

**Design
Organisation
Approval**

**Initial Investigation Information
Paper**





DOA Initial Investigation Information Paper



Introduction

The intent of this information paper is to make potential applicants for a Design Organisation Approval aware of the complexity of the EASA investigation process and to emphasize the need for the applicant's self preparation, even well before an application for a Design Organisation Approval is sent to the Agency.

This will enable an efficient utilization of EASA resources which will be directed at DOA applicants that are in a better state of application readiness

This document is organised in Modules, with the intention to easily expand it in future. Here below the content of each Module is briefly addressed.

Module 1 - DOA Concept provides an illustration of what a Design Organisation Approval is, why it is needed, and which "advantages" can be obtained by setting up such organizational system.

Module 2 – DOA Initial Investigation “end to end” process overview provides a detailed description of the investigation steps performed by the Agency to result in a DOA Approval.

Module 3 – DOA Initial Investigation Highlights is organised in PARTS, addressing some topics largely debated during the investigation or some aspects of the investigation process itself.

The content in Module 3, when relevant, is not substitutive of Commission Regulation (EU) No 748/2012, but it builds on it by

providing more insight on the practical implementation of specific requirements.

Module 3 comprises 4 Parts:

- PART 1: Terms of Approval
- PART 2: DOA Staff
- PART 3: Handbook
- PART 4: PART 21 Compliance Check List

Module 4 – Synchronization between DOA Initial Investigation and other investigation activities provides some general principles on how to progress in parallel a DOA application and e.g. a Type Investigation, to ensure that the Type investigation deliverables are released in a “mature organizational environment” and on sufficiently “mature processes”. With this principle in mind, a DOA applicant should only file an application for a certification exercise when the necessary level of maturity is achieved within the Design Assurance System and demonstrated to the Agency, by the achievement of certain milestones/gates disseminated all along the DOA initial investigation path.

The expectation of the Agency is that potential applicants can follow this material, conduct the necessary self-assessment and preparatory steps to be in a better state of readiness for the application process and ultimately be in the “driving seat” regarding its execution.

Applicant self-assessment is formalized in **Module 5 - DOA Applicant Readiness Checklist** to be provided along with the application for a DOA (EASA Form 80).

In the following modules, the COMMISSION REGULATION (EU) No 748/2012, laying down implementing



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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 will be referred to as Part 21, 'Part 21' being the Annex I in that regulation. Some references to Points in this regulation are also made.



Useful link:

To familiarize with the relevant regulatory environment, please visit the following link:

[Initial Airworthiness | EASA \(europa.eu\)](https://easa.europa.eu/initial-airworthiness)

In case more exchange is needed with the Agency for the preparation of the "Readiness Check List" a request for a pre-application meeting can be filed to doa@easa.europa.eu.



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Module 1: DOA concept



Foreword

Before describing the **DOA** concept, some basic answers are introduced here below to remind of the context and key words.

WHAT is a DOA?



The core business of a DOA is the aeronautical **design**, the creative work delivered by the engineers. This work needs to be organised according to applicable rules and once the right **organisation** is demonstrated to the authority, an **approval** can be granted.

A company granted with a DOA is named a **DOA Holder**.

A company wishing to obtain a DOA and that has applied for it is a **DOA applicant**.

A DOA holder can obtain **recognized capabilities** e.g., the right to design STC, major repairs, **privileges** e.g., to classify changes and to approve minor changes. With the recognition and privileges, also come **obligations** e.g. to collect the occurrences that may happen in service, to keep records of the design work.



WHY is a DOA needed?



In accordance with Article 8 of **COMMISSION REGULATION (EU) No 748/2012**, an organisation responsible for the design of products, parts and appliances or for changes or repairs thereto shall demonstrate its capability in accordance with Annex I (Part 21).

In other words, a DOA is one possibility to **demonstrate capability** to design e.g. aircraft or changes or repairs thereto (21.A.14; 21.A.112B; 21.A.432B; 21.A.602B).

WHEN is a DOA needed?

It is not necessary to have a DOA for all types of design activities. For instance, to demonstrate the capability to design an ELA 2 airplane (definition in Article 1(j)) or to obtain an ETSO authorisation, an alternative to DOA is possible and named 'alternative procedures to DOA' (ADOA). Another example with the design of an ELA1 airplane (definition in Article 1(i)), for which only a certification programme is needed.



With an **ADOA** or a **certification programme**, the design holder has obligations but no privileges, or very limited privileges in the case of ETSOA.



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With an ADOA, the demonstration of compliance with Part 21 is done through a set of procedures that are to be agreed by the Agency. The ADOA procedures must remain compliant with Part 21 and any applicable amendment of Part 21.

The table below offers a comprehensive overview of the minimum required *capability* against the type of design activities:

Type of design	Demonstration of Capability			
	DOA	ADOA	CP	None
Aircraft Type Certificate				
- All Aircraft	Yes			
- ELA 2*	Yes	Yes		
- ELA 1*	Yes	Yes	Yes	
Engine Type Certificate				
- All Engines	Yes			
- Piston Engine	Yes	Yes		
- Engine installed in ELA2 Aircraft	Yes	Yes		
- Engine installed in ELA1 Aircraft	Yes	Yes	Yes	
Propeller Type Certificate				
- All propellers	Yes			
- Fixed or adjustable pitch propeller	Yes	Yes		
- Propeller installed in ELA2 Aircraft	Yes	Yes		
- Propeller installed in ELA1 Aircraft	Yes	Yes	Yes	
Supplemental Type Certificate (STC)				
- All STC's	Yes			
- STC Group 1 **	Yes			
- STC Group 2 **	Yes	Yes		
- STC on ELA1 or its engine or propeller	Yes	Yes	Yes	
Minor Changes	Yes	Yes	Yes	Yes
Repairs				
- Minor	Yes	Yes	Yes	Yes
- Major	Yes	Yes***		
- Major on ELA1 or its engine or propeller	Yes	Yes	Yes	
ETSO Authorisation (ETSOA)		Yes		

* For definition see EU Regulation (EC) 748/2012 Article 1
 ** For definition see GM 21.A.112B
 *** Upon Agency agreement



Nevertheless, the exercise of privileges represents the major payback for the *effort* to establish and to maintain a DOA. A DOA is not always needed, but it is worth, when the applicant is seeking a certain level of *autonomy*.



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The Concept



The Part 21 requirements defining a DOA are the ones written in **Subpart J**. The Subpart J is directly linked to other relevant subparts of Part 21 through requirements applicable in accordance with the type of activities performed by the DOA (see **Module 3 – Part 4 Part 21 Compliance Check List**).

Usually, an organisation relies on individuals. It is the same for a DOA, but the **DOA staff**, in all technical departments, shall be of **sufficient numbers** and **experience** (21.A.245). It is the task of the management of the DOA to hire competent persons and maintain those competences.

In order to perform their work, the DOA staff need suitable facilities, **means and tools** such as office space, software, mock-up, prototyping facilities, ... (21.A.245)



The DOA staff shall work in accordance with **processes/procedures** that are adapted and scaled to the type of their design activities. The **'core document'** of the DOA is the **Handbook**. The procedures can be embedded in the DO Handbook or cross-referenced. Depending on the design activities, a Flight Test Operating Manual may be needed and referenced in the Handbook. (21.A.243)

As mentioned before, a DOA is needed to demonstrate capability, a capability to design **safe** products.

Aiming at enabling this capability, the **design assurance system** (21.A.239) is the organisational structure, responsibilities, procedures and resources to ensure the proper functioning of the design organisation.

The Design Assurance System enables the organisation:

- to design in accordance with applicable Certification Specifications (CSs) and Environmental Protection (EP) requirements,
- to ensure compliance with applicable CSs and EP requirements, and
- to discharge the DOA staff responsibilities in accordance with applicable requirements in Part 21.



