

The Part 21 Design Organisation – How to get there

PART 21 - REGULATORY ISSUES

In 2002 the European Parliament and the European Council formulated the basis for the new European aviation safety agency EASA. The main objective of EASA is to establish and maintain a high uniform level of civil aviation safety and environmental protection in Europe.

The basic regulation EC 1592/2002¹ defined the principles, the applicability, the recognition of certificates as well as basic principles of the organisational structure and their applied working methods.

The basic regulation further levelled the ground for the European Commission to issue individual rules to specify and define all aspects of product, part and appliance certification, Continuing airworthiness requirements, Maintenance organisation approvals, Certifying Staff qualification, and training organisation requirements.

EASA is to assist the EU in the form of technical expertise for the adoption and amendment of legislation, performing certification (airworthiness and environmental protection) of aeronautical products, design-, production- and maintenance- organisations and to assist the European Commission in monitoring the application of European Community legislation.

In Article 5 and 6 of the basic regulation¹ the provision for the Commission Regulation EC 1702/2003² was laid down. Article 5(4) and 6(3) specifically address the issues of product, parts and appliance certification, the conditions under which organisations are allowed to perform design and manufacture products, parts and appliances and how these parts shall comply to the specified environmental protection requirements.

EC 1702/2003 was first drafted and issued for consultation on the 5th June 2003. The comment period was set to 6 weeks.

On the 24th September 2003 EC Regulation 1702/2003 was adopted and issued by the Commission, on the basis of a formal opinion of the Agency, just days before the agency took on responsibility for certification tasks on the 28th September 2003 the EC. The 28th September was both a remarkable event as well as a dramatic change for the European aviation authorities as well as for the involved industry. For the first time in history supranational EU law took precedence over national law in aviation.

EC 1702/2003 consists of three parts:

- 1) The text with relevance for the European Economic Area containing the text approved by the Commission of the European Communities³.
- 2) The Annex to the Commission regulation containing the Part 21 implementing rules⁴. These implementing rules have been developed by the Agency as draft Opinions based on the consultation and received comments to it. It is further separated into
 - o Part A: The requirements for applicants and acquired rights and obligations mainly derived from Section 1 of JAR⁵ 21 including some material originally developed for JAR 39 and for environmental protection requirements.
 - o Part B: The procedures for competent authorities derived from the JAA Joint Implementation Procedures (JIPs).
 - o Appendices: EASA Forms and completion instructions.

On the 3rd July 2003 the draft proposal for the acceptable means of compliance (AMC) and guidance material (GM) to Part 21 was issued for comments. AMC and GM are to assist in the understanding of the Basic Regulation and its implementation rules. The AMC and GM to Part 21 was issued on the 17th October 2003 as a Decision of the Executive director of the Agency⁶.

¹ Regulation (EC) No 1592/2002 of the European Parliament and of the Council of 15 July 2002 on common rules in the field of civil aviation and establishing a European Aviation Safety Agency. In: Official Journal of the European Communities. Brussels. 15 July 2002. *Repealed by Regulation (EC) 216/2008 on 20 February 2008.*

² Commission Regulation (EC) No 1702/2003 of 24 September 2003 laying down implementing rules for airworthiness and environmental certification of aircraft and related products, parts and appliances, as well as for the certification of design and production organisations. In: Official Journal of the European Union. Brussels. 24 September 2003. *Repealed by (EC) 748/2012 on 03 August 2012.*

³ Ibid.: p. L243/6 ff

⁴ Ibid.: p. L243/11 ff

⁵ Joint Aviation Requirements issued by Joint Aviation Authorities.

⁶ Decision No. 2003/1/RM of the executive director of the agency of 17 October 2003 on acceptable means of compliance and guidance material for the airworthiness and environmental certification of aircraft and related products, parts and appliances, as well as for the certification of design and production organisations ("AMC and GM to Part 21"). In: European Aviation Safety Agency – the executive director. Brussels. 17 October 2003. *Repealed by Issue 2 on 30 October 2012*

AMC have roughly the same meaning as under the JAA system⁷. They illustrate a means, but not the only means, by which a specification contained in an airworthiness code or a requirement of an implementing rule can be met. Satisfactory demonstration of compliance using a published AMC shall provide for presumption of compliance with the related specification or requirement. They are a way to facilitate certification tasks for the applicant and the national aviation authority (NAA).

