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QRS-117

Qualification and Quality Assurance Complex Electronic Hardware Requirements for Suppliers of Equipment during Design and Development Phases

Issue Date: April 2015

Issue: 02

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CHANGES LOG

Issue	Approval Date	Main changes	Interested Paragraphs
01	December 2013		
02	April 2015	Clerical Error correction and new layout	All

APPLICABLE DOCUMENTS

Documents Code	Document title
EN/AS/JISQ9100	Quality Management Systems – Requirements for Aviation, Space and Defense Organisations § 6.2, 6.2.1 and 6.2.2
EASA Part 21	Certification procedure for Aircraft and related Products and Parts” § 21A.145(c) (1), 21A.145(c) (2), 21A.145 (d) (1).
EASA Part 145	§ M.A. 606, M.A. 607, M.A. 707, 145.A.35
ISO 9001	Quality management systems - Requirements § 6.2, 6.2.1 and 6.2.2
RTCA DO-254	Design Assurance Guidance for Airborne Electronic Hardware
RTCA DO-178B	Software Considerations in Airborne Systems and Equipment Certification
AC No. 20-152	RTCA, Inc., Document RTCA/DO-254, Design Assurance Guidance for Airborne Electronic Hardware
Order 8110.105	Simple and Complex Electronic Hardware Approval Guidance

REFERENCE DOCUMENTS

Documents Code	Document title

CONTENTS

1 PURPOSE4

2 APPLICABILITY4

2.1 Complex Electronic Hardware 4

2.2 Previously Developed Hardware 4

2.3 Commercial Off The Shelf (COTS) Components Usage 5

3 APPLICABLE DOCUMENTS.....5

3.1 AgustaWestland Documents 5

4 DEFINITIONS AND ACRONYMS6

4.1 Definitions..... 6

4.2 Acronyms 6

5 GENERAL REQUIREMENTS7

5.1 Supplier Approval 7

5.2 Subcontractors..... 7

5.3 Access 7

6 INTRODUCTION8

6.1 Hardware Development Life Cycle 8

6.2 Work Products and Verification..... 8

6.3 Tools Qualification 9

7 Phase 1 – PLANNING11

7.1 Main Goals and Activities 11

7.1.1 Goals11

7.1.2 Activities11

7.2 Work Products 12

7.3 Verification 12

8 Phase 2 – PRELIMINARY DESIGN.....13

8.1 Main Goals and Activities 13

8.1.1 Goals13

8.1.2 Activities14

8.2 Work Products 14

8.3 Verification 14

9 Phase 3 – DESIGN IMPLEMENTATION15

9.1 Main Goals and Activities 15

9.1.1 Goals15

9.1.2 Activities16

9.2 Work Products 16

9.3 Verification 16

10 Phase 4 – PRODUCTION17

10.1 Main Goals and Activities 17

10.1.1 Goals17

10.1.2 Activities17

10.2 Work Products 18

10.3 Verification 18

11 MANUFACTURING18

11.1 Acceptance test 19

11.2 Series production 19

ANNEX A.....20

Qualification and Quality Assurance Complex Electronic Hardware Requirements for Suppliers of Equipment during design and development phases	QRS-117 Issue 02	Page 4/21
	April 2015	

1 PURPOSE

This document provides guidelines for the AgustaWestland Suppliers of systems, sub-systems and/or equipment containing Complex Electronic Hardware.

This document contains the AgustaWestland engineering requirements for the Suppliers in terms of compliance to the applicable standards and documentation to be provided in order to ensure that the delivered product is in accordance with the applicable specifications.

In particular, it defines Quality and Qualification requirements to be met during the development phase by Suppliers using Complex Electronic Hardware.

2 APPLICABILITY

2.1 Complex Electronic Hardware

This document is applicable to Complex Electronic Hardware used for airborne systems, sub-systems and equipment installed on AgustaWestland aircrafts.

According to the definition given in paragraph 4.1, the following is a list of Complex Hardware for which this document applies (the list is not exhaustive and does not include all the possible devices):

- PLD (Programmable Logic Devices)
- ASIC (Application Specific Integrated Circuits)
- FPGA (Field Programmable Gate Array)

2.2 Previously Developed Hardware

Modifications to previously developed Hardware refer to the following situation:

- Change of Aircraft Installation
- Change of Application or Design Environment
- Upgrade of a Design Baseline

In these cases the requirements of this document shall be tailored according to what stated in the paragraph 11.1 of the RTCA DO-254.

The intention to use previously developed Hardware shall be stated in the PHAC.

Qualification and Quality Assurance Complex Electronic Hardware Requirements for Suppliers of Equipment during design and development phases	QRS-117 Issue 02	Page 5/21
	April 2015	

2.3 Commercial Off The Shelf (COTS) Components Usage

The use of COTS components shall be verified through the overall Hardware life cycle, as defined in this document. Requirements shall be tailored according to what stated in the paragraph 11.2 of the RTCA DO-254.

Both for previously developed Hardware and COTS components, the service experience data can be used for design assurance; the relevance and acceptability of the service experience data shall be verified according to the aspects described in the paragraph 11.3 of the RTCA DO-254.

