AIRWORTHINESS AND ENVIRONMENTAL CERTIFICATION

Consolidated version of
Part-21 Implementing Rules and related Acceptable Means of Compliance Material
relevant to light aircraft

Part-21 – Section B
Subpart G

Certification of aircraft and related products, parts and appliances, and of design and production organisation
Annex I of the Commission Regulation (EU) 748/2012*,
as amended by
Regulation (EU) 7/2013
Regulation (EU) 69/2014
Regulation (EU) 2015/1039
Regulation (EU) 2016/5

+ AMC-ELA to Part-21

INITIAL DRAFT
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* Commission Regulation (EU) No 748/2012 of 03/08/2012 laying down implementing rules 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.
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SECTION B
PROCEDURES FOR COMPETENT AUTHORITIES

SUBPART G— PRODUCTION ORGANISATION APPROVAL

AMC-ELA No. 1 to Part 21, Section B, Subpart G – Production Organisation Approval – Scope of AMC-ELA

The full set of AMC-ELA defines an acceptable means of compliance to conduct investigations and issue Production Organisation Approvals for companies that manufacture aircraft, or engines, or propeller, or articles under ETSO authorisation, when the aircraft is within, or the products and articles are limited to be used on aircraft within the following limitations:

- aircraft not classified as complex-motorpowered aircraft; and
    - aeroplanes of 2 730 kg maximum take-off mass (MTOM) or less; or
    - rotorcraft of 1 200 kg MTOM or less, certified for a maximum of up to 4 occupants; or
    - other ELA2 aircraft, including for example sailplanes and balloons.

Each AMC titled as AMC-ELA is considered applicable to this case.

AMC-ELA No. 2 to Part 21, Section B, Subpart G – Production Organisation Approval – General Considerations

The full set of AMC-ELA as implemented here is based upon a set of preconditions that are detailed within AMC-ELA No. 2 to 21.A.131. All AMC-ELA provided in this Section B is provided on the basis of these preconditions and must always be seen in context with AMC-ELA to Section A. AMC-ELA to Section B only provides further definitions and preconditions in those cases, where not already covered by AMC-ELA to Section A, or where different due to the focus on Competent Authority.

For both, Section A and Section B, AMC-ELA does not change the applicable regulations. AMC-ELA does not replace the existing GM and AMC. It provides an alternative, complete and self-contained set of AMC to the existing ones. Applicants that manufacture aircraft or products within the Scope as per AMC-ELA No. 1 to 21.A.131 may elect to apply AMC-ELA to Section A instead of the existing set of AMC, or instead of alternative means. Investigations of those applicants shall be conducted in full under application of AMC-ELA to Section B.

The system defined by AMC-ELA to Section A provides the minimum means for the applicant to comply with Part 21 Subpart G. The system allows for scalability and seamless growth of a company towards application of AMC for companies outside of the scope of AMC-ELA. However, the logic applied to AMC-ELA is that the reasons that push a company to go beyond the minimum described by AMC-ELA, while still being within the scope of AMC-ELA, do not originate from Part 21 Subpart G, but from numerous other aspects such as liability, economy, customer perception, market acceptance, social and ethical environment, and others. Investigations for adherence to AMC-ELA, and therefore implied compliance to Part-21 Subpart G, should consider this fact. Compliance with Part-21 Subpart G does only require adherence to AMC-ELA, disagreements related to consideration of the other aspects listed before should not be considered as non-compliance with Part 21 Subpart G.

The full set of AMC is recognised by the Agency as a complete means to satisfy all of Section 1, Subpart G requirements. In direct analogy to EU product legislation, this is seen equivalent to a “harmonized standard”, consequently allowing to ensure compliance with Part 21 Subpart G by virtue of demonstrating compliance with the full set of AMC-ELA. In this case, assessments may be conducted purely against AMC-ELA.

AMC-ELA to Section 1 Subpart G frequently refers to “methods to be practiced”. Documented process descriptions are not required for “methods to be practiced”. Investigation in those cases may only refer to factual observations of actual work conducted, by evidence of process records, or by direct observation, even when the company elects to hold process descriptions out of other reasons.

In some instances, AMC-ELA to Section 1 Subpart G allows that certain functions only need to be provided by either of design organisation or production organisation, when both entities operate as one consolidated entity. In this case, the respective function is only assessed as part of the surveillance of the entity that has adopted this functionality. With respect to the other entity, compliance with the respective requirements of Part 21 Section 1 is assumed by virtue of a current surveillance result with no level 1 finding on that specific subject.

In cases where the specific characteristic of the company renders individual elements of AMC-ELA impracticable or not applicable, a case specific resolution shall be agreed between applicant and Competent Authority only for those aspects, while keeping the remainder of AMC-ELA applicable.

AMC-ELA has been defined on the basis of granting relaxations compared to established methods used for large aeroplane industry, in return for the possibility to build a trustful relationship between the typically very compact team of the applicant and the relevant CA. It is the clear expectation that this trustful relationship is developed by both, applicant and CA, through open communication. The applicant is strongly encouraged to ask the relevant contact person at the CA for mutual clarification of any questionable item, in case of any doubt.

AMC-ELA No. 2 to Part 21, Section B, Subpart G – Production Organisation Approval – Documentation provided “for information, only”

One helpful step to build a trustful relationship between production organisation and competent authority is to share documents on a basis of “for information, only”. When a production organisation that applies AMC-ELA is providing documentation, that is not required by any of the definitions in AMC-ELA, on “for information, only” basis, this information is to be considered solely to enhance awareness of aspects that might become of relevance during the next surveillance activity. The CA is not required to conduct formal activity on the basis of documents submitted “for information, only”. The pure availability of these documents to the CA is not intended to imply any responsibility or liability with respect to EASA Part 21, for the Competent Authority. The information is to be seen similar to the kind of information used by the Agency to determine an applicant specific “Level of Involvement”.

21.B.220 Investigation

(a) The competent authority shall appoint a production organisation approval team for each applicant, or holder of, a production organisation approval to conduct all relevant tasks related to this production organisation approval, consisting of a team leader to manage and lead the approval team and, if required, one or more team members. The team leader shall report to the manager responsible for the activity as defined in point 21.B.25(b)(2).

(b) The competent authority shall perform sufficient investigation activities for an applicant for, or holder of, a production organisation approval to justify recommendations for the issuance, maintenance, amendment, suspension or revocation of the approval.

(c) The competent authority shall prepare procedures for the investigation of a production organisation approval as part of the documented procedures covering at least the following elements:

1. evaluation of applications received;

2. determination of production organisation approval team;

3. investigation preparation and planning;

4. evaluation of the documentation (production organisation exposition, procedures, etc.);

5. auditing;

6. follow up of corrective actions;

7. recommendation for issuance, amendment, suspension or revocation of production organisation approval;

8. continued surveillance.

