

Notification of a Proposal to issue a Certification Memorandum

Eligibility for type certificate application

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Regulatory requirement(s): 21.A.13

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Log of issues

Issue	Issue date	Change description
01	19.10.2022	First issue.

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1. Introduction

1.1. Purpose and scope

The European Aviation Safety Agency, hereafter referred to as the “Agency”, may receive requests from organizations to provide technical advice services prior to or outside an actual certification process conducted within the scope of Part 21. These activities or “pre-application services” are performed by the Agency on a purely voluntary basis and are regulated by a contract between the Agency and the client. When a product becomes sufficiently mature, an application is submitted to the Agency.

The purpose of this Certification Memorandum is to support applicants, before they submit a TC application to EASA, in assessing their readiness for such an application. It therefore provides specific guidance for potential type certificate (TC) applicants in meeting EASA expectations regarding their eligibility and the related demonstration of capability in the context of certification. When an applicant is not ready, the above pre-application services may be used as appropriate.

1.2. References

It is intended that the following reference materials be used in conjunction with this Certification Memorandum:

Reference	Title	Code	Issue	Date
Commission Regulation (EU) No 748/2012 (including its subsequent amendments)	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	N/A	N/A	03/08/2012

1.3. Abbreviations

ADOA	Alternative Procedures to Design Organisation Approval
AMC	Acceptable Means of Compliance
CERT	Certification
CM	Certification Memorandum
CONOPS	Concept of Operation (including operations, air space, licensing)
DOA	Design Organisation Approval
EASA	European Union Aviation Safety Agency
FC	Flight Conditions
GM	Guidance Material
IPC	Innovation Partnership Contract

PAC	Pre-application Contract
SC	Special Condition
TC	Type Certificate

2. Background

2.1. Problem statement

The Agency observes an increasing number of certification projects initiated at a development stage when the respective project has not an adequately defined concept of operations (CONOPS) or the product is not sufficiently mature to allow the type investigation to progress in an effective manner.

This situation becomes even more evident when the applicant itself is a 'newcomer'. Such applicants may have to deal with several challenges at the same time: the establishment of the CONOPS, the development of the product and the setup of an organization able to demonstrate its design capability and perform the product type certification.

This situation can lead to inefficiencies and unnecessary delays in the certification activities. The purpose of this guidance is to support industry in their innovation efforts, by giving guidance on what is the optimum timing, from a technical and organisational readiness perspective, to apply for product certification.

2.2. Regulatory context

For a TC application, Annex I (Part 21) to Regulation (EU) No 748/2012 specifies the eligibility criteria for the applicant in point 21.A.13:

'Any natural or legal person that has demonstrated, or is in the process of demonstrating, its capability in accordance with point 21.A.14 shall be eligible as an applicant for a type-certificate or a restricted type-certificate under the conditions laid down in this Subpart.'

The available options for demonstration of capability are provided in point 21.A.14 and depending on the product complexity these are:

- holding a DOA;
- EASA agreement for the use of Alternative Procedures (ADOA);
- EASA acceptance of the certification programme.

Currently, point 21.A.13 has no GM or AMC helping a potential applicant to prepare themselves for starting the product certification and determine the right timing for submitting the TC application.



3. EASA Certification Policy

3.1. Organisational maturity and capability demonstration

A TC applicant shall have demonstrated its capability or, at least, shall be in the process of demonstrating its capability (ref: 21.A.13 and 21.A.14). The options available for the demonstration of capability are prescribed in point 21.A.14 and depend on the product category.

A potential applicant decides when the right moment is to apply for the TC. When taking this decision, various aspects related to the organizational and the product maturity should be assessed.

In particular, for a first TC application, a new applicant might deal with several challenges related to the need to secure its resources (e.g. financial and human) and build up an organization that should work efficiently and at the same time conform with the regulatory environment.

