

Annex I to ED Decision 2019/003/R

'AMC/GM to Part-21 — Issue 2, Amendment 8'

The Annex to ED Decision 2012/020/R of the Executive Director of the Agency of 30 October 2012 is amended as follows:

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

- deleted text is ~~struck through~~;
- new or amended text is highlighted in grey;
- an ellipsis '(...)' indicates that the rest of the text is unchanged.

Annex to ED Decision 201X/XXX/R

'Acceptable Means of Compliance (AMC) and Guidance Material (GM) for the airworthiness and environmental certification of aircraft and related products, parts and appliances, as well as for the certification of design and production organisations ('AMC and GM to Part 21')

The Annex to ED Decision 2012/020/R of the Executive Director of the Agency of 30 October 2012 is amended as follows:

1. New AMC&GM-ELA to 21.A.131 are added before GM 21.131 as follows:

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.

2. New AMC-ELA Nos 1 and 2 are added after AMC No 2 to 21.A.133(b) and (c) as follows:

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 <ul style="list-style-type: none"> — 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 <ul style="list-style-type: none"> — 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 <ul style="list-style-type: none"> — 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 <i>the POE</i>	
<i>[If the design organisation is not the same legal entity as the production organisation approval holder]</i> 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.	
<i>[If the design organisation is not the same legal entity as the production organisation approval holder]</i> 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.	
For the [NAME of the design organisation/DOA holder] Date: xx.xx.xxxx	For the [NAME of the POA holder] Date: xx.xx.xxxx
Signature: [NAME in block letters]	Signature: [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.

3. New GM-ELA No 1 is added after GM 21.A.134 as follows:

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

GM 21.A.134 applies.

4. New GM-ELA No 1 and GM-ELA No 2 are added before GM No 1 to 21.A.139(a) as follows:

GM-ELA No 1 to 21.A.139(a) Quality system

The focus of the quality system is on the key workflows that are indispensable to ensure conformity to the relevant parameters of the applicable design data. The quality system should include elements to determine that there is conformity to the relevant parameters of the applicable design data and, if applicable, the production process definitions. The quality system should mitigate any repetitive non-conformities found in products or spare parts.

The production organisation should demonstrate that it has established, and will maintain, a quality system via integration or by making use of one of the following, as applicable:

- a valid ISO 9001 certificate;
- a valid EN 9100 certificate;
- compliance with ASTM F2972 for organisations that have only the production of CS-LSA aircraft in their scope of approval; or
- an individual quality system that meets all the definitions of the full set of AMC-ELA.

It should be ensured that the existing quality system covers all the aspects defined in 21.A.139(a). The quality system should be documented in such a way that the documentation can be made easily available to any personnel who need to use the material to perform their duties.

GM-ELA No 2 to 21.A.139(a) Quality system

The documentation of the quality system can be done by any method that ensures that members of the organisation can obtain the actual and relevant information in a reasonable way. This explicitly includes the provision of such information by electronic means, for example, on the intranet of the organisation, by the use of an electronic database such as DMS, on paper, by illustration, by using workflow definitions within IT-based ERP systems, by other means, or by a combination of several such means.

The person responsible for the definition, implementation and maintenance of the quality system should be identified. This person should coordinate the maintenance of the system. For small-sized companies with low (product) complexity, typically the accountable manager bears this responsibility, even if that manager delegates tasks to a quality manager.

5. New AMC-ELA No 1 and GM Nos 1 and 2 are added before GM 21.A.139(b)(1) as follows:

AMC-ELA No 1 to 21.A.139(b)(1) Quality system — Control procedures

Note: This AMC-ELA is numbered in accordance with the numbering of the subparagraphs of point 21.A.139(b)(1).

These minimum means are considered to be acceptable unless repeated non-conformities show otherwise. The quality system should contain, as applicable, the following structured information that may be provided and embedded in various documents and systems.

- (i) Information is provided that shows how control procedures for the issuing, approval, or change of documents are organised and practised. This information also specifies to which documents it is applicable. A practised method describes how the use of invalid or superseded information in production is prevented.
- (ii) A practised method describes how and when the assessment and surveillance of any vendors and subcontractors are carried out. This information explains how this is controlled. The assessment and

surveillance of vendors and subcontractors are only required in cases where the methods identified in (iii) below or in other production control mechanisms are not able to detect non-conformities with the applicable design data.

(iii) Verification that incoming products, parts, materials, and equipment, including items supplied new or used by buyers of products, are as specified in the applicable design data can be achieved by one or more of the following practised methods:

- inspections of incoming articles;
- assessment and surveillance of vendors and subcontractors;
- other production control mechanisms that are able to detect non-conformities with the applicable design data.

(iv) Information is provided to show that procedures are practised that ensure the identification and traceability of parts and material in stock, in completed parts or in parts in process. Where the applicable design data specifies that parts require specific individual traceability, these parts are identified and records are kept.

(v) Information is provided for the procedures of the manufacturing process for:

- specific manufacturing process information as required in the applicable design data; and/or
- complementary procedures established by the production organisation.

Practised methods that use standard manufacturing processes do not require specific documentation.

If strict adherence to a manufacturing process is required in order to ensure that safety-critical product characteristics are met, this is specified in the manufacturing procedure.

(vi) Information is provided on the scope and sampling rate of production inspections and testing that, as a minimum, covers the inspection and testing that is defined as part of the applicable design data. If needed, it is complemented by inspections and testing as defined by the production organisation.

Information is provided for the flight test plan and flight conditions defined for the purpose of production acceptance flight tests, when applicable.

(vii) Information is provided on the tools, jigs and test equipment on which verification or calibration is performed and recorded. A statement that all other production tooling is controlled via practised methods is acceptable.

(viii) General practised methods are described that prevent the release of non-conforming products and their parts that would have an impact on the safe operation of the aircraft. Non-conformities are recorded in order to control the quality system.

(ix) General practised methods are described for adequate airworthiness coordination with the applicant for, or the holder of, the design approval. The documented DO/PO arrangement is used to define responsibilities.

(x) Information is provided about which production records are kept, and how completed records are kept in an adequately protected environment.

(xi) Information is provided that shows what the required competences and qualifications are for certifying staff, and how records on the certifying staff are kept.

(xii) Information is provided on the procedures to issue airworthiness release documents by the:

- identification of the persons permitted to issue airworthiness release documents; and
- identification of the relevant forms, and instructions for filling in the forms.

(xiii) Information is provided on the handling, storage and packaging methods that are adequate if:

- inappropriate handling, storage or packaging could lead to damage or deterioration;
- standard inspections prior to the use of the component would not detect defects; and
- such damage or deterioration would endanger the airworthiness of a component or a part.

- (xiv) Information is provided on how internal quality audits and the resulting corrective action procedure are covered by practised surveillance mechanisms that allow the organisation to verify the efficiency of all the elements of the quality system as per this listing.
- (xv) Work conducted in places other than the ‘major place of activity’ and the premises specified in the POE should be approved by the accountable manager, who must ensure that the critical process parameters for the work conducted, such as the light, temperature, humidity, etc., and adequate tooling, are identified and considered. Work conducted at such a location cannot be of a kind that would be performed at a ‘major place of activity’. The information on this kind of work is considered to be a change to the production approval, and it requires approval.
- (xvi) Work carried out after the completion of the product, but prior to its delivery, is conducted according to the same definitions and procedures and by the same staff as are relevant for the regular production process. It is the responsibility of the accountable manager to ensure the adherence to this requirement.
- (xvii) A workflow is defined that shows how to issue flight conditions and permits to fly (PtFs) for the purpose of the production flight testing of new production aircraft. When the flight test plan, the completed flight conditions and Forms 18a and 20b for the purpose of conducting the flight tests are provided as part of the approved type design, the workflow can be limited to:

- making the required entries in those documents (i.e. the reference to the individual aircraft S/N and the configuration);
- verification that the product configuration conforms with the definitions provided within the flight conditions document (which may be an integral part of the type inspection as part of the production workflow); and
- the issuing of the documents.