GM is issued by the Agency to assist in the understanding of the Basic Regulation, its implementing rules and CS. The difference between AMC and GM is currently reflected through the use of the terms "must" and "should" respectively.⁸

The regulatory hierarchy in the field of airworthiness and certification is thus proposed as follows:

- Level 1: Basic Regulation (including essential requirements);
- Level 2: Part 21
- Level 3: Agency measures: AMC and GM to Part 21 plus airworthiness codes.

The introduction of EC 1702/2003 made all previously national implemented versions of JAR 21 and their related advisory material joint (AMJ) and GMs obsolete.

The scope of the regulation is described as follows:

- (a) the issue of type-certificates, restricted type-certificates, supplemental type-certificates and changes to those certificates;
- (b) the issue of certificates of airworthiness, restricted certificates of airworthiness, permits to fly and authorised release certificates;
- (c) the issue of repair design approvals;
- (d) the showing of compliance with environmental protection requirements;
- (e) the issue of noise certificates;
- (f) the identification of products, parts and appliances;
- (g) the certification of certain parts and appliances;
- (h) the certification of design and production organisations;
- (i) the issue of airworthiness directives.

Part 21 (as per Article 1 of the basic regulation) applies to the design and production of aeronautical products, parts and appliances, as well as personnel and organisations involved in the design and production of such products.

Part 21 does not apply to products, parts, appliances, personnel and organisations engaged in military, customs, police, or similar services.

The Part 21 is further divided into following subparts:

Subpart A	General Provisions
Subpart B	Type Certificates (TC) and restricted TC's
Subpart D	Changes to TC's and restricted TC's
Subpart E	Supplemental Type Certificates (STC)
Subpart F	Production w/o PO
Subpart G	Production Organisation Approval
Subpart H	Certificates of Airworthiness and restricted C's of AW
Subpart I	Noise Certificates
Subpart J	Design Organisation Approval
Subpart K	Parts and Appliances
Subpart M	Repairs
Subpart O	ETSO authorisations
Subpart P	<i>Permit to Fly</i>
Subpart Q	Identification of products, parts and appliances

The responsible department within EASA is the Certification Directorate⁹. The Director of the directorate was Norbert Lohl a former LBA employee. Below you find an organisational chart valid as per August 2005.

On May 2012 Trevor Woods took over the positions as Director of the Certification Directorate (see: <https://www.easa.europa.eu/the-agency/agency-organisation-structure/certification-director>).

Below you find an organisational chart valid as per May 2012.

⁷ AMC and GM to Part 21 – Explanatory Note. In: EASA. Brussels. 17 October 2003. p.1. *Repealed by Issue 2 on 30 October 2012*

⁸ Ibid; p.2.

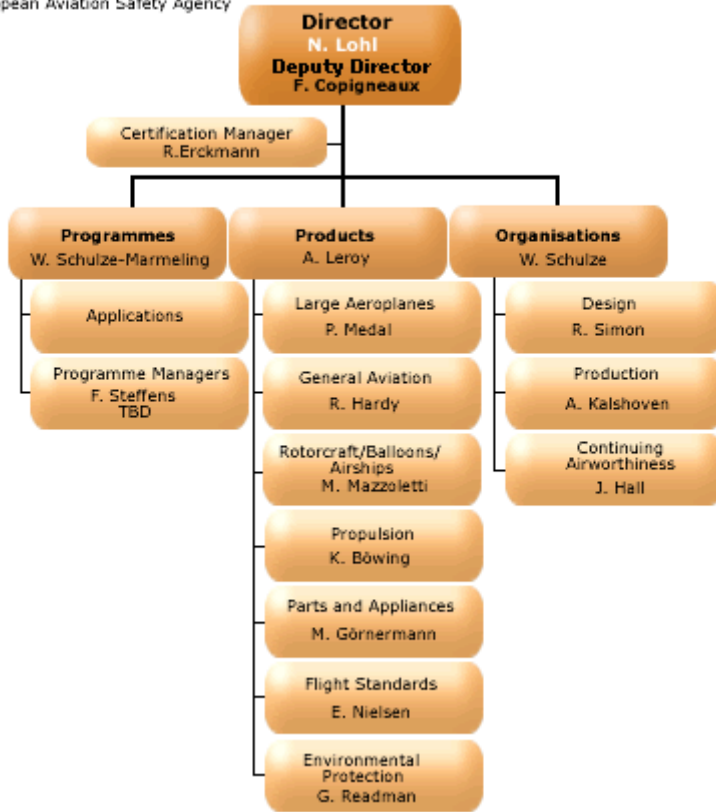
⁹ EASA: Certification – the certification directorate. In: Webpage. Certification. Cologne. August 2005. *Replaced May 2012.*