Each member of the DOA staff needs to understand the DOA's concept/environment, the scope of work, the processes, their own tasks, role, place in the organisation. The persons **responsibilities** shall be made clear.

The DAS relies on some pillars that we will see in more details just after: 1. **independent checking function**, 2. **ISM** and 3. **supplier control**.



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The concept of DOA introduces ‘**safeguard**’ elements through the DAS to ensure compliance to the rules and to reduce the possibility of mistakes and errors to a minimum during the daily work. The basic principle of those elements is to check, verify, control, monitor, update and improve the procedures. This ‘safeguard’ is to be carried out by certain roles within the DOA staff. More precisely, the key elements are:

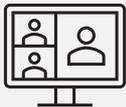


1. the CVE role which is the checking of the demonstration of compliance produced by another staff member:

2. the ISM with:



- the monitoring of compliance (adherence) of the daily work (certification activities such as tests, certification documents, ... and even the ISM itself) to the Handbook/procedures and
- the monitoring of the adequacy of these procedures (in accordance with PART 21 and the DAS itself),



3. the integration of the supplier (control and monitoring) when some of the DOA work is performed by suppliers.

The DOA certificate is granted on a certain day- recorded as the DOA anniversary date and is associated to the “**definition**” of the organisation, namely the **Terms of approval** (21.A.251). Those terms can be seen as a contract between the industry and the Agency.



Nevertheless, a DOA is a living and evolving organisation. While some **changes** can occur, it must remain **compliant** to Part 21. The way such changes are classified triggers different levels of **coordination** with the Agency, which should be described and anticipated as well in the Handbook (21.A.247, 21.A.253).





Module 2: Initial Investigation end to end process overview

Foreword

The DOA initial investigation process is aimed at building the necessary confidence in the **capability** of a design organisation to perform **design work** within its **terms of approval** and to fulfill its **obligations**. The DOA Team leader (DOATL) allocated to the organisation is the major process operator from the authority side, but the organisation itself shall be in the driving seat to ensure the expected progress.

The DOATL establishes a team (advisors and team members) to receive the necessary technical support all along the stages of the investigation. The DOA Team is constituted by members coming from Product Certification, such as Product Certification Managers (PCMs) and Panel Experts (e.g. Structure, Cabin Safety...) and even Production/Maintenance Organisation Approval Experts, depending upon the scope and the interfaces of the subject Design Organisation.

The investigation, starting officially with an application to EASA, develops over a series of phases with respective milestones, with the intent to progressively evaluate the maturity of the Design Assurance System until an approval can be granted to the organisation.

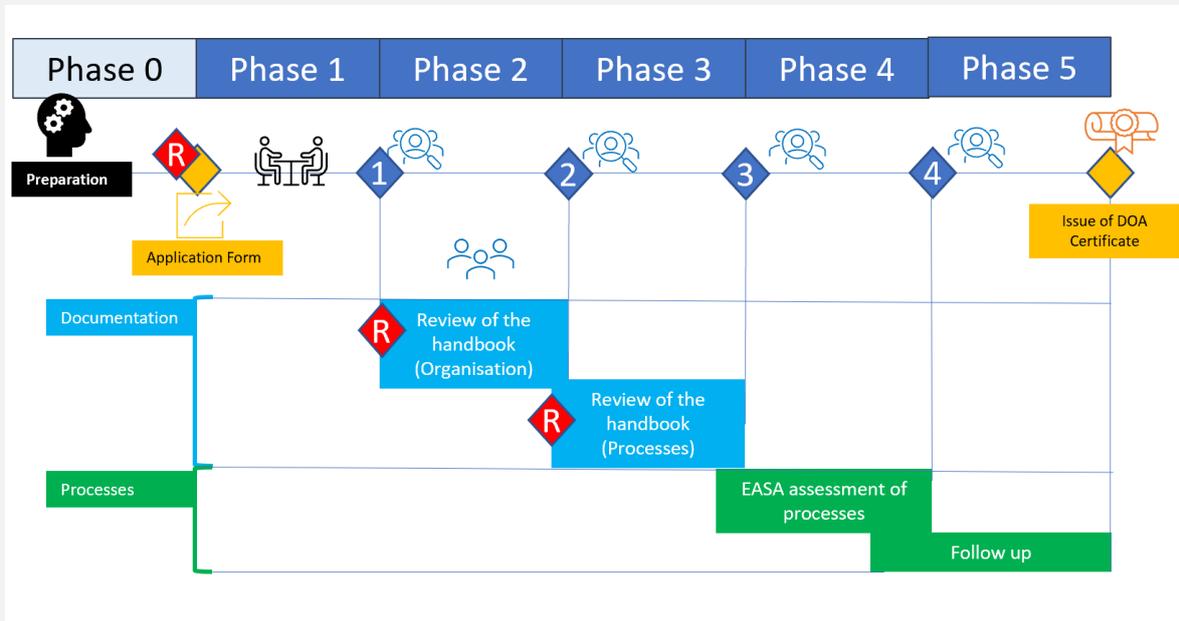
As with any major **endeavor**, the DOA applicant needs to get the necessary **preparation** and knowledge to progress with confident steps in a regulatory environment which might be completely new at start of the path.

The intent of this Module is to provide an overview of the initial investigation process, allowing the organisation to acquire an overall understanding of the route from the status of “**DOA applicant**” to the one of “**DOA holder**”. More details, about key aspects, are provided in additional Modules, which are cross-referred within the text.



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The graph below briefly illustrates the process structure:



In a nutshell, four milestones (between the application and the issue of the DOA certificate) disseminated along six phases, which are described hereafter.



Preparation

Phase 0: Applicant Preparation

This represents the phase where the future applicant starts shaping its “**design needs**” and getting familiar with the regulatory framework. The applicant should ponder the engagement of **competent staff** supported by a sound recruitment plan. Key staff should be identified to anticipate any training needs and to fulfill them in a reasonable time. The less the knowledge of PART 21 and certification requirements, the more preparation is needed (See also **Module 3 – PART 2 Organisation – staff**)

This phase is not immediately transparent to the Agency and it is meant to prepare the organisation to fulfill the expectancy of EASA: to face a **smooth** and **successful** investigation. The application for a Design Organisation Approval should be preceded by a **self-assessment**, an evaluation of the organisation maturity on the different topics captured in the **Readiness checklist** (See also **Module 5 DOA Applicant Readiness Checklist**)



Useful link:

<https://www.easa.europa.eu/regulations>
EASA Learning Gateway (ELG) for Aviation Authorities and Aviation Organisations.



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Readiness checklist



The applicant should fill out the readiness checklist and attach, where applicable, supporting evidence.

Application Form

This should be not thought of as an administrative exercise, but as a **truthful self-evaluation** of the organisation. The applicant should focus on its immediate needs (e.g. customer request), limiting the initial ambition for a very comprehensive **scope of work** (see also **Module 3 – PART 1 Terms of Approval**). The applicant should find the right balance between complexity of the scope (**design activities, areas** and **privileges**) and expected target date for the DOA approval. After an approval is granted by the Agency, the applicant can still expand the DOA perimeter by means of the significant change mechanism.

Going back to the Readiness checklist, if any gap is identified (not accomplished item, partially accomplished items), the applicant should provide an action plan to bring the specific topic(s) to the expected level of “**maturity**”. An overall plan, synchronized with the various milestones of the initial investigation process, should be provided by the applicant during the kick-off meeting.

The Readiness Checklist and supporting evidence, should be submitted along with the application to EASA.



Useful link:

Application form: [FO.DOA.00080 | EASA \(europa.eu\)](#)



Phase 0 deliverables

- Readiness check list and supporting evidence
- Application Form FO.DOA.0080
- Business registration stating the company name, business registration number and legal seat of the company.



