

**QRS-116 Software Development,
Quality Requirements for Suppliers**



QRS-116

Software Development, Quality Requirements for Suppliers

Owned by: G. Cirino

G.Cirino

Approved by: Head of SQA

Fabio Mencioti

Issue Date:

Issue:

06

CHANGES LOG

| Issue | Approval Date | Main changes | Interested Paragraphs |
|-----------|----------------------|---|---|
| 01 | December 2013 | First Issue | |
| 02 | April 2015 | Clerical Errors and layout | All |
| 03 | June 2018 | Document significantly rewritten and reformatted | All |
| 04 | June 2019 | Tool Assessment and Qualification steps Identification of sub-phases Add Version Description Document (draft) | 6.3 7, 8, 9, 10, 11 10.2 and 10.3 |
| 05 | April 2025 | Global revision with requirements borrowed from QRS-01 and Traceability matrix issue Vs EN9115 requirements | All |
| 06 | February 2026 | Added Specific Requirement for AW09 | 13 |

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/JISQ 9100 | 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-178B or DO-178C as contractually applicable | Software Considerations in Airborne Systems and Equipment Certification |
| AQAP 2210 | NATO Supplementary Software Quality Assurance Requirements to AQAP 2110 |
| AS9006 | Quality Management Systems - Aerospace - Requirements for Software |
| EASA CM No.: EASA CM - SWCEH – 002 | EASA CERTIFICATION MEMORANDUM Software Aspects of Certification |

CONTENTS

| | |
|---|-----------|
| 1 Purpose | 4 |
| 2 Applicability | 4 |
| 3 Effective date | 5 |
| 4 Acronyms, definitions and abbreviations | 5 |
| 4.1 Acronyms and Abbreviations | 5 |
| 5 General requirements | 6 |
| 5.1 Supplier Approval | 6 |
| 5.2 Sub-tier Suppliers | 6 |
| 6 Introduction | 6 |
| 6.1 Software Development Life Cycle | 6 |
| 6.2 Work Products and Verification | 7 |
| 6.3 Tools Qualification | 8 |
| 7 Phase 1 – Planning | 10 |
| 7.1 Planning - Activities | 10 |
| 7.1.1 Requirements for Software Development Environment | 10 |
| 7.2 Planning - Work Products | 11 |
| 7.3 Planning - Verification | 11 |
| 8 Phase 2 – Software requirements | 11 |
| 8.1 Software Requirements - Activities | 11 |
| 8.1.1 High-level Requirements Development | 11 |
| 8.1.2 Derived High-level Requirements Definition | 12 |
| 8.2 Software Requirements - Work Products | 12 |

| | |
|---|--------------------------------|
| 8.3 Software Requirements - Verification..... | 12 |
| 9 Phase 3 – Software design | 12 |
| 9.1 Software Design - Activities | 12 |
| 9.1.1 SW Architecture and Low-level Requirements Development..... | 12 |
| 9.1.2 Derived Low-level Requirements Definition..... | 12 |
| 9.2 Software Design - Work Products | 13 |
| 9.3 Software Design - Verification | 13 |
| 10 Phase 4 – Software coding/integration..... | 13 |
| 10.1 Software coding/integration - Activities..... | 13 |
| 10.1.1 Source Code Development..... | 13 |
| 10.1.2 Test Procedures Definition..... | 13 |
| 10.2 Software coding/integration - Work Products | 14 |
| 10.3 Software coding/integration - Verification | 14 |
| 11 Phase 5 –Qualification | 15 |
| 11.1 Qualification - Activities..... | 15 |
| 11.1.1 Completion of All Life Cycle Activities..... | 15 |
| 11.1.2 Demonstration of Software conformity..... | 15 |
| 11.2 Qualification - Work Products | 16 |
| 11.3 Qualification - Verification | 16 |
| 12 Delivery | 17 |
| 12.1 Before Delivery | 17 |
| 12.2 Delivery Documentation..... | 18 |
| 12.3 Identification..... | 19 |
| 12.4 After Delivery | 19 |
| 12.4.1 Defects Revealed by the Supplier | 19 |
| 12.4.2 Defects Revealed by Leonardo Helicopters | 19 |
| 13 Specific Requirements for AW09 | 20 |
| 14 Appendices, Annexes and Forms | 20 |
| Annex A – Guidelines for FCA and PCA Verification | 21 |
| Annex B – Compliance Matrix..... | 25 |
| Annex C – Traceability Matrix QRS Vs EN9115..... | 28 |
| Annex C – Traceability Matrix QRS Vs EN9115..... | Error! Bookmark not defined.29 |

1 Purpose

This document provides guidelines for the Leonardo Helicopters Suppliers of Software for airborne systems and equipment, in order to achieve a level of confidence in safety that complies with airworthiness requirements.

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.

It defines Quality and Qualification requirements to be met during the development phase by Software Suppliers both for stand-alone deliverable Software and for Software specifically devoted to a deliverable equipment (embedded SW).

2 Applicability

This document is applicable to new development of Software for airborne systems and equipment installed on LH aircrafts.

In particular, the following Software are included:

- SW stand-alone (Field Loadable Software included)
- SW embedded with LH Part Number
- SW embedded without LH Part Number

Non airborne Software shall be managed according to the requirements of this document, assuming that an equivalent RTCA DO-278A is applied, according to specific contract requirements.

In case of COTS Software this document is not applicable, but the Supplier shall confirm the Software validation status in accordance with the criticality level estimated for it. Records of such activity shall be forwarded to LH for acceptance.

In case of Software derived from a modified COTS, the Supplier shall meet the requirements of this document for the newly developed part, evaluating acceptability of the records related to the originator COTS.

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

This document shall be applied jointly with the QRS-115 for the general requirements

3 Effective date

Issue date

4 Acronyms, definitions and abbreviations

4.1 Acronyms and Abbreviations

| | |
|------|--|
| ABL | Allocated Baseline |
| CDR | Critical Design Review |
| CO | Concession |
| CoC | Certificate of Conformity |
| COTS | Commercial Off The Shelf |
| CSC | Computer Software Component |
| CSCI | Computer Software Configuration Item |
| CSU | Computer Software Unit |
| DDP | Declaration of Design and Performance |
| DR | Delivery Review |
| ECR | Engineering Change Requests |
| FBL | Functional Baseline |
| FCA | Functional Configuration Audit |
| LH | Leonardo Helicopters |
| FQR | Formal Qualification Review |
| MoM | Minute of Meeting |
| N.A. | Not Applicable |
| P/N | Part Number |
| PCA | Physical Configuration Audit |
| PDR | Preliminary Design Review |
| PLR | Planning Review |
| PP | Production Permit |
| PR | Problem Reports |
| PSAC | Plan for Software Aspects of Certification |
| S/N | Serial Number |
| SAS | Software Accomplishment Summary |
| SCR | Software Conformity Review |
| SECI | Software Environment Configuration Index |
| SSR | Software Specification Review |
| SW | Software |
| VDD | Version Definition Document |
| TRR | Test Readiness Review |

5 General requirements

5.1 Supplier Approval

LH Suppliers are classified and approved in accordance with QRS-01. The classification is reported in the Certificate delivered to the Supplier.