2005:



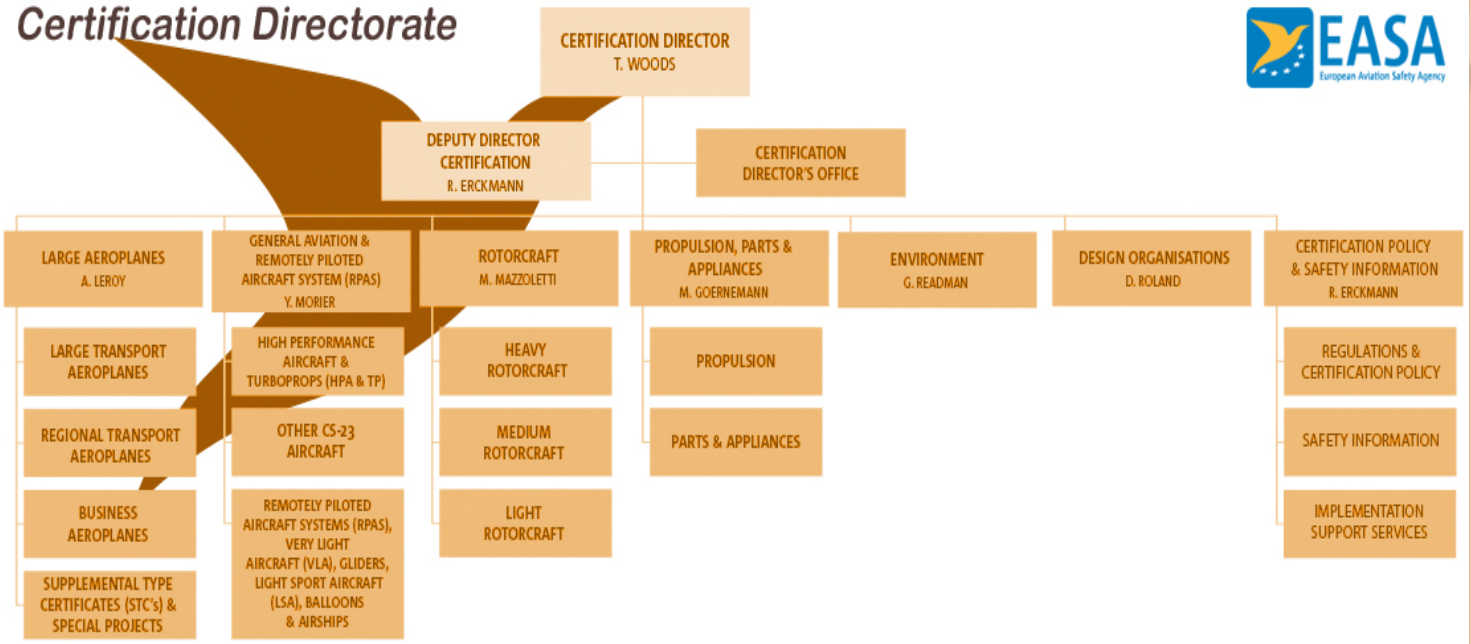
European Aviation Safety Agency

Certification Directorate



Since 2012:

Certification Directorate



PART 21 DESIGN ORGANISATION

Benefit of a Part 21 (Alternative) Design Organisation Approval (A)DOA

Below a simplified decision process for a design organisations with a capability for avionic or electric changes will be explained.

