QRS-117 Complex Electronic Hardware, Quality Requirements for Suppliers

LEONARDO

HELICOPTERS

QRS-117

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CHANGES LOG

Issue	Approval Date	Main changes	Interested Paragraphs
01	December 2013	First issue	All
02	April 2015	Clerical Error correction and new layout	All
03	June 2018	Document significantly rewritten and reformatted	All
04	June 2019	Work Products and Verification Identification of sub-phases	6.2 6; 7; 8; 9; 10; 11

APPLICABLE DOCUMENTS

This document *shall* be applied together with the main document (QRS-01 Quality Requirements for Suppliers) and with the other applicable modules.
The external documents in the table below also apply.

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
EASA CM No.: EASA CM - SWCEH - 001	EASA CERTIFICATION MEMORANDUM Development Assurance of Airborne Electronic Hardware

CONTENTS

1   Purpose

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

This document contains the LH 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 LH aircrafts, and shall be *shall* be applied jointly with the QRS-115 for the general requirements

According to the definition given in paragraph 4.2, 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.

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   Effective date

Issue date

4   Acronyms, definitions and abbreviations

4.1   Acronyms and abbreviation

ASIC   Application Specific Integrated Circuits
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
LH   Leonardo Helicopters
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

4.2   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*.

5   General Requirements

5.1   Supplier Approval

Leonardo Helicopters 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 LH approved Suppliers database and its product range shall include the capability to supply *Complex Electronic Hardware*.

5.2   Sub-tiers

Whenever the Supplier transfers the design and/or qualification of a system, sub-system and/or equipment containing Complex Electronic Hardware to any Subcontractor (completely, or partially), the Supplier remains responsible towards Leonardo Helicopters of both the Hardware design and its qualification.

6   Introduction

6.1   Hardware Development Life Cycle
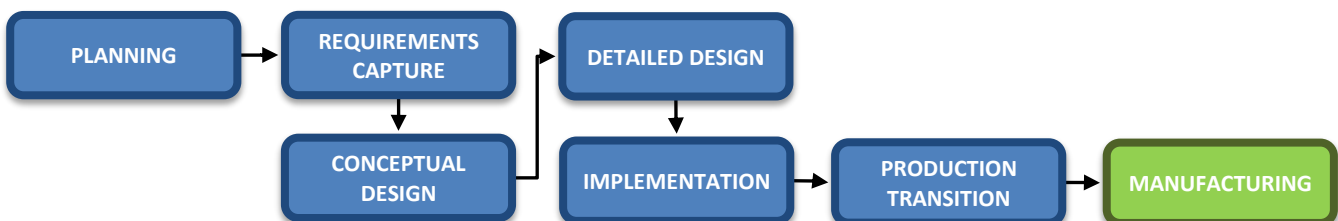
For the scope of this document, the Hardware development process is outlined as follow:
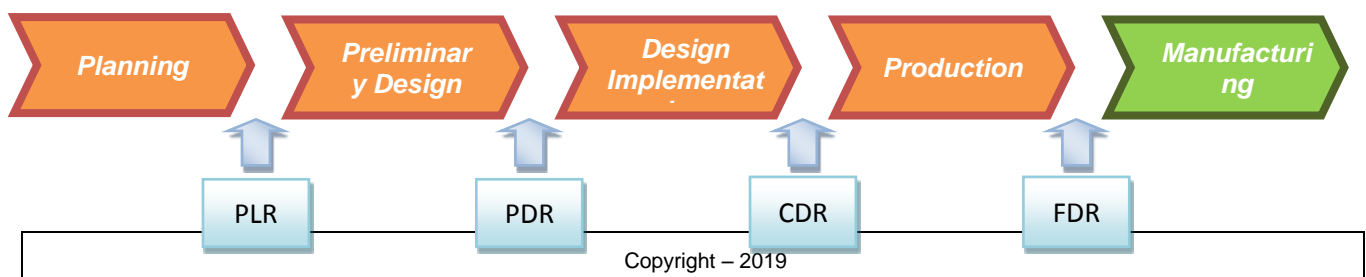
The main process is characterised by four phases (Planning, Preliminary Design, Design Implementation and Production). Preliminary and Design Implementation phases consist of the sub-phases from Requirements Capture to Implementation.
Established transition criteria shall be satisfied to access from a phase to the following one. Transition criteria shell 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 LH approval is defined in each contract
Approval	Work product shall be formally approved by LH deputed people through COMO or equivalent
Acceptance	No **LH** formal approval required, but work product *shall* be signed for knowledge
Available	Work product shall be available and verifiable during LH audits or progress meetings
Review	No LH formal approval required, but comments can be raised
Information	No LH formal approval required

