

# 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 A Subpart J

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**

**generated by RMT.0689 PART-21 PROPORTIONALITY**

\* 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.

Initially published on 21/8/2012, Official Journal L 224, p. 1-85

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## SUBPART J — DESIGN ORGANISATION APPROVAL

### **21.A.231 Scope**

This Subpart establishes the procedure for the approval of design organisations and rules governing the rights and obligations of applicants for, and holders of, such approvals.

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

The full set of AMC-ELA defines an acceptable means of compliance to qualify for the issuance of a design organisation approval for companies that apply for, or hold, a type-certificate, restricted type-certificate or supplemental type certificate for aircraft, or engine, or propeller, when the aircraft is within, or the engine or propeller is limited to be used on aircraft within the following limitations:

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

Each AMC titled as AMC-ELA is considered applicable to companies producing products to this definition.

#### **AMC-ELA No. 2 to 21.A.231 Scope – General Considerations**

The full set of AMC-ELA as implemented here is based upon a set of preconditions.

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 design aircraft or products within the Scope as per AMC-ELA No. 1 to 21.A.231 may elect to apply AMC-ELA instead of the existing set of AMC, or instead of alternative means.

DOA approval is based upon compliance with the airworthiness requirements imposed by Part 21 Subpart J. There are numerous other external influences that trigger decisions and processes within an organisation that is engaged in design of aircraft. Such aspects can be, but not limited to:

- Liability aspects,
- Economic requirements,
- Customer perception,
- Market acceptance,
- Social and ethical environment,
- and others.

DOA approval process is not intended to provide a verification with respect to those other aspects, as long as not explicitly requested by Part 21 requirements.

However, the presence of and need to consider these aspects will require the management of the company to go beyond the extent that is defined within AMC-ELA and therefore gives the minimum content needed to comply with DOA requirements. AMC-ELA is defined in a way that this flexibility exists on company level, in response to increasing company size and product complexity, and adequate to the exact environment of the specific company. The applicant should implement each of the means defined here on an individual basis, commensurate to the kind of product and its associated risk. In this step, it is highly important to apply the scalability on observed evidence. Extended means may be necessary when it gets visible that the design results do not meet the expectations in a specific way, or when the company decides so, related to increasing complexity and/or criticality of the product. Extended means do not need to be applied just because it “was always done this way”.

It should be clarified that a setup that just meets the minima defined by AMC-ELA will provide a setup that just allows to verify that the development results are acceptable to meet the relevant certification and environmental requirements, and therefore are eligible to obtain type certification. Such a minimum system would neither provide a lean design process, nor ensure marketable products.

When using the term “A method needs to be practiced” throughout AMC-ELA, this shall imply that it is sufficient when the applicant can show what is actually done in order to comply with a requirement in a systematic way, without necessarily having a formally documented procedure established and introduced. Documented procedures that go beyond a “declaration” of the principles considered within the practiced method are typically not required. Evidence is provided by work result, by demonstration of actual conduct during surveillance activities, or by similar means. Only when the actual “doing” continues to be inconsistent, or does not satisfy the needs, documentation may be one of the alternatives to be considered to rectify the situation, but not the only one.

AMC-ELA differentiates between delegation of tasks, and delegation of responsibilities. From a certain company size and complexity onwards, that is different from company to company, it may be more efficient to delegate tasks with responsibilities, and this way to build a more formal organisation structure in the classical way. For companies with smaller size and complexity, delegation of responsibilities is creating overly burdensome administrative processes that do not meet reality. AMC-ELA fully accepts this increased efficiency and offers the possibility to delegate tasks while maintaining the responsibility associated with this task. As identified with respect to the individual requirements, this may significantly reduce the effort of documentation towards the Authority, and allows for streamlined methods to be practiced.

AMC-ELA refers to the “major place of activity”, when speaking of the company location. This term refers to those locations where the major design activities take place, where the design activities are controlled from, and where compliance is found. This major place of activity is defined by the address of the premises. For an example company that has one major location but employs satellite offices where design staff provides detail design work, the one major location presents the relevant location to be identified within the DOH, while possible satellite locations would not be mentioned, there. For another example company that has two locations where design control is exercised, both those locations would need to be shown in the DOH and approved.

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 with the Agency, just for those aspects. A justification that the means applied to satisfy those aspects meet the underlying requirements of Part-21 is only developed for those aspects.

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 Agency. It is the clear expectation that this trustful relationship is developed by both, applicant and the Agency, through open communication. The applicant is strongly encouraged to ask the relevant contact person at the Agency for mutual clarification of any questionable item, in case of any doubt.

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### **21.A.233 Eligibility**

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

- (a) in accordance with points 21.A.14, 21.A.112B, 21.A.432B or 21.A.602B; or
- (b) for approval of minor changes or minor repair design, when requested for the purpose of obtaining privileges under point 21.A.263.

**AMC-ELA No. 1 to 21.A.233 Eligibility**

Companies that apply for or hold a type-certificate, restricted type-certificate or supplemental type certificate, or that want to exercise privileges for one of the products identified in AMC-ELA No. 1 to 21.A.231 are eligible for an approval under this subpart on the basis of compliance with the full set of AMC-ELA.

**21.A.234 Application**

Each application for a design organisation approval shall be made in a form and manner established by the Agency and shall include an outline of the information required by point 21.A.243, and the terms of approval requested to be issued under point 21.A.251.

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

EASA Form 80 should be obtained from EASA website and completed by the Head of Design Organisation. The completed form should be submitted to EASA accompanied by a copy of the company registration.

**21.A.235 Issue of design organisation approval**

An organisation shall be entitled to have a design organisation approval issued by the Agency when it has demonstrated compliance with the applicable requirements under this Subpart.

**AMC-ELA No. 1 to 21.A.235 Issue of design organisation approval**

The full set of AMC-ELA satisfies all Subpart J requirements. When adhering to this set of AMC in full, in exact analogy to established EU product legislation processes, compliance with all requirements of EASA Part 21 Subpart J is implied, without the need to consider any further aspects raised by alternative GM or AMC to this subpart of Part 21.

In cases where AMC-ELA declare some of the requirements of this Subpart not applicable for this scope of companies, this definition can be applied by the applicant without further justification.