Before trying to define the organisation type (DOA versus ADOA) which best fits the business need, it is wise to thoroughly discuss the advantages and disadvantages of a design organisation first. Only a clear picture of the involved work and the expected effort can lead to a satisfying outcome.

First the organisation wants to make sure that a design organisation is what they need. The questions below should help to define whether this need exists. The questions should be discussed within the organization between the management and the proposed postholders as well as with the NAA:

- Evaluate the need for the DOA: How many potential projects do I forecast for the next period and how many of them are major¹⁰ and minor changes? Is it necessary to do them myself, or am I able to buy this STC on the market.
- What kind of organisation would cover best the scope of our organisation: Would it be best to apply for a DOA in accordance to Subpart J or will an ADOA with its limited scope do the job?
- Discuss the process, the schedule and the implications with your NAA and ask them about their opinion.
- Your organisation should make sure that it can support and provide enough resources for the investigation and approval process throughout the whole time period until approval.
- Are the nominated postholders and nominated personnel experienced enough to fulfil their intended positions.
- Ensure that the number, experience and competence of the persons involved in the compliance finding and the support of the system is sufficient at the time of the approval and any time later. This needs to be maintained during the post approval time in relation to the number and complexity of projects being processed by the (A)DOA.
- Will the organisation be able to accommodate the cost for the approval and surveillance cost of the (A)DOA?
- A supporting person to help and guide the organisation thru the approval process might be a major advantage for companies not currently holding a similar national or JAA approval.
- How do I support my customers during the time the approval process is going on? This is especially true and important if you are not holding a similar national or JAA approval.
- How does it affect my operation in the future if I am lacking a design capability?
- In accordance with 21A.92(b)¹¹ MINOR changes only can be applied by any natural or legal person without an organisation approval. Longer lead times to gain approval have to be expected however.
- There are plenty of reasons why an organisation (usually connected to a P145 Organisation) should spend time and money on a (A)DOA approval. Here a list of reasons which you should consider when making your decision:
 - A STC is a scarce commodity especially on new equipment type installation.
 - Selling your own STC can be a business case.
 - Design Organisations tend to be the more competent partner for a customer due to advantage in certification experience.
 - Special mission installations (applicable to only a limited number of aircrafts) might only be possible if you are able to provide the design approval for it.
 - Increased Trouble shooting capability due to experience with equipment.
 - To be able to approve Minor changes without authority involvement. (DOA only).
 - Create a second backbone (design capability) for your organisation besides maintenance.
 - Closer touch to regulatory issues, latest requirements and mandates.
 - The design capability might become an issue in the renewal of your dealership with the Original Equipment Manufacturer (OEM).

¹⁰ Decision No. 2003/1/RM of the executive director of the agency of 17 October 2003 on acceptable means of compliance and guidance material for the airworthiness and environmental certification of aircraft and related products, parts and appliances, as well as for the certification of design and production organisations ("AMC and GM to Part 21"). In: European Aviation Safety Agency – the executive director. Brussels. 17 October 2003. p. 33f. *Repealed by Issue 2 on 30 October 2012*

¹¹ Commission Regulation (EC) No 1702/2003 of 24 September 2003 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. In: Official Journal of the European Union. Brussels. 24 September 2003. p. L243/24 *Repealed by (EC) 748/2012 on 03 August 2012.*

Without Design Approval

- Only minor changes will be processed by the agency/NAA! No major change possible.
- Cost disadvantage because minor changes need to be processed thru the NAA.
- Consider lead times in getting minor changes approved by the NAA.
- Even if a contract with another appropriately approved organisation is in place, limitations might be applicable.

