Certification Memorandum

Development Assurance Considerations in Product Certification

EASA CM No.: CM–DASA-002 Issue 01 issued 17th December 2024

Regulatory requirement(s):

JAR/CS 23.1301 and JAR/CS 23.1309 from Initial Change/Issue for Normal, Utility, Aerobatic and Commuter Aeroplanes
CS 23.2500 and CS 23.2510 from Amdt. 5 for Normal, Utility, Aerobatic and Commuter Aeroplanes
JAR/CS 25.1301 and JAR/CS 25.1309 from Initial Change/Issue for Large Aeroplanes
JAR/CS 27.1301 and JAR/CS 27.1309 from Initial Change/Issue for Small Rotorcraft
JAR/CS 29.1301 and JAR/CS 29.1309 from Initial Change/Issue for Large Rotorcraft
JAR/CS-E 50 (d, f) and JAR/CS-E 510 from Initial Change/Issue for Engines
JAR/CS-P 150 and JAR/CS-P 440 from Initial Amendment for Propellers
JAR/CS-APU 90 from Initial Change/Issue for Auxiliary Power Units
CS-ETSO from Initial Issue for European Technical Standard Orders Parts
SC VTOL.2500 and VTOL.2510 from Issue 1 for Vertical Take-Off and Landing Aircraft
SC Light-UAS High Risk 01 Light-UAS.2510 from Issue 1 for Light Unmanned Aircraft Systems - High Risk
SC Light Unmanned Aircraft Systems - Medium Risk Light-UAS.2500 and Light-UAS.2510 from Issue 1 for Light Unmanned Aircraft Systems - Medium Risk

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Log of issues

Issue	Issue date	Change description
1	14.02.2024	First issue.
01 Final	17.12.2024	Final Issue 1 Post Consultation process

Table of Content

1. Introduction

1.1. Purpose and scope

The purpose of this Certification Memorandum (CM) is firstly to provide guidance on the use of a structured approach to Development Assurance , such as detailed in ED-79B/ARP 4754B[1], when developing different kinds of products (see section 3) to be certified[2] by EASA, and secondly to highlight Development Assurance considerations when installing certified products (such as propulsion systems) or (E)TSO articles on a product.

It does not cover:

- aspects that are specific to items (Software and Airborne Electronic Hardware) for which sufficient guidance already exists (please refer to AMC 20-115D and AMC 20-152A),
- the Safety Assessment process. In consideration of ED-79B, Table A1 objectives 3.x and sections associated to it are outside of the scope of this certification memorandum. However, all the activities that address the interfaces between the Safety Assessment process and the other processes addressed in ED-79B are included.

Light UAS SAIL III, systems used for “enhanced containment” principles from SORA 2.0, and CMU (Control and Monitoring Unit) are not included in this version of the CM. They will be included in a later issue.

As a simplification, when used in this document:

- “Development Assurance ” refers to activities at aircraft, system and equipment level only (item level excluded), and performed according to a structured approach such as detailed in ED-79B,
- “system” is used to refer to any level from aircraft to equipment,
- “aircraft requirements” and “product requirements” are used to refer to any appropriate set of requirements from the aircraft or product,
- “applicant” refers to any applicant for product certification or (E)TSO authorisation, unless a specific applicant such as “aircraft applicant” or “propulsion system applicant” is stated.

This CM contains, as an introduction, the reasons for a Development Assurance approach, describes general aspects regarding applicability , and introduces Development Assurance appropriate for different product types, for newly designed products and for changes to products. It lists Means of Compliance (MoC) acceptable by EASA and provides typical examples of when these MoC are applicable.

Finally, this CM provides additional information to be considered when integrating certified products and authorised articles, and clarifies aspects of certification authority coordination and expected applicant oversight.

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[1] The ‘’*Guidelines for Development of Civil Aircraft and Systems*’’ released under ref. ARP 4754 by the US organization Society of Automotive Engineers SAE International and the document ref. ED-79 released by the European Organization for Civil Aviation Equipment EUROCAE are considered equivalent since the release of Rev. A of these documents in 2010. For sake of clarity, this CM does only refer to ED-79B, but ARP-4754B can equally be used.

[2] Throughout the whole document, the word “certification” (or any related word like “to certify” etc) is used. However, in case of products for which a DVR is issued, this should be understood as an assessment of the design related OSO.

