other applicable requirements;
- (6) management systems, including the assessment of the effectiveness of a management system, in particular hazard identification and risk assessment, and non-punitive reporting techniques in the context of the implementation of a 'just culture';
- (7) auditing techniques;



- (8) procedures of the competent authority that are relevant to the inspectors' tasks;
- (9) human factors principles;
- (10) the rights and obligations of inspecting personnel of the competent authority;
- (11) on-the-job training relevant to the inspector's tasks;
- (12) technical training that is appropriate to the role and tasks of the inspector, in particular for those areas that require approvals.
- NOTE: The duration of the on-the-job training should take into account the scope and complexity of the inspector's tasks. The competent authority should assess whether the required competency has been achieved before an inspector is authorised to perform a task without supervision.
- (b) Recurrent training programme

Once qualified, the inspector should undergo training periodically, as well as whenever it is deemed necessary by the competent authority, in order to remain competent to perform the allocated tasks. The recurrent training programme for inspectors should include, as appropriate to their role, at least the following topics:

- (1) changes in aviation legislation, the operational environment and technologies;
- (2) procedures of the competent authority that are relevant to the inspector's tasks;
- (3) technical training that is appropriate to the role and tasks of the inspector; and
- (4) results from past oversight.
- (c) Assessments of an inspector's competency should take place at regular intervals that do not exceed 3 years. The results of these assessments, as well as any actions taken following these assessments, should be recorded.

## AMC1 21.B.25(a)(5) Management system

### SAFETY RISK MANAGEMENT PROCESS

- (a) The safety risk management process required by point (a)(5) of point 21.B.25 should be documented. The following should be defined in the related documentation:
  - (1) means for hazard identification and the related data sources, taking into account data that comes from other competent authorities with which the competent authority interfaces in the State or from the competent authorities of other Member States;
  - (2) risk management steps including:
    - analysis (in terms of the probability and the 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;
  - (3) who holds the responsibilities for hazard identification and risk management;



- (4) who holds the responsibility for the follow-up of risk mitigation actions;
- (5) the levels of management who have the authority to make decisions regarding the tolerability of risks;
- (6) means to assess the effectiveness of risk mitigation actions; and
- (7) the link with the compliance monitoring function.
- (b) To demonstrate that the safety risk management process is operational, competent authorities should be able to provide evidence that:
  - (1) the persons involved in internal safety risk management activities are properly trained;
  - (2) hazards that could impact the authority's capabilities to perform its tasks and discharge its responsibilities have been identified, and the related risk assessment is documented;
  - (3) regular meetings take place at appropriate levels of management of the competent authority to discuss the risks identified and to decide on the risk tolerability and possible risk mitigations;
  - (4) in addition to the initial hazard identification exercise, the risk management process is triggered as a minimum whenever changes occur that may affect the competent authority's capability to perform any of the tasks required by Part 21;
  - (5) a record of the actions taken to mitigate risks is maintained, showing the status of each action and the owner of the action;
  - (6) there is follow-up on the implementation of all risk mitigation actions;
  - (7) risk mitigation actions are assessed for their effectiveness;
  - (8) the results of risk assessments are periodically reviewed to check whether they remain relevant.

## GM1 21.B.25(a)(5) Management system

### SAFETY RISK MANAGEMENT PROCESS

The purpose of safety risk management as part of the management system framework for competent authorities is to ensure the effectiveness of the management system. As for any organisation, hazard identification and risk management are expected to contribute to effective decision-making, to guide resource allocation and contribute to organisational success.

The safety risk management process required by point 21.B.25 is intended to address the safety risks that are directly related to the competent authority's organisation and processes, and which may affect its capability to perform its tasks and discharge its responsibilities. This process is not intended to be a substitute for the State safety risk management SARPs defined in ICAO Annex 19, Chapter 3. This does not mean, however, that the competent authority may not use information and data that is obtained through its State Safety Programme (SSP), including oversight data and information, for the purpose of safety risk management as part of its management system.



The safety risk management process is also to be applied to the management of changes (point 21.B.35), which is intended to ensure that the management system remains effective whenever changes occur.

## AMC1 21.B.25(d) Management system

#### **PROCEDURES AVAILABLE TO EASA**

- (a) Copies of the procedures related to the management system of the competent authority of the Member State, and their amendments, that should be made available to EASA for the purpose of standardisation, should provide at least the following information:
  - (1) the competent authority's organisational structure for the continuing oversight functions that it undertakes, with a description of the main processes. This information should demonstrate the allocation of responsibilities within the competent authority, and that the competent authority is capable of carrying out the full range of tasks regarding the size and complexity of the Member State's aviation industry. It should also consider the overall proficiency and the scope of authorisation of the competent authority's personnel;
  - (2) for personnel who are involved in oversight activities, the minimum required professional qualification and amount of experience, and the principles that guide their appointment (e.g. assessment);
  - (3) how the following are carried out: assessments of applications and evaluations of compliance; the issuance of certificates, approvals, authorisations and letters of agreement; continuing oversight activities; the follow-up of findings; enforcement measures; and the resolution of safety concerns;
  - (4) the principles used to manage exemptions and derogations;
  - (5) the processes that are in place to distribute applicable safety information for timely reaction to a safety problem;
  - (6) the criteria for planning continuing oversight activities (i.e. an oversight programme), including the management of interfaces when conducting continuing oversight activities;
  - (7) an outline of the initial training of newly recruited oversight personnel (taking future activities into account), and the basic framework for the recurrent training of oversight personnel.
- (b) As part of the continuous monitoring of a competent authority, EASA may request details of the working methods used, in addition to a copy of the procedures of the competent authority's management system (and any amendments). These additional details are the procedures and related guidance material that describe the working methods for the personnel of the competent authority who conduct oversight activities.
- (c) Information related to the competent authority's management system may be submitted in an electronic format.



## GM1 21.B.30 Allocation of tasks to qualified entities

## **CERTIFICATION TASKS**

The tasks that may be performed by a qualified entity on behalf of the competent authority include those that are related to the initial certification and the continuing oversight of persons and organisations as defined in Part 21.

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

#### **DATA RELATED TO DESIGN APPROVALS**

Record keeping related to design approvals, for which the responsibility is transferred to the Agency, will remain initially with the competent authority of the Member State that has granted the design approvals, but will be at the disposal of the Agency. This GM specifies the administrative documents to be kept for the various kinds of design approvals. It does not repeat the requirements for design approvals holders to keep records (ref.: point 21.A.5-21.A.605).

- 1.(a) Type certificate
  - (1)a) Copy of the type-certificate TC
  - (2)b) Copy of the type certificate data sheet TCDS
  - (3)c) Environmental protection approval data
  - (4)d) Documents defining the type-certification basis including information to justify special conditions, equivalent safety findings and exemptions (Certification Review Items or equivalent)
  - (5)e) List of approved modifications,
  - (6)f) List of the competent authority's approved publications (Flight Manual, Repair Manual, Airworthiness Limitations, Certification Maintenance Requirements)
  - (7)g) Airworthiness directives
  - (8)h) Master Minimum Equipment List
  - (9);) Maintenance Review Board Report
- 2.(b) Supplemental type certificate



- —(1) Copy of supplemental type certificate the STC
- —(2) Environmental protection approval data
- —(3) Documents defining the certification basis including information to justify special conditions, equivalent safety findings and exemptions (Certification Review Items or equivalent)
- —(4) List of the competent authority's approved documents
- —(5) Airworthiness directives
- **₃(c) JETSO** Authorisation
  - —(1) Copy of JETSO authorisation letter
  - —(2) Copy of Declaration of Design and Performance
  - —(3) Statement of compliance with applicable standards
  - —(4) Airworthiness directives
- 4(d) Other part or appliance approvals
  - a)(1) Copy of the approval letter,
  - b)(2) Copy of the Declaration of Design and Performance or equivalent
  - c)(3) Statement of compliance with applicable standards
  - d)(4) Airworthiness Ddirectives
- **5** (e) Changes from non TC or STC holders
  - a)(1) Modification approval sheet, or equivalent document
  - b)(2) Documents required by 21.A.105 point 21.A.5, or equivalent national requirement

Note: Not applicable to minor design changes approved approvals issued under a DOA privilege, for which record-keeping is under the DOA holder responsibility.

- 6 (f) Repair design approvals
  - a)(1) Repair approval sheet
  - b)(2) Documents listed in 21.A.447 point 21.A.5, or equivalent national requirement

Note: Not applicable to repair designs approved under a DOA privilege, for which recordkeeping is under the DOA holder responsibility.

## GM1 21.B.65 Suspension, limitation and revocation

### **DEFINTIONS**



#### (a) SUSPENSION

A suspension is a temporary withdrawal of all the privileges of an organisation's approval. No activities that invoke the approval can be made while the suspension is in force. Approval privileges may be reinstated when the circumstances that caused the suspension are corrected and the organisation can once again demonstrate full compliance with the requirements.

#### (b) LIMITATION

A limitation is an amendment to the certificate, approval, authorisation or letter of agreement that partially limits the privileges of the organisation.

### (c) REVOCATION

A revocation is a permanent cancellation of the whole of an approval. All the rights and privileges of the organisation under the approval are withdrawn, and, after revocation, the organisation cannot perform activities that invoke the approval, and must remove all references to the approval from its company documentation.

## GM2 21.B.65 Suspension, limitation and revocation

## LINK BETWEEN FINDINGS AND SUSPENSION OR LIMITATION OR REVOCATION

The level 1 findings are those which may lead, if not properly addressed, to suspension, limitation or revocation of the approval. If appropriate, these negative decisions on the approval may be taken immediately, or after the organisation fails to comply within the time period agreed by the competent authority.

The type of the negative decision — i.e. suspension, limitation or revocation — should depend upon the contents and the extent of the level 1 finding. Normally, a limitation or a suspension should be considered first.

## SUBPART B — TYPE-CERTIFICATES AND RESTRICTED TYPE-CERTIFICATES

[...]

## SUBPART F — PRODUCTION WITHOUT PRODUCTION ORGANISATION APPROVAL



## AMC1 21.B.120(a) Initial certification procedure

#### **INVESTIGATION TEAM AND PROCEDURES**

- (a) The competent authority should appoint a team for each applicant for, or holder of, a letter of agreement. This team is responsible for conducting all the relevant tasks related to the issuance of the letter of agreement. The team should consist of a team leader to manage and lead the team, and, if needed, one or more team members. The team leader should report to the manager who is responsible for the activities of the competent authority as defined in point 21.B.25(b).
- (b) The competent authority should perform sufficient investigation activities for an applicant for, or holder of, a letter of agreement, to justify the recommendations for the issuance, maintenance, amendment, suspension, limitation or revocation of the letter of agreement.
- (c) The competent authority should prepare procedures for the investigation of applicant for, or a holder of, a letter of agreement, as part of the documented procedures that cover at least the following elements:
  - (1) evaluation of the application received;
  - (2) appointment of the investigation team;
  - (3) preparation and planning of the investigation;
  - (4) evaluation of the documentation (manual, procedures, etc.);
  - (5) auditing;
  - (6) follow-up of corrective actions; and
  - (7) recommendations for the issuance, amendment, suspension, limitation or revocation of a letter of agreement; and
  - (8) oversight.

AMC2 21.B.120(a) Initial certification procedure

- Qualification criteria for the investigation team members

#### **QUALIFICATION CRITERIA FOR THE INVESTIGATION TEAM MEMBERS**

The competent authority must should ensure that the team leader and team members have received appropriate training in the relevant Subparts of Part 21 and in the related competent authority documentation before performing investigations in accordance with AMC1 21.B.25(a)(3). They must should also have knowledge and experience at the appropriate level in aviation production and inspection activities relative related to the particular application for a letter of agreement.

AMC<mark>3</mark> 21.B.120(a)(c)(1) Initial certification procedure Evaluation of applications

#### **EVALUATION OF APPLICATIONS**

(a) 1. General



When applying Part 21 Section A, Subpart F and Section B, Subpart F, the competent authority should must consider that these Subparts are only an alternative way alternatives for production to Part 21 Section A, Subpart G and Section B, Subpart G. To meet the ICAO airworthiness obligations and to issue a ccertificate of Aairworthiness for an individual aircraft in a practical and efficient way, the competent authority must should use a system of approval of production organisations (POA) under Part 21 Section A, Subpart G and Section B, Subpart G, providing to the competent authority the necessary confidence in the technical standards. The consistent standards of these approvals will also support the standardisation efforts by the Agency EASA. Nevertheless, it is recognised that it is not always practical, economical and/or advisable to use the POA.

Considering the ICAO airworthiness obligations as well, Part 21 Section A, Subpart F and Section B, Subpart F is are provided for such a case on the basis of the following principles:

- (1)a) Subpart F should must be considered as an alternative option for particular cases.
- (2)b) Its adoption should must be done on an individual basis, as a consequence of an assessment by the competent authority (see point 21.A.121, 21.A.133(a) and its their associated CS AMC and GM).

## (b)2. Application

The competent authority should must receive an application for a letter of agreement on an EASA Form 60 (see AMC1 21.A.124below) completed by the applicant. The eligibility of the application should be verified in relation to the competent authority procedures, based on point 21.A.121 and its associated AMC CS and GM. The applicant should be advised accordingly about the acceptance or rejection of the application.

#### 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.

#### (c)3. Location of the applicant

The location of the applicant seeking acceptance for production under Part 21 Section A, Subpart F determines which competent authority is responsible for issuing the letter of agreement.



EASA Form 60  Application for agreement of production under Part 21 Subpart F		
Competent authority		
<del>of an EU Member State or</del>		
<u>EASA</u>		
1. Registered name and address of the applicant:		
2. Trade name (if different):		
3. Location(s) of manufacturing activities:		
4. Description of the manufacturing activities under application		
— a) Identification (TC, P/N , as appropriate):		
— b) Termination (No. of units, Termination date,):		
5. Evidence supporting the application, as per 21.A.124(b):		
6. Links/arrangements with design approval holder(s)/ design organisation(s) where different from Block 1.:		
7. Human resources:		
8. Name of the person signing the application:		

EASA Form 60 Issue 3

Block 1: The name of the applicant must be entered. For legal entities the name must be as stated in the register of the National Companies Registration Office. In this case a copy of the entry in the register of the National Companies Registration Office must be provided to the competent authority.



- Block 2: State the trade name by which the applicant is known to the public if different from the information given in Block 1. The use of a logo may be indicated in this Block.
- Block 3: State all locations of manufacturing activities that are covered by the application. Only those locations must be stated that are directly under the control of the applicant stated in Block 1.
- Block 4: This Block must include further details of the manufacturing activities under the approval for the addresses indicated in Block 3. The Block 'Identification' must indicate the products, parts or appliances intended to be produced, while the Block 'Termination' must address any information on the limitation of the activity, e.g., by stating the intended number of units to be manufactured or the expected date of completion of the manufacturing activities.
- Block 5: This Block must state evidence supporting the determination of applicability as stated in <u>21.A.121</u>. In addition an outline of the manual required by <u>21.A.125A(b)</u> must be provided with the application.
- Block 6: The information entered here is essential for the evaluation of eligibility of the application. Therefore special attention must be given concerning the completion of this Block either directly or by reference to supporting documentation in relation to the requirements of 21.A.122 and AMC No 1 to 21.A.122.
- Block 7: The information to be entered here must reflect the number of staff, or in case of an initial approval the intended number of staff, for the manufacturing activities under this application and therefore must include also any associated administrative staff.

Block 8: State the name of the person authorised to sign the application.

# AMC4GM 21.B.120(a)(c)(3) Initial certification procedure Investigation preparation and planning

#### INVESTIGATION PREPARATION AND PLANNING

Following acceptance of an application for a letter of agreement and before commencing an investigation, the competent authority should:

- -(a) identify the site locations that they needing need to investigate investigation;
- —(b) liaise with the competent authority of another a Member State where the investigation of the organisation should include a there is seen to be a need to visit a production facility in that Member State for one of the following reasons:
  - (1)a) where a manufacturer production organisation has contracted part of the production to another organisation holding a POAproduction organisation approval and a need arises to ensure that the contract has the same meaning for all the parties to the contract, and the local competent authority of the Member State agrees;
  - (2)b) to inspect a product (or part or appliance) under production where the sub-contractor subcontractor is does not hold holding a POA.
- -(c) co-ordinate coordinate with the competent authority of a third country and/or the Agency EASA where the investigation of the organisation should include there is seen to be a need to visit a production a facility in that country for one of the following reasons:
  - (1)a) where a manufacturer production organisation has contracted part of the production to another organisation holding a POAproduction organisation approval issued by the Agency EASA or accepted through an recognition agreement in accordance with Article



- 12 68 of the Basic Regulation (EU) 2018/1139, and a need arises to ensure that the contract has the same meaning for all the parties to the contract, and the Agency EASA and/or the competent authority agrees;
- (2)b) to inspect a product (or part or appliance) under production where the sub-contractor subcontractor is does not holding hold a POA.

