QRS-115 Requirements for Design & Development Suppliers

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HELICOPTERS

QRS-115

Requirements for Design & Development Suppliers

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CHANGES LOG

Issue	Approval Date	Main changes	Interested Paragraphs
01	December 2013	Superseded IQ S015 Part A rev. C	
02	April 2015	Updated according to EASA findings and requests	All
03	June 2018	Document significantly rewritten and reformatted Management of Design Changes (major/minor)	All 5.3

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
EASA Part 21	Certification procedure for Aircraft and related Products and Parts"
AQAP 2110	NATO Quality Assurance Requirements for Design and Development
5000 Series	Design Modification (DME) Regulatory Articles

CONTENTS

1 Purpose

This document defines the mandatory requirements for Suppliers of activities concerning design, qualification and requalification of parts, equipment and systems that *shall* be installed, certified/qualified on aircraft or test benches and rigs of **LH** responsibility.

These activities have the purpose to demonstrate:

- The compliance of each part, system or equipment to the Airworthiness applicable requirements
- The compliance of each part, system or equipment to the Functional design requirements (Functional Qualification)
- The ability of the manufacturing process to produce items in conformity with the Design Data Set (Manufacturing Process Qualification), through FAI (QRS-101 applies).

A part, system or equipment is qualified only when both Functional and Manufacturing Qualification Processes have been successfully completed.

2 Applicability

This document is applicable to the Suppliers of development, design, qualification and/or certification activities of new part, system or equipment including the requalification activities and modifications on P/N already qualified.

The activities are concluded when the supplier is informed by LHEO that the Type Certification process or the modification thereto, has been completed.

This procedure is applicable to all **LH** and cooperation programs, unless otherwise specified in this document.

This procedure *shall* be supplemented by the following, where applicable:

- QRS-116, for new development of Software for airborne systems and equipment installed on **LH** aircrafts
- QRS-117, for Complex Electronic Hardware used for airborne systems, sub-systems and equipment installed on **LH** aircrafts;

If an equivalent program procedure exists, the program procedure prevails.

The following table 1 highlights the subjects of this procedure that apply depending on component classification and/or the activities correlated to the component design and development.

This document is not applicable for STANDARD parts.

Subject	Applicability						Notes
	L	D	C	Q	T	S	
General requirements	X	X	X	X			For the Organization responsible of TSO/ETSO products, or equivalent, the recognition of the Production Organization it is under the Authority responsible of TSO/ETSO approval.
General requirement of Quality System	X	X	X	X		X	
Supplier organization	X	X	X	X		X	
Program requirements	X	X	X	X		X	
Sub-tier suppliers requirements	X	X	X	X		X	
Process's phases	X	X		X			
General	X	X		X			
Process description	X	X		X			
Preliminary Design		X		X			
Detailed Design		X		X			
Compliance demonstration	P	X		X		X	For the "L" is not applicable the requirement for test item availability because under LHEO responsibility. It is applicable the requirements concerning the availability and suitability of the test equipment.
Flight authorization		P		X		P	"D" *shall* give to LHEO all design data necessary to prepare a DDP or equivalent document for flight authorization.
Qualification		P		X		P	For "D" to evaluate the applicability on the basis of paragraph contents; can request a contribution to prepare the documents of LHEO responsibility.
Continued Airworthiness		X		X	X	X	
Production		X		X	X	X	
Design specific requirements	X	X	X	X			
Documentation requirements	X	X	X	X			
Detailed Technical Specification		X		X		X	
Qualification Program Plan (QPP)		P		X		X	"D", if requested by LHEO, *shall* contribute to issue the document and/or supply the necessary technical information.
Qualification documents (QD)	X	P		X		X	
Qualification Test Proposal (QTP)	X	P		X			
Qualification Test	X	P		X		X	

Result (QTR)							
Analysis report (AR)		P		X			
Similarity justification		P		X			
Acceptance Test Procedure (ATP)		X		X			
Maintenance Manual		X		X			
Declaration of Design and Performance (DDP)	P	P		P		X	"D" *shall* give to LHEO the design data necessary to prepare a DDP or equivalent documentation to authorize the flight
Delivery documentation			X	X	X	X	
Design Review (DR)		P		X			
Change control		X		X			
General requirements		X		X			
Modification to the contractual technical specification or to equipment specification		X		X			
Change classification: impact on equipment		X		X		X	
Interim changes to programmed equipment		X		X			
Data exchange		X		X			
Configuration Management		X		X		P	
Identification and marking		X		X	X	X	
Equipment/parts identification		X		X	X	X	
Equipment containing SW/AEH		X		X	X	X	
Identification of equipment with provisional P/N		X		X	X	X	
Sub component identification		X		X	X	X	
Special identification		X		X	X	X	
Critical parts management		X		X	X	X	
Definition		X		X	X		
Equipment/part with classification defined in LH Technical Specification		X		X			
Equipment/part which functions are classified in LH System Technical Specification		X		X			
Management of Critical Parts		X		X			
Test Article Conformity	X	X	X	X			

(TAC)							
General	X		X	X			
Conformity to the Applicable Technical Data		P	X	X	X	X	"D" *shall* define only the requirements necessary to demonstrate the conformity of the test article
Test article representativeness and Test Authorization Form	X			X			
Non conformity management		X	X	X	X	X	
TAC for equipment with temporary P/N		X	X	X			
Design Data Set (DDS)		X		X		X	
DDS contents		X		X		X	
DDS approval		X		X			
DDS filling		X		X			
Access and data visibility	X	X	X	X			
Access to the sites	X	X	X	X		X	
Documentation	X	X	X	X		X	

Table 1

L = Supplier responsible for Test; D = Supplier responsible for Design; C = Supplier responsible for manufacturing of test items; Q = Supplier responsible for design and demonstration of compliance to the requirements; T = TSO/ETSO Supplier; S = COTS (Off-The-Shelf) Supplier

P = Partially applicable; refers to the note and/or the relevant paragraph; X = Complete applicability

3 Effective date

Issue date

4 Acronyms, definitions and abbreviations

4.1 Acronyms and abbreviations

AEH	Airborne Electronic Hardware
ATP	Acceptance Test Procedure
ATR	Acceptance Test Report
CDR	Critical Design Review
CMP	Configuration Management Plan
CoC	Certificate of Conformity
COMO	Coordination Memo
COTS	Commercial Off The Shelf
CS	Certification Specification
CVE	Compliance Verification Engineer
D&D	Design And Development (Engineering)

DDP	Declaration of Design and Performance
DO	Design Organization
DR	Design Review
EFA	Experimental Flight Approval
EO	Engineering Order
TSO/ETSO	Technical Standard Order/European Technical Standard Order
FAI	First Article Inspection
FRR	Flight Readiness Review
HDO	Head of Design Organization
HW	Hardware
LHEO	Leonardo Helicopters Engineering Organisation
LHPO	Leonardo Helicopters Production Organisation
MoC	Means of Compliance
P/N	Part Number
PDR	Preliminary Design Review
PO	Production Organization
QD	Qualification Document
QP	Quality Plan
QPP	Qualification Program Plan
QTP	Qualification Test Plan
QTR	Qualification Test Report
S/N	Serial Number
SADD	Statement of Approved Design Data
SCD	Source Control Drawing
SCN	Specification Change Note
SoW	Statement of Work
STTE	Special Type Test Equipment
SW	Software
TAC	Test Article Conformity
TRR	Test Readiness Review
VIL	Vendor Item List

4.2 Definitions

Product: According to the definitions of EASA rules, "Product" is intended an object for which is foreseen a type certification as: aircraft, engine, and propeller. The components that form a "Product" are defined "Parts", "Systems" or "Equipment".