As part of the workflow, it should be defined that the production organisation can only issue flight conditions and PtFs for this case, and as long as this flight test plan and flight conditions can be fully adhered to.

When the production organisation issues flight conditions and PtFs for a purpose other than the production flight testing of new production aircraft, a flight test operations manual (FTOM) needs to be put in place, which should define the relevant workflows.

For companies that work as one consolidated team, it is sufficient to have one set of flight test procedures that have been established on the basis of an FTOM within either the design or the production organisation.

GM-ELA No 1 to 21.A.139(b)(1) Quality system — Control procedures

The documentation of the quality system, and the associated training, is limited to what is necessary to demonstrate that the products that are produced conform to the relevant design definition, and are in a condition for safe operation. If products are repeatedly found that do not conform, or if evidence is available that the products may be or may become unsafe, then enhanced procedures and documentation that go beyond the AMC-ELA may be one of the means, but not the only possible means, to rectify that situation.

The control procedures of a quality system can be defined by flow charts, process cards, or similar means. If enterprise resource planning (ERP) systems or other IT systems that manage workflows are applied, then separate workflow documentation is not necessary, as long as the workflow can be demonstrated on the basis of the IT system that is applied. The quality system methods should cover those aspects for which a failure to control these elements is expected to have a direct impact on the safe operation of the aircraft.

GM-ELA No 2 to 21.A.139(b)(1) Conformity of supplied parts or appliances

The organisation is responsible for ensuring that the delivered product conforms to the type design. This includes components that are used on the product and that are obtained from outside. To discharge this

responsibility, the organisation needs to implement practised methods that ensure that non-conforming products are detected at a suitable point in time, prior to the declaration of conformity of the final product or the delivery of spare parts to the customer.

Organisations that apply AMC-ELA No 1 to 21.A.139(b)(1) should ensure, as a minimum, the conformity of supplied parts to a level that is defined as part of the approved type design by using one or more of the following methods:

- supplier control;
- the inspection of incoming goods;
- inspections conducted at a suitable stage of the production and verification flow;
- verification of the performance and the characteristics of the completed product; or
- other means that have an equivalent purpose.

If methods for the verification of conformity are defined as part of the approved type design, the organisation does not need to go beyond these verification methods in their extent, method or frequency.

If the type design does not determine the conformity criteria, the organisation may need to extend reasonable quality assurance methods to the related supplier if non-conformities of the parts would create a hazard.

6. New AMC-ELA No 1 and GM-ELA No 1 are added before GM No 1 to 21.A.139(b)(2) as follows:

AMC-ELA No 1 to 21.A.139(b)(2) Quality system — Independent quality assurance function

The responsibility for the independent checking that the quality system functions in accordance with point 21.A.139(b)(1)(xiv) is specified within the organisation. The responsible person(s) establish(es) a schedule, which verifies all the elements of the quality system at least once a year. The schedule can be complemented by unplanned audits if needed. The person(s) responsible obtain(s) direct monitoring results and ensure(s) that corrective actions are taken when necessary.

GM-ELA No 1 to 21.A.139(b)(2) Quality system — Independent quality assurance function

The term 'adequacy of procedures' means that the quality system, through the use of the practised methods or procedures as documented, is capable of meeting the conformity objectives identified in point 21.A.139(a). This can be shown with the results from the implemented quality system, carried out in accordance with point 21.A.139(b)(1)(xiv). Independent quality assurance monitoring can be accomplished by structured experience exchanges, regular quality meetings, brainstorming or lessons-learned sessions, project reviews at appropriate phases of the development, or by other similar means.

The adequacy of the quality system should be assessed on the basis of the continued conformity of the product with the approved type design. If the practised methods and the level of documentation of procedures are not found to be adequate, a more detailed documented procedure may need to be implemented to rectify the situation.

7. New AMC-ELA No 1 and GM-ELA No 1 are added before GM 21.A.143 as follows:

AMC-ELA No 1 to 21.A.143 Exposition

Note: The following provides the information, the acceptable level of detail and the format to be used for the production organisation exposition (POE), and this section is numbered in accordance with the numbering of point 21.A.143(a). If it is needed for completeness, the text of the implementing rule is quoted in italics.

The exposition should contain:

- 1 *A statement signed by the accountable manager that confirms 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.*
- 2 *The titles and the names of the managers accepted by the competent authority in accordance with point 21.A.145(c)(2). The titles and the names of the managers should include the accountable manager (AM), and a statement that this manager is accountable for all the tasks, even if the manager delegates some individual tasks. The delegation of tasks without a delegation of responsibility is not required to be shown within the POE. Persons such as, for example, the quality manager (QM) and the production manager (PM) should only be identified within the POE if responsibilities are delegated to them as outlined by AMC-ELA No 1 to 21.A.145(c).*
- 3 A statement that the AM is the formal point of contact with the competent authority unless other persons under the direct responsibility of the AM are identified.
- 4 An organisational chart if the AM delegates responsibilities. The organisational chart should identify the positions and the reporting lines of those persons who hold delegated responsibilities. In cases where all the responsibilities remain with the AM, even though individual tasks may be delegated, this delegation should be briefly described, and no organisational chart is necessary.
- 5 A list of the certifying staff. This may be identified by a reference to a separate source (e.g. a document, listing, intranet, etc.), and should be easily accessible to everyone concerned within the company.
- 6 A general description of the manpower resources. This can be provided by stating the approximate size of the organisation in full-time equivalents (FTEs).
- 7 A general description of the facilities. This should identify the addresses of the major places of activity. The 'major places of activity' are those locations where the major activities take place that finally lead to the completion of the product and the issuance of the statement of conformity/release certificate.
- 8 The general description of the organisation's scope of work should be provided as defined by point 21.A.151 (see GM-ELA No 1 to 21.A.151), on the basis of the product type(s).
- 9 The procedure for the notification of organisational changes. This can be provided through a reference to that procedure in the company manual (see also GM-ELA No 1 to 21.A.147).
- 10 The procedure for the notification of organisational changes to the competent authority, which can be provided by a declaration that the POE is kept up to date under the responsibility of the AM, when changes to the organisation occur that affect the POE. Amendments to the POE are released by the AM, and are distributed by following the implemented method for the control of documented information to the locations identified in a generic or document-specific distribution list, including distribution to the competent authority.
- 11 The description of the quality system and the procedures in the POE, which may use references to the company manual, or to any other document applied in the quality system (e.g. in accordance with ISO 9001, EN 9100, ASTM F2972 or other suitable standards). These references do not need to explicitly include the revision status of these documents.
- 12 The list of outside parties, which should contain the outside parties that operate under the quality system and the procedures of the manufacturer (i.e. the extended workbench).
- 13 The flight test operations manual (FTOM). The POE can use a reference to an FTOM that is adequate for the production flight testing of new production aircraft, if this is applicable. If both the design and

manufacturing entities work within one consolidated flight test team, it is acceptable to have one set of FTOM procedures defined for the whole team.

GM-ELA No 1 to 21.A.143 Exposition

The purpose of the production organisation exposition (POE) is to provide in a concise and documented format the organisational relationships, responsibilities, terms of reference, and the associated authority, procedures, means and methods of the organisation.

The POE is not the top-level mechanism for organisational control and oversight, and it therefore does not need to provide revision-controlled links to referenced documents. The POE should provide a high-level summary of the organisation's control and oversight methods, and appropriate cross references that allow access to the manuals, procedures and instructions, if applicable.

The POE should be an accurate definition and description of the production organisation. The document does not require approval in itself, but it will be considered when approving the organisation.

The scope of the production organisation and the oversight is not limited to the locations that are identified in the POE, which only shows the 'major places of activity'.

The sublevel production location(s) does (do) not need to be identified in the POE. To ensure transparency to the authority, and in analogy to the management of external suppliers, at least those sublevel locations where manufacturing processes are exercised that require close process control ('special processes') should be identified, but not necessarily as part of the POE. They may be identified within the company manual or in a separate listing.