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Phase 1: EASA Administrative work and review of the readiness checklist

The initial part of this phase relates to the EASA administrative work associated with the application. The eligibility check is performed and when successfully passed, a DOATL is allocated for the technical investigation of the case. The DOATL is responsible for reviewing the completed DOA Applicant **readiness checklist**. Upon satisfactory completion of the readiness evaluation, the DOATL will liaise with the applicant to plan the Kick-off meeting. In case the checklist is not complete and/or missing supporting evidence, the **DOATL is not obliged to proceed with the meeting and the applicant is informed accordingly**.



Kick off Meeting

The Kick off Meeting represents the initial maturity gate of the process.

The meeting can be organised at EASA or at applicant own's premises, depending on the size/complexity of the organisation and the number of attendees. The applicant is advised to share as much information as possible / progress of the investigation across the organisation, to promote awareness and involvement of key staff. The applicant should carefully consider who from the Organisation should be involved in the critical steps of the process (including the kick-off meeting) to balance efficiency and effectiveness.

The meeting follows a structured Agenda involving three main streams:

- 1) Presentation of the organisation & readiness check list **(Applicant)**
- 2) Detailed Presentation of the initial investigation process & supporting tools **(EASA DOATL)**
- 3) Review of the applicant's implementation plan **(Applicant and EASA DOATL)**.

If the applicant intends to apply in parallel for a TC or a STC (or other certification exercise) and/or for a Production Organisation Approval, the Agenda should contain following additional streams of discussion:

- 4) Design Activity status and plan for certification **(Applicant)**
- 5) POA implementation plan and status **(Applicant)**
- 6) Interactions between organisational approval plans and the plan for certification **(Applicant)**

In such instances, an EASA PCM allocated to the product category and the POA Team Leader allocated to the organisation, will be requested to attend the meeting.

A Product Certificate (e.g., TC approval, STC approval ...) cannot be obtained without a Design Organisation Approval, but the two streams are not just converging at the end. The applicant and EASA should seek for synchronization all along the route to reach an effective deployment of DOA processes before associated certification deliverables are provided to the Agency.



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Same principle applies with an ongoing POA investigation, with those processes/deliverables at the interface between the two domains, e.g. transfer of applicable design data, conformity of test specimen, ... (see **Module 4 Synchronisation between DOA Initial Investigation and other investigations**)

All streams need to be discussed in depth (timing is a key factor) and conclusions captured in the minutes of meeting. When the DOATL has achieved enough confidence in the future development of the investigation, the first milestone of the process (**Check Point 1**) is achieved.



Check point 1 (CP1)

First milestone in the initial investigation. It is achieved when the DOATL has got sufficient confidence in the development of the investigation based upon the readiness level of the applicant.



Phase 1 Deliverables:

- Minutes of Kick Off meeting
- Customized PART 21 CCL
- Customized Terms of Approval Tool
- Applicant's investigation plan(s)
- Communication to the applicant of CP1 achievement
- Readiness check list



Phase 2: Handbook Review (Organisational element)

This phase revolves around the review of the Handbook's organisational element. In principle, the drafting of the processes should be initiated only upon achievement of a mature allocation of roles and responsibilities within the Organisation. People with the right **competences** and **experience**, familiar with the organisation environment and available tools, can conceive processes which have a better chance to be applied effectively in practice in the daily operations. It then becomes crucial to consolidate and to freeze the organisational aspects before launching drafting of the procedures.



Readiness evaluation

The EASA DOA team should only start the review when the applicant has validated in depth, the proposed content of the Handbook and proof of this review has been provided to EASA. This constitutes a subsequent **readiness check** in the initial investigation process, where the applicant should evaluate the maturity of the organisation, prior submitting the Handbook to the Agency for review.

See also **Module 3 PART 3 Design Organisation Handbook**.

Issues identified in this phase, resulting from an unsatisfactory outcome from EASA's review, may lead to significant delay in the investigation or even the investigation being put on temporary hold.



Key personnel assessment

Still in Phase 2, with the intent to "test" the validation mechanism installed by the applicant, the DOATL may proceed with the assessment of competence of the key personnel of the organisation, namely the HDO, Chief of Office Airworthiness and HoISM and CVEs (**Module 3 PART 2 DOA Staff**).

When EASA's review of the Handbook (Organisation) and assessment are satisfactorily concluded, the DOATL takes the decision to progress the investigation to the second milestone (**Check Point 2**).



Check point 2 (CP2)

Second milestone along the initial investigation process which is enabled through a **mature organisation set up**. It is aimed at capturing consolidated data from the applicant and at synchronizing the next steps of EASA investigation with the applicant's own plan. Collected information and performed activities are documented in the EASA form "Checklist for Checkpoint 2" and proposed by the DOATL for review and approval to their technical supervisor (Delegated DOATL).



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Phase 2 Deliverables

- Updated Applicant's investigation plan
- Proof of readiness of the Handbook (Organisation)
- Draft Handbook (Organisation)
- EASA Document Review Report
- EASA Investigation plan
- Checklist for Checkpoint 2
- Communication to the applicant of CP2 achievement

Phase 3: Handbook Review (Processes)

This phase may overlap with Phase 2, depending on the progress of the drafting process of the Handbook and its validation mechanism. The principles illustrated in Phase 2 are still valid: each process should be conceived by the relevant process owner with the contribution of the process operators. An independent person (or team) should validate (review/test/audit) the associated procedures considering two axes:



Adequacy: e.g., does it comply with PART 21? Does it fit to the organisation?

Adherence: e.g., is the DOA staff able to operate the steps and decisions within the process? Or is the process prone to deviations?

Experience and competences ensure good results, especially when facing the peculiarities of a given organisation.

The EASA DOA Team initiates their review only when the applicant has finalised the validation of the proposed process(es). This is once again a **readiness check**, where the applicant evaluates the maturity of the processes and associated deliverables (**feedback loop**) to gain the necessary operational confidence, before proposing any items for review to the DOATL. Evidence of this internal validation mechanism should be also provided to the DOATL along with a mature draft of the Handbook. It is crucial to keep the development of processes, procedures, etc. at the same pace of any on-going certification applications.

See also **Module 3 PART 3 Design Organisation Handbook**.

PART 21 requirements applicable to this part of the Handbook are numerous and depending on the scope of work of the organisation. The PART 21 CCL tool (see **Module 3 PART 4 PART 21 Compliance Check List**) allows the identification of the relevant set of requirements based upon filtering criteria tailored to the design activities.

For each relevant requirement, the applicant should provide the references to the applicable procedures, with an indication also of the internal validation means (e.g., in the remark



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column). The PART 21 CCL, filled out with Handbook/procedures reference and validation means, is the way to demonstrate to the Agency that an in-depth self-assessment has been carried out.

The EASA DOATL, based on their review, will confirm in the tool, whether compliance has been demonstrated or further investigation is needed in Phase 4.

When EASA review is satisfactorily concluded, the DOATL takes the decision to progress the investigation to the next stage (**Check Point 3**).



Check point 3 (CP3)

Third milestone along the initial investigation process. The PART 21 CCL is proposed by the DOATL for review and approval to their technical supervisor (Delegated DOATL). The technical supervisor will randomly select applicant's procedures to check the DOATL's compliance statement.



Phase 3 Deliverables

- Updated Applicant's investigation plan
- Proof of readiness of the Handbook (Processes)
- Draft Handbook (Processes)
- EASA Document Review Report(s)
- PART 21 CCL (for Handbook Organisation & Processes)
- Communication to the applicant of CP3 achievement



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Phase 4: EASA assessment of processes



This phase is meant to allow the EASA DOA Team to perform an assessment of the processes in operation. Phase 4 may overlap with Phase 3 depending on the maturity of certain processes and compliance status against Part 21 requirements.

