



Part 21 Proportionality

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7 April 2017

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RMT. 068 is using a task force as sounding board to develop proportionate improvements to Part-21 implementations. ToR defines:

2. Objectives

The objective is to provide additional flexibility and simplification in Part-21 certification for GA that is proportionate to risks and meets an acceptable safety level. This task should be regarded as a change to the certification process that is in-line and within the new framework being developed in the proposals to change Regulation (EC) No 216/20082 (hereinafter referred to as 'the Basic Regulation'). This task will also consider using performance based regulations (PBR) principles that are being developed in coordination with the EASA advisory bodies. At the same time improvements to the certification process are also expected from a more pragmatic implementation and guidance. Options to be considered are:

- to simplify and/or support of approval processes;
- to change competent authority involvement and to redistribute responsibilities between competent authorities and stakeholders

With this ToR, the TF pursues three initiatives:

- 1. Develop alternatives to Part-21 AMC/GM for smaller companies for:
 - Subpart G POA
 - Subpart J DOA
- 2. Test these new AMC in pilot cases
- 3. Develop a new approach for Part-21(Light)
 - Implementing Basic Regulation updates



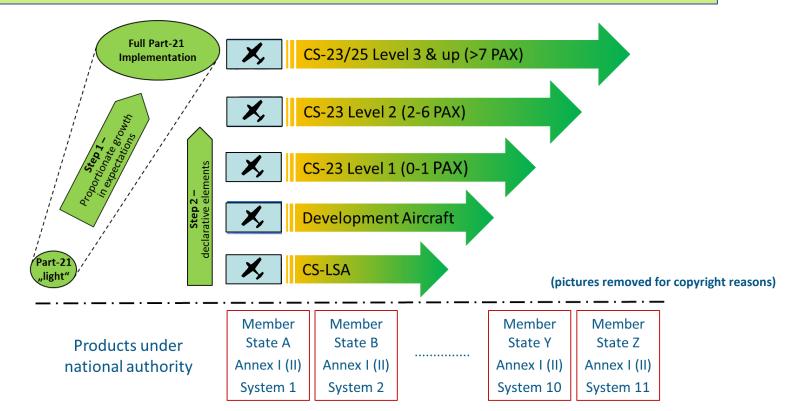
RMT.0689 Part-21 proportionality

2016 Q4 2017 Q1 2017 Q2 2017 Q3 2017 Q4

(Phase 1) Draft AMC/GM Part-21

(1A) Pilot cases

(Phase 2) Part-21 (Light) – Use of new options from BR





Step 1 –

AMC-ELA



Step 1 – Developing (draft) AMC-ELA to Part-21

Today there are three main problem areas:

- Existing AMC/GM to Part-21 is written for large aircraft and companies; especially POA is lacking alternatives
- Non-natural split between approvals for DOA & POA (and Maintenance) of small, consolidated teams
- Part-21 Section B (Procedures for competent authorities) mandate a process-oriented approach



Step 1 – Developing (draft) AMC-ELA to Part-21

How to improve the situation:

- ➤ Ensure common sense for small companies:
 - >> Know for every specific means why it is requested
 - Ensure that general means required are really <u>necessary</u> to meet the requirement
 - Define the means so that it <u>serves</u> the intent

Applying this in a strict way makes numerous elements unrelated for companies designing and producing small aircraft.



Step 1 – Developing (draft) AMC-ELA to Part-21

Besides rulemaking this requires...:

- → A Cultural Change!!
- ➤ A change towards <u>product</u> oriented surveillance, instead of today's <u>process</u> oriented approach.
- ➤ A change towards <u>utilisation</u> of other influences to companies, instead of <u>duplicating aspects</u>
- ➤ A change towards <u>integrated</u> assessments, instead of <u>individual certificates</u>
- ➤ A change towards <u>partnership and trust</u>, instead of <u>hierarchy and suspicion</u>

Step 1 – AMC-ELA for Subpart G (POA)