The scope of work automatically includes the products and all the spare parts required for the identified products, without any further specifications or details. Capability lists are not required by Subpart G. Separate from the statement of scope itself, a listing is provided that identifies the type(s) produced by the approved production organisation.

Note: A POE template, which may be used for a small company (adapted to the company's specifics), is published by EASA.

When changes to the organisation occur that have an impact on the POE, the POE should be updated in accordance with the agreed procedure. Significant changes to the approved production organisation (as explained in GM-ELA No 1 to 21.A.147) require approval by the competent authority, and could also change the POE. The POE document, which is amended in accordance with the approved change, is not intended to be approved by the competent authority, and visual evidence of the approval of the POE document is not needed.

8. New AMC-ELA Nos 1 and 2 are added after GM 21.A.143 as follows:

AMC-ELA No 1 to 21.A.143(a)(13) Exposition — Policies and procedures related to flight test

The objective of this AMC is to identify the items that need to be considered for a safe flight test, that need to be practised, and, if necessary, defined in the flight test operations manual (FTOM) or related procedures, templates or checklists. Those items are the following:

- A flight test plan, completed flight conditions, and the related Forms 18a and 20b for the purpose of conducting the production flight testing of a new production aircraft that are provided as part of the approved type design. These define:
 - a crewing policy, including its composition, and any competence, currency and flight time limitations;
 - procedures for the carriage of persons other than crew members, and for flight test training;
 - a policy for risk and safety management, and associated methodologies that are adequate for the purpose of the flight;
 - a definition of the instruments and equipment to be carried on board during this test flight; and

- a list of the records that need to be produced when conducting this flight test.
- This flight test plan constitutes the FTOM for this limited purpose.

AMC-ELA No 2 to 21.A.143(a)(13) Exposition — Policies and procedures related to flight test

For companies to which AMC-ELA No 1 to 21.A.143(a)(13) is not appropriate, the POA may implement policies and procedures for conducting these activities that include a proportionate and efficient risk and safety management system. This approach is documented either within a separate FTOM or as an integral part of any other valid manual of the organisation, such as the company manual, or any other relevant quality manual. The FTOM, or its equivalent, should be proportionate to the complexity of the aircraft and the organisation.

The risk and safety management system, documented within the FTOM, or its equivalent, covers the following aspects:

- The definition of the key qualifications, responsibilities and accountabilities for the staff involved in conducting the flight test, and should cover at least:
 - The Head of Flight Test (HoFT), who coordinates all the activities related to flight test, and who assumes the responsibility for flight testing (which can be shared with other management positions within the PO);
 - The Flight Test Engineer, who manages the individual flight tests (or campaigns);
 - The Test Pilot, who conducts any flight tests; and
 - The Flight Test Mechanic, who conducts all the maintenance tasks and makes all the configuration changes to the test aircraft.

One person who has adequate qualifications may act in more than one role. The HoFT should have a direct reporting line to the AM.

- A method that provides practical guidance to conduct a hazard assessment to classify flight tests according to the risks involved. At least two categories should be identified:
 - Category 1: for high-risk flight tests; and
 - Category 2: for medium- and low-risk flight tests.
- Definitions of generic risk mitigation strategies, such as the use of minimum and maximum altitudes or airspeed safety margins, and safety rules to be obeyed for the typical major test phases and missions.
- The identification of the aircraft-related safety equipment that needs to be available, including references to the maintenance requirements of this equipment.
- The policy on how to alert and involve rescue services, such as the fire brigade or emergency physicians, in order to provide sufficiently short reaction times.
- Crew qualifications, including requirements for their qualifications to be current and crew (refresher) training, as required.
- For aircraft with MTOMs of 2 000 kg or more:
 - the provisions of Appendix XII to Part-21 apply;
 - the minimum flight experience per year should be:
 - for pilots: 50 hours. In addition:
 - for pilots who have flight test ratings, the 50 hours should include 20 flight test hours in any flight test category;
 - for pilots to perform Category 3 flight tests, their flight test experience should be expressed in terms of the number of flights that led to the issuing of a certificate of airworthiness (CofA) (e.g. first flights);
 - for pilots to perform Category 4 flight tests, their minimum flight test experience should be proportionate to the activity envisaged.
- Crew composition and duty time limitations that are adequate for the kind of testing and the risk category of the flight tests conducted by the POA.

The procedural aspects, documented within the FTOM, or its equivalent, should cover the following aspects:

- The initiation and planning of a flight test activity, including, for example, but not limited to:
 - hazard analysis;
 - detailed flight test planning;
 - the generation and approval of flight conditions;
 - the definition and verification of the test-aircraft configuration;
 - the preparation of the aircraft;
 - the integration, calibration and verification of any flight test equipment;
 - verification of the fitness of the aircraft for flight;
 - issuing or obtaining a PtF;
 - the preflight briefing, and conducting the flight test; and
 - debriefing and data reporting.
- The identification of all the documents and records that are required to be generated or maintained in relation to the flight test, including the definitions for the authority to sign.
- Identification of how training for flight tests is organised.

The definition of the methods required may be provided in different ways including but not limited to flow charts, process descriptions, forms that are detailed enough to enforce adherence to the required workflow, workflow implementation in IT-based ERP systems, or similar means.

The implementation of the standard FTOM, including its associated process definitions and forms, ensures that there will be adherence to this AMC, and hence that there will be compliance with the relevant requirements of Part-21.

Any flight tests that are subcontracted to a third party should comply with the FTOM of the POA, unless the third party has established an FTOM that is in compliance with Part-21, and its use has been agreed between the two organisations.

9. New AMC-ELA No 1 is added before GM 21.A.145(a) as follows:

AMC-ELA No 1 to 21.A.145(a) Approval requirements — General

The adequacy of the infrastructure and staffing may be demonstrated by producing conforming products (on the basis that the type inspection results are part of the production final acceptance process), at the anticipated production rate, and with an adequate staff workload.

10. New AMC-ELA No 1 is added before GM 21.A.145(b)(2) as follows:

AMC-ELA No 1 to 21.A.145(b) Approval requirements — Airworthiness, noise, fuel venting and exhaust emissions data

For applicants whose design and production entities operate in one consolidated team, and for which the applicable design data is provided as part of the approved type design data, the availability of all the necessary airworthiness, noise, fuel venting and exhaust emissions data is considered to be met.

In all other cases, in accordance with the practised methods and procedures that were established as part of the quality system, the PO can demonstrate that the production data contains all the necessary data to determine that there is conformity with the applicable design data, and that this data is kept up to date and is available to the relevant personnel.

11. New AMC-ELA No 1 is added before GM 21.A.145(c)(1) as follows:

AMC-ELA No 1 to 21.A.145(c) Approval requirements — Management and staff

EASA Form 4 should be used to nominate the accountable manager (AM) to the competent authority. Further management staff members are not required to be nominated if the AM elects to take all the required

responsibilities (e.g. including quality manager responsibilities). If the AM delegates any of the responsibilities as defined in 21.A.145(c) to sublevel managers, the sublevel managers who receive this delegation have to be nominated to the competent authority by the use of EASA Form 4, and have to be listed in the POE.

It should be demonstrated that the AM has sufficient power within the company to control the production activity on the basis of the available resources, up to the point of stopping production when adequate resources cannot be provided.

The AM may delegate individual tasks to sublevel managers, while still maintaining his/her responsibilities and the power to make decisions; at the sublevel, in this case, the manager should monitor the sublevel activities. Such delegation of tasks to sublevels is defined internally and does not need to be formally declared to the competent authority.

12. New AMC-ELA No 1 is added before AMC 21.A.145(d)(2) as follows:

AMC-ELA No 1 to 21.A.145(d)(1) Approval requirements — Certifying staff

Certifying staff (CS) are nominated by the production organisation to ensure that products qualify for statements of conformity or release certificates. The number of CS and their positions within the organisation should be adequate to perform their duties and commensurate with the complexity of the product and the production rate.