## GM1 21.B.120(c)(5) and (6) Initial certification procedure Auditing and investigation findings

### **AUDITING AND INVESTIGATION FINDINGS**

During its investigation process, the competent authority may raise make findings which should then be recorded. These may be non-conformities to the requirements, the manual as supplied by the production organisation manufacturer describing its inspection procedures, or non-conformities related to the items under inspection. The manner in which the findings will be handled by the competent authority before and during the validity of the letter of agreement, should be detailed in its procedures.

## AMC1 21.B.120(d) Initial certification procedure

### **ISSUE OF THE LETTER OF AGREEMENT**

- (a) 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.
- (b) The agreement should include or reference a predefined 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 points 21.A.129 and 21.B.120(a) and their associated AMC and GM. The plan should clearly identify the inspection points, places, inspection subjects (materials, processes, tooling documentation, human resources, etc.), as well as the focal points and the method of communication between the production organisation and the competent authority.
- (c) The competent authority should detail the method by which it will assure itself that the production organisation is working in accordance with the manual and the agreed inspection procedures during the validity period of the agreement. For a renewal of this validity period, the procedure as defined in point 21.B.140 should be used.
- (d) Any conditions under which the agreement will expire (such as the termination date and/or number of units to produce) should be clearly stated in the letter of agreement.



## GM1 21.B.125(b) 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 a non-compliance that:

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

# GM24 21.B.125(b), and 21.B.225(b) and 21.B430(b) Findings and corrective actions; observations

#### **EVIDENCE**

### A finding can only be raised on the basis of evidence.

Evidence is a fact that is, or can be, documented based on observations, measurements, or tests that can be verified. 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 activities, as applicable.

## AMC1 21.B.125(d) and 21.B.225(d) Findings and corrective actions; observations

#### **NOTIFICATION OF FINDINGS**

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

A <u>Level 1 and level 2</u>-findings requires <u>timely and</u> effective oversight by the competent authority to <u>ensure</u>monitor the <u>timely</u> 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(e) and 21.B.225(e) 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 to 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(e)).
  - However, tThe competent authority may decide to issue a 'level 2' finding' when the 'observations' process is not managed correctly or is overlooked (see points 21.A.125B(c) and 21.A.158(c)).
- (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(b)(1)(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;
- (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').
- (cd) The color of the 'unserviceable' tag of the tools may generate some confusion. The organisation should consider changing the color of that unserviceable tag to better alert its staff on the particular status of the unserviceable tools (potential improvement).

## AMC 21.B.140 Amendment of a letter of agreement

The competent authority must be satisfied that any change affecting a letter of agreement comply complies with the shows of Section A Subpart F before implementation can start. A plan for the change should be agreed with the applicant in accordance with AMC1 21.B.120(d) AMC 21.B.130. If the change affects the content of the letter of agreement, a new application should be filed, and an amended/revised letter of agreement should be obtained subsequently.

## SUBPART G — PRODUCTION ORGANISATION APPROVAL

## AMC1 21.B.220 Initial certification procedure

## **INVESTIGATION TEAM AND PROCEDURES**

- (a) The competent authority should appoint a production organisation investigation team for each applicant for a production organisation approval. This team is responsible for conducting all the relevant tasks related to the approval. The team should consist of a team leader to manage and lead the approval team and, if needed, one or more team members. The team leader should report to the manager who is responsible for the activities of the competent authority as defined in point 21.B.25(b).
- (b) The competent authority should perform sufficient investigation activities for an applicant for a production organisation approval, to justify the recommendations for the issuance of the approval.
- (c) The competent authority should prepare procedures for the investigation of a production organisation as part of the documented procedures that cover at least the following elements:
  - evaluation of the application received;
  - (2) appointment of the investigation team;
  - (3) preparation and planning of the investigation;
  - (4) evaluation of the documentation (production organisation exposition, procedures, etc.);
  - (5) auditing;
  - (6) follow-up of corrective actions;



- (7) recommendation for the issuance of a POA; and
- (8) continued surveillance.

## **GM-ELA No 1 to 21.B.220 Investigation**

The AMC indicated with 'AMC-ELA' and the GM related to them (as indicated with 'GM-ELA'), provide an alternative set of AMC and GM to the other available AMC and GM.

The AMC-ELA provide acceptable means to meet the requirements for small, non-complex organisations that produce aircraft as specified in AMC ELA No 1 to 21.A.131.

## GM-ELA No 1 to 21.B.220(a) Investigation team

#### 1. Type of team

When appointing a production organisation approval team (POAT), it is important for the member(s) of that team to have a very good understanding of the organisational processes, as well as of the nature and the established manufacturing practices for products that are within the scope of work of the applicant.

The AMC ELA of Section A of Subpart G for production organisations substantially relies on product conformity and uses, if possible, existing quality management systems. The team should, therefore, be familiar with:

- (a) conducting product conformity audits;
- (b) alternative quality management systems that are typically applied by companies that produce light aeroplanes, such as ISO 9001, EN 9100, ASTM F2972, or similar standards;
- (c) the typical practices used for the production of light aeroplanes and the related products and parts.

If the team is not able to cover all the aspects of the product that are considered to be within the scope of work of the applicant, the production organisation approval team leader (POATL) should coordinate with both the competent authority and the production organisation on identifying suitable subject matter expert(s) who may provide support during the investigation. The overall size of the team should be adequate for the size of the company to be investigated.

## AMC1 21.B.220 Initial certification procedure

### **VERIFICATION OF COMPLIANCE — INITIAL CERTIFICATION AUDITS**

- (a) In order to verify the organisation's compliance with the applicable requirements, the investigation by the competent authority should include one or more audits of the organisation, together with interviews of the personnel, carried out at the organisation's facilities.
- (b) The competent authority should only conduct such an audit if it is satisfied that the application and supporting documentation are in compliance with the applicable requirements.
- (c) The audit should focus on the following areas:



- the detailed management structure, notably its adequacy;
- (2) the personnel: the adequacy of the number of staff, and of their qualifications and experience with regard to the intended terms of approval and the associated privileges;
- (3) the processes used for safety risk management and compliance monitoring;
- (4) the facilities and their adequacy regarding the organisation's intended terms of approval including its scope of work; and
- (5) the documentation based on which the approval should be granted.
- (d) If an application for an approval is refused, the applicant should be informed of the right of appeal that exists under national or EU law.

AMC2 GM No 1 to 21.B.220(c) Procedures for investigation— Investigation preparation and planning Initial certification procedure

#### **INVESTIGATION PREPARATION AND PLANNING**

Following the acceptance of the application for a POA and before commencing an investigation, the competent authority should, for the preparation and planning of the investigation:

- (a) identify the site locations that they need to investigate needing investigation taking into account the scope of any other POA issued by a Member State, which are valid in the circumstances;
- liaise with the Agency for the appointment of any necessary observer(s) for standardisation purposes
- (b) establish any necessary liaison arrangement with other competent authorities;
- (c) agree the size and composition of the investigation team POAT and any specialist tasks likely
  to be covered and to select suitable team members from all involved competent authorities; and
- seek any necessary advice and guidance from the Agency
- (d) liaise with the competent authority of the other a Member State where the investigation of the organisation should include a there is seen to be a need to visit a production approval holder facility in that Member State for one of the following reasons:
  - (1) where a production organisationmanufacturer has subcontracted production to another organisation and therefore a need arises to ensure that the contract has the same meaning for all the parties to the contract, and the competent authority of the Member State agrees;
  - (2) to perform the audit of the production of inspect a product, part, appliance, or material under production at the approved organisation facilities in that Member State. for its own, Member States or non-EU register.



## AMC3GM 21.B.220(a) Initial certification procedure Investigation team

#### **INVESTIGATION TEAM**

## (a)1. Type of Team team

Where the applicant is located in a Member State, tThe competent authority should appoint a production organisation approval team (POAT) leader (POATL) and members appropriate to the nature and scope of the applicant's organisation.

Where the facilities of the applicant are located in more than one Member State, the competent authority of the country of manufacture should liaise with the other involved competent authorities to agree and appoint a POATL-leader and members appropriate to the nature and scope of the applicant's organisation.

## (b)2. Team leader selection

The team leader should satisfy all of the criteria for a team member and will be selected by considering the following additional criteria:

- (1)a) the capability to lead and manage a team;
- (2)b) the capability to prepare reports and be diplomatic;
- (3)e) experience in approval team investigations (not necessarily only Part 21 Section A, Subpart G);
- (4)d) a knowledge of production and quality systems for aircraft and related products and parts; and
- 5) a knowledge of management systems of production organisations.

#### (c)3. Team member selection

The team leader should agree with the The competent authority should determine on the size of the POA team and the specialisations to be covered taking into account the scope of work and the characteristics of the applicant. Team members should be selected by considering the following criteria:

- (1) training, which is mandatory, for Part 21 Section A, Subpart Subparts A and G and Section B, Subpart Subparts A and G;
- (2) education and experience, to cover appropriate aviation knowledge, audit practices and approval procedures; and
- (3) the ability to verify that an applicant's organisation conforms to its own POA procedures, and that its key personnel are competent.



## AMC-ELA No 1 to 21.B.220(b) Extent of the investigation

The initial and the continued investigations of a company should primarily be conducted by investigating the conformity of products on which work is in progress, or following their completion, and by direct product assessment, or the assessment of product related production records.

When conducting investigations on companies that apply either a production organisation exposition (POE) and/or a company manual that is based on a template [11] provided in accordance with the GM-ELA to Subpart G of Section A, the competent authority should verify whether the documentation has been adequately adapted to the specific details of the company.

Note [1]: A POE template, published by EASA, is provided as additional informative material. This material should not be considered as an AMC.

In order to avoid any duplication of oversight, the competent authority may use systems that implement ISO 9001 or AS/EN 9100 (including audit records) as evidence for compliance investigations.

When the company is capable of manufacturing products that are within the scope of work in a repeatable way, so that they conform to the type design, the competent authority should consider this to be sufficient evidence for the issuance, maintenance or amendment of the approval.

If non-conformities are encountered that reveal a lack of consistent production control, further investigations should be conducted by the company to establish the root cause and the appropriate corrective actions.

# AMC 21.B.220(c) Procedures for investigation – Evaluation of applications

The competent authority must receive an application for POA on an EASA Form 50 (see below) completed by the applicant. The eligibility and appropriateness of the application must be evaluated in accordance with <u>21.A.133</u> at that time and the applicant must be advised about acceptance or rejection of its application in writing accordingly.

EASA Form 50 Application for Part 21 production organisation approval		
Competent authority		
of an EU Member State or		
<del>EASA</del>		
1. Registered name and address of the organisation:		

## AMC and GM to Part 21 Issue 2, Amendment 16

2. Trade name (if different):		
3. Locations for which the approval is applied for:		
4. Brief summary of proposed activities at the item 3 addresses		
<del>a) General:</del>		
——b) Scope of approval:		
— c) Nature of privileges:		
5. Description of organisation:		
6. Links/arrangements with design approval holder(s)/design organisation(s) where different from 1.:		
7. Approximate number of staff engaged or intended to be engaged in the activities:		
8. Position and name of the accountable manager:		

#### EASA Form 50

<del>Date</del>

Block 1: The name of the organisation must be entered as stated in the register of the National Companies

Registration Office. For the initial application a copy of the entry in the register of the National

Companies Registration Office must be provided to the competent authority.

Signature of the accountable manager

- Block 2: State the trade name by which the organisation is known to the public if different from the information given in Block 1. The use of a logo may be indicated in this Block.
- Block 3: State all locations for which the approval is applied for. Only those locations must be stated that are directly under the control of the legal entity stated in Block 1.
- Block 4: This Block must include further details of the activities under the approval for the addresses indicated in Block 4. The Block 'General' must include overall information, while the Block 'Scope of approval' must address 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 the requested privileges as defined in 21.A.163(b) (e). For an application for renewal state 'not applicable'.
- Block 5: This Block must state a summary of the organisation with reference to the outline of the production organisation exposition, including the organisational structure, functions and responsibilities. The



nomination of the responsible managers in accordance with <u>21.A.145(c)(2)</u> must be included as far as possible, accompanied by the corresponding EASA Forms 4.

For an application for renewal state 'not applicable'.

- Block 6: The information entered here is essential for the evaluation of eligibility of the application. Therefore special attention must be given concerning the completion of this Block either directly or by reference to supporting documentation in relation to the requirements of 21.A.133(b) and (c) and the AMC to 21.A.133(b) and (c).
- Block 7: The information to be entered here must reflect the number of staff, or in case of an initial approval the intended number of staff, for the complete activities to be covered by the approval and therefore must include also any associated administrative staff.
- Block 8: State the position and name of the accountable manager.

## AMC-ELA No 1 to 21.B.220(c) Procedures for investigation – Evaluation of applications

- EASA Form 50 from AMC 21.B.220(c) applies, with the following instructions for its completion:
- Block 1: The name of the organisation must be entered as stated in the register of the National Companies Registration Office. For the initial application, a copy of the entry in the register of the National Companies Registration Office must be provided to the competent authority.
- Block 2: state the trade name by which the organisation is known to the public if different from the information given in Block 1. The use of a logo may be indicated in this Block.
- Block 3: State the major place of activity as per definition in <u>GM-ELA No 2 to 21.A.131</u> and where the products are completed and checked out, and for which the approval is applied for.
- Block 4: This Block must include further details of the activities under the approval for the addresses indicated in Block 4. 'General' shall include the relevant part of the Scope definition provided by AMC ELA No 1 to 21.A.131. 'Scope of approval' shall name the applicable scope (refer to GM-ELA No 1 to 21.B.230). A reference to the product type(s) may be provided for further clarification, even when this information will not be part of the terms of approval of the approved production organisation. 'Nature of privileges' shall list what is applicable of '21.A.163(a), (b), (c), (d), (e)'.
- Block 5: If existing at the time of application, make reference to the draft version of the POE as per AMC-ELA No 1 to 21.A.143. Otherwise state: 'Will be provided when the POE draft is available.' For an application for renewal, state: 'Not applicable.'
- Block 6: Depending on the case, either of 'Production and holder of the type certificate/design approval operate within one consolidated entity and under one management'; or 'Satisfactory coordination between production and type certificate/design approval holder is ensured by implementation of adequate responsibilities for the coordination in both directions.'
- Block 7: The information to be entered here must reflect the approximate number of staff, or in case of an initial approval, the intended number of staff, for the complete activities to be covered by the approval and therefore must include also any associated administrative staff.



Block 8: State the position and name of the accountable manager.

### AMC-ELA No 2 to 21.B.220(c) Procedures for investigation - General

#### General

The competent authority needs to investigate the applicant's production organisation for its ability to produce products within the scope of work and that conform to the type in a repeatable way, so that they conform to the type design. It should establish procedures that include the following aspects:

- Preparation and planning for an investigation
  - 2.1. The POA team leader (POATL) should initiate the investigation of a new applicant by arranging a meeting with the applicant, in which the applicant should provide a general presentation of its organisation and products, parts or appliances, and in which the POATL should describe the investigation process to the applicant.
  - 2.2. The POA team (POAT) should study the information gathered in the initiation phase, including information from other teams of the competent authority of the Member State or EASA on the functioning of the applicant's organisation, especially when the production organisation and the design organisation form one consolidated team.
  - 2.3. The POAT should establish an investigation plan that:
    - takes account of the location of the POA applicant's facilities;
    - defines the subject matter that will be covered by the team members;
    - identifies any areas of expertise that the team may be lacking in, and how to seek external advice;
    - includes a comprehensive plan for auditing a representative set of products while work is in progress or following its completion, and by direct product assessment, or assessment of product related production records; and
    - includes liaison with the applicant in order to plan mutually suitable dates and times
      for visits, to determine the necessary size of the investigation team on both sides,
      and to agree on the investigation plan and the approximate timescales.