The EASA assessment may vary based on evidence provided by the applicant from **its own validation mechanism**. The internal monitoring system of the organisation should investigate how processes are operated with the use of e.g. **dummy cases** offering a good representativeness of the design activities and associated deliverables. The Applicant's effort to provide proof of processes execution in specific areas may support DOATL's decision to focus on complementary aspects/areas and to delay further investigation at a later stage during surveillance (see Module ...).

The above justifies the statement that EASA assessment of processes is not only performed in an audit mode, but it can also encompass the review of applicant's internal audits results/validation mechanism.

During this phase, the DOATL may raise actions which can be categorized as **mandatory** or **not mandatory** for the approval. Follow up of these actions can be initiated already in Phase 4. When the EASA assessment is concluded and mandatory actions processed as necessary, the DOATL takes the decision to progress the investigation to the fourth milestone (**Check Point 4**).



Check point 4 (CP4)

Fourth milestone of the initial investigation process which revolves around a meeting between the DOATL and a panel of Delegated DOATLs. The DOATL is in charge for authoring an **Initial Investigation Report**, which is the core document for the conduct of the CP4 meeting and it is meant to provide exhaustive:

- I. Administrative data:
 - ▶ for the proper identification of the DOA holder within the EASA DOA database.
 - ▶ for defining the content of the DOA certificate and Terms of Approval
- II. Description of the investigation and methods of work
- III. Review of key processes in the DOA
- IV. Surveillance data (anticipation of the surveillance activities in the first cycle).
- V. Conclusion Statement (recommending the approval of the organisation)



The target for a CP4 meeting is to review the main steps of the initial investigation, looking not only at the way key subjects were addressed, but also at the peculiarities and at any kind of difficulties experienced by the DOA Team during the process.

This event is established also to ensure a certain level of standardisation within the DOATL



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community and a uniform application of the rules and guidance.

The Panel of Delegated DOATLs may still raise **mandatory** actions to be transferred by the DOATL on the organisation and to be followed up during Phase 5 of the investigation.

The Initial Investigation Report is ultimately approved by a Delegated DOATL.



Phase 4 Deliverables

- Final draft of the Handbook (missing only the DOA certificate and the Terms of Approval)
- Approved DOA Initial Investigation Final Report (and supporting evidence)
- Surveillance plan for the coming cycle
- PART 21 CCL
- Actions list (with status)
- Draft DOA certificate
- Draft Terms of Approval
- Communication to the applicant of CP4 achievement

Phase 5: Follow up

This phase is meant for the follow up of the mandatory actions and the accomplishment of the administrative steps in the process. Satisfactory conclusion of this phase triggers the issuance of the DOA certificate and Terms Approval.



Issue of DOA Certificate

The DOA applicant becomes a DOA holder, entitled to perform design activities (within its **terms of approval**), with a set of advantages (**privileges**) and responsibilities (**obligations**), relying on a mature framework (**design assurance system**) enabler of an airworthy (**safe**) design. The DOATL in charge for the initial investigation, in most of the cases, will oversee the organisation during the coming cycle.



Good communication and transparency between the responsible persons in the DOA and the DOATL are essential to build and maintain a trustful work relationship.

Phase 5 Deliverables

- DOA Certificate
- Terms of Approval
- Handbook approved by the DOA
- Communication to the holder with formal letter including the DOA Certificate and the Terms of Approval



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Module 3 DOA Initial Investigation Highlights

PART 1 Terms of Approval



What is the content of the **DOA Terms of Approval**?

With reference to **21.A.251**:

*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 with regard to the airworthiness, operational suitability and environmental characteristics of the products. For design organisation approvals covering type-certification or European Technical Standard Order (ETSO) authorisation for auxiliary power units (APUs), the terms of approval shall contain in addition the list of products or APUs. Those terms shall be issued as part of a design organisation approval.***

This PART intends to provide an illustrative explanation of the Terms of Approval.

The generation of the Terms Approval stems from a dedicated tool and a detailed explanation is provided to the DOA applicant by the DOATL at the time of the kick-off meeting.



The **types of design work** are related to those aspects of a product (e.g., Large Aeroplane, Small Aeroplane, Rotorcraft) where a DOA can perform **design activity** (e.g., TC, changes, repairs, flight condition privilege, permit to fly privilege). These aspects are defined in two levels for non-TCH cases: **Scopes** and **Areas**.



❖ SCOPE

This is the highest **level** of scope defined in the Terms of



Approval:

- ▶ Flight
- ▶ Structures
- ▶ Cabin
- ▶ Avionics
- ▶ Electrical systems
- ▶ Hydro-mechanical systems
- ▶ Environmental control systems
- ▶ Rotor drive systems
- ▶ Powerplant and fuel systems
- ▶ Propulsion



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❖ AREAS



Within each scope, Areas might need to be identified.

Examples:

- ▶ [Flight]:
 - ▶ Flight characteristics
 - ▶ NVIS
- ▶ [Structures]:
 - ▶ Fuselage
 - ▶ Wings,
 - ▶ Landing gears, etc.
- ▶ [Cabin]:
 - ▶ Cabin interiors
 - ▶ Electrical cabin systems, etc.
- ▶ [Avionics]:
 - ▶ Auto Flight systems
 - ▶ Communication systems, etc.

❖ TECHNICAL DISCIPLINES



Not appearing directly on the Terms of Approval, are those technical fields where the DOA must have **sufficient competence** to be able to perform design activities for the scope of work. These are defined per EASA panels (ref. to DOA SCOPE OF WORK tool).

Examples:

- Flight disciplines:
 - Flight Test
 - Handling Qualities
 - Performance
 - Human Machine Interface and Cockpit integration
 - Flight Manual
 - Human Factors
- Structures disciplines:
 - Loads
 - Static strength and proof of structure
 - Fatigue and damage tolerance
 - Materials & Manufacturing
 - Aeroelasticity
 - Crashworthiness
 - Rapid decompression
 - Impact
- Cabin Safety disciplines:
 - Occupant crashworthiness/restraint
 - Fire Protection - pressurised areas
 - Occupant evacuation
 - Cargo restraint
 - Security aspects
 - Human External Cargo Restraint
 - Standard cabin interior items
 - Rotorcraft Ditching
 - Special Interior Features
- MMEL
 - Impact assessment / Engineering judgement
 - Detailed Safety Analysis
 - Flight Crew aspects (workload, etc.)

Disciplines in the DOA might be not completely matching EASA panels, as the applicant remains entitled to define them in relation to the actual scope of a DOA.



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❖ LIMITATIONS



They might be needed to further define the scope of approval. These are normally based on technical disciplines and are in most cases standardised.

Examples:

» **Scope: Cabin**

- ▶ **[Structures]:** Primary structure is excluded
- ▶ **[Cabin Safety]:** Seat installation requiring new demonstration of compliance to CS-xx.562 "Emergency landing dynamic conditions" is excluded
- ▶ **[Flight]:** Design activities requiring flight testing are excluded
- ▶ **[OSD]:** Changes affecting OSD are excluded

» **Scope: Avionics**

- ▶ **[Development Assurance]:** Development of AEH with IDAL A, B and C is excluded
- ▶ **[Avionics]:** Design activities on Navigation systems with hazardous failure conditions are excluded
- ▶ **[Flight]:** Design activities requiring flight testing are excluded
- ▶ **[OSD]:** Development of Operational Suitability Data excludes the OSD constituents FCD and SIMD

The Terms of Approval indicate also:

- ❖ **Privileges:** the benefits from setting up a Design Organisation Approval. They are captured under 21.A.263 and those applicable to the given DOA are mirrored on the Terms of Approval.
- ❖ **Obligations:** specified under 21.A.265 and must be continuously fulfilled by the DOA.

