

## **Applications**

## How long does it take to obtain a design organisation approval (DOA)?

#### **Answer**

It is not possible to give a single answer to this question here, but to give an indication – on average the duration of the investigation process is approximately 1.5 year.

The actual duration of the investigation is dependent on many aspects: Quality of the Design Organisation Handbook, Complexity of the Design Organisation, Resources, Responsiveness, Training, Implementation, Communication, etc.

See also the FAQ "Can you explain the process to obtain a design organisation approval (DOA)?" in which the process to obtain a DOA is explained.

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https://www.easa.europa.eu/ro/faq/20106

## Can you explain the process to obtain a design organisation approval (DOA)?

#### Answer

After the application has been submitted by the company, the Agency will start its so-called Initial Investigation process. A DOA Team Leader (DOATL) will be appointed to lead the investigation, and will invite you for a Kick-off meeting, preferably at the Agency. During this meeting the investigation process will be explained in detail, taking into account specific characteristics of the organisation applying for DOA. For this purpose, the applicant should prepare a presentation of the company in general, as well some specific information of the design organisation (e.g. organisation setup, type of design projects). It is not expected that a DOA handbook is already prepared prior to the Kick-off meeting.

The DOATL will form a DOA Team (DOAT) so that all relevant fields of expertise are available to conduct the investigation. The investigation process will be processed step-by-step. Initial reviews will stay high-level, and are aimed to make sure all essential elements are covered.

These will be followed by detailed reviews for each core process of the design organisation. When the process descriptions are satisfactory and documented, the DOATL will plan one audit (or more, depending on the complexity of the case) at the company facility (and, if relevant, supplier(s) facilities as well) to verify the implementation of the design organisation handbook. Along this process, the DOAT will also perform interviews with management staff and CVE's.

All along the initial investigation process, the company will have to:

- Create and keep up-to-date a DOA development and deployment plan
- Draft and update the design organisation handbook and associated procedures
- Train the design organisation staff
- Prepare sample certification projects
- Execute the Independent System Monitoring function (e.g. perform internal audits, etc.) When it is demonstrated that the design organisation complies to all relevant requirements, the investigation process will be completed and the DOA certificate can be issued.

If you are considering to apply for DOA, but you would like to discuss your case prior to making the application, please do not hesitate to contact the DO Department at: doa [at] easa.europa.eu

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## What are the expectations of the Agency in respect to the numbers and experience of the staff of a design organisation?

## **Answer**

Requirement 21.A.245(a) and associated GM no. 1 applies. Design organisations should have a documented system to select personnel based on minimum knowledge and experience requirements defined for each technical role, complemented by training programs identified for each role and adapted to single individuals, which are periodically reviewed, taking into consideration the state of the art and new experience. The design assurance system should also allow the organisation to demonstrate that the numbers of skilled personnel is sufficient to carry out all planned design and compliance demonstration activities in compliance with the approved procedures. Project estimated hours workloads versus capacity and Gantt charts for planning are typical tools used to show compliance with the relevant Part-21 requirements.

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## What are the expectations of the Agency in respect to the independent system monitoring of a DOA holder?

#### **Answer**

First of all the Agency expects the Independent System Monitoring of a DOA Holder to:

- be properly placed within the Design Organisation in order to have the Independency ensured (above process owners and below the Head of Design Organisation);
- be properly staffed with persons having relevant Part-21 expertise and process monitoring (auditing) skills;
- have a feed-back system to person(s) having the responsibility to ensure corrective actions (such as process owner, DOA Management or Head of Design Organisation).

Independence means that the ISM staff should not be involved in the processes and produce deliverables of the processes but may:

- Support process owners in defining processes compliant with Part-21;
- Support process owners in the analysis of the root cause of the issues collected during process monitoring;
- Support process owners in defining corrective actions;
- Support process owners in verifying the effectiveness of the corrective actions;
- Liaise with the EASA DOATL;
- Report summarised information related to Design Assurance System performance / health to the Head of Design Organisation.

This function may:

- be subcontracted or,
- be performed by the Quality Organisation under some conditions mentioned in the presentation Independent System Monitoring on the EASA website.

The Agency considers that effective monitoring means to ensure:

- Compliance of the Handbook and procedures with Part-21;
- The adequacy of the procedure;
- Appropriate technical content of the deliverables;
- Process adherence (compliance with procedures);
- Monitoring and analysis at process level performed by competent staff;

- Systematic collection of issues arising during a given process (e.g. difficulties or good performances during change or STC process);
- Systematic and complete reporting about health of the process (performance and not only non-conformities).

For further details please refer to the presentation Independent System Monitoring.

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# Can I, as a DOA holder, appoint a deputy for one of the key management positions? And is an EASA DOA Form 4 required for such a deputy?