Sub-tier supplier: A company to which the main supplier delegates part or all activities, required by the contract.

Supplier: Company (according to the different types and categories) that provides an article or a service.

Designer: A company that is proprietary of "Know How" of the part, system or equipment; all the drawings are issued with the relevant logo and signatures of responsible managers of this Company. The Company has the full responsibility of the Design Process and methods used to show compliance to **LH** specifications issued under **LH** Design Authority.

Designer Part Number: it is the P/N assigned to the supplier that has the design responsibility. When the supplier subcontracts the design of one or more part, system or equipment to other organizations, the P/N *shall* be assigned by the first-tier supplier.

Remark: a supplier having *design responsibility* is not intended to have the *design authority* on the part/system/equipment, which is held by the Type Certificate holder (i.e. LH, unless otherwise specified). Even for suppliers having design authority on their systems (e.g. TSO/ETSO) LH has ultimate responsibility for integration of parts/systems/equipment on Aircraft.

Deliverable Part, system or equipment: Part, system or equipment defined by LHEO as individually manageable by the end user and / or at aircraft level. The P/Ns of these part, system or equipment are reflected in the **LH** Part List, meanwhile the subcomponents are managed and coded by the supplier that manages and maintains under control the configuration. These parts, systems or equipment are divided in:

- STANDARD
- TSO/ETSO
- COTS
- P/N to be qualified

Part Numbers "To Be Qualified": For this type of part, system or equipment two classes are defined:

1) New development equipment/part; when the part (at least one of the following cases occurs):

a) has been already TSO/ETSO certified or Military approved or COTS but modified and identified by an **LH** P/N

b) has been classified "CRITICAL"

c) is not "CRITICAL" but with functional requirements for which design validation activities are required

d) has been identified with a **LH** P/N

e) Is not classified as above categories, therefore similar to standard or simple part (racks, pipes, wires, screws, etc...), but is part of a system design whose responsibility is recognized to a Supplier.

The "new development equipment/part" group is subdivided into two subgroups:

I) **"Significant" P/N to be qualified** [a), b), c) and d) bullet point]: for each "significant" part the **LH** P/N *shall* be defined and an **LH** specific document *shall* be issued (Technical Specification or Source Control Drawing). For these equipment/parts, the supplier *shall* provide evidence of compliance to the technical requirements applicable by issuing of DDP approved by LHEO. The SW deliverable is always considered a significant P/N.

II) **"Not significant" P/N to be qualified** [e) bullet point]: these parts will be qualified as part of system without the issuing of a dedicated DDP.

2) New development equipment that will achieve a TSO/ETSO certification

In this case, the requirements for new development equipment *shall* be applied until the TSO/ETSO certification has been achieved. After this, the equipment will be managed as TSO/ETSO after the demonstration that the relevant requirements, the characteristics and the ATP approved by the competent Authority, are equivalent and in compliance with LHEO requirements.

5 Requirements

5.1 General Requirements

The Supplier *shall* meet the requirements of this chapter. The supplier *shall* be aware, organized and able to comply (and support LH to comply) to the relevant specifications (i.e. Part 21, EN 9100 etc.).

5.1.1 General Quality System requirements

The Supplier *shall*, for all activities described in this document, be organized according to the requirements listed in QRS-01 document and applicable modules and *shall* be approved by the **LH** "Supplier Quality Assurance".

5.1.2 Supplier organization

In order to meet the requirements specified in this document, the supplier *shall* have a Design Organization, including:

- Design Organization responsible (Technical Director) to guarantee the design compliance to the contract technical requirements
- One or more technicians, delegates by the Technical Director, who have the responsibility to receive and control the contents of the technical documents
- One or more technicians responsible for testing activities, including verification of compliance of the test articles
- Personnel authorized to sign the technical documents
- Defined responsibility allocated for each signature of technical documents
- Defined technical profiles for the personnel signing the technical documents
- A process for design
- A process for classification and management of the Critical Part
- A process for demonstrating compliance with design requirements
- A process for change management
- A process for approval of non-conformities on manufactured parts
- A process for continuing airworthiness
- A process for managing and filing of technical documentation
- A process for Sub-tier suppliers management.

5.1.3 Program requirements

Following the acquisition of a contract for the development of a new part, system or equipment, the Supplier *will* issue a Quality Plan (QP) per **QRS-108**, as requested by Purchase Order, and submit it to **LH** for approval through the **LH** technical focal point.

In compliance with the requirements of the present document, the Supplier *shall* describe, in a proper section of the QP, how the Design Organization, and its relevant processes, meets the specific requirements of the program.

In particular, as far as the D&D process is concerned, the QP *shall* define:

- The manager responsible to declare the compliance of the product to the applicable/approved design data
- The technical Focal Point for **LH** Technical Area (D&D) - Engineering.
- A Matrix to provide compliance with the requirements of this document.
- List of Sub-tiers involved in design and development activities of the parts, systems/equipment and criteria for their management and risk assessment based surveillance
- Any specific **LH** program requirements implemented contractually required by technical specifications and Statement of Work

5.1.4 Sub-tier supplier requirements

The Main Supplier is always responsible towards **LH** for the compliance with contract requirements also in case it delegates part of the activities to a Sub-tier supplier.

The Supplier *shall*:

- guarantee and give evidence to LHEO of Sub-tier supplier qualification according to LH requirements and the relevant facilities (i.e. laboratories)
- transmit to its Sub-tier suppliers the requirements of this document
- Guarantee that its Sub-tier suppliers comply with requirements of this document tailored according the subcontracted activities and risk based analysis; the Sub-tier suppliers responsible for design of the deliverable component *shall* meet all the requirements of this document.

5.2 Process Phases

5.2.1 General

Following paragraphs describe the phases of development, design, compliance to the technical requirements, etc. involved in the whole design process.

5.2.2 Process Description

The whole design process is outlined in figure 1.

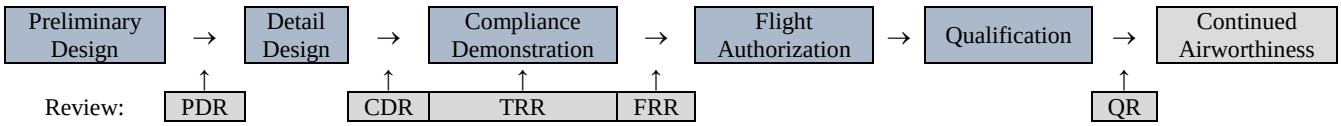


Figure 1

The process here described could be tailored according with type and complexity of the part, system or equipment being developed, providing it is approved by LHEO at the PDR or in a dedicated planning review.

The outputs from the process phases *shall* be verified with formal reviews (Design Reviews), whose positive results confirm the completion of all anticipated activities, the due conformity to the applicable standards of the produced documentation and authorize the passage from a phase to the following one.

- Design and development verification is taken into CDR activity and will ensure that the design and development outputs have met design and development requirements.
- Design and development validation is taken into QR activity and will ensure that the resulting product meets the requirements of the specified application.

