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Quality requirements for the supply of Design and Development

SUMMARY:

This document defines the quality requirements applicable to the supply of Design and Development to the Defence Systems Division of Leonardo S.p.A.

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For conformance to original Italian edition

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AMENDMENT RECORD

Rev.	Date	BMSCP No.	Description	Authors
00	07/07/2017	-	First issue	C. Pagni
01	15/03/2018	007	Whole document(*) updated and reformatted to match general requirements of the new procedure PQA004-L: - adapted the text of requirements to include references to the requirements of PQA004-L; - modified the applicability to refer the types of supplies identified in PQA004-L; - introduced information on the supply Classification Index; - introduced requirements for production of prototype. *(*) For this reason the marking of the outer edge is omitted.*	C. Pagni
02	22/10/2018	057	Para. 2.1 - Updated ref. to UNI EN 9100:2018; Para. 5.2 - Added requirement: the Risk Management Plan shall be submitted for approval; Para. 5.2 – Removed option to include planning documents in the Quality Plan (only requirements in Appendix B apply); Para. 5.8 – Specified difference between design review "Passed" or "Passed under Reserve"; - Added requirement for joint reviews to be approved by Leonardo-SDI; Appendix A - Removed case of IC not specified in the PO; Appendix B – Table 2 modified	C. Pagni

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1 INTRODUCTION

1.1 Purpose

The purpose of this document is to define the specific quality requirements for the supply of Design and Development activities to the Defence Systems Division of Leonardo S.p.A. (hereinafter Leonardo-SDI).

The document is complementary (not an alternative) to ISO 9001:2015 and EN 9100 where applicable and AQAP2110 Ed 3, AQAP2210 rev. 1 and AER-Q-2110 where applicable.

More general quality requirements applicable to all supplies are defined in the PQA004-L document

1.2 Applicability

This document applies to all supplies that are to be incorporated into products and services for Leonardo-SDI's customers or used in their production.

In particular, it applies to the following types of supplies as identified in document PQA004-L:

- Type A: Design and Development Supplies;
- Type C: Supplies of Manufacturing products, where the design of the product is assigned to the supplier (see PQA006-L);
- Type E: Supplies of Ammunition, Exploding devices and Weapons, where the design of the product is assigned to the supplier (see PQA009-L);

1.3 Supply Classification Index

As provided for in document PQA004-L, for quality purposes, each supply is characterised by its Type and a Classification Index, which details the activities and documents required of the supplier.

*For example, code **A2** indicates a Design and Development Supplies; (Type A) with a Classification Index of 2.*

The possible values and meaning of the Classification Index for Design and Development supplies are defined in Appendix A; the corresponding activities and documents required from the supplier are listed in Appendix B.

For each supply, the Type and Classification Index are indicated in the Purchase Order.

2 REFERENCES

2.1 Documents

Ref.	Code	Title
D1	AER-Q-2110 issued April 2005	DGAA (Directorate General for Aeronautical Armaments) Quality Assurance Requirements for design, development and production.
D2	ACMP 2100 Ed A	Configuration Management Contractual Requirements.
D3	AQAP 2070 Ed B	NATO Mutual Government Quality Assurance (GQA) Process
D4	AQAP 2110 Ed D	NATO Quality Assurance Requirements for Design, Development and Production
D5	AQAP 2210 Ed A	NATO Supplementary Software Quality Assurance Requirements to AQAP-2110
D6	AS/EN 9100:2018	Quality Management Systems-Requirements for Aviation, Space and Defense Organizations.
D7	ISO 10005:2005	Quality Management System - Guidelines for quality plans
D8	ISO 10007:2003	Quality Management System - Guidelines for configuration management
D9	ISO 9001:2015	Quality Management System – Requirements.
D10	NAV-50-9999-0026-13-00B000	Obligations of Italian Industry towards technical bodies of the MMI (Italian Navy)
D11	STANAG 4107	Mutual acceptance of government quality assurance and usage of the allied quality assurance publications (AQAP).
D12	STANAG 4427	Introduction of allied configuration management publications (ACMP's)
D13	STANREC 4174	Guidance for Dependability Management
D14	PQA004-L	Quality Requirements for Supplies to the Defence Systems Division of Leonardo S.p.A.
D15	PQA006-L	Quality requirements for the supply of Manufacturing
D16	PQA009-L	Quality Requirements for supplies of Ammunition, Exploding devices and Weapons
D17	PQA011-L	Quality requirements for the supply of Software Design and Development

3 DEFINITIONS AND ACRONYMS

3.1 Definitions

See document PQA004-L.

3.2 Acronyms

Acronym	Description
ADMP	Allied Dependability Management Publications
GQA	Government Quality Assurance
CDR	Critical Design Review
FCA	Functional Configuration Audit
FQR	Final Qualification Review
FMEA	Failure Mode and Effect Analysis
FMECA	Failure Mode, Effects, and Criticality Analysis
GQA	Government Quality Assurance
GQAR	Government Quality Assurance Representative
ISO	International Standardization Organisation
LCC	Life Cycle Cost
LSA	Logistics Support Analysis
PO	Purchase Order
PCA	Physical Configuration Audit
PDR	Preliminary Design Review
PRR	Production Readiness Review
PHST	Packaging Handling Storage Transportation
GQAR	Government Quality Assurance Representative
RAMS	Reliability Availability Maintainability and Safety
TRR	Test Readiness Review

4 INTRODUCTION

4.1 Requirements of the Supplier

The following requirements specified in the document PQA004-L shall apply:

- "Assessment and monitoring of suppliers" (par. 5.1)
- “General requirements for the Supplier's Quality System” (par. 6.1)

4.2 Requirements of the Supplies

The requirements set out in the document PQA004-L ('Transmission of delivery requirements' - paragraph 5.2) shall apply.