#### **Answer**

It is considered good practice by the Agency to anticipate temporary absence of the key managers (Head of Design Organisation, Head of Office of Airworthiness and Head of Independent System Monitoring), but usually the Agency will not require an EASA DOA Form 4 for any deputy function.

It is expected that the deputy function is established to ensure continuity in the execution of tasks – in absence of the main post holder - while the responsibilities remain with the nominated manager. This delegation of tasks is feasible whilst properly described in the Design Organisation Handbook.

An exemption should be considered the case when the key manager will be absent for a long time (e.g. maternity leave or extensive sick leave) and cannot be realistically expected to assume responsibility during his/her absence, but is expected to return to his/her nominated function (and thus remaining in the key management position within the company). In this case, a deputy should be nominated to cover the period of absence. This should be considered a significant change to the Design Assurance System (covered by an EASA Form 82), and the nomination of the deputy functionary should be made including EASA DOA Form 4.

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https://www.easa.europa.eu/ro/faq/20111

My organisation is based in a country outside the EU. Can I apply for DOA?

#### **Answer**

Any company, independently of where it is based, can apply for DOA by means of the form FO.DOA.00080, which can be downloaded from the EASA webpage. Each application received from a company based outside the EU is evaluated, and final decision (regarding the acceptability or rejection of the application) is made on a case by case basis by the Agency. Some considerations however apply: the applicant may be requested to demonstrate that the DOA is needed in relation with an application for a design approval (TC, STC, ...). For those companies established in a country where there is a bilateral agreement in place signed with the EU (such as United States, Brazil and Canada), such applications will normally be rejected, because the purpose of the bilateral agreements is to rely on each other's design approval system.

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Do I, as a DOA holder that only deals with minor changes and minor repairs, need to have an occurrence reporting system?

#### **Answer**

According to 21.A.3A, a DOA holder that only deals with minor changes and minor repairs does not need to have an occurrence reporting system. This doesn't prevent the DOA holder from having a system for collecting feedback from their customers.

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When is an organisation, designing a product (aircraft, engine, propeller), exempt from having a DOA?

### Answer

An Organization designing:

- a piston engine, or
- a fixed or adjustable pitch propeller, or
- an aircraft belonging to ELA 1 or ELA 2 Category, or
- an engine or a propeller installed in an ELA1 or ELA 2 aircraft

is exempt from being required to have a DOA. (See 21.A.14(b) and (c))

Following definitions apply (COMMISSION REGULATION (EC) No 748/2012, article 1):

"ELA1 aircraft" means the following manned European Light Aircraft:

- i. an aeroplane with a Maximum Take-off Mass (MTOM) of 1200 kg or less that is not classified as "complex motor-powered aircraft";
- ii. a sailplane or powered sailplane of 1200 kg MTOM or less;
- iii. a balloon with a maximum design lifting gas or hot air volume of not more than 3400 m3 for hot air balloons, 1050 m3 for gas balloons, 300 m3 for tethered gas balloons;
- iv. an airship designed for not more than four occupants and a maximum design lifting gas or hot air volume of not more than 3400 m3 for hot air airships and 1000 m3 for gas airships;

"ELA2 aircraft" means the following manned European Light Aircraft:

- i. an aeroplane with a Maximum Take-off Mass (MTOM) of 2000 kg or less that is not classified as "complex motor-powered aircraft";
- ii. a sailplane or powered sailplane of 2000 kg MTOM or less;
- iii. a balloon;
- iv. a hot air ship;
- v. a gas airship meeting all of the following elements:
  - 3% maximum static heaviness,
  - Non-vectored thrust (except reverse thrust),
  - Conventional and simple design of: structure, control system and ballonet system
  - Non-power assisted controls;
- vi. a Very Light Rotorcraft.

An aeroplane, meeting the MTOM requirements for ELA 1 or ELA 2 Category, is nevertheless classified as "complex motor-powered aircraft" when it is certificated for operation with a minimum crew of at least two pilots, or it is equipped with (a) turbojet engine(s) or more than one turboprop engine.

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## How does the Agency accept the management staff of a design organisation?

#### **Answer**

A design organisation has to nominate its management staff:

- the Chief Executive
- the Head of the Design Organisation
- the Chief of the Office of Airworthiness
- the Chief of the independent monitoring function

The person or persons nominated should represent the management structure of the organisation and be responsible through the Head of design organisation to the Chief Executive for the execution of all functions as specified in Part-21, Subpart J. Depending on the size of the organisation, the functions may be combined or subdivided under individual managers.

The design organisation shall furnish a statement of the qualifications and experience of the management staff to the Agency: this means that the nominated managers should be identified and, except the case of Chief Executive, their credentials furnished to the Agency on EASA Form 4-DOA 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.