Any Supplier responsible for a Software design and development activity shall be included in the LH approved Suppliers database and its product range shall include the capability to supply **Software**.

5.2 Sub-tier Suppliers

Whenever the Supplier transfers the design and/or qualification of the Software product to sub-tier Suppliers (completely or partially), the Supplier remains responsible towards LH of both the Software design and its qualification.

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

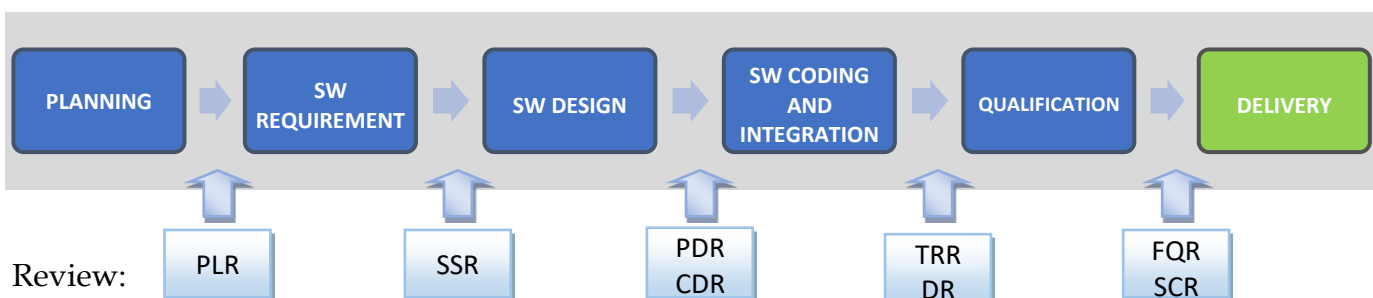
The Supplier shall:

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

6 Introduction

6.1 Software Development Life Cycle

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



6.2 Work Products and Verification

For each phase, this document lists the typical expected work products (having as a reference the RTCA DO-178 and the AQAP 2210) 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 |
| Acceptance | Work product shall be formally accepted by LH deputed people and by Civil or Military Authorities as applicable. Double acceptance is required (LH and Authority) |
| 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 Supplier shall tailor the list according to contractual requirements, applicable Standards and Software criticality level, justifying if a work product or a verification event will be not considered.

The Supplier Design Review procedures shall be defined within the Plans. In particular, as a minimum, the following aspects shall be described:

- Involved personnel and respective responsibility;
- Applicable documentation;
- Quality Assurance role and activity.

A Review MoM shall be prepared, including an action list to trace all the possible sources of problems, proposing the corresponding corrective actions. For each action item a Responsible and a due date shall be defined.

Before each Design Review which requires presence of LH the Supplier, through its Quality Assurance, shall guarantee that:

- an internal equivalent Design Review was performed, including MoM and actions list as described above
- all the necessary products are ready and available
- all the activities pertinent to the phase to be verified have been done in accordance with the applicable procedures

The work products related to the Review and requiring LH Approval/Review shall be delivered to LH at least 15 working days before.

6.3 Tools Qualification

Software tools may be classified as follows:

- SW development tools
Tools whose output is part of the airborne Software and thus can introduce errors (e.g. a tool which generates source code directly from low-level requirements).
- SW verification tools
Tools that cannot introduce errors by their own, but may fail to detect them (e.g. test tools, syntax controllers, emulators/simulators).

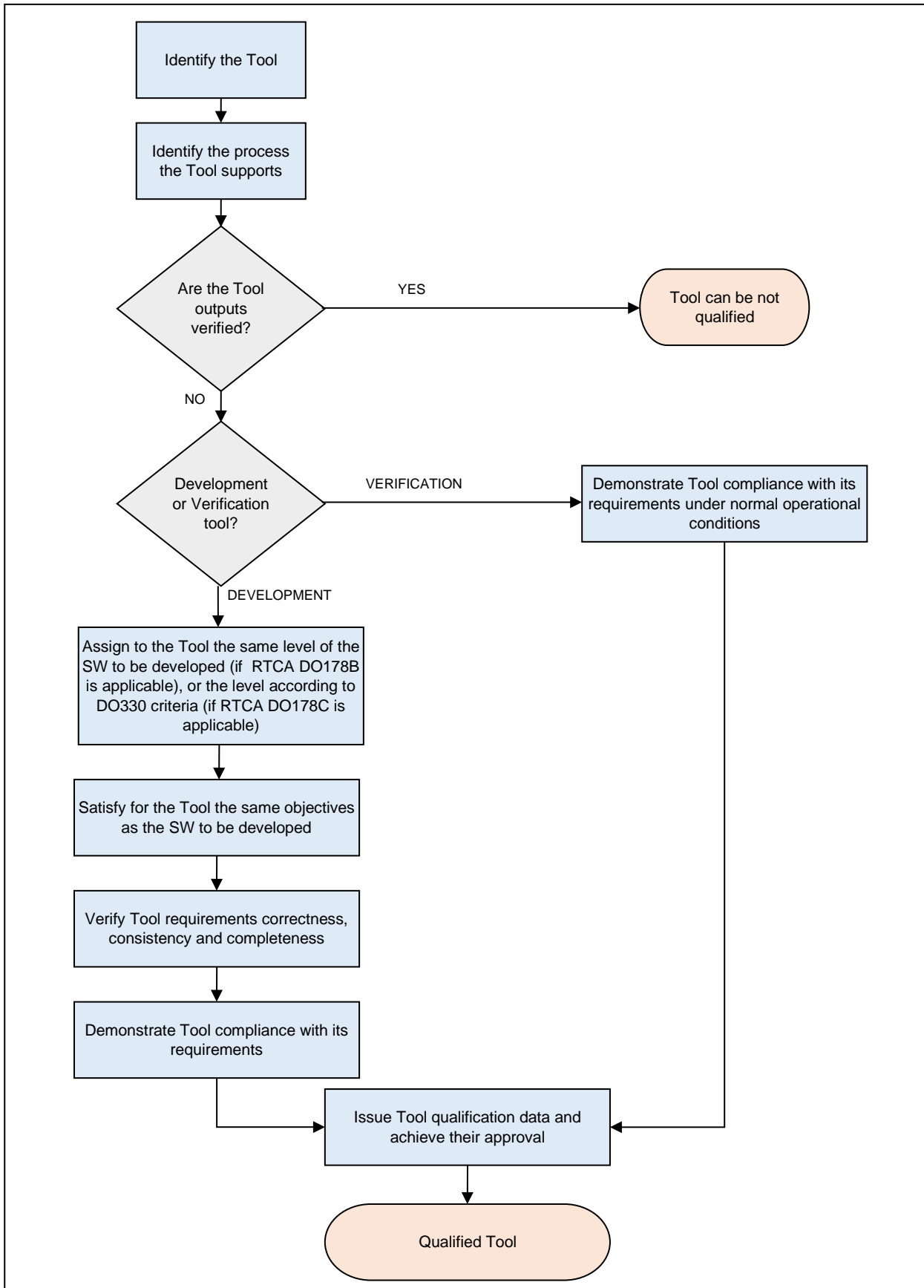
If the Supplier intends to use one or more of the above described tools and their outputs are not verified manually or by other qualified tools, these shall be qualified.