The nomination of the CS is based on their knowledge, background and experience, and specific training (or testing) is established by the organisation to ensure that the CS members are appropriately qualified for the product, part, or appliance to be released. This can be ensured by utilising appropriately qualified Part-66 licence holders as inspectors, or inspectors who are qualified to comparable standards that are agreed with the relevant competent authority.

The training of personnel who support CS at the subcomponent level may be ensured by on-the-job training.

For the release of products, parts or appliances, the responsibilities for issuing statements of conformity or release certificates (EASA Form 52, EASA Form 1), or PtFs and approvals of flight conditions (if applicable), are allocated under the responsibility of the AM to individuals that are nominated as CS.

13. New AMC-ELA No 1 is added after AMC 21.A.145(d)(2) as follows:

AMC-ELA No 1 to 21.A.145(d)(2) Approval requirements — Records of certifying staff

The following data should be recorded for each certifying staff (CS) member:

- (a) name;
- (b) date of birth;
- (c) basic training and the standard attained;
- (d) specific training and the standard attained;
- (e) if appropriate, continuation training;
- (f) experience;
- (g) scope of the authorisation;
- (h) date of first issue of the authorisation;
- (i) if applicable, the expiry date of the authorisation;

- (j) identification (number) of the authorisation;
- (k) documented acceptance of the nomination.

The above information is deemed to be sufficient to provide the CS with evidence of their scope of authorisation.

The record of this data may be kept in any format. Each CS member should be given reasonable access on request to his or her own records.

The organisation should keep these records for at least 2 years after the CS member has ceased to be employed by the organisation, or 2 years after the withdrawal of their authorisation, whichever occurs first.

14. New AMC-ELA No 1 is added after AMC 21.A.145(d)(3) as follows:

AMC-ELA No 1 to 21.A.145(d)(3) Approval requirements — Evidence of authorisation

Evidence of the scope of the authorisation may be provided in a reasonably accessible way within the company, so that a staff member that needs to be aware of the authorisation can verify their status whenever needed. This can be achieved by the provision of accessible listings of the nominated CS members, or by other means. The issuing of individual badges or passes is not required.

15. New GM-ELA No 1 is added before GM 21.A.147(a) as follows:

GM-ELA No 1 to 21.A.147 Changes to the approved production organisation

The company should consider whether to verify the classification of changes with the competent authority.

The following changes are considered to be significant and require approval by the competent authority prior to the implementation of the changes:

- significant changes to the production capacity or methods;
- changes in the structure of the organisation, especially those parts of the organisation that are in charge of quality;
- a change of the accountable manager (AM) or of any other person nominated under point 21.A.145(c)(2);
- changes in the production or quality systems that may have an important impact on the conformity/airworthiness of each product, part or appliance;
- changes in the placement or control of significant subcontracted work or supplied parts;
- relocation of the major place of activities to a different geographic location, city, airfield or similar;
- changes in the scope of approval; and
- changes in ownership.

16. New GM-ELA No 1 is added following AMC 21.A.148 as follows:

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 GM-ELA No 1 to 21.A.147.

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.

17. New AMC-ELA No 1 is added after AMC 21.A.153 as follows:

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 AMC No 1 to 21.B.240) 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 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.

18. New GM-ELA No 1 is added after GM 21.A.157 as follows:

GM-ELA No 1 to 21.A.157 Investigations — Arrangements

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

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

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

19. New GM-ELA No 1 is added before GM No 1 to 21.A.158(a) as follows:

GM-ELA No 1 to 21.A.158 Findings

An uncontrolled non-compliance with the applicable design data is a non-compliance that:

- cannot be discovered through systematic analysis; or
- prevents the identification of the affected products, parts, appliances, or materials.

A finding may only be classified as level 1 if the non-compliance has an effect on the condition of the aircraft.

Any failure to allow the competent authority to have access to facilities to conduct investigations should be classified as a level 1 finding.

It is recommended that the company should reach agreement with the competent authority on the administrative closure of level 2 findings at regular surveillance intervals.

20. New AMC-ELA No 1 is added after AMC No 2 to 21.A.163(c) as follows:

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.’

21. New AMC-ELA No 1 is added before GM 21.A.165(a) as follows:

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.

22. New GM-ELA No 1 is added before GM No 1 to 21.A.165(c) as follows:

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.

23. Four new AMC-ELA No 1 to 21.A.165(d) through (h) are added after GM 21.A.165(d) and (h) as follows:

AMC-ELA No 1 to 21.A.165(d) Obligations of the holder — Recording and archiving system

The POA holder should establish (in coordination with the design holder) which details are to be recorded to support the production process and to assist the design holder in dealing with continued airworthiness matters. The level of detail chosen for the production process records can have a substantial impact on the scope of any corrective actions.

AMC-ELA No 1 to 21.A.165(e);(f) Obligations of the holder — Reporting to the design holder

The production organisation should record and evaluate any occurrences that may affect the safety of the product. Occurrence reports are collected and assessed in order to identify adverse trends, or to address deficiencies, and to extract reportable occurrences.

The production organisation should share all of its information that is related to potential product deficiencies, observed in the field or during or after production and delivery, with the design approval holder. The production and the design organisations should jointly determine any product design and / or corrective actions that may be required in the field.

The production organisation should have procedures in their quality system to determine whether a production-related deficiency results in an 'unsafe condition' in accordance with point 21.A.3B. This may be done by applying the method described in ASTM F2295, as follows:

- any occurrence that is categorised as an 'urgent safety of flight situation' in ASTM F2295 is considered to be an 'unsafe situation'; and
- any occurrence that falls into the category of a 'potential safety of flight bulletin' in ASTM F2295 is considered to have the potential to be an 'unsafe situation'. Further analysis is required, and possibly in coordination with the competent authority or with EASA.

Production deficiencies, in which the assessment leads to a potential 'unsafe situation', should be reported to the competent authority, within the terms and in the manner determined by the competent authority.

If the design and production entities both work within one consolidated team, then it is sufficient for either the design or the production entity to establish and maintain an internal occurrence reporting system that is accessible to both entities.

AMC-ELA No 1 to 21.A.165(g) Obligations of the holder — Continuing airworthiness assistance

The production organisation should actively communicate with and assist the holder of the type certificate or the design approval when dealing with any continuing airworthiness actions that are related to the products, parts or appliances that have been produced. Compliance with this requirement can be shown by effective coordination regarding the corrective actions.

If the design and production entities both work within one consolidated team, assistance to the type design holder is expected to be provided as an intrinsic function of the cooperation, and no further evidence of the assistance needs to be provided.

AMC-ELA No 1 to 21.A.165(d);(h) Obligations of the holder — Recording and archiving system

Records of production that have been used to determine conformity with the type design, such as those records mentioned in relation to point 21.A.165(c) and (d), should be archived and preserved using an adequate archiving method that should be defined within the company manual. Those records need to be held at the disposal of the competent authority, and need to be retained in order to provide the information necessary to ensure the continuing airworthiness of the products, parts or appliances.

All forms of recording media are acceptable (paper, database, etc.), provided that the preservation of the records for the retention period for archiving can be ensured.

The production organisation should:

- define the records to be retained. If the type design defines which data needs to be recorded, the production organisation is not required to go beyond this data;
- implement a structured method of archiving. If IT-based ERP systems with workflow management are used, a detailed description of the system is not required;
- ensure that there is effective protection of the records from deterioration or accidental damage, e.g. by holding hard and soft copies in separate locations;
- ensure the continued readability of the records by selecting an adequate method of archiving;
- define a retention period for each type of data, taking into account that the determination of conformity is subject to the following:

- data which supports the conformity of a product, part or appliance should be kept for not less than 3 years from the issue date of the related statement of conformity or authorised release certificate;
- data considered to be essential for continuing airworthiness should be kept throughout the operational life of the product, part or appliance.

