QRS-118 Requirements for Laboratories and Manufacturers of Non-Airborne Equipment for LH Engineering





QRS-118

Requirements for Laboratories and Manufacturers of Non-Airborne Equipment for LH Engineering

Issue Date:	June 2019	Issue:	00

CHANGES LOG

Issue	Approval Date	Main changes	Interested Paragraphs
00	June 2019	First Issue	All

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		
ISO9001	Quality Management System		
ISO/IEC17025	General requirements for the competence of testing and calibration laboratories		
EN/AS/JISQ9100	Quality Management Systems – Requirements for Aviation, Space and Defense Organisations		

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1 Purpose

This procedure defines the process to meet minimum requirements for Laboratories and Manufacturers of Non-Airborne Equipment for Engineering, in terms of quality system, Supplier management and organization, personnel requirements, processes, tools and facilities. The specific kind of requirement depends on the type of activity. The activities are divided into the following clusters:

- Laboratories
- Manufacturer of Non-Airborne equipment

2 Applicability

Applicable to all the LHEO Laboratories and to all the Manufacturers of Non-Airborne Equipment for LHEO, on all the LH civil product lines. For military product where specific rules are established, those will take priority on the content of this procedure.

3 Acronyms, definitions and abbreviations

3.1 Acronyms and Abbreviations

- ARP Aerospace Raccomanded Practices
- CS Customer
- CVE Chief Verification Engineer
- DO Design Organization
- DOA Design Organization Approval
- LH Leonardo Helicopters
- LHEO Leonardo Helicopters Engineering Organization
- REACH Registration, Evaluation, Authorisation and Restriction of Chemicals
- SoW Statement of Work
- WP Work Package

4 General requirements

4.1 General Personnel

The resource level shall be adequate in number and skills, at the Supplier's discretion, to meet the technical objectives, the scheduled delivery dates and all the other binding requirements contained in the contract, SoW and Technical Specifications (as applicable).

Knowledge of written and spoken English is a general requirement. The language skill level shall be defined in relation to the specific activity.

The requesting LH Engineering Department shall indicate into the Statement of Work the specific requirements tailored on the type of activities to be performed.

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4.2 Quality System

The Suppliers (Laboratories and Manufacturers of Non-Airborne Equipment) shall meet the minimum certification requirements specified in QRS-01 (Ref. Table 1).

5 Laboratories

5.1 End to End Testing and Measuring

This section describes the steps of test process for an individual test campaign and the related requirements.

The test organization should document and implement a test process covering the steps below.

Step1: Test specification establishment

Step2: Test preparation

Step3: Test execution

Step4: Archiving

Step5: Test results validation and reporting

Depending on the case, one or more phases of the process could be not performed if already covered by LH.

In the following table Actors, Outputs and Quality gates for each step are reported:

Actors	Activity	Output	Quality Gates
LH DO	Step1: Test specification establishment	Test Proposal	
LH Laboratory/ Supplier	Step2: Test preparation	Rig design, assembly & test set-up	Test Readiness Review & Test execution authorization form (ref. QRS-115) as output
LH Laboratory/ Supplier	Step3: Test execution	Test Result Data Sheet & Lab Test Report	
LH DO/Supplier	Step4: Archiving	Test Data saved in secured environment Test article and test set-up stored as decided	
LH DO (D&D and/or Fatigue as applicable)	Step5: Test results Validation and Reporting	Test Analysis Report (including test conclusions)	

 Table 1- Test process description and requirements

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The description of roles and responsibilities for each step is reported in the following.

5.1.1 Test specification establishment

The test specification is defined into the Test proposal provided from LHEO to the Supplier The test proposal shall be provided to the Supplier together with the SoW. The LHEO shall provide information to the Supplier about "what" and "how" has to be tested through a Test Proposal covering at least the following:

- Certification requirements (e.g.: CS requirements, DO or ARP requirements), to which compliance should be shown;
- Test article configuration and concessions if present;
- Condition to be applied (loads, environmental conditions);
- Test installation including instrumentation requirements;
- Measurement to be made before, during and after the test;
- Test sequence and number or cycles to be obtained, if applicable;
- Inspection requirements;
- Alarm thresholds, if applicable;
- Test pass/fail criteria or reference to the related CS requirements;
- Acceptance procedure for test article and test set-up;
- Conformity verification;
- Format for test deliverable (results, report);
- Requirement for Test Witnessing (by EASA Military Authority, DOA Holder CVE or delegate, Test specialist...).

5.1.2 Test preparation

The following diagram explains the steps performed during test preparation activity, in case of *Specialized Laboratory*. Depending on the typology of Laboratory involved the responsibility of each single phase could be held by the Supplier or by the LH Laboratory as specified in the SoW.

For test set-up those documents/evidences must be collected:

- Certificate of Conformity to set-up definition (drawing and/or specified characteristic) signed off by authorized personnel.
- Certificate of calibration for the measuring equipment. An attachment as a picture/drawing with the identification of all equipment of the expected set-up should be necessary.
- Demonstration that measuring equipment is adequate for the purpose of the test.
- A list of deviations of test set-up, if needed in order to show that the purpose of the test can still be met and set-up is still considered to be representative.
- Functional test for acceptance of test set-up to make sure that healthy and conformity to requirements are accomplished. Functional tests are part of the validation of test set-up. Pass/fall criteria may be established. If functional test needs to be performed during the test, it may be reported in the test procedure. Functional tests may include but they are not limited to:
 - Performance tests
 - Calibration tests

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- Safety tests
- Particular specimen handling requirements, if present
- Instruction to configure the test rig and to install the test article in the rig.
- Quality requirement imposed by the design organization for test set-up design should be satisfied, when applicable. Design organization may participate in reviews as:
 - Test set-up concept validation
 - Test set-up manufacturing drawings validation
- Test Activity Checklist
- An authorization to carry out Supplier tests referred to procedure
- Acceptance data archiving system description.