For each tool that needs to be qualified, the supplier shall apply the EASA CM SWCEH-002 and DO330 (where applicable)

The following documents shall be provided to LH:

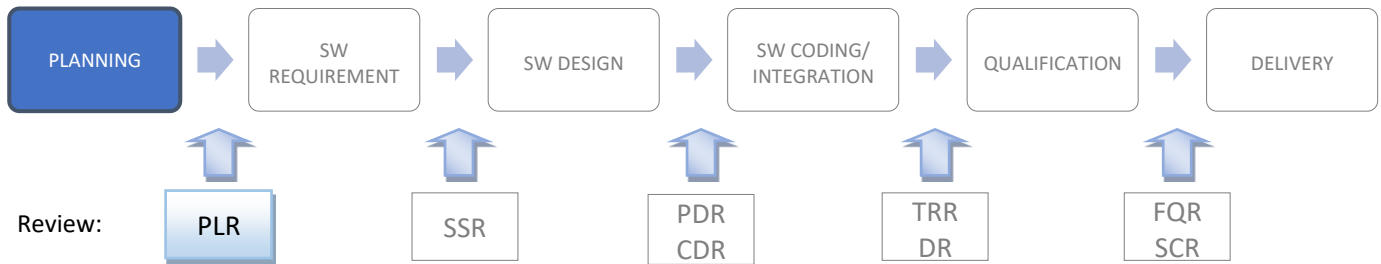
| Document | RTCA DO-178 | AQA P 2210 | Submission Criteria |
|---------------------------------|-------------|------------|---------------------|
| 1 Tool Qualification Plan | 12.2.3.1 | N.A. | Acceptance |
| 2 Tool Operational Requirements | 12.2.3.2 | - | Acceptance |
| 3 Tool Design Document | - | - | Acceptance |
| 4 Tool Test Procedure | - | - | Acceptance |
| 5 Tool Test Results | - | - | Acceptance |
| 6 Configuration Index (final) | - | - | Acceptance |
| 7 Tool Accomplishment Summary | 12.2.3.c(3) | N.A. | Acceptance |

The tool qualification process is summarized in the flow chart of the following page.



Tool Assessment and Qualification steps

7 Phase 1 – Planning



7.1 Planning - Activities

7.1.1 Requirements for Software Development Environment

The Software life cycle environment, including the methods and tools to be used for the activities of each Software life cycle process (requirements management, design and coding, configuration management, verification and validation) shall be defined and included in the Plans.

The Supplier shall identify (usually in Software Quality Assurance Plan) people in charge and thus responsible for:

- Declaring the Software Airworthiness, by signing the technical documents of the Design Data Set;
- Declaring released Software conformity, by signing the Certificate of Conformity and the relative documentation (Concession, etc...), if applicable.

In addition, the Supplier shall list the reference people ("Focal Points") for Software Quality and Design activities.

The Supplier shall include in the Software Quality Assurance Plan a "Compliance Matrix" against the paragraphs from 5 to 12 of this document (summarised in Annex B), tailoring these requirements to the contractual ones (reference to contractual documents shall be included).

If RTCA DO-178 applies, a "Compliance Matrix" against sections 8 and 11.5 shall be also included.

The Plan shall list all the main Subcontractors (if any) and the relative responsibilities establishing the different activities between Supplier and Subcontractor.

The Supplier shall describe configuration management activities in terms of:

- rules of Software P/N definition
- changes and non conformities management

Software Quality Assurance Plan shall include or refer to the above configuration management activities.

7.2 Planning - Work Products

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

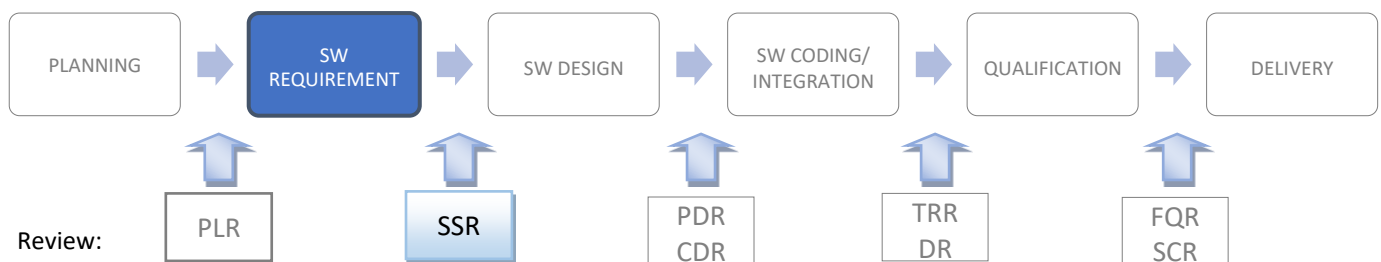
| Document | RTCA DO-178 | AQAP 2210 | Submission Criteria |
|---|-------------|-----------|---------------------|
| 1 Software Quality Assurance Plan | 11.5 | 2.2.2 | Approval |
| 2 Software Development Plan | 11.2 | 2.2.4.1 | Acceptance |
| 3 Software Verification Plan | 11.3 | 2.2.6 | Acceptance |
| 4 Software Configuration Management Plan | 11.4 | 2.2.4.6 | Acceptance |
| 5 Plan for Software Aspects of Certification (PSAC) | 11.1 | N.A. | Acceptance |
| 6 SW Requirement Standards | 11.6 | - | Review |
| 7 SW Design Standards | 11.7 | - | Review |
| 8 SW Code Standards | 11.8 | - | 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 SSR (Software Specification Review, see [paragraph 8.3](#)).