Unless differently specified, each work product shall be submitted to the Engineering LH focal point defined in the SoW, who is in charge to coordinate and provide approval inside LH.
The work products related to the Review requiring LH Approval/Review shall be delivered to LH 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.

```
          ┌──────────────┐
          │      1       │
          │ Identify the │
          │     Tool     │
          └──────┬───────┘
                 │
          ┌──────▼───────┐
          │      2       │
          │ Identify the │
          │ process the  │
          │ Tool supports│
          └──────┬───────┘
                 │
          ┌──────▼───────┐
   YES    ╱      3        ╲
 ◄────────  Is the Tool
          ╲  output       ╱
             independently
          ╲  assessed?   ╱
                 │
                NO
                 │
   NO     ┌──────▼───────┐      YES   ╱   5    ╲   NO   ┌──────────────┐
 ◄────────╱      4        ╲──────────  Does the  ──────►│      6       │
          ╱ Level A, B or C╲          ╲ Tool have ╱     │ Establish    │
          ╲ design Tool or ╱           relevant         │ baseline and │
             Level A or B             ╲ history? ╱       │ problem      │
          ╲ verification  ╱                │             │ reporting... │
                                          YES            └──────┬───────┘
                                                                │
                                                         ┌──────▼───────┐
                                                         │      7       │