Some applicants interpret the eligibility criteria in 21.A.13 in the way that the TC application may be submitted in the same day (or the day after) as the capability demonstration application (e.g. the Design Organisation Approval application). Even if this is still in line with 21.A.13, practice shows that this late capability demonstration application for compliance with 21.A.14(a) or (b) is not efficient and leads to an increased workload due to necessary retroactive corrections.

Depending on the capability demonstration option that applies according to 21.A.14, the following cases can be differentiated:

3.1.1. Demonstration of capability through the Certification Programme (21.A.14(c))

In this case the applicant does not apply separately for the capability demonstration. The capability is demonstrated in a limited, simplified way, through the ability to submit a mature certification programme.

The type certificate application should include, or be supplemented after by, the certification programme. In the absence of a mature certification programme, the activities of the EASA certification team cannot be initiated.

Guidance on the contents of the Certification Programme can be found on the EASA website ([here](#)).

3.1.2. Demonstration of capability through the agreement of Alternative Procedures (21.A.14(b))

In this case the applicant should seek the EASA agreement for the use of Alternative Procedures to Design Organisation Approval (ADOA) before the TC application. The applicant should set up procedures that state the specific design practices, resources and sequence of activities in accordance with AMC1 21.A.14(b). These procedures should describe the pre-TC and the post-TC activities.

At the time of the TC application, the applicant should be able to present a mature set of procedures covering at least the pre-TC activities. Based on this set of procedures, the Agency should be able to find compliance with the applicable requirements in Part 21 in order to provide its agreement.



3.1.3. Demonstration of capability through the Design Organisation Approval (21.A.14(a))

In this case the applicant should apply for a Design Organisation Approval (DOA) with sufficient time before the TC application, thus allowing the applicant to build up its organisation.

For the guidance related to a DOA application refer to 'DOA Initial Investigation Information Package' published on the EASA website / [Design organisations page](#).

Once EASA receives the DOA application it initiates a specific investigation process. This process has its own phases, and the applicant should look for a proper coordination between the DOA investigation and the related type certification activities.

At the time of the TC application, the applicant should have already demonstrated through the DOA investigation an appropriate level of maturity. The organization should have key position holders nominated, relevant design and certification processes defined and documented and staff competences found satisfactory (see more details in the Appendix to this Certification Memorandum).

In addition, independent of the route selected for capability demonstration, a potential applicant for a TC should also consider that the type certification activities may require the identification and establishment of interfaces with production organisations (manufacture of test specimens and prototypes), design subcontractors (including suppliers of testing services) and flight test organisations (flight testing activities).

3.2. Product maturity

The design and development of a product depends on the nature of the product. In general, it is a complex process which requires coordination of various contributors and synchronization of related activities. To be effective and efficient, such a process needs to be planned and controlled.

For this purpose, the applicant may consider establishing and implementing a product development plan, which should define the design and development stages / phases, the maturity milestones and the related criteria for progressing from one stage / phase to another. At the established milestones, the applicant should conduct design and development reviews to ensure that the maturity criteria are met and to identify any problem.

Such an approach may help the applicant to also establish the right timing of the TC application. One of the elements that should be considered is the maturity of the product configuration. If the application is made too early and the product configuration is not mature enough then later evolutions of the configuration may invalidate the type-certification basis or may invalidate the already performed compliance demonstrations. On the other hand, if the application is too late, the applicant may fail to consider certain requirements EASA considers applicable. This could result in the need to re-design the product (or parts of it) to demonstrate compliance with those requirements.

An applicant should consider the novel or unusual design features of the product or its unusual intended use because the Agency may prescribe Special Conditions (refer to 21.B.75) that may impact the overall product design and development (see section 3.1, above).