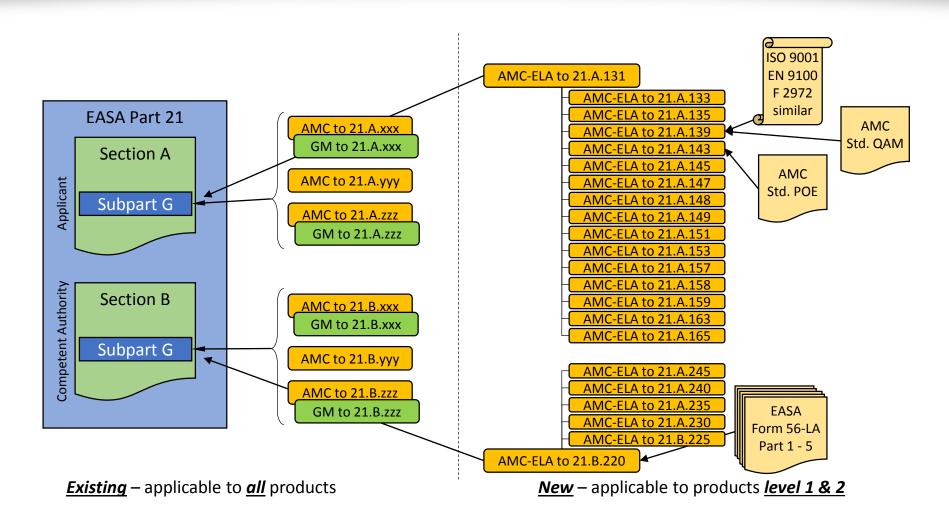


21.G – Spirit of AMC-ELA for small POA (Step 1)

- Apply product-oriented surveillance instead of process-oriented
- Significantly tailor the extent of documentation of the Quality System
- ➤ Make use of "practiced methods" in many areas demonstration of repeatable procedures by evidence of work results is enough
- ➤ The competent authority oversight will focus on work results instead of process overhead verification



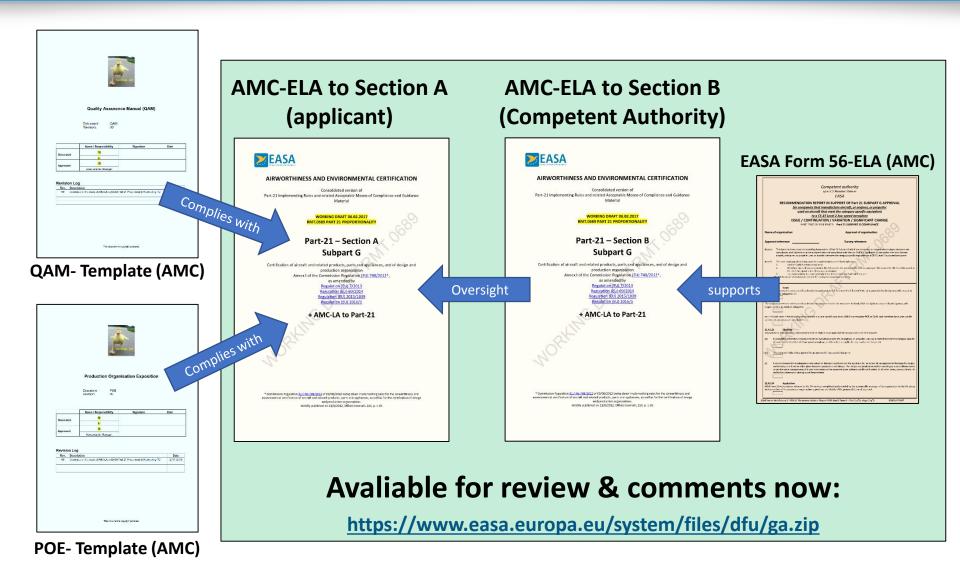
21.G – System of AMC-ELA



Note: "ELA" relates to light aircraft in a much wider scope than ELA 1/2



21.G – AMC-ELA documents





Applicability of the new AMC is covering a broad range of products:

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

The full set of AMC-ELA defines an acceptable means of compliance to qualify for the issuance of a production organisation approval 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
 - 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.131 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 manufacture aircraft or products within the Scope as per AMC-ELA No. 1 to 21.A.131 may elect to apply AMC-ELA instead of the existing set of AMC, or instead of alternative means.



Focus tailored to verification of product conformity:

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

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

POA 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.

Required level of detail in the quality system:

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. Only 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 should include elements that care for the related deficiency.



"presumption of compliance":

AMC-ELA No. 1 to 21.A.135 Issue of POA

The full set of AMC-ELA satisfies all Subpart G 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 G 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 POE and QAM without changes but adapted to the company constitutes full adherence to AMC-ELA. In this case the applicant is not required to demonstrate that the standard POE and QAM as such meet the provisions of AMC-ELA, hence Part 21 Subpart G. In cases where the specific characteristic of the company renders individual means of AMC-ELA impracticable or not applicable, a case specific resolution shall be agreed with the relevant Competent Authority, 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.