8 Phase 2 – Software requirements



8.1 Software Requirements - Activities

8.1.1 High-level Requirements Development

Each system requirement allocated to Software shall be traceable to one or more Software high level requirements.

The high-level requirements shall conform to the Software Requirements Standards and be verifiable and consistent. They shall be stated in quantitative terms with tolerances, where applicable.

8.1.2 Derived High-level Requirements Definition

Derived high-level requirements shall be indicated to the system safety assessment process.

8.2 Software Requirements - Work Products

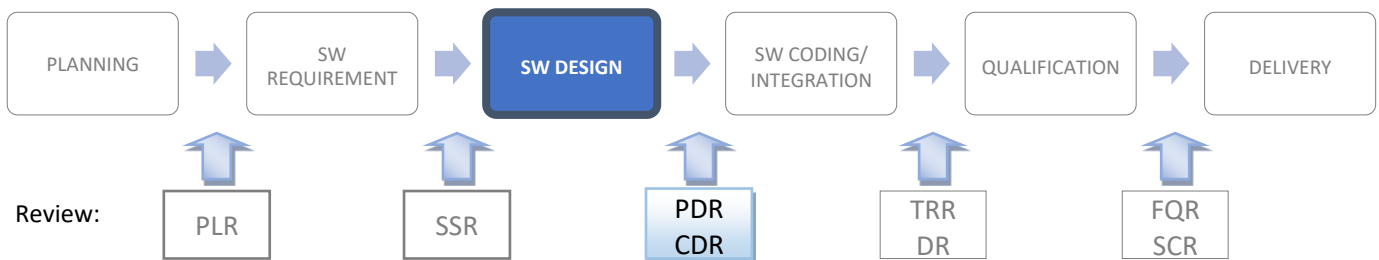
According to the applicable Standard, the following document represent the output of the Software Requirement Phase.

| Document | RTCA DO-178B/C | AQAP 2210 | Submission Criteria |
|------------------------------------|----------------|-----------|---------------------|
| 1 | - | 2.2.3 | Approval |
| Software Requirement Specification | 11.9 | - | |

8.3 Software Requirements - Verification

Work products originated during this phase shall be verified in a *SSR - Software Specification Review*.

9 Phase 3 – Software design



9.1 Software Design - Activities

9.1.1 SW Architecture and Low-level Requirements Development

Low-level requirements and Software architecture developed during the Software design phase shall conform to the Software Design Standards and be traceable, verifiable and consistent.

9.1.2 Derived Low-level Requirements Definition

Derived requirements shall be defined and analysed to ensure that the higher level requirements are not compromised.

9.2 Software Design - Work Products

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

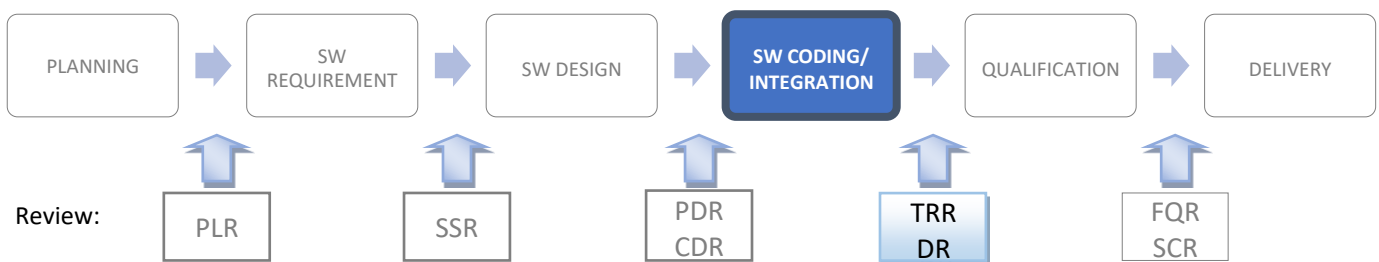
| Document | RTCA DO-178B/C | AQAP 2210 | Submission Criteria |
|--------------------------------------|----------------|-----------|---------------------|
| 1 Software Requirement Specification | 11.9 | 2.2.3 | Approval |
| 2 Software Design Description | 11.10 | - | Approval |

9.3 Software Design - Verification

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

The PDR, depending on the complexity of the design, can be joined with the CDR.

10 Phase 4 – Software coding/integration



10.1 Software coding/integration - Activities

10.1.1 Source Code Development

Source code is developed that is traceable, verifiable, consistent, and correctly implements low-level requirements according to Software architecture.

10.1.2 Test Procedures Definition

Test specifications shall be prepared which define test cases, required test data and expected results.

10.2 Software coding/integration - Work Products

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

| Document | | RTCA DO-178B/C | AQAP 2210 | Submission Criteria |
|----------|--|----------------|-----------|---------------------------|
| 1 | Source Code | 11.11 | - | According to the contract |
| 2 | Object Code | 11.12 | - | According to the contract |
| 3 | Software Verification Cases and Procedures | 11.13 | - | Acceptance |
| | Test Specifications | | 2.2.6.1 | |
| 4 | Software Configuration Index (draft) | 11.16 | - | Information |
| | Version Description Document (draft) | | | |

10.3 Software coding/integration - Verification

The codes and the documents originated during this phase shall be verified during one or more *TRR - Test Readiness Review*.

According to what established by the contract, during the TRRs can be presented also the results from suitable Code verification methods.

If the Supplier needs to freeze an intermediate SW development configuration delivered for Avionics integration RIG test, or subsystem test, or flight test before conclusion of the whole integration test phase, a *DR – Delivery Review* shall be done. In this case, an agreed subsystem of the work products listed for the FQR (see the following table) shall be also presented and delivered.