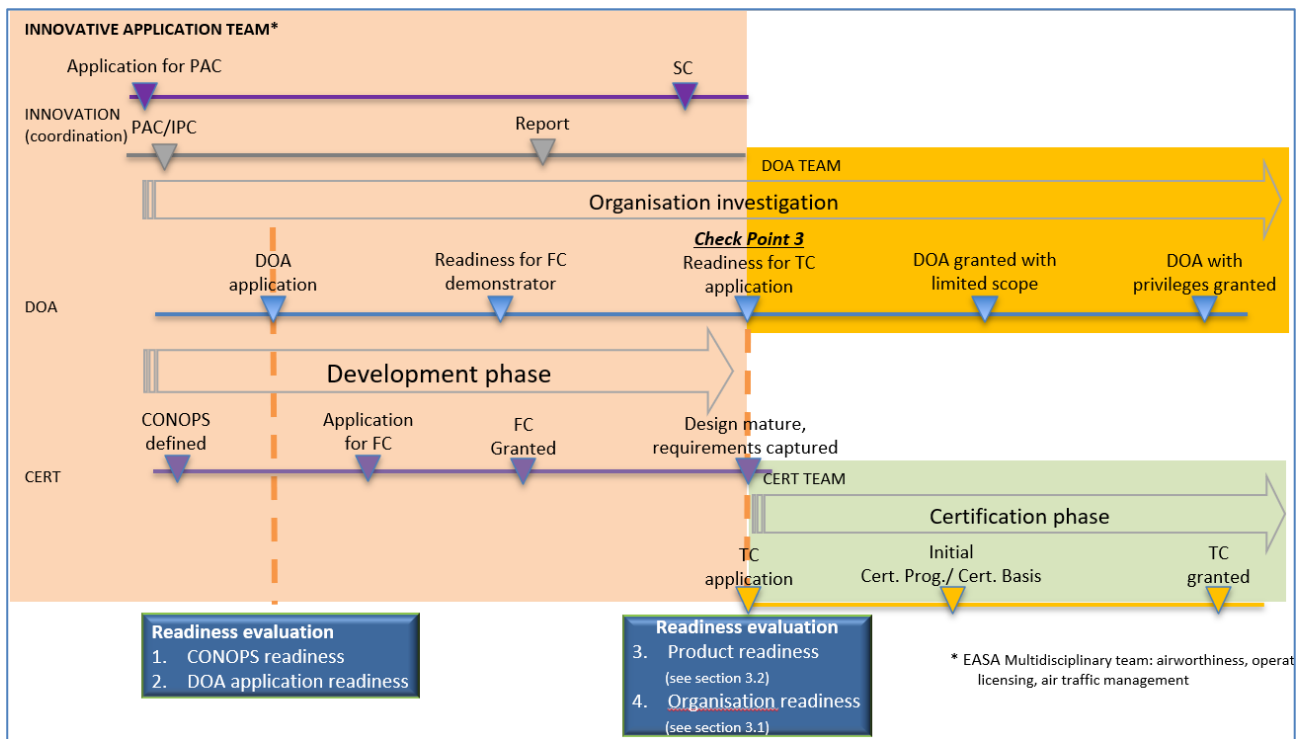
3.3. Readiness Checklist

Based on the considerations made above in Sections 3.1 and 3.2, a checklist is presented in the Appendix to this Certification Memorandum to help a potential applicant to evaluate its maturity and its readiness to apply for a TC.

This checklist differentiates between a potential TC applicant who still needs to demonstrate its capability and a potential TC applicant who has already demonstrated its capability (e.g. being already a TC and DOA Holder and applying for a new TC). It provides the relevant criteria for each category of applicants. These criteria are by no means exhaustive and each applicant should detail or customize its own assessment based on the organizational and product complexity.

3.4. Example of parallel processes for an aircraft development and certification

The picture below presents an example of different processes an applicant may have to go through for an aircraft development and certification and it illustrates the various elements presented in the previous sections of this certification memorandum.



Parallel processes for aircraft development and certification

3.5. Who this Certification Memorandum affects

This certification memorandum affects potential TC applicants who need to check their eligibility under point 21.A.13 and need to demonstrate their capability under point 21.A.14.