Implementation of the standard DOH without changes but adapted to the company constitutes full adherence to AMC-ELA. The applicant is not required to verify that the standard DOH as such meets the provisions of AMC-ELA, hence Part 21 Subpart J. In cases where the specific characteristic of the company renders individual means of AMC-ELA impracticable or not applicable, a case specific resolution is agreed with EASA, but only for those aspects. A justification that the means applied to satisfy those aspects meet the underlying requirements of Part-21 is only developed for those aspects.

**21.A.239 Design assurance system**

- (a) The design organisation shall demonstrate that it has established and is able to maintain a design assurance system for the control and supervision of the design, and of design changes, of products, parts and appliances covered by the application. This design assurance system shall be such as to enable the organisation:
  - 1. to ensure that the design of the products, parts and appliances or the design change thereof, comply with the applicable type-certification basis, the applicable operational suitability data certification basis and environmental protection requirements; and
  - 2. to ensure that its responsibilities are properly discharged in accordance with:
    - (i) the appropriate provisions of this Annex I (Part 21); and
    - (ii) the terms of approval issued under point 21.A.251;

3. to independently monitor the compliance with, and adequacy of, the documented procedures of the system. This monitoring shall include a feed-back system to a person or a group of persons having the responsibility to ensure corrective actions.
- (b) The design assurance system shall include an independent checking function of the showings of compliance on the basis of which the organisation submits compliance statements and associated documentation to the Agency.
  - (c) The design organisation shall specify the manner in which the design assurance system accounts for the acceptability of the parts or appliances designed or the tasks performed by partners or subcontractors according to methods which are the subject of written procedures.

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

When speaking of the “Design Assurance System” (DAS), this refers to those elements of product development and certification, that ensure for the control and supervision of initial design, changes or repairs to the design, with respect to the applicable type-certification basis, operational suitability data certification basis and environmental protection requirements. Therefore, elements to be considered as part of the DAS are:

- Generation, iteration, EASA agreement and maintenance of the Certification Programme;
- Verification of Compliance within the Design Organisation;
- Declaration of Compliance by the Design Organisation towards EASA;
- Monitoring functions to ensure continued airworthiness of the certified product, including resulting activities;
- Independent System Monitoring of the compliance with, and adequacy of, the documented procedures of this system.

A typical development process will include a number of additional activities that are not part of the DAS, even when elements of the DAS form specific milestones in the development path. Those other activities are consequently excluded from the assessment of the DAS, even when they are directly influenced by aspects of the DAS.

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

The elements of the DAS as defined in AMC-ELA 21.A.239 (a) are further broken down to the following activities:

- Generation, iteration, EASA agreement and maintenance of the Certification Programme:
  - Ensure that adequate product, change or repair specification(s) have been generated and are available to support a meaningful certification programme;
  - Generation of a Certification Program that is tailored to the product, or change, or repair specified, and identifies:
    - product and kind of operations envisaged;
    - proposed certification basis, special conditions, equivalent safety findings and environmental protection requirements;
    - compliance checklist together with the means of compliance intended to be used and any guidance material;
    - relevant CVE to be used on the project;
    - the programme milestones for interaction with the Agency.
  - Iteration of the CP, until reaching agreement with the Agency
  - Monitoring of the workflow in line with the CP
    - Update the CP and find new agreement with the Agency, when necessary

- Ensure that relevant staff is adhering to the CP when conducting certification
  - Structured method for classification of changes, repairs or deviations by adequate process flow, or following adequate decision forms (matrices); in case of major changes directly supporting the change related Certification Programme.
- Verification of Compliance within the Design Organisation:
  - Ensure that a complete set of data has been developed, in order to form a complete and concise Type Design definition
  - Ensure that the selected way of defining the Type Design allows for adequate configuration management, for the purposes of design and design variant management, and for the later production management;
  - Ensure coordinated and repeatable handling of changes within the type investigation process and post-TC/STC;
  - Ensure that analysis and test has been conducted using methods adequate to support the means of compliance defined, and documented to allow use for showing of compliance
  - Ensure that formal demonstration of compliance for the intended type design, change design or repair design, including generation of compliance statements with respect to any relevant certification requirement is provided
  - Conduct formal verification of compliance demonstrated for the intended type design, change to the type design or repair design, including verification of compliance statements with respect to any relevant certification requirement by an independent person nominated within the design organisation (Compliance Verification Engineer)
  - Ensure that the product relevant documentation such as the applicable of AFM, ICA or MMEL (MMEL obtained by adoption of CS-MMEL or CS-GEN-MMEL, but only required for products that are intended for commercial operation, other than VLA, LSA or powered sailplane) is provided
  - Ensure that prototypes or test specimen, produced by a connected production organisation, or by prototyping capacities 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 continued airworthiness of the certified product;
  - Conduct monitoring of significant events;
  - Ensure investigation and classification of reported significant events;
  - Ensure occurrence reporting for events classified as “safety critical” which constitute an unsafe or potentially unsafe condition;
  - Ensure generation and publication of Notifications, as applicable, whereas Notifications and any related design activity have to be verified following the same principles as any type design, change design or repair design activity / documentation.
- Declaration of Compliance by the Design Organisation towards the Agency:
  - Verification of the completeness of the compliance verification and type design documentation as defined within the Certification Programme by the Head of Airworthiness;
  - Issue of the Declaration of Compliance by the Head of Design Organisation towards the relevant authority, subsequent to the satisfactory completion of compliance verification against all 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, at least the following set of responsibilities have to be allocated to persons fulfilling the functions of:

- Head of Design Organisation (HDO)
  - o Control on budget and staffing to ensure completion of the development and certification tasks of the DOA within reasonable timeframes, expressed by adequate workload of DOA members.
  - o Issuing of declaration of compliance (see 21.A.20(d) and 21.A.97(a)(3)) with the applicable CS and environmental protection requirements after verification of satisfactory completion of the Type Investigation.
  - o Ensure adequate and timely information to the Agency in matters affecting the DOA as such.
- Compliance Verification Engineer (CVE)
  - o Conduct verification of compliance demonstration with the applicable CS and environmental protection requirements and its technical content within its subject matter of nomination. Successful verification of a compliance demonstration implicitly includes approval of all referenced and supporting documents. The applicant may elect to separately document approval of the individual supporting documents.
- Head of Airworthiness (HoA)
  - o Ensure verification of compliance with the applicable CS and environmental protection requirements by adequately qualified staff and that compliance demonstration as necessary to demonstrate compliance with all CS and environmental protection requirements is complete.
  - o Ensure that a Design Organisation Handbook is prepared and updated as required
  - o Ensure adequate and timely interaction with the authorities and internally on all relevant matters with respect to type certification, changes to type certificates, approval of repairs and approval of the design organisation as such. This includes the coordination that the documentation required is adequately generated.
  - o Ensure continued airworthiness activities are properly performed.
  - o Approval of Certification Program, classification of changes/repairs, minor changes/repairs, Major Repairs, and Flight Conditions and the issue of Permit to Fly under the relevant privileges,
  - o Providing verification to the head of the design organisation that all activities required for Type Investigation have been properly completed.
- Independent System Monitor (ISM)
  - o Monitoring of compliance with, and adequacy of the implemented Design Assurance System, using structured experience exchange, regular quality meetings, brainstorming or lessons-learned-sessions, project reviews at reasonable phases of company development, planned and unplanned audits, or other similar means.
  - o Independent conduct of ISM activities and direct reporting of observations to HDO.

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

Monitoring of compliance with, and adequacy of the implemented Design Assurance System is done by systematic means. Systematic monitoring means can be accomplished by structured experience exchange, regular design meetings, brainstorming or lessons-learned-sessions, project reviews at reasonable phases of company development, or other similar means.

Audits may be one element of monitoring. When implemented, those audits should be conducted as combined process/product (project) audits focussing on the implemented key processes or methods practiced as per DOH (or equivalent document), also allowing the design organisation to find possibilities for becoming more efficient by continuous improvement.

Systematic monitoring means are coordinated by the ISM, under the responsibility of the HDO, and with a direct reporting line to the HDO. In cases where the ISM is not independent of the activity monitored, especially when the HDO also fulfills the role of the ISM, he may involve auditors that are adequately



knowledgeable of the applicable requirements and of the implemented Design Assurance System. The system monitoring function may be undertaken by the existing quality assurance organisation, when existing and having adequate reporting lines to the HDO.

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

The design assurance system defines methods to ensure independent verification of the compliance demonstration on the basis of which the organisation submits compliance statements and associated documentation to the Agency.

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

Compliance verification is provided by approval of documented information by a person not creating the approved data in a function as Compliance Verification Engineer (CVE). Approval is given after verification of the completeness and technical accuracy of the report, and correctness of the derived statement of compliance. Approval must be documented in a way that the date and the person giving approval can be identified.

CVEs are nominated for specific scopes. The structure of these scopes is defined by the applicant and follows a logical structure, commensurate to the type of product, such as for example by disciplines (for example Structures, Flight, Electrical System, etc.), by set of CS- requirements (for example Subpart B, Subpart C, ...), by (set of) ATA-Chapters (for example 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 that the CVE scope is broken down to only few different disciplines, commensurate to the kind of product.

Compliance verification as part of the Design Assurance System is the only task within the DOA where the creation and CVE-check of documents is mandatory performed by different persons. It is acceptable for one person to hold multiple CVE nominations. For small companies, it is acceptable that persons holding other functions such as CE, HDO and HOA are also nominated as CVE.

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

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

One acceptable means to ensure this is by conduct of compliance verification through Compliance Verification Engineer(s) of the applicant, in line with the definitions of the Design Assurance System of the applicant. As compliance verification remains with the applicant, no specific qualification measures are required other than a pragmatic verification of the capabilities of the external party, and ensuring that the required level of detail is supplied as to enable adequate verification of the work results. Verification of the capability of an external party should be conducted when more complex activities are subcontracted. This still may be achieved by pragmatic means such as, for example, by expert reputation, or experience in performing this task with a comparable scope also for other DOA.

When subcontracting the CVE functionality to the same external party that conducts the task, but does not hold an own DOA, the identical requirements to qualification, nomination and documentation of

qualification and nomination apply to that person nominated as CVE. Availability of all relevant information for the subcontracted CVE to perform its duties are ensured by the applicant. The relevant contract defines that when acting as CVE, the external person acts on behalf and with direct reporting to the applicant's Head of Airworthiness.

Alternatively, when obtaining design substantiation from a subcontractor that holds a DOA, and when the work conducted is within the approved scope of this subcontractor DOA, design data become acceptable when the ELA 2 design company has verified that the result adequately meets the needs of product under development. Additional formal compliance verification is not required in this case.

### **21.A.243 Data**

- (a) The design organisation shall furnish a handbook to the Agency describing, directly or by cross-reference, the organisation, the relevant procedures and the products or changes to products to be designed. If flight tests are to be conducted, a flight test operations manual defining the organisation's policies and procedures in relation to flight test shall be furnished. The flight test operations manual shall include:
  - (i) a description of the organisation's processes for flight test, including the flight test organisation involvement into the permit to fly issuance process;
  - (ii) crewing policy, including composition, competency, currency and flight time limitations, in accordance with Appendix XII to this Annex I (Part 21), where applicable;
  - (iii) procedures for the carriage of persons other than crew members and for flight test training, when applicable;
  - (iv) a policy for risk and safety management and associated methodologies;
  - (v) procedures to identify the instruments and equipment to be carried;
  - (vi) a list of documents that need to be produced for flight test.
- (b) Where any parts or appliances or any changes to the products are designed by partner organisations or subcontractors, the handbook shall include a statement of how the design organisation is able to give, for all parts and appliances, the assurance of compliance required by point 21.A.239(b), and shall contain, directly or by cross-reference, descriptions and information on the design activities and organisation of those partners or subcontractors, as necessary to establish this statement.
- (c) The handbook shall be amended as necessary to remain an up-to-date description of the organisation, and copies of amendments shall be supplied to the Agency.
- (d) The design organisation shall furnish a statement of the qualifications and experience of the management staff and other persons responsible for making decisions affecting airworthiness and environmental protection in the organisation.

#### **AMC-ELA No. 1 to 21.A.243 Data – Design organisation handbook**

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

To discharge this responsibility, the DOA implements practiced methods to ensure adequate means to positively establish and verify compliance of the design and associated documentation generated. The

completeness of those methods is documented within the Design Organisation Handbook, together with required supporting and company specific definitions.