1.2. References

The following reference materials may be used in conjunction with this Certification Memorandum:

Reference	Title	Code	Issue	Date
21.A.20	Demonstration of compliance with the type certification basis, operational suitability data certification basis and environmental protection requirements	Annex I (Part 21) to Regulation (EU) No 748/2012	Regulation (EU) 2019/897	12 March 2019
21.A.95	Requirements for approval of a minor change	Annex I (Part 21) to Regulation (EU) No 748/2012	Regulation (EU) 2019/897	12 March 2019
21.A.97	Requirements for approval of a major change	Annex I (Part 21) to Regulation (EU) No 748/2012	Regulation (EU) 2019/897	12 March 2019
21.A.115	Requirements for approval of major changes in the form of a supplemental type-certificate	Annex I (Part 21) to Regulation (EU) No 748/2012	Regulation (EU) 2019/897	12 March 2019
21.A.239	Design management system	Annex I (Part 21) to Regulation (EU) No 748/2012	Regulation (EU) 2022/201	10 December 2021
AMC1 21.A.239(d)	Design management system – Design assurance element	AMC&GM to Part 21	ED Decision 2022/021/R	16 December 2022
21.A.243	Handbook	Annex I (Part 21) to Regulation (EU) No 748/2012	Regulation (EU) 2022/201	10 December 2021

Reference	Title	Code	Issue	Date
AMC 25.1309	Equipment, systems and installations		Amdt 27 or later	24 November 2021
ED-79	Certification Considerations for Highly-Integrated or Complex Aircraft Systems		-	November 1996
ED-79	Guidelines for Development of Civil Aircraft and Systems		A	December 2010
ED-79	Guidelines for Development of Civil Aircraft and Systems		B	20 December 2023
AMC 20-1	Certification of Aircraft Propulsion Systems Equipped with Electronic Control Systems		Amdt 23 or later	21 January 2022
AMC 20-3B	Certification of Engines Equipped with Electronic Engine Control Systems		Amdt 19 or later	1 January 2021
AMC1 27.1309	Equipment, systems, and installations		Amdt 10 or later	27 January 2023
AMC1 29.1309	Equipment, systems, and installations		Amdt 11 or later	27 January 2023
MOC SC-VTOL	Proposed Means of Compliance with the Special Condition VTOL		2 or later	12 May 2021
MOC Light-UAS.2510-01	Means of Compliance with Light-UAS.2510 Equipment, Systems and Instal		1 or later	01 February 2024
AMC 20-170	Integrated modular avionics (IMA)		Amdt 15 or later	27 August 2018
ASTM F3230	Standard Practice for Safety Assessment of Systems and Equipment in Small Aircraft		Issue 17	15 February 2017

1.3. Abbreviations

AL	Aeroplane certification Level
AMC	Acceptable Means of Compliance
APU	Auxilliary Power Unit
CAI	Certification Action Item
CAT	Catastrophic
CIA	Change Impact Analysis
CM	Certification Memorandum
CMU	Control and Monitoring Unit
DA	Development Assurance
DOA	Design Organisation Approval
DOH	Design Organisation Handbook
DVR	Design Verification Report
EASA	European Union Aviation Safety Agency
EEC	Electronic Engine Control
EHPS	Electric / Hybrid Propulsion System
EPU	Electric Propulsion Unit
ETSO	European Technical Standard Order
EU	European Union
FDAL	Function Development Assurance Level
GAS	Gas Airships
HAZ	Hazardous
IDAL	Item Development Assurance Level
IMA	Integrated Modular Avionics
JAR	Joint Aviation Requirements
LSA	Light Sport Aeroplane

MoC	Means of Compliance
MPS	Minimum Performance Standards
OSO	Operational Safety Objectives
PA	Process Assurance
PID	Project Information Document
STC	Supplemental Type Certificate
TC	Type Certificate
TSO	Technical Standard Order
UAS	Unmanned Aircraft System
VLA	Very Light Aeroplane
VLR	Very Light Rotorcraft
VTOL	Vertical Take-Off and Landing aircraft

1.4. Definitions

Article	Any part and appliance to be used on civil aircraft (Source: Regulation (EU) 2023/1028)
Complex System	A system is Complex when its operation, failure modes, or failure effects are difficult to comprehend without the aid of analytical methods, such as systems embedding software and/or complex airborne electronic hardware. (Derived from AMC 25-1309)
Control and Monitoring Unit	Equipment to control unmanned aircraft remotely, meaning any instrument, equipment, mechanism, apparatus, appurtenance, software or accessory that is necessary for the safe operation of an unmanned aircraft, which is not a part, and which is not carried on board of that unmanned aircraft. (Source: Regulation (EU) 2024/1110 Amdt 5 and Regulation (EU) 2018/1139, initial issue)
Conventional System	A conventional system is a system whose function, the technological means to implement its function, and its intended usage are all the same as, or closely similar to, that of previously approved systems that are commonly used. (Source: ASTM F3230 iss 17)
Derived Requirements	Requirements that introduce behaviors or characteristics beyond those specified in higher-level requirements. (Source: ED-79B)
Development Assurance	All planned and systematic actions used to substantiate, at an adequate level of confidence, that development errors have been identified and corrected such that the system satisfies the applicable safety objectives. (Source: ED-79B)
Development Error	A mistake in requirements, design, or implementation (Source: ED-79B)
Equipment	A physical object that can be installed and removed from the aircraft and performs one or more specific functions. Equipment contains one or more items. (Source: ED-79B)
Error	An omitted or incorrect action by a manufacturer, crew member, or maintenance person, or a mistake in requirements, design, or implementation. (Source: ED-79B)
External Event	An occurrence which has its origin distinct from the aircraft or the system being examined, such as atmospheric conditions (e.g., wind gusts/shear, temperature variations, icing, lightning strikes), operating environment (e.g., runway conditions, conditions of communication, navigation, and surveillance services), cabin and baggage fires, and birdstrike. The term is not intended to cover sabotage. (Source: ED-79B)
Failure	An occurrence which affects the operation of an aircraft, system, equipment, item, or piece-part such that it can no longer function as intended (this includes both loss of function and malfunction). Note: Errors may cause Failures, but are not considered to be Failures. (Source: ED-79B)
Failure Condition	A condition having an effect on the aircraft and/or its occupants, either direct or consequential, which is caused or contributed to by one or more failures or