The PHAC shall specifically address those aspects where the design assurance of parts of an application relies on service experience data.

In case programme specific requirements are present, this procedure shall be used to integrate not foreseen activities. In any case, whenever a conflict arises, programme requirements prevail on this document.

3 APPLICABLE DOCUMENTS

3.1 AgustaWestland Documents

- QRS01 – Quality Requirements for Suppliers

4 DEFINITIONS AND ACRONYMS

4.1 Definitions

Complex Electronic Hardware - A hardware item is identified as simple only if a comprehensive combination of deterministic tests and analyses, appropriate to the design assurance level, can ensure correct functional performance under all foreseeable operating conditions, with no anomalous behaviour.

When an item cannot be classified as simple, ***it is classified as complex.***

4.2 Acronyms

ASIC	Application Specific Integrated Circuits
AW	AgustaWestland
CDR	Critical Design Review
COTS	Commercial Off The Shelf
CVE	Compliance Verification Engineer
DAL	Design Assurance Level
FCA	Functional Configuration Audit
FDR	Final Design Review
FPGA	Field Programmable Gate Array
HAS	Software Accomplishment Summary
HW	Hardware
MoM	Minute of Meeting
N.A.	Not Applicable
PCA	Physical Configuration Audit
PDR	Preliminary Design Review
PHAC	Plan for Hardware Aspects of Certification
PLD	Programmable Logic Devices
PLR	Planning Review
SW	Software

Qualification and Quality Assurance Complex Electronic Hardware Requirements for Suppliers of Equipment during design and development phases	QRS-117 Issue 02	Page 7/21
	April 2015	

5 GENERAL REQUIREMENTS

5.1 Supplier Approval

AgustaWestland Suppliers are classified and approved in accordance with what established by AW internal procedures.

The classification is reported in the Certificate delivered to the Supplier.

Any Supplier responsible for a design and development activity where Complex Electronic Hardware is involved shall be included in the AgustaWestland approved Suppliers database and its product range shall include the capability to supply **Complex Electronic Hardware**.

5.2 Subcontractors

Whenever the Supplier transfers the design and/or qualification of a system, sub-system and/or equipment containing Complex Electronic Hardware to some Subcontractor (completely, or in part), the Supplier remains responsible toward AgustaWestland of both the Hardware design and its qualification.

The Supplier shall produce to AgustaWestland all the required evidences and work products issued by the Subcontractor, adding its approval as a key element of the supply.

The Supplier shall:

- assure that its Subcontractors are able, on their turn, to satisfy the requirements of this document.
- warrant and produce evidence to AgustaWestland about Subcontractors qualification, including facilities they intend to utilise (the laboratories, for instance).

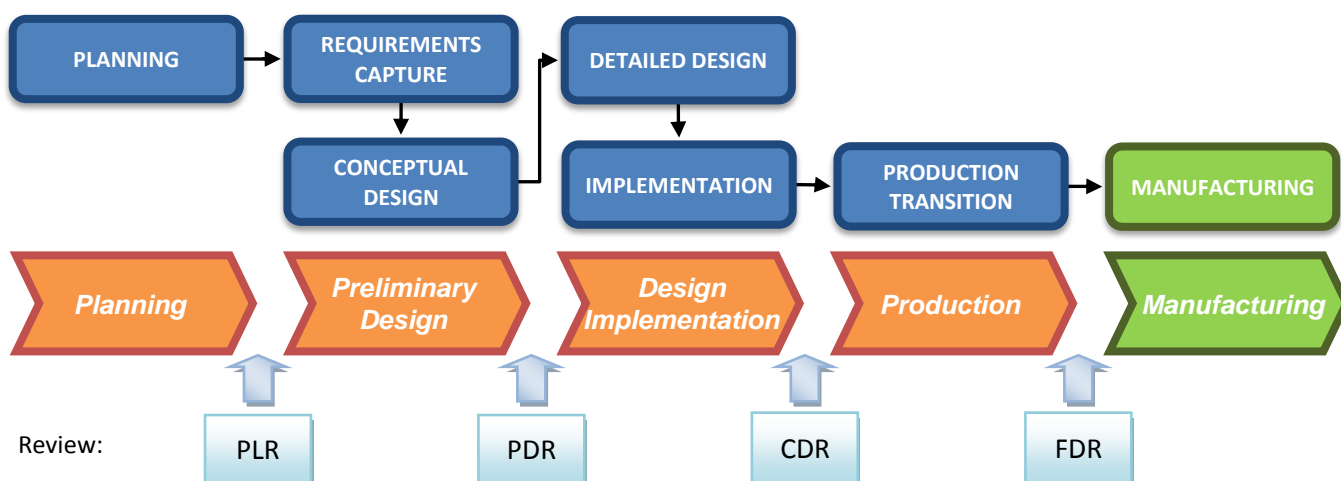
5.3 Access

The Supplier shall permit the access to all AgustaWestland representatives and Civil or Military Authorities accompanied by AgustaWestland; furthermore, the Supplier shall guarantee the access to Subcontractors facilities.