In a nutshell, the DOA Terms of Approval indicates:

1. **Scope of work**

» It will refer to an [annex A](#), which will include:

▶ **Scope of work**

- ▶ Product/Scope/Area
- ▶ Type of design work (TC, STC, minor changes, etc.)

▶ **List of types**

▶ **Limitations**

2. **Privileges**

» As per 21.A.263

3. **Obligations**

» As per 21.A.265



DOA Initial Investigation Information Paper

Example of Scope of Work

Scope of Work

	TC	STC	major changes	minor changes	major repairs	minor repairs	flight conditions	permit to fly
Large aeroplane								
Avionics								
Communication systems		■	■	■				
Diagnostic and Maintenance systems		■	■	■				
Indicating, Alerting systems		■	■	■				
Navigation systems		■	■	■				
Recording systems		■	■	■				
Surveillance systems		■	■	■				
Cabin								
All areas		■	■	■	■	■	■	■
Small aeroplane								
All scope (TCH)								
All areas	■		■	■	■	■	■	■
Avionics (non-TCH activity)								
All areas		■	■	■			■	■

List of products and types

Product	Design Activity	Types
Small aeroplane	TC	GA-Type-01 GA-Type-02

Limitations

	Common Limitations
	[Development Assurance] Development of SW and AEH with IDAL A, B and C is excluded
Product	Product Limitations
Large aeroplane	[Flight] Design activities requiring flight testing are excluded [Structures] Primary structure is excluded
Small aeroplane	None



DOA Initial Investigation Information Paper

The attached file “**DOA SCOPE OF WORK**” provides the link among Scopes, Areas and Technical Disciplines.



This file (which is appended to the EASA Terms of Approval Tool – see Figure below) can support the DOA applicant in the translation of its design needs into EASA scope of work and in the determination of competence required to support those design needs.

EASA Terms of Approval Tool

The screenshot shows the EASA Terms of Approval Tool interface. It includes several key sections:

- TCH activity:** A yellow callout pointing to the 'TCH DOA Activity' section, which lists various types of changes (e.g., minor change, major repair) with 'yes' or 'no' options.
- DOA Scope / Areas:** A yellow callout pointing to the 'Large aeroplane' and 'Non-TCH design activity' sections, which define the scope of the design activity.
- Non-TCH Design activity:** A yellow callout pointing to the 'Non-TCH design activity' section, which lists specific design activities like 'major changes', 'major repairs', etc.
- Limitations:** A yellow callout pointing to the 'LIMITATIONS' section, which lists various limitations such as 'Lift-off weight and balance', 'Stress strength', etc.
- Technical disciplines:** A green callout pointing to the 'TECHNICAL DISCIPLINES' section, which is a large grid listing various technical disciplines (e.g., Aerodynamics, Structures, Electrical) and their applicability to different products.



The functionalities in the tool are presented to the applicant during the Kick Off meeting with the responsible EASA DOATL.



DOA Initial Investigation Information Paper

PART 2 DOA staff

This module aims at focusing on the Part 21 expectancy with regard to **Design Organisation's Human Resources**.



As briefly introduced in **Module 1 – DOA concept**, **21.A.245** intends to give approval requirements at organisational level. Namely:

- to have, in all technical department, competent staff in sufficient number, with appropriate authority,
- to ensure efficient coordination in-between people responsible for airworthiness, OSD and environmental protection matters.

Depending on the complexity and scope of the DO, the staff in all technical departments referred above may involve different positions (e.g. design engineer, configuration engineer, calculation engineer, test engineer, etc.) for the different technical activities necessary for the certification of a product or a change/repair, etc. For simplicity we refer to all these positions as Design Engineers.

The GM No 1 to 21.A.245 introduces general and personnel aspects to be considered by the DOA for ensuring the competence of all the Design Engineers.

The GM makes clear that the DOA has to show that the Design Engineers have the skills, the special qualifications and the ability to provide assurance of design and compile the compliance data needed to meet the applicable requirements and must consider the state of the art and new experience.

In addition to 21.A.245, two other requirements shall be considered – **21.A.243(d)** and **21.A.239(a)**:

21.A.243(d) and related GM are dedicated to **key management staff**, for which a statement of qualification and experience shall be furnished. This requirement is usually answered by completing an 'EASA **Form 4**' for the following function holders:



- Head of the Design Organisation,
- Chief of the Office of Airworthiness and
- Chief of the independent monitoring function of the Design Assurance System (DAS)

Some of these functions may be combined or subdivided.



DOA Initial Investigation Information Paper



The Agency is not approving individuals; Form-4 nomination should be the result of a nomination process part of the Design Assurance System (DAS) itself.

The nominated managers should be identified and their credentials furnished to the Agency on EASA Form 4-DOA (see EASA website: <http://easa.europa.eu/certification/application-forms.php>) 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.

GM No.1 to **21.A.239(a)** describes the minimum tasks to be performed in the frame of the DAS and the tasks/responsibilities of the Chief Executive, the 'Form 4' holders and the CVEs.

TIPS



The following points are key aspects to be covered as part of the DAS, together with some illustrations:

► Quality (competences)

Criteria in terms of minimum education and experience should be defined for each type of position in the DOA and respected during the selection process of a new staff member.

► Quantity (enough staff to absorb the workload)

Project estimated hours workloads versus capacity and Gantt charts for planning are typical tools used to show compliance with 21.A.245(a).

► Redundancy (deputisation in case of absence)

'Form 4 holders' should have deputies in case on long absence, CVE positions should be doubled as well.

► Authority/ empowerment (position in the company and nomination to a DOA role)

Letters of nomination are usually issued to formalise 'Form 4 holders' and to define technical scope of CVE/DE.



DOA Initial Investigation Information Paper

➤ Responsibility

Staff working in the DOA shall be fully aware that they are part of the DOA organisational structure and the tasks they are responsible for. This also applies to persons working in a department which is at an interface of the DOA (e.g. procurement) who shall also be aware of their position.

➤ Competence (training and monitoring of competences)

A training program should define the needs for the different DOA roles

➤ Assets (accommodation, facilities and equipment)

the relevant persons should have means to perform their daily work (offices, computers, Software, access to tests facilities, workshops, production facilities, prototype parts...)

➤ Organigramme

The position of the DOA within a company needs to be clearly identified, for instance, which Departments, Sections and/or which staff belong to the Design Organisation

Inside the DOA, hierarchical and functional links should be clearly identified

➤ working together efficiently

Periodical and frequent meetings, involvement in and debriefing of audits are example of means allowing good coordination and improvement on DOA and Certification subjects.



Useful link

For more information, please refer to the following J-News articles:

- J-News [2018/2/2](#) *Item 2. Nomination of key personnel & Deputy roles*
- J-News [2019/3/5](#) *Are you competent at competence? – Part 1*
- [Design and Certification Newsletter 2021](#) *Are you competent at competence? – Part 2*



PART 3 Design Organisation Handbook

A Design Organisation needs to follow documented procedures, to perform *planned* and *systemic* actions when it comes to *Design*, *Certification* and *Continued Airworthiness activities*. This is the key reason why a Handbook is needed and why the organisation should ensure adherence to it.

Following key PART 21 requirement supports the drafting process of the Handbook:



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.

and **AMC1 21.A.243(a) Data requirements.**

Other requirements, supporting the drafting process of the handbook, are directly linked to the scope of work and can be determined by using the PART 21 Compliance Check List ((see **Module 3 PART 4 PART 21 Compliance Check List**)

Nevertheless, before starting the drafting process, the applicant should invest some time in defining the structure of the handbook itself.

Different options are available, but in choosing the option fitting best the organisational environment, the applicant should also strive to:



install an easy process to keep the handbook up to date (**21.A.243 c**) and to maintain it in conformity with the Design Assurance System (**21.A.265 a**), and



to ensure that this handbook or the relevant procedures included by cross-reference are used as a basic working document within the organisation (**21.A.265 b**).