	errors, considering flight phase and relevant adverse operational or environmental conditions, or external events (AMC 25.1309). (Source: ED-79B)
Function	Intended behavior of an aircraft, system, equipment, or item regardless of implementation. (Source: ED-79B)
Item	A defined and bounded set of either (one or more) hardware elements or (one or more) software elements which are treated as a single entity for analytical purposes. (Source: ED-79B)
Process	A set of interrelated activities performed to produce a prescribed output or product. (Source: ED-79B)
Process Assurance	Activities that ensure that the Development Assurance activities are maintained and followed. (Source: ED-79B)
Product	An aircraft, an engine, a propeller or an APU. (Source: Derived from Basic Regulation). For the purpose of this certification memo, APUs are considered as products given that a Type Certificate is granted by EASA.
Unmanned Aircraft	Any aircraft operating or designed to operate autonomously or to be piloted remotely without a pilot on board (Source: Regulation (EU) 2018/1139)
Unmanned Aircraft System	An unmanned aircraft, as defined in Article 3(30) of Regulation (EU) 2018/1139, and its control and monitoring unit (Source: Regulation (EU) 2024/1110 Amendment 5)
Validation	The determination that the requirements for a product are correct and complete. (Source: ED-79B)
Verification	The evaluation of an implementation of requirements to determine that they have been met. (Source: ED-79B)

2. Background

In 2003 the necessity to use appropriate techniques to manage system complexity, integration, and to minimize the risk of development errors was recognized in airworthiness regulations with the introduction of the concept of development assurance, in JAR25 Change 16. Development Assurance, in some form and even if not always identified as such, has been and still is applied on most products . However the concern is that traditional techniques may not provide adequate safety coverage for more complex systems.
To address this concern, the 'technique' of Development Assurance has been developed. This utilises a combination of process assurance, validation and verification coverage criteria or structured analysis or assessment techniques (applied at the product level if necessary, or, at least, across integrated or interacting systems).
The use of this technique increases confidence that risk of development error is reduced to an acceptable level.
The trend for ever increasing complexity and integration of systems is still ongoing and is not limited to new products or types. Some products certified more than 20 years ago have undergone extensive changes, including the introduction of complex systems that were absent in their initial design. Examples include the development of distributed architecture such as Integrated Modular Avionics (IMA), the development of system functions within other systems (e.g., aircraft functions embedded in engine controls systems), the addition of new functionality, more automation such as fly-by-wire systems, or new design features that require a high-level of integration (e.g. Propulsion, Flight Control and Electrical Distribution systems for Vertical Take-Off & Landing (VTOL) products). This trend also has consequences on the complexity of the workshare between applicants and their suppliers, and on the potential for common mode and cascaded failures within the architectures. Hence a structured and rigorous process is essential.

In addition to the trend for increasing system complexity and integration, other considerations in the development of this CM include:

- the current lack of guidance on the applicability of Development Assurance for some categories of products,
- the emergence of products with new technology, architecture and/or operational use,
- ensuring the approach is proportionate and consistent with the expected level of safety across the different products, and
- credit given to ETSO authorisation when installed on a product.

Thus, the development of this CM is aimed at providing guidance on:

- the use of Development Assurance considering the full range of products,
- addressing the installation of (E)TSO articles or certified products,
- addressing the use of Development Assurance on changes to products, for which the use of Development Assurance is expected per the applicable certification basis to the changed product,
- coordination of activities with EASA, and
- the activities expected to be performed by TC/STC applicants to ensure adequate application and oversight of those activities.

3. Applicability

3.1. Scope

When applicable to a product Development Assurance should be applied to all complex systems of that product, unless it is agreed by Certification Authorities that for some systems other standard and systematic methodology used for certification reduces the likelihood of development errors to an acceptable level.

Systems such as mechanical systems (e.g. Gas Turbine mechanical systems, fully verifiable hydro-mechanical systems) fall into this category and hence do not require Development Assurance.