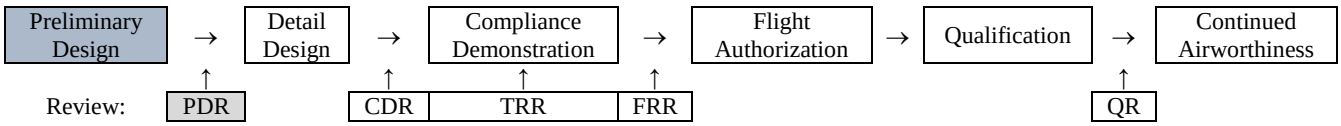
In the following chapter, for each phase main activities are described, including documents (work products) to be issued.

In the table below, the submission criteria are listed for the work products verified during Design Review.

Submission criteria	Level of **LH** approvals defined in the contract
Approval	Work product *shall* be formally approved by **LH** deputed people
Available	Work product *shall* be available and verifiable during LHEO activities or progress meetings
Review	No **LH** formal approval required, but comments can be raised
Information	No **LH** formal approval required

The TRR is a pre-condition for compliance activities that need Laboratory testing.

5.2.2.1 Preliminary Design



The Supplier *shall* receive from LHEO:

- A Technical Specification or equivalent document (i.e. Source Control Drawing – SCD) for each part, system or equipment/part to develop and qualify
- A System Technical Specification for the development and qualification of an Aircraft system
- A Process Requirement Document, issued either as independent document or as an annex to a Statement of Work, reporting the working arrangements to be put in place for the coordination between LHEO and the Supplier and the agreed procedures to be used by the Supplier.

Technical Specifications contain all the technical and quality requirements for the equipment/part to be qualified and to which compliance must be given.

The Process Requirement Document customizes for the specific Supplier the following working arrangements:

- **LH** focal points and contact details
- Means of communication between the parts
- Input data from **LH**
- Deliverable output from Supplier
- Data formats
- Approval workflows inside **LH** for the different data to be exchanged and relevant authorised signatories
- Planning and progress reporting to be provided
- Record Keeping provisions
- Identification of testing facilities
- Access to data and facilities to be granted

This document *shall* also specify the agreed procedures for the following topics, to be used by the Supplier for the execution of the assigned tasks:

- Establishment of compliance documentation, including the Independent Checking Function action
- Classification and approval of changes and repairs
- Configuration control
- Approval of production deviation (when the supplier is also the manufacturer)
- Coordination of design activities
- Internal Monitoring System
- Control of sub-tiers
- Execution of testing

After the acquisition of the contract, the supplier *shall* define:

- The Detail Technical Specification for “significant” equipment/part or drawing specification for simple components (only for supplier of Aircraft system)

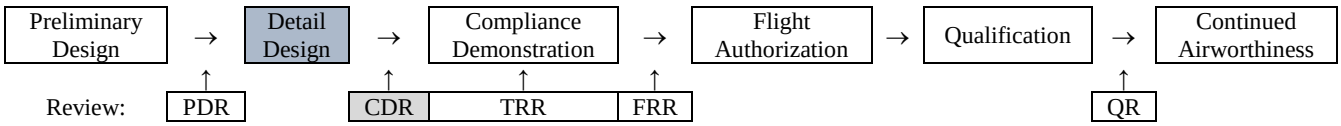
- Assemblies/interfaces drawings and/or 3D models for components of the system (only for equipment in case of single equipment)
- A Qualification Program Plan (QPP) with the list of documents to be issued in order to provide evidence of compliance with the requirements of LHEO specification, organized in a preliminary compliance matrix.
- A Quality Plan (QP), as requested by Purchase Order, which contents *shall* be in line with the **LH** prescriptions
- The DO-PO Arrangement (for EASA Part 21 Subpart G approved Suppliers)
- A Configuration Management Plan (CMP), using the Supplier's own template unless differently directed by LH
- The list of critical equipment/parts (only for System suppliers) and a critical part list for each of the relevant equipment.
- A Statement of Works (SOW); the planning tool of all the activities that *shall* be performed related to the System/Part provision. The SOW *shall* include, as a minimum the following aspects:
    - the sequence of project development phases
    - the moments of project reviews
    - the qualification activities date of start and end (and subsequent availability of the first qualified item)
    - The requested documents and their issuing dates (drawings issuing deadlines, QTP, QTR, DDP, etc…)
    - the possible Mock-up construction
    - the possible functional prototypes construction
    - The availability of pre-series and of subsequent series production.

The works products in this stage *shall* be verified during the Preliminary Design Review (PDR)

	Document	Submission Criteria	**LH** responsible
1	Detail Technical Specification	Approval	**LH** D&D
2	Quality Plan (QP)	Review Approval	**LH** D&D **LH** Quality
3	Qualification Program Plan (QPP)	Approval	**LH** D&D
4	Configuration management plan (CMP)	Approval	**LH** D&D
5	Interface/assembly Drawing/3D Model (to be approved and included in the specification	Approval	**LH** D&D

	documentation)		
6	Critical equipment list (only for system; status preliminary)	Review	**LH** D&D
7	Critical Part list (preliminary)	Review	**LH** D&D
8	Safety/weight/reliability analysis (preliminary)	Review	**LH** D&D

5.2.2.2 Detail Design



The Supplier, at this stage, *shall* develop the part, system or equipment and/or system defining the detail of the individual parts and the test procedure.

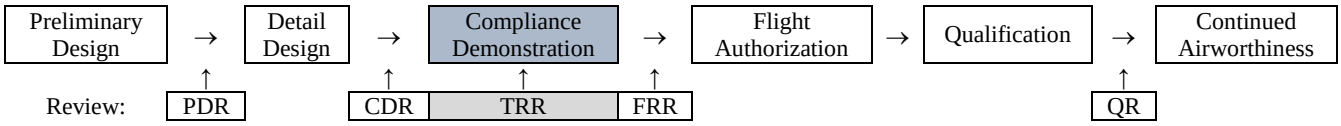
When the detailed design has been completed and before the first test qualification or "flight clearance", the Supplier *shall* perform the Critical Design Review (CDR) to verify the correct implementation of the design, the applicable technical documents and to define the Basic Configuration (Baseline Configuration).

In the Critical Design Review the documents listed in the table below *shall* be verified:

	Document	Submission Criteria	**LH** responsible
1	Part List or Design Data Set (system or equipment where applicable)	Approval	**LH** D&D
2	Interface/assembly Drawing/3D Model	Approval	**LH** D&D
3	Drawing/3D model for components	Review	**LH** D&D
4	Acceptance Test Procedure (First issue)	Approval	**LH** D&D
5	Vendor Item list (VIL) (list of bought-out items purchased by the Supplier)	Review	**LH** D&D

6	Critical Equipment list (final)	Review	**LH** D&D
7	Critical Part list (final)	Review	**LH** D&D
8	Design Data Set	Approval	**LH** D&D
9	Safety/Weight/Reliability analysis	Approval	**LH** D&D
10	Stress Analysis	Approval	**LH** D&D
11	Preliminary Maintenance Manual / Installation Manual / Mandatory Maintenance Requirements / Fault Check / Troubleshooting	Approval	**LH** D&D

5.2.2.3 Compliance Demonstration



The supplier at this stage, as applicable, *shall*:

- Issue and approve the Qualification Test Proposal report
- Issue the analysis reports, calculation, design justifications, etc...
- Produce and make available (within the contract scheduling) the items to be tested in the laboratories under supplier responsibility or **LH** laboratories, as applicable. In the latter case, it *shall* make available the necessary documentation to demonstrate the compliance of the test article with the applicable design data and issue a DDP (preliminary) that **LH** *shall* approve before the items' delivery.