Test readiness review completes test preparation phase. The aim of this review is the validation of test set-up with the participation of design organization. Test plan, Test procedure and Acceptance procedure for test articles and test set-up must be accepted in order to complete the Test readiness review.





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5.1.3 Test execution

The test is executed by test organization as defined in test procedure, checklists are filled as indicated in test procedure and results are collected, with the required frequency, in the result data sheet defined in test procedure. Logbook may be updated. Before test execution, the Supplier shall inform the LH Focal Point, to guarantee the involvement of the relevant functions.

In case of any change in the test schedule, the test organization shall inform the design organization of the change, in writing, at least three weeks before the test execution, when a test is witnessed by the design organization.

The output is the Test Report that should include (at least):

- Cross reference to the applicable test specification, test plan and test procedure;
- Description of the actual set-up;
- Statement of calibration of measurement equipment;
- Checklist filled in, including any deviation from initial plan;
- Description of the actual test articles with all applicable concessions;
- Authorization to carry out Supplier tests for the test articles and test set-up (ref. QRS-115_F01);
- Name of the operator;
- Name of witnesses;
- Test result including all the relevant occurrencies happened during the tests;
- A table summarizing the tests performed;

Approval signature from the relevant authorized signatory of the test organization;

5.1.4 Archiving

To ensure traceability and integrity of test documentation, archiving is necessary. Test articles, test data and specific test rigs are stored. Logbook shall be checked to be updated, with references to executed tests. Availability of those data in the LH SAP system shall be considered when possible.

5.1.5 Test results validation and reporting

Test completion review is needed to complete this phase and it is conducted with the design organization.

- The test completion review addresses:
- Review of the checklist;
- Check consistency of the results;
- Review and acceptance of the test report;
- Capture the lesson learned.

If a deviation from predicted values is found, this could lead to a partial or complete rework.

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6 Manufacturer of non-airborne product design & production

6.1 Non-Airborne Equipment Design Process

This paragraph describes the general requirements for the phases of development, design, compliance to the technical requirements, etc. involved in the whole design process of Non-Airborne Equipment, such as tools, Test Benches and Test Rigs, demanded to a Supplier.

The detailed requirements for design specific activities are defined into departmental procedures. The following requirements must be considered like general indication.

The Development for Non-Airborne Equipment shall be structured following the principal phases reported below, to be specified depending on the type of equipment and :

- Requirement Definition;
- Design;
- Qualification/Validation.

TheSupplier shall define a focal point responsible for the activity.

The number and the type of Reviews to be done during the whole process shall be identified and reported into the properly section of the SoW or the Technical Specifications (where applicable).

6.1.1 Requirement Definition

LH Department shall identify technical requirements for the equipment and identify, into the SoW, the requirements that has to be provided to the Supplier.

In consequence of LHEO requirements specifications, the Supplier shall issue for each part of the equipment:

• A Detailed Technical Specification (Equipment Specification) or, for relatively simple components, a Specification Drawing.

Manufacturer shall also provide:

- A Qualification Program Plan (QPP) within the list of the documents that must be issued in order to provide evidence of compliance with requirements of LHEO specifications¹;
- A Quality Plan (QP)¹;
- A Configuration Management Plan (CMP);
- Interface/assembly Drawing/3D Model;
- Environmental compliance requirements / REACH statement (see applicable paragraph of QRS-01)

¹ Only if required in the SoW

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These work products are object of a Preliminary Design Review (PDR) that must be performed, to shift from the preliminary design to the detail design and development. This design review shall assure that preliminary design is in line with the established goals, such to allow relevant development. It will be verified how the equipment satisfies the functionality, production and maintenance requirements and if all interfaces between equipment and helicopter/component have been properly defined

6.1.2 Design Phase

The Supplier, at this stage, shall develop the equipment, defining the detail of the individual parts for production.

During this phase, the Supplier shall issue the document listed below:

- Part list or Design Data Set;
- Drawings/3D Models;
- Applicable Analysis reports
- Applicable interface and functional compliance reports
- Maintenance Manual (or similar) when applicabl;
- General handling requirements / REACH statement.

When the detail design has been completed, the Supplier must perform the Critical Design Review (CDR) to shift from detail design to manufacturing. The detail design and the relevant fulfilment of functionality requirements and interface capability with other subsystems will be checked. The documents listed before are verified during this phase.

The manufacture/purchase of the prototype is then authorized

6.1.3 Compliance demonstration Phase\Validation

The equipment shall be subjected to the following type of validation:

- Table top: in case of simplicity/similarity with an existing equipment;
- Simulated: when functionality and compliance with the technical requirements of prototype can be verified without the accomplishment of the dedicated maintenance task;
- Pratical: when the prototype has to be used/operated in order to ascertain its functionality to the requirements.

A successful validation is necessary to proceed with the formal issue of the technical documentation

6.2 Sub-tiers Requirements

If the Supplier uses one or more Sub-tiers, the requirements defined in QRS-01 (see applicable paragraph of QRS-01) are applicable.