3.2. Activities and interfaces providing data to support Development Assurance

In order to specify, design and verify a product, particularly a complex product, many disciplines may be involved. These could include but are not limited to:

- Aerodynamics
- Airframe structures
- Safety assessment
- Security assessment
- Environmental assessment
- Handling Qualities
- Performance
- Installation
- Maintenance scheduling

Data generated by activities in these areas will be used to support the Development Assurance process. For example data provided for validation and verification of design requirements that are considered in the Development Assurance scope. It is important that the robustness of this data is commensurate with the rigor of the Development Assurance approach being applied to the product. Then development assurance plans do not necessarily need to cover all activities used for generating the data in the above disciplines, but do need to address the use and control of these data.

Just as the data produced by the activities in the various disciplines must be suitably robust, so the robustness of the interface data from interfacing systems, whether these are within or external to the product, must be commensurate with the rigor of the Development Assurance approach being applied to the product. The way this is achieved will depend on the nature of the interfacing system and the interface itself. Interfaces between aircraft systems and propulsion systems, and between product systems and (E)TSO articles are addressed in this CM (refer respectively to 4.4 and 4.5).

For both the data generated by the disciplines mentioned above and the interfaces with other systems, evidence should be provided that processes exist to ensure they are adequate to support Development Assurance. As a minimum, processes defined by each discipline should provide evidence that the produced data are reviewed for completeness and correctness by the appropriate people and that these data are properly managed in configuration.

3.3. Products

The need for, and the extent of, Development Assurance depends on the complexity of the product,on its safety objectives and on the level of integration between the embedded systems.

In order to determine the extent of Development Assurance needed, the different products are categorised in the sections below:

- 3.3.1 addresses all products except CS-23 and CS-27;
- 3.3.2 focuses on CS-23 and CS-27 products.

3.3.1. Development Assurance categories for all products except CS-23 and CS-27

Each product type is categorised in one of three Development Assurance categories as per Table 1: "Full", "Some" and "No". These terms are not intended to imply the number of systems in scope (see Section 3.1 for systems in scope) but the extent of Development Assurance to be applied. The applicant should follow the guidance in section 4.1, 4.2, or 4.3 as appropriate.

Table 1: Development Asurance categories for all products except CS-23 and CS-27

Development Assurance applies (Note 3)		No Development Assurance (Note 1)
Full (see section 4.1)	Some (Note 5) (see section 4.2)	No (see section 4.3)
CS-25 CS-29 CS-E (turbine engines) CS-P (with complex propeller control system) SC light UAS High Risk Category SAIL V SC light UAS High Risk Category SAIL VI Certified Category UAS SC-VTOL (Enhanced and Basic 3 categories) SC-GAS (Large Airships) SC E-19 EHPS (installed on products in the "Full" Category) Tiltrotors CS-APU (Essential)	SC E-18 EPU (installed on CS-23 AL1) CS-APU (Non essential)[3] CS-E (Piston engines) SC-VTOL (Basic 1 and 2 categories) SC E-19 EHPS (installed on products of the "Some" Category) SC light UAS : SAIL IV	SC E-18 EPU (except those installed on CS-23 AL1) CS-22 CS-31x CS-VLA CS-VLR CS-LSA CS-P (without complex propeller control system) SC light UAS: SAIL I and II

Note 1: Even though no development assurance is required for products listed in the "No Development Assurance" category, early coordination with EASA is necessary where such products embed critical systems that are novel and/or not conventional.

[3] No DA may be acceptable if there is a demonstration of containment and foreseeable failure conditions at installation level are no more than minor – please refer to Note 4 for additional information.

Note 2: As specified in SC E-19, this special condition only applies to Electric and / or Hybrid Propulsion System when the intended aircraft application is identified. The category of development assurance applicable to these systems should then be consistent with the one applicable at aircraft level.
Applicants may, however, choose to apply guidance from the Full DA category from the first application to facilitate installation of the Propulsion System (or a modification of it) on a wide range of aircraft including those where full Development Assurance is required.

Note 3: Even though DA applies in principle to all products in the "Full" and "Some" category, there may be products, especially older products, which have no complex system and hence, in line with Section 3.1, no DA would be required. This may be the case for certain old turbine engines that have no EEC.

Note 4: For propulsion systems and propellers, Development Assurance as indicated in Table 1 is required to meet the safety objectives of the propulsion system or propeller specification, considering the level of complexity expected in the system. The safety objectives in the propulsion system and propeller specifications are defined to align with the expected requirements of the aircraft into which the products are installed. This does not preclude more stringent safety objectives being required for installation of the propulsion system into the aircraft due to the specific aircraft design, with potential impact on the Development Assurance activities needed for aircraft certification. Where engines and propellers are certified at aircraft level (e.g., as provisioned by CS-23.2400(b)), the Development Assurance category appropriate to the aircraft applies.