If the production organisation has decided that the records of any partner, supplier or subcontractor do not need to be supplied to the production organisation, then the production organisation should extend its requirements for record keeping to that partner, supplier or subcontractor.

24. New AMC-ELA No 1 and GM-ELA Nos 1, 2 & 3 to 21.A.231; AMC-ELA No 1 to 21.A.234; and AMC-ELA Nos 1, 2, 3 & 4 to 21.A.239(a) are added before GM No 1 to 21.A.239(a) as follows:

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.

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

The term ‘design assurance system (DAS)’, in the context of the AMC-ELA to Subpart J, refers to those elements of product development and certification that ensure the control and supervision of the initial design, of changes or repairs to the design, and its continued airworthiness with respect to the applicable type-certification basis, the operational suitability data certification basis and the environmental protection requirements. Therefore, elements to be considered as part of the DAS are:

- the generation, iteration, EASA acceptance and maintenance of the certification programme;
- the demonstration of compliance and its verification within the design organisation;
- the declaration of compliance provided by the design organisation to EASA;
- monitoring functions to ensure the continued airworthiness of the certified product, including the resulting activities;
- independent system monitoring of the compliance with, and the adequacy of, the documented procedures of this system.

A typical development process will include a number of additional activities, such as preliminary design, project management elements (a PDR, CDR, etc.), or development activities (test platforms, demonstrators, feasibility studies), etc., that are not part of the DAS, even when elements of the DAS form specific milestones in the development path. In the context of this Subpart, those other activities are consequently excluded from the assessment of the DAS, even when elements of the DAS are also applied to those activities.

AMC-ELA No 2 to 21.A.239(a) Design assurance system — Ensuring compliance

An acceptable design assurance system (DAS) contains the elements of the DAS that are described in AMC-ELA No 1 to 21.A.239(a), and which are further broken down below into the following activities:

- The generation, iteration, EASA acceptance and maintenance of the certification programme:
 - ensure that adequate product, change or repair specifications have been generated and are available to support a meaningful certification programme;
 - generate a certification programme that is tailored to the product, or change, or repair specified, and that identifies:
 - the product and the kinds of operations envisaged, or the changes to them;
 - the proposed certification basis;
 - a description of how compliance will be demonstrated, with the proposed means of compliance and any selected guidance material, if this is not clearly visible from the compliance/means of compliance (MOC) checklist;
 - a compliance checklist, together with the means of compliance that is intended to be used, and any guidance material;
 - the relevant CVE to be used on the project;
 - the programme milestones for interaction with EASA;
 - iteration of the certification programme, until EASA acceptance is reached;
 - monitoring of the workflow in line with the certification programme:
 - updating the certification programme and seeking a new acceptance by EASA, if necessary;
 - ensuring that the relevant staff members adhere to the certification programme when they conduct certification activities;
 - structured methods for the classification of changes, repairs or deviations by using an adequate process flow, or by following adequate decision forms (matrices) if there are major changes that directly support the change-related certification programme.
- Demonstration of compliance and its verification within the design organisation:
 - ensure that a complete set of data has been developed in order to form a complete and concise definition of the type design;
 - ensure that the selected method for defining the type design allows for adequate configuration management, for the purposes of design and design variant management, and for the later management of production;
 - ensure that the handling of changes within the type investigation process and post-TC/-STC is controlled, coordinated and repeatable;

- ensure that analyses and tests have been conducted by using methods that are adequate to support the means of compliance that was defined, and that they are documented to allow their use for showing compliance;
- ensure that the formal demonstration of compliance for the intended type design, change design or repair design, including the generation of compliance statements with respect to any relevant certification requirement, is provided;
- conduct the formal verification of compliance for the intended type design, change design or repair design, including the verification of compliance statements with respect to any relevant certification requirement by an independent person nominated within the design organisation (i.e. a compliance verification engineer (CVE));
- ensure that the applicable product-relevant documentation, such as the AFM, ICA or MMEL, is established and provided;

Note: For more information, see GM No 1 to 21.A.15(d), clarification of the term 'as applicable'.

- ensure that prototypes or test specimens, produced by a connected production organisation, or by any prototyping facilities of the design organisation itself, are used on the basis of an adequate configuration verification against the design definitions specified for the relevant test;
- ensure that coordinated flight test activities with adequate risk mitigations are performed.

— Monitoring functions to ensure the continued airworthiness of the certified product:

- conduct monitoring of any significant events;
- ensure that all reported occurrences and events are investigated and classified;
- ensure that there is occurrence reporting for events that are classified as 'safety-critical' and that constitute unsafe or potentially unsafe conditions;
- ensure that information and instructions are generated and published, as applicable, and that information or instructions and any related design activity are verified by following the same principles as for any type design, change design or repair design activity/documentation.

— Declaration of compliance by the design organisation to EASA:

- verification of the completeness of the compliance verification and type design documentation as defined within the certification programme by the head of airworthiness (HoA);
- issuing of the declaration of compliance by the head of the design organisation (HDO) to EASA, subsequent to the satisfactory completion of the verification of compliance against all the applicable certification requirements.

AMC-ELA No 3 to 21.A.239(a) Design assurance system — Discharge of responsibilities

As part of the design assurance system (DAS), at least the following responsibilities have to be allocated:

— Head of the design organisation (HDO):

- control of budget and staffing to ensure the completion of the development and certification tasks of the design organisation approval (DOA) within reasonable time frames and workload. The HDO is ultimately responsible for providing the necessary resources for the proper functioning of the design organisation;
- issuing the declaration of compliance (see points 21.A.20(d) and 21.A.97(a)(3)) with the applicable type-certification basis, the applicable operational suitability data certification basis and the environmental protection requirements after verifying the satisfactory completion of the type investigation;

- ensuring that adequate and timely information is provided to EASA in matters that affect the DOA.

— Compliance verification engineer (CVE):

- conducting the verification that compliance has been demonstrated with the applicable type-certification basis, the applicable operational suitability data certification basis and the environmental protection requirements and its technical content within its subject matter of nomination. Verification of a compliance demonstration implicitly includes the approval of all the referenced and supporting documents. The applicant may elect to separately document the approval of the individual supporting documents, e.g. by having a cover sheet with the supporting documents in the attachment.

— Head of airworthiness (HoA):

- ensuring the verification of compliance with the applicable type-certification basis, the applicable operational suitability data certification basis and the environmental protection requirements by adequately qualified staff and that the activities that are necessary to demonstrate compliance are complete;
- ensuring that a design organisation handbook (DOH) is prepared and updated as required;
- ensuring that there is adequate and timely interaction with the authorities and internally on all relevant matters with respect to type certification, changes to type certificates, the approval of repairs and the approval of the design organisation. This includes the coordination that the required documentation (type design documents, compliance documentation and service documents including manuals/ICA and the MMEL, if applicable) is adequately established;
- ensuring that the continued airworthiness activities are properly performed;
- accepting the certification programme and the approval of the classification of changes/repairs, minor changes/repairs, major repairs, and flight conditions and the issue of PtFs under the relevant privileges;
- providing verification to the HDO that all the activities required for the type investigation have been properly completed.

— Independent system monitoring (ISM):

- monitoring that the implemented DAS is adequate, and that it is complied with, by using structured experience exchanges, regular quality meetings, brainstorming or lessons-learned sessions, project reviews at appropriate phases of the development, planned and unplanned audits, or other similar means;
- conducting independent ISM activities and directly reporting any observations to the HDO.

AMC-ELA No 4 to 21.A.239(a) Design assurance system — Independent system monitoring

Monitoring that the implemented design assurance system (DAS) is adequate, and that it is complied with, is done by systematic means. The systematic means of monitoring may include structured experience exchanges, regular design meetings, brainstorming or lessons-learned sessions, project reviews at appropriate phases of the development, or by other similar means.

Audits may be one element of monitoring. When implemented, audits should be conducted as combined process/product (project) audits that focus on the implemented key processes or methods practised according to the DOH (or the equivalent document), and the audits should also allow the design organisation to find ways to become more efficient by continuous improvement.