The format of the Handbook/Procedures may vary also over a range of possible options:

- Classic Handbook (paper or pdf)
- HTML based system
- Quality Management IT system
- ...

Guidance provided on next pages are applicable, in terms of content, to any of the above options.

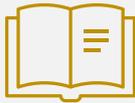


DOA Initial Investigation Information Paper

As explained in **Module 2**, the content of the handbook develops over the different phases of the DOA initial investigation process and should support especially the achievement of **CP2** (organisation and competences) and **CP3** (processes).

Bearing this in mind, in most of the cases the applicant could organize the handbook in three main Parts:

INTRODUCTION



As an example...

- Objective of the handbook and binding statement
- Statement of undertaking (if relevant)
- Description of the structure of the handbook
- Amendment and approval process (which can vary over the different Parts of the handbook or over the “entity” amendment)
- List of effective pages (if relevant)
- Distribution List (or method for making the handbook available)
- Acronyms and Abbreviations
- ...

PART I - ORGANISATION



As an example...

- History of the Company
- Scope of work (description of tasks which can be performed under the approval, e.g., examples of changes to products to be designed, list of products if applicable)
- DOA Certificate and Terms of Approval
- Presentation of the Design Organisation [general description of the organisation, including locations, its main departments, their functions and the names of those in charge]
- Organisation charts (along with a description of the line management and of functional relationships between the various departments)
- A description of assigned responsibilities and delegated authority of all parts of the organisation which, taken together, constitute the organization’s Design Assurance System together with a chart indicating the functional and hierarchical relationship of the system to Management and to other parts of the organisation (e.g., **POA**,



DOA Initial Investigation Information Paper

- PART 145**...); also the chains of responsibilities within the Design Assurance System; and the control of the work of all partners and sub-contractors
- clear definition of the tasks & areas of responsibility of the **Office of Airworthiness**
 - clear definition of the tasks & areas of responsibility of the **Independent System Monitoring Function**;
 - List of Partners and Subcontractors along with the subcontracted tasks (cross reference would work better in case of frequent update)
 - Design Organisation Manpower (calculated i.a.w. the instructions provided in EASA Form 80) distributed over the different locations
 - The names of the Design Organisation authorised signatories
 - DO staff competence requirements; selection and appointment process scope of authorisation; training policy (initial and recurrent); personnel records retention
 - Tools (e.g., **software & equipment**)
 - Facilities (e.g., **for Ground & Flight Test**)
 - outline of the system for controlling and informing the Staff of the organisation of current changes in engineering drawings, specifications and design assurance procedures (e.g., **cooperative platform, intranet, notification system**)
- ...



PART II - PROCEDURES & FORMS

As an example, procedures addressing:

- Management of Significant/Non significant changes
- Management of EASA findings/requests
- The means by which the continuing evaluation (**system monitoring**) of the design assurance system will be performed to ensure that it remains effective, including reporting to the management staff (e.g., Head of Design Organisation)
- Type Investigation process
- Management of Certification Programme (content and update)
- Classification and approval of changes and repairs
- Documentation control & configuration control
- Management of specific privileges (e.g., **Certain Major Changes** or **Certain STCs**)
- Transfer of applicable and approved data from DO to PO/PART 145
- Approval of unintentional deviations from the approved design data occurring in production (concessions or non-conformance's)
- Selection & Surveillance of Design Subcontractors



DOA Initial Investigation Information Paper

- Establishment and control and distribution of the maintenance and operating instructions
- Establishment and control of the operational suitability data
- The way in which the organisation performs its functions in relation to the continuing airworthiness of the product it designs, including co-operation with the production organisation when dealing with any continuing airworthiness actions that are related to production of the product, part or appliance, as applicable
- The means by which the organisation collects, monitors, analyses and responds to reports of problems which cause or might cause an adverse effect on the airworthiness of its product, part or appliance during design, production and in service (include both mandatory and voluntary occurrence reports from organisations and natural persons involved in the operation and maintenance of the product, part or appliance)
- Record-keeping system
- List of all forms supporting the above procedures

TIPS



The Handbook could also be organised in a way that PART II provides only a short summary of the DOA procedures; their full scope can be addressed then in stand-alone documents. This approach simplifies the amendment process of the Handbook.

For large Companies, where the approval loop for an update of the Handbook may take a while, it could be beneficial to install a streamlined validation system (for a predefined set of updates, e.g., editorial) w/o involvement of the HDO or other High management representative in the approval of the specific amendment.

Forms should be provided with filling instructions (directly or indirectly).

Procedures should be authored and verified by the relevant process owners; nevertheless, the applicant should strive for a harmonized approach across the Handbook. Combination of styles (the use “narrative only” for some procedures and “flowchart only” for others, should be discouraged).

Procedures should be easy to read and understand, to minimize the risk of staff deviating from them. A suitable approach is a combination of flowcharts (identifying steps, steps ‘operators, inputs, outputs, tools) and narrative (explaining in further details the step, where deemed necessary).



DOA Initial Investigation Information Paper

The applicant should install a system to collect and process feedback from the process operators, for early detection of adequacy issues and/or difficulties in the day-by-day application.

Copy and paste of Part 21 requirements or AMC/GM directly in the procedures should be avoided (except for the statements), as procedures and forms should reflect the implementation of applicable requirements and ways of working of the DOA.



PART 4 PART 21 Compliance Check List (CCL)

This part intends to provide an illustrative explanation of the Part 21 CCL DOA tool, hereafter referred to as 'Part 21 CCL'.

The Part 21 CCL can be linked to 21.A.235 Issue of Design Organisation Approval and 21.A.259 Duration and continued validity in the sense that it supports and records the initial and continuous demonstration of compliance to Part 21.



This Excel-based tool is used to record compliance to Part 21 information all along the DOA life.

It should be used as a support when reviewing the handbook and procedures by the applicant who fulfil the column 'company procedures' and by the DOATL who checks the accuracy of data, by using and referring to its own validation means.

The selection of applicable Part 21 requirements is linked to the Terms of Approval of the DOA. Whereas the selection is anticipated at the beginning of the initial investigation, it can change together with the Terms of approval evolution and in a more recurrent way with the successive amendments of Part 21.



The Part 21 CCL is provided to the applicant at the beginning of the initial investigation and the functionalities in the tool are presented.

The DOA receive Part 21 CCL updates triggered by an amendment of Part 21 from the DOATL.

Usage of the P21CCL by the DOA is not mandatory, but it has proven to be a very useful tool in the relationship between DOA and EASA.

The DOATL uses the Part 21 CCL to structure the surveillance activities and to record the audits results. This can be equally done by the DOA holder during its own internal surveillance.

The DOA can use it to build the internal audits'.