The supplier, if the tests are conducted in its laboratories, *shall*:

- Make available the test articles with the documentation of compliance
- complete and make available the form of "Test Execution Authorization" (refer form QRS-115_F01) and the documents necessary for the tests
- Alert the **LH** CVE (if applicable), and representatives of the authorities (civil/military) that *may* need to attend the test.

The Test Readiness Review (TRR) *shall* be performed before any of the following events, as attested by the first occurring in chronological order:

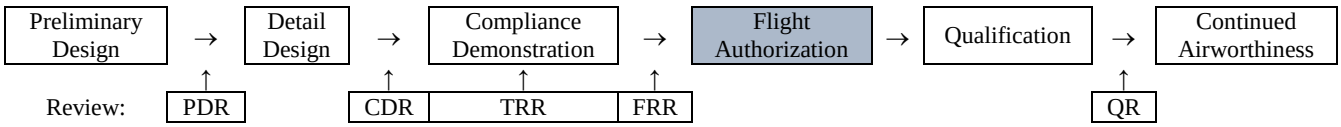
- Beginning of the test at the supplier facilities

- Delivery of part, system or equipment to **LH** for laboratory tests not under the direct control of the supplier.

The documents that *shall* be verified during the TRR are listed in the table below.

	Document	Submission Criteria	**LH** responsible
1	Qualification Test Proposal document	Approval	**LH** D&D
2	Compliance reports (analysis, justification, calculation, safety assessment, etc.)	Approval	**LH** D&D
3	DDP (preliminary)	Approval	**LH** D&D
4	Test Article Conformity (TAC)	Approval	**LH** D&D
5	Certificate of conformity	Available	**LH** D&D
6	Test Execution Authorization form	Approval	**LH** D&D/CVE

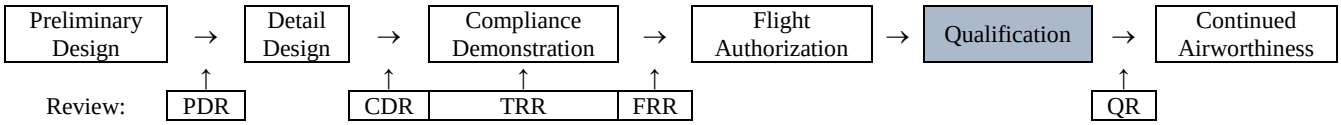
5.2.2.4 Flight Authorisation



At the first flight clearance, the Supplier *shall* issue the DDP and all documentation necessary to declare the "Flight clearance" of part/equipment and sent the documents to LHEO.

	Document	Submission Criteria	**LH** responsible
1	DDP	Approval	**LH** D&D
2	Design reports (limits justification if any)	Approval	**LH** D&D
3	ATR (with limitation justification, if any)	Approval	**LH** D&D

5.2.2.5 Qualification



At the conclusion of the demonstration of compliance activities, the supplier *shall* issue the final DDP and all applicable documents.

The Qualification Review is the formal moment in order to evaluate the whole qualification process and freeze the contents of documents of compliance.

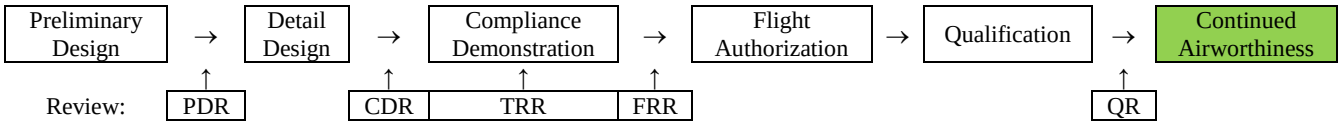
At this stage all documents, including those of configuration (part list and drawings tree), *shall* be frozen; the table below lists these documents.

The LHEO approval of the DDP establishes the conclusion of the design activities. In addition, for civil programs the conclusion of the certification process by the competent Authority is established by the LHEO issue of SADD document (for POA manufacturers only).

Remark: before the issuance of SADD, the Supplier shall ensure that the latest version of design data has been provided to LH, including any very minor changes implemented after the DDP.

	Document	Submission Criteria	**LH** responsible
1	Qualification Test Results	Approval	**LH** D&D
2	ATP (final)	Approval	**LH** D&D
3	Design Data Set (final)	Approval	**LH** D&D
4	DDP (final)	Approval	**LH** D&D
5	Vendor Item List (final)	Approval	**LH** D&D
6	Critical equipment/part list (final)	Approval	**LH** D&D
7	Production facilities list	Approval	**LH** D&D
8	Maintenance Manual	Approval	**LH** D&D

5.2.2.6 Continued Airworthiness



The continued airworthiness phase gathers all activities after the qualification of the equipment/system, and can be divided into the two following activities.

5.2.2.6.1 Production

The series production control of the part, system or equipment will be executed by the **LH** Production Organization (LHPO) as established by the contract.

The supplier in the first instance *shall* ensure that the part, system or equipment manufactured in series is identical to those used for qualification.

This evidence will be given by the First Article Inspection (FAI) activities on the first production batch that will be done under the control of the LHPO.

The supplier *shall* guarantee that, during the entire period of production, the part, system or equipment/parts will be in compliance with the requirements of the next paragraph.

5.2.2.6.2 Continued Airworthiness

The Supplier, in order to guarantee that the items already delivered and/or those that will be produced in future are in compliance with the original requirements, *shall*:

- Maintain updated the maintenance documentation applicable to the items (see also QRS-122)
- Manage and control the design changes
- Manage the defects resolution (see also QRS-107).
- Manage the outcomes of the field operation of the component, informing **LH** about involved supplied parts, supporting LH on investigations and containment/corrective actions and granting support and information towards Airworthiness Authorities, if a potential unsafe condition is identified (see also QRS-107).

5.3 Design Specific Requirements

5.3.1 Documentation requirements

In the following paragraphs, the compilation requirements of the technical documents of supplier's competence are defined.

5.3.1.1 Detailed Technical Specification

In consequence of LHEO System Specification, the Supplier *shall* issue for each part of the system to qualify a Detailed Technical Specification (Equipment Specification) or, for relatively simple components, a Specification Drawing.

If the supplier uses one or more Sub-tier suppliers, it *shall* issue for each of them a design specification equivalent, in terms of technical and quality contents, to LHEO Technical Specification; this document *shall* clearly define the envelope of the requirements to be followed by the Sub-tier suppliers.

5.3.1.2 Qualification Program Plan (QPP)

For each contract, the Supplier *shall* issue the QPP containing the "Compliance Matrix".

The QPP document scope is to give evidence of: the process traceability, the activities that will be performed and the documents that will be issued in order to demonstrate the compliance with the design requirements of the equipment/parts.

The table below shows an example of Compliance Matrix.

Spec. Para	Applicable QP reference	Means of Compliance	Type of requirement			Notes and MoC justification
			F	EFA	Q	

Where the type of requirement *could* be:

- **EFA:** requirements to be demonstrated for the "Experimental Flight Clearance"
- **F:** acceptance requirements (ATP)
- **Q:** final Qualification.

The Means Of Compliance (MoC) *could* be:

- **By Test**: the tests will be performed and Test Proposal and Test Result reports will be issued
- **By Analysis**: analytical calculations will be made and an Analysis Report will be issued
- **By Similarity**: a technical justification must demonstrate that the requirements were already verified "By testing" an equipment or systems equivalent and that the differences between the already tested and the new one do not impact the results of the tests
- **By Design**: the requirement is demonstrated automatically because the design and the requirements of the drawing ensure compliance
- **By Manufacturing**: as stated for "By Design"

For the last two MoC, the formal evidence of compliance is also done by the positive verification of the Test Article Conformity.