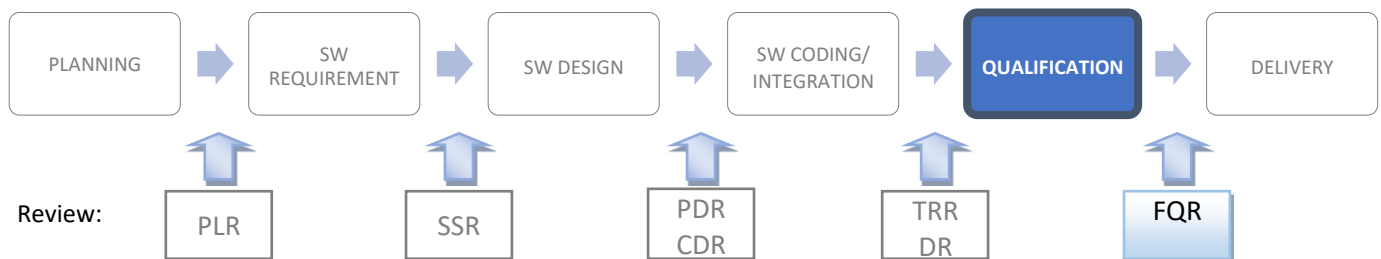
| Document | | RTCA DO-178B/C | AQAP 2210 | Submission Criteria |
|----------|---|----------------|-----------|---------------------|
| 1 | Software Verification Results | 11.14 | - | Acceptance |
| 2 | Software Configuration Index | 11.16 | - | Acceptance |
| | Version Description Document | | | |
| 4 | DDP – Declaration of Design and Performance | - | - | Approval |

The subsystem of the work products shall be agreed with LH in advance and included in the Delivery Review MoM.

For further intermediate deliveries related to the same Software Part Number is acceptable that the Supplier formally informs LH (i.e. with a Coordination Memo) about the work products “delta”, without an updating of the documents; only the DDP shall be always re-issued when the delivery is for flight test.

NOTE - Once the Integration/Qualification activities are positively concluded, the work products shall be re-issued, incorporating all the “delta” occurred during intermediate deliveries.

11 Phase 5 –Qualification



11.1 Qualification - Activities

11.1.1 Completion of All Life Cycle Activities

Each activities described in the Software Plans shall be completed and verified.

11.1.2 Demonstration of Software conformity

Test, inspections or analytical processes shall be able to demonstrate that each Software configuration item meets the specific contractual performance requirements.

11.2 Qualification - Work Products

According to the applicable Standard, the following documents represent the output of the Integration/ Qualification Phase.

| Document | | RTCA DO-178B/C | AQAP 2210 | Submission Criteria |
|----------|---|----------------|-----------|---------------------|
| 1 | Software Verification Results | 11.14 | - | Acceptance |
| 2 | Software Configuration Index | 11.16 | - | Acceptance |
| | Version Description Document | - | - | |
| 3 | Software Environment Configuration Index ¹ | 11.15 | - | Acceptance |
| 4 | PCA – FCA Results | - | - | Review |
| 5 | DDP – Declaration of Design and Performance | - | - | Approval |
| 6 | Software Accomplishment Summary (SAS) | 11.20 | N.A. | Acceptance |

In case of Software with LH Part Number, the Software Configuration Index (or the Version Description Document) represents the Design Data Set according to LH rules.

The Supplier shall submit for approval to LH Engineering focal point the complete list of known problems and limitations before their inclusion in relevant documentation (SCI/VDD/SAS) for the Review.

11.3 Qualification - Verification

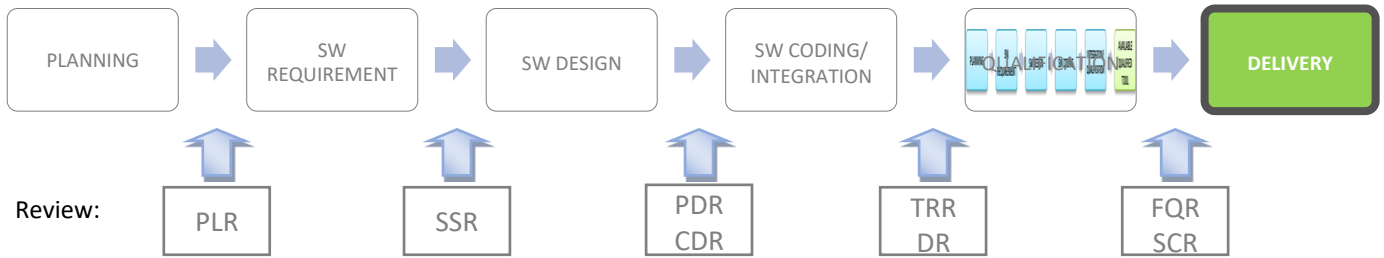
The outputs originated during this phase shall be verified according to the following:

- Software not submitted to Civil Airworthiness Certification
FQR – Formal Qualification Review, including PCA and FCA verification².
- Software submitted to Civil Airworthiness Certification (or considered “certifiable”)
SCR – Software Conformity Review according to RTCA DO-178B/C requirements applies; contents of FQR shall be in any case verified before or contextually the SCR.

¹ The Software Environment Configuration Index can be included in the SCI/VDD

² A guideline for PCA and FCA verification is provided in Annex A.

12 Delivery



12.1 Before Delivery

The Supplier shall ensure conformity of new or modified Software before delivery, providing a process for the inspection, verification and documentation of the Software item.

This shall apply to the documentation, Software and procedures to ensure that the end item configuration is defined, meets LH requirements and can be consistently reproduced. A successful process results in acceptance of the product baseline and allows the delivery of Software to LH.

The Supplier shall demonstrate that:

- All life cycle data and documents are complete and records retained
- All problem reports and changes are identified and dispositioned
- The deliverable object code can be recreated from the source code
- Software requirement deviations are recorded and approved
- The software can be loaded into the target computer and initialised
- The software item was tested and accepted in accordance with the governing requirements
- Traceability exists of the end item documentation to the governing requirements
- The software item is correctly identified, virus checked, and corruption free
- The source code is identified and under configuration control

These objectives may be met through verifications throughout the Software life cycle and evidences contained in the work products accepted during Design Reviews.

12.2 Delivery Documentation

Each Software shall be delivered with specific documentation, depending on the following case:

- Stand-alone SW

It shall be delivered on a suitable media (USB Key or CD) with the following documentation:

- Certificate of Conformity (CoC)
- EASA Form 1 or Tag FAA 8130-3 or -9 or national equivalent document or military reassurance certificate (when contractually required)
- Version Description Document (VDD)
- Acceptance Test Report (ATR), if applicable
- Declaration of Design and Performance (DDP)
- Number of the approved Concessions/Deviation Permits, if any

- SW embedded with LH P/N

It shall be delivered embedded in the system with the documentation described in QRS-01 (Delivery Documentation for Complex Systems) ~~paragraph 13.3~~:

- CoC
- DDP
- Software Configuration Index (SCI) or VDD
- ATR

Only for the first system, the SW shall be delivered also on a separated media (USB Key, CD-ROM) and with the documentation described in the previous case (Stand Alone SW).