6 INTRODUCTION

6.1 Hardware Development Life Cycle

For the scope of this document, the Hardware development process is outlined as follow:



The main process is characterised by four phases (Planning, Preliminary Design, Design Implementation and Production). Preliminary and Design Implementation phases consist of the sub-phases from Requirements Capture to Implementation.

Established transition criteria shall be satisfied to access from a phase to the following one. Transition criteria shall be documented in the Hardware plans.

The phase outputs shall be verified in formal reviews (see next paragraph), whose positive results confirm the completion of all anticipated activities and the due conformity of the produced documentation.

In the following chapters, for each phase main goals and activities are described, including documents (work products) to be issued.

6.2 Work Products and Verification

For each phase, this document lists the typical expected work products and verification events (Design Reviews).

The Submission Criteria listed for the work products verified during Design Review shall be understood as follows:

According to the contract	The level of AgustaWestland approval is defined in each contract
Approval	Work product shall be formally approved by AgustaWestland deputed people
Available	Work product shall be available and verifiable during AgustaWestland audits
Review	No AgustaWestland formal approval required, but comments can be raised
Information	No AgustaWestland formal approval required

Unless differently specified, each work product shall be submitted to the Engineering AW focal point. The work products related to the Review requiring AW Approval/Review shall be delivered to AW at least 15 working days before.

The Supplier shall tailor the list according to contractual requirements and Hardware Design Assurance Level, justifying if a work product or a verification event will be not considered. The reference for work product tailoring and configuration control category is the Table A-1 contained in the Appendix A of the RTCA DO-254.

The identification of the Supplier Design Reviews along the life cycle shall be defined within the Plans.

In particular, as a minimum, the following aspects shall be described:

- Purpose of Review (or Analysis);
- Organisations to participate in the Review;
- Review (or Analysis) criteria;
- Detailed instructions for conducting the Review (or Analysis)
- Review (or Analysis) acceptability and completion criteria.

For Design Assurance Level A and B the above information can be included in the following document:

Document	RTCA DO-254	Submission Criteria
Review and Analysis Procedures	10.4.2	Review

Independently from Design Assurance Level, Reviews results can be included in the following document:

Document	RTCA DO-254	Submission Criteria
Review and Analysis Results	10.4.3	Information

6.3 Tools Qualification

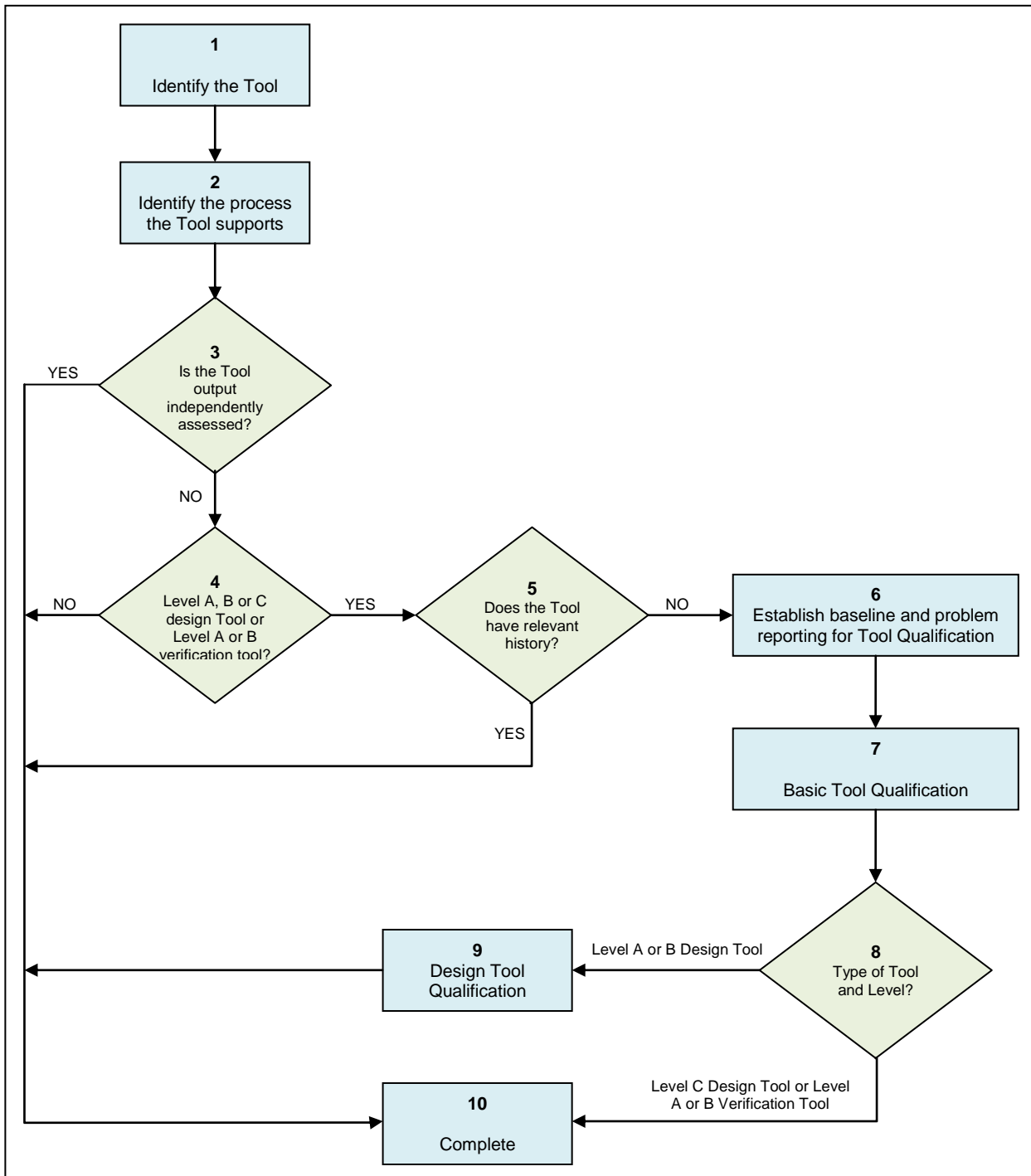
RTCA DO-254 tools may be classified as follows:

- RTCA DO-254 development tools
They provide outputs which are actually present in the embedded operational avionics Hardware.
- RTCA DO-254 verification tools
They are used to assist RTCA DO-254 verification.

Such tools shall apply RTCA DO-254 Hardware lifecycle aspects to ensure integrity and, when they automate or replace process steps cited by RTCA DO-254 and their outputs are not verified manually or by other qualified tools, they shall be qualified.

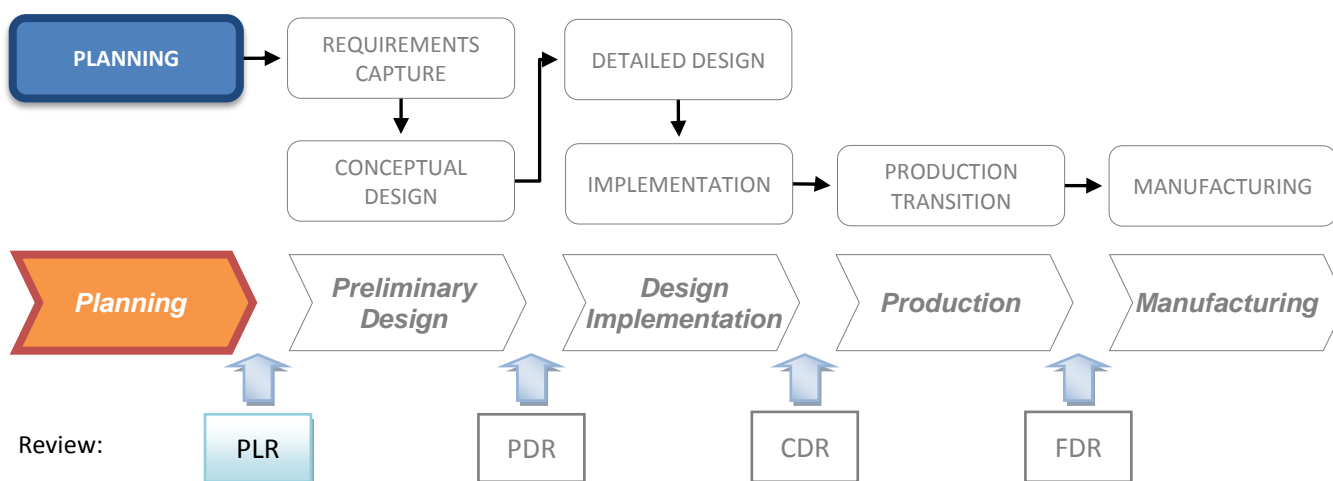
Tools assessment and qualification steps are described in the paragraph 11.4 of the RTCA DO-254; in the same paragraph, tools data needed to substantiate the assessment and qualification activities are also listed.

The process is summarized in the following flow chart.



Tool Assessment and Qualification steps

7 Phase 1 – PLANNING



The purpose of the Hardware planning phase is to define the means by which the functional and airworthiness requirements are converted into a Hardware item with an acceptable amount of evidence of assurance that the item will safely perform its intended functions.

The main output of this phase is the issuing of the Hardware Plans.

The Standards required for Hardware development are also defined (*Requirements, Design, Validation and Verification and Archive Standards*).

7.1 Main Goals and Activities

7.1.1 Goals

The objectives of the Hardware planning phase are the following:

- Definition of the Hardware design life cycle processes
- Selection and definition of the Standards
- Selection or definition of the Hardware development and verification environments
- Proposal to the Certification Authority of the means of compliance of the Hardware design assurance objectives

7.1.2 Activities

The activities related to the planning phase objectives are those described in the paragraph 4.2 of the RTCA DO-254.

In addition, the Supplier shall list, in the Hardware Process Assurance Plan, all the main Subcontractors (if any) and the relative responsibilities establishing the different activities between Supplier and Subcontractor.