Note 5: For systems built with (E)TSO equipment which fall into the "some DA" category, the activities related to (E)TSO are limited to integration aspects as defined in section 4.5.1. No additional activities or justifications are required at equipment level.

3.3.2. Development Assurance categories for CS-23 and CS-27

There is an important variability in terms of complexity and integration level in CS-23 and CS-27 products. This implies that applying a category of Development Assurance to a specific category of product may not be completely relevant.

1. Specificities for CS-23 AL[4] 1, AL 2, CS-27 Class I and Class II products

No DA is expected for a system of those products, when the system meets the following criteria:
- The system failure or combination of failures cannot directly lead to CAT or HAZ aircraft level failure condition OR
- The system is not integrated and is conventional.

A non integrated and conventional system means:
(0) A system that can be verified independently from the other systems (limited and well-bounded interfaces with other systems), and
(1) A system that falls under the definition of conventional system per section 0, and
(2) A system built with (E)TSO'd equipment.

"Directly" means:
(0) Single failure of the System X, or
(1) Combination of failures of the System X, or

[4] The paragraph mentions only AL classification of CS-23 products. However the CM also applies to CS-23 products certified before CS-23 Amendment 5. For those aeroplanes, the applicant can determine the AL of its product based on the current CS 23.2005 in order to define the Development Assurance category to follow.

(2) Single failure of the System X in combination with external events.

Note: Failure of the System X in combination with failures of other systems is not considered as a direct contribution.

2. Other cases

In order to define the category applicable to the product or some of its systems, different factors should be assessed:

- Safety objectives of the product
- Level of integration and complexity of the different systems
- Criticality of each system.

Applicants should perform this analysis and provide the results to EASA for review and agreement. Early coordination with EASA is necessary.

Consideration for propulsion systems and propellers (Note 2 and Note 4) as per section 3.3.1 are applicable.

4. EASA Certification Policy

4.1. Products in the "Full" Development Assurance category

4.1.1. Guidance/AMC

A Development Assurance process should be followed. The standard currently recognised as an Acceptable Means of Compliance is ED-79B.

Note that ED-79B provides a proportional approach to the rigor of the Development Assurance activities via the Development Assurance Levels. For example, functions contributing to Catastrophic Failure Conditions for aircraft falling under SC-VTOL may be allocated an FDAL A, B, or C depending on the VTOL category (Enhanced/Basic 3, Basic 2, or Basic 1).

4.1.2. Management of Changes

The information in the following sections provide more detailed guidance on change management of affected area as per Part 21.A.101. They in no way modify the elements defined in Part 21.A.101 or its guidance material.

4.1.2.1. Changes to products initially certified in accordance with a Development Assurance standard recognised by EASA

The process for such changes should already be in place and can still be used. If the process is modified or a new process is introduced (for example in case of an STC), then the process change should be identified and assessed according to the standard applicable to the product.

However, the existing process may also need to be updated if issues have been identified and need to be addressed (e.g. following continued airworthiness investigations or during other activities (development…)).

Applicants using previous revision of the ED-79 standard (rev – or rev A) may elect to consider the gaps provided in section 4.8 to improve their process.

4.1.2.2. Changes to products not initially certified according to a Development Assurance process using a standard recognised by EASA.

The need for Development Assurance when making a change depends mainly on the criticality of the impacted system(s) and the scope of the change. Early coordination with EASA is recommended.

Typical examples of changes where Development Assurance is required include modifications of systems contributing to FDAL A or B functions or modifications of systems contributing to catastrophic failure conditions:

- which modify the architecture (reallocated functions, new equipment or interfaces, reallocation of common resources, …),
- which introduce new function(s) or new technology,
- which are implemented in software or complex airborne electronic hardware (unless the change has limited and well bounded effects on the system activities and is covered by processes in place), or
- which are developed with a new process.

An impact analysis should be performed for each change and should include an evaluation of the impact of the change on the previous Development Assurance processes and data.

This activity should consider but need not be limited to:

- the extent of the change to the design ,
- the availability of previous Development Assurance life cycle data that are relevant for the change , and
- the potential issues previously identified that are relevant for the change (e.g. following continued airworthiness investigations or during other activities (development…)).

This analysis should justify that either the processes in place are adequate for the change under consideration or that some changes to the existing processes/data are necessary and detail them. This analysis should be documented and referenced in the Certification Programme (see section 4.6).

When applicable, those changes should be managed in accordance with the currently recognised Development Assurance standard according to section 4.1.1. This means that the processes in place to manage these changes should be shown to meet the objectives of that standard. The change process should account for the fact that the original design data may not have been produced with the level of rigor that might be achieved with the current standard and ensure that this does not impair the level of assurance achieved. Both the change itself and the assurance that the change will not induce regression on the existing product must be addressed.