5.3.1.3 Qualification Documents (QD)

The supplier, on the basis of the information indicated in the QPP, *shall* prepare a set of reports (QD), in order to demonstrate the compliance with requirements. These reports are, for example: the test proposal, test results, analysis reports, similarity's justifications etc.

These documents *shall* always show the P/N of equipment or system for which the demonstration of compliance must be given.

The complete and clear traceability between the "matrix of compliance" of QPP and the number of sub matrix of individual QD is a mandatory requirement; it is also important that the demonstrations shown on the QD is divided into paragraphs and subparagraphs homogeneous for MoC.

5.3.1.3.1 Qualification Test Proposal (QTP)

The QTP *shall* contain, as minimum, the following information:

- equipment/system description and the relevant P/N
- number of specimens to be tested, test conditions, parameters and equipment (STTE)
- acceptance criteria for the test results
- Step by step flow of activities, containing detail to acceptance criteria tolerance, conditions, etc.
- the laboratory responsible to perform the test

The table is an example of a Compliance Matrix to be included in the QTP

Spec. Para	**QTP Para**	**Test Condition**	**Type of requirement**			**Notes**
			1	**2**	**…**	

(*) for each item used for qualification tests, indicate which test will be used for.

5.3.1.3.2 Qualification Test Report (QTR)

For each QTP the relevant QTR *shall* be issued containing, at least, the following information:

- The P/N used for testing and the relevant configuration status (drawing issue or Modification Status), the applicable Technical Specification and item description

- For each item used for testing, evidence of conformity to the applicable technical data (ref. TAC)
- Copies of the Test Authorization approved by L**H**, if applicable
- justification of configuration differences between the items tested and the items of which is to demonstrate compliance with the requirements, if necessary
- Date and place of testing
- Configuration of STTE, tools, etc.
- Qualification status of laboratories
- For each requirements, the reference to the applicable paragraph of QTP
- Test results with deviation and/or limitations with respect to the requirements
- A Compliance Matrix as in the following table

Specification Para	**QTR Para**	**Description**	**Deviation/Limitation**

5.3.1.3.3 Analysis report (AR)

The Analysis Report *shall* contain:

- Details of the analysis performed such calculation methods, assumptions, etc...
- Results of the analysis/calculations
- Deviations/limitations with respect to the requirements
- Test results with deviations and/or limitations with respect to the requirement
- A Compliance Matrix as in the following table

Specification Para	**AR Para**	**Description**	**Deviation/Limitation**

5.3.1.3.4 Similarity justification

The supplier can report the justifications "by similarity" in one or more documents; these documents *shall*, at least, contain this information:

- The P/N already qualified, taken as a reference to similarities
- The QTR reference of the P/N already qualified.
- The detailed description of the similarity criteria and justification for any possible deviation.

5.3.1.3.5 Acceptance Test Procedure (ATP)

For all “significant” P/N to be qualified, the supplier *shall* issue a testing procedure in order to identify anomalies or malfunctions of equipment/part produced.

If some performances are associated to functionalities of system or subsystem, the appropriate ATP applied to the system or subsystem *shall* be provided.

The ATP *shall* contain:

- The applicable P/N
- Physical inspections necessary to ensure compliance with design documentation such as identification, size, weight, etc.
- Functional tests to ensure the proper functioning of the part including the environmental test conditions and electrical testing (where applicable)
- All the part, system or equipment that *shall* be used for the execution of ATP including the SW test
- The form to record the results of ATP (Acceptance Test Report - ATR).
- A troubleshooting procedure.

5.3.1.3.6 Maintenance Manual

LHEO, as type certificate holder, has the responsibility to place, in the manuals of the aircraft, the actions required for the operators, to ensure the normal operations and continued airworthiness of each part/equipment and therefore of the aircraft itself.

Supplier *shall* prepare and deliver to LHEO, the following documentation and information:

- For first and second level activities, data necessary for maintenance activities; LHEO *shall* endorse these data, including them on an own manual.
- For third level activities, the equipment Maintenance Manual; these activities cannot be delegated to Operators, but must be performed by the manufacturer or by an authorized service station according to EASA Part 145. Contents of this manual are under Supplier's responsibility.

The above documentation *shall* be referenced in the appropriate box of DDP

- <u>First Level (or Organisational Level)</u>

The aim of Level 1 maintenance is to keep each aircraft available. This implies, in case of a malfunction, the quick and easy exchange of components and modules, as well as engines replacement.

Level 1 activities are expected to include:

- Servicing activities
- Pre- and post-flight inspection
- Functional checks
- Trouble shooting
- Preventive maintenance
- Corrective maintenance (parts replacement)
- Software loading

- Simple modifications

- Second Level (or Intermediate Level)

The aim of Level 2 maintenance is to maintain at the highest possible level of efficiency the aircraft fleet. This implies, mainly, repair of assemblies and subassemblies replaced at Level 1.

Level 2 activities are expected to include:

- Repairs down to modules and subassemblies
- Minor structural repairs to the airframe
- Scheduled inspections
- Modifications
- Technical assistance to the Level 1 organisation

- Third Level (or Depot Level)

The aim of Level 3 maintenance is to assure the achievement of all repairs and overhaul activities beyond Levels 1 and 2 capabilities. Such activities are generally performed at OEM facilities.

Level 3 activities are expected to include:

- Repairs down to full reconditioning
- Repairs requiring special skills or (test) equipment
- Major structural repairs to the airframe
- Major scheduled inspections
- Modifications and update programmes
- Technical assistance to the Level 1 and 2 organisations
- Software modifications
- Preservation of complete aircraft.

5.3.1.3.7 Declaration of Design and Performance (DDP)

DDP is always required for each "Significant" P/N to qualify and, where applicable, one or more DDPs for the traceability of requirements integration at level of the system and subsystem.

The qualification of deliverable parts of a system, not counted among the Significant P/N to qualify, is implicitly declared by the issue of the System DDP.

If the Main Supplier delegates to a Sub-tier suppliers the design and/or qualification of one or more Significant P/N, the DDP *shall* refer the P/N and the name of the designer.

If the Sub-tier supplier performs and/or is responsible for activities of qualification, the DDP and all the documents used in demonstration of compliance *shall* be signed by the designer Sub-tier supplier and by the Main Supplier for approval and, where applicable, by **LH**.

The DDP *shall* be revised and resubmitted to LHEO for approval when at least one of the following cases occurs:

- The criticality class of a P/N is changed from Not Critical to Critical
- The design validation activities change the usability of the P/N listed in box 21 of DDP form QRS-115 F03 (rig use, ground use, EFA etc.), or there is a change in the limitations
- The applicable Technical Specification, referenced on DDP, has been changed ("Equipment Specification" for single deliverable or System Specification, in case of System DDP),
- The referenced ATP has been changed.

The DDP *shall* be prepared according to the form QRS-115_F03.

5.3.1.3.8 Delivery documentation

The equipment/parts which will be delivered to perform the tests to demonstrate compliance *shall* be accompanied by the following documents:

- "Certificate of Conformity" to the applicable design data
- TAC approved by LHEO or reference to the TAC already approved and delivered with previous test articles, if still applicable ATR, if applicable

5.3.2 Design Review (DR)

The control of design process *shall* be performed by means of Design Reviews; the previous figure 1 shows the minimum Design Review to be performed.

The Supplier *shall* provide the review notification, with delivery of all the relevant documentation, to LHEO at least 10 working days before the intended review date. LHEO can require participating in reviews.