The Supplier shall also include in the Hardware Process Assurance Plan a "Compliance Matrix" against the paragraphs from 5 to 11 of this document (summarised in Annex A), tailoring these requirements to the contractual ones (reference to contractual documents shall be included).

NOTE - For Design Assurance Levels C and D (for which a Hardware Process Assurance Plan is not required) the above information shall be included in the general Quality Assurance Plan.

The Hardware Configuration Management Plan shall include how the Supplier intends to manage possible changes/evolutions affecting the physical chips contained in the Complex Electronic Hardware devices (for example caused by obsolescence, performances improvements, HW resources modifications).

At least in this cases, the Supplier shall:

- inform AgustaWestland about the content of the change/evolution
- perform a regression analysis evaluating the change/evolution impact on the device required functionality

7.2 Work Products

According to the applicable Standard, the following documents represent the output of the Planning Phase.

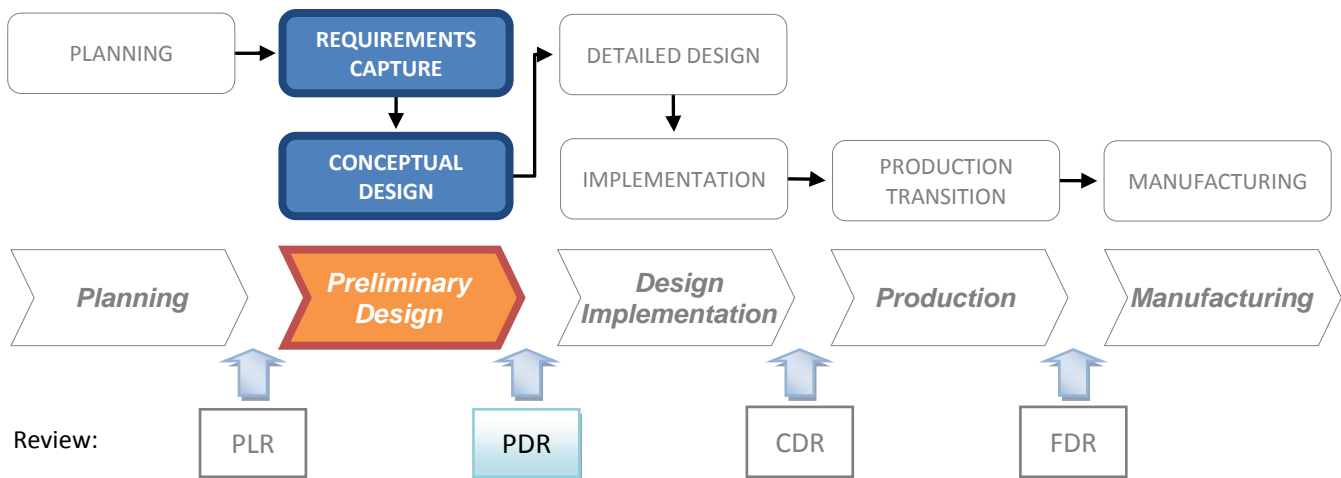
Document		DAL				RTCA DO-254	Submission Criteria
		A	B	C	D		
1	Plan for Hardware Aspects of Certification (PHAC)	✓	✓	✓	✓	10.1.1	Approval (AW CVE)
2	Hardware Design Plan	✓	✓	✓		10.1.2	Approval
3	Hardware Validation Plan	✓	✓	✓		10.1.3	Approval
4	Hardware Verification Plan	✓	✓	✓	✓	10.1.4	Approval
5	Hardware Configuration Management Plan	✓	✓	✓	✓	10.1.5	Approval Review (Quality)
6	Hardware Process Assurance Plan (see Note above)	✓	✓			10.1.6	Approval (Quality)
7	Requirements Standards	✓	✓			10.2.1	Review
8	Hardware Design Standards	✓	✓			10.2.2	Review
9	Validation and Verification Standards	✓	✓			10.2.3	Review
10	Hardware Archive Standards	✓	✓			10.2.4	Review

7.3 Verification

Work products originated during this phase shall be verified in a *PLR - Planning Review*.

The Planning review can be combined with the PDR (*Preliminary Design Review*, see paragraph 8.3), including the verification of Requirement Capture and Conceptual Design steps.

8 Phase 2 – PRELIMINARY DESIGN



The Hardware preliminary design phase includes the two steps of Requirement Capture and Conceptual Design.

The requirements capture step identifies and records the hardware item requirements. This includes those derived requirements imposed by the proposed hardware item architecture, choice of technology, the basic and optional functionality, environmental, and performance requirements as well as the requirements imposed by the system safety assessment. This step may be iterative since additional requirements may become known during design.

The conceptual design step produces a high-level design concept that may be assessed to determine the potential for the resulting design implementation to meet the requirements.

The main output of this phase are documents where the Hardware requirements are defined.

8.1 Main Goals and Activities

8.1.1 Goals

The objectives of the Hardware preliminary design phase are the following:

- Identification, definition and documentation of requirements
- Developing of the Hardware item conceptual design consistently with its requirements
- Derived requirements produced are fed back to the appropriate process
- Requirement omissions and errors are provided to the appropriate process for resolution

8.1.2 Activities

The activities related to the preliminary design phase objectives are those described in the paragraphs 5.1.2 and 5.2.2 of the RTCA DO-254.