Part 21 DOA CCL														Name - 21J.nnn					
Part 21 point	Title	Part 21 requirement	Auditable?	DOA Core Process	Key subject	TC	STC & minor changes	Changes by TCR & Contr. Airw.	Repairs	Minor changes only	Minor repair only	ETSOA for APU	ETSOA (except APU)	Company procedures allowed	Compliant?	Year 1	Year 2	Year 3	Remarks
GENERAL																			
21.1 (a)	General	For the purpose of this Part, 'Competent Authority' shall be: for organisations having their principal place of business in a Member State, the authority designated by that Member State; for organisations having their principal place of business in a non-member State, the authority designated by that non-member State.	No			No	No	No	No	No	No	No	No						
21.1 (b)	General	For the purpose of this Part, 'Competent Authority' shall be: for organisations having their principal place of business in a Member State, the authority designated by that Member State; for organisations having their principal place of business in a non-member State, the authority designated by that non-member State.	No			No	No	No	No	No	No	No	No						
SUBPART A - GENERAL PROVISIONS																			
21.A.1	Scope	General provisions governing the issue, validity, suspension, revocation, and renewal of certificates of approval, and the conditions and obligations required to be undertaken by the holder of, or applicant for, a certificate for a product, part, or appliance under this Section may be undertaken on its behalf by the holder of, or applicant for, a certificate for a product, part, or appliance under this Section.	Yes	Core process	Key subject	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes						
21.A.2	Validity	Validity of a certificate of approval shall be subject to the conditions and obligations required to be undertaken by the holder of, or applicant for, a certificate for a product, part, or appliance under this Section.	Yes	Core process	Key subject	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes						
21.A.3A(a)	Reporting to the Agency	System for Collection, Investigation and Analysis of Data. The holder of a type-certificate, restricted type-certificate, supplemental type-certificate, European Technical Standard Reporting to the Agency.	Yes	Core process	Key subject	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes						
21.A.3A(b)(1)	Failures, malfunctions and defects	The holder of a type-certificate, restricted type-certificate, supplemental type-certificate, ETSO authorisation, major repair design approval, or approval for a part, shall report to the Agency, as soon as practicable and in any case dispatched not later than 72 hours after the occurrence, the following information:	Yes	Core process	Key subject	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes						
21.A.3A(b)(2)	Failures, malfunctions and defects	These reports shall be made in a form and manner established by the Agency, as soon as practicable and in any case dispatched not later than 72 hours after the occurrence.	Yes	Core process	Key subject	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes						
21.A.3A(c)(1)	Failures, malfunctions and defects	Investigation of Reported Occurrences. When an occurrence reported under point (b), or under points 21.A.129(F)(2) or 21.A.165(F)(2) results from a deficiency, the holder of the type-certificate, restricted type-certificate, supplemental type-certificate, major repair design approval, or approval for a part, shall report to the Agency, as soon as practicable and in any case dispatched not later than 72 hours after the occurrence, the following information:	Yes	Core process	Key subject	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes						
21.A.3A(c)(2)	Failures, malfunctions and defects	If the Agency finds that an action is required to correct the deficiency, the holder of the type-certificate, restricted type-certificate, supplemental type-certificate, major repair design approval, or approval for a part, shall report to the Agency, as soon as practicable and in any case dispatched not later than 72 hours after the occurrence, the following information:	Yes	Core process	Key subject	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes						



DOA Initial Investigation Information Paper

The tool provides for filtering versus the activities performed by the company and instructions to do so. Other criteria such as "Auditable?", "DOA Core Process", "Key subject" and "Company procedure references" may be used to filter requirements.

The applicant is encouraged to familiarise themselves with the tool. All functionalities will be presented by the DOATL during the kick off meeting.



DOA Initial Investigation Information Paper

Module 4 Synchronization between DOA Initial Investigation and other investigation activities



When the DOA Initial Investigation runs in parallel with a Type Investigation (e.g., STC), the DOA applicant shall ensure that two applications are kept progressing at the same pace.

This is to fulfill the basic principle that Type Investigation associated deliverables (e.g., certification documents, compliance data...) are released:



- based upon agreed procedures and
- By involving competent DOA staff

With reference to [GM1 21.A.239\(a\)](#) Design Assurance System

“Type Investigation” means the tasks of the Organisation in support of the Type-Certificate, Supplemental Type-Certificate or other Design Approval processes necessary to demonstrate and verify and to maintain compliance with the applicable CS and Environmental Protection requirements.

“Design Assurance “ is the complete process, starting with the CS and Environmental Protection requirements and product specifications and culminating with the issuing of a Type-Certificate.

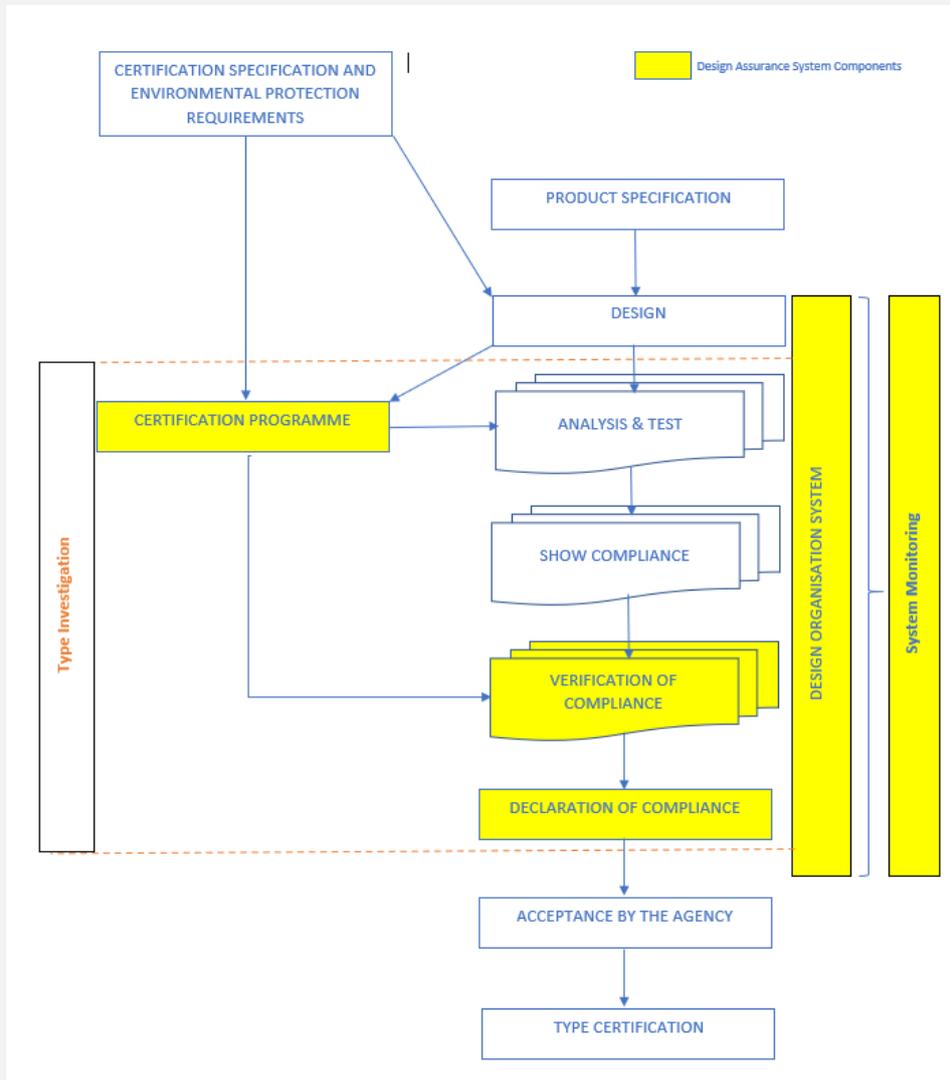
The EASA expectation is that a DOA applicant should file an application for a certification exercise when the necessary level of maturity is achieved within the Design Assurance System and demonstrated to the Agency, by the achievement of agreed milestones/gates disseminated all along the DOA initial investigation path.

Bearing those definitions in mind, and looking at the figure and explanation on the next page, the applicant can better understand why such synchronisation is needed.



DOA Initial Investigation Information Paper

The Figure below (PART 21) highlights the relationship among the Design, the Type Investigation and Design Assurance Processes.



Investigation and Design Assurance Processes.

Tasks supporting the type investigation are in turn supported by processes and processes operators, in which, during the DOA initial investigation, EASA shall gain progressively the necessary level of confidence

The intent of this Module is to provide some good examples of synchronisation, but it is far from representing an exhaustive list. The purpose is more to instill the correct principles, rather than providing a synchronisation model proven to address all possible cases.



DOA Initial Investigation Information Paper

Example 1: Application for a Supplemental Type Certificate (with an ongoing DOA Initial Investigation)

What does the applicant need to establish before sending:



- an application to the Agency for an STC?
- Certification Programme?
- Compliance data?