4.2. Products in the "Some" Development Assurance category

4.2.1. Guidance/AMC

RESERVED[5]

4.2.2. Management of Changes

4.2.2.1. Changes to products initially certified in accordance with a Development Assurance standard recognised by EASA

RESERVED[5]

4.2.2.2. Changes to products not initially certified according to a Development Assurance standard recognised by EASA

RESERVED[5]

4.3. Products in the "No" Development Assurance category

4.3.1. Guidance/AMC

Even if no development assurance is expected for products listed in this category, in case of products that embeds critical systems that are novel and/or not conventional, early coordination with EASA is necessary.

In other cases, on a voluntary basis, an applicant may choose to use ED-79B or other Development Assurance standards as a guide in the development of their products.

[5] The definition of a standard for this product category is currently ongoing. The information required for this chapter will be provided at a later Issue of this CM.

4.4. Installation considerations for propulsion systems (Engines, Propellers, APU, EHPS…)

Guidance on the extent of Development Assurance needed for the certification of propulsion systems is given in Section 3. However, as well as being certified in its own right, an engine – or propulsion system – is an aircraft system and has to be installed on an aircraft and considered when Development Assurance is applied at aircraft level during aircraft certification.

In addition to the activities covered during the development and type certification of the propulsion system, some Development Assurance activities will remain at propulsion system level that need to be addressed during the integration into the aircraft. They include but need not be limited to the following:

- Ensuring that relevant aircraft requirements have been allocated and traced to the propulsion system requirements,
- Ensuring that propulsion system requirements are validated toward the relevant aircraft requirements,
- Ensuring that all derived requirements whose functional and safety impact cannot be fully determined by the propulsion system applicant are provided to the aircraft processes including the safety process for validation, and
- Ensuring that any problems, limitations or deviations applicable to the propulsion system, as listed in the Instructions for Engine Installation, are assessed and accounted for at the relevant aircraft level.

Relevant aspects may be defined in the Development Assurance plan applicable at Propulsion system level.

Close cooperation between the aircraft applicant and the propulsion system applicant, with respect to Development Assurance at the propulsion system/aircraft interface, is recommended during the design and certification of both the propulsion system and aircraft. This is especially important when there are unusual or particularly complex or critical requirements flowed down from the aircraft level to the propulsion system level.

4.5. Installation considerations for (E)TSO articles

Section 4.5.1 is applicable to any article for which either an ETSO or a foreign TSO authorisation has been issued.
Section 4.5.2 and 4.5.3 are applicable only to articles for which an ETSO authorisation has been issued. Indeed, unlike for some ETSO as required by CS-ETSO subpart A, foreign TSO standards do not currently address Development Assurance. As a consequence, there is no evidence that foreign TSO certification authorities have assessed these aspects. As a result, EASA cannot consider any credit from such foreign TSO authorisation. This would then need to be demonstrated during the installation approval for example with the support of the TSO applicant or could be addressed as part of a reuse strategy. However, if foreign TSO frameworks are revised to address Development Assurance, similar credit could be granted.

4.5.1. General Installation considerations

(E)TSO'd article installed in a product, as any other equipment or system, must meet the safety objectives allocated by the safety assessment. Therefore, the product applicant should ensure that the development process of the (E)TSO'd article has been commensurate with the objectives applicable to its product as per section 3.3.

The purpose of the (E)TSO authorisation is to provide evidence that the article meets a minimum performance standard prior to and independently of the installation. As such, there may be a gap between the level of Development Assurance requested at installation and that which is used for the (E)TSO'd article development. Thus additional activities and/or justification may be required at product level during the installation phase.

In addition to the activities mentioned in the paragraph above, when Development Assurance is applied at product level during product certification, additional activities will be required during the integration of an (E)TSO'd article into the product subject of the application. The activities include but need not be limited to the following:

- Ensuring that relevant product requirements have been allocated and traced to the (E)TSO'd article requirements,
- Ensuring that (E)TSO'd article requirements are validated toward the relevant product requirement,
- Ensuring that all derived (E)TSO'd requirements whose functional and safety impact cannot be fully determined by the (E)TSO applicant are provided to the product system process including the safety process for validation and
- Ensuring that any problems, limitations or deviations applicable to the (E)TSO'd article are assessed and accounted for at the relevant product level.

4.5.2. Credit for ETSO article and equipment constituting the ETSO article

Per CS-ETSO subpart A and the European Technical Standard Order Authorisation (ETSOA) process, when implementing software or airborne electronic hardware, the ETSO article is developed with Development Assurance. This is assessed as such by EASA to grant the ETSOA. When the ETSO'd article is composed of pieces of equipment, Development Assurance is demonstrated for each individual piece of equipment, as well as for the ETSO article itself.