Systematic means of monitoring are coordinated by the ISM, under the responsibility of the HDO, and with a direct reporting line to the HDO. If the ISM is not independent of the activity that is monitored, especially if the HDO also fulfills the role of the head of ISM, the HDO may involve auditors that have adequate knowledge of the applicable requirements and of the implemented DAS. The system monitoring function may be undertaken by the existing quality assurance organisation, provided that it has adequate reporting lines to the HDO.

25. New AMC-ELA No 1 to 21.A.239(b) and AMC-ELA No 1 to 21.A.239(c) are added before GM 21.A.239(c) as follows:

AMC-ELA No 1 to 21.A.239(b) Design assurance system — Independent checking function

The design assurance system (DAS) defines methods to ensure there is an independent verification of the compliance demonstration on the basis of which the organisation submits compliance statements and associated documentation to EASA.

Compliance verification therefore means the approval of all those compliance documents that are necessary for the verification of compliance with the applicable type-certification basis, the applicable operational suitability data certification basis and the environmental protection requirements, as defined in the certification programme. This shall include all the relevant aspects that ultimately lead to the showing of compliance, and therefore, for example, it may need to be extended to test programmes or data analysis reports if the higher-level compliance report itself does not adequately cover all the necessary levels of detail.

Compliance verification is provided by the approval of documented information by a person who did not create the approved data, and who acts as a compliance verification engineer (CVE). Approval is given after the completeness and technical accuracy of the report and the correctness of the derived statement of compliance have been verified. The approval must be documented in such a way that the date and the person who gives approval can be identified.

CVEs are nominated for specific scopes of responsibility. The structure of these scopes is defined by the applicant, and it should follow a logical structure, commensurate with the type of product, such as, for example, by disciplines (e.g. structures, flight, electrical system, etc.), by a set of CS requirements (Subpart B, Subpart C, etc.), by a (set of) ATA chapters (ATA 27 Flight Controls, ATA 32 Landing Gear, ATA 51 Structures, etc.), or by any other appropriate logic. For the kind of product addressed by this AMC, it is explicitly acceptable for the scope of the CVE to be broken down into only a few different disciplines, commensurate with the kind of product.

Compliance verification as part of the DAS is the only task within the DOA in which the creation and the CVE check of documents is mandatorily performed by different persons. It is acceptable for one person to hold multiple CVE nominations. For small companies, it is acceptable for persons who hold other functions, such as the CE, HDO and HOA, to also be nominated as design engineers and CVEs, provided they have the proper competence.

AMC-ELA No 1 to 21.A.239(c) Design assurance system — Acceptability of tasks performed by external parties

The organisation is responsible for ensuring that the type design of the product complies with the applicable type-certification basis, the applicable operational suitability data certification basis and the environmental protection requirements. This includes the determination that components designed by, or tasks performed by, external parties are acceptable. To discharge this responsibility, the DO has to implement documented methods that ensure the compliance of the final product, and that make use of these components or task results, prior to making the final declaration of compliance.

One acceptable means to ensure this is whether the CVE(s) of the applicant conducts (conduct) the verification of compliance, in line with the definitions of the DAS of the applicant. As the verification of

compliance remains with the applicant, no specific qualification measures are required other than to pragmatically verify the capabilities of the external party, and to ensure that the required level of detail is supplied to enable the work results to be adequately verified. The capability of an external party should be verified if more complex activities are subcontracted.

If a DOA subcontracts the CVE function to an external party that conducts the task, but does not hold its own DOA, then the same requirements for the qualification, nomination and documentation of qualification and nomination apply to the person who is nominated as a CVE as are defined in the design organisation handbook (DOH) of the contracting DOA. The availability of all the relevant information for the subcontracted CVE to perform their duties is ensured by the applicant. The relevant contract defines that when acting as a CVE, the external person acts on behalf of, and with direct reporting to, the applicant's head of airworthiness (HoA). The person who acts as a CVE is named in this contract, or in an attachment to it.

Alternatively, if an organisation with a DOA obtains design substantiation data from a subcontractor that also holds a DOA, and the work that is conducted is within the approved scope of this subcontractor DOA, the subcontractor's design data becomes acceptable when the contracting DOA has verified that the results adequately meet the needs of the product under development. Additional formal compliance verification by the contracting DOA is not required if the CVE of the contracted DOA signs and approves the document under its DOA.

26. New AMC-ELA Nos 1 and 2 to 21.A.243 and AMC-ELA No 1 to 21.A.243(d) are added after AMC No 2 to 21.A.243(a) as follows:

AMC-ELA No 1 to 21.A.243 Data — Design organisation handbook

The organisation is responsible for ensuring that the type design complies with the applicable type-certification basis, the applicable operational suitability data certification basis and the environmental protection requirements. This includes components that are part of the product, but are designed by external parties, and that are not covered by the applicable and individual parts-related (ETSO) approvals or (type) certificates.

To discharge this responsibility, the DOA implements practised methods to ensure that there are adequate means to positively establish and verify the compliance of the design and the associated documentation that is generated. The completeness of those methods is documented within the design organisation handbook (DOH), together with the required supporting and company-specific definitions.

The extent of the documentation, and the associated training, is mandated only to the extent that is required to be able to demonstrate that the generated type designs, design changes or repair designs comply with the applicable type-certification basis, the applicable operational suitability data certification basis and the environmental protection requirements, and that the continued airworthiness activities are properly conducted. If evidence is found that the system described is not effective, then enhanced documentation may be one of the means, but not the only possible means, to rectify that situation.

The documentation of the elements within the DOH may be limited to workflow definitions (e.g. flow charts, process cards, or similar items) or to forms that are sufficiently process-oriented. If ERP systems or other IT systems that manage workflows are used, separate workflow documentation is not necessary, as long as the workflow can be demonstrated during surveillance activities on the basis of the IT system that is applied.

The 'practising of methods' is confirmed by observing that the methods are practised in an organised and repeatable manner on several examples. Those methods do not automatically require detailed documentation if they are otherwise defined. Nevertheless, 'practised methods' should be at least identified with a declarative statement.

The documentation at least covers the relevant items in the list below:

1. A unique identifier for the DOH, and a means to identify and record its revision status.

2. The name of the organisation and the address of its major place of activity, including any side offices where DAS functions as per AMC-ELA No 2 to 21.A.239(a) are performed under the DOA. If this location differs from the legal place of business, both addresses should be provided. Floor plans, or similar data, are not required.
3. A statement signed by the head of the design organisation (HDO) confirming that the DOH will be complied with at all times, and that it is used as a basic working document (i.e. a binding declaration).
4. A statement of the scope of the DOA (refer to GM-ELA No 1 to 21.A.251), which lists the key technologies used for airframe design and propulsion concepts on the projects in that scope.
5. The title and the name of the HDO, HoA and ISM, with statements of their accountability per AMC-ELA No 1 to 21.A.239(a). The delegation of tasks without responsibility does not affect accountability, and it is not required to be mentioned within the DOH.
6. The identification of the formal position and the reporting lines of the HDO, HoA and ISM within the company, possibly, but not necessarily, by means of an organisational chart.
7. A statement that the HDO assumes all the duties and responsibilities associated with the DOA, unless delegation of responsibility, beyond the delegation of tasks, is applied. In such a case, the allocation of responsibilities should be shown along with this statement.
8. A statement that the HoA is the formal point of contact for EASA.
9. Definitions of the required competences and qualifications that are necessary for the HDO and the HoA (which may be consolidated if both functions are provided by one person), and for design engineers, CVEs and ISMs.
10. A listing of the CVEs, either directly in the DOH or in a separate source (a document, listing, the intranet, etc.) that is linked to the DOH, and this data should be easily accessible to everyone concerned within the company. This list should be made available to EASA in its current version.
11. The approximate size of the company in full-time equivalent staff members, accurate enough to determine the related fees and charges that are laid down in Commission Regulation (EU) No 319/2014 (the Fees and Charges Regulation). This should include a declaration that the company ensures that the numbers and the qualifications of the staff involved in the design activities are adequate, that the company monitors these aspects, and that it takes action if necessary.
12. A confirmation that any significant changes to the DO, and any changes to the organisation that affect the contents of the DOH, will be notified to EASA in a timely manner by the responsible person defined in the DOH.
13. A confirmation that, when changes to the organisation occur that affect the documentation required here, the DOH is kept up to date by the responsible person defined in the DOH, but under the responsibility of the HDO, or their delegate. Amendments to the DOH should be released by the HDO, or by their delegate, and distributed according to the implemented method for the control of documented information, to locations that are identified in a generic or document-specific distribution list, including the responsible design organisation approval team leader (DOATL).
14. A definition of the methods that are practised to verify the effectiveness of the elements of the DAS that are stated in this listing. The main targets of Subpart J are to ensure that the type design of the product complies with the applicable type-certification basis, the applicable operational suitability data certification basis and the environmental protection requirements, and that the continued airworthiness activities are properly conducted. The surveillance mechanisms that are used may include structured experience exchanges, regular quality meetings, brainstorming or lessons-learned sessions, project reviews at appropriate phases of the development, planned and unplanned audits, or other similar means. Corrective actions that are identified should be followed up, and the means of resolution should be recorded. The DOH should define how this is accomplished.
15. A declaration that control methods are practised, and that the general principles of the applied document revision and access management processes ensure the use of current information.