AMC-ELA No. 1 to 21.B.220 (a) Investigation Team

The competent authority shall appoint a production organisation approval team (POAT) leader with excellent understanding of the nature and established manufacturing practice of products within the scope of work of the applicant, which often significantly differs to those applied on larger products. The team leader shall be selected by considering the following criteria:

a) the capability to lead and manage a team;
b) the capability to prepare reports and be diplomatic;
c) A thorough knowledge in conducting product conformity audits; and
d) Experience level to allow "equal speaking terms" with the production organisation, through:
    1. thorough knowledge of the typical production practice of light aeroplanes and related products and parts; and
    2. thorough knowledge in alternative quality management systems typically applied by companies doing light aeroplanes, such as ISO9001, EN9100, ASTM F2972, or similar.

The team leader reports to the manager responsible for the activity as defined in point 21.B.25(b)(2).

In cases where the team leader is not able to cover all aspects of the product considered under the Scope of Work of the applicant, the team leader shall coordinate with both, the competent authority and the production organisation on suitable subject matter expert(s) that may support during the investigation. The overall size of the team shall be adequate to the size of such a company, aiming for a proper balance in participants at the surveillance event between competent authority and production organisation.

AMC-ELA No. 1 to 21.B.220 (b) Extent of Investigation

Initial and continued investigation of the company is primarily conducted on the basis of conformity investigation of products with work in progress or following completion, and on the basis of direct product assessment, or assessment of product related production records.

When conducting investigations on companies that apply the POE and QAM template provided as AMC-ELA to Book A of Part-21 Subpart G, Investigation of the documentation is limited to the verification that the templates have been adequately adopted to the company specific details.

In cases where the production organisation has been audited by an accredited third party for compliance with ISO 9001 or AS/EN 9100 and where the company holds a respective and valid certificate, and where the production activity to be covered by the production organisation approval is explicitly covered by the Scope of the QM approval, the competent authority should use and accept this to the best extent as evidence of successful implementation and practicing of methods required by AMC-ELA, with the aim to reduce duplication in regular assessment.

Recommendation for issue or continuation of a POA shall be given when the investigation shows that the company is capable to manufacture products within the scope of work in a repeatable way, so that they conform to the Type Design in such a way, that the safe operation of the product can be expected.

AMC-ELA No. 1 to 21.B. 220 (c) Procedures for Investigation - General

The purpose of the procedures is to investigate the applicant production organisation for the ability to manufacture products within the scope of work that conform to the Type in a repeatable way, so that they conform to the Type Design in such a way, that safe operation of the product can be expected.

Instead of defining CA specific procedures, the CA may adopt the definitions provided by the full set of AMC-ELA to Section B, Subpart G. Individual procedures, when generated, should cover the following aspects:

1. Evaluation of applications received per AMC-ELA No. 2 to 21.B.220 (c).
2. Determination of the production organisation approval team per AMC-ELA No. 1 to 21.B.220 (a).
3. Initiation

   The POA Team Leader initiates the procedure with a new applicant by arranging a meeting with the applicant in order to enable the applicant to make a general presentation of its organisation and products, parts or appliances, and to enable the POATL to describe the investigation process.
4. Preparation

   The POATL:

   a. studies the information gathered in the initiation phase

   b. establishes an investigation plan which:

      – takes account of the location of the POA applicants facility

      – defines areas of coverage of possible subject matter experts

      – establishes the need for external advice where the available expertise may be lacking

      – includes a comprehensive plan for auditing a representative set of products with work in progress or following completion, and on the basis of direct product assessment, or assessment of product related production records.

   c. establishes liaison with the applicant to plan mutually suitable dates and times for visits at the location needing investigation, to coordinate a balanced size of the investigation team on both sides, and to agree upon the investigation plan and approximate time scales.
5. Investigation

   The POATL:

   a. makes a check of the POE for compliance with AMC-ELA No. 1 to 21.A.143 (a), (b) on the basis of EASA Form 56-ELA Part 3, or to the correct adoption of the sample POE provided, as applicable.

   b. audits the product and its associated documentation for conformity with the provisions of the relevant type design. Where discrepancies show up on the audited product, the POATL assesses if the definitions of the Quality System have been adhered to, and if those definitions may have been misleading and contributing to the discrepancies, warranting possible need for modification. The audit is conducted using EASA Form 56-ELA Part 2 as a guide during the investigation with direct link to AMC-ELA to Section A, Subpart G, and as a checklist at the end of it.

   c. confirms any EASA Form 4 completed by the key nominated personnel in accordance with AMC-ELA No. 1 to 21.A.145 (c), on the basis of a review of the skills of the nominee, used as the basis for the nomination.

   d. makes sample audits at adequate work stages to verify that:

- products, parts, appliances or material produced by the organisation are in conformity with the applicable design data.
- the level of product conformity achieved gives indication that facilities, working conditions, equipment and tools are appropriate for the work being performed in a repeatable way.
- achieved production rate and number of product non-conformities give indication that competence and numbers of personnel is appropriate for the work being performed in a repeatable way.
- identified responsibilities and examples show a satisfactory and effective coordination between production and design entity.

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

The POATL should co-ordinate with the subject matter experts for an efficient investigation process, which will provide consistent and effective investigation and reporting standards.

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

6. Conclusions

   a. The POATL holds a meeting with the subject matter experts to review findings and observations so as to produce a final agreed report of findings.

   b. The POATL, on completion of the investigation, holds a meeting to verbally present the report to the applicant.

   c. The meeting should agree the findings, corrective action time scales, and preliminary arrangements for any follow up that may be necessary.

   d. The POATL will transmit the final signed report on EASA Form 56-ELA together with notes of the final meeting with the applicant to the competent authority where the applicant is located. The report will include recommendations and significant findings, together with appropriate conclusions and corrective actions. In particular, it should indicate if the POE is acceptable, or changes are required.

   e. If the findings made during the investigation mean that approval recommendation will not or cannot be issued, then it is essential that such findings are confirmed in writing to the organisations within two weeks of the visit. The reason for confirmation in writing is that many organisations take a considerable time to establish compliance. As a result, it is too easy to establish a position of confusion where the organisation claims it was not aware of the findings that prevented issue of an approval.

7. Follow up of corrective actions

   The POATL tracks the feedback obtained from the applicant under consideration of the timelines specified by AMC-ELA No. 1 to 21.B.225 (a). In case of level 2 findings, follow-up of corrective action should be aligned with the schedule for subsequent regular surveillance activities.

The POATL prepares a recommendation for issuance, amendment, suspension or revocation of production organisation approval, considering the definitions provided by AMC-ELA No. 1 to 21.B.230. The recommendation is documented using EASA Form 56-ELA, Part 5.