#### Investigation

3.1. Evaluation of the documentation (production organisation exposition (POE), procedures, etc.)

#### The POAT should:

- assess the POE for compliance with point <u>21.A.143</u>, e.g. by using <u>AMC-ELA No 1 to</u> <del>21.A.143</del>;
- evaluate (as applicable) the use of ISO 9001 or AS/EN 9100 in accordance with AMC-ELA No 1 to 21.B.220(b).

#### 3.2. Auditing



#### The POAT should:

- audit the product and its associated documentation for conformity with the
  provisions of the relevant type design. If discrepancies are found on the audited
  product, the POATL should assess whether the definitions of the quality system have
  been adhered to, and whether those definitions may have been misleading and may
  have contributed to the discrepancies, which may indicate a need for a modification;
- review the acceptance of the key nominated personnel, confirmed by the completed EASA Form 4 (refer to <u>AMC-ELA No 1 to 21.A.145(c)</u>), on the basis of a review of the skills of each nominee, used as the basis for the nomination;
- conduct sample audits at appropriate stages of production to verify that:
  - (i) the products, parts, appliances and material produced by the organisation are in conformity with the applicable design data;
  - (ii) the level of product conformity achieved indicates that the facilities, working conditions, equipment and tools are appropriate to allow the work to be performed in a repeatable way;
  - (iii) the achieved production rate and the number of product non-conformities indicate that the number of personnel and their competences are sufficient to allow the work to be performed in a repeatable way; and
  - (iv) the identified responsibilities and examples show that there is satisfactory and effective coordination between the production entity and the design entity.

The investigation team should be accompanied during the sample audits by company representatives who are knowledgeable about the applicant's organisation and procedures. This will ensure that the organisation is aware of the progress of the audit and of any problems as they arise. This will also make it easier for the investigation team to gain access to the information of the company;

- coordinate with the subject-matter experts who provide external advice for any areas
  of expertise that the team may be lacking in, and enable an efficient investigation to
  take place, which will provide consistent and effective investigations and reporting;
- meet the accountable manager at least once during the investigation process, and preferably twice. The accountable manager should be briefed on the investigation process and on the results of the investigation.

#### 3.3. Follow-up of corrective actions

In order to draft the audit report, the POAT should hold a meeting with the applicant to review any findings and observations.

The POAT, upon completion of the investigation, should hold a meeting with the applicant to verbally present the report.

The POAT should present the findings, the corrective action plan, and the preliminary arrangements for any follow-up that may be necessary.



The POATL should transmit the final report, together with the minutes of the final meeting with the applicant, to the competent authority of the applicant. The report should include any recommendations for improvements and any significant findings, together with appropriate conclusions and a corrective action plan. In particular, it should indicate whether the POE is acceptable, or changes are required.

If the findings made during the investigation mean that a recommendation for approval will not or cannot be issued, then the related findings should be provided to the applicant in writing within 2 weeks' time from the date of the visit.

3.4. Recommendation for the issuance, amendment, suspension or revocation of a production organisation approval

The POATL should track the feedback obtained from the applicant, taking into consideration the timelines specified in point <u>21.A.158(c)</u>. The POATL should consider the means provided by <u>AMC No 1 to 21.B.230</u>. The recommendation should be documented using EASA Form 56, Part 5.

#### 3.5. Continued surveillance

Subsequent to an initial approval, the POATL should coordinate with the applicant on a mutually agreed surveillance plan that is appropriate for the size, product range and production rate of the company, taking into consideration the means provided by <u>AMC-ELA No 1 to 21.B.235</u>.

# GM1 No 2 to 21.B.220(a)(c) Initial certification procedure Procedures for investigation — General

#### ORGANISATION APPROVAL — GENERAL

#### (a) 1. Purpose of the Pprocedures

The purpose of the procedures is to investigate the applicant's production organisation for compliance with Part 21 Subpart G in relation to the requested terms of approval. When appropriate, this procedure these procedures should also be used to investigate significant changes or applications for variation variations of in the scope of approval.

The following procedure assumes that the application has been accepted and that an investigation team has been selected.

#### (b)2. Initiation

The POA Tteam Lleader initiates the procedure by:

2.(1) arranging a meeting with the POAT team members to review the information provided in accordance with the application (according to point 21.A.134) and to take account of any other information available within the competent authority about the applicant knowledge that the POAT members have regarding the production standards of the applicant;



- 2.(2) obtaining collecting information from other investigation or oversight teams of a competent authorities authority of the Member State or the Agency EASA on the functioning of the applicant's organisation (see GM No 1 to 21.B.45);
- 2.(3) arranging a meeting with the applicant in order to:
  - (i) enable the applicant to make a general presentation of its organisation and products, parts or appliances;
  - (ii) ensure that the accountable manager understands his or her role and accountability when signing the statement specified in point 21.A.143(a)(1);
  - (iii) enable the investigation team POAT to describe the proposed investigation process;
  - (iv) enable the investigation team POAT to confirm to the applicant the identity of those managers nominated in accordance with Part 21 Subpart G, Section A. who need to complete an EASA Form 4 (See EASA Form 4 for Production Organisations on EASA website: <a href="http://easa.europa.eu/certification/application-forms.php">http://easa.europa.eu/certification/application-forms.php</a>). The applicant should provide a completed copy of EASA Form 4 for each of the key management staff identified by Part 21 Subpart G. The EASA Form 4 is a confidential document and will be treated as such.

#### (c)3. Preparation

The investigation team POAT:

- 3.(1) studies the information gathered in the initiation phase;
- 3.(2) establishes an investigation plan which:
  - (i) takes account of the location of the POA applicant's facility as identified per GM3 21.B.65(c); GM No 3 to 21.B.220(c)
  - (ii) defines areas of coverage and work-sharing between teamPOAT members taking account of their individual expertise;
  - (iii) defines areas where more detailed investigation is considered necessary;
  - (iv) establishes the need for external advice to team<del>POAT</del> members where expertise may be lacking within the team;
  - (v) includes completion of a comprehensive plan for the investigation in order to present it to the applicant; and
  - (vi) recognises the need to:
    - (A) review the documentation and procedures;
    - (B) verify compliance and implementation; and
    - (C) audit a sample of products, parts, and appliances;
- 3.(3) co-ordinates with the appropriate Part 21 Section A Subpart J design organisation approval Tteams sufficiently for both parties to have confidence in the applicant's co-ordination links with the holder of the approval of the design (as required by point 21.A.133); and



3.(4) establishes liaison with the applicant to plan mutually suitable dates and times for audits or inspections visits at each location needing investigation, and also to agree the investigation plan and approximate time scales with the applicant.

#### (d)4. Investigation

The investigation team **POAT**:

- 4.(1) makes a check of the exposition POE for compliance with Part 21; Subpart G
- 4.(2) audits the organisation, its organisational structure, and its working procedures and processes for compliance with Part 21 Subpart G, using internal compliance checklist EASA Form 56 as a guide during the investigation, and as a checklist and at the end of it the investigation, prepares the EASA Form 56 as a summary document;
- 4.3. generates compliance checklists for investigations of working processes and procedures on site as required
- 4.4 accepts or rejects each EASA Form 4 completed by the key nominated personnel in accordance with 21.A.145(c)(2)
- 4.(35) checks that the exposition production organisation exposition (POE) standard reflects the organisation, its procedures, practices and the requirements defined in point 21.A.143. Having checked and agreed a an exposition POE issue or subsequent amendment, the competent authority should have a clear procedure to indicate its acceptance or rejection;
- 4.(46) makes performs sample audits at working level to verify that:
  - (i) work is performed in accordance with the system described in the exposition POE;
  - (ii) products, parts, appliances or material produced by the organisation are in conformity with the applicable design data (see GM 21.B.235(b)(4));
  - (iii) facilities, working conditions, equipment and tools are in accordance with the exposition POE and appropriate for the work being performed;
  - (iv) competence competency and numbers of personnel is are appropriate for the work being performed; and
  - (v) co-ordination coordination between production and design is satisfactory; and
- 4.(57) at an advanced stage of the investigation, conducts an interim team review of audit results and matters arising, in order to determine any additional areas requiring investigation.

Each investigation team should be accompanied during the process by company representatives who are knowledgeable of the applicant's organisation and procedures. This will ensure that the organisation is aware of the audit progress and problems as they arise. Access to information will also be facilitated.

The team leader POATL should co-ordinate coordinate the work of the team POAT members for an efficient investigation process, which will provide a consistent and effective investigation and reporting standards.



#### (e)5. Conclusions

- 5.(1) The team leader POATL holds a team meeting to review the findings and observations so as to produce a final agreed report of findings.
- 5.(2) The team leader POATL, on completion of the investigation, holds a meeting to verbally presents the report to the applicant.
  - The team leader POATL should be the chairman of this meeting, but individual team members may present their own findings and observations.
- 5.(3) The meeting should agree the findings, corrective action time scales, and preliminary arrangements for any follow-up that may be necessary.
- 5.(4) Some items may as a result of this meeting be withdrawn by the team leader POATL but if the investigation has been correctly performed, at this stage there should be no disagreement over the facts presented.
- 5.(5) Inevitably there will be occasions when the team POAT leader/member carrying out the audit may find situations in the applicant or POA approval holder where he or she it is unsure about compliance. In this case, the organisation is informed about possible non-compliance at the time and advised that the situation will be reviewed within the competent authority before a decision is made. The organisation should be informed of the decision without undue delay. Only if the decision results in a confirmation of non-compliance, this is recorded in the audit report, eventually in Part 4 of EASA Form 56 at the end of investigation, if not solved before.
- 5.6 The POATL will transmit the final signed report on EASA Form 56 together with notes of the final meeting with the applicant to the competent authority where the applicant is located. The report will include recommendations and significant findings, together with appropriate conclusions and corrective actions. In particular, it should indicate if the POE is acceptable, or changes are required.
- 5.(67) Completion of the audit report EASA Form 56 includes the need to record in Part 4 findings, observations, comments, criticisms, etc., and this must should reflect any problems found during the auditvisit and must should be the same as the ones the comments, criticisms made to the organisation during the debrief at the end of each audit. Under no circumstances should additional findings, observations, comments, criticisms, etc., be included in the audit Part 4 of the report, unless the applicant or POA approval holder has previously been made aware of such comments.

Many applicants An applicant may need to take corrective action and amend the proposed exposition before the competent authority is able to conclude its investigation. Such corrective actions should be described in a corrective action plan submitted by the organisation and agreed by the investigation team summarised in Part 4 of the EASA Form 56 and a copy always given to the applicant, so that there is a common understanding of the actions necessary before approval can be granted.

The intention of the EASA Form 56 Part 4 is to provide a summary report of findings and outstanding items during initial investigation and major changes. The competent



authority will need to operate a supporting audit system to manage corrective action monitoring, closure etc. While the EASA Form 56 Part 4 format may be used for monitoring purposes, it is not adequate on its own to manage such system.

- 5.(78) If the findings Findings raised made during the investigation mean that approval recommendation will not or cannot be issued, then it is essential that such findings are communicated at the last day of the audit to the organisation. The final version of the audit report is confirmed in writing to the organisations within two 2 weeks of the visit each audit. The reason for confirmation in writing is that many organisations take a considerable time to establish compliance. As a result, it is too easy to establish a position of confusion where the organisation claims it was not aware of the findings that prevented the issue of an approval.
- (8) At the end of the investigation, the team leader will prepare the final report through an EASA Form 56 and in accordance with the competent authority internal procedures. The report will include the recommendations and any open finding or observation, together with the supporting documentation e.g. audit reports, corrective action plan, closure of findings, minutes of meetings held during the investigation, etc.
  - The intention of Part 4 of the EASA Form 56 is to provide a summary report of open findings, observations and outstanding items at the end of initial investigation or significant changes to recommend the issue of the approval, or the issue of the significant change approval.

#### (f) 6. Management linvolvement

The investigation team should meet the accountable manager will be seen at least once during the investigation process and preferably twice, because he or she is ultimately responsible for ensuring compliance with the requirements for the initial grant granting and subsequent maintenance of the production organisation approval. Two Twice is the preferred number of visits to meetings with the accountable manager, with the first one being conducted at the beginning of the investigation the audit to explain the investigation process, and the second, at the end, to debrief on the results of the investigation.



# Competent authority of an EU Member State or EASA

### RECOMMENDATION REPORT IN SUPPORT OF Part 21 SUBPART G APPROVAL ISSUE / CONTINUATION / VARIATION / SIGNIFICANT CHANGE

PART 1 OF 5:	BASIC DETAILS OF THE ASSESSMENT
Name of the organisation	
Approval reference:	
Address(es) of the facilitie	surveyed:
Main Part 21 Subpart G ac	ivities at facilities surveyed:
Date(s) of survey:	
Names and positions of th	e organisation's senior management attended during survey:
Names of the competent	uthority staff:

O.C.	
Office:	EASA Form 56 completion date:
Note:	If it is determined that a recommendation for issue/continuation/variation/significant change of
	approval cannot be made because of a non-compliance with Part 21 Subpart G, the reasons for the non-compliance need to be identified in Part 4 of the report. A copy of Part 1 and Part 4, or at least
	the information included in these parts, must be given to the organisation to ensure that the
	organisation, in failing to obtain Part 21 Subpart G approval, even if only temporarily, has the same
	information as that in the files of the competent authority.

EASA Form 56 Issue 4 — POAT Recommendation Audit Report — Part 1 of 5, Page 1 of 1

**MONTH YEAR** 



Competent authority

of an EU Member State or

EASA

### RECOMMENDATION REPORT IN SUPPORT OF Part 21 SUBPART G ISSUE / CONTINUATION / VARIATION/SIGNIFICANT CHANGE

PART 2 OF 5:	Part 21 SUBPART G COMPLIANCE
Name of orga	anisation:
Approval of c	organisation:
Approval refe	erence: Survey reference:
	form has been compiled according to those points of Part 21 Subpart G which are relevant toganisation trying to demonstrate compliance.
Note B: The	right-hand part of each box must be completed with one of the following three indicators:
1.	a tick (✓) which means compliance;
2.	NR which means that the requirement is NOT RELEVANT to the activity at the address surveyed; (the reason for NR should be stated in Part 4 of the report, unless the reason is obvious)
3.	a number relating to a comment which must be recorded in Part 4 of the report.
Tho	left hand part of each boy is entional for use by the competent authority.



#### 21.A.3A Reporting system

- (a) N/A
- (b) Without prejudice to Regulation (EU) No 376/2014 of the European Parliament and of the Council and its delegated and implementing acts, any natural or legal person that holds or has applied for a production organisation approval certificate under Subpart G of this Section, or that produces a product, part or appliance under Subpart F of this Section, shall:
  - (1) establish and maintain a system for collecting and assessing occurrence reports, including reports on errors, near misses and hazards, in order to identify adverse trends or to address deficiencies and extract occurrences whose reporting is mandatory in accordance with points 2 and 3 and those which are reported voluntarily. For organisations that have their principal place of business in a Member State, a single system may be established to meet the requirements of Regulation (EU) No 376/2014 of the European Parliament and of the Council and its implementing acts and of Regulation (EU) 2018/1139 and its delegated and implementing acts;
  - (2) report to the responsible design approval holder all the cases where products, parts or appliances have been released by the production organisation and possible deviations from the applicable design data have been subsequently identified, and investigate with the design approval holder to identify those deviations which could lead to an unsafe condition;
  - (3) report to the competent authority of the Member State responsible in accordance with point 21.1 and the Agency the deviations that have been identified in accordance with point 21.A.3A(b)2 and which could lead to an unsafe condition;
  - (4) if the production organisation acts as a supplier to another production organisation, also report to that other organisation all the cases where it has released products, parts or appliances to that organisation and possible deviations from the applicable design data have been subsequently identified.
- (c) Without prejudice to Regulation (EU) No 376/2014 of the European Parliament and of the Council and its delegated and implementing acts, any natural or legal person, when reporting in accordance with points (a)(3), (b)(2), (b)(3) and (b)(4), shall appropriately protect the confidentiality of the person who reports and of the person(s) mentioned in the report.
- (d) Without prejudice to Regulation (EU) No 376/2014 of the European Parliament and of the Council and its delegated and implementing acts, any natural or legal person shall make the reports referred to in points (a)(3) and (b)(3) in a form and manner established by the Agency or the competent authority, respectively, and dispatch them as soon as practicable and in any case not later than 72 hours after the natural or legal person has identified that the occurrence may lead to a possible unsafe condition, unless exceptional circumstances prevent this.
- (e) Without prejudice to Regulation (EU) No 376/2014 of the European Parliament and of the Council and its delegated and implementing acts, if an occurrence reported under point (a)(3) or under point (b)(3) results from a deficiency in the design or a production deficiency, the holder of the type certificate, restricted type certificate, supplemental type certificate, major repair design approval, ETSO authorisation or any other relevant approval deemed to have been issued under this Regulation, or the production organisation as appropriate, shall investigate the reason for the deficiency and report to the competent authority of the Member State responsible in accordance with point 21.1 and to the Agency the results of its investigation and any action it intends to take or proposes to be taken to correct that deficiency.