                                                         │ Basic Tool   │
                                                         │ Qualification│
                                                         └──────┬───────┘
  ┌──────────────┐   Level A or B Design Tool              ╱   8    ╲
  │      9       │◄────────────────────────────────────────  Type of
  │ Design Tool  │                                         ╲ Tool and ╱
  │ Qualification│                                            Level?
  └──────────────┘                                         ╲         ╱
                                   Level C Design Tool or       │
  ┌──────────────┐                 Level A or B Verification    │
  │     10       │◄─────────────────────────Tool───────────────┘
  │  Complete    │
  └──────────────┘
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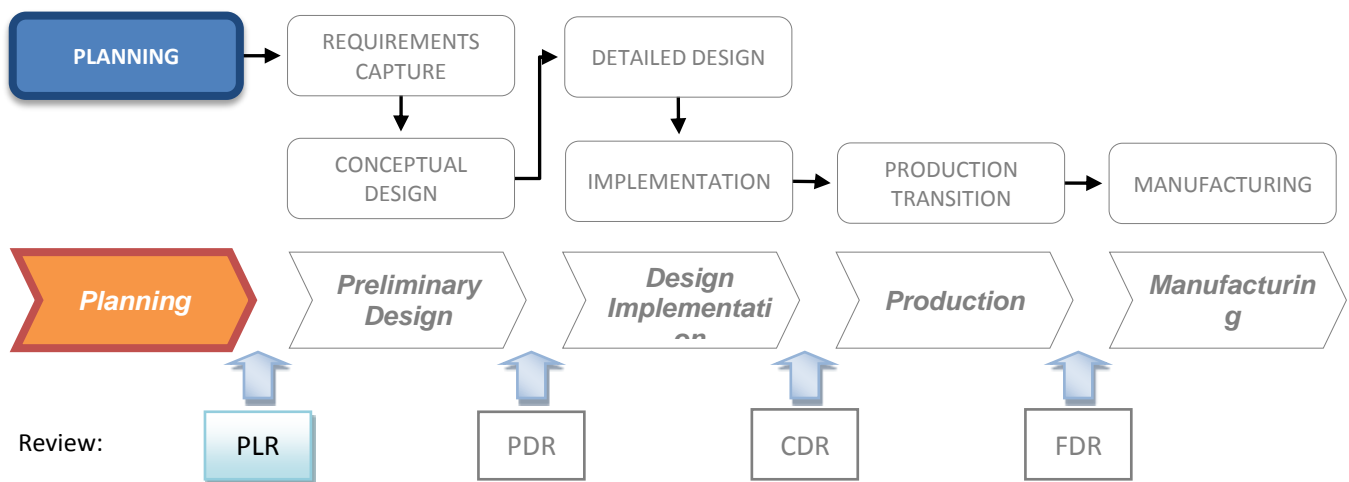
Tool Assessment and Qualification steps

7   Phase 1 – Planning

7.1   Planning - 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 LH about the content of the change/evolution
- perform a regression analysis evaluating the change/evolution impact on the device required functionality
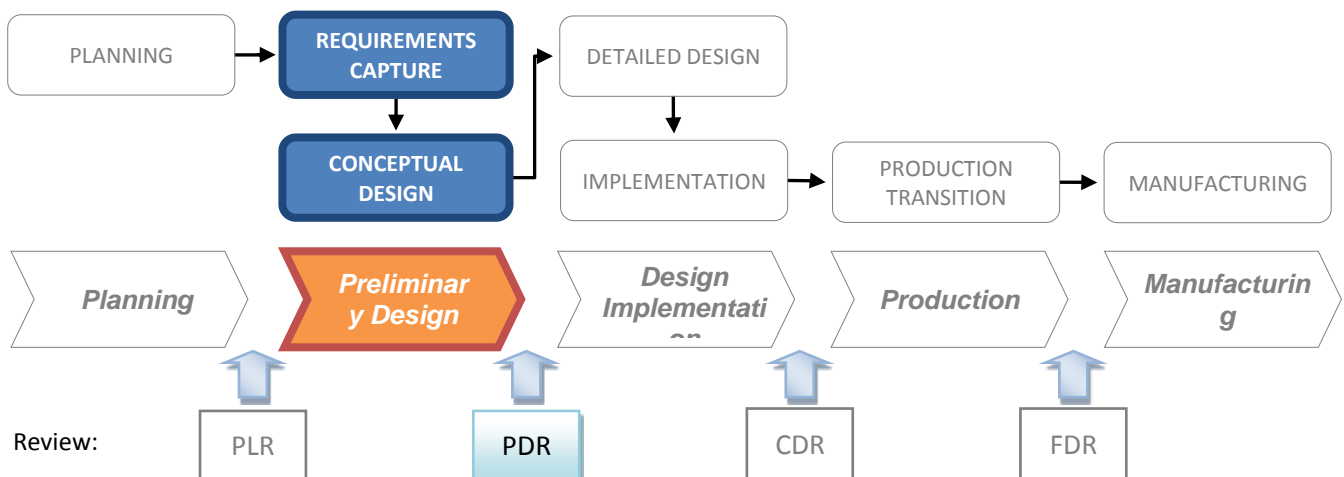
7.2 **Planning** - Work Products

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	Acceptance
2	Hardware Design Plan	✓	✓	✓		10.1.2	Acceptance
3	Hardware Validation Plan	✓	✓	✓		10.1.3	Acceptance
4	Hardware Verification Plan	✓	✓	✓	✓	10.1.4	Acceptance
5	Hardware Configuration Management Plan	✓	✓	✓	✓	10.1.5	Acceptance
6	Hardware Process Assurance Plan (see Note above)	✓	✓			10.1.6	Approval