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

Documentation of the elements within the DOH may be limited to workflow definitions (flow charts, process cards, or similar) or to adequately process oriented forms. When applying ERP systems or other IT systems that manage workflows, a separate workflow documentation is not necessary, as long as the workflow can be demonstrated during surveillance activities on the basis of the applied IT system.

“Practicing of methods” is confirmed by observation of the actual conduct, using several examples as an indicator that the method is practiced in an organised and repeatable way. Those methods do not automatically require detailed documentation. Nevertheless, “practiced methods” should be identified with a declarative statement.

The documentation at least covers the relevant ones of the subsequently listed elements.

1. Unique identifier for the DOH, a means to identify and record the revision status.
2. Organisation name and address of the major place of activity. When this location differs from the legal place of business, both addresses should be provided. Floor plans, or similar, are not required.
3. A statement signed by the Head of Design Organisation confirming that the DOH will be complied with at all times and is used as a basic working document (binding declaration).
4. Quotation of the Scope of the DOA per definition of AMC-ELA No. 1 to 21.A.251, listing the key technologies used for airframe design and propulsion concept on the projects in scope.
5. Title and name of the HDO, HoA and ISM with quotation of their accountability per AMC-ELA No. 1 to 21.A.239(a). Delegation of tasks without responsibility does not affect accountability and is not required to be expressed within the DOH.
6. Identification of the formal position and reporting lines of HDO, HoA and ISM within the company, possibly, but not necessarily, through an Org Cart.
7. Definition of the HDO to assume all duties and responsibilities associated with the DOA, unless delegation of responsibility, beyond delegation of tasks, is applied. In this case, the allocation of responsibilities is shown, here.
8. Definition of the HoA as formal communication point to the Agency.
9. Definitions for the required competence and qualification are available for HDO, HoA (maybe consolidated in case both functions are provided by one person), CVE and ISM.
10. Confirmation that Compliance Verification Engineers are identified by a separate source (document, listing, intranet, etc.), and that this identification is easily accessible to everyone concerned within the company. This list is to be held available to EASA in the current version.
11. Approximate size in FTE's, with an accuracy as relevant for fees & charges, including a declaration that the adequacy of staff involved in the design activities is ensured in number and qualification is monitored and action taken, if necessary.
12. Confirmation that significant changes to the DO, and changes to the organisation that affect contents of the DOH, will be notified by the HoA to the Agency in a timely manner.
13. Confirmation that when changes to the organisation occur that affect the documentation required here, the DOH is kept up to date by the HoA but under the responsibility of the HDO, or its delegate. Amendments to the DOH are released by the HDO, or by its delegate, and distributed following the

implemented method for control of documented information, to locations identified in a generic or document specific distribution list, including EASA DOATL.

14. Confirmation that methods are practiced that allow to verify the efficiency of the elements of the quality system as per this listing. The main target of Subpart J is to ensure that the Type Design of the product complies with the applicable type certification basis, the applicable operational suitability data certification basis and environmental protection requirements and continued airworthiness activities are properly conducted. Considering this, surveillance mechanisms may include structured experience exchange, regular quality meetings, brainstorming or lessons-learned-sessions, project reviews at reasonable phases of company development, planned and unplanned audits, or other similar means. Corrective actions identified are followed up and the way of resolution is recorded.
15. A declaration that control methods are practiced, and the general principles of the applied document revision and access management, ensuring the use of current information.
16. A general identification of the documentation being the result of all the design functions in relation to airworthiness, operational suitability and environmental protection approvals, and continued airworthiness, each one in content, style and format commensurate to the product complexity and risk level, including:
  - a. Listing of document types that form the Type Design, such as example specifications, drawings, Bill of Materials, instructions, Manuals, ICA, MMEL (if required) and others;
  - b. Listing of document types that form compliance documentation, such as for example compliance reports, compliance summary documents, compliance checklists, means of compliance checklists and others;
  - c. Listing of document types that form change and repair design specific documentation, such as classification matrix and approvals of minor changes, repairs or production deviations.
17. Declaration of the applied principles, and accepted related duties, of the key elements of the Design Assurance System, as defined in AMC-ELA No. 2 to 21.A.239 (a). Definition of the elements can be provided by different means such as precise forms that guide 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, commensurate to the complexity and criticality of the products. When referencing to other definitions outside the DOH, the DOH should include a declaration as to which principles are followed on each of the listed items.
18. Confirmation that methods are practiced that enable adequate airworthiness coordination with the applicant for, or 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 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. However, it should be described how non-conformities in production are handled within the design organisation when a concession process or a direct approval of such non-conformities under DOA is sought, for example by using the change process.
19. Declaration of the method applied to accept design work conducted by outside parties, in line with AMC-ELA No. 1 to 21.A.239 (c).
20. Identification of outside parties and secondary locations that operate under the DAS of the manufacturer, and fulfil functions required by the DAS, or are directly involved in critical aspects of compliance demonstration, such as for example flutter investigation and analysis. This identification may be integral part of the DOH, or provided by a separate listing that is only identified from within the DOH.

21. 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, it is sufficient to have FTOM procedures defined for only one of the entities. FTOM shall identify the workflow defining how to issue Flight Conditions and Permit to Fly for the purpose of factory acceptance test flights.

#### **AMC-ELA No. 2 to 21.A.243 Data – Policies and procedures in relation to Flight Test**

In order to conduct flight test activities, the DOA is required to implement policies and procedures for the conduct of 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 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 aircraft and the organisation complexity.

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

- Definition of the key qualifications, responsibilities and accountabilities for the staff involved in the conduct of flight test, covering at least:
  - o Head of Flight Test – coordinates all activities related to flight test and is assuming responsibility for flight testing (can be shared with other management position within the DO)
  - o Flight Test Engineer – manages individual flight test (campaigns)
  - o Test Pilot – conducts any flight test
  - o Flight Test Mechanic – conducts all maintenance tasks and configuration changes to the test aircraft

One person with adequate qualification may act in more than one role. The HoFT should have a direct reporting line to the HDO.