(f)□ If the competent authority finds that action is required to correct the deficiency, the holder of the type certificate, restricted type certificate, supplemental type certificate, major repair design approval, ETSO authorisation or any other relevant approval deemed to have been issued under this Regulation, or the production organisation as appropriate, shall submit the relevant data to the competent authority upon its request.
 21.A.5 Record-keeping
 All natural or legal persons that hold or have applied for a type certificate, restricted type certificate, supplemental type certificate, ETSO authorisation, design or repair approval, permit to fly, production organisation approval certificate or letter of agreement under this Regulation shall:

#### (a) N/A

- (b) when they produce a product, part or appliance, record the details of the production process relevant to the conformity of the product, part or appliance with the applicable design data, and the requirements imposed on their partners and suppliers, and make that data available to their competent authority in order to provide the information that is necessary to ensure the continuing airworthiness of the product, part or appliance;
- (c) with regard to permits to fly:
  - (1) maintain the documents that are produced to establish and justify the flight conditions, and make them available to the Agency and to their competent authority of the Member State in order to provide the information that is necessary to ensure the continued airworthiness of the aircraft;
  - (2) when they issue a permit to fly under the privilege of approved organisations, maintain the documents associated with it, including inspection records and documents that support the approval of the flight conditions and the issuance of the permit to fly itself, and make them available to the Agency and to their competent authority of the Member State responsible for the oversight of the organisation in order to provide the information that is necessary to ensure the continued airworthiness of the aircraft;
- (d) ☐ retain records of the competence and qualifications, referred to in points 21.A.139(c), 21.A.145(b), 21.A.145(c), 21.A.239(c), 21.A.245(a) or 21.A.245(e)(1), of the personnel that are involved in the following functions:
  - (1) □ design or production;
  - (2) ☐ independent monitoring of the compliance of the organisation with the relevant requirements;
  - (3) ☐ safety management;
- (e) ☐ retain records of the authorisation of personnel, when they employ personnel that:
  - (1) □ exercise the privileges of the approved organisation pursuant to points 21.A.163 and/or 21.A.263, as appropriate;
  - (2) carry out the independent function to monitor the compliance of the organisation with the relevant requirements pursuant to points 21.A.139(e) and/or 21.A.239(e), as appropriate;
  - (3) □ carry out the independent verification function of the demonstration of compliance pursuant to point 21.A.239(d)(2).



#### 21.A.9 Access and investigation

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

- (a) □ grant the competent authority access to any facility, product, part and appliance, document, record, data, process, procedure or to any other material in order to review any report, make any inspection, or perform or witness any flight and ground test, as necessary, in order to verify the initial and continued compliance of the organisation with the applicable requirements of Regulation (EU) 2018/1139 and its delegated and implementing acts;
- (b) make arrangements to ensure the competent authority has access, as provided for in point (a), also in respect of the natural or legal person's partners, suppliers and subcontractors.

#### 21.A.133 Eligibility

Any natural or legal person ('organisation') shall be eligible as an applicant for an approval under this Subpart. The applicant shall:

- (a) ignstify that, for a defined scope of work, an approval under this Subpart is appropriate for the purpose of showing conformity with a specific design; and
- (b) ☐ hold or have applied for an approval of that specific design; or
- (c) have ensured, through an appropriate arrangement with the applicant for, or holder of, an approval of that specific design, satisfactory coordination between production and design.

#### 21.A.134 Application

Each application for a production organisation approval shall be made to the competent authority in a form and manner established by that authority, and shall include an outline of the information required by point 21.A.143 and the terms of approval requested to be issued under point 21.A.151.

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**MONTH YEAR** 



### PART 2 OF 5 (CONTINUED): **SURVEY REFERENCE:** 21.A.139 Production management system (a) The production organisation shall establish, implement and maintain a production management system that includes a safety management element and a quality management element, with clearly defined accountability and lines of responsibility throughout the organisation. The production management system shall: (b) (1) $\Box$ correspond to the size of the organisation, and to the nature and complexity of its activities, taking into account the hazards and associated risks inherent in these activities; (2) □ be established, implemented and maintained under the direct accountability of a single manager appointed pursuant to point 21.A.145(c)(1). As part of the safety management element of the production management system, the production (c) organisation shall: (1) □ establish, implement and maintain a safety policy and the corresponding related safety objectives; (2) $\square$ appoint key safety personnel in accordance with point 21.A.145(c)(2); (3) □ establish, implement and maintain a safety risk management process to identify safety hazards entailed by its aviation activities, evaluate them and manage associated risks, including taking actions to mitigate the risks and verify their effectiveness; (4) □ establish, implement and maintain a safety assurance process that includes: (i) the measurement and monitoring of the organisation's safety performance; (ii) the management of changes in accordance with point 21.A.147; and (iii) ☐ the principles for the continuous improvement of the safety management element; (5) □ promote safety in the organisation through: (i) □ training and education; (ii) □ communication; (6) □ establish an occurrence reporting system in accordance with point 21.A.3A in order to contribute to the continuous improvement of safety. As part of the quality management element of the production management system, the production organisation shall: (1) —ensure that each product, part or appliance produced by the organisation or by its partners, or supplied from or subcontracted to outside parties, conforms to the applicable design data and is in condition for safe operation, thus enabling the exercise of the privileges set out in point 21.A.163; (2) establish, implement, and maintain, as appropriate, within the scope of the approval, control procedures for:



(i)		document issue, approval or change;
(ii)		vendor and subcontractor assessment, audit and control;
(iii)		verifying that incoming products, parts, materials and equipment, including items supplied new or used by buyers of products, are as specified in the applicable design data;
(iv)		identification and traceability;
(v)		manufacturing processes;
(vi)		inspection and testing, including production flight tests;
(vii)		the calibration of tools, jigs, and test equipment;
(viii)		non-conforming item control;
(ix)		airworthiness coordination with the applicant for, or holder of, the design approval;
(x)		the completion and retention of records;
(xi)		the competence and qualifications of personnel;
(xii)		the issue of airworthiness release documents;
(xiii)		handling, storage and packing;
(xiv)		internal quality audits and the resulting corrective actions;
(xv)		work within the terms of approval performed at any location other than the approved facilities;
(xvi)		work performed after the completion of production but prior to delivery, to maintain the aircraft in a condition for safe operation;
(xvii)		the issue of a permit to fly and approval of associated flight conditions;
	(3) inclu	ude specific provisions in the control procedures for any critical parts.
(e)		ction organisation shall establish, as part of the production management system, an
	_	nt monitoring function to verify compliance of the organisation with the relevant nts of this Annex as well as compliance with and adequacy of the production management
		lonitoring shall include feedback to the person or group of persons referred to in
	point 21.A.	145(c)(2) and to the manager referred to in point 21.A.145(c)(1) to ensure, where
	necessary,	the implementation of corrective actions.



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

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#### PART 2 OF 5 (CONTINUED): **SURVEY REFERENCE:** 21.A.143 Production organisation exposition The production organisation shall establish and maintain a production organisation exposition (POE) (a) that provides directly or by cross reference the following information related to the production management system as described in point 21.A.139: (1) □ a statement signed by the accountable manager confirming that the production organisation exposition and any associated manuals which define the approved organisation's compliance with this Subpart will be complied with at all times; the title(s) and names of managers accepted by the competent authority in accordance with (2)point 21.A.145(c)(2); (3)the duties and responsibilities of the manager(s) as required by point 21.A.145(c)(2) including matters on which they may deal directly with the competent authority on behalf of the organisation; (4)an organisational chart showing associated chains of responsibility of the managers as required by point 21.A.145(c)(1) and (2); a list of certifying staff as referred to in point 21.A.145(d); (5)a general description of man-power resources; (6)a general description of the facilities located at each address specified in the production (7)organisation's certificate of approval; (8)a general description of the production organisation's scope of work relevant to the terms of approval; (9)the procedure for the notification of organisational changes to the competent authority; (10)the amendment procedure for the production organisation exposition; a description of the production management system, the policy, processes and procedures as (11)provided for in point 21.A.139(c); (12)a list of the outside parties referred to in point 21.A.139(d)(1); if flight tests are to be conducted, a flight test operations manual defining the organisation's policies and procedures in relation to flight test. The flight test operations manual shall include: (i) a description of the organisation's processes for flight test, including the flight test organisation involvement into the permit to fly issuance process; (ii) crewing policy, including composition, competency, currency and flight time limitations, in accordance with Appendix XII to this Annex I (Part 21), where applicable; (iii) □ procedures for the carriage of persons other than crew members and for flight test training, when applicable; (iv) □ a policy for risk and safety management and associated methodologies; (v) procedures to identify the instruments and equipment to be carried; (vi) $\Box$ a list of documents that need to be produced for flight test.



(b) ☐ The initial issue of the POE shall be approved by the competent authority.					
(c)  The POE shall be amended as necessary so that it remains an up-to-date description of the organisation. Copies of any amendments shall be supplied to the competent authority.					
<mark>21.A.145</mark> Resources					
The production organisation shall demonstrate that:					
<ul> <li>(a) the facilities, working conditions, equipment and tools, processes and associated materials, number and competence of staff, and general organisation are adequate to discharge its obligations under point 21.A.165;</li> </ul>					
(b) with regard to all necessary airworthiness, and environmental protection data:					
(1) ☐ the production organisation holds all data it needs to determine conformity with the applicable design data. Such data may originate from the Agency and from the holder of, or applicant for, the type certificate, restricted type certificate or design approval, and may include any exemption granted from the environmental protection requirements;					
(2) the production organisation has established a procedure to ensure that the airworthiness and environmental protection data are correctly incorporated in its production data;					
(3) such data are kept up to date and made available to all personnel that need access to such data to perform their duties;					
(c) with regard to management and staff:					
(1) an accountable manager has been appointed by the production organisation with the authority to ensure that, within the organisation, all production is performed to the required standards and that the production organisation is continuously in compliance with the requirements of the production management system referred to in point 21.A.139, and the data and procedures identified in the POE referred to in point 21.A.143;					
(2) □ a person or group of persons has/have been nominated by the accountable manager to ensure that the organisation is in compliance with the requirements of this Annex, and are identified, together with the extent of their authority; such person or group of persons shall be responsible to the accountable manager and have direct access to him. The person or group of persons shall have the appropriate knowledge, background and experience to discharge their responsibilities;					
(3) ☐ staff at all levels have been given the appropriate authority to be able to discharge their allocated responsibilities and that there is full and effective coordination within the production organisation in respect of airworthiness and environmental protection data matters;					
(d) with regard to certifying staff authorised by the production organisation to sign the documents issued under point 21.A.163 within the scope of the terms of approval:					
<ul> <li>(1) they have the appropriate knowledge, background (including other functions in the organisation) and experience to discharge their allocated responsibilities;</li> <li>(2) they are provided with evidence of the scope of their authorisation.</li> </ul>					

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**MONTH YEAR** 



#### PART 2 OF 5 (CONTINUED): SURVEY REFERENCE:

#### 21.A.147 Changes in the production management system

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

#### 21.A.148 Changes of location

A change of the location of the manufacturing facilities of the approved production organisation shall be deemed of significance and therefore shall comply with point 21.A.147.

#### 21.A.149 Transferability

□ Except as a result of a change in ownership, which is deemed significant for the purposes of point 21.A.147, a production organisation approval is not transferable.

#### 21.A.151 Terms of approval

☐ The terms of approval shall identify the scope of work, the products or the categories of parts and appliances, or both, for which the holder is entitled to exercise the privileges under point 21.A.163.

Those terms shall be issued as part of a production organisation approval.

#### 21.A.153 Changes to the terms of approval

Each change to the terms of approval shall be approved by the competent authority. An application for a change to the terms of approval shall be made in a form and manner established by the competent authority. The applicant shall comply with the applicable requirements of this Subpart.

#### 21.A.163 Privileges

Pursuant to the terms of approval issued under point 21.A.135, the holder of a production organisation approval may:

- (a) perform production activities under this Annex I (Part 21);
- (b) in the case of complete aircraft and upon presentation of a statement of conformity (EASA Form 52) under point 21.A.174, obtain an aircraft certificate of airworthiness and a noise certificate without further showing;
- (c) in the case of other products, parts or appliances, issue authorised release certificates (EASA Form 1) without further showing;
- (d) maintain a new aircraft that it has produced and issue a certificate of release to service (EASA Form53) in respect of that maintenance;
- (e) under procedures agreed with its competent authority for production, for an aircraft it has produced, and when the production organisation itself is controlling under its POA the configuration of the aircraft and is attesting conformity with the design conditions approved for the flight, to issue a permit to fly in accordance with point 21.A.711(c) including approval of the flight conditions in accordance with point 21.A.710(b).

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PART 2 OF 5 (CONTINUED):	SURVEY REFERENCE:
21.A.165 Obligations of the holder	
The holder of a production organisation	approval shall:
	nisation exposition furnished in accordance with point 21.A.143 and are used as basic working documents within the organisation;
(b) ☐ maintain the production organisa production organisation approva	ation in conformity with the data and procedures approved for the l;
	pleted aircraft conforms to the type design and is in condition for bmitting statements of conformity to the competent authority; or
design data and are in a co	ucts, parts or appliances are complete and conform to the approved ondition for safe operation before issuing an EASA Form 1 to certify esign data and condition for safe operation;
(3) Additionally, in the case of	fenvironmental requirements, determine that:
	is in compliance with the applicable engine exhaust emissions of manufacture of the engine; and
	ne is in compliance with the applicable CO <sub>2</sub> emissions requirements cate of airworthiness is issued;
(4) ☐ determine that other pro issuing an EASA Form 1 as	ducts, parts or appliances conform to the applicable data before a conformity certificate;
	of the type certificate or other design approval in dealing with any that are related to the products, parts or appliances that have been
a certificate of release to service	al, the holder of a production organisation approval intends to issue e, determine, prior to issuing the certificate, that each completed cessary maintenance and is in condition for safe operation;
(f) where applicable, under the prive which a permit to fly can be issued	rilege set out in point 21.A.163(e), determine the conditions under ed;
	rivilege set out in point 21.A.163(e), establish compliance with e issuing an aircraft with a permit to fly;
(h) comply with Subpart A of this Sec	ction.

EASA Form 56 Issue 4 — POAT Recommendation Report POA Audit Report — Part 2 of 5, Page 5 of 5

**MONTH YEAR** 



#### **Competent authority**

#### of an EU Member State or

#### **EASA**

RECOMMENDATION REPORT IN SUPPORT OF Part 21 SUBPART G ISSUE / CONTINUATION VARIATION/SIGNIFICANT CHANGE

PART 3 OF 5: Part 21 SUBPART G EXPOSITION COMPLIANCE

Name of organisation:

Approval of organisation:

Approval reference: Survey reference:

Note A: Each box must be completed with one of the three following indicators:

- a tick (✓) which means compliance;
- NR which means that the requirement is NOT RELEVANT to the activity at the address surveyed; (The reason for NR should be stated in Part 4 of the report unless the reason is obvious.);
- 3. a number relating to a comment which must be recorded in Part 4 of the report.

Note B: The exposition may be compiled in any subject order as long as all applicable subjects are covered.

Note C: If the organisation holds another Part approval requiring an exposition or handbook, it is acceptable to use this index as a supplement to the existing exposition or handbook and to cross-refer each subject to the position in the existing exposition or handbook.