Design Organisation Approval (DOA) and Alternative Design Organisation Approval (ADOA) versus

The process to receive a DOA/ADOA is slightly different depending on the intended scope of the organisation. To be able to make a decision which approval form is the best for a given organisation it is important to know the differences between the two forms of approvals:

	DOA	ADOA	Applicant i.a.w.
Scope of work	Unlimited based on the capability of the organisation.	Limited MAJOR as per GM 21A.112B Group 2 cases.	Only MINOR changes
Privileges	to approve MINOR changes to type design	NONE	NONE
Organisation setup	Design assurance system as per 21A.239	As per AMC 21A.14(b)	No Organisation
Application for Organisation	Form 80 ¹²	Form 8112	NONE
Applied EASA working procedure	ADOA ¹³	DOAP ¹⁴	NONE
Fees & Charges Approval/surveillance of the organisation	charged using a flat fee plus an hourly rate as per Para. (vi) of the Annex to EC 488/2005 ¹⁵	charged on hourly basis as per Para. (vii) of the Annex to EC 488/2005.	NONE
Fees & Charges STC's and Minor Changes	No charges for MINOR changes due to exercised privilege.	Charges applied for both MINOR and MAJOR changes.	Charges applied for MINOR changes.
Personal Requirement	As per GM No. 1 to 21A.239(a)	As per AMC 21A.14(b)	Will be checked while processing the MINOR change.

¹² Can be found on the EASA webpage.

¹³ European Aviation Safety Agency. EASA. Certification Directorate Exposition. Part 3, Subpart 1. Internal Working Procedure. Design Organisation Approval (DOAP). In: EASA. Cologne. 20 December 2004. Issue 1.

¹⁴ European Aviation Safety Agency. EASA. Certification Directorate Exposition. Part 3, Subpart 2. Internal Working Procedure. Alternative Design Organisation Approval (ADOAP). In: EASA. Cologne. 20 December 2004. Issue 1.

¹⁵ Commission Regulation (EC) No 488/2005 of 21 March 2005 on the fees and charges levied by the European Aviation Safety Agency. In: Official Journal of the European Union. Brussels. 21 March 2005.

What a (A)DOA holder cannot do

- Does not allow production of parts on stock or on request. This will need to have a Production Organisation involved.
- A (A)DOA does not allow to perform the installation/modification work. As required a Part 145 or a Part 21 Subpart G (Production Organisation) is necessary.

Application, allocation and investigation process

Once the decision is taken to apply for a design organisation you will have to run through the process as defined in the EASA working procedures as referenced above.

Application and eligibility of an organisation

As per the Section 21A.112B of the regulation an organisation applying for an STC (major change) in accordance with Subpart E "...shall demonstrate its capability by holding a design organisation approval, issued by the agency in accordance with Subpart J." called Design Organisation Approval (DOA) or otherwise "...an applicant may seek Agency agreement for the use of procedure setting out of specific design practices, resources and sequence of activities necessary to comply with this regulation." called Alternative DOA (ADOA).

An organisation, being the applicant for a supplemental type-certificate, a major repair design approval or an Auxiliary Power Unit design approval which does not hold on 28. September 2003 an appropriate design organisation approval issued by a Member State under applicable JAA procedures shall demonstrate its capability before 28 September 2005 in accordance with Part 21, 21A.112, 21A.432B, or in the case of an Auxiliary Power Unit, 21A.602B. That means that after 28 September 2005 a design organisation previously not recognised by the local authority or JAA may not exercise design work covered by Part 21.

The application shall be made in a form and manner established by the agency and depends on the organisation type.

21A.234 Application – DOA: "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 21A.243, and the terms of approval requested to be issued under 21A.251", or application for ADOA in accordance with 21A.112B(b): "... an applicant may seek agency agreement for the use of procedures setting out the specific design practices, resources and sequence of activities necessary to comply with the subject".

The application for either organisation type should be done on a Form 80 (DOA) or Form 81 (ADOA) respectively. The application should be addressed to the agency and contain the organisations preferred NAA performing the investigation process in case the NAA cannot or does not want to perform it. The application shall contain a draft handbook describing the design organisation. A MAJOR change project which forms the basis for the application should be listed, supporting the request for the need of such an approval. The scope of the (A)DOA is usually closely linked to the P145 organisation the (A)DOA is working with.