- Method providing practical guidance to conduct a hazard assessment that allows to classify flight tests by the risk involved. At least two categories should be differentiated: Category 1 – high risk and Category 2 – medium and low risk.
- Definitions of generic risk mitigation strategies such as minimum and maximum altitudes or airspeed safety margins, and safety rules to be obeyed for the typical major test phases and missions.
- Identification of aircraft related safety equipment held available, including references to maintenance requirements of this equipment.
- Policy how to alert and involve rescue services such as fire brigade or emergency physicians in order to allow adequately short reaction times.
- Crew qualification, including currency requirements and crew (refresher) training, as adequate.
- For aircraft with a MTOM of or above 2.000 kg:
  - o The provisions of EASA Part 21, Appendix XII apply.
  - o minimum flight experience by year should be:
    - for pilots: 50 hours. In addition:
      - for pilots with a flight test rating, the 50 hours should include 20 flight test hours in any flight test category.
      - for pilots performing a Category 3 flight test, the flight test experience should be expressed in terms of a number of flights leading to the issue of a Certificate of Airworthiness (CofA) (e.g. first flights).
      - for pilots performing a Category 4 flight test, the minimum flight test experience should be proportionate to the activity envisaged.

- Crew composition and duty time limitations, as adequate in relation to the kind of testing and risk category of flight test conducted by the DOA.

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

- Initiation and planning of a flight test activity, including, for example and not limited to:
  - o hazard analysis,
  - o detailed flight test planning,
  - o generation and approval of flight conditions,
  - o definition and verification of the test aircraft configuration,
  - o preparation of the aircraft,
  - o integration, calibration and verification of any flight test equipment,
  - o verification of aircraft fitness for flight,
  - o issue or obtaining of Permit to Fly,
  - o pre-flight briefing and conduction of the flight test,
  - o de-briefing and data reporting,

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

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

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

Implementation of the standard FTOM, including its associated process definitions and forms, ensures adherence to this AMC, hence compliance with the relevant requirements of Part 21.

When subcontracting flight tests to third parties, they should comply with the FTOM of the DOA, unless they have established an FTOM in compliance with Part-21, the use of which has been agreed between the two organisations.

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

Evidence of qualification and experience is documented for the persons accepting duties defined for the following roles:

- Head of Design organisation HDO
- Head of Airworthiness HoA
- Independent System Monitoring ISM
- Compliance Verification Engineer CVE

The credentials of HDO, HoA and ISM are furnished to DOATL of EASA using EASA Form 4-DOA as published on the EASA webpage in order that they may be seen to be appropriate in terms of relevant knowledge and satisfactory experience related to the nature of the design activities as performed by the organisation.

For CVE, no individual statement is required. They are selected by the applicant on the basis of their knowledge, background and experience as defined in the DOH. When necessary, complementary training should be established, to ensure sufficient background and knowledge in the scope of their authorization.

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

The following minimum information should be kept on record:

- a) Name
- b) Date of birth
- c) Experience and training
- d) Position in organisation
- e) Scope of the authorisation
- f) Date of first issue of the authorisation
- g) If appropriate, date of expiry of the authorisation
- h) Identification number of the authorisation
- i) Documented acceptance of the nomination by the CVE.

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 staff, or other means. Issuing of individual badges or passes is not required.

The organisation must keep the record for at least two years after the certifying person has ceased employment with the organisation or withdrawal of the authorisation, whichever is the sooner.

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#### **21.A.245 Approval requirements**

The design organisation shall demonstrate, on the basis of the information submitted in accordance with point 21.A.243 that, in addition to complying with point 21.A.239:

- (a) the staff in all technical departments are of sufficient numbers and experience and have been given appropriate authority to be able to discharge their allocated responsibilities and these, together with the accommodation, facilities and equipment, are adequate to enable the staff to achieve the airworthiness, operational suitability and environmental protection objectives for the product;
- (b) there is full and efficient coordination between departments and within departments in respect of airworthiness, operational suitability and environmental protection matters.

#### **AMC-ELA No. 1 to 21.A.245 Approval Requirements**

The organisation demonstrates adequate staffing, infrastructure, facility access and discharge of responsibilities by the continued ability to certify type designs after having ensured positive compliance with the applicable certification basis, environmental requirements and operational suitability data. 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 which are suitable for manufacturing prototype models and test specimens
- Accommodation and test facilities which are suitable for carrying out tests and measurements needed to demonstrate compliance with the CS and environmental protection requirements. The test facilities may be subjected to additional technical conditions related to the nature of tests performed.

The Head of the design organisation for which an application for approval has been made has the direct or functional responsibility for all departments of the organisation which are responsible for the design of the product. If the departments responsible for design are functionally linked, the Head of the design organisation still carries the ultimate responsibility for compliance of the organisation with Part 21Subpart J.



The function of the head of airworthiness is established with a direct reporting line to the HDO, and the person filling this function is required to have a direct contract with the DO.

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

Especially with respect to small companies within the scope of AMC-ELA, constellations are acceptable where:

- The role of the HDO may be fulfilled by the Chief Executive (CE) of the legal entity, who may as well fill the role of the AM within a parallel POA.
- HDO and HoA are the same person, provided the person has the competence to fulfil both functions;
- HoA and ISM are the same person, provided the ISM assessment of working activities that directly affect the person in its second role is conducted by another independent person, on behalf of ISM;
- HDO and ISM are the same person, provided the auditing activity is conducted by another independent person, under the responsibility of the ISM;
- External persons are acceptable for all or parts of the role of ISM;
- Part time HoA is acceptable, provided the person is directly involved to the DOA, and not per agreement between two DOA's, and provided the availability of the person is such as to ensure adequate response times;
- CVE may also hold any of the other nominations, as long as an independent checking of compliance per AMC-ELA No. 1 to 21.A.239 (b) is ensured;
- other, comparable configurations that ensure the independent system monitoring function per AMC ELA No. 4 to 21.A.239 (a), and the independent checking function per AMC ELA No. 1 to 21.A.239 (b).

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

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### **21.A.247 Changes in design assurance system**

After the issue of a design organisation approval, each change to the design assurance system that is significant to the showing of compliance or to the airworthiness, operational suitability and environmental protection of the product, shall be approved by the Agency. An application for approval shall be submitted in writing to the Agency and the design organisation shall demonstrate to the Agency, on the basis of submission of proposed changes to the handbook, and before implementation of the change, that it will continue to comply with this Subpart after implementation.