To answer the above questions, the applicant should be aware of the different phases associated to (S)TC investigations. The following table illustrates all phases and associated deliverables (applicant and EASA).

These phases are applicable to all Certification projects, but for smaller projects they may be condensed and/or combined.

Phase	0	I	II	III	IV
Description	Definition and agreement of the working methods	Technical familiarisation and establishment of the TC basis	Agreement of the Certification Programme and Level of Involvement	Compliance determination	Final phase
Deliverables from the applicant	<ul style="list-style-type: none"> • Application form • General Technical description • Classification of the change/STC (if applicable) • Initial proposal of Cert. Programme • Proposal of certification basis 	<ul style="list-style-type: none"> • Detailed Technical description normally at system level • Proposal of certification basis • Cert. programme (revised as needed) including draft identification of CDI 	<ul style="list-style-type: none"> • Cert. Programme (CP) • Identification of CDI (in the CP if suitable) • Justified proposal classification of CDI (likelihood and severity) according to EASA Certification Memorandum (in the CP, if suitable); • Proposal of LOI for each CDI (in the CP, if suitable); 	<ul style="list-style-type: none"> • Certification reports on the compliance activities (statements, descriptions, analysis, inspections, tests, audit, etc.); • Inform EASA on every difficulty; 	<ul style="list-style-type: none"> • Declaration of compliance; • Draft TCDS/N • Any other deliverables according to EASA internal procedure (Certification Handbook)
Deliverables from EASA		<ul style="list-style-type: none"> • First draft of CRI A-01 (or certification basis) 	<ul style="list-style-type: none"> • Acceptance of cert. programme; • Notification of LOI (through specific CRI/CAI, letter, email or form) 	<ul style="list-style-type: none"> • Any deliverable required by the nature of the Agency's involvement • Adaptation of the notified LOI on the basis of experience during project duration 	<ul style="list-style-type: none"> • SoTS (modified to reflect the LOI concept); • TV; • TCDS/N; • Final CRI A-01 (and closure of other CRI/CAI); • Any other deliverables according to EASA internal procedure (Certification Handbook); • Final report.



DOA Initial Investigation Information Paper

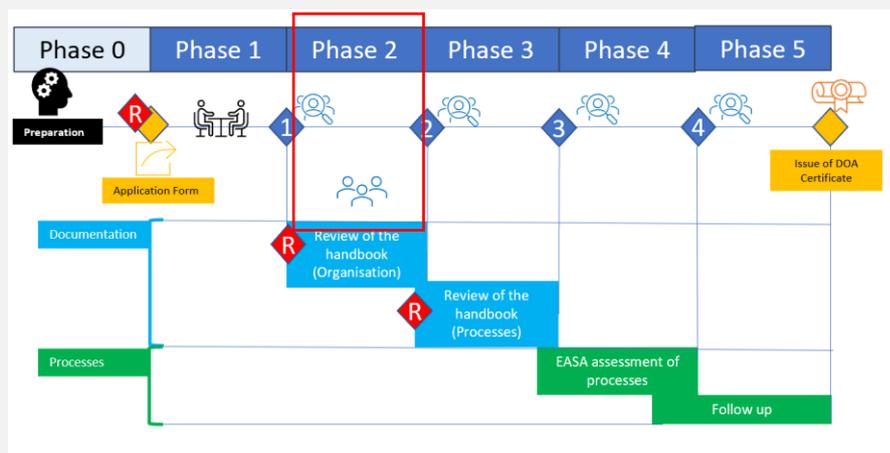
Let's try to get some answers now!



➤ **What does the applicant need to establish/determine before sending an application to the Agency for an STC?**

From a process perspective, the applicant should be able to:

- ✓ verify if the project fits in the expected scope of work (**Terms of Approval**). This is a crucial step, as the organisation shall evaluate if the right competences (inside the company and/or subcontracted) are available. The expected level of maturity from an organisational point of view is achieved when the DOA initial investigation has gone through Phase 2 and CP2 has been successfully passed. To locate this phase in the process, see picture below (and Module 2 for more details):



- ✓ identify if the design activities have achieved the expected maturity level (design freeze with respect to the initial product specification) such to enable the decision to progress into the Certification exercise (Type Investigation);
- ✓ propose an adequate Certification Basis;
- ✓ build the initial Certification Programme.

In other words, the applicant shall be, as minimum, able to master above concepts and to translate them into procedures.



DOA Initial Investigation Information Paper

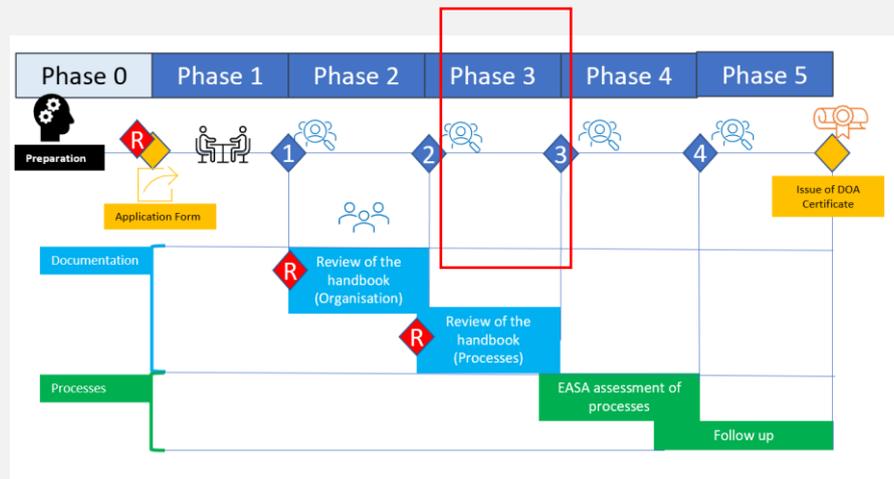


➤ What does the applicant need to establish before sending the Certification Programme?

The Certification Programme (with a progressive level of completeness and complexity) is the main deliverable across Phases 0, I, II of an (S)TC investigation.

- ✓ On a background defined by the Type Investigation end to end process, the applicant should define the procedure to determine the content of the Certification Programme (including all relevant elements in 21.A.15) and to update it across the project.

Procedures for the management of Type Investigation Process and for the definition/management of the Certification Programme (and associated templates) are reviewed by EASA during the Phase 3 of the DOA Initial Investigation. To locate this phase in the process, see picture below (and Module 2 for more details):



Phase 3 of the DOA initial investigation should anticipate, Phase II of the type investigation, in order to allow a solid and formal agreement of the proposed LOI.



➤ What does the applicant need to establish before sending compliance data for EASA review?

- ✓ Following the same principle illustrated so far, release of compliance data (retained and not by EASA) should be based on a process managing identification, content, verification/approval and update of such data.
Assessment of the maturity of an Organisations competences does not take place prior to CP2 completion.
Related process maturity is assessed during Phase 3 of the initial investigation.
The above two steps enable Phase III of the STC investigation.



DOA Initial Investigation Information Paper

Example 2: Application for a Type Certificate (with an ongoing DOA initial investigation and POA initial investigation)

The synchronization requires more effort in case a POA investigation is also ongoing. Processes dealing with the interfaces between DOA/POA should be mature (Phase 3 of the DOA Initial Investigation).



➤ What does the DOA applicant need to ensure when starting the manufacturing of a test specimen?

From a process perspective the applicant should have defined procedures/systems/responsibilities

- For the transfer of up-to-date applicable data;
- To deal with unintentional deviations and requests for changes of released design data.

On the other side, the POA should have already process in place to:

- Receive up-to-date data and to translate them in manufacturing data;
- Reporting deviations/queries for design data update;
- Conformity process.