EASA grants the following credit for Development Assurance of an ETSO article (and its equipment) :

Table 2: Credit for ETSO article Development Assurance

ED-79B[6] Table A1 Objectives	Process/Activity	Credit for ETSO article Development Assurance	Remarks
All Objectives (1.x)	Planning Process	Full credit except for the Process Assurance aspects (see objectives 7.x)	Per CS-ETSO section 2.4 Note: planning life cycle data delivered in the context of ETSOA.
All Objectives (2.x)	Aircraft and System Development Process and Requirements Capture	Not Relevant for 2.1 and 2.2 objectives. Full credit for the scope of the ETSO article (and not for the system integrating the ETSO article) for 2.3, 2.4, 2.5, 2.6 and 2.7 objectives.	Per CS-ETSO section 2.4 Note: accomplishment summary life cycle data delivered in the context of ETSOA.

[6] This table equally applies with objectives from previous revisions of ED-79.

ED-79B[6] Table A1 Objectives	Process/Activity	Credit for ETSO article Development Assurance	Remarks
Objective 4.1 Objective 4.4	Aircraft/system requirements are complete and correct. Validation substantiation is provided	When assessed to the sole scope of the ETSO article (and not for the system integrating the ETSO article): Full credit for ETSO functions. Partial credit for non-ETSO functions – no credit for validation activity towards the system integrating the ETSO article.	For ETSO functions: validation is performed against the ETSO standard, including its MPS. Partial for non-ETSO functions: requirements for non-ETSO functions are reviewed by the ETSO applicant, but there is no credit for validation activity towards the upper level. This activity must be completed during the installation project. Process Independence is considered achieved from the ETSOA process.
Objective 4.2	Assumptions are managed.	Full credit for the ETSO'd article.	Per CS-ETSO section 2.4 , assumptions are managed and documented in relevant documentation (e.g. DDP, installation manual, safety assessment…). The installer should however address assumptions that are flowed to the installer by these documents (see 4.5.1).
Objective 4.3	The functional and safety impacts of derived requirements are acceptable at relevant higher levels.	Not Relevant for ETSO'd article - no credit.	The functional and safety impacts of derived requirements are acceptable at ETSO article level. DDP contains declaration of Non-ETSO function(s). The installer should however validate derived requirements (see 4.5.1).
All Objectives (5.x)	Implementation Verification Process	Full credit for the ETSO'd article.	Process Independence is considered achieved from the ETSOA process.
All Objectives (6.x)	Configuration Management Process	Full credit for the ETSO'd article.	
All Objectives (7.x)	Process Assurance Process	- No systemic credit for ETSO article installed in product in the Full DA category.	For product in the Full DA category, if ETSO applicants demonstrate compliance with ED-79B Table A1 section 7.x objectives, credit will be

ED-79B[6] Table A1 Objectives	Process/Activity	Credit for ETSO article Development Assurance	Remarks
		- Credit granted for ETSO article installed in product in the "Some DA" category.	granted within ETSOA process.

4.5.3. Installation considerations of an ETSO'd article

As a pre-requisite, when selecting an ETSO'd article for its installation, the applicant installing an ETSO'd article must verify that:

- The ETSO standard MPS fulfil the product level installation needs.
- The problems, deviations and limitations approved with the ETSO article authorisation are acceptable at installation level.
- The ETSO article safety assessment and the failure conditions classification, as anticipated by the ETSOA applicant/holder, fulfil the product level installation needs.
- The DAL (FDAL and IDAL) allocation to the ETSO article functions and items fulfil the product level installation needs.

Depending on the Development Assurance objectives, as per Section 3.3, the applicant installing an ETSO article should perform the following Development Assurance activities:

A. Allocate system requirements to the ETSO'd article and identify any derived requirements in the ETSO article specification
B. Validate the ETSO article requirements against the system requirements:
    a. If the system encompasses the MPS as requirements, then it is possible to use these MPS as an intermediate level for the ETSO functions and consider ETSOA credit for the part of validation activities from the ETSO article to the MPS.
    b. If the applicant has developed its system requirements covering the equipment level without using the MPS, then validation of the ETSO article requirements should be performed as part of the installation activities.
    c. Validation of the non-ETSO functions requirements must be performed as part of the installation activities.
C. Assess the functional and safety impacts of derived requirements and demonstrate they are acceptable at product level.

For product in the full Development Assurance category, the applicant installing an ETSO article should either perform the process assurance activities per ED-79B Table A1 section 7.x objectives on the ETSO article life cycle data or ensure that those objectives have been demonstrated in the frame of the ETSOA process (cf. EASA certificate).

4.6. Certification authority coordination

The Certification Programme should provide all the necessary information related to the use of Development Assurance .

It should include as a minimum:

- A declaration whether Development Assurance applies according to sections 3.1 and 3.2,
- If it applies:
    - A definition of the scope, applicable guidance and considerations for section 4.8 if applicable,
    - The outcome of the CIA and the impact on existing processes (when applicable, e.g. changes per section 4.1.2.2),
    - A reference to the main applicable plans and procedures
    - A reference of the document that will provide evidence of compliance demonstration to the applicable Development Assurance objectives.