8.2 Work Products

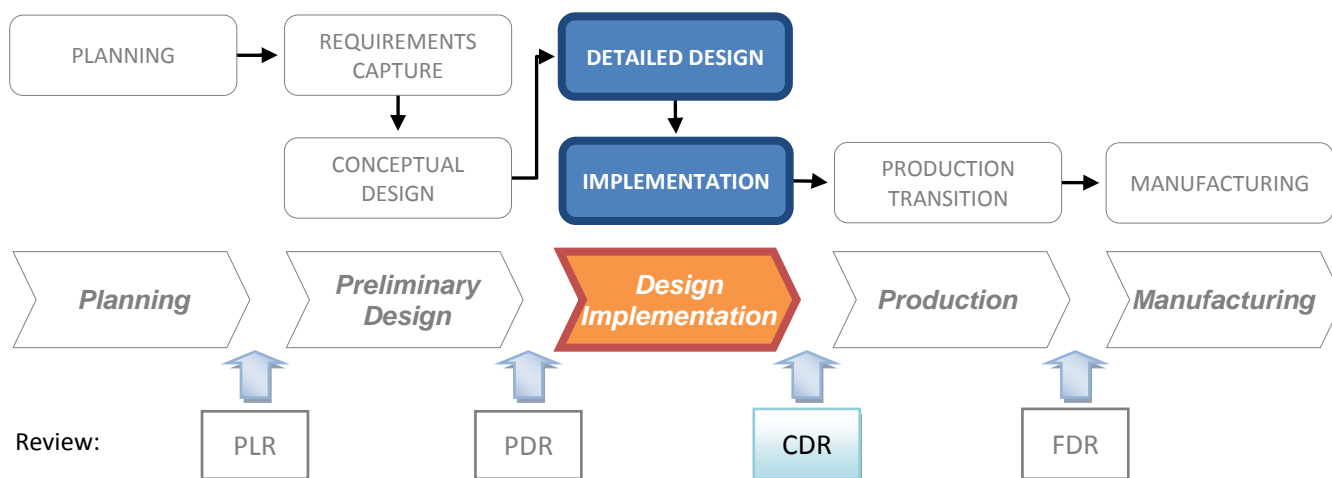
According to the applicable Standard, the following document represent the output of the preliminary design Phase.

Document		DAL				RTCA DO-254	Submission Criteria
		A	B	C	D		
1	Hardware Requirements	✓	✓	✓	✓	10.3.1	Approval
2	Conceptual Design Data	✓	✓			10.3.2.1	Review

8.3 Verification

Work products originated during this phase shall be verified in a *PDR – Preliminary Design Review*.

9 Phase 3 – DESIGN IMPLEMENTATION



The Hardware Design Implementation phase includes the two steps of Detailed Design and Implementation.

The Detailed Design step produces detailed design data using the Hardware item requirements and conceptual design data as the basis for the detailed design.

The Implementation step uses the detailed design data to produce the Hardware item that is an input to the testing activity.

The main outputs of this phase include the documents containing the detail requirements and the test procedures.

9.1 Main Goals and Activities

9.1.1 Goals

The objectives of the Hardware design implementation phase are the following:

- Developing of the detailed design from the Hardware item requirements and conceptual design data
- Producing of a Hardware item which implements the Hardware detailed design using representative manufacturing processes
- Conclusion of Hardware item implementation, assembly and installation data
- Derived requirements produced are fed back to the appropriate process
- Requirement omissions and errors are provided to the appropriate process for resolution

9.1.2 Activities

The activities related to the design implementation phase objectives are those described in the paragraphs 5.3.2 and 5.4.2 of the RTCA DO-254.

9.2 Work Products

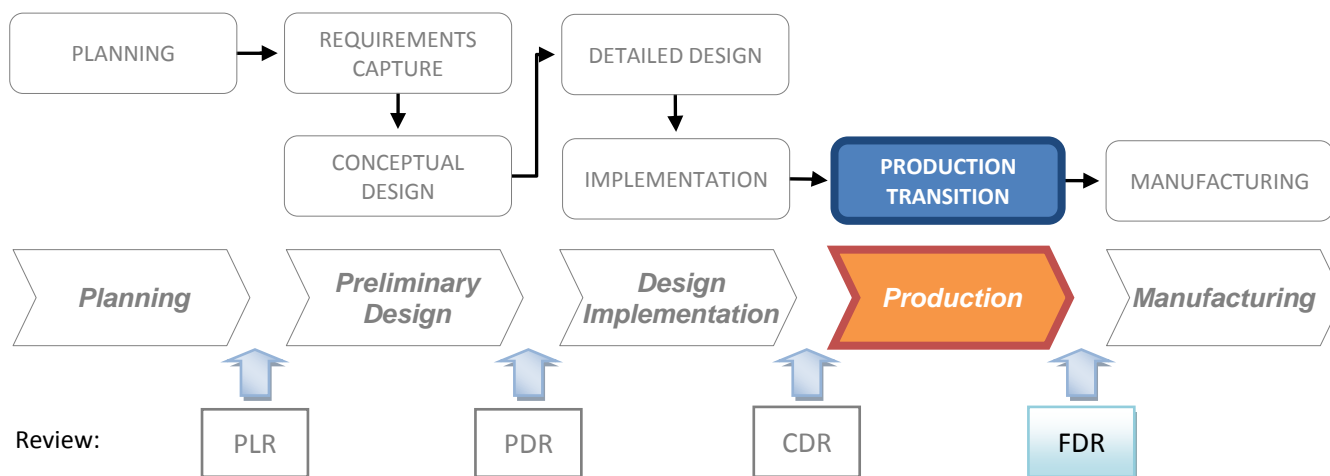
According to the applicable Standard, the following document represent the output of the design implementation Phase.