#### Production organisation exposition

#### **Revision status:**

(Content as required by point 21.A.143(a))

- (1) a statement signed by the accountable manager confirming that the production organisation exposition and any associated manuals which define the approved organisation's compliance with this Annex will be complied with at all times;
- the title(s) and names of the managers accepted by the competent authority in accordance with point 21.A.145(c)(2);
- (3) the accountability and responsibilities of the manager(s) as required by point 21.A.145(c)(2) including matters on which they may deal directly with the competent authority on behalf of the organisation;
- (4) an organisational chart showing the associated chains of accountability and responsibility of the managers as required by points 21.A.145 (c)(1) and (c)(2);
- (5) a list of certifying staff as referred to in point 21.A.145(d);

[Note: a separate document may be referenced]



(6) a description of man-power resources;

EASA Form 56 Issue 4 — POAT Recommendation Report POA Audit Report — Part 3 of 5, Page 1 of 2 MONTH YEAR



### PART 3 OF 5 (CONTINUED): **SURVEY REFERENCE:** a general description of the facilities located at each address specified in the production (7) organisation's certificate of approval; (8)a general description of the production organisation's scope of work that is relevant to the terms of approval; the procedure for the notification of organisational changes to the competent authority; (9)the amendment procedure for the production organisation exposition; (10)a description of the production management system and the policy, processes and procedures as (11)required by point 21.A.139(b)(1); a list of those outside parties referred to in point 21.A.139 (d)(1); and (12)[Note: a separate document may be referenced] (13) if flight tests are to be conducted, a flight test operations manual defining the organisation's policies and procedures in relation to flight test.

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**MONTH YEAR** 



VARIATION/SIGNIFICANT CHANGE

Name of organisation:

Approval reference:

# **Competent authority** of an EU Member State or **EASA** RECOMMENDATION REPORT IN SUPPORT OF Part 21 SUBPART G APPROVAL ISSUE / CONTINUATION / PART 4 OF 5: FINDINGS ON Part 21 SUBPART G COMPLIANCE STATUS Survey reference:

Note A: Each finding must be identified by a number and the number must cross-refer to the same number in a box in Parts 2 or 3 of the Part 21 Subpart G survey report.

Note B: As stated in Part 1, any comments recorded in this Part 4 should be copied to the organisation surveyed, together with Part 1.

Note C: In the case of a partial clearance of a finding with some outstanding actions remaining, these actions have to be identified.

NO:	FINDING	LEVEL	OUTSTANDING ACTION	CLEARANCE	
NO.	FINDING	LEVEL	OUTSTANDING ACTION	DATE	REP.REF.

NAME	NAME & SIGNATURE OF INSPECTOR: Date:				

EASA Form 56 Issue 4 — POAT Recommendation Report POA Audit Report — Part 4 of 5, Page 1 of 2 MONTH YEAR



PART	PART 4 OF 5 (CONTINUED): Sheet of					
SURV	SURVEY REFERENCE:					
NO:	FINDING	LEVEL	OLITSTANDING ACTION	CLEARANCE		
NO.	FINDING	LEVEL	OUTSTANDING ACTION	DATE	REP.REF.	



NAME & SIGNATURE OF INSPECTOR: Date:					
147 (1412	a districted of more coroni			Date.	

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of an EU Member State or					
EASA					
RECOMMENDATION REPORT IN SUPPORT OF Part 21 SUBPART G APPROVAL ISSUE / CONTINUATION / VARIATION/SIGNIFICANT CHANGE					
PART 5 OF 5: Part 21 SUBPART G APPROVAL RECOMMENDATION					
Name of organisation:					
Americal references					
Approval reference: Survey reference:					
Recommendation for issue / variation of approval/significant change:					
The following Part 21 Subpart G terms of approval are recommended for the above organisation at the address(es) specified in Part 1 of this report:					
<mark>or</mark>					
Recommendation for continuation of existing approval:					
It is recommended that the Part 21 Subpart G terms of approval identified in EASA Form 55 referenced					
be continued.					
Reporting performed according to the procedure for authority surveillance of suppliers of a POA holder located in other Member States, if applicable. (Strict confidentiality to be observed)					
Name of the competent authority inspector making the recommendation:					

	<u> </u>		
Signature of the competent autho	rity inspector:		
Competent authority office:		Date:	
EASA Form 56 Issue 4 — POAT Recomn	nendation Report POA Audit Report -	– Part 5 of 5, Page 1 of 1	MONTH YEAR
	Competent authority		
	of an EU Member State or		
	EASA		
	<del></del>		
RECOMMENDATION	N REPORT IN SUPPORT OF Part 2:	L SUBPART G APPROVAL	
	NTINUATION / VARIATION / SIGN		
15552 /	The state of the s		
PART ONE OF FIVE PARTS:	BASIC DETAILS OF THE ASSESSM	<del>1ENT</del>	
Name of the organisation:			
Approval reference:			
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Address(es) of the facilities survey	<del>red:</del>		
The restriction of the restriction of vey	<del></del> -		
Main Part 21 Subpart G activities a	at facilities surveyed:		
main rait 21 Support o decivities t	ac tacilities sui reyeu.		
Date(s) of survey:			
Dute(s) or survey.			



Names and positions of the organisation's senior management attended during survey:		
Names of the competent authority staff:		
Office: EASA Form 56 completion date:		
Note: If it is determined that recommendation for issue/continuation/variation/significant change of approval cannot be made because of non-compliance with Part 21 Subpart G, the reasons for non-compliance need to be identified in PART 4 of the report. A copy of PART 1 and PART 4, or at least the information included in these parts, must be given to the organisation to ensure that the organisation, in failing to obtain Part 21 Subpart G approval, even if only temporarily, has the same information as is on the files of the competent authority.		

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#### Competent authority

#### of an EU Member State or

EASA

### RECOMMENDATION REPORT IN SUPPORT OF Part 21 SUBPART G ISSUE / CONTINUATION / VARIATION/SIGNIFICANT CHANGE

PART TWO OF	FIVE PARTS:	Part 21 SUBPART G COMPLIANCE
Name of organ	<del>isation:</del>	
Approval of org	<del>ganisation:</del>	
Approval refer	ence:	Survey reference:
	m has been compiled according thos rate compliance.	se points of Part 21 Subpart G which are relevant to an organisation trying to
Note B: The right	nt hand part of each box must be cor	mpleted with one of three indicators:
<del>1.                                      </del>	a tick (✓) which means compliance;	
	NR which means the requirement is lose stated in Part 4 of the report, unle	Not Relevant to the activity at the address surveyed; (the reason for NR should ess the reason is obvious)
3.	a number relating to a comment whi	ch must be recorded in Part 4 of the report.
The left	hand part of each box is optional fo	r use by the competent authority.



21.A.133 Eligibility
Any natural or legal person ('organisation') shall be eligible as an applicant for an approval under this Subpart. The applicant shall:
(a) justify that, for a defined scope of work, an approval under this Subpart is appropriate for the purpose of showing conformity with a specific design; and
(b) hold or have applied for an approval of that specific design; or
(c) have ensured, through an appropriate arrangement with the applicant for, or holder of, an approval of that specific design, satisfactory co-ordination between production and design.
21.A.134 Application
Each application for a production organisation approval shall be made to the competent authority in a form and manner established by that authority, and shall include an outline of the information required by point 21.A.143 and the terms of approval requested to be issued under point 21.A.151.

EASA Form 56 Issue 3 POAT Recommendation Report POA Audit Report Part 2 of 5, Page 1 of 5 MONTH YEAR



PART	TWO OF FIV	'E (CONTINUED): SURVEY REFERENCE:
21.A.	139 Quality (	System
<del>(a)</del>	system. The organisation partners, or	tion organisation shall demonstrate that it has established and is able to maintain a quality e quality system shall be documented. This quality system shall be such as to enable the in to ensure that each product, part or appliance produced by the organisation or by its ir supplied from or subcontracted to outside parties, conforms to the applicable design in condition for safe operation, and thus exercise the privileges set forth in point 21.A.163.
<del>(b)</del>		system shall contain:
		as applicable within the scope of approval, control procedures for:
<del>(i)</del>		document issue, approval, or change;
<del>(ii)</del>		vendor and sub-contractor assessment audit and control;
<del>(iii)</del>		verification that incoming products, parts, materials, and equipment, including items supplied new or used by buyers of products, are as specified in the applicable design
<del>(iv)</del>		data; identification and traceability;
<del>(v)</del>		manufacturing processes;
<del>(vi)</del>		inspection and testing, including production flight tests;
<del>(vii)</del>		calibration of tools, jigs, and test equipment;
<del>(viii)</del>		non-conforming item control;
<del>(ix)</del>		airworthiness co-ordination with the applicant for, or holder of, a design approval;
<del>(x)</del>		records completion and retention;
<del>(xi)</del>		personnel competence and qualification;
<del>(xii)</del>		issue of airworthiness release documents;
<del>(xiii)</del>		handling, storage and packing;
<del>(xiv)</del>		internal quality audits and resulting corrective actions;
<del>(xv)</del> facilit	ies;	work within the terms of approval performed at any location other than the approved



<del>(xvi)</del> aircraf	t in a cond	work carried out after completion of production but prior to delivery, to maintain the lition for safe operation;
<del>(xvii)</del>		issue of permit to fly and approval of associated flight conditions.
		The control procedures need to include specific provisions for any critical parts.
<del>(b)</del>	The qua	nlity system shall contain (cont'd) —
	<del>do</del> sys	independent quality assurance function to monitor compliance with, and adequacy of, the cumented procedures of the quality system. This monitoring shall include a feedback stem to the person or group of persons referred to in point 21.A.145(c)(2) and ultimately to a manager referred to in point 21.A.145(c)(1) to ensure, as necessary, corrective action.

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#### Issue 2, Amendment 16

#### PART TWO OF FIVE (CONTINUED):

#### **SURVEY REFERENCE:**

#### 21.A.143 Exposition

- (a) The organisation shall submit to the competent authority a production organisation exposition providing the following information: (see Part 3 of this Form)
- (b) The production organisation exposition shall be amended as necessary to remain an up-to-date description of the organisation, and copies of any amendments shall be supplied to the competent authority.

#### 21.A.145 Approval requirements

The production organisation shall demonstrate, on the basis of the information submitted in accordance with point 21.A.143 that:

- (a) with regard to general approval requirements, facilities, working conditions, equipment and tools, processes and associated materials, number and competence of staff, and general organisation are adequate to discharge obligations under 21.A.165;
- (b) with regard to all necessary airworthiness, noise, fuel venting and exhaust emissions data:
  - (1) the production organisation is in receipt of such data from the Agency, and from the holder of, or applicant for, the type-certificate, restricted type-certificate or design approval to determine conformity with the applicable design data;
  - (2) the production organisation has established a procedure to ensure that airworthiness, noise, fuel venting and exhaust emissions data are correctly incorporated in its production data;
  - (3) such data are kept up to date and made available to all personnel who need access to such data to perform their duties;
- (c) with regard to management and staff:
  - (1) A manager has been nominated by the production organisation, and is accountable to the competent authority. His or her responsibility within the organisation shall consist of ensuring that all production is performed to the required standards and that the production organisation is continuously in compliance with the data and procedures identified in the exposition referred to in point 21.A.143.
  - (2) a person or a group of persons have been nominated by the production organisation to ensure that the organisation is in compliance with the requirements of this Annex I (Part 21), and are identified, together with the extent of their authority. Such person(s) shall act under the direct authority of the accountable manager referred to in point (1). The knowledge, background and experience of the persons nominated shall be appropriate to discharge their responsibilities;
  - (3) staff at all levels have been given appropriate authority to be able to discharge their allocated responsibilities and that there is full and effective co-ordination within the production organisation in respect of airworthiness, noise, fuel venting and exhaust emission data matters;
- (d) with regard to certifying staff, authorised by the production organisation to sign the documents issued under point <u>21.A.163</u> under the scope or terms of approval:
  - (1) the knowledge, background (including other functions in the organisation), and experience of the certifying staff are appropriate to discharge their allocated responsibilities;
  - (2) the production organisation maintains a record of all certifying staff which shall include details of the scope of their authorisation;
  - (3) certifying staff are provided with evidence of the scope of their authorisation.

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## PART TWO OF FIVE (CONTINUED): SURVEY REFERENCE:

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

- (a) After the issue of a production organisation approval, each change to the approved production organisation that is significant to the showing of conformity or to the airworthiness and characteristics of noise, fuel venting and exhaust emissions of the product, part or appliance, particularly changes to the quality system, shall be approved by the competent authority. An application for approval shall be submitted in writing to the competent authority and the organisation shall demonstrate to the competent authority before implementation of the change, that it will continue to comply with this Subpart.
- (b) The competent authority shall establish the conditions under which a production organisation approved under this Subpart may operate during such changes unless the competent authority determines that the approval should be suspended.

#### 21.A.148 Changes of location

A change of the location of the manufacturing facilities of the approved production organisation shall be deemed of significance and therefore shall comply with point 21.A.147.

#### 21.A.149 Transferability

Except as a result of a change in ownership, which is deemed significant for the purposes of point 21.A.147, a production organisation approval is not transferable.

#### 21.A.151 Terms of approval

The terms of approval shall identify the scope of work, the products or the categories of parts and appliances, or both, for which the holder is entitled to exercise the privileges under point 21.A.163.

Those terms shall be issued as part of a production organisation approval.

## 21.A.153 Changes to the terms of approval

Each change to the terms of approval shall be approved by the competent authority. An application for a change to the terms of approval shall be made in a form and manner established by the competent authority. The applicant shall comply with the applicable requirements of this Subpart.

## 21.A.157 Investigations

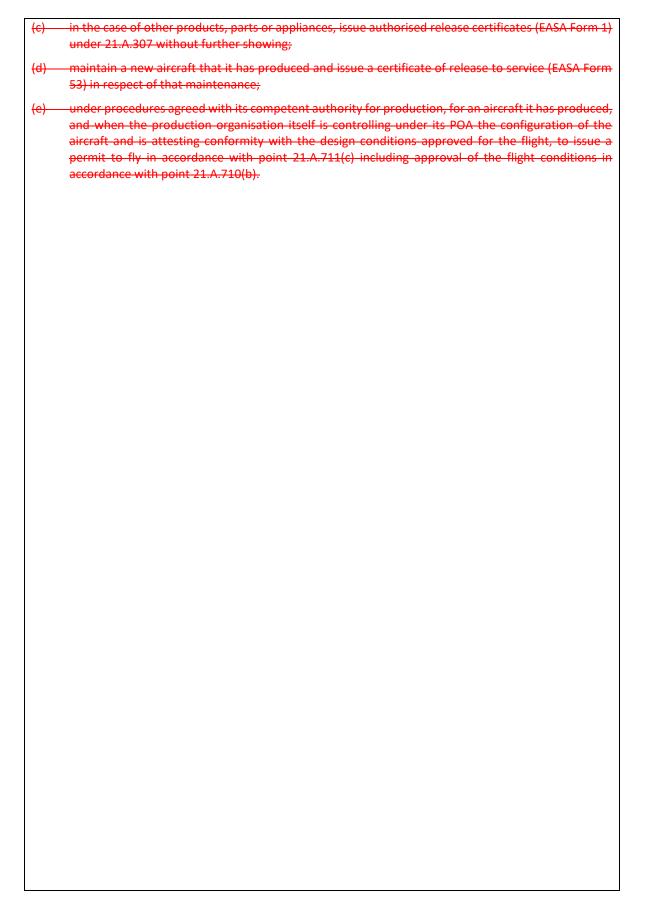
A production organisation shall make arrangements that allow the competent authority to make any investigations, including investigations of partners and sub-contractors, necessary to determine compliance and continued compliance with the applicable requirements of this Subpart.