Contrary to the Development Assurance standards for software and airborne electronic hardware which identify the necessary artifacts to be produced for supporting the compliance demonstration, no guidance is provided in the currently recognised Development Assurance standard for systems ED-79B. As per points 21.A.20 (a), 21.A.95 b1, 21.A.97 (b).1 and 21.115 (b).2, compliance with the type-certification basis has to be demonstrated. Thus, the applicant should identify the documentation that will be developed to support the compliance demonstration with the certification basis of the product.

The demonstration that the processes in place meet the applicable objectives should be provided in a compliance document.

Additional information regarding certification coordination is generally shared with the applicant through a CAI, PID or as part of the Design Organisation Handbook (DOH) for EU applicants. It includes aspects such as the different reviews and pre-requisite for each review.

4.7. Applicant independent review for compliance demonstration

To demonstrate the applicable Development Assurance objectives are met, the applicant is required to carry out suitable independent reviews. In this context, independent means someone that is not directly involved in the development assurance activities of the project.

This activity must not be confused with process assurance as defined in ED-79B.

It is usually performed via a gated process which includes a planning review, a design review, a verification review and a final compliance review. These independent reviews addresses all aspects of Development Assurance activities, including the ones related to process assurance such as an evaluation of the plans, procedures and evidence. They should include oversight of the suppliers involved in the development of systems.

The applicant is expected to conduct and record the activities that contribute to the demonstration of compliance. These activities can be tailored based on predefined criteria accepted by EASA. For EU applicants, this would be addressed within the DOH.

4.8. Use of previous versions of a recognised Development Assurance standard

While the use of the latest version of a recognised Development Assurance standard is recommended, the use of previous versions of the standard is considered acceptable for existing products. However, it is recommended to assess whether the existing processes cover the gaps identified in this section.

4.8.1. Gaps between ED-79A vs ED-79B that should be considered for FDAL A, B and C

4.8.1.1. Derived Requirement

In ED-79A, there is an ambiguity between the definition of derived requirement and section 5.3.1.4. The definition states that if a requirement is directly traced to higher-level requirement, then it is not derived. The section 5.3.1.4 related to derived requirements states " [requirements which] may not be uniquely related to a higher-level requirement [..] are referred to as derived requirements".

The definition given in ED-79B which is consistent with ED-79A section 5.3.1.4 should be adopted and is: "Requirements that introduce behaviors or characteristics beyond those specified in higher-level requirements"

4.8.1.2. Change management

While the intent is the same, some of the content has been rewritten and reorganized (section 6.1 to section 6.4).The examples provided in section 6.6 of ED-79A are incomplete and should not be used as a reference. Modification impact analysis as defined in ED-79A or ED-79B section 6.3 should be used instead.

4.8.2. Gaps between ED-79- vs ED-79B that should be considered for FDAL A, B and C

In addition to the gaps identified in Section 4.8.1, projects using ED-79 - should consider the following:

4.8.2.1. Change management

Section 11 dealing with "modified aircraft" does not adequately address the need for change impact analysis and defines some examples which are incomplete. Change management should follow an adequate modification process to ensure both correct implementation of the change and the absence of regression on existing systems. ED-79B section 6 should then be used to manage changes.

4.8.2.2. Process Independence

Process Independence is a cornerstone of Development Assurance in terms of increasing the level of confidence and deemed necessary for FDAL A and B systems as well as for process monitoring (process assurance).

Process Independence should then be ensured for validation, verification and process assurance as per ED-79B Appendix A, Table A-1 Objectives 4.x, 5.x and 7.x.

4.8.2.3. Validation methods

Section 7.6.2 of ED-79 - identifies several validation methods and whether they are recommended or "as negotiated". However, in ED-79 –, traceability is not required to be bi-directional, traceability is not identified as recommended for FDAL C systems, and traceability and engineering review are not identified as a minimum for any validation activity.

As stated in ED-79B, bi-directional traceability is always necessary (including for FDAL C systems) and the need for an additional validation method on top of engineering review is to be determined based on whether correctness and completeness can be ensured only with these methods (traceability and Engineering review) or if they need to be complemented to achieve validation process objectives.

Validation methods should be consistent with that defined in ED-79B section 5.4.6.

4.8.2.4. Control categories

The concept of control categories and the need for a robust change control process does not exist in ED-79 initial revision. Similar to independence, control categories are also a cornerstone of Development Assurance in terms of increasing the level of confidence and enhanced configuration control is deemed necessary for FDAL A, B and C systems to improve the traceability and the rigor associated to design and some verification data.

Development Assurance data should meet the system control categories defined in ED-79B Appendix A.

4.9. Who this Certification Memorandum affects

This Certification Memorandum affects applicants showing compliance to the certification requirements mentioned on the front page (i.e. certification of a new type design or any changes falling in the scope defined in 4.1.2/4.2.2, for any products as aircraft, propulsion systems, propellers, APU).

Remarks

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