4. Remarks

1. This EASA Proposed Certification Memorandum will be closed for public consultation on **11 November 2022**. Comments received after the indicated date for consultation might not be taken into account.
2. For any question concerning the technical content of this EASA Certification Memorandum, please contact:

Name, First Name: Enache, Alexandru

Function: Senior Regulations Officer

Phone: +49 (0)221 89990 6028

E-mail: alexandru.enache@easa.europa.eu



Appendix - Readiness Checklist

Potential TC demonstration	applicant first capability	Potential TC demonstration	applicant repeated capability
No. Criteria			
A. Organisational maturity and capability demonstration			
1.	Resources are secured	Resources are secured	
		<i>Note:</i> <i>Even if the applicant is a well-established organization, launching a new TC project requires resources to be secured (e.g. financial resources, additional staff)</i>	
2.	Staff competences are sufficient	Staff competences are sufficient	
		<i>Note:</i> <i>The focus of this evaluation should be on the novelties introduced by the new TC project (e.g. novel / unusual design features)</i>	
3.	Responsibilities are allocated	N/A	
		<i>Note:</i> <i>Top level responsibilities are usually not affected.</i>	
4.	Working practices are established, tested, and documented	Working practices are up to date for the new TC application	
5.	Subcontractors and their workshare are identified.	Subcontractors and their workshare are identified.	
6a.	(when capability is demonstrated according to 21.A.14(c)) A mature Certification Programme is ready.	(when capability is demonstrated according to 21.A.14(c)) A mature Certification Programme is ready.	
		<i>Note:</i> <i>As it is a new TC for an existing/experienced design organisation, the applicant should be able to submit a mature 'Certification Programme'</i>	
6b.	(when capability is demonstrated according to 21.A.14(b)) The Agency agreement for alternative procedures, covering at least the pre-TC activities, is received.	N/A	
		<i>Note:</i> <i>The Agency's Finding of Compliance is already in place. An application will be needed for extending this Finding of Compliance to the new TC application. However, this is not a critical point since the procedures accepted by the Agency should not be impacted</i>	
6c.	(when capability is demonstrated according to 21.A.14(a)) In the frame of the investigation for the Design Organisation Approval, the following elements are established:	N/A	
		<i>Note:</i> <i>In this case the applicant has already a DOA. A Significant Change application will be required for</i>	



- the organisation is fully defined and stable (roles, responsibilities, reporting lines, resources);
- the key position holders are nominated (Head of Design Organisation, Head of Office of Airworthiness, Head of Independent System Monitoring, Compliance Verification Engineers)
- the relevant processes are defined and documented (e.g. configuration control, TC process / procedures, compliance demonstration);
- the competence assessment is successfully completed (or well advanced)

extending the Terms of Approval of the DOA to cover the new TC application. However, the investigation of this Significant Change will focus only on the novelties introduced by the new TC application.
e.g. – additional competencies required;
- new subcontractors / work sharing;
- new DO-PO arrangements.

Note:

The DOA investigation process is composed of several phases. The milestones between these phases are called Check Points. An applicant may consider the above conditions fulfilled when the EASA DOA Team has confirmed the satisfactory completion of Check Point 3.

7. The interfaces with the production organizations are defined and the approach to be used for conformity determination are established.

N/A

Note:

The TC applicant has, in most of the cases, production capability (POA) in-house. The respective POA may need to be extended to cover the new product, but necessary interfaces should be already in place.

8. If required, a flight test organization is defined or interfaces with an external one are established.

N/A

B. Product maturity

9. A product development plan including maturity milestones and criteria is defined.

A product development plan including maturity milestones and criteria is defined.

10. The product configuration is sufficiently mature

The product configuration is sufficiently mature

11. The product novelties (e.g. design features, technologies, intended use) have been addressed.

The product novelties (e.g. design features, technologies, intended use) have been addressed.

12. The relevant maturity milestones are achieved and the respective criteria successfully satisfied.

The relevant maturity milestones are achieved and the respective criteria successfully satisfied.