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 **Planning** - 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

8.1 Preliminary Design - 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.
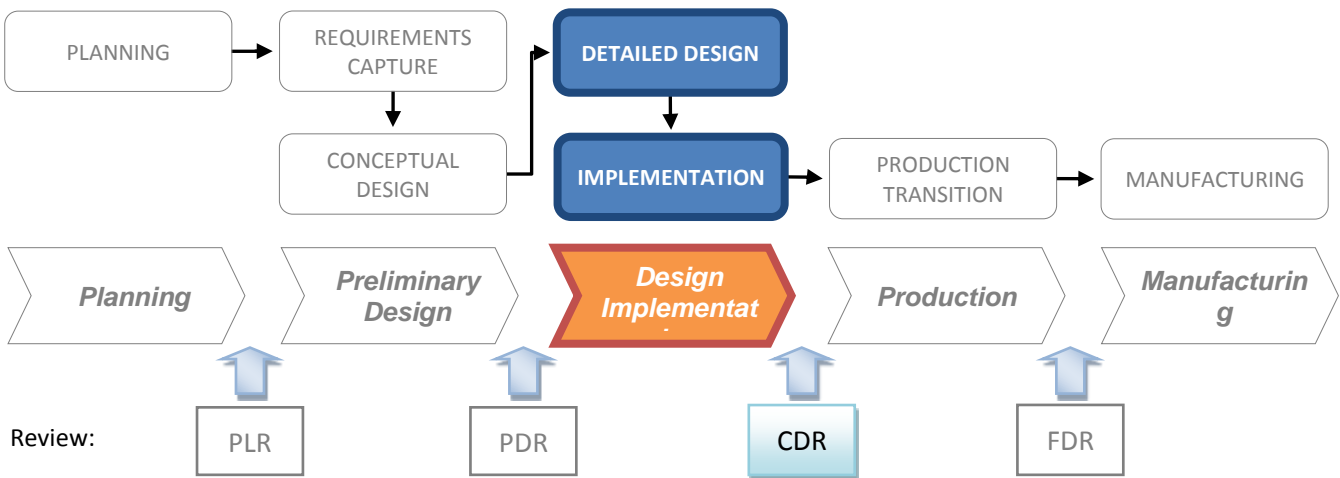
8.2 Preliminary Design - Work Products

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 Preliminary Design - Verification

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

9   Phase 3 – Design Implementation

9.1 Design Implementation - 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 Design Implementation - 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 Design Implementation - Verification

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

10 Phase 4 – Production
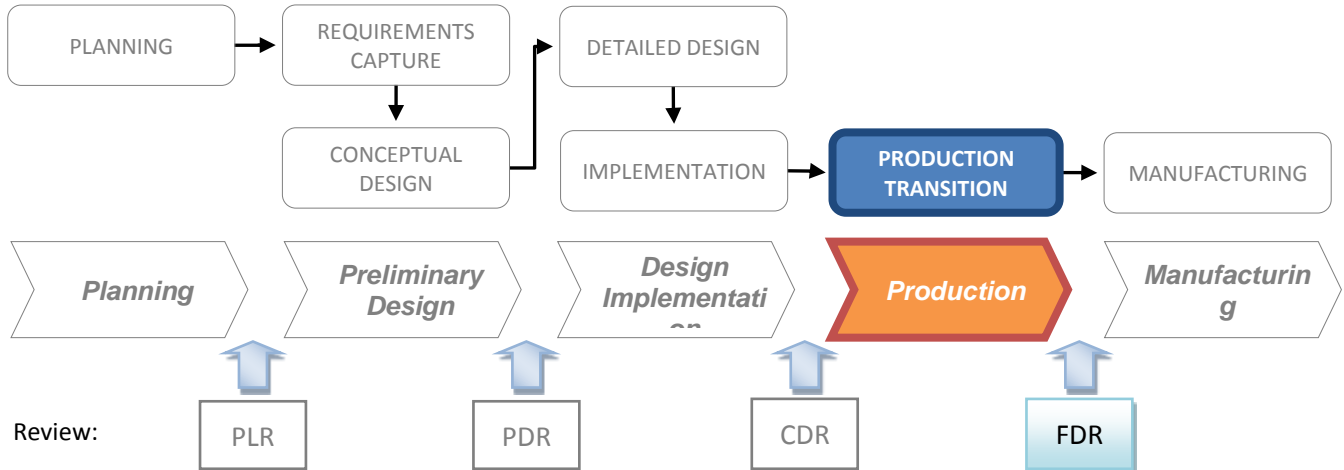
10.1 Production - Activities

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

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). These FCA/PCA or

FAI results shall be reported within any First Article Inspection applicable for higher level assemblies (ref. QRS-101)

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

10.2 Production - 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	Acceptance
4	Hardware Configuration Index	✓	✓	✓	✓	10.7	Acceptance

The Supplier shall submit for approval to LH 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 Production - Verification

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

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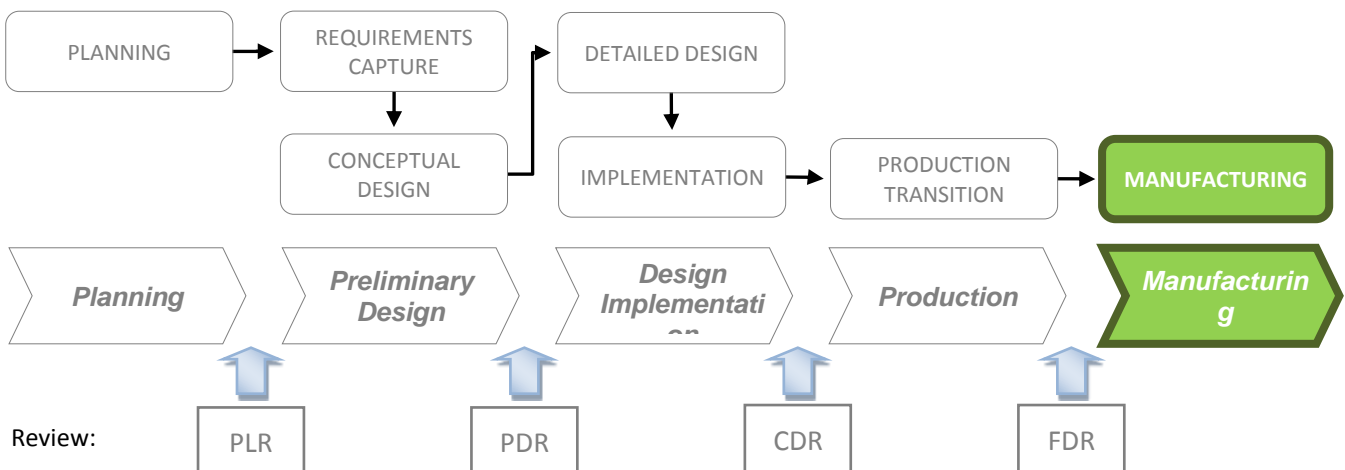
The manufacturing phase assures the consistent replication of the Hardware item.

11.1   Manufacturing - 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 shell be identified and other assurance means provided. These means may include analysis, design control, statistical process control or other means as appropriate.

11.2   Manufacturing - 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.

12   Appendices, Annexes and Forms

Annex A: Compliance Matrix

Annex A - 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 for Level C and D).

Paragraph	Requirement
5.1	The Supplier shall be included in the LH 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 LH of both the Software design and its qualification.
5.2	The Supplier shall produce to LH 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 LH about Subcontractors qualification, including facilities they intend to utilise.
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 LH Approval/Review shall be delivered to LH 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) Organizations to participate in the Review c) Review criteria d) Detailed instructions for conducting the Review e) Review acceptability and completion criteria
6.3	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	The Plan shall list all the main Subcontractors (if any) and the relative responsibilities establishing the different activities between Supplier and Subcontractor.
7.1	The Supplier shall include a "Compliance Matrix" against this document.
7.1	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	In case of chip change/evolution, the Supplier shall: • inform LH 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 LH 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.