#### **AMC-ELA No. 1 to 21.A.247 Changes in design assurance system**

After the issue of a design organisation approval, the following changes are considered 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 neighbour building on the same premises, or similar, do not require prior approval, as long as the interface and access possibilities to the related production organisation are not negatively influenced;
- Changes in scope of approval;
- changes in nomination or allocation of responsibilities to HDO, HoA, ISM; or
- Change in the parts of the organisation that contribute directly to the airworthiness, operational suitability or environmental protection, such as changes to the principles to procedures related to:



- the type certification
- the classification of changes and repairs as ‘major’ or ‘minor’
- the treatment 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 privilege of
- the approval of minor revisions to the Aircraft Flight Manual
- the approval of the design of major repairs
- continued airworthiness or continued operational suitability
- the configuration control, when airworthiness, operational suitability or environmental protection is affected;

Significant changes require Agency approval prior to implementation. The organisation shall submit the application for approval of significant change to DOA with EASA Form 82 to the Agency sufficiently ahead of time of the nature of any significant change, supported by an updated version of the DOH, so that the required extent of investigation can be agreed upon and conducted in a reasonable way. Focus of the assessment is the continued ability to comply with the provisions defined on the basis of AMC-ELA, in compliance with Part 21 Subpart J.

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

To ensure that changes do not result in non-compliance with applicable requirements of Part 21 it is in the interest of both, the Agency and the approval holder, to establish a relationship and exchange during the implementation of a change. As part of this relationship the company should consider to also inform the Agency sufficiently ahead of the next regular surveillance activity of non-significant changes.

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#### **21.A.249 Transferability**

Except as a result of a change in ownership, which is deemed significant for the purposes of point 21.A.247, a design organisation approval is not transferable.

#### **AMC-ELA No. 1 to 21.A.249 Transferability**

Transfer of approval is only possible in cases where the ownership changes.

Changes in ownership where the organisation itself remains effectively unchanged are not considered to be significant changes to the quality system, and are not required to be treated in line with AMC-ELA No. 1 to 21.A.247. Possible effects will be addressed at the subsequent regular oversight activity.

All other changes of ownership are considered significant and are treated in line with AMC-ELA No. 1 to 21.A.247.

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#### **21.A.251 Terms of approval**

The terms of approval shall identify the types of design work, the categories of products, parts and appliances for which the design organisation holds a design organisation approval, and the functions and duties that the organisation is approved to perform in regard to the airworthiness, operational suitability and characteristics of noise, fuel venting and exhaust emissions of products. For design organisation approval covering type-certification or ETSO authorisation for Auxiliary Power Unit (APU), the terms of approval shall contain in addition the list of products or APU. Those terms shall be issued as part of a design organisation approval.

### AMC-ELA No. 1 to 21.A.251 Terms of Approval

Terms of approval identify the types of design work, the categories of products for which the design organisation holds a design organisation approval, and the functions and duties that the organisation is approved to perform with regard to the airworthiness, operational suitability and characteristics of noise, fuel venting and exhaust emissions of products.

For products within the framework defined in AMC-ELA No. 1 to 21.A.231, the Scope of Work will be described by the Agency using standard terms as follows:

<i>Starts with selection of:</i>	<i>... ends with selection from:</i>
Designing of new types of, changes and repairs to	aeroplanes of 2.730 kg MTOM or less, not classified as complex motor-powered aircraft,
	very light rotorcraft,
Designing of new types of, changes and repairs to engines used on	rotorcraft of 1.200 kg MTOM or less, certified for a maximum of up to 4 occupants, not classified as complex motor-powered aircraft,
	sailplanes or powered sailplanes of 2.000 kg MTOM or less,
	balloons,
Designing of new types of, changes and repairs to propeller used on	hot air airships,
	gas airships complying with 3% maximum static heaviness, non-vector thrust (except reverse thrust), conventional and simple design of structure, control system and ballonnet system, and non-power assisted controls,

The Terms of Approval are completed by a listing of the products covered, by listing the type as (intended to be) identified by the TCDS.

### 21.A.253 Changes to the terms of approval

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

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

Changes that affect the terms of approval must be approved by the Agency before becoming effective. An application for approval is filed by the applicant using the most current version of EASA Form 82.

### 21.A.257 Investigations

- (a) The design organisation shall make arrangements that allow the Agency to make any investigations, including investigations of partners and subcontractors, necessary to determine compliance and continued compliance with the applicable requirements of this Subpart.
- (b) The design organisation shall allow the Agency to review any report and make any inspection and perform or witness any flight and ground test necessary to check the validity of the compliance statements submitted by the applicant under point 21.A.239(b).

**AMC-ELA No. 1 to 21.A.257 Investigations – Arrangements**

Arrangements shall be in place that allow the Agency to make investigations at the location of the DOA. In cases where design partners or subcontractors fulfil nominated functions within the DOA, for example as CVE, the organisation is required to coordinate access to the subcontractor, when explicitly requested by the DOATL of EASA on a specific subject. Additional agreements between DOA and partner or subcontractor to ensure EASA access at any time are not required.

Investigations may include enquiries, questions, discussions and explanations and inspections of products developed under the scope of work of the DOA. Inspection of products and witnessing of flight and ground tests may become part of the investigation when objective evidence is found that could make compliance statements submitted subsequent to the working steps described in AMC No. 1 to 21.A.239(b) are questionable.

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

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**21.A.258 Findings**

- (a) When objective evidence is found showing non-compliance of the holder of a design organisation approval with the applicable requirements of this Annex I (Part 21), the finding shall be classified as follows:
  - 1. a level one finding is any non-compliance with this Annex I (Part 21) which could lead to uncontrolled non-compliances with applicable requirements and which could affect the safety of the aircraft;
  - 2. a level two finding is any non-compliance with this Annex I (Part 21) which is not classified as level one.
- (b) A level three finding is any item where it has been identified, by objective evidence, to contain potential problems that could lead to a non-compliance under point (a).
- (c) After receipt of notification of findings under the applicable administrative procedures established by the Agency,
  - 1. in case of a level one finding, the holder of the design organisation approval shall demonstrate corrective action to the satisfaction of the Agency within a period of no more than 21 working days after written confirmation of the finding;
  - 2. in case of level two findings, the corrective action period granted by the Agency shall be appropriate to the nature of the finding but in any case initially shall not be more than three months. In certain circumstances and subject to the nature of the finding the Agency may extend the three months period subject to the provision of a satisfactory corrective action plan agreed by the Agency;
  - 3. a level three finding shall not require immediate action by the holder of the design organisation approval.
- (d) In case of level one or level two findings, the design organisation approval may be subject to a partial or full suspension or revocation under the applicable administrative procedures established by the Agency. The holder of the design organisation approval shall provide confirmation of receipt of the notice of suspension or revocation of the design organisation approval in a timely manner.