8. Continued Surveillance

Subsequent to initial approval, the POATL coordinates with the applicant for a mutually agreed surveillance plan adequate to the company size, product range and production rate, considering the definitions provided by AMC-ELA No. 1 to 21.B.235.

AMC-ELA No. 2 to 21.B. 220 (c) Evaluation of applications

The competent authority must receive an application for POA on an EASA Form 50 completed by the applicant. To qualify for evaluation in line with the complete set of AMC-ELA, the applicant shall fill EASA Form 50 following the specific filling instructions given below.

After confirmation of the entries in line with the definitions provided here, the eligibility and appropriateness of the application is considered given in accordance with 21.A.133 and the applicant is advised about acceptance of its application in writing.

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

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 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 code per AMC-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 the applicable of "21.A.163 (a), (b), (c), (d), (e)".

Block 5: If existing at the time of application, reference to the draft version of the POE per AMC-ELA No. 1 to 21.A.143. Otherwise: "Will be provided when 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: "below xx FTE", giving the approximate size of the company by Full-Time Equivalents with relevance to the classification per fees and charges.

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

AMC-ELA No. 3 to 21.B. 220 (c) Procedures for Investigation - Investigation preparation and planning

When investigating companies that manufacture aircraft, or engines, or propeller used on aircraft that meet the category specific equivalent to a CS-23 Level 2 low-speed aeroplane:

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

1. liaise with the Agency for the appointment of any necessary observer(s) for standardisation purposes
2. establish any necessary liaison arrangement with other competent authorities
3. Identify the POATL on the basis of thorough production experience with respect to nature, technology and size of the product in scope
4. seek any necessary advice and guidance from the Agency

AMC-ELA No. 4 to 21.B. 220 (c) Procedures for Investigation – Investigation documentation

EASA Form 56-ELA Parts 1 – 5 should be used to document conduct of the investigation, possible findings, and recommendations for issue or continuation of a POA. Parts 2 and 3 are organised as checklists, directly aligned with the relevant definitions of AMC-ELA to Section A, Subpart G.

Competent authority

of an EU Member State or

EASA

RECOMMENDATION REPORT IN SUPPORT OF Part 21 SUBPART G APPROVAL
for companies that manufacture aircraft, or engines, or propeller used on aircraft that meet the category specific equivalent to a CS-23 Level 2 low-speed aeroplane
ISSUE / CONTINUATION / VARIATION / SIGNIFICANT CHANGE

PART ONE OF FIVE PARTS: **BASIC DETAILS OF THE ASSESSMENT**

Name of the organisation:

Approval reference: _____

Address(es) of the facilities surveyed:

Main Part 21 Subpart G activities at facilities surveyed:

Date(s) of survey:

Names and positions of the organisation's senior management attended during survey:

Names of the competent authority staff:

Office: **EASA Form 56-ELA completion date:**

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

EASA Form 56-ELA Issue 1-– POATL Recommendation Audit Report - Part 1 of 5, Page 1 of 1 MONTH YEAR

Competent authority
of an EU Member State or
EASA

RECOMMENDATION REPORT IN SUPPORT OF Part 21 SUBPART G APPROVAL
for companies that manufacture aircraft, or engines, or propeller
used on aircraft that meet the category specific equivalent
to a CS-23 Level 2 low-speed aeroplane
ISSUE / CONTINUATION / VARIATION / SIGNIFICANT CHANGE
PART TWO OF FIVE PARTS: **Part 21 SUBPART G COMPLIANCE**

Name of organisation: **Approval of organisation:**

Approval reference: **Survey reference:**

Note A: This form has been compiled according those points of Part 21 Subpart G which are relevant to an organisation trying to demonstrate compliance, and implementing the accepted means of compliance published as AMC-ELA, applicable to companies that manufacture aircraft, or engines, or propeller used on aircraft that meet the category specific equivalent to a CS-23 Level 2 low-speed aeroplane.

Note B: The right hand part of each box must be completed with one of three indicators:
1. a tick (✓) which means compliance;
2. NR which means the requirement is Not Relevant to the activity at the address surveyed; (the reason for NR should be stated in Part 4 of the report, unless the reason is obvious)
3. a number relating to a comment which must be recorded in Part 4 of the report.

The left hand part of each box is optional for use by the competent authority.

Generic Issues
To be verified as part of regular scheduled surveillance events:

When considering the level of communication exercised between production organisation and competent authority in both directions, is the level of communication adequate to the level of trust exercised?

Is the amount and kind of organisation recorded production non-conformities appropriate to the kind of products and to the level of quality management exercised? Are the non-conformities resolved in an adequate way, so as to identifying possible implications for methods exercised or processes defined? Does the corrective action that has been taken show effect so as to avoid re-occurrence of comparable non-conformities?

Does the production organisation still feel comfortable when applying the simplifications of AMC-ELA? Does it still meet the specific needs, or has the company developed such that a modified approach should be considered, jointly between applicant and competent authority?

21.A.131 Scope
The company meets the criteria and has decided to apply a system in line with the full set of AMC-ELA as provided by the Agency with respect to Part-21, Book A, Subpart G; or

The company meets the criteria and has decided to apply the handbooks templates for both, POE and QAM as provided by the Agency with respect to Part-21, Book A, Subpart G;

and – in both cases – there are items that deviate in a case-specific way from AMC-ELA or template POE or QAM, and therefore have case specific agreements on means of compliance.

When applicable, deviating aspects relate to:

PART TWO OF FIVE (CONTINUED): SURVEY REFERENCE:

21.A.133 Eligibility

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

(a) It is confirmed that the company intends to manufacture aircraft, or engines, or propeller used on aircraft not classified as complex-motorpowered aircraft, that are either aeroplanes of 2 730 kg maximum take-off mass (MTOM) or less; or rotorcraft of 1 200 kg MTOM or less and certified for a maximum of up to 4 occupants; or other ELA2 aircraft, including for example sailplanes and balloons, and therefore is eligible for approval under Subpart G. ☐

(b) The applicant holds or has applied for an approval of that specific design; or ☐

(c) Satisfactory coordination and communication between production and design is achieved to an extent that responsibilities for the coordination and communication are adequately assumed. This is verified by observation during surveillance events, documentation to support this is not required and may not be needed. ☐

21.A.134 Application

EASA Form 50 in the version relevant to the CA has been completed under consideration of the filling instructions provided by AMC-ELA No. 2 to 21.B.220 (c), and provided by the accountable manager of the organisation to the CA, along with an outline of the production organisation exposition, and details of the proposed terms of approval. ☐

21.A.139 Quality System

(a) The production organisation demonstrates to have established and maintain a quality system by holding a valid ISO9001 or EN9100 certificate with a scope that includes the POA activities; or by declaring compliance to ASTM F2972 for aircraft with a CS-LSA certification basis; or by installing the quality system defined by the standard QAM; or by installing an individual quality system that meets all the definitions of the full set of AMC-ELA.
The focus of the required quality system is on the key workflows that are indispensable to ensure conformity of delivered products to the relevant parameters of the applicable design data. Where evidence on product level shows that the methods of quality inspection are not sufficient to determine conformity with the relevant parameters of the applicable design data, and when the type design is not providing process definitions for these cases, the Quality System provides elements that care for the related deficiency. ☐

(b) As applicable within the scope of approval, the quality system contains control procedures for only those of the subsequent elements, where failure to control these elements is expected to impact directly on the safe operation of the aircraft. Compliance is provided when it is confirmed by observation of the actual conduct, that the applicant is practicing methods in the way specified as follows.