## 21.A.163 Privileges

Pursuant to the terms of approval issued under point <u>21.A.135</u>, the holder of a production organisation approval may:

- (a) perform production activities under this Annex I (Part 21).
- (b) in the case of complete aircraft and upon presentation of a statement of conformity (EASA Form 52) under point 21.A.174, obtain an aircraft certificate of airworthiness and a noise certificate without further showing;





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## PART TWO OF FIVE (CONTINUED):

#### **SURVEY REFERENCE:**

#### 21.A.165 Obligations of the holder

The holder of a production organisation approval shall:

- (a) ensure that the production organisation exposition furnished in accordance with point 21.A.143 and the documents to which it refers, are used as basic working documents within the organisation;
- (b) maintain the production organisation in conformity with the data and procedures approved for the production organisation approval;
- (c) (1) determine that each completed aircraft conforms to the type design and is in condition for safe operation prior to submitting statements of conformity to the competent authority; or
  - (2) determine that other products, parts or appliances are complete and conform to the approved design data and are in a condition for safe operation before issuing an EASA Form 1 to certify conformity to approved design data and in a condition for safe operation, and additionally in case of engines, determine according to data provided by the engine type-certificate holder that each completed engine is in compliance with the applicable emissions requirements as defined in point 21.8.85(b), current at the date of manufacture of the engine, to certify emissions compliance; or
  - (3) determine that other products, parts or appliances conform to the applicable data before issuing EASA Form 1 as a conformity certificate;
- (d) record all details of work carried out;
- (e) establish and maintain an internal occurrence reporting system in the interest of safety, to enable the collection and assessment of occurrence reports in order to identify adverse trends or to address deficiencies, and to extract reportable occurrences. This system shall include evaluation of relevant information relating to occurrences and the promulgation of related information;
- (f) (1) report to the holder of the type-certificate or design approval, all cases where products, parts or appliances have been released by the production organisation and subsequently identified to have possible deviations from the applicable design data, and investigate with the holder of the type-certificate or design approval in order to identify those deviations which could lead to an unsafe condition;
  - (2) report to the Agency and the competent authority of the Member State, or both, the deviations which could lead to an unsafe condition identified according to point (1). Such reports shall be made in a form and manner established by the Agency under point 21.A.3A(b)(2) or accepted by the competent authority of the Member State;
  - (3) where the holder of the production organisation approval is acting as a supplier to another production organisation, report also to that other organisation all cases where it has released products, parts or appliances to that organisation and subsequently identified them to have possible deviations from the applicable design data;
- (g) provide assistance to the holder of the type-certificate or design approval in dealing with any continuing airworthiness actions that are related to the products parts or appliances that have been produced;
- (h) establish an archiving system incorporating requirements imposed on its partners, suppliers and subcontractors, ensuring conservation of the data used to justify conformity of the products, parts or appliances. Such data shall be held at the disposal of the competent authority and be retained in order to provide the information necessary to ensure the continuing airworthiness of the products, parts or appliances;
- (i) where, under its terms of approval, the holder issues a certificate of release to service, determine that each completed aircraft has been subjected to necessary maintenance and is in condition for safe operation, prior to issuing the certificate;



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- (j) where applicable, under the privilege of point 21.A.163(e), determine the conditions under which a permit to fly can be issued;
- (k) where applicable, under the privilege of point 21.A.163(e), establish compliance with point 21.A.711(c) and (e) before issuing a permit to fly to an aircraft.

#### **Competent authority**

#### of an EU Member State or

#### **EASA**

RECOMMENDATION REPORT IN SUPPORT OF Part 21 SUBPART G ISSUE / CONTINUATION / VARIATION/SIGNIFICANT CHANGE

PART THREE OF FIVE PARTS: Part 21 SUBPART G EXPOSITION COMPLIANCE

Name of organisation:

Approval of organisation:

Approval reference: Survey reference:

Note A: Each box must be completed with one of three indicators:

- 1. a tick (✓) which means compliance;
- 2. NR which means the requirement is NOT RELEVANT to the activity at the address surveyed; (The reason for NR should be stated in Part 4 of the report unless the reason is obvious.);
- 3. a number relating to a comment which must be recorded in Part 4 of the report.

Note B: The exposition may be compiled in any subject order as long as all applicable subjects are covered.

Note C: If the organisation holds another Part approval requiring an exposition or handbook it is acceptable to use this index as a supplement to the existing exposition or handbook and to cross-refer each subject to the position in the existing exposition or handbook.

**Production organisation exposition** 

**Revision Status:** 

(Content as required by 21.A.143(a))

- (1) A statement signed by the accountable manager confirming that the production organisation exposition and any associated manuals which define the approved organisation's compliance with this Subpart will be complied with at all times;
- the title(s) and names of the managers accepted by the competent authority in accordance with point 21.A.145(c)(2);



## AMC and GM to Part 21

#### Issue 2, Amendment 16

- (3) the duties and responsibilities of the manager(s) as required by point 21.A.145(c)(2) including matters on which they may deal directly with the competent authority on behalf of the organisation.
- (4) an organisational chart showing associated chains of responsibility of the managers as required by point 21.A.145(c)(1) and (c)(2);
- (5) a list of certifying staff as referred to in point 21.A.145(d) [Note: a separate document may be referenced]
- (6) a general description of man-power resources;

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# (7) a general description of the facilities located at each address specified in the production organisation's certificate of approval. (8) a general description of the production organisation's scope of work relevant to the terms of approval; (9) the procedure for the notification of organisational changes to the competent authority; (10) the amendment procedure for the production organisation exposition; (11) a description of the quality system and the procedures as required by point 21.A.139(b)(1); (12) a list of those outside parties referred to in point 21.A.139(a). [Note: a separate document may be referenced]

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Competent authority						
	<del>of a</del> i	<del>r EU Mer</del>	<del>nber State or</del>			
	EASA .					
	MMENDATION REPORT IN SUPPORT OF ATION/SIGNIFICANT CHANGE	Part 21	SUBPART G APPROVAL ISSUI	<del>E / CONTINUA</del>	<del>TION /</del>	
PART	PART FOUR OF FIVE PARTS: FINDINGS ON Part 21 SUBPART G COMPLIANCE STATUS					
Name	Name of organisation:					
Approval reference: Survey reference:						
Note A: Each finding must be identified by number and the number must cross-refer to the same number in a box in Part 2 or 3 of the Part 21 Subpart G survey report.						
Note B: As stated in Part 1 any comments recorded in this Part 4 should be copied to the organisation surveyed together with Part 1.						
Note C: In case of a partial clearance of a finding with some outstanding action remaining, this action has to be identified.						
				CLEARANCE		
NO:	FINDING	LEVEL	OUTSTANDING ACTION	DATE	REP.REF.	

NAME & SIGNATURE OF SURVEYOR: Date:					

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PART	FOUR OF FIVE (CONTINUED):		Sheet of			
SURVEY REFERENCE:						
	TIMBING.	. = = .		CLEARANCE		
<del>NO:</del>	FINDING	LEVEL	OUTSTANDING ACTION	DATE	REP.REF.	



NAME & SIGNATURE OF SURVEYOR: Date:				

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Competent authority				
of an EU Member State or				
EASA				
RECOMMENDATION REPORT IN SUPPORT OF Part 21 SUBPART G APPROVAL ISSUE / CONTINUATION / VARIATION/SIGNIFICANT CHANGE				
PART FIVE OF FIVE PARTS: Part 21 SUBPART G APPROVAL RECOMMENDATION				
Name of organisation:				
Approval reference: Survey reference:				
Recommendation for issue / variation of approval/significant change:				
The following Part 21 Subpart G Terms of approval are recommended for the above organisation at the address(es) specified in Part 1 of this report:				
<del>Of</del>				
Recommendation for continuation of existing approval:				
It is recommended that the Part 21 Subpart G Terms of approval identified in EASA Form 55 referenced				
be continued.				
Reporting performed according to procedure for authority surveillance of suppliers of a POA holder located in other Member States, if applicable (Strict confidentiality to be observed)				
Name of competent authority surveyor making recommendation:				



Signature of the competent authority surveyor:	
Competent authority office:	— <del>Date:</del>
competent dutilonty office.	- butc.

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GM2 No 3 to 21.B.220(c) Initial certification procedure Procedures for investigation – POA applications received from organisations with facilities/partners/ suppliers/sub-contractors located in a third country

APPLICATION RECEIVED FROM ORGANISATIONS WITH FACILITIES/PARTNERS/ SUPPLIERS/SUBCONTRACTORS LOCATED IN A THIRD COUNTRY

The obligations of the applicant are totally independent from the surveillance exercised by the competent authority. It is not acceptable that the applicant relies on the surveillance activities of the competent authority to simplify its tasks.

## Facilities located in a third country

When any part of the production facilities of an applicant for a POA is located outside the Member States, then the location will be treated in all aspects as part of the applicant's POA organisation.

Therefore, the investigating competent authority will include the facilities outside the Member States:

- (a) include the facilities outside the Member States fully in their investigation and surveillance activities for the applicant for, or holder of, the POA;
- (b) include the facilities outside the Member States in the terms of approval of the EASA Form 55 (see Annex I Part 21 Appendix X) when issuing the POA.

## Partners/suppliers/subcontractors-contractors located in a third country

The competent authority should define, on the basis of Part 21 and, its associated AMCCS and GM, a clear procedure on supplier control. This procedure should include the control of partners/suppliers/subcontractors-contractors of the applicant for, or holder of, a POA that are located outside the Member States.

In respect of the applicant for, or holder, of the POA, the competent authority should:

- (1) investigate, for the initial approval and consequent continued surveillance, the production organisation, and its partners/suppliers/subcontractors-contractors at the necessary level, to ensure that the organisation can comply with the requirements of Part 21,
- (2) in accordance with the competent authority procedure, assess and accept the documented procedure for supplier control as part of the POA holder's quality system, and changes to that procedure prior to implementation; and,



(3) in accordance with the competent authority procedure, assess the necessary level of surveillance to be exercised by the production organisation on partners / suppliers / subcontractors-contractors and check the audit plan of the production organisation against this level.

The level of cooperation co-operation between the competent authority and the competent authority of the third country where a partner/supplier/subcontractorsub-contractor of the production organisation is located may influence the authorities' activities concerning this partner/supplier/subcontractor-contractor. Cooperation Co-operation with the competent authority of the third country should be based on the capability and goodwill of that authority, and a complete interchange of necessary information.

The involvement of this competent authority of the third country in the surveillance of the partner/supplier/subcontractor-contractor will be based on the following principles:

- (a) When a A recognition agreement under Article 6812 of Regulation (EU) 2018/1139(EC) No 216/2008 covering production subjects has been concluded:
  - a)(1) The competent authority in accordance with GM1 No 2 to 21.A.139(d)(1)(a) may decide that direct surveillance of the POA holder activities at the foreign location may not be necessary.
  - b)(2) In any other case, provisions of the recognition agreement on the subject apply (technical assistance, etc....).
- (b) If a recognition agreement has not been concluded, or it does not cover production subjects, it may be necessary that the competent authority of the Member State, the Agency EASA, and the competent authority of a third country enter into a specific working arrangement addressing the following matters:
  - a)(1) acceptance by the competent authority of the third country of conducting manufacturing surveillance of the relevant production activities on behalf of the competent authority, under the respective quality standards defined by the competent authority.
  - b)(2) tasks to be performed; and
  - c)(3) practical methods.

These arrangements are between authorities and do not relieve the applicant of its obligations.

- In all cases, even though surveillance tasks are delegated to the competent authority of the third country, the competent authority remains the responsible authority and may consequently exercise direct surveillance if necessary.
- If In case that it is not possible to delegate surveillance tasks to the competent authority
  of the third country, the competent authority will have to establish a direct surveillance
  programme in accordance with its procedure concerning supplier control as part of the
  overall surveillance of the POA holder.



GM3-No-4-to 21.B.220(c) Initial certification procedure Procedures for investigation — Competent authority surveillance of suppliers of a POA holder located in other Member States

# COMPETENT AUTHORITY SURVEILLANCE OF SUPPLIERS OF A POA HOLDER LOCATED IN OTHER MEMBER STATES

(a) 1. The aviation legislation identifies specific State obligations in relation to complete products.

The State of manufacture, as used in ICAO Annex 8, normally identifies the country where the final assembly and the final determination of airworthiness is made. However, sub-assemblies and parts may be produced by POA holders in other countries and the EASA Form 1 - Authorised Release Certificate will identify those countries as the locations for production.

Among Member States, the obligations of the State of manufacture may be discharged through the use of the Part 21 POA system.

According to Part 21 Section A, Subpart G, each POA holder must have established and documented in its POE a system for its own control of suppliers/supplies. Surveillance of this system is part of the responsibility of the competent authority of the POA holder wherever the suppliers are located.

This surveillance may be exercised through the POA holder and/or at supplier level especially in the cases where the supplier would be eligible for its own POA.

The purpose of this procedure is to ensure the completeness of the **chain of** responsibilities **chain**-so that no separate technical agreement between these **national competent** authorities is necessary, and when necessary to establish a means of communication between the involved competent authorities of the Member States.

(b)2. Principle to organise competent authority supplier surveillance between Member States:

In order to avoid duplication and to take the best advantage of Regulation (EU) 2018/1139(EC) No 216/2008 that establishes under Article 6711 mutual recognition of certificates issued by production organisations approved in accordance with Part 21 Section A, Subpart G by an Member State, the principle for the competent authority surveillance of the suppliers of a POA holder located in other Member States is for the responsible competent authority to delegate surveillance activities to the other competent authority of the supplier.

This applies between Member States and for suppliers holding a Part 21 POA.

Delegation of surveillance tasks does not imply a delegation of the overall responsibility, therefore the competent authority of the contractor always retains the right of direct supervision at the supplier location especially when serious quality problems are encountered. In such a case, co-ordination will be organised there will be coordination between both competent authorities.

This delegation of surveillance is to be considered automatic as soon as the supplier holds a Part 21 POA, provided that the intended supply is included in the approved scope of work. Evidence of that approval will normally be found through the release of the supplied parts with



an EASA Form 1. In addition, the competent authority of the supplier should immediately inform the competent authority of the contractor in any case of a serious quality problem.

In the cases where the competent authority of the contractor considers that it is necessary to establish closer ties with the competent authority of the supplier (i.e., critical or significant parts), the exchange of information between the competent authorities should be organised as follows:

2.(1) Tasks of the competent authority of the POA contractor

The competent authority of the contractor should inform in writing the competent authority of the subcontractor-contractor with of the following:

- (i)a. The Hidentification (and location) of the contractor;
- (ii)b. The lidentification (and location) of the subcontractor; -contractor
- (iii) . The lidentification of the subcontracting (parts, contract NoN<sup>o</sup>, etc.);
- (iv)d. A Rreference to the quality requirements attached to the contract;
- (v)e. The Nname and address of the competent authority office/person in charge of the POA:
- (vi)f. Whether Ddirect Ddelivery Aauthorisation (DDA) applies;
- (vii)g. Any specific action item/requirement from the competent authority; and
- (viii) h. A Rrequest for a bi-annual reporting (both ways).

EASA Form 58A is provided for the convenience of the competent authority for this purpose.

The competent authority of the contractor should require that the contract/order from the contractor to the subcontactor-contractor should to indicate that it is placed under the surveillance of its competent authority on behalf of the competent authority of the contractor, and should address the subject to the payment of the possible surveillance fees.

2.(2) Tasks of the competent authority of the supplier (subcontractor-contractor)

On receipt of the information from the competent authority of the contractor, the competent authority of the subcontractor-contractor should:

- (i) \frac{\forall v}{\text{v}} \text{erify that the scope of work of the POA of the supplier covers the intended supply (or envisage extending to extend it in liaison with the supplier).
- (ii) \(\frac{\sqrt{v}}{v}\)erify that the specific quality requirements for the parts have been introduced in to the quality system of the supplier.
- (iii) Confirm to the competent authority of the contractor that the procurement is included in the POA of the supplier and that their surveillance will cover this activity; and.
- (iv) Indicate the name and address of the competent authorities authority's office/person in charge of the POA.



If the supplier has no POA under Part 21, or does not want to extend it, and/or if its competent authority cannot conduct surveillance on behalf of the other competent authority, the competent authority of the supplier will inform the competent authority of the contractor in order for it to decide on the appropriate actions.

2.(3) Exchange of information between the competent authorities

This information should normally take two forms:

- Immediate exchange of information between both competent authorities in case of serious quality problems;
- A bi-annual exchange of information at on a given date in order to guarantee proper ongoing on going control of the subcontract by both competent authorities.

This information should cover in a concise form:

- a(i) Ffor the competent authority of the contractor:
  - A resume a résumé of the quality problems encountered by the contractor, on receipt inspection, on installation on aircraft or on in service aircraft; and
  - Aa status of the reference documents.
- b(ii) For the competent authority of the subcontractor-contractor.
  - Aresume a résumé of at least the following subjects:
    - Cchanges in organisation and qualification of the subcontractorcontractor. (in case of impact on the procurement);
    - Quality problems encountered during manufacture;
    - Ccorrective actions following problems encountered earlier on the procurement;
    - Ffindings from national competent authorities surveillance that may have an impact on the procurement; and,
    - Qquality problems related to the contractor procurement (materials, documentation, procedures, processes).

Any Eexchange of information between national competent authorities according to this procedure is strictly confidential and should not be disclosed to other parties.