- SW embedded without LH P/N

It shall be delivered embedded in the system with the documentation described in QRS-01 (Delivery Documentation for Complex Systems)

12.3 Identification

Each Software (“stand alone” or embedded) with LH Part Number shall be delivered in a suitable media.

The kind of media shall be agreed during the Planning phase.

When applicable, the media shall be marked with the following information:

- Supplier Name
- Supplier Software Part Number
- LH Software P/N
- Software Description
- Release Date
- Supplier Quality Stamp (if available), or reference to the related Certificate of Conformity
- Number of approved Concession, Waiver or Production Permit (if any)

If not applicable, the above information shall be provided to LH.

If not differently specified in the contract, the embedded Software without LH Part Number is delivered loaded in the system.

12.4 After Delivery

12.4.1 Defects Revealed by the Supplier

If the Supplier reveals a non-conformity on a Software already delivered, the Supplier shall inform LH by a dedicated Problem Report within 24 hours for defects involving airworthiness and/or safety, 1 week for defect involving qualification or product characteristics, 1 month for the other cases.

At the conclusion of the required investigation, the Supplier shall deliver to LH the updated Problem Report including the investigation results and the proposed corrective actions.

Once LH has approved the corrective actions, the Supplier shall implement them.

12.4.2 Defects Revealed by Leonardo Helicopters

If LH reveals a non-conformity on a Software already delivered, LH inform the Supplier by a Problem Report.

The Supplier shall trace the LH Problem Report in a dedicated one, performing the investigation. At the conclusion of the required investigation, the Supplier shall deliver to LH its Problem Report including the investigation results and the proposed corrective actions.

Once LH has approved the corrective actions, the Supplier shall implement them.

13 Specific Requirements for AW09

The QRS-116 applies entirely, additionally the Supplier shall consider the Criteria, Standards and Procedures from Kopter's Statement of Work and Technical Requirements Documents and/or Quality Plan. In case of conflict with these requirements the definitions in the Statement of Work prevail.

For all activities performed and deliverables produced under the AW09 program, the following role and definition conversion table shall be applied

| Where is written | Reads/Replacement |
|--|---|
| QRS-01 | QRSK-01 |
| LH or AW or Agusta Westland Leonardo | Kopter |
| LHEO | Kopter DO |
| LH or Leonardo in a DO task | Kopter DO |
| LH Engineering focal point | Person Assigned by the Chief Engineer or Head of Design Engineering |
| LH Quality focal point | Person Assigned by the Head of Quality |

14 Appendices, Annexes and Forms

- Annex A: Guideline for FCA and PCA Verification
- Annex B: Compliance Matrix

Annex A – Guidelines for FCA and PCA Verification

The following Check Lists represent a guideline in order to conduct Physical and Functional Configuration Audits (PCA and FCA).

They are not to be considered as a mandatory constraint, but a guideline for the Supplier to verify Software configuration; nevertheless, their accomplishment assures the compliance with LH requirements.

[Square brackets contain, when applicable, the reference to the paragraph of this document where the work product/activity is described]

PCA (Physical Configuration Audit)

1. Are the Software Plans [\[7.2\]](#) up to date, approved and under configuration control according to the Software Configuration Management Plan [\[7.2\]](#)?
2. Are the Software Requirement Specifications/Data [\[8.2\]](#) up to date, evaluated according to the Plans, approved and under configuration control according to the Software Configuration Management Plan?
3. Are the Software Design Descriptions [\[9.2\]](#) up to date, evaluated according to the Plans, approved and under configuration control according to the Software Configuration Management Plan?
4. Is the Source Code [\[10.2\]](#) up to date, evaluated according to the Plans, approved and under configuration control according to the Software Configuration Management Plan?
5. Have the CSC tests [\[11.2\]](#) been performed on the version to be delivered? Are they evaluated according to the Plans and under configuration control according to the Software Configuration Management Plan?
6. Have the CSU test data [\[11.2\]](#) been updated according to remarks raised during evaluations?
7. Have the integration tests [\[11.2\]](#) been performed on the version to be delivered? Are they evaluated according to the Plans and under configuration control according to the Software Configuration Management Plan?
8. Have the integration test data [\[11.2\]](#) been updated according to remarks raised during evaluations?
9. Have the CSCI tests [\[11.2\]](#) been performed on the version to be delivered? Are they evaluated according to the Plans and under configuration control according to the Software Configuration Management Plan?
10. Have the Software Test Description [\[10.2\]](#)/Software Test Results [\[11.2\]](#) been updated according to remarks raised during evaluations and approved?
11. Have the link activities [\[11.1.2\]](#) been verified to ensure that :
 - there is no dead CSU linked ?
 - the good versions of CSUs have been used ?
12. Can the executable object code [\[10.2\]](#) be generated from the stored source code with the dedicated procedures for executable code production?

13. If the compiler and/or linker has been changed since the previous Software version [6.3], what was the strategy for :
 - generating the executable code (reused object codes re-generated or not)
 - testing (exhaustive validation or not, replay of all CSU tests or not ...)
14. Can the executable object code be successfully loaded on target with a dedicated procedure?
15. Does the Software Configuration Item/Version Description Document [11.2] identify the correct Software Part Number?
16. Does the Software Configuration Item/Version Description Document identify the Functional Baseline (FBL) (references and issues)?
17. Does the Software Configuration Item/Version Description Document identify the Software Plans [7.2], the Software Standards [7.2] and the tool qualification plans [6.3] (references and issues)?
18. Does the Software Configuration Item/Version Description Document identify the Allocated Baseline (ABL) (Software Requirement Specifications/Data references and issues)?
19. Does the Software Configuration Item/Version Description Document identify Design Data, source code, and executable files?
20. Does the Software Configuration Item/Version Description Document identify the used software libraries?
21. Does the Software Configuration Item/Version Description Document list all the Problem Reports (PR)/Engineering Change Requests (ECR) which are still open and classify these PR/ECR according to criteria defined in the Software Configuration Management Plan?
22. Does the Software Configuration Item/Version Description Document identify the compatibility of the Software with :
 - the hardware (equipments P/N)
 - the other CSCIs of the system (software P/N)
23. Does the Software Configuration Item/Version Description Document identify the used versions of Software and Hardware tools & means [6.3]?
24. Is the Software Configuration Item/Version Description Document up to date, evaluated according to the Plans, approved and under configuration control according to the Software Configuration Management Plan?
25. Is the Software Accomplishment Summary [11.2] up to date, evaluated according to the Plans and under configuration control according to the Software Configuration Management Plan?