(i) ☐ The use of invalid or superseded information in production is prevented;

(ii) ☐ Only when there are cases where (b)(1)(iii) or any other production control mechanism are not able to mitigate Production Risks, Methods for vendor and subcontractor assessment and surveillance are practiced;

(iii) ☐ In cases where there is no other production control mechanism able to mitigate Production Risks, such as for example later inspection or testing requirements with parts already installed to products, methods for incoming inspection of products, parts, materials and equipment are practiced. Incoming goods verification is limited to those aspects that the Type Design defines to be verified;

(iv) ☐ Methods for identification and traceability are practiced to the extent defined as part of the approved Type Design;

(v) ☐ Manufacturing process information is provided as part of the Type Design, possibly using standard established process information, and required only for those aspects where strict process adherence is imperative in order to ensure safety critical product characteristics;

(vi) ☐ The scope of inspection and testing is defined as part of the approved Type Design data; and

☐ Production flight test procedures are provided in form of a set of test plan and flight conditions that have been provided as part of the Type Design for that purpose; or

☐ Production flight test procedures are defined by an FTOM maintained by the design entity and jointly applied by design and production; or

☐ Production flight test procedures are defined by an FTOM maintained by the production organisation;

(vii) ☐ In those cases, and for this equipment where the approved Type Design defines that a high accuracy is required, that cannot be verified by other means throughout the production process, calibration and tooling verification methods are practiced;

PART TWO OF FIVE (CONTINUED): SURVEY REFERENCE:

(viii) ☐ Methods are practiced that prevent the release of non-conforming products and their parts that would have an impact on the safe operation of the aircraft. Elements considered are identification (which may be obtained by electronic means for example using ERP systems), or method of separation, or destruction in case there is no possibility to bring the affected part into an airworthy condition;

(ix) ☐ Methods are practiced that enable adequate airworthiness coordination with the applicant for, or holder of, the design approval. Dedicated methods for airworthiness coordination with the design approval holder is not required when the design and production entity works within one consolidated team, or where the control of airworthiness relevant information is conducted by the same group of persons for design and production;

(x) ☐ Methods are in place to safeguard completed records. Safeguarding is ensured by keeping the records in an adequately protected environment, as suitable supported by keeping accessible backup copies;

(xi) ☐ For certifying staff, definitions for the required competence and qualification are available, and the selected staff satisfies these requirements;

(xii) ☐ The persons permitted to issue airworthiness release documents are identified. Reference to the relevant forms and filling instructions is provided. Reference to the identification of the relevant forms, and to a place where the relevant CA is providing the forms and filling instructions is considered sufficient;

(xiii) ☐ Adequate handling, storage and packaging methods are practiced for critical items where inappropriate handling, storage or packaging can lead to damage or deterioration that standard inspection prior to the use of the component would not detect, and where such damage or deterioration would endanger the airworthiness of a component or part;

(xiv) ☐ Surveillance mechanisms are practiced that allow to verify the efficiency of the elements of the quality system as defined by AMC-ELA No. 1 to 21.A.139 (b). Considering the main target of Subpart G to ensure conforming products in a safe condition of operation, surveillance mechanisms may include planned and unplanned audits, but also other means such as structured experience exchange, regular quality meetings, brainstorming or lessons-learned-sessions, project reviews at reasonable phases of company development, or other similar means. Corrective actions identified are followed up and the way of resolution is recorded;

(xv) ☐ Work within the terms of approval performed at any location other than the approved facilities is conducted under the responsibility and following recorded permission of the AM, and it has been ensured that the critical process parameters for the work conducted, such as light, temperature, humidity, etc. and adequate tooling have been identified and ensured to be adequate. If applicable, work conducted at such a location has been of a kind as to not be considered as “major place of activity”;

(xvi) ☐ work carried out after completion, but prior to delivery of the product is conducted following the identical definitions and procedures and by the same staff as relevant for the regular production process;

(xvii) ☐ The workflow to issue a permit to fly for the purpose of factory acceptance test flights on the basis of flight test plan and flight conditions that have been provided as part of the approved type design is adequately exercised. Evidence shows that production acceptance flight tests are conducted in full adherence to the flight test program for the purpose of production acceptance flight tests approved through the Type Design.

OR:

☐ The company is working as one consolidated entity and is using FTOM procedures that are defined within the design entity, and current surveillance status of this flight test section did not lead to open level 1 findings;

OR:

☐ The production organisation has defined a stand-alone FTOM, and adherence to all relevant aspects defined by Part 21 has been individually verified on the basis of AMC-ELA No. 2 to 21.A.143 as part of this assessment.

☐ By nature of the scope of products within the scope of AMC-ELA, there are no critical parts required. The applicant has the possibility to voluntarily define some, in this case control procedures adequate to the related risk are confirmed to be exercised.

(b)

(2) Monitoring of compliance with, and adequacy of the implemented quality system is done by systematic means, accomplished by structured experience exchange, regular quality meetings, brainstorming or lessons-learned-sessions, project reviews at reasonable phases of company development, or similar. Audits may be one element of monitoring and when implemented are conducted as process audits focussing on the implemented key processes or methods practiced as per the installed Quality System.

☐

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

21.A.143 Exposition

(a) The organisation has provided a POE (providing the information as verified in Part 3 of this Form) in form of a consolidated interface document towards the CA. The POE may be integral part of another company (quality) (management) manual. In this case the elements being considered part of the POE should be easily identifiable. The POE content meets the definitions provided by AMC-ELA No. 1 to 21.A.143 (a) (b). The POE is approved by virtue of obtaining the POA approval as such, the document does not require approval by the CA.

(b) The production organisation amends the POE as necessary to remain an up-to-date description of the organisation. Copies of amendments are provided to the competent authority.

21.A.145 Approval requirements

(a) Adequacy of infrastructure and staffing is demonstrated by achieving conforming products in the anticipated production rate. The manufacturer has defined reasonable intervals to evaluate the adequacy of the available resources.

(b) With regard to all necessary airworthiness, noise, fuel venting and exhaust emissions data:
It is confirmed that design and production entity of the applicant operate in one consolidated team and production data are provided as part of the approved Type Design data, therefore requiring no further provisions for obtaining the data.