It is recommended to plan at least every 5 years a meeting between industry and the two national competent authorities to review each major subcontract to verify that there is proper management by the various parties involved.

- 3. Miscellaneous
  - (a) Release documentation

The Rrelease of parts by the POA subcontractor-contractor to the contractor will be accompanied by an "Authorised Release Certificate EASA Form 1' issued for "Airworthiness' or for "Conformity' as appropriate.

(b) Sub-Subsubcontracting



If the subcontractor-contractor wants itself to subcontract, it is up to the competent authority of the subcontractor-contractor to verify that this is done in accordance with the conditions of the contract, to organise as necessary the related authority surveillance and to inform the competent authority of the contractor.

## (c) Language

Except if it is agreed otherwise, it is recommended to use the English language for the exchange of information between the competent authorities.



# Competent authority of an EU Member State or EASA

## REQUEST FOR REPORTING ON SUB-SUBCONTRACTOR SURVEILANCE Document reference number: <REQUEST REF. NO.> As competent authority which issued a POA to: <CONTRACTOR COMPANY> With approval reference: <CONTRACTOR POA REF. NO..> The <COMPETENT AUTHORITY> has determined that there <SUB-SUBCONTRACTOR COMPANY> is a need for direct authority supplier surveillance of: With approval reference: <<u>SUB-</u>SUBCONTRACTOR POA REF.NO.> <COUNTRY OF SUB-SUBCONTRACTOR Which is situated in: COMPANY> As part of the surveillance as required for the Part 21 Section A, Subpart G approved production organisation, according to GM3 No. 4 to 21.B.220(c), the competent authority of the sub-subcontractor is requested to perform authority surveillance on the specific sub-assemblies sub-assembly and parts as details and requirements are defined below. Identification of subcontracting (parts, contract No-, etc...): Reference to the quality requirements attached to the contract between contractor and sub-subcontractor: Name and address of the requesting competent authority office/person in charge of the POA: Direct **D**delivery **A**authorisation (DDA) applies: Yes No Specific action item/requirement from the competent authority of the contractor: Request and details required for a bi-annual reporting (both ways) according to GM3 No. 4 to 21.B.220(c) (Strict confidentiality to be observed): Name and signature of the competent authority person making the request: Competent authority office: Date:

EASA Form 58A – Request for reporting on sub-subcontractor surveillance, Page x of x



# Competent authority of an EU Member State or EASA

## REPORT ON SUB-SUBCONTRACTOR SURVEILLANCE

REPORT ON SOB-SUBCONTRACTO	JR SURVEILLAINCE
Document reference number:	<report no.="" ref.=""></report>
Reporting request reference number:	< REQUEST REF. NO >
As responsible competent authority, the <i>COMPETENT</i> AUTHORITY issued a POA to and is performing direct authority surveillance of:	< <u>SUB-</u> SUBCONTRACTOR COMPANY>
With approval reference:	< <u>SUB-</u> SUBCONTRACTOR POA REF. NO>
Which is a subcontracted supplier of:	<contractor company=""></contractor>
With approval reference :	<contractor poa="" ref.no.=""></contractor>
Which is situated in:	<country company="" contractor="" of=""></country>
According to GM <mark>3 No. 4 to 21.B.220(c) and on request of the cothe <competent authority=""> reports on the results of its a appliances defined below:</competent></mark>	and the control of th
Identification of subcontracting (parts, contract No-, etc):	
Identification of attachments to this report (if needed):	
Date and identification of the previous report:	
Resume Résumé of surveillance results:	
Changes in organisation and qualification of the sub- subcontractor- (in case of impact on the procurement):	
Quality problems encountered during manufacture:	
Corrective actions following problems encountered earlier on in the procurement:	
Findings from competent authority surveillance that may have an impact on the procurement:	
Quality problems related with the contractor procurement (materials, documentation, procedures, processes):	
Note: The Eexchange of information between national compessions strictly confidential and should not be disclosed to other	<del>-</del>
Name and signature of the competent authority person report	ing:
Competent authority office:	Date:



EASA Form 58B – Report on <del>sub</del>-subcontractor surveillance, Page x of x



# AMC1 21.B.220(e) Initial certification procedure

## **ISSUE OF THE CERTIFICATE**

- (a) The competent authority should base its decision to issue a POA on the recommendation report (EASA Form 56, see GM1 21.B.220) of the investigation team submitted by the POA team leader. EASA Form 56 includes a proposal by the investigation team for the scope and terms of approval that define the products, parts and appliances for which the approval is to be granted, with appropriate limitations.
- (b) When the competent authority issues the approval, a final controlled copy of an acceptable exposition for the organisation should be supplied to the competent authority.
- (c) A record should be kept by the competent authority and should upon request be brought to the attention of EASA for standardisation purposes.

## AMC1 21.B.221 Oversight principles

## **OVERSIGHT TEAM AND PROCEDURES**

- (a) The competent authority should appoint a production organisation oversight team for each holder of a production organisation approval. This team is responsible for conducting all the relevant tasks related to the approval. The team should consist of a team leader to manage and lead the oversight team and, if needed, one or more team members. The team leader should report to the manager who is responsible for the activities of the competent authority as defined in point 21.B.25(b).
- (b) The competent authority should perform sufficient oversight activities for the holder of a production organisation approval, to justify the recommendations for the maintenance, amendment, limitation, suspension or revocation of the approval.
- (c) The competent authority should prepare procedures for the oversight of a production organisation as part of the documented procedures that cover at least the following elements:
  - (1) appointment of the production organisation oversight team;
  - (2) review of result of past oversight activities;
  - (3) appointment of the production organisation oversight team;
  - (4) preparation and planning of the oversight;
  - (5) evaluation of the documentation (production organisation exposition, procedures, etc.);
  - (6) auditing;
  - (7) follow-up of corrective actions;
  - (8) recommendation for the amendment, limitation, suspension or revocation of a production organisation approval; and



(9) continued surveillance.

## AMC2 21.B.221 Oversight principles

## MANAGEMENT SYSTEM ASSESSMENT

- (a) As part of the initial certification of an organisation in accordance with point 21.B.220, the competent authority should assess the organisation's management system and its processes to make sure that all the required enablers of a functioning management system are present and suitable.
- (b) As a result of their oversight, the competent authority should be satisfied as to the effectiveness of the organisation's management system and processes.
- (c) When significant changes take place in the organisation, the competent authority should determine whether there is a need to review the existing assessment to ensure that it is still valid.

# AMC1 21.B.221(f) Oversight principles

## INFORMATION DEEMED NECESSARY FOR OVERSIGHT

This information should include, as a minimum:

- (a) any occurrence reports received by the competent authority;
- (b) the results of the following types of inspections and surveys if they indicate an issue that originates from a Part 21 Section A, Subpart G organisation:
  - (1) ramp inspections performed in accordance with Subpart RAMP of Annex II (Part-ARO) to Commission Regulation (EU) No 965/2012 on air operations;
  - (2) product audits conducted pursuant to point 21.B.222(b)(1); and
  - (3) results from other POA Investigations.

# AMC1 21.B.222 Oversight programme

## **ANNUAL REVIEW**

- (a) The oversight planning cycle and the related oversight programme for each organisation should be reviewed annually to ensure that they remain adequate regarding any changes in the nature of the organisation, the complexity of its activities or the safety performance of the organisation.
- (b) When reviewing the oversight planning cycle and the related oversight programme, the competent authority should also consider any relevant information collected in accordance with points 21.A.3A and 21.B.215(d).



## AMC1 21.B.222(a) and (b) Oversight programme

## **OVERSIGHT PLANNING**

- (a) When defining the oversight programme, the competent authority should assess the risks related to the activity and set-up of each organisation and adapt the oversight to the level of risk identified and to the effectiveness of the organisation's management system, in particular its ability to effectively manage safety risks.
- (b) The competent authority should establish a schedule of assessments, audits and inspections that is appropriate to each organisation. The planning of assessments, audits and inspections should take into account the results of the hazard identification and risk assessment conducted and maintained by the organisation as part of the organisation's management system. Inspectors should work in accordance with the schedule provided to them.
- (c) When the competent authority, having regard to the level of risk identified and the effectiveness of the organisation's management system, varies the frequency of an audit or inspection, it should ensure that all the aspects of the organisation's activities are audited and inspected within the applicable oversight planning cycle.

# AMC1 21.B.222(b) Oversight programme

# SPECIFIC NATURE OF THE ORGANISATION AND COMPLEXITY OF ITS ACTVITIES — RESULTS OF PAST OVERSIGHT ACTIVITIES

When determining the oversight programme, including a relevant sample of production activities under the scope of the organisation as product audits, the competent authority should consider in particular the following elements, as applicable:

- (a) the effectiveness of the organisation's management system in identifying and addressing non-compliances and safety hazards;
- (b) the implementation by the organisation of any industry standards that are directly relevant to the organisation's activity subject to Part 21;
- (b) the procedures for the management and the scope of non-significant changes;
- (c) any specific procedures implemented by the organisation that are related to any alternative means of compliance used;
- (d) the number of approved locations and the activities performed at each location;
- (e) the number and scope of subcontractors that perform production activities; and
- (f) the volume of activity for each product or parts.

# AMC2 21.B.222(b) Oversight programme

## SUBCONTRACTED ACTIVITIES

If a production organisation subcontracts production activities, the competent authority should determine whether the subcontracted organisations need to be audited and include this in the oversight programme, taking into account the specific nature and complexity of the subcontracted



activities, the results of previous oversight activities of the production organisation, and assessment of the associated risks.

For such an audit, the competent authority inspectors should ensure that they are accompanied throughout the audit by a representative of the production organisation.

NOTE: If a production organisation subcontracts production activities, the competent authority should verify that the production organisation has sufficient control over the subcontracted activities and manages the related risks.

## AMC1 21.B.222(b)(1) Oversight programme

## **ASSESSMENTS, AUDIT AND INSPECTIONS**

- (a) The oversight programme should indicate which aspects of the approval will be covered by each assessment, audit or inspection.
- (b) Audits may be complemented by a review of the independent monitoring function results related to the topic of the audit.
- (c) At the conclusion of the assessment, audit or inspection, the POA team should complete a report that identifies the areas and processes that were covered and includes all the findings and observations that were raised.
- (d) At the completion of each oversight planning cycle, the POATL responsible for the POA should complete an EASA Form 56 (see GM1 21.B.220) as a summary report for the continued surveillance, including the recommendation for a continuation of the POA, as applicable. EASA Form 56 should be countersigned by the person responsible within the competent authority for the acceptance. At this stage, there is no limitation on the number of level 2 findings that may be open, provided that they are within the time limits of the respective corrective action plans.

# GM1 21.B.222(b)(1)(ii) Oversight programme

## GUIDE TO THE CONDUCT OF MONITORING PRODUCTION STANDARDS

- (a) Point 21.B.222(b)(1)(ii) identifies the need for a sample investigation of products, parts or appliances, their associated conformity determinations and the certifications made by a POA holder. For this to be performed effectively and efficiently, the competent authority should integrate a sampling plan as part of the planning of the investigation and continued surveillance activities that are appropriate to the scope and size of the relevant applicant.
- (b) The sample investigation could, for example, include:
  - a modification (or change);
  - (2) the installation, testing, or operation of a major part or system;
  - (3) the accuracy and generation of the flight test report data;
  - (4) the accuracy and generation of the weighing report data;
  - (5) an engine test bed run;



- (6) the traceability of records;
- (7) the accuracy and generation of the statement of conformity data and the associated safe operation determination; and
- (8) the accuracy and generation of EASA Form 1 data.



# AMC1 21.B.222(c) Oversight programme

## **OVERSIGHT PLANNING CYCLE — AUDIT**

- (a) For each organisation approved by the competent authority, all applicable requirements including processes should be audited at periods that do not exceed the applicable oversight planning cycle. The beginning of the first oversight planning cycle is normally determined by the date of issue of the first approval. If the competent authority wishes to align the oversight planning cycle with the calendar year, it should shorten the first oversight planning cycle accordingly.
- (b) The oversight planning should include at least one on-site audit within each oversight planning cycle. For organisations that carry out their regular activities at more than one site, the determination of the sites and the requirements to be audited at these sites should consider the results of past oversight activities and the volume of activity at each site, as well as the main risk areas identified.
- (c) For organisations that hold more than one approval under Regulation (EU) 2018/1139, the competent authority may define an integrated oversight schedule to include all the applicable audit items. In order to avoid any duplication of audits, credit may be granted for any specific audit items already completed during the current oversight planning cycle, provided that:
  - (1) the specific audit item is the same for all the approvals under consideration;
  - (2) there is satisfactory evidence on record that the specific audit items were carried out and that all corrective actions have been implemented to the satisfaction of the competent authority; and
  - (3) the competent authority should be satisfied that there is no evidence that standards have deteriorated regarding those specific audit items for which credit is granted.

# GM1 21.B.222(c) Oversight programme

## STANDARD OVERSIGHT PLANNING CYCLE

The expression 'shall not exceed 24 months' does not imply that 24 months is a minimum duration for the oversight cycle. Based on the elements specified in 21.B.221(c) and 21.B.222(b) (e.g. safety priorities, assessment of the risks, complexity of activities), the competent authority may decide to apply a cycle of less than 24 months (e.g. 12 months).

# AMC1 21.B.222(d) and (e) Oversight programme

## **EXTENSION OF THE OVERSIGHT PLANNING CYCLE BEYOND 24 MONTHS**

(a) Regardless of planning cycle length, the competent authority should perform at least one focused inspection of the organisation (inspection of a specific area, element or aspect of the organisation) within each 12-month segment of the applicable oversight planning cycle, to support the determined length of the planning cycle.



- (b) If the oversight planning was beyond 24 months and the results of the focused inspection indicate a decrease in the safety performance of the organisation, the competent authority should revert to a 24-month (or shorter) oversight planning cycle and review the oversight programme accordingly.
- (c) In order to be able to apply an oversight planning cycle of up to 36 months, the competent authority should agree on the format and contents of the continuous reporting to be made by the organisation on its safety performance and regulatory compliance.
- (d) To enable the competent authority to apply an oversight planning cycle of up to 48 months, the competent authority should establish, implement and maintain a methodology to evaluate the safety performance of the organisation, focusing on the organisation's ability to effectively identify aviation safety hazards and manage the associated risks.

## GM1 21.B.222(d)(2) Oversight programme

## ORGANISATION'S CONTROL OVER THE CHANGES

For the purpose of extending the oversight planning beyond 24 months, the continuous compliance of the organisation with 21.A.147 and 21.A.148, and the full control over all changes referred to in point 21.B.222(d)(2), includes in particular the ability of the organisation to manage adequately the changes not requiring prior approval foreseen in 21.A.147 and 21.A.148.

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

## **EXAMPLE OF A LEVEL 1 FINDING**

The production organisation cannot demonstrate compliance with 21.A.139(d)2.(xii) and 21.A.163(c), as evidenced by:

The POA holder released the 'critical' Part No XXX, Serial Number YYY with EASA Form 1 No ZZZZ having ticked the box 'Certifies that the items identified above were manufactured in conformity to: approved design data and are in a condition for safe operation'; while:

- (a) the released part is not included in the organisation's capability list/scope of work; and/or
- (b) the POA holder could not demonstrate that the released part is covered by an EASA approved/accepted type design.

Consequently, the released part is not eligible for installation on in-service type-certificated aircraft.



# AMC-ELA No 1 to 21.B.240 Amendment of a production organisation approval

The competent authority should conduct adequate investigations in accordance with <u>AMC-ELA No 1</u> to 21.B.220(c) prior to an amendment of the POA that is classified as a significant change. Refer to <u>GM-ELA No 1 to 21.A.147.</u>

Minor changes are monitored by the competent authority in the course of the regularly scheduled surveillance activities.

## AMC1 21.B.240 Changes in production management system

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

- (a) The competent authority should have adequate control over any changes to the personnel specified in points 21.A.145 (c)(1) and (c)(2). Such changes in personnel will require an amendment to the exposition.
- (b) When an organisation submits the name of a new nominee for any of the personnel specified in points 21.A.145 (c)(1) and (c)(2), the competent authority may require the organisation to produce a written résumé of the proposed person. The competent authority should reserve the right to interview the nominee or call for additional evidence of their suitability before deciding upon the nominee being acceptable.
- (c) For changes requiring prior approval, in order to verify the organisation's compliance with the applicable requirements, the competent authority should conduct an audit of the organisation, limited to the extent of the changes, and determine whether the organisation needs to provide a safety risk assessment.
- (d) If required for verification, the audit may include interviews and inspections carried out at the organisation's facilities.
- (e) The competent authority should receive an application for any significant changes or for a change to the terms of approval of the POA on an EASA Form 51 completed by the applicant.
- (f) The applicable part(s) of EASA Form 56 should be used to document the assessment of any changes to the POA.