➤ POE used purely as interface document:

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

The organisation provides a POE 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 is approved by virtue of obtaining the POA approval as such. The document as such is not intended to be approved by the CA, visual evidence of approval beyond issuing of the POA certificate with Scope of Approval is not applied.

The following key elements of the PO are to be covered by the POE:

1 A statement signed by the associatable manager confirming that the DOE and OAM as referenced



➤ This is how it looks for a full POE:

Production Organisation Exposition (POE) This manual provides the Production Organisation Exposition of Ducklings, Ink. in application of the LA set of AMC to EASA Part 21 Subpart G. Full application of the LA set of AMC constitutes implicit compliance with all applicable requirements of EASA Part 21 Subpart G, without further The extent of the documentation of this POE and applicability of the LA set of AMC is consistent with the Scope of Work being limited to ELA 2 aircraft and related spare parts. The POE in itself does not require approval by the CA. 1. Commitment of the Accountable Manager By signing this commitment, the accountable manager confirms that the manufacturer will comply with the definitions of this POE at all times, and that all affected employees are instructed, accordingly. All employees are instructed to report observations of non-adherence to the AM, and to cooperate with the CA when exercising its oversight duties. Purpose of this POE is to provide approval relevant information to the Competent Authority as per EASA Part 21, Subpart G, It is acknowledged that possible new requirements need to be considered and complied with, even when they are in conflict with definitions implemented so far It is acknowledged that the related company approval is issued on the basis of continued adherence to this commitment, and that the relevant CA may apply limitations or withdraw the approval in certain cases of non-adherence, when conformity of the product with the Type Design has not been ensured, or when safe operation of the product is not ensured. Date, Signature of AM: 2. Nominated Managers 21.A.143(a)2.; 21.A.143(a)3.; 21.A.143(a)4.; 21.A.145(c)1.; 21.A.145(c)1.; The following person is nominated as Accountable Manager of Remos AG: Duck Duckling, CTO of Ducklings, Ink. It is the responsibility of the AM to ensure that all production is performed to the required standards and to the data and procedures referenced by this POE. The AM is responsibile to ensure that the company is in compliance with the requirements of EASA Part 21 Subpart G, regardless of possible delegation of individual tasks. As this duty is with the AM, no organisational chart is required within this POE. The AM is the formal communication point towards the CA in all matters. 3. Certifying Staff Nominated Certifying Staff (CS) is identified in form of a separate list showing: Type and scope limitations, if applicable, authority to issue conformity or release certificates. The list of CS is made available to all relevant employees, so that the relevant CS can be identi-Changes to this list do not constitute a change of the POE. The approximate company size with relevance to production activities is below 50 FTE. Production Organisation Exposition Dokument: POE Revision: 00 Page: 2

Major Place of Business The major place of business, where the products are completed and checked out, is located at: Duckstreet 42 12345 Quaking This location is equivalent to the legal place of business. 6. Scope of Work The scope of Work is in its entirety defined by the product Type(s): Scope Category: A10 (Light-Sport Aeroplanes); Type of Product: RubberDuck D-1 (EASA.A.xxx); Scope of work automatically includes the aircraft and all spare parts required for the identified products, without further specification, detailing or need for capability lists. 7. Notification of Organisational Changes This document gets revised in case of significant changes to the PO, or in case of changes to the organisation that affect the documentation provided here, under the resposnibility of the AM. 8. POE Amendment Procedure 21.A.143(a)10.: 21.A. 143(b): Amendments to the POE are released by the AM, and distributed following the implemented method for control of documented information. One copy is provided to the CA through the AM. The QS of the company is defined and documented by the Quality Assurance Manual (QAM). The QAM is in compliance with Part 21 Subpart G, and with ASTM F2972. Outside parties that operate within a typical extended workbench arrangement and under the quality system this company are not involved 11. Flight Test Activities Flight Test activities are only conducted for the purpose of production acceptance flights and strictly follow a Flight Test Plan and adhere to Flight Conditions that both have been developed as part of the approved type design. FC with FTP define: the complete process for production aceptance flight test of this type, including discovery of non-conformities and fixes; crewing policy, including composition, competency, currency and flight time limitations; procedures for the carriage of persons other than crew members and for flight test training: precautions in consequence to the applied risk and safety management; definition of instruments and equipment to be carried; forms that need to be filled to document the results of the production acceptance flight test. The company identifies the persons involved to the production acceptance flight test when applying it. The AM is responsible to ensure adherence to the qualification and currency requirements Production Organisation Exposition Dokument: POE Revision: 00 Page: 3

➤ Extended use of "practiced methods", as opposed to documented procedures:

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.