Otherwise, responsibilities to obtain airworthiness, noise and exhaust emission data from the Agency and from the Type Design holder are established and e.g. shown by task descriptions of responsible functions in the organisation. IT based systems are one acceptable means to ensure correct information flow;

(c) with regard to management and staff:
(1)
The applicant has named the accountable manager to the CA using EASA Form 4. It is evident 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.

(2)
The AM has elected to delegate the responsibility to ensure that the production organisation is continuously in compliance with the data and procedures identified in the POE to sub-level managers, and these sub-level managers are nominated to the CA using EASA Form 4.

The AM has elected to delegate the responsibility to ensure that the organisation is in compliance with the provisions of the full set of AMC-ELA to sub-level managers, and these sub-level managers are nominated to the CA using EASA Form 4.

(3) The AM may delegate individual tasks to sub-level managers, while still remaining responsible for the decisions taken at sub-level and being required to monitor activities on sub-level. Such delegations on sub-levels is defined internally;

(d) with regard to certifying staff, authorised by the production organisation to sign the documents issued under point 21.A.163 under the scope or terms of approval:
(1) Qualification to release completed products is ensured by utilizing Part 66 qualified inspectors, or equivalently qualified personnel per national regulations. This required level of qualification is defined and nominations adequately reflect those requirements.

(2) the production organisation maintains a record of all certifying staff which shall include details of the scope of their authorisation.

(3) Evidence of authorization is provided in a reasonably accessible way within the company, so that staff that needs to be aware of the authorization can verify the status whenever needed. This can be achieved by provision of accessible listings of nominated certified staff, or other means. Issuing of individual badges o passes is not required.

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

21.A.147 Changes to the approved production organisation

(a) For the following cases, the company is applying in writing for approval from the relevant CA, prior to implementation:
- Relocation of the major place of activities to a different geographic location, city, airfield or similar. Relocation within one building, or to a neighbour building on the same premises, or similar, do not require prior approval, as long as the critical parameters to environment, infrastructure or equipment remain ensured under the responsibility of the AM;
- First-time introduction of material or production technologies that are new to the approved organisation;
- Changes in staff that is nominated towards the relevant CA using EASA Form 4;
- Changes in scope of approval; or
- Changes in ownership in line with AMC-ELA No. 1 to 21.A.149.

(b) The competent authority and the approval holder have established a relationship and exchange during the implementation of a change that ensures that changes do not result in non-compliance with Part 21 Book A Subpart G.

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 considered significant by the production organisation and is treated in line with AMC-ELA No. 1 to 21.A.147.
For relocations within one building, or to a neighbour building on the same premises, or similar, that are not considered significant, the production organisation ensures that the critical parameters to environment, infrastructure or equipment are achieved.

21.A.149 Transferability

The company has implemented that transfer of approval is only possible in cases where the ownership changes but the organisation itself remains effectively unchanged. Such changes in ownership are generally not considered to be significant changes to the quality system, and do not require separate oversight measures. Possible effects will be addressed at the subsequent regular oversight activity.

21.A.151 Terms of approval

Terms of approval identify the scope of work and the product categories for which the holder is entitled to exercise the privileges defined in 21.A.163, by using the relevant elements as defined within AMC-ELA No. 1 to 21.A.151. Listing of Type and Model are not required within the formal Scope of Work. Those terms are adopted as part of a production organisation approval.

21.A.153 Changes to the terms of approval

EASA Form 51 in the version of the relevant the competent authority is used, completed in accordance with the instructions provided by the CA and forwarded to the CA. Submission of further and especially more detailed documentation is only submitted if applicant and CA agree that the assessment for change in approval can be completed on paper basis.

21.A.157 Investigations

Arrangements shall be in place that allow the competent authority to make investigations at the location of the production organisation that include enquiries, questions, discussions and explanations and inspections of products produced under the scope of work of the POA. Monitoring, witnessing, checks, flight and ground tests may become part of the investigation when non-conformities to the Type Design are identified that have the potential to endanger safe operation of the product.

21.A.163 Privileges

Pursuant to the terms of approval issued under point 21.A.135, the holder of a production organisation approval may:
(a) perform production activities under this Annex I (Part 21).

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

(c) in the case of other products, parts or appliances, issue authorised release certificates (EASA Form 1) under 21.A.307 without further showing;

(d) maintain a new aircraft that it has produced and issue a certificate of release to service (EASA Form 53) in respect of that maintenance;

(e) When implementing a flight test plan and prepared flight conditions that are provided as part of the Type Design for the purpose of production acceptance flight test, to approve those flight conditions and subsequently issue the related permit to fly; or

Under procedures agreed with this competent authority, for an aircraft it has produced, and when the production organisation itself is controlling under its POA the configuration of the aircraft and is attesting conformity with the design conditions approved for the flight, to issue a permit to fly in accordance with point 21.A.711(c) including approval of the flight conditions in accordance with point 21.A.710(b).

21.A.165 Obligations of the holder

The holder of the production organisation approval:

(a) Ensures that personnel have access to and are familiar with that part of the content of the POE or the QAM, which covers their activities. Staff at the production organisation with relevance to the production of products under the POA approval is able to demonstrate awareness of the definitions provided within the POE and QAM.

(b) Monitors of compliance with this documentation is ensured by systematic means that do not need to be limited to, or even include auditing, but may be accomplished by structured experience exchange, regular quality meetings, brainstorming or lessons-learned-sessions, project reviews at reasonable phases of company development, or other similar means.

(c) Before the production organisation issues a Statement of Conformity / Release Certificate, it is adequately conducting investigations so as to be satisfied that:

(1) Each completed part or product conforms to the type design and is in condition for safe operation. Verification or all items can be ensured by having adequate checklists provided as part of the Type Design or as part of the QAM definitions, or by having adequate checking points mandated by an IT based ERP system, or by equivalent means.

(2) On case of engines, each completed engine is in compliance with the applicable emissions requirements at the date of manufacture of the engine.

(3) Other products, parts or appliances conform to the applicable data before issuing EASA Form 1 as a conformity certificate. Verification or all items can be ensured by having adequate checklists provided as part of the Type Design or as part of the QAM definitions, or by having adequate checking points mandated by an IT based ERP system, or by equivalent means;

(d) This part of the work, where the approved Type Design requires so, has been recorded.

(e) Occurrences are recorded and evaluated, in order to identify adverse trends or to address deficiencies, and to extract reportable occurrences. In cases where the design and manufacturing entities both work within one consolidated team it is sufficient, when either the design or the production entity maintains the required provisions for occurrence management. Proper information flow between both entities is considered ensured by virtue of the close cooperation.

(f) All its information related to potential product deficiencies, observed in-field or during or after production and delivery, is shared with the holder of the Type Certificate and joint conclusions with respect to possibly required product design and / or in-field activities are achieved.