# AMC-ELA No1 to 21.B.245 Suspension and revocation of a production organisation approval

If there is a level 1 finding and the competent authority intends to limit the production organisation approval (POA), the competent authority 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 competent authority may apply conditions for the issue or release of conformity certificates.



# SUBPART H — CERTIFICATES OF AIRWORTHINESS AND RESTRICTED CERTIFICATES OF AIRWORTHINESS

[...]

## SUBPART I — NOISE CERTIFICATES

[...]

## SUBPART J — DESIGN ORGANISATION APPROVAL

# AMC1 21.B.430 Initial certification procedure

## **VERIFICATION OF COMPLIANCE — INITIAL CERTIFICATION AUDITS**

- (a) In order to verify the organisation's compliance with the applicable requirements, the investigation by the competent authority should include one or more audit(s) of the organisation, together with interviews of the personnel, typically carried out at the organisation's facilities.
- (b) The competent authority should only conduct such an audit if it is satisfied that the application and supporting documentation are in compliance with the applicable requirements.
- (c) The audit(s) should address the following areas:
  - (1) the organisation's core processes;
  - (2) the detailed management structure, notably its adequacy;
  - (3) the personnel: the adequacy of the number of staff, and of their qualifications and experience with regard to the intended terms of approval and the associated privileges;
  - (4) the processes used for safety risk management and compliance monitoring (independent monitoring function);
  - (5) the facilities and their adequacy regarding the organisation's intended terms of approval including its scope of work; and
  - (6) the documentation based on which the approval should be granted.

# AMC2 21.B.430 Initial certification procedure

## **INVESTIGATION TEAM AND PROCEDURES**



- (a) The competent authority should appoint a design organisation investigation team for each applicant for a DOA. This team is responsible for conducting all the relevant tasks related to the initial certification. The team should consist of a team leader to manage and lead the team and, if needed, one or more team members. The team leader should report to the manager who is responsible for the activities of the competent authority as defined in point 21.B.25(b).
- (b) The competent authority should perform sufficient investigation activities for an applicant for a DOA to justify the recommendations for the issuance of the approval.
- (c) The competent authority should prepare procedures for the investigation of a design organisation as part of the documented procedures that cover at least the following elements:
  - evaluation of the application received;
  - (2) appointment of the investigation team;
  - (3) preparation and planning of the investigation;
  - (4) evaluation of the documentation (design organisation handbook, procedures, etc.);
  - (5) auditing;
  - (6) follow-up of corrective actions;
  - (7) recommendation for the issuance of a design organisation approval; and
  - (8) oversight.

# AMC3 21.B.430 Initial certification procedure

## **ALTERNATIVE MEANS OF COMPLIANCE**

The competent authority should have a procedure for formally recording the proposal, discussion and disposition of alternative means of compliance (deviations from existing AMC). This procedure is necessary to record satisfaction by the competent authority that the use of alternative means provides for compliance with the applicable requirements. The alternative means of compliance should only be allowed to be used by the organisation once agreement has been found with the competent authority. For those alternative means of compliance where previously no formal satisfaction was recorded, a pragmatic approach should be followed on both organisation and competent authority side as to the need to formally record acceptance of such an alternative means of compliance.

Note: EASA Management Board Decisions 03-2004 (Section 2, Article 2, Paragraph 2) and 12-2007 (Section 2, Article 3, Paragraph 2) already required a formal process on the handling of deviations from AMC.

# AMC1 21.B.430(a) Initial certification procedure

## **INVESTIGATION TEAM SELECTION**

(a) Team leader selection



The team leader should satisfy all of the criteria for a team member and will be selected by considering the following additional criteria:

- (1) the capability to lead and manage a team;
- (2) the capability to prepare reports and be diplomatic;
- (3) experience in investigations (not necessarily only Part 21 Section A, Subpart J); and
- (4) a knowledge of design management systems.
- (b) Team member selection

The competent authority should determine the size of the team and the specialisations to be covered, taking into account the scope of work and the characteristics of the applicant. Team members should be selected by considering the following criteria:

- training for Part 21;
- (2) education and experience, to cover the appropriate aviation knowledge, investigation practices; and
- (3) the ability to verify that an applicant's organisation conforms to its own procedures, and that its key personnel are competent.

## AMC1 21.B.430(e) Initial certification procedure

## **ISSUE OF THE CERTIFICATE**

- (a) The competent authority should base its decision to issue a DOA on the recommendation in the DOA investigation report submitted by the DOA team leader. The report includes a proposal by the DOA team for the certificate and terms of approval that define the products, technical scope and privileges for which the approval is to be granted, with appropriate limitations.
- (b) When the competent authority issues the approval, a final controlled copy of an acceptable handbook for the organisation should be supplied to the competent authority. Alternatively, when no physical handbook exists, the organisation should provide access to equivalent data.
- (c) In some cases, it may be acceptable for some actions to not be fully closed because work is still in progress. The competent authority may decide according to the following principles:
  - (1) Actions may not represent a non-compliance with the rule. Such non-compliances should be findings and need to be resolved before the approval can be issued.
  - (2) Actions still to be taken by the organisation which do not prevent the design organisation from working properly in the period when the action is open, can remain open at the time of the approval when an action plan, including timescales, is found to be acceptable.
  - (3) Recommendations only need acknowledgement of receipt by the organisation at the time of the approval.



# AMC1 21.B.431 Oversight principles

## **OVERSIGHT TEAM AND PROCEDURES**

- (d) The competent authority should appoint a design organisation oversight team for each holder of a DOA. This team is responsible for conducting all the relevant tasks related to the oversight. The team should consist of a team leader to manage and lead the team and, if needed, one or more team members. The team leader should report to the manager who is responsible for the activities of the competent authority as defined in point 21.8.25(b).
- (e) The competent authority should perform sufficient oversight activities for a holder of a DOA to justify the recommendations for the maintenance, amendment, limitation, suspension or revocation of the approval.
- (f) The competent authority should prepare procedures for the oversight of a design organisation as part of the documented procedures that cover at least the following elements:
  - (1) appointment of the investigation team;
  - (2) review of results of past oversight activities;
  - (3) preparation and planning of the investigation;
  - (4) evaluation of the documentation (design organisation handbook, procedures, etc.);
  - (5) auditing;
  - (6) follow-up of corrective actions;
  - (7) recommendation for the amendment, limitation, suspension or revocation of a design organisation approval; and
  - (8) continued surveillance.

# AMC2 21.B.431 Oversight principles

## **OVERSIGHT TEAM SELECTION**

(c) Team leader selection

The team leader should satisfy all of the criteria for a team member and will be selected by considering the following additional criteria:

- (5) the capability to lead and manage a team;
- (6) the capability to prepare reports and be diplomatic;
- (7) experience in oversight (not necessarily only Part 21 Section A, Subpart J); and
- (8) a knowledge of design management systems.
- (d) Team member selection

The competent authority should determine the size of the team and the specialisations to be covered, taking into account the scope of work and the characteristics of the applicant. Team members should be selected by considering the following criteria:



- (4) training for Part 21;
- (5) education and experience, to cover the appropriate aviation knowledge, investigation practices; and
- (6) the ability to verify that an applicant's organisation conforms to its own procedures, and that its key personnel are competent.

## AMC3 21.B.431 Oversight principles

## MANAGEMENT SYSTEM ASSESSMENT

- (a) As a result of the oversight, the competent authority should be satisfied as to the effectiveness of the organisation's management system and processes.
- (b) When significant changes take place in the organisation, the competent authority should determine whether there is a need to review the existing assessment to ensure that it is still valid.

# AMC4 21.B.431 Oversight principles

## **ALTERNATIVE MEANS OF COMPLIANCE**

The competent authority should have a procedure for formally recording the proposal, discussion and disposition of alternative means of compliance (deviations from existing AMC). This procedure is necessary to record satisfaction by the competent authority that the use of alternative means provides for compliance with the applicable requirements. The alternative means of compliance should only be allowed to be used by the organisation once agreement has been found with the competent authority. For those alternative means of compliance where previously no formal satisfaction was recorded, a pragmatic approach should be followed on both organisation and competent authority side as to the need to formally record acceptance of such an alternative means of compliance.

Note: EASA Management Board Decisions 03-2004 (Section 2, Article 2, Paragraph 2) and 12-2007 (Section 2, Article 3, Paragraph 2) already required a formal process on the handling of deviations from AMC.

# AMC1 21.B.432 Oversight programme

## **ANNUAL REVIEW**

(a) The oversight planning cycle and the related oversight programme for each organisation should be reviewed annually to ensure that they remain adequate regarding any changes in the nature of the organisation, the complexity of its activities or the safety performance of the organisation.



(b) When reviewing the oversight planning cycle and the related oversight programme, the competent authority should also consider any relevant information collected in accordance with point 21.B.431(c).

# AMC1 21.B.432(a) and (b) Oversight programme

## **OVERSIGHT PLANNING**

- (a) When defining the oversight programme, the competent authority should assess the risks related to the activity and set-up of each organisation, and adapt the oversight to the level of risk identified and to the effectiveness of the organisation's management system, in particular its ability to effectively manage safety risks.
- (b) The competent authority should establish a schedule of assessments, audits and inspections that is appropriate to each organisation. The planning of assessments, audits and inspections should take into account the results of the hazard identification and the risk assessment conducted and maintained by the organisation as part of the organisation's management system.

# AMC1 21.B.432(b) Oversight programme

# SPECIFIC NATURE OF THE ORGANISATION AND COMPLEXITY OF ITS ACTIVITIES — RESULTS OF PAST OVERSIGHT ACTIVITIES

When determining the oversight programme, including a relevant sample of design activities under the scope of the organisation as product audits, the competent authority should consider in particular the following elements, as applicable:

- (a) the effectiveness of the organisation's management system in identifying and addressing non-compliances and safety hazards;
- (b) the implementation by the organisation of any industry standards that are directly relevant to the organisation's activity subject to Part 21;
- (c) the procedure for the management and the scope of non-significant changes;
- (d) the number of locations and the activities performed at each location;
- (e) the number and scope of subcontractors that perform design activities; and
- (f) the overall volume of activity and, as applicable, per specific product.

# AMC2 21.B.432(b) Oversight programme

## SUBCONTRACTED ACTIVITIES

If a design organisation subcontracts design activities, the competent authority should determine whether the subcontracted organisations need to be audited and include this in the oversight programme, taking into account the specific nature and complexity of the subcontracted activities,



the results of previous oversight activities of the design organisation, and assessment of the associated risks.

For such an audit, the competent authority inspectors should ensure that they are accompanied throughout the audit by a representative of the design organisation.

NOTE: If a design organisation subcontracts design activities, the competent authority should verify that the design organisation has sufficient control over the subcontracted activities and manages the related risks.

## AMC1 21.B.432(b)(1) Oversight programme

## **ASSESSMENTS, AUDITS AND INSPECTIONS**

- (a) The oversight programme should indicate which aspects of the approval will be covered by each assessment, audit or inspection.
- (b) Audits may be complemented by a review of the independent monitoring function results related to the topic of the audit.
- (c) At the conclusion of the assessment, audit, or inspection, the DOA team should complete a report that identifies the areas and processes that were covered and includes all the findings and observations that were raised.

## AMC2 21.B.432(c) Oversight programme

## **OVERSIGHT PLANNING CYCLE — AUDIT**

- (a) The beginning of the first oversight planning cycle is determined by the date of issue of the first approval.
- (b) The oversight planning should include at least one on-site audit within each oversight planning cycle. For organisations that carry out their regular activities at more than one site, the determination of the sites to be audited should consider the results of past oversight activities and the volume of activity at each site, as well as the main risk areas identified.

# AMC1 21.B.432(d) and (e) Oversight programme

## **EXTENSION OF THE OVERSIGHT PLANNING CYCLE BEYOND 24 MONTHS**

- (a) When at the time before applicability of Commission Delegated Regulation (EU) 2022/201 the oversight planning cycle was determined to be 36 months, the oversight planning cycle can continue to be 36 months unless the criteria of point (b) would apply.
- (b) If the results of the oversight activities indicate an overall decrease in the safety performance or regulatory compliance of the organisation, the competent authority should consider reverting back to a 24-month oversight planning cycle or adapt the oversight planning accordingly.



(c) In order to be able to apply an oversight planning cycle beyond 36 months, the competent authority should agree on the format and contents of regular reporting to be made by the organisation on its safety performance and regulatory compliance.

## GM1 21.B.433(b) Findings and corrective actions; observations

## **EVIDENCE**

A finding can only be raised on the basis of evidence.

Evidence is a fact that is, or can be, documented based on observations, measurements, or tests that can be verified. 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 activities, as applicable.

# AMC1 21.B.433(d) Findings and corrective actions; observations

## **NOTIFICATION OF FINDINGS**

- (a) Findings should be notified to the design organisation through:
  - (1) the debrief at the end of an audit (only when no further internal review is necessary); or
  - (2) the audit report; or
  - (3) a separate communication.
- (b) The finding notification should be supplemented by a record in which all relevant data to the finding are specified, such as notification date, identification of evidence, the corrective action implementation period, and the relevant Part 21 requirement(s).
- (c) Level 1 findings should only be notified to the design organisation after an internal review by the competent authority, to make sure that the prerequisites for such a finding are fulfilled. Confirmation should be obtained in a timely manner that the head of the design organisation has taken note of the level 1 finding and its details.
- (d) A finding requires effective oversight by the competent authority to monitor the timely completion of the corrective action.

# GM1 21.B.433(e) Findings and corrective actions; observations

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

'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 could be considered for continuous improvement (see points (1), (2) and (3) of point 21.B.433(e)).

The competent authority may decide to issue a level 2 finding when the observations process is not managed correctly or overlooked (see point 21.A.258(c)).

## AMC1 21.B.435 Changes in the design management system

## APPLICATION FOR SIGNIFICANT CHANGES OR CHANGE OF TERMS OF APPROVAL OF THE DOA

- (a) The competent authority should review any changes in the personnel specified in points 21.A.245 (a) and (b).
- (b) When an organisation submits the application for a significant change for any of the personnel positions specified in points 21.A.245 (a) and (b), the competent authority should require the organisation to produce a résumé of the proposed person. The competent authority may interview the nominee or request additional evidence of their suitability before deciding upon the nominee being acceptable.
- (c) For changes requiring prior approval, in order to verify the organisation's compliance with the applicable requirements, the competent authority should determine the necessary activities to verify continued compliance of the organisation, limited to the extent of the changes, and determine whether the organisation needs to provide a safety risk assessment.
- (d) If required for verification, the activities may include interviews and inspections carried out at the organisation's facilities.

# AMC2 21.B.435 Changes in the design management system

## **ALTERNATIVE MEANS OF COMPLIANCE**

The competent authority should have a procedure for formally recording the proposal, discussion and disposition of alternative means of compliance (deviations from existing AMC). This procedure is necessary to record satisfaction by the competent authority that the use of alternative means provides for compliance with the applicable requirements. The alternative means of compliance should only be allowed to be used by the organisation once agreement has been found with the competent authority. For those alternative means of compliance where previously no formal satisfaction was recorded, a pragmatic approach should be followed on both organisation and competent authority side as to the need to formally record acceptance of such an alternative means of compliance.

Note: EASA Management Board Decisions 03-2004 (Section 2, Article 2, Paragraph 2) and 12-2007 (Section 2, Article 3, Paragraph 2) already required a formal process on the handling of deviations from AMC.



## **SUBPART K — PARTS AND APPLIANCES**

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(SUBPART L — NOT APPLICABLE)

[...]

**SUBPART M — REPAIRS** 

[...]

(SUBPART N — NOT APPLICABLE)

[...]

# SUBPART O — EUROPEAN TECHNICAL STANDARD ORDER AUTHORISATIONS

[...]

**SUBPART P — PERMIT TO FLY** 

[...]

# SUBPART Q — IDENTIFICATION OF PRODUCTS, PARTS AND APPLIANCES

[...]

## **APPENDICES TO ANNEX I**

[...]