FCA (Functional Configuration Audit)

1. Are all required documents updated and approved? Has any modification been correctly taken into account?
2. Are the Software requirements data [9.2] consistent and traceable with system requirements?
3. Have all the requirements been implemented and tested?

4. Do CSC and CSC testing procedures take into account any change incorporated during the Software life cycle?
5. Have CSU and integration tests been successfully performed [11]?
6. Is the functional coverage achieved for CSU and integration test?
7. Is the structural coverage achieved for CSU and integration test (according to the required software criticality level)?
8. Is the data coupling coverage verified (e.g. each global variable initialised before being used) and the results presented in a Coverage Analysis Document?
9. Is the control coupling coverage verified (e.g. CSU activated at least once) and the results presented in a Coverage Analysis Document?
10. Have the performance requirements allocated to CSCs been verified during integration testing (timing, memory measurements, ...)? Are the results compliant?
11. Are the global performance achieved?
12. Does the Software Verification Results identify the Software executable object code, the tests RIG and tools (Hardware and Software), the equipment used (P/N and S/N)?
13. Are the Software Verification Cases and Procedures/ Test Specifications [10.2] consistent with the applicable Plans and Standards [7.2]?
14. Are the Software Verification Cases and Procedures/ Test Specifications traceable with the specification requirements?
15. Are the Software Verification Cases and Procedures/ Test Specifications adequate?
16. Are the test RIG and tools (Hardware and Software) used for the testing activities identified in the Software Configuration Index/ Version Description Document and validated?
17. Is the Software which has been tested identified?
18. Have the Software modifications performed during CSCI testing been identified in the Software Verification Results with the corresponding tests?
19. Does a non-regression analysis define accurately the whole tests (CSCI testing) replayed to check these software modifications?
20. Is the non-regression analysis compliant with the non regression strategy defined in the Plans (i.e. Software Verification Plan)?
21. Has every CSCI test been executed in compliance with procedures? Or are deviations justified, if exist?
22. Have CSCI tests been successfully performed? Is the functional coverage achieved?
23. Have the variation ranges of each input data been verified during CSCI testing (minimum, mean and maximum values as well as out of range values)?
24. Are corrective actions related to software test limitations (requirements not fully covered) performed?
25. Are the Software Verification Results complete, updated and recorded?
26. Is the coverage matrix (Software Verification Cases and Procedures/Test Specifications / Software Verification Results vs. ABL) complete, updated and approved?
27. Is the simulation environment representative of the Software functional environment?

28. Is the development of the Software products supplied by Subcontractors (if any) correctly achieved (acceptance formally approved)?
29. Is the Subcontractor's documentation available, complete, up to date and approved?
30. Are all CO/PP cleared or accepted by Leonardo Helicopters?
31. Has an SCR been performed?

Annex B – 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 Software Quality Assurance Plan.

| Paragraph | Requirement |
|--------------|--|
| <u>6.1</u> | The Supplier shall be included in the LH approved Suppliers database. |
| <u>6.1</u> | The Supplier product range shall include the capability to supply Software. |
| <u>6.2</u> | Whenever the Supplier transfers the design and/or qualification of the Software product to some Subcontractor (completely, or in part), the Supplier remains responsible toward Leonardo Helicopters of both the Software design and its qualification. |
| <u>6.2</u> | The Supplier shall produce to LH all the required evidences and work products issued by the Subcontractor, adding its approval. |
| <u>6.2</u> | The Supplier shall assure that its Subcontractors are able to satisfy the requirements of this document. |
| <u>6.2</u> | The Supplier shall warrant and produce evidence to LH about Subcontractors qualification, including facilities they intend to utilise. |
| <u>6.3</u> | The Supplier shall permit the access to all LH representatives and Civil or Military Authorities accompanied by LH. |
| <u>6.3</u> | The Supplier shall guarantee the access to Subcontractors facilities. |
| <u>7.1</u> | The Supplier shall establish transition criteria that are to be satisfied to access from a life cycle phase to the following one. The inter-relationships between the phases, their sequencing, feedback mechanisms and transition criteria shall be described in the Plans. |
| <u>8.1.2</u> | |
| <u>7.1</u> | The Supplier shall verify phase outputs in formal reviews. The list of reviews to be performed along the Software life cycle is required. |
| <u>7.2</u> | |
| <u>7.2</u> | The Supplier Design Review procedures shall be defined within the Plans. |
| <u>7.2</u> | The following aspects shall be described: |
| | a) Involved personnel and respective responsibility |
| | b) Applicable documentation |
| <u>7.2</u> | c) Quality Assurance activity |
| | Before each formal Design Review, The Quality Assurance of the Supplier shall guarantee that: |
| | a) all the necessary products are ready and available |
| <u>7.2</u> | b) all the activities pertinent to the phase to be verified have been done in accordance with the applicable procedures |
| | A Review MoM shall be prepared, including an action list to trace all the possible sources of problems, proposing the corresponding corrective actions. For each action item a Responsible and a due date shall be defined. |
| <u>7.2</u> | If the presence of LH is required, the Review scheduling shall be anticipated. |
| <u>7.2</u> | The work products related to each Review and requiring LH Approval/Review shall be delivered to LH at least 15 working days before the Review itself. |
| <u>7.2</u> | The MoM shall be delivered to LH (Quality and Engineering focal points) for information. |