Document		DAL				RTCA DO-254	Submission Criteria
		A	B	C	D		
1	Hardware Requirements	✓	✓	✓	✓	10.3.1	Approval
2	Top-Level Drawing	✓	✓	✓	✓	10.3.2.2.1	Review
3	Assembly Drawings	✓	✓	✓	✓	10.3.2.2.2	Available
4	Installation Control Drawings	✓	✓	✓	✓	10.3.2.2.3	Available
5	Hardware/Software Interface Data	✓	✓	✓	✓	10.3.2.2.4	Review
6	Hardware Acceptance Test Criteria	✓	✓	✓	✓	10.5	Approval
7	Hardware Traceability Data	✓	✓	✓	✓	10.4.1	Available
8	Hardware Test Procedures	✓	✓	✓	✓	10.4.4	Approval

9.3 Verification

Work products originated during this phase shall be verified in a *CDR - Critical Design Review*.

10 Phase 4 – PRODUCTION



In the Production phase manufacturing data, test facilities and general resources are examined to ensure availability and suitability for production. The production transition step uses the outputs from the implementation and verification processes to move the product into production.

The main outputs of this phase are represented by test results and evidences in order to ensure that the Hardware item is built in compliance with its design data (this can be achieved, for example, by FCA/PCA activity or First Article Inspection).

The issuing of the Hardware Accomplishment Summary closes the activities related to the certification.

10.1 Main Goals and Activities

10.1.1 Goals

The objectives of the Hardware production phase are the following:

- Establishing of a baseline including all design and manufacturing data needed to support the consistent replication of the Hardware item
- Identification and documentation of the manufacturing requirements related to safety and establishing of manufacturing controls
- Derived requirements produced are fed back to the appropriate process
- Requirement omissions and errors are provided to the appropriate process for resolution

10.1.2 Activities

The activities related to the production phase objectives are those described in the paragraph 5.5.2 of the RTCA DO-254.

10.2 Work Products

According to the applicable Standard, the following document represent the output of the production Phase.

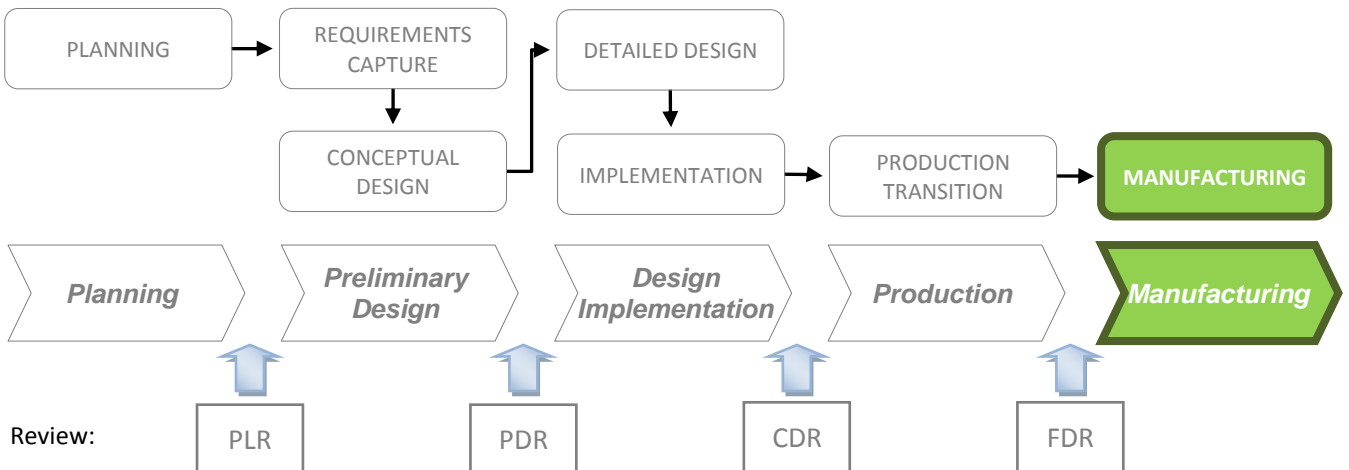
Document	DAL				RTCA DO-254	Submission Criteria	
	A	B	C	D			
1	Hardware Test Results	✓	✓	✓	✓	10.4.5	Review
2	FCA/PCA Report	✓	✓	✓	✓	8.2.5	Review
	First Article Inspection Report	✓	✓	✓	✓	8.2.5	Review
3	Hardware Accomplishment Summary	✓	✓	✓	✓	10.9	Approval (AW CVE)

The Supplier shall submit for approval to AW Engineering focal point and CVE the complete list of known problems and limitations before their inclusion in relevant documentation (HAS) for the Review.