Occurrences where the assessment leads to a potential “unsafe situation” are reported to the Agency (in case of design related issues), or to the CA (in case of production related issues), within the times and by the methods published by the Agency of CA. Determination of an “unsafe condition” may be done by application of ASTM F2295, whereas occurrences that fall into the classification “urgent safety of flight situation” shall be considered as “unsafe situation”, and occurrences that fall into the category “potential safety of flight bulletin” have the potential of an “unsafe situation”, and shall be therefore further analysed in that respect, possibly in coordination with the relevant of CA or Agency.

(g) Active communication with and assistance of the holder of the type-certificate or design approval when dealing with any continuing airworthiness actions that are related to the products that have been produced is exercised. In cases where the design and manufacturing entities both work within one consolidated team and under one management, assistance to the type design holder is expected given as intrinsic function of the cooperation and does not require further showing;

☐

(h) Records of production that have been used to determine conformity with the type design are archived and preserved, using adequate archiving methods defined by the Quality System. Those records are held at the disposal of the CA, in case required to determine configuration and conformity situation of a product. All forms of recording media are acceptable (paper, database, …) provided they can meet the required duration for archiving under the conditions provided.

☐

(i) Before issuing a certificate of release to service, equivalent means are used as during original production of the product to determine that each completed product has been subjected to necessary maintenance and is in condition for safe operation.

☐

(j) Where applicable, when conducting flight test on the basis of a FTOM administered by the manufacturer itself, the conditions under which a permit to fly can be issued are determined.

☐

(k) Where applicable, compliance with point 21.A.711(c) and (e) is established before issuing a permit to fly to an aircraft.

☐

Alternatively, full adherence to the flight test program and flight conditions for the purpose of production acceptance flight tests, provided as part of the Type Design, is ensured before issuing a permit to fly to an aircraft.

☐

Competent authority
of an EU Member State or
EASA

RECOMMENDATION REPORT IN SUPPORT OF Part 21 SUBPART G APPROVAL
for companies that manufacture aircraft, or engines, or propeller used on aircraft that meet the category specific equivalent to a CS-23 Level 2 low-speed aeroplane
ISSUE / CONTINUATION / VARIATION / SIGNIFICANT CHANGE
PART THREE OF FIVE PARTS: **Part 21 SUBPART G EXPOSITION COMPLIANCE**

Name of organisation: **Approval of organisation:**

Approval reference: _____ **Survey reference:**

Note A: This form has been compiled implementing the accepted means of compliance published as AMC-ELA to 21.A.143(a), applicable to companies that manufacture aircraft, or engines, or propeller used on aircraft that meet the category specific equivalent to a CS-23 Level 2 low-speed aeroplane.

Note B: Each box must be completed with one of three indicators:
1. a tick (✓) which means compliance;
2. NR which means the requirement is NOT RELEVANT to the activity at the address surveyed; (The reason for NR should be stated in Part 4 of the report unless the reason is obvious.);
3. a number relating to a comment which must be recorded in Part 4 of the report.

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

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

Production Organisation Exposition

Revision Status:

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

(1)	☐	A statement signed by the accountable manager confirming that the POE and QAM as referenced from the POE will be complied with at all times.
(2)	☐	Title and name of the Accountable Manager, and that he is accountable for all, despite delegations of individual tasks. Delegation of tasks without responsibility is not required to be shown within the POE. Only when persons such as for example QM and PM receive delegation of responsibilities as outlined by AMC-ELA No. 1 to 21.A.145 (c), those persons are identified within the POE as well.
(3)	☐	Definition of the AM as formal communication point. If a separate QM is nominated and shall take this function, the QM needs to be identified, here. When further delegation of responsibility is applied, in addition to delegation of tasks the allocation of responsibilities is shown within the POE.
(4)	☐	In cases where all responsibility stays with the AM, despite delegation of individual tasks, this is to be expressed and no Org Cart is provided. Only in cases where the AM delegates responsibilities and not only individual tasks, an organisation chart is included to the POE, that identifies the position and reporting lines of those persons that hold delegated responsibilities.
(5)	☐	Confirmation that Certifying Staff is identified by a separate source (document, listing, intranet, etc.), and that this identification is easily accessible to everyone concerned within the company. A direct reference to the identification is not required and changes to this identification do not constitute a change to the POE
(6)	☐	Approximate size in FTE's, as relevant for fees & charges;

PART THREE OF FIVE (CONTINUED):	**SURVEY REFERENCE:**

(7)		Identification of the address of the major place of business. When this location differs from the legal place of business, it shall be indicated. Floor plans, or similar, are not required.
(8)		Quotation of the Scope of Work per definition of AMC-ELA No. 1 to 21.A.151, on the basis of the product Type(s). Scope of work automatically includes the product and all spare parts required for the identified products, without further specification or detailing. Capability lists are not required by Subpart G. Separate to the Scope statement as such, a listing is provided that identifies the type(s) produced by the approved PO.
(9)		Significant changes to the PO, and changes to the organisation that affect contents of the POE, have to be notified to the CA by the AM.
(10)		Confirmation that when changes to the organisation occur that affect the documentation required here, this documentation is required to be kept up to date under the responsibility of the AM. Amendments to the POE are released by the AM, and distributed following the implemented method for control of documented information to locations identified in a generic or document specific distribution list, including POATL of the relevant CA.
(11)		Reference to the definition of the QS of the company. This may be a reference to the QAM, or any other company handbook, possibly in compliance with ISO9001, or EN9100, or ASTM F2972, or other suitable standards.
(12)		Outside parties that operate under the quality system and procedures of the manufacturer, classical extended workbench cases, are identified.
(13)		Reference to an FTOM adequate to the flight test activities of the manufacturer. When both the design and manufacturing entities work within one consolidated team and under one management, it is sufficient to have FTOM procedures defined for only one of the entities. In cases where the production organisation limits itself to conduct of production acceptance flight tests only, simplifications as per AMC-ELA no. 1 to 21.A.143 (a) (b) are applied.

Competent authority
of an EU Member State or
EASA

RECOMMENDATION REPORT IN SUPPORT OF Part 21 SUBPART G APPROVAL
for companies that manufacture aircraft, or engines, or propeller
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to a CS-23 Level 2 low-speed aeroplane
ISSUE / CONTINUATION / VARIATION / SIGNIFICANT CHANGE

PART FOUR OF FIVE PARTS: **FINDINGS ON Part 21 SUBPART G COMPLIANCE STATUS**

Name of organisation: **Approval of organisation:**

Approval reference: _____ **Survey reference:**

Note A: Finding classification shall follow the logic applied by the relevant AMC-ELA.
Note B: Each finding must be identified by number and the number must cross-refer to the same number in a box in Part 2 or 3 of the Part 21 Subpart G survey report.
Note C: As stated in Part 1 any comments recorded in this Part 4 should be copied to the organisation surveyed together with Part 1.
Note D: In case of a partial clearance of a finding with some outstanding action remaining, this action has to be identified.