### AMC-ELA No. 1 to 21.A.258 Findings

A level 1 finding is raised when objective evidence exists for a non-compliance with the applicable requirements of Part 21, in the implementation defined by AMC-ELA, that has the clear potential to lead to a (potential) unsafe condition of the product due to uncontrolled non-compliance with applicable requirements.

A level 2 finding is raised when objective evidence exists for a non-compliance with the applicable requirements of Part 21, in the implementation defined by AMC-ELA, that does not directly lead to a (potential) unsafe condition of the product due to uncontrolled non-compliance with applicable requirements.

A finding level 3 may be raised when a situation is observed that may lead to future non-compliances with the applicable requirements of Part 21, in the implementation defined by AMC-ELA.

Failure to allow access of the Agency to facilities for the conduct of investigations, in particular to obtain access, is classified as a level one finding for formal reasons.

Corrective action to findings is to be implemented as follows:

- Level 1: no more than 21 working days after written confirmation of the finding;
- Level 2: Appropriate to the nature of the finding, an agreed action plan is in place latest 3 months after written confirmation of the finding, leading to an agreement on the timeline for closing of the finding, that typically is connected to the schedule of the regular surveillance on the discretion of the DOATL;
- Level 3: no timeline associated.

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### **21.A.259 Duration and continued validity**

- (a) A design organisation approval shall be issued for an unlimited duration. It shall remain valid unless:
1. the design organisation fails to demonstrate compliance with the applicable requirements of this Subpart; or
  2. the Agency is prevented by the holder or any of its partners or subcontractors to perform the investigations in accordance with point 21.A.257; or
  3. there is evidence that the design assurance system cannot maintain satisfactory control and supervision of the design of products or changes thereof under the approval; or
  4. the certificate has been surrendered or revoked under the applicable administrative procedures established by the Agency.
- (b) Upon surrender or revocation, the certificate shall be returned to the Agency.

### AMC-ELA No. 1 to 21.A.259 Duration and Continued Validity

The design organisation approval is issued for an unlimited duration and remains valid unless:

- the design organisation fails to demonstrate compliance with the applicable requirements Part-21 Subpart J, implemented by the full set of AMC-ELA; or
- the Agency is prevented to perform its investigations; or

- there is a positive finding by the Agency of a continued non-compliance, or a combination of several non-compliances, with the applicable requirements of this subpart that lead to (potential) non-compliances with the applicable product requirements; or
- the certificate has been surrendered or revoked by the Agency.

Upon surrender or revocation, the certificate shall be returned to the Competent Authority.

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### **21.A.263 Privileges**

- (a) The holder of a design organisation approval shall be entitled to perform design activities under this Annex I (Part 21) and within its scope of approval.
- (b) Subject to point 21.A.257(b), the Agency shall accept without further verification the following compliance documents submitted by the applicant for the purpose of obtaining:
  1. the approval of flight conditions required for a permit to fly; or
  2. a type-certificate or approval of a major change to a type-certificate; or
  3. a supplemental type-certificate; or
  4. an ETSO authorisation under point 21.A.602B(b)(1); or
  5. a major repair design approval.
- (c) The holder of a design organisation approval shall be entitled, within its terms of approval and under the relevant procedures of the design assurance system:
  1. to classify changes to the type-certificate and repairs as 'major' or 'minor';
  2. to approve minor changes to type-certificate and minor repairs;
  3. to issue information or instructions containing the following statement: 'The technical content of this document is approved under the authority of DOA ref. EASA. 21J. [XXXX].';
  4. to approve minor revisions to the aircraft flight manual and supplements, and issue such revisions containing the following statement: 'Revision No [YY] to AFM (or supplement) ref. [ZZ] is approved under the authority of DOA ref. EASA. 21J. [XXXX].';
  5. to approve the design of major repairs to products or Auxiliary Power Units for which it holds the type-certificate or the supplemental type-certificate or ETSO authorisation;
  6. to approve the conditions under which a permit to fly can be issued in accordance with point 21.A.710(a)(2), except for permits to fly to be issued for the purpose of point 21.A.701(a)(15);
  7. to issue a permit to fly in accordance with point 21.A.711(b) for an aircraft it has designed or modified, or for which it has approved under point 21.A.263(c)(6) the conditions under which the permit to fly can be issued, and when the design organisation itself is controlling under its Design Organisation Approval the configuration of the aircraft and is attesting conformity with the design conditions approved for the flight.

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

Adherence to the full set of AMC-ELA entitles the company to the following privileges:

- (a) As part of the agreement of the Certification Program for any project, Company and EASA will agree upon the level of involvement of EASA for this project. This will include identification of documents that have to be submitted to EASA for checking. All other compliance documents will be accepted by EASA without further verification, for the purpose of:
1. the approval of flight conditions required for a permit to fly; or
  2. a type-certificate or approval of a major change to a type-certificate; or
  3. a supplemental type-certificate; or
  4. a major repair design approval.

- (b) Privilege to classify minor/major changes and repairs is given on the basis of the application of the method defined in response to AMC-ELA No. 2 to 21.A.239(a).

The method covers the following points:

- the identification of changes to type design or repairs
- classification as major, minor where additional work is required to demonstrate compliance with applicable requirements, or minor where no additional work is required to demonstrate compliance with applicable requirements
- recording of the classification, and documented justification of the classification for those that are not straightforward
- acceptance of the classification by the HoA, or an alternative nominated person within the DAS having adequate scope

A 'minor change' is one that has no appreciable effect on the mass, balance, structural strength, reliability, operational characteristics, noise, fuel venting, exhaust emission, operational suitability data or other characteristics affecting the airworthiness of the product. All other changes are 'major changes'.