16. A general identification of the documentation that is the result of all the design functions in relation to the airworthiness, operational suitability and environmental protection approvals, and continued airworthiness, each one of which should be commensurate with the complexity of the product and the risk level in terms of its content, style and format, including:
 - a. a listing of the document types that form the type design, such as, for example, specifications, drawings, bills of materials, instructions, and other documents;
 - b. a listing of the document types that form the compliance documentation, such as, for example, compliance reports, compliance summary documents, compliance checklists, means of compliance checklists, manuals, instructions for continued airworthiness (ICAs), master minimum equipment lists (MMELs) (if required), and others;
 - c. a listing of the document types that form the change and repair design-specific documentation, such as classification matrices and approvals of minor changes, repairs, or production deviations;
 - d. a listing of the documents related to continued airworthiness activities (information and instructions such as, for example, service bulletins/service instructions), if not already listed to address point a.
17. A declaration and a definition of the principles that are applied, and the accepted related duties, of the key elements of the DAS, as defined in AMC-ELA No 2 to 21.A.239(a). The definition of the elements can be provided by various means, such as precise forms that guide the user through the process, workflow modelling in IT-based design or document management systems, process charts, flow diagrams, classical process definition documents, or other comparable means that are commensurate with the complexity and the criticality of the products. If references are made to other documents that are outside the DOH, the DOH should contain a listing of those documents.
18. A confirmation that methods are practised that enable adequate airworthiness coordination with the applicant for, or the holder of, the production approval. Dedicated procedures and/or DO-PO agreements for the purpose of airworthiness coordination with the production approval holder are not required if the design and the production entities work within one consolidated team, or if the control of airworthiness-related information is conducted by the same group of persons for both design and production. However, it should be described how any occurrences, and any unintentional deviations from the approved design data that occur in production (i.e. concessions or non-conformances) are handled within the design organisation, and when a concession process or a direct approval of such non-conformities under the DOA is sought, for example by using the change process. In addition, the methods/processes that are required by other AMC-ELA and GM-ELA should be defined, either directly in the DOH or in a document that is linked to it.
19. A declaration and a definition of the method applied to accept design work that is conducted by external parties, in line with AMC-ELA No 1 to 21.A.239(c).
20. The identification of the design subcontractors and satellite locations that operate under the DAS of the design organisation, and that fulfil functions required by the DAS, or are directly involved in critical aspects of compliance demonstration, such as, for example, flutter investigations and analyses. This identification may be an integral part of the DOH, or it may be provided in a separate listing that is only identified from within the DOH.
21. A reference to a flight test operations manual (FTOM) that is adequate for the flight test activities of the design organisation. If both the design and the manufacturing entities work within one consolidated team, it is sufficient to have FTOM procedures defined for only one of the entities. The FTOM shall then identify the workflow that defines how to issue flight conditions and PtFs for the purpose of conducting factory acceptance test flights.

AMC-ELA No 2 to 21.A.243 Data — Policies and procedures in relation to flight tests

In order to conduct flight test activities, the DOA is required to implement policies and procedures for conducting these activities that include a proportionate and efficient risk and safety management system. This approach is documented either within a separate flight test operations manual (FTOM) or as an integral part of any other valid manual of the organisation, such as the DOH, or any other relevant quality manual. The FTOM, or its equivalent, should be proportionate to the risk of the product and the complexity of the organisation.

The risk and safety management system, documented within the FTOM, or its equivalent, covers the following aspects:

- The definition of the key qualifications, responsibilities and accountabilities of the staff involved in conducting the flight tests, which covers at least:
 - the head of flight test (HoFT), who coordinates all the activities related to flight test and assumes responsibility for flight testing (this can be shared with other management positions within the DO);
 - the flight test engineer, who manages individual flight tests (or test campaigns);
 - the test pilot, who conducts any flight tests;
 - the flight test mechanic, who conducts all maintenance tasks and configuration changes to the test aircraft.
- One person who has adequate qualifications may act in more than one role. The HoFT should have a direct reporting line to the HDO.
- A method that provides practical guidance on conducting a hazard assessment to classify flight tests according to the risk involved. At least two categories should be identified: Category 1 for high-risk flight tests, and Category 2 for medium- and low-risk flight tests.
 - Definitions of generic risk mitigation strategies such as the use of minimum and maximum altitudes or airspeed safety margins, and safety rules to be obeyed for the typical major test phases and missions.
 - Identification of the aircraft-related safety equipment that needs to be available, including references to the maintenance requirements of this equipment.
 - A policy on how to alert and involve rescue services, such as the fire brigade or emergency physicians, in order to allow sufficiently short reaction times.
 - Crew qualifications, including requirements for the qualifications to be current and for crew (refresher) training, as adequate.
 - For aircraft with MTOMs of 2 000 kg or more:
 - the provisions of EASA Part-21 Appendix XII apply.
 - the minimum flight experience per year should be:
 - for pilots: 50 hours. In addition:
 - for pilots who have flight test ratings, the 50 hours should include 20 flight test hours in any flight test category;
 - for pilots to perform Category 3 flight tests, their flight test experience should be expressed in terms of the number of flights that led to the issuing of a certificate of airworthiness (CofA) (e.g. first flights);
 - for pilots to perform Category 4 flight tests, their minimum flight test experience should be proportionate to the activity envisaged.
 - Crew composition and duty time limitations that are adequate for the kind of testing and the risk category of the flight tests conducted by the DOA.

The procedural aspects, documented within the FTOM, or its equivalent, should cover the following aspects:

- The initiation and planning of a flight test activity, including, for example, but not limited to:
 - hazard analysis;
 - detailed flight test planning;
 - the generation and approval of flight conditions;
 - the definition and verification of the test-aircraft configuration;
 - preparation of the aircraft;
 - the integration, calibration and verification of any flight test equipment;
 - verification of the fitness of the aircraft for flight;
 - issuing or obtaining a PtF;
 - the preflight briefing, and conducting the flight test; and
 - debriefing and data reporting.

The FTOM, or its equivalent, identifies all the documents and records that are required to be generated or maintained in relation to the flight test, including the definitions for the authority to sign.

The FTOM, or its equivalent, identifies how training for flight tests is organised.

The definition of the methods required may be provided in different ways, including but not limited to flow charts, process descriptions, forms that are detailed enough to enforce adherence to the required workflow, workflow implementation in IT-based ERP systems, or similar means.

The implementation of the standard FTOM, including its associated process definitions and forms, ensures adherence to this AMC, and hence that there will be compliance with the relevant requirements of Part-21.