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

NAME & SIGNATURE OF SURVEYOR: **Date:**

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PART FOUR OF FIVE (CONTINUED): **Sheet ___ of ___**

SURVEY REFERENCE:

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

NAME & SIGNATURE OF SURVEYOR: **Date:**

EASA Form 56-ELA Issue 1- POATL Recommendation Report POA Audit Report - Part 4 of 5, Page 2 of 2 MONTH YEAR

Competent authority
of an EU Member State or
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RECOMMENDATION REPORT IN SUPPORT OF Part 21 SUBPART G APPROVAL
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Name of organisation:

Approval reference: _____ **Survey reference:**

Recommendation for issue / variation of approval/significant change:

The following Part 21 Subpart G Terms of approval are recommended for the above organisation at the address(es) specified in Part 1 of this report:

or

Recommendation for continuation of existing approval:

It is recommended that the Part 21 Subpart G Terms of approval identified in EASA Form 55 referenced

_____ be continued.

☐ **Reporting performed according to procedure for authority surveillance of suppliers of a POA holder located in other Member States, if applicable (Strict confidentiality to be observed)**

Name of competent authority surveyor making recommendation:

Signature of the competent authority surveyor:

Competent authority office: **Date:**

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21.B.225 Findings

(a) When during audits or by other means objective evidence is found by the competent authority, showing non-compliance of the holder of a production organisation approval with the applicable requirements of Section A, this finding shall be classified in accordance with point 21.A.158(a).

(b) The competent authority shall take the following actions:

1. for level 1 findings, immediate action shall be taken by the competent authority to limit, suspend or revoke the production organisation approval, in whole or in part, depending upon the extent of the finding, until successful corrective action has been completed by the organisation;

2. for level 2 findings, the competent authority shall grant a corrective action period appropriate to the nature of the finding that shall not be more than 3 months. In certain circumstances, at the end of this period and subject to the nature of the finding, the competent authority can extend the 3 months period subject to a satisfactory corrective action plan provided by the organisation.

(c) Action shall be taken by the competent authority to suspend the approval in whole or in part in case of failure to comply within the timescale granted by the competent authority.

AMC-ELA No. 1 to 21.B.225(a) Findings

Findings require an evident or imminent non-compliance of the product with the relevant type design as basis, at any stage of audited production. Further assessment of the root cause for the finding shall identify the relevant AMC-ELA to Section A, Subpart G, that leads to the non-compliance. The finding is raised against the applicable requirement of Section A, that is referenced from the relevant AMC-ELA. AMC-ELA No. 1 to 21.A.158 shall be used to classify findings.

In case of a level one findings:

1. The POATL shall coordinate with the applicant and find a position, if immediate action such as limiting, suspending or revoking the production organisation approval, in whole or in part, until successful corrective action has been completed by the organisation is imperative, depending upon the safety effect of the finding.

2. Confirmation must be obtained in a timely manner that the accountable manager received the letter containing details of the level one finding and of any applicable approval suspension details.

3. Resolution of a level 1 finding shall include reporting of the applicant to the POATL, and may include a subsequent subject specific audit at the applicant's location.

In case of level 2 findings:

1. The POATL shall ask for presentation of a corrective action plan within 3 months latest.

2. On the basis of an agreed corrective action plan, the POATL shall agree with the production organisation to an appropriate timeline for closing of the finding, that typically should be connected to the schedule of the regular surveillance.

3. The POATL shall receive information about completion of implementation of corrective action from the production organisation.

4. Surveillance of effective implementation, followed by the formal closing of the finding, should be typically conducted at the next regular surveillance activity.

5. Failure to adhere to the agreed timeline should lead to a re-consideration of the finding, leading to a revised timeline, or possibly to a more severe classification of the finding with related possible action taken by the CA.

21.B.230 Issue of certificate

(a) When satisfied that the production organisation is in compliance with the applicable requirements of Section A, Subpart G, the competent authority shall issue a Production Organisation Approval (EASA Form 55, see Appendix X) without undue delay.

(b) The reference number shall be included on the EASA Form 55 in a manner specified by the Agency.

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

Compliance with the applicable requirements of Section A, Subpart G, is demonstrated by virtue of adherence to the provisions defined by AMC-ELA to Section A, Subpart G.

It is acceptable that remaining level 2 findings are not closed, when

1. agreed corrective action plan exists; and
2. agreed schedule for implementation of the corrective action plan exists; and
3. the agreed schedule for implementation is not exceeded.

This includes acceptability of findings that have been closed by the applicant, but where the competent authority has accepted to defer verification of effectivity of the corrective action to a later (scheduled) surveillance activity, as part of the corrective action schedule.

When satisfied that the observed adherence to AMC-ELA to Section A, Subpart G, implies compliance with the applicable requirements of Section A, Subpart G, the competent authority shall issue a Production Organisation Approval using EASA Form 55, without undue delay.

The competent authority should base its decision to issue or amend a POA on the recommendation report (EASA Form 56-ELA) of the POATL. EASA Form 56 includes a proposal by the POATL for the scope and terms of approval defining the products, parts and appliances for which the approval is to be granted, with appropriate limitations.

When the competent authority issues the approval a final controlled copy of the POE for the organisation should have been supplied to the competent authority.

A record should be kept by the competent authority and should be brought to the attention of the Agency on request for standardisation purposes.

21.B.235 Continued surveillance

(a) In order to justify the maintenance of the production organisation approval the competent authority shall perform continued surveillance:

1. to verify that the production organisation approval holder's quality system complies with Section A Subpart G ;

2. to verify that the organisation of the production organisation approval holder operates in accordance with the production organisation exposition;

3. to verify the effectiveness of the production organisation exposition procedures; and

4. to monitor by sample the standards of the product, part or appliance.

(b) Continued surveillance shall be performed in accordance with point 21.B.220.

(c) The competent authority shall provide through planned continued surveillance that a production organisation approval is completely reviewed for compliance with this Annex I (Part 21) during a period of 24 months. The continued surveillance may be made up of several investigation activities during this period. The number of audits may vary depending upon the complexity of the organisation, the number of sites and the criticality of the production. As a minimum the holder of a production organisation approval shall be subject to continued surveillance activity by the competent authority at least once every year.

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

Continued compliance with Part 21 Subpart G regulations, adherence to the procedures laid out by the Quality System referenced by the POE, and effectiveness of these procedures is determined by virtue of the continued ability to manufacture products that conform to the Type Design in a repeatable way, such that safe operation of the product can be expected. Conformity to the type design is determined on the basis of an assessment of a representative number of sample products at different stages of production.