QAM Examples for practiced methods:

3.1. Control of Documented Information

21.A.139(b)1.(i), (x); 21.A.139(b)1.(x); 21.A.165(h);

Document control is ensured by workflow management being part of the IT based Document Management System (DMS). The workflow ensures revision management, adequate document approval and adequate document access to employees on the basis of defined user authorizations. Adequate backup procedures are in place that ensure safe copies of the database at a separate location.

This commitment applies to all documented information related to this QMS, especially to those of relevance for the production of conforming and safe products, including records, and to the Type Design.

3.4. Identification and Traceability

21.A.139(b)1.(iv);

ASTM F2792-14, 7.4;

All material on stock is properly identified, by reference to the part number or material specification, as applicable.

The manufacturer follows the definitions for identification provided as part of the approved Type Design. The manufacturer does not apply marking beyond this level. Traceability is ensured by identification of each material on stock, completed part or part in process through the IT based ERP system. Definition of method of traceability is provided by the approved Type Design. Identification is done by labels with barcodes, with the labels applied directly to the part, or stored together with the part in case of bulk or small goods.



- Supplied parts are inspected when it makes sense, only in seldom cases supplier oversight
- ➤ Internal audits audits are not the primary, and by far not the only means accepted for internal monitoring
- ➤ For companies that already have a QM system installed, this can be utilised:
- ➤ Definition and use of the "major place of activity" ensures greater flexibility and eliminates elaborate detail definition, such as floor plans, etc.
- Only one FTOM needed, typically coordinated from DOA
- Only one entity does Occurrence Monitoring



Section B requires the CA to use a product oriented oversight, still based upon evidence

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.



Section B requires the CA to use a product oriented oversight, still based upon evidence

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.

Step 1 – AMC-ELA for Subpart J (DOA)



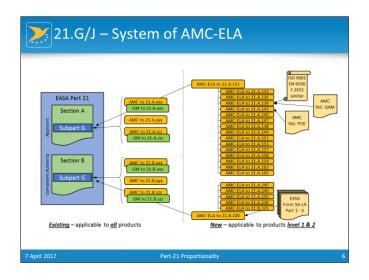
21.J – Spirit of AMC-ELA for small DOA (Step 1)

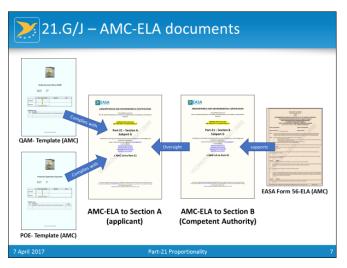
- ➤ Focus on "verification" elements of the Design Assurance System as "Gateway"
- ➤ Type Certificate related requirements of Part-21 go to Certification Program, not to DO-Handbook
- Significantly tailor the extent of documentation of the Quality System
- ➤ Make use of "practiced methods" in many areas demonstration of repeatable procedures by evidence of work results is enough
- ➤ Agency oversight to focus on DAS "Gateway"-Function, not on basic engineering process



21.J – System of AMC-ELA

Equivalent approach as for Subpart G





Avaliable for review now:

https://www.easa.europa.eu/system/files/dfu/ga.zip

Same approach as for Subpart G is used for the following issues:

- Applicability of the new AMC is covering a broad range of products
- "presumption of compliance"
- Exclusion of external aspects
- Extended use of "practiced methods", as opposed to documented procedures
- Internal audits audits are not the primary, and by far not the only means accepted for internal monitoring
- Definition and use of the "major place of activity"
- Only one FTOM needed, typically coordinated from DOA
- Only one Occurrence Management needed



Focus limited to the independent cheking elements:

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.