Any flight tests that are subcontracted to a third party should comply with the FTOM of the DOA, unless the third party has established an FTOM that is in compliance with Part-21, and its use has been agreed between the two organisations.

AMC-ELA No 1 to 21.A.243(d) Data — Statement of qualifications and experience

Evidence of their qualifications and experience is documented for the persons who accept the duties defined for the following roles:

- head of the design organisation (HDO);
- head of airworthiness (HoA);
- independent system monitoring (ISM);
- compliance verification engineer (CVE).

The credentials of the HDO, HoA and ISM are provided to EASA using EASA Form 4-DOA. The form is published on the EASA webpage.

For the CVE, no individual statement is needed. CVEs are selected by the applicant/approval holder on the basis of their knowledge, background and experience as defined in the DOH. When necessary, complementary training should be established to ensure that CVEs have sufficient background and knowledge in the scope of their authorisation.

The organisation maintains a record of the CVE personnel, which includes details of the scopes of their authorisations. The CVE personnel are given reasonable access on request to their own records. As part of its investigations, EASA has the right to access the data held in such a system.

The following minimum information on each of the CVEs should be kept on record:

- a) name,
- b) date of birth,
- c) experience and training,
- d) position in the organisation,
- e) scope of the authorisation,

- f) date of the first issue of the authorisation,
- g) if applicable, the date of expiry of the authorisation,
- h) identification number of the authorisation,
- i) documented acceptance of the nomination by the CVE.

Evidence of the authorisation is provided in a reasonably accessible way within the company, so that a staff member who needs to be aware of the authorisation can verify their status whenever needed. This can be achieved by the provision of accessible listings of the nominated staff members, or by other means. The issuing of individual badges or passes is not required.

The organisation should keep the records of a CVE for at least 2 years after the CVE has ceased to be employed by the organisation, or 2 years after the withdrawal of the CVE's authorisation, whichever occurs first.

27. New AMC-ELA No 1 is added before GM No 1 to 21.A.245 as follows:

AMC-ELA No 1 to 21.A.245 Approval requirements

The organisation demonstrates adequate staffing, infrastructure, access to facilities and discharge of responsibilities by means of the continued ability to certify type designs after it has ensured that there is positive compliance with the applicable type-certification basis, the operational suitability data certification basis and the environmental protection requirements. Adequate staffing is observed on the basis of reasonable workload, working time and project completion times.

The applicant should have access to:

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

The HDO for which an application for approval has been made has the direct or functional responsibility for all the departments of the organisation that are responsible for the design of the product. If the departments responsible for the design are functionally linked, the HDO still has the ultimate responsibility for the compliance of the organisation with Subpart J.

The function of the head of airworthiness (HoA) should be established with a direct reporting line to the HDO, and the person who fulfils this function is required to have a direct contract with the DO.

Responsibilities for all the tasks related to type investigations should be assigned in such a way that there are no gaps in authority.

Combinations of responsibilities are acceptable where:

- the role of the HDO may be fulfilled by the chief executive (CE) of the legal entity, who may also fill the role of the AM within a parallel POA;
- the HDO and the HoA are the same person, provided that the person has the competence to fulfil both functions;
- the HoA and the ISM are the same person, provided that the ISM assessment of working activities that directly affect the person in their second role is conducted by another independent person, on behalf of the ISM;
- the HDO and the ISM are the same person, provided that the auditing activity is conducted by another independent person, under the responsibility of the ISM;
- external persons are acceptable for all or for parts of the role of the ISM;

- a part-time HoA is acceptable, provided that the person is directly involved in the DOA, and not by an agreement between two DOAs, and provided that the availability of the person ensures that response times will be adequate;
- a CVE may also hold any of the other nominations, as long as there is an independent check of compliance per AMC-ELA No 1 to 21.A.239(b).

Due to the typically small size of the design organisations and the low complexity and criticality of the products within the scope of AMC-ELA, no specific provisions are required to ensure that there is full and efficient coordination between departments and within departments in respect of airworthiness, operational suitability and environmental protection matters, provided that evidence of this coordination can be observed during the surveillance activities.

28. New AMC-ELA No 1 is added before GM No 1 to 21.A.245 as follows:

GM-ELA No 1 to 21.A.247 Changes in design assurance 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 HoA, 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.

29. New GM-ELA No 1 is added after GM No 2 to 21.A.251 as follows:

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

1. 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 21.A.253 will lead to an amendment of the certificate of approval.
3. The certificate of approval references the design organisation handbook (DOH), which has been provided in accordance with point 21.A.243. 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 AMC-ELA No 1 to 21.A.231 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.

30. New GM-ELA No 1 is added before GM 21.A.257(a) as follows:

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.

31. New GM-ELA No 1 is added before GM 21.A.257(a) as follows:

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

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

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

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

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

32. New GM-ELA No 1 is added before GM 21.A.263(b) as follows:

AMC-ELA No 1 to 21.A.263 Privileges

(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, GM 21.A.435(a) 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.263(c)(3) is defined. The DOH should state how documents under this privilege 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: 'Revision No [YY] to AFM (or supplement) ref. [ZZ] is approved under the authority of 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 21.A.708;
- 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.

33. New AMC-ELA No 1 to 21.A.265(a) and AMC-ELA No 1 to 21.A.265(b) are added after AMC 21.A.265(a) as follows:

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 AMC-ELA No 1 to 21.A.243 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.

34. New AMC-ELA No 1 to 21.A.265(c) and AMC-ELA No 1 to 21.A.265(e) are added after GM 21.A.265(b) as follows:

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

The organisation should apply the methods detailed in AMC-ELA No 2 to 21.A.239(a) 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.

35. New GM-ELA No 1 to 21.B.220 and GM-ELA No 1 to 21.B.220(a) are added before GM 21.B.220(a) as follows:

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.

36. New AMC-ELA No 1 to 21.B.220(b) is added before AMC 21.B.220(c) as follows:

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^[1] 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.

37. New AMC-ELA No 1 to 21.B.220(c) and AMC-ELA No 2 to 21.B.220(c) are added after AMC 21.B.220(c) as follows:

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 AMC-ELA No 2 to 21.A.131 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.A.151). 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

1. 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:

2. 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.

3. Investigation

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

The POAT should:

- assess the POE for compliance with point 21.A.143, e.g. by using AMC-ELA No 1 to 21.A.143;
- 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 AMC-ELA No 1 to 21.A.145(c)), 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 21.A.158(c). The POATL should consider the means provided by AMC-ELA No 1 to 21.B.230. 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 AMC-ELA No 1 to 21.B.235.

38. New GM-ELA No 1 is added after AMC No 1 to 21.B.230 as follows:

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

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

<i>Starts with selection of:</i>	<i>...continues with selection from:</i>	<i>...ends with:</i>
Manufacturing of	aeroplanes that are within the scope of CS-LSA, CS-VLA and CS-23 level 1, not classified as complex motor-powered aircraft,	where <company> holds the type design approval, including all related spare parts.
Manufacturing of engines used on	sailplanes or powered sailplanes that are within the scope of CS-22,	
Manufacturing of propeller used on	balloons,	
	hot-air airships,	
	gas airships that comply with 3 % maximum static heaviness, non-vectorised thrust (except reverse thrust), conventional and simple design of structure, control system and ballonet system, and non-power-assisted controls,	

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

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

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

39. New AMC-ELA No 1 and GM-ELA No 1 to 21.B.235 are added before GM 21.B.235(a)(4) as follows:

AMC-ELA No 1 to 21.B.235 Continued surveillance

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

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

Surveillance activities are:

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

GM-ELA No 1 to 21.B.235 Continued surveillance

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

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

It is recommended that flexibility should be allowed in the sampling plan so as to:

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

40. New AMC-ELA No 1 to 21.B.240 is added after AMC 21.B.240 as follows:

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

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

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

41. New AMC-ELA No 1 to 21.B.245 is added before GM 21.B.245 as follows:

AMC-ELA No 1 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.