Surveillance activities are:

1. Planned activities to a schedule and in a way adequate to the company size, product range and production rate, so as to ensure a complete review within 24 months. To obtain the required complete review of the production organisation within 24 months, all relevant stages of production shall be audited once within this time.
2. Unplanned activities in response to applications for change of approval; or
3. Unplanned activities in response to unsafe situations that may find its cause within the production organisation and are of a significance where a detailed assessment cannot be delayed up to the next scheduled surveillance event.

A sampling plan in support of item 1. above could, for example, investigate:

- a (part of the) product with modification (or change);
- the installation, testing, or operation of a major part or system;
- the accuracy and generation of the Flight Test report data;
- the accuracy and generation of the Weighing report data;
- an engine test bed run;
- traceability of production records as defined from the Type Design;
- the accuracy and generation of the Statement of Conformity data and the associated safe operation determination;
- the accuracy and generation of EASA Form 1 data.

The sampling plan should be flexible so as to:

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

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

- are on equal speaking terms with the applicant
  - have a good practical knowledge of the specific kind of product;
  - have a good practical knowledge of the manufacturing processes, specific to the kind of product investigated;
  - have an up to date knowledge of the manufacturers production programme;
- use an appropriate and up to date sample plan and compliance check lists;
- have a suitable recording system for the results;
- have a properly operating feedback system to their national authority's organisation for POA and to the manufacturer;
- maintain an effective working relationship with the manufacturer and his staff;
- are able to communicate effectively.

AMC-ELA no. 2 to 21.B.235 Continuation of POA

At the end of the 24 months continued surveillance cycle, the POATL completes an EASA Form 56-ELA as a summary report for the continued surveillance including the recommendation for continuation of the POA, as applicable.

The EASA Form 56-ELA is countersigned by the person responsible within the competent authority for his acceptance. There is no limitation to the number of level two findings that may be open, provided they are within the time limits of the respective corrective action plans, or where the competent authority has accepted to defer verification of effectivity of the corrective action to a later (scheduled) surveillance activity, as part of the corrective action schedule.

21.B.240 Amendment of a production organisation approval

(a) The competent authority shall monitor any minor change through the continued surveillance activities.

(b) The competent authority shall investigate as appropriate in accordance with point 21.B.220 any significant change of a production organisation approval or application by the holder of a production organisation approval for an amendment of the scope and terms of approval.

(c) When the competent authority is satisfied that the requirements of Section A, Subpart G continue to be complied with it shall amend the production organisation approval accordingly.

AMC-ELA No. 1 to 21.B.240 Amendment of a POA

The CA shall conduct adequate investigations in accordance with AMC-ELA No. 1 to 21.B. 220 (c), prior to an update of the POA that reflects this significant change.

Significant changes are limited to:

- Relocation of the major place of activities to a different geographic location, city, airfield or similar. Relocation within one building, or to a neighbour building on the same premises, or similar, do not require prior approval, as long as the critical parameters to environment, infrastructure or equipment remain ensured under the responsibility of the AM;
- First-time introduction of material or production technologies that are new to the approved organisation;
- Changes in staff that is nominated towards the relevant CA using EASA Form 4;
- Changes in scope of approval; or
- Changes in ownership in line with AMC-ELA No. 1 to 21.A.149.

When satisfied that the observed adherence to AMC-ELA to Section A, Subpart G, implies continued compliance with the applicable requirements of Section A, Subpart G, the competent authority shall ammend the Production Organisation Approval, accordingly.

All other changes are considered minor. Minor changes are monitored by the competent authority as part of the regularly scheduled surveillance activities.

21.B.245 Suspension and revocation of a production organisation approval

(a) In case of a level one or level two finding, the competent authority shall partly or fully limit, suspend or revoke a production organisation approval as follows:

1. in case of a level one finding the production organisation approval shall be immediately limited or suspended. If the holder of the production organisation approval fails to comply with point 21.A.158(c)(1), the production organisation approval shall be revoked;

2. in case of a level two finding, the competent authority shall decide on any restriction to the scope of approval by temporary suspension of the production organisation approval or parts thereof. If the holder of a production organisation approval fails to comply with point 21.A.158(c)(2), the production organisation approval shall be revoked.

(b) The limitation, suspension or revocation of the production organisation approval shall be communicated in writing to the holder of the production organisation approval. The competent authority shall state the reasons for the suspension or revocation and inform the holder of the production organisation approval of its right to appeal.

(c) When a production organisation approval has been suspended it shall only be reinstated after compliance with Section A, Subpart G has been re-established.

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

In case of a level one finding, the POA approval shall be limited such that the manufacturer must not issue release or conformity certificates (as applicable), without presence of the competent authority. If the manufacturer fails to demonstrate corrective action within 21 days after written confirmation of the finding, the POA shall be revoked.

In case of a level 2 finding, the competent authority shall decide upon restrictions or limitations, when the manufacturer fails to provide corrective action plans within three months following initiation of the finding, or fails to provide confirmation of implementation of the corrective action within the timeframe agreed upon as part of the corrective action plan, or when the manufacturer has confirmed implementation of corrective action, but the corrective actions is found not to be implemented during the subsequent surveillance event.

Any limitation, suspension or revocation of the production organisation approval is communicated in writing to the holder of the production organisation approval. The competent authority states the reasons for the suspension or revocation and inform the holder of the production organisation approval of its right to appeal.

When a production organisation approval has been suspended, it is reinstated after compliance with Section A, Subpart G has been re-established by observed adherence to AMC-ELA to Section A, Subpart G, which implies compliance with the applicable requirements of Section A, Subpart G.

21.B.260 Record-keeping

(a) The competent authority shall establish a system of record-keeping that allows adequate traceability of the process to issue, maintain, amend, suspend or revoke each individual production organisation approval.

(b) The records shall at least contain:

1. the documents provided by the applicant for, or holder of, a production organisation approval certificate;

2. documents established during the investigation, in which the activities and the final results of the elements defined in point 21.B.220 are stated, including findings established in accordance with point 21.B.225;

3. the continued surveillance programme, including records of investigations performed;

4. the production organisation approval certificate, including changes;

5. minutes of the meetings with the holder of the production organisation approval.

(c) The records shall be archived for a minimum retention period of six years.

AMC-ELA No. 1 to 21.B. 245 Record keeping

The competent authority maintains a system of record-keeping that allows adequate traceability of the process to issue, maintain, amend, suspend or revoke each individual production organisation approval.

The records contain:

1. the documents provided by the applicant for, or holder of, the production organisation approval certificate;
2. documents established during the investigation, in which the activities and the final results of the elements defined in AMC-ELA No. 1 to 21.B.220 (c) are stated, including findings established in accordance with AMC-ELA No. 1 to 21.B.225;
3. the continued surveillance programme, including records of investigations performed;
4. the production organisation approval certificate, including changes;
5. minutes of the meetings with the holder of the production organisation approval.

The records are archived for a minimum retention period of six years.