10.3 Verification

Work products originated during this phase shall be verified in a *FDR - Final Design Review*.

11 MANUFACTURING



The manufacturing phase assures the consistent replication of the Hardware item.

Qualification and Quality Assurance Complex Electronic Hardware Requirements for Suppliers of Equipment during design and development phases	QRS-117 Issue 02	Page 19/21
	April 2015	

11.1 Acceptance test

Each manufactured Hardware item shall be submitted to an acceptance test.

Scope of the test is to demonstrate compliance with the key attributes of the item on which certification is based.

Acceptance test criteria should ensure that:

- Electrical tests are identified.
- Environmental screening tests are identified when necessary.
- The acceptance test provides coverage of those design aspects necessary to meet the safety requirements. Safety related item or sub-items that are not covered by the test shall be identified and other assurance means provided. These means may include analysis, design control, statistical process control or other means as appropriate.

11.2 Series production

This process reproduces the Hardware item on a routine basis that complies with the production data and requirements.

During series production the following aspects shall be considered:

- Management of change of the production processes or the design provides assurance that change does not adversely impact existing safety or certification or compliance to the requirements.
- Updating of all documentation related to changes is performed in compliance with approved configuration management plans.

Qualification and Quality Assurance Complex Electronic Hardware Requirements for Suppliers of Equipment during design and development phases	QRS-117 Issue 1	Page 20/21
	Draft September 2013	

ANNEX A

Title **COMPLIANCE MATRIX**

The following table summarise the requirements listed in this document for which the Supplier shall demonstrate compliance (or give a reference) in its Hardware Process Assurance Plan (see Note of paragraph 7.1.2 for Level C and D).

Paragraph	Requirement
5.1	The Supplier shall be included in the AgustaWestland approved Suppliers database.
5.1	The Supplier product range shall include the capability to supply Complex Electronic Hardware.
5.2	Whenever the Supplier transfers the design and/or qualification of a system, sub-system and/or equipment containing Complex Electronic Hardware to some Subcontractor (completely, or in part), the Supplier remains responsible toward AgustaWestland of both the Software design and its qualification.
5.2	The Supplier shall produce to AgustaWestland all the required evidences and work products issued by the Subcontractor, adding its approval.
5.2	The Supplier shall assure that its Subcontractors are able to satisfy the requirements of this document.
5.2	The Supplier shall warrant and produce evidence to AgustaWestland about Subcontractors qualification, including facilities they intend to utilise.
5.3	The Supplier shall permit the access to all AgustaWestland representatives and Civil or Military Authorities accompanied by AgustaWestland.
5.3	The Supplier shall guarantee the access to Subcontractors facilities.
6.1	The Supplier shall establish transition criteria that are to be satisfied to access from a life cycle phase to the following one.
6.1, 6.2	The Supplier shall verify phase outputs in formal reviews. The list of reviews to be performed along the Hardware development life cycle is required.
6.2	The work products related to the Review requiring AW Approval/Review shall be delivered to AW at least 15 working days before.
6.2	The Supplier Design Review procedures shall be defined within the Plans.
6.2	The following aspects shall be described (or the reference included):
	a) Purpose of Review
	b) Organisations to participate in the Review
	c) Review criteria
	d) Detailed instructions for conducting the Review
6.3	e) Review acceptability and completion criteria
	RTCA DO-254 tools for which the outputs are not verified manually or by other qualified shall be qualified.
6.3	The Supplier shall list the development and verification tools, specifying how their qualification will be demonstrated.
7	List of work products that the Supplier will issue during the Planning phase shall be provided.
7.1.2	The Plan shall list all the main Subcontractors (if any) and the relative responsibilities establishing the different activities between Supplier and Subcontractor.
7.1.2	The Supplier shall include a "Compliance Matrix" against this document.
7.1.2	The Hardware Configuration Management Plan shall include how the Supplier intends to manage possible changes/evolutions affecting the physical chips contained in the Complex Electronic Hardware devices.
7.1.2	In case of chip change/evolution, the Supplier shall: <ul style="list-style-type: none"> • inform AgustaWestland about the content of the change/evolution • perform a regression analysis evaluating the change/evolution impact on the device required functionality
8	List of work products that the Supplier will issue during the Hardware Preliminary Design phase shall be provided.
9	List of work products that the Supplier will issue during the Design Implementation phase shall be provided.
10	List of work products that the Supplier will issue during the Production phase shall be provided.
10.2	The Supplier shall submit for approval to AW Engineering focal point and CVE the complete list of known problems and limitations before their inclusion in relevant documentation (HAS).
11.1	An acceptance test for each manufactured item shall be established.
11.2	Management of change of the production processes shall be defined.