➤ Complete AMC for an adequate FTO

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:
 - 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)
 - Flight Test Engineer manages individual flight test (campaigns)
 - Test Pilot conducts any flight test
 - Flight Test Mechanic conducts all maintenaircraft



Step 1 – Spirit of AMC-ELA for consolidated teams

Practical combination of DO & PO allows:

- Sufficient to have <u>one</u> Flight Test group in either DOA or POA
- ➤ Sufficient to have <u>one</u> Occurrence Management process in either DOA or POA
- ➤ Recognize "<u>inherent</u>" communication and widely eliminate DO/PO agreement procedures
- ➤ Prepare the base for "combined investigation" with subsequent "<u>combined</u> approvals" – allow Maintenance Approvals to join



Step 1 – New AMC-ELA for small organisations

Challenges

- ➤ Educate the affected people towards the cultural change when performing product oriented POAoversight
- ➤ Short term action that will need adjustment when the BR changes

Opportunities

- ➤ AMC-ELA makes the EASA direction for the lower end of GA immediately accessible
- ➤ Possibility for adjustment when the BR changes allows to rapidly adopt Lessons Learned



Step 1 – Accelerated rulemaking procedure

Fast implementation of Step 1 by:

- **▶** Dedicated meeting at AERO to explain:
 - ➤ This is Step 1 in the Part-21 proportionality RMT
 - Scope and principles used for this AMC; and
 - ➤ What is Step 2 of the RMT about to offer
- ➤ Focussed consultation (Workshop @ EASA in May 2017)
- ➤ Consultation with stakeholders and Competent Authorities via the advisory bodies (STeB and GA Sectorial team) May / June 2017.
- ➤ Direct publication of a Decision Summer 2017

Step 2 – Updated Part-21

Declarative Elements in a Proportionate Environment



Step 2 – Adopting declarative elements

- ➤ New Basic Regulation will require re-definition of Part-21
- ➤ Re-definition of Part-21 will allow for follow-on steps for light aviation:
 - ➤ Apply "lessons learned" to AMC-ELA from pilot phase
 - ➤ Implement declarative elements
 - ➤ Adopt an objective rule approach, making use of AMC
- ➤ New Basic Regulation is expected to allow declarative elements

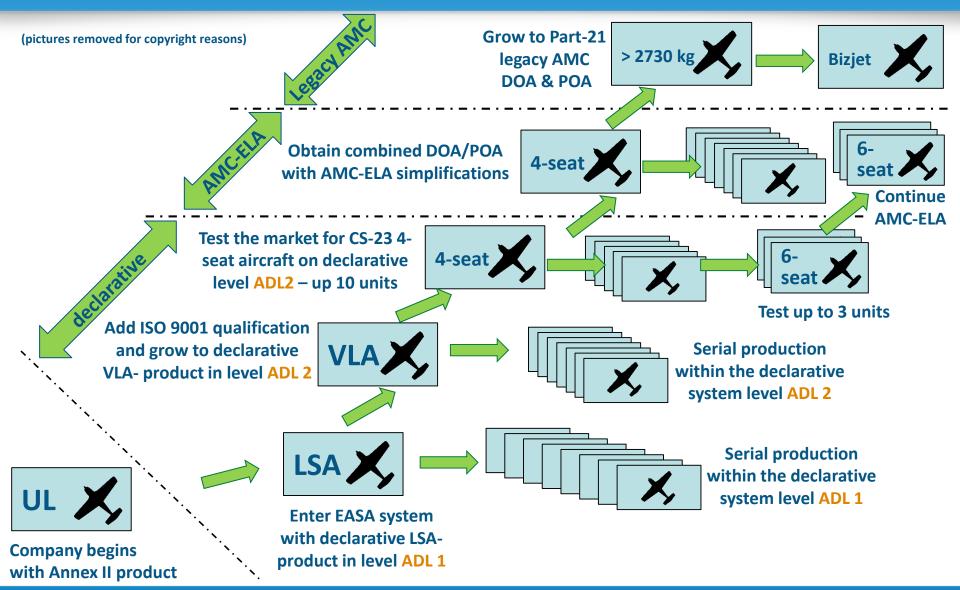


21.J/G – Spirit of declarative elements (Step 2)

- ➤ Use experience from existing declarative systems
- ➤ Definition of an "assisted" declaration system
 - ➤ Guide the applicant & encourage to use experienced staff
 - Declaration requires submission of content statements
- System oversight by Authorities using spot-checks
 - experience level of applicant gives credit
- ➤ Allow to explore next bigger product categories
- ➤ Connect seamless to Step 1 AMC-ELA approach



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Part-21 Proportionality

Example products for the different options

(pictures removed for copyright reasons)







Declarative – ADL 2



Alleviated Part-21
AMC-ELA



Established Part-21 Legacy AMC

Proportionate growth



Your feedback is required:

→ Does this give you the improvement that you need to make GA grow again?

Your safety is our mission.