A minute *shall* be prepared for each review, reporting all actions, the responsible and the scheduling of their closure.

The minutes of Design Review *shall* be managed such a technical document.

The review can be formally closed and a new phase can be started only when all actions are closed and relevant documentation approved.

5.3.3 Change control/Configuration Management

5.3.3.1 General requirements

The Supplier *shall* have in place a system for the management of the changes that guarantees the control of the evolutions of the requirements during the development phase and

subsequently the management of the baseline configuration, after its achievement at the CDR. This *shall* happen both during the demonstration of compliance phase and the production, when the configuration of each part delivered *shall* be attested.

The Supplier *shall* demonstrate that its design system is capable of:

- Ensuring a satisfactory configuration control, this means that:
  - a Part Numbering system *shall* be defined to identify uniquely the parts
  - a process *shall* be available to ensure traceability from requirements specification to the drawings included the P/N equipment and all relevant components
  - a code structure, not included in the P/N, *shall* be defined to guarantee the traceability of minor changes (both physical and documental), usually using the "modification status" or "amendment" or equivalent code
- Evaluate and correctly classify the changes to the baseline configuration
- Provide an internal form to record the changes, stating:
  - reason for change
  - classification, considering “fit, form and function” criteria or airworthiness criteria as applicable (ref. 5.3.3.4 or 5.3.3.5)
  - justification of classification decision, unless self-evident
  - P/N affected by the change
  - generation of new P/N in case of impact on form, fit or function
  - generation of new ”modification status” in case of no impact on form, fit or function
  - Level of impact on design data (drawings to be amended, ATP, etc...)
- Manage the process of requalification
- Manage the system for assigning new identification numbers (P/N, mod status numbers), consistent with the class of the change.

The Supplier must have in place a procedure for the management and approval of changes to the design of the parts, system or equipment supplied to **LH**, in agreement with the criteria reported in this document. The references to the applicable Supplier procedures *shall* be reported in the Quality Plan.

Unless waived by the contract, the process of control/configuration management *shall* be described in a "Configuration Management Plan" (CMP).

5.3.3.2 Modification to the contractual technical specification or to equipment specification

Changes to the contents of the Technical Specification can be originated by a request of LHEO or of the Supplier.

They can occur either during the development phase (before the CDR) or after the achievement of the baseline configuration to be used for the demonstration of compliance and the production.

If the Supplier needs to modify one or more content of the **LH** Technical Specification, it *shall* initiate the process of evaluation and after the phase of informal contacts and agreements with LHEO, all traced through the issue of Coordination Memos (COMO), it *shall* request the modification through the issuance of a SCN.

The SCN *shall* be prepared and compiled using the form QRS-115_F04.

The Supplier *shall* use the SCN also in case of Part Number change in the configuration of the deliverable equipment/part, independently from the reason that has generated it.

The L**H** Technical Area in charge *shall* proceed with the technical evaluation of the change and the analysis of the impact of identified change on each part, system or equipment, as described in subsequent paragraphs

A change to the Technical Specification proposed or required by **LH** *shall* be anticipated by the issue of an SCN, otherwise directly managed with the review of the document.

If the modifications to the Technical Specification requirements occur before the Critical Design Review (before the achievement of the configuration baseline and the issue of the relevant preliminary Part List) and before the delivery of part, system or equipment or the start-up of any certification activity, the P/N will not change.

5.3.3.3 Management of Design Changes before Qualification

Until qualification is obtained (as defined in paragraph 5.2.2.5), the Supplier *shall* submit design changes to LH for acceptance if there is an impact on fit, form or function.

5.3.3.4 Management of Design Changes after Qualification

The design of any part, system or equipment procured from a Supplier who is also the designer of the part, system or equipment, once certified, becomes part of the Type Design of the **LH** product.

Alteration to any of the following data, which constitutes the type design, is considered a change to Type Design:

- Drawings and their lists necessary to identify the configuration
- Specifications and their lists necessary to identify the configuration
- Information on materials, processes, methods of manufacture and assembly
- Approved airworthiness limitation sections of instructions for continued airworthiness
- Any data necessary to allow comparisons with later products for the determination of the airworthiness

Changes applied to them after the achievement of the qualification *shall* be classified by LH as per EASA PART 21

5.3.3.4.1 Change approval

- **All Changes *shall* be communicated to LH for classification and approval.**

- For each Changes, the Supplier *shall* send to the **LH** Technical Area in charge to follow the design activity the following:
  - Engineering change order documents, in the format identified in the Quality Plan and in the DO-PO Arrangement.
  - The drawings relevant to the change and all the documents proposing or testifying the demonstration of compliance to the applicable Technical Specification requirements, applicable airworthiness requirements (CS paragraphs) and environmental protection requirements. These documents *may* be compliance statements, description reports, analytical substantiation reports, safety analysis reports, test plans/test reports etc.

Changes cannot be implemented until its approval is communicated by LHEO with signature on the SCN.

- **The changes in the table below are pre-classified as Very Minor Changes to the design data not requiring further demonstration of compliance**. Only these specific changes do **not require any LH approval before the implementation.**

Correction of drawing clerical errors *E.G. → Graphical errors; formal errors on quotations or references*
Correction of Drawing Part list clerical errors *E.G. → Formal errors; incorrect or superseded recall of materials or standards*
Translation of the data set on a different CAD system keeping technical contents
Change affects part / specification identification without change of contents (for example: evolution from MIL to SAE; MIL to NAS etc.). Except for contracted and deliverable P/Ns
Re-arrangement of drawing tree without altering technical contents (for example moving P/N from an assy drawing to another one transposing the installation instruction and keeping the technical contents). Without impact on contracted and deliverable P/Ns

In this case the Supplier *shall* send through COMO (form QRS-115_F02) to the **LH** Technical Area in charge to follow the design activity the following:

- Engineering change order document, in the format identified in the Quality Plan and in the DO-PO Arrangement.
- Possible additional documentation to complete change description.

5.3.3.4.2 Procedure for the management of changes

The procedure for management and approval of design changes to type design as described above must be implemented in a supplier's internal procedure. This procedure *shall* also:

- describe the flow down of such criteria and its implementation at the supplier's sub-tiers involved in design activities.
- detail the approval criteria in agreement with paragraph 5.3.3.3.1
- specify the responsible signatories in the supplier's organisation
- describe how the information of changes is exchanged between the supplier and **LH**, according to the rules in paragraph 5.3.3.3.1
- include planning and execution of auditing activities (both internal and sub-tiers) to monitor the correct flow down of design changes criteria and approval criteria. This applies to both supplier's internal organisation and to its sub-tiers, where applicable.

5.3.3.5 Interim changes to programmed equipment

This paragraph is applicable to suppliers responsible for the development of programmed equipment.

For such equipment, during the development phase after the qualification status of EFA, a fast management and traceability of changes can be required, in particular concerning SW changes. In these cases; traceability will be ensured through the use of provisional P/N.

The supplier having this necessity *shall*:

- agree in advance with the **LH** Project Leader the use of this methodology;
- Ask to **LH** Project Leader, for each interim change that must be introduced and tested by **LH**, the number of provisional P/N (equivalent to the number of EO Development Test Trial).The identification of equipment, recording and traceability of changes on the applicable technical documentation *shall* be made as indicated in the relevant paragraphs.

5.3.3.6 Data Exchange

The change request to the requirements of the Technical Specification *shall* be managed using the SCN form.

The supplier *shall* prepare the SCN also in case of major change to the configuration of the deliverable equipment/part; independently from the event that has generated it.