| Paragraph | Requirement |
|--------------|---|
| <u>7.3</u> | Software tools for which the outputs are not verified manually or by other qualified tools shall be qualified. |
| <u>7.3</u> | The Supplier shall list the development and verification tools, specifying how their qualification will be demonstrated. |
| <u>7.3</u> | For each tool at least two verification events are required. The list of verification events and relative work products is required. |
| <u>8</u> | List of work products that the Supplier will issue during the Planning phase shall be provided. |
| <u>8.1.1</u> | The Software life cycle environment, including the methods and tools to be used for the activities of each Software life cycle process (requirements management, design and coding, configuration management, verification and validation) shall be defined and included in the Plans. |
| <u>8.1.1</u> | The Supplier shall identify people in charge and thus responsible for: a) Declaring the Software Airworthiness, by signing the technical documents of the Design Data Set b) Declaring released Software conformity, by signing the Certificate of Conformity and the relative documentation (Concession, etc...) |
| <u>8.1.1</u> | The Supplier shall list one or more "Focal Points" for Software Quality and Design activities. |
| <u>8.1.1</u> | The Supplier shall include a "Compliance Matrix" against this document. |
| <u>8.1.1</u> | If RTCA DO-178B/C applies, a "Compliance Matrix" against RTCA DO-178B/C sections 8 and 11.5 shall be included. |
| <u>8.1.1</u> | The Plan shall list all the main Subcontractors (if any) and the relative responsibilities establishing the different activities between Supplier and Subcontractor. |
| <u>8.1.1</u> | The Supplier shall describe configuration management activities in terms of: a) rules of Software P/N definition b) changes and non-conformities management |
| <u>8.1.1</u> | Software Quality Assurance Plan shall include or refer to the configuration management activities. |
| <u>8.1.2</u> | Definition of the activities of the Software development processes and integral processes of the Software lifecycle shall be defined and included in the Plans. |
| <u>8.1.2</u> | Standards consistent with the system safety objectives for the Software to be produced shall be defined and issued. |
| <u>9</u> | List of work products that the Supplier will issue during the Software Requirements phase shall be provided. |
| <u>9.1.1</u> | Each system requirement allocated to Software shall be traceable to one or more Software high level requirements. |
| <u>9.1.1</u> | The high-level requirements shall conform to the Software Requirements Standards and be verifiable and consistent. They shall be stated in quantitative terms with tolerances, where applicable. |
| <u>9.1.2</u> | Derived high-level requirements shall be indicated to the system safety assessment process. |
| <u>10</u> | List of work products that the Supplier will issue during the Software Design phase shall be provided. |

| Paragraph | Requirement |
|---------------|--|
| <u>10.1.1</u> | Low-level requirements and Software architecture developed during the Software design phase shall conform to the Software Design Standards and be traceable, verifiable and consistent. |
| <u>10.1.2</u> | Derived requirements shall be defined and analysed to ensure that the higher level requirements are not compromised. |
| <u>11</u> | List of work products that the Supplier will issue during the Software Coding phase shall be provided. |
| <u>11.1.1</u> | Source code is developed that is traceable, verifiable, consistent, and correctly implements low-level requirements according to Software architecture. |
| <u>11.1.2</u> | Test specifications shall be prepared which define test cases, required test data and expected results. |
| <u>11.3</u> | Reference to suitable Code verification methods (if any) shall be included in the Plans. |
| <u>12</u> | List of work products that the Supplier will issue during the Integration/Qualification phase shall be provided. |
| <u>11.1.1</u> | Each activities described in the Software Plans shall be completed and verified. |
| <u>11.1.2</u> | Test, inspections or analytical processes shall be able to demonstrate that each Software configuration item meets the specific contractual performance requirements. |
| <u>12.2</u> | The Supplier shall submit for approval to LH Engineering focal point the complete list of known problems and limitations before their inclusion in relevant documentation (SCI/VDD/SAS). |
| <u>12.1</u> | The Supplier shall include in the Software Quality Assurance Plan where the objectives are met. |
| <u>12.2</u> | The Supplier shall list the documentation delivered with each Software. |
| <u>12.3</u> | The Supplier shall describe the media and the information that will be marked/supplied. |
| <u>12.4.1</u> | The Supplier shall describe how the defects revealed by the Supplier itself shall be managed. |
| <u>12.4.2</u> | The Supplier shall describe how the defects revealed by LH shall be managed. |

Annex C – Traceability Matrix QRS Vs EN9115

EN9115 are covered and linked to each QRS module and verified through the following table:

| EN9115 PARAGRAPH | EN9115 REQUIREMENT | QRS Module PARAGRAPH |
|------------------|--|----------------------|
| 4.3 | Determining the Scope of the Quality Management System | QRS-01 2 |
| 4.4 | Quality Management System and Its Processes | QRS-116 7.1.1 |
| 6 | PLANNING | |
| 6.1 | Actions to Address Risks and Opportunities | QRS-01 8.5.2 |
| 7 | SUPPORT | |
| 7.1.3 | Infrastructure | QRS-01 7.3 |
| 7.1.4 | Environment for the Operation of Processes | QRS-01 7.4 |
| 7.1.5 | Monitoring and Measuring Resources | QRS-01 7 |
| 7.2 | Competence | QRS-01 7.2 |
| 7.3 | Awareness | QRS-01 7.1 |
| 7.5.3 | Control of Documented Information | QRS-116 6.1 |
| 8 | OPERATION | |
| 8.1 | Operational Planning and Control | QRS-116 7.1 |
| 8.1.1 | Operational Risk Management | QRS-01 8.5.2 |
| 8.1.1.1 | Product Integrity | QRS-116 11.2 |
| 8.1.2 | Configuration Management | QRS-116 7.1 |
| 8.1.3 | Product Safety | QRS-116 7.1 |
| 8.1.4 | Prevention of Counterfeit Parts | QRS-01 8.4 |
| 8.2.2 | Determining the Requirements for Products and Services | QRS-116 8.1 |
| 8.2.3 | Review of the Requirements for Products and Services | QRS-116 8.3 |
| 8.3 | Design and Development of Products and Services | QRS-116 9 |
| 8.3.2 | Design and Development Planning | QRS-116 9 |
| 8.3.3 | Design and Development Inputs | QRS-116 9 |
| 8.3.4 | Design and Development Controls | QRS-116 9 |

| | | |
|------------|--|----------------------|
| 8.3.5 | Design and Development Outputs | QRS-116 9 |
| 8.3.6 | Design and Development Changes | QRS-116 9 |
| 8.4.1 | General | QRS-01 9.1 |
| 8.4.3 | Information for External Providers | QRS-01 9.1 |
| 8.5 | Production and Service Provision | |
| 8.5.1 | Control of Production and Service Provision | QRS-116 11.1 |
| 8.5.1.1 | Control of Equipment, Tools, and Software Programs | QRS-116 6.3 |
| 8.5.1.3 | Production Process Verification | QRS-116 10.3 |
| 8.5.2 | Identification and Traceability | QRS-116 8-9-10 |
| 8.5.4 | Preservation | QRS-116 7.1 |
| 8.5.6 | Control of Changes | QRS-116 7.1 |
| 8.6 | Release of Products and Services | QRS-116 12 |
| 8.7 | Control of Nonconforming Outputs | QRS-116 7.1 |
| 9. | PERFORMANCE EVALUATION | |
| 9.1.3 | Analysis and Evaluation | QRS-01 8.5.2 |
| 9.2 | Internal Audit | QRS-115 5.3.3.4.2 |
| 9.3 | Management Review | |