Allocation of technical investigation tasks:

Following receipt of the application, the EASA Manager of Applications Certification (MAC) together with the EASA Design Organisation (DO) Manager will make first check on eligibility according to Part 21 and will determine how it will proceed with the application. They will be

communicating this, together with the applicable requirements, to the applicant within the month following receipt of the correct application.

For the time being the technical investigation will be allocated to an external party (NAA) which will handle the technical investigation on behalf of EASA. The selected external party may only be a NAA which is appropriately accredited and has appropriate contractual arrangements with EASA, according to the current applicable legal framework.

The DO Manager will check if the NAA of the country in which the applicant design organisation has its main place of business and main establishment fulfil the above mentioned requirements and, if so, will notify this NAA the name and location of the applicant and the expected scope of work. The NAA will be given a month period in which to express an interest to perform the technical investigation tasks on behalf of EASA.

If this NAA does not fulfil the above conditions or is not willing to or cannot carry out the technical investigation, the EASA DO Manager will check which of the other NAA fulfil the above mentioned requirements and notify those which comply with them the name and location of the applicant and the expected scope of work.

In order to speed up the process, the applicant should seek the NAA consent to accept the allocation by EASA prior to the formal application.

The selected NAA will be informed by the Agency in writing of the selection together with the reasons thereto. A DOAT Leader will be nominated by the EASA DO Manager and will form a Design Organisation Approval Team (DOAT). The DO Manager will communicate the composition of the DOAT to the applicant.

The DOAT Leader will initiate the investigation process by organising a first (Initial or Kick-off) Meeting with the applicant (Phase 1):

- Presentation of the applying organisation and it's intended scope.
- Description of the investigation process (presented by DOAT)
- Presentation of the NAA DOA investigation team.
- General discussion about time frame.
- Should be used to raise special issues or discuss open questions by the organisation.

After the first meeting the preparatory phase (Phase 2) starts. It includes the study of the DO handbook and associated data by the NAA which leads to the preparation of an investigation program containing a time schedule which will be presented to the applicant (Phase 3).

In Phase 4, the complete system shall be reviewed, first to check exhaustively that the design organisation of the applicant complies with the Part 21 Subpart J and other Subparts relevant for the scope of work applied for, secondly to check, as practical, on a sample basis that the applicant is actually working in accordance with the system described. When all subjects have been processed as defined above, and the sample audits completed to the satisfaction of the DOAT, then the phase 4 shall be deemed complete. However, it is accepted that some actions required by the DOAT may take time for implementation and may remain open at the end of this phase, subject to a corrective action programme agreed by the DOAT.

During the conclusion Phase 5 the DOAT Leader will prepare a final report and send the report to the EASA DO Manager for review. The DOAT Leader will provide the applicant with the conclusion of the investigation. Following the submission of the final report, approval by the EASA DO Manager and confirmation of agreed terms of approval, the DOA Certificate will be prepared and signed by the EASA DO Manager.

The EASA Manager Application Certification will send the DOA Certificate and associated terms of approval to the applicant and enter the information in the database of approvals.

The whole process from application of a new established design organisation to the issue of the final approval may take at least 10 months up to an average of 15 months.

Design Organisation Handbook

The handbook builds the core element of a Design Organisation. The purpose of the handbook is to set forth in a concise document format the organisational relationships, responsibilities, terms of reference, and associated authority, procedures, means and methods of the organisation.

Compliance with the handbook is a prerequisite for obtaining and retaining a design organisation approval. Monitoring of compliance with the handbook is normally the responsibility of the quality assurance function.

The content of the handbook is described in AMC No. 2 to 21A.243(a). Where this information is documented and integrated in manuals, procedures and instruction, the handbook should provide a summary of the information and an appropriate cross reference.

Writing handbook is a task on its own and someone may invest between 150 and 400 manhours in writing and formulating the handbook and the associated procedures. Unfortunately there are no sample documents yet provided by the NAA or the agency.