The supplier *shall* prepare the internal "Change Form", by implementing the following rules:

- For Major Change; the supplier *shall* send the SCN, the "Change Form" and all the documentation to the **LH** Technical Area in charge. The change cannot be implemented until approved by **LH** D&D, by signature on the SCN.
- For Minor Changes (that involve the CS requirements), the supplier *shall* send the "Change Form". D&D reserves, within 30 days, to request a re-evaluation and reclassification of the change. In case of no request from **LH**, the supplier *may* proceed to the introduction of the amendment.

- For Minor Changes (clerical error etc...), the supplier *shall* send the COMO to the **LH** technical area. These changes are sent to **LH** for communication only, and the supplier can precede the introduction of the amendment after the invoice of COMO.

For all the Changes, the relevant documentation (including **LH** transmission and approval evidences) *shall* also be kept and formally recorded by the Supplier for any check and evaluation, carried out either by **LH** or by the Airworthiness Authorities.

5.3.4 Configuration Management

Unless waived by the contract, the process of control/configuration management *shall* be described in a "Configuration Management Plan" (CMP).

5.3.5 Identification and marking

5.3.5.1 Equipment/parts identification

All the parts or equipment deliverable (End Item) *shall* be identified according to the LHEO Technical Specification.

When a supplier which is the designer responsible in accordance with the Technical Specification, uses Sub-tier supplier, the following two cases can occur:

- the Sub-tier supplier produces the equipment/part using the detailed drawings of the main supplier; in this case the Main Supplier's P/N *shall* be marked on the equipment/part
- The Sub-tier supplier produces the equipment/part using own drawings (designer responsible of the part); in this case the equipment/part *shall* be identified with the Sub-tier supplier's P/N.

The parts/equipment *shall* be marked permanently and legibly with the following data:

- name, mark or symbol of the Manufacturer as identified by the applicable design data
- P/N as defined by the Designer of the applicable design data
- Modification status: it is the revision of the applicable detail drawing or Part List. The Modification status (or equivalent) *shall* be marked in a distinct manner from the P/N
- S/N of the manufacturer or Batch Number if the serialization is not required
- P/N of the Main Supplier in case that the Designer is different from the Main Supplier, *shall* be added also the Supplier P/N as responsible of compliance with the **LH** Technical Specification)
- **LH** P/N or program P/N as defined by **LH** Technical Specification
- Equipment/part description
- Manufacturing date
- The number of Concession/Production Permit (if any)

5.3.5.2 Equipment containing SW/AEH

For equipment containing any type of SW (Operations, Mission, Equipment, Application, etc.), the P/N *shall* include indications on the combination of HW and SW.

Any changes to SW *shall* have an impact on the P/N of the end item and *shall* be managed according to what described for the major changes (ref. § 5.3.3.3).

The code of the SW *shall* not be marked on the label.

SW modification management performed adding an additional label referred to SW configuration, without changing the End Item identification code (P/N), is strictly forbidden.

NOTE: The supplier that design and development software and/or complex Hardware *shall* refer to QRS-116 and QRS-117.

5.3.5.2.1 Identification of part, system or equipment with provisional P/N

The programmed part, system or equipment managed with provisional P/N (ref. § 5.3.3.6) *shall* be identified by:

- name plate in accordance with paragraph 5.3.5.1 requirements
- additional name plate with the provisional P/N

The name plates with the provisional P/N *shall* be marked with a strikethrough line when superseded, and maintained on the part, system or equipment for the entire duration of the tests until the final qualification of the equipment itself.

5.3.5.3 Sub components identification

Each subassembly *shall* be correctly identified in accordance with the principles of the above paragraphs; the identification *shall* include, as minimum:

- Manufacturer P/N (the form)
- S/N or "Batch Number" assigned by "Manufacturer"
- Modification Status

In case that a module/subassembly with embedded the SW, the module P/N *shall* take into account the SW Version and Release (ref. 5.3.5.2).

5.3.5.4 Special identification

In case of delivery of equipment/parts declared “NOT FOR FLIGHT” due to their configuration or non-conformities and the relevant limitation is not removable without physical alteration (through repairs, reworks or retrofit), the part *shall* be subjected to the following requirements:

- *Shall* be identified by means of a red band, 20 mm large compatibly with the item dimensions.

- CoC and Log Card (if required) *shall* clearly indicate "NOT FOR FLIGHT"

These requirements do not apply to components for which the "NOT FOR FLIGHT" limitation has been declared due to the fact that demonstrations of compliance of the design or manufacturing process have not yet been performed.

These items will change their compliance status in "FOR FLIGHT", and DDP will be revised, after the removing of the non-conformities or the performing of demonstrations.

In this case, the applicable DDP, referenced with its identification code (without revision) to CoC, will declare achievement of the new compliance status.

5.3.6 Critical parts management

5.3.6.1 Definition

Parts/equipment are classified into two categories on the basis of the consequences of a failure on the airworthiness of the aircraft, according to CS 27/29 definition below:

CS 27/29.602 Critical parts

(a) Critical part - A critical part is a part, the failure of which could have a catastrophic effect upon the rotorcraft, and for which critical characteristics have been identified which must be controlled to ensure the required level of integrity.

(b) If the type design includes critical parts, a critical parts list shall be established. Procedures shall be established to define the critical design characteristics, identify processes that affect those characteristics, and identify the design change and process change controls necessary for showing compliance with the quality assurance requirements of Part-21.

- Critical part: is the part where a single failure results are catastrophic in the terms stated by CS 27/29.602.
- Non-critical part: is the part the failure of which does not cause a catastrophic event.

A "catastrophic failure condition" is a failure condition which "…would result in multiple fatalities to occupants, fatalities or incapacitation to the flight crew, or result in loss of rotorcraft" (AC29-2C).

(It means e.g. the inability to conduct an autorotation to a safe landing, without exceptional piloting skills, assuming a suitable landing surface.)

5.3.6.2 Part/System/Equipment classified (critical/non critical) by LH Technical Specification

In this case, the **LH** Technical Specification, on the basis of the safety analysis performed and the relevant functionality of the whole aircraft, defines the classification of the part (critical/non critical). The supplier *shall* classify and manage the parts accordingly.

5.3.6.3 Part/System/Equipment with functions classified by LH System Technical Specification

In this case **LH** defines, in the System Technical Specification, the functions of the system whose loss might cause dangerous situations and classifies it in accordance with the typical following categories:

- Catastrophic
- Hazardous
- Major

After definition of the system composition, the Supplier *shall* perform a safety analysis on the functions of the system components assigning their role based on the functional failures defined in the Technical Specification, and classify them accordingly.

5.3.6.4 Management of Critical Parts

Considering the principles and requirements detailed in paragraphs 5.3.6.2 and 5.3.6.3, the Supplier *shall*:

- report on the drawings of critical part, system or equipment the legend "CRITICAL PART" or equivalent
- Identify, on manufacturing drawings and/or 3D models of critical parts/system/equipment, the critical characteristics. The critical characteristics *shall* be identified with a "c" inside a diamond unless otherwise specified.
- Ensure the production traceability through the serialization of the part.

The supplier must be able to associate the S/N of the internal components classified as critical with the S/N of the higher level part/equipment and *shall*:

- Maintain a critical components list of critical part, system or equipment
- Manage changes to the production process, including as described below.
  Any changes to the production process included in the list below *shall* be approved by **LH** D&D before its implementation and with the execution of a new TAC (§ 5.3.7):
    - modification of: plant, raw material, critical operation, special process, numerical control program, special tools, particular part of a tool (for tools for forming foundry, for example, a change of the scheme of casting and feeding)
    - Change or new lay-out of the production site.