The classification process for changes and repairs is the same, obtaining the privilege to classify changes automatically qualifies for the privilege to classify repairs.

- (c) Privilege to approve minor changes and minor repairs is given 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 method covers the following points:

- when additional work is required to demonstrate compliance with applicable requirements, compliance documentation is established and verified following the identical workflow as applied for initial design and certification
- approval under the DOA privilege using a formalised approach, for example defined by an adequately structured form, providing adequate identification of the change, identification of applicable requirements, reference to compliance documents, effects on limitations and approved documentation, if any, evidence of conducted independent checking, date and evidence of the approval given by the relevant nominated staff
- definition that the HoA, or an alternative nominated person within the DAS having adequate scope, is authorised to approve minor changes / repairs
- definition that the approval of minor changes / repairs is conducted using the same provisions as defined for design work that is used during initial design and certification.

The approval process for minor changes and repairs is the same, obtaining the privilege to approve minor changes automatically qualifies for the privilege to classify repairs.

- (d) Privilege to issue Service Instructions or similar information containing the following statement: ‘The technical content of this document is approved under the authority of DOA ref. EASA. 21J. [XXXX].’, when the contents of the information has been developed and verified following the same principles as any other type design aspect for a new or changed design.
- (e) Approval of minor changes to the AFM and supplements and issuing containing 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 change to the Type Design, as the AFM formally is a part of the Type Certificate, and 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 to be related to a “minor” design change. Administrative revisions to the AFM, such defines for example defined as follows, are also expected to be classified as “minor”:
  - 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 certification data;
  - 4. Conversions of previously FAA or EASA approved combinations of units of measurement added to the AFM in a previously approved manner.
  - 5. The addition of aircraft serial numbers to an existing AFM where the aircraft configuration, as related to the AFM, is identical to aircraft already in that AFM.
  - 6. The removal of reference to aircraft serial numbers 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.
- (f) Privilege to approve FC and issue PtF is granted when having an adequate FTOM per AMC-ELA2 No. 2 to 21.A.243 in place, and limited to products designed and produced by the company, and where the company has full configuration control. Authorised signatories shall be defined within the FTOM, or equivalent.

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### **21.A.265 Obligations of the holder**

The holder of a design organisation approval shall:

- (a) maintain the handbook in conformity with the design assurance system;
- (b) ensure that this handbook is used as a basic working document within the organisation;
- (c) determine that the design of products, or changes or repairs thereof, as applicable, comply with applicable requirements and have no unsafe feature;
- (d) except for minor changes or repairs approved under the privilege of point 21.A.263, provide to the Agency statements and associated documentation confirming compliance with point (c);
- (e) provide to the Agency information or instructions related to required actions under point 21.A.3B;
- (f) where applicable, under the privilege of point 21.A.263(c)(6), determine the conditions under which a permit to fly can be issued;
- (g) where applicable, under the privilege of point 21.A.263(c)(7), establish compliance with points 21.A.711(b) and (e) before issuing a permit to fly to an aircraft.

**AMC-ELA No. 1 to 21.A.265 (a) Obligations of the holder – Administration of the Handbook**

The handbook of the applicant must be in the language which will permit the best use of it by all personnel charged with the tasks performed for the purpose of the design organisation. The handbook may be completely or partially integrated into the company organisation manual. Information specified in AMC-ELA No. 1 to 21.A.243, items 1. 2. and 13. is provided within the handbook.

**AMC-ELA No. 1 to 21.A.265 (b) Obligations of the holder – Use of the Handbook as Basic Working Document**

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

The organisation shall ensure that personnel have access to and are familiar with that part of the content of the DOH, which covers their activities. This may be done for example by distributing 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 with relevance to the demonstration of compliance of products under the DOA approval should be able to demonstrate awareness of the definitions provided within the DOH. This can be achieved by any suitable means and does not necessarily require training sessions. Regular internal monitoring should be used to internally verify that the relevant staff is aware of the relevant definitions.

Monitoring of compliance with this documentation is done by systematic means. These means do not need to be limited to, or even include auditing, but can 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.

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

The DOA shall establish that the product has no unsafe features and conduct all necessary steps to determine compliance of the products within scope of the DOA with the applicable requirements. This is obtained by applying the methods detailed in AMC-ELA No. 2 to 21.A.239 (a).

**AMC-ELA No. 1 to 21.A.265 (d) Obligations of the holder – Confirmation of compliance**

Except for minor changes or repairs, and subsequent to the finding of compliance as defined in AMC-ELA No. 1 to 21.A.265 (c) and supported by AMC-ELA No. 2 to 21.A.239 (a), the DOA shall submit a formal declaration of compliance to the Agency, together with the documentation that has been identified as part of the Certification Programme to be submitted to EASA for checking, as basis for the subsequent Agency approval of the design, change or repair procedure.

**AMC-ELA No. 1 to 21.A.265 (e) Obligations of the holder – Providing of information in response to Airworthiness Directives**

In cases where the Agency has issued Airworthiness Directives in response to potentially unsafe conditions of the product in responsibility of the DOA, the DOA proposes the appropriate corrective action or required inspections, or both, and submits details of these proposals to the Agency for approval. Following the approval by the Agency of the proposals referred to under this point, the DOA makes available to all known operators or owners of the product and, on request, to any person required to comply with the airworthiness directive, appropriate descriptive data and accomplishment instructions.

**AMC-ELA No. 1 to 21.A.265 (f), (g) Obligations of the holder – Permit to Fly**

When conducting flight test on the basis of a FTOM administered by the DOA, the methods detailed by AMC-ELA No. 2 to 21.A.243 are practiced to determine the Flight Conditions that shall be used as basis for a permit



to fly. When applying the privilege to issue Flight Conditions, the DOA must be satisfied that the aircraft is capable of safe flight under the specified conditions and restrictions.

When conducting flight test on the basis of a FTOM administered by the DOA, the methods detailed by AMC-ELA No. 2 to 21.A.243 are practiced to confirm that a permit to fly is only issued under privilege of the DOA, when the related Flight Conditions have been approved as well by the DOA and under privilege, and when the purpose(s) and any conditions and restrictions on the Permit to Fly are consistent with those approved within the Flight Conditions.