The Agency does not approve individuals; therefore the acceptance of the nominated managers has to be understood:

- either through the Approval of the Design Organisation following the initial investigation. The nominated management staff of an approved design organisation, their hierarchical links and allocated responsibilities shall be then identified in the DOA's Handbook,
- or through the Approval of Significant Change to the DOA related to a change of the
  management staff, to be done as described in the DOA procedures. Once the Application for
  the Significant Change to the DOA shall be submitted by the DOA and accepted by the
  Agency, the DOA Team Leader will investigate the case and summarise his/her assessment
  and recommendation for acceptance in his investigation final report. On that basis, EASA
  shall issue the formal Letter of Approval of the Significant Change to be sent to the DOA.

See also the following relevant regulatory material:

• GM No. 1 to 21.A.239(a) Design assurance system, para (3.1.2)

- 21.A.243 Data, para (d)
- AMC No. 1 to 21.A.243(a) Data requirements, para (2.)
- AMC No. 2 to 21.A.243(a) Data requirements Model content of handbook for organisations designing minor changes to type design or minor repairs to products, para (1.10)
- GM No. 1 to 21.A.243(d) Statement of qualifications and experience
- GM No. 2 to 21.A.243(d) Data requirements Statement of the qualification and experience-Organisations designing minor changes to type design or minor repairs to products, para (1.)
- GM No. 1 to 21.A.245 Requirements for approval, para (4.1)
- GM 21.A.247 Significant changes in the design assurance system, para (2.)

GM 21.A.265(b) Use of the Handbook, para (1.)

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https://www.easa.europa.eu/ro/faq/20107

## What are the expectations of the Agency in respect to the appointment of CVEs?

#### **Answer**

The Agency expects the DOA Holder, first of all, to:

- properly define the CVE function (Independent Checking Functions) and associated responsibilities:
  - Approval by signing of all compliance documents, including test programmes and data, necessary for the verification of compliance with the applicable CS and environmental protection requirements as defined in Type Investigation programme;
  - Approval of the technical content (completeness, technical accuracy...), including any subsequent revisions, of the manuals approved by the Agency (Aircraft Flight Manual, the Airworthiness Limitations section of the Instructions for Continued Airworthiness and the Certification Maintenance Requirements (CMR) document, where applicable).
- ensure appropriate level of independency, meaning that the CVE must not be involved in the creation of the compliance data.

To put in place procedures covering, as a minimum, the following:

- Role Description
  - tasks and responsibilities
- Independence
  - signatory flow (to be properly defined)

- design engineer/ CVE ratio and quantity (all relevant technical fields have to be covered by design and compliance verification engineers)
- availability provisions
- use of external CVEs
- · Nomination and Training
  - selection/ nomination process flow
  - selection/ nomination team and process when the DO has already competence for the technical field in house;
  - selection/ nomination team and process when the DO has no competence for the technical field in house;
  - minimum nomination/qualification criteria are to be defined
  - scope of authorisation
  - provisions for records (records to be produced by the DO for the nomination of a CVE)
  - evidence that the nominated CVE has accepted the role
  - training policy
- External CVEs
  - DO Interface Document or equivalent
- Provisions to maintain the Approval as CVE.

#### Notes:

- During the Initial Investigation Process (before the Design Organisation Approval is granted)
   the CVEs must have been properly authorised internally under the appropriate procedures
   prior to the competence assessment by the Agency.
- The results of the assessments of competence are used by the DOA Team to determine compliance or non-compliance of the Design Organisation with 21A.243(d) and 21A.245(a), they do not constitute an approval or rejection of the individual.
- During the Surveillance process the DOA is expected to nominate the CVEs, within the
  approved Scope of Approval, according to the appropriate procedures. Therefore the DOA is
  not requested to notify the Agency but to provide this information during regular surveillance
  activities.
- In case of a Significant Change to extend the Scope of Approval, the DOA must notify the Agency and proceed according to the appropriate procedures.

For further details please refer to the presentation Independent Checking Function Assessment.

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## Can an electronic management system fulfil the requirements for a DOA handbook and procedures?

#### **Answer**

Yes.

The term "handbook and procedures" can be understood as any means to document a DO's processes and procedures. This can be:

- an online Integrated Management System with flowcharts and descriptions embedded;
- an online system referring to single documents;
- a classic handbook with reference to online procedures;
- or any other combination.

In any case, the Management System should clearly identify the DO relevant content and the means to update the system. Furthermore Agency access to the system or copy of the relevant information should be made available.

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## Can you provide me any guidance or template, how I should write a DOA handbook?

#### **Answer**

EASA provides a DOA handbook template providing guidance for drafting a DOA handbook here. The template has to be adapted to your company's scope of work, organisation and the way of working.

Be aware that this DOH template is not a standard manual, does not introduce new or modified rules and does not constitute any legal obligations or right for the Agency or the organisations. It must not be regarded as formally adopted Acceptable Means of Compliance (AMC) or Guidance Material (GM).

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