  Remark: these requirements are applicable also for the internal components classified as “CRITICAL”.

5.3.7 Test Article Conformity (TAC)

5.3.7.1 General

For any part, system or equipment used for demonstration of compliance testing, the supplier *shall* produce a "Certificate of Conformity" to the Applicable Design Data.

For each significant P/N to qualify, evidences necessary to issue the statement *shall* be collected in a report called TAC.

The TAC, like the First Article Inspection for the First Production Run phase, *shall* be performed in accordance with the reference document QRS-101 and EN9102 requirements. The TAC report *shall* be approved by the **LH Engineering Chief Project**.

For each of the items that will be used for the tests there *shall* be evidence that:

- the items are in compliance with applicable technical data
- any non-compliance with applicable technical data are irrelevant to the effects of test results

5.3.8 Conformity to the applicable technical data

For the manufacturing of prototypical parts and/or pre-series for qualification testing, the supplier *shall* establish a process to ensure compliance with the applicable design data.

In addition, a Test Article Conformity (TAC) shall be performed including as a minimum:

- A complete dimensional check with record of the results detected
- Execution of ATP and its recording (ATR)
- Further verification of compliance with applicable requirements of the detailed design
- Evidence of successful implementation of manufacturing procedures and inspection
- Any destructive tests on a sample
- Evidence of qualification of special processes
- Any other verification necessary to demonstrate that the manufacturing process is suitable to produce parts in compliance with the applicable technical data

The Supplier can define additional inspections to be performed to ensure the demonstration of compliance.

All the evidence *shall* be collected in a TAC report, with the addition of the following data:

- The equipment/part drawing assembly together with all the subpart drawings assembly required for evaluation by LHEO completeness checks
- Part List of the equipment/part
- Copies of the control specifications of any critical characteristics and/or evidence that those specifications are equivalent to those normally used by **LH** for identical processes.

The TAC report *shall* be sent to LHEO for approval with Form TAC,

If the TAC is not approved, the parts cannot be delivered to **LH** laboratories or used for testing in the supplier's laboratories.

The TAC activities *shall* be performed and/or repeated in the following cases:

- At the first test of demonstration of compliance for that P/N, regardless of the site or laboratory where the test will be performed
- If there are any significant changes in the manufacturing process (impacting the performances) of the prototypical units, this case will be managed by a revision of the existing TAC
- In case of changes to equipment configuration, with change of P/N: in this case, the TAC will be reissued with new numbers

5.3.9 Test article representativeness and Test Authorization Form

When a TAC is approved, the equipment/parts manufactured with the same process *may* be used for test.

The supplier *shall* perform the following actions:

- The equipment/part for testing *shall* be accompanied by a Certificate of conformity, issued on the basis of the result of the TAC applicable and further verification (ATP, dimensional check, etc.)
- Any non-conformity *shall* be managed as described in paragraph 5.3.10. The non-conformities *shall* be approved by the relevant **LH** D&D to authorize the execution of the test if the non-conformity is irrelevant to the effects of the test.

Once carried out the above described actions, two cases can occur:

- for tests that will be performed at the supplier sites (or its Sub-tier suppliers), the supplier *shall* prepare the "Test Execution Authorization" form (QRS-115_F01), with the evidences described above
- For tests that will be performed at other sites, the supplier *shall* send to LHEO the evidence of compliance of the part delivered.

5.3.10 Non conformity management

For the test item, the supplier *shall* give evidence of any non-conformity to the applicable technical data, reporting the relevant reference in the "Certificate of Conformity".

The findings *shall* be managed according to the supplier procedures, recognized by **LH**.

Except in cases where the supplier decides to scrap the part, the supplier *shall*:

- Fill the "Concession" form QRS-107_F01 (see QRS-107) and submit to LHEO D&D for evaluation and approval
- Ensure that the non-conformity report includes:
  - traceability

  - identification of the root cause
  - evidence of management of any corrective actions taken
- Report on the "Certificate of Conformity" reference to all the non-conformities and the applicable repair drawings, attaching a copy of the documentation
- Mark on the equipment/part the concession number if requested by LHEO decision
- In case of approval by LHEO, and after the application of corrective actions, the supplier *will*:
  - deliver the part or
  - test the part, if this activity is performed by the Supplier

5.3.11 TAC for equipment with provisional P/N

When a change is introduced to programmed equipment managed with a provisional P/N, a sheet *shall* be added to the TAC already issued and approved in the EFA phase.

This sheet *shall* report the description of the changes from the previous configuration and *shall* be approved by the supplier's Design Organization responsible.

5.3.12 Design Data Set (DDS)

The Supplier *shall* issue the document which defines the DDS at the Critical Design Review and keep it updated during design evolution for each major modification to the configuration and for modifications to documents referred by the configuration itself.

The Design Data Set has to be approved by LHEO before Supplier Engineering release to its PO.

The data *shall* be transferred, from Supplier Engineering to LHEO and vice versa, as agreed in the Quality Plan.

For the DDS issue and subsequent variations a COMO *shall* be issued.

5.3.12.1 DDS contents

The following indications refer to the Form QRS-115_F05.

The front page of the document must report, as a title, a description of the assembly or the part of the Technical Specification or Source Control Drawing issued by **LH**.

The heading of tables composing the document has to report reference to **LH** and Supplier P/Ns, with the relative revisions.

5.3.12.2 DDS approval

Supplier Configuration Control approval states that the drawings tree reported in the document is the one formally issued and managed in accordance with the procedure of Change Management.

Supplier Chief Designer approval states that the reported configuration is the applicable one; it is up-to-date and suitable for the issue of product documentation.

LH Chief Designer accepts what stated by Supplier Chief Designer and assures the correspondence between Supplier and **LH** P/Ns.

LH CPE, with his signature, freezes the applicable technical data package which has to be used by the PO for the issue of product documentation.

At the end of the approval process, **LH** returns the document to the Supplier.

5.3.12.3 DDS filing

The Supplier is responsible of filing the document which states DDS approval by **LH** and of presenting it if required by **LH** or Civil or Military Authorities.

5.4 Access and data visibility

5.4.1 Access to the sites

The supplier *shall* guarantee the access to all design, qualification and manufacturing sites used for activities concerning the program and contract, to all **LH** and the Authority representatives, in according with the purpose and time scale defined in the program/contract.

5.4.2 Documentation

In addition to the documentation required in this document, which *shall* be provided to LHEO by contract, the supplier *shall* provide, on the request of LHEO or of the competent Authorities, copies of all documents deemed necessary to complete the certification process.

The supplier *may* refuse the resolution of a requested document if the same is considered confidential or exclusive property for industrial reasons. In this case the supplier *shall* allow the consultation and auditing of such documents at any time with modalities to be defined Case by case.

LHEO, the Authorities (Civil or Military) or **LH** customers (always through **LH** organisation), *may* require the supplier to produce a document equivalent to that considered "confidential", removing confidential information, if the availability of such document is necessary for closure of the certification process and/or acceptance by LHEO the customer.

6 Attachments, Appendices and Forms

- QRS-115_F01: Test Execution Authorization (TAF) form
- QRS-115_F02: Coordination Memo (COMO) form
- QRS-115_F03: Declaration of Design and Performance (DDP) form
- QRS-115_F04: Specification Change Notice (SCN) form
- QRS-115_F05: Design Data Set (DDS) form