The scope of supply may include the following:

a) analysis of the requirements, design and development of the product by the supplier, on the basis of higher level requirements defined by Leonardo-SDI in a Technical Specification;
b) design and development of the product by the supplier, based on a Technical Specification of requirements written by Leonardo-SDI.

If the scope of supply also includes software design and development, the specific requirements defined in PQA011-L shall also apply.

4.3 Leonardo-SDI interfaces with the Supplier

The information contained in the document PQA004-L (paragraph 5.3) shall apply.

5 REQUIREMENTS FOR DESIGN AND DEVELOPMENT ACTIVITIES

5.1 Inputs to design and development

5.1.1 Determining and reviewing requirements

The supplier shall review the technical and quality requirements communicated by Leonardo-SDI via the PO and the associated documents to ensure that they are clear, complete, consistent and suitable for the development of the design. If the supplier considers the information received to be non-exhaustive, it shall agree with Leonardo-SDI on the necessary actions to fully share the supply requirements.

The supplier shall also identify the statutory and regulatory requirements applicable to the project and any requirements not defined by Leonardo-SDI but considered necessary for carrying out the required activities; moreover, it shall take into account the requirements implicit in the expected use of the product, including *Safety* and *Dependability* requirements.

The supplier shall retain a record of the outcome of the review and shall ensure the requirements are tracked through the design development stages including product verification and validation.

If changes are introduced by Leonardo-SDI to the technical and/or quality requirements associated with the PO, the supplier shall ensure that these changes are incorporated into the project and the related documentation.

5.1.2 RAMS, LSA, PHST and LCC requirements

Any RAMS, LSA, PHST and LCC requirements (qualitative and quantitative) are defined by Leonardo-SDI in specific specifications attached to the PO.

In the event that these requirements are not made explicit in the technical specifications attached to the PO, or that others emerge during the analysis, the supplier shall in any case develop the project in conformity with the applicable standards, agreed with Leonardo-SDI.

The following is a non-exhaustive list of possible applicable standards:

- EN 50126 (national and European market);
- MIL-STD-882;
- MIL-HDBK-470 (US market);
- STANREC 4174 and NATO ADMP publications (if contractually required).

As a result of the above requirements, the supplier shall carry out and document one or more of the following specific activities, as specified in Appendix B:

a) Safety analysis;
b) Ergonomic analysis;
c) Forecast reliability analysis;
d) FMEA and FMECA analysis;
e) Analysis of preventive and corrective maintenance;
f) PHST Analysis;
g) Definition of the spare parts and equipment needed for the different logistics levels;
h) Definition of costs and average repair times;
i) Definition of user and maintenance manuals.

The formats of the documents are to be agreed with Leonardo-SDI.

5.2 Planning

General requirements

The requirements set out in the document PQA004-L (paragraph 7.2) shall apply.

Specific requirements

The supplier shall provide the following documents in accordance with Appendix B:

- Within 30 calendar days from acceptance of the PO, and anyway before the start of activities: Quality Plan, Time Schedule of Activities (GANTT) and Risk Management Plan, to be submitted for approval;

- As part of the Preliminary Design Review, or anyway within 60 calendar days from acceptance of the PO: Design and Development Plan and Configuration Management Plan to be submitted for approval.

Plans and schedules shall cover all project phases and provide, at the end of each phase, appropriate milestones to verify design and development outputs and authorize formal transition to the next project phase.

The requirements for drawing up the Plans are defined in document PQA004-L.

5.3 Outputs of design and development

The supplier shall document the results of the design and development activities and submit them to Leonardo-SDI for approval.

The documents produced shall:

a) Specify the product requirements (if required) and provide evidence that they are met;
b) Define the physical and functional characteristics of the product, including critical elements and key characteristics as applicable;
c) Ensure producibility, testability and the feasibility of purchasing the product;
d) Define the acceptance criteria and procedures for the supply.

The documents shall be subject to Configuration Management and shall demonstrate the supplier's internal approval.

Unless otherwise specified in the PO, the list of documents required from the supplier is given in Appendix B.

The contents of the documents shall comply with the guidance given in PQA004-L (Appendix C).

Further requirements relating to the documentation may be communicated to the supplier through the PO.

5.4 Prototype production

Based on the outputs of the Design phase, the supplier shall produce a prototype, that will be used to test the technical solutions applied, and, subsequently, to perform the formal verification and validation activities.

The output of this phase is the prototype itself, the applied Manufacturing and Control Plan and the documented collection of the results of the tests carried out.

If special processes have been used in the production of the prototype, the applicable certifications and/or documents shall be made available.

The supplier shall also document any precautions to be taken for use of the prototype.

If any problem occurs while manufacturing the prototype, or the need to modify design documents already approved by Leonardo-SDI emerges, the supplier shall promptly inform Leonardo-SDI in order to agree on a solution in accordance with the contractual procedures.

It is the responsibility of the supplier to ensure the availability of suitable equipment, resources and personnel for the manufacture of the prototype, as well as adhering to the timescales set out in the contractual documents.

Unless explicitly defined in the PO, the supplier shall agree with Leonardo-SDI the methods for identifying the Part Numbers of the prototype and its components.

5.5 Design verification

The supplier shall submit the results of the Design and Development to verification to demonstrate that the design conforms to the specified requirements.

For this purpose, the supplier shall prepare and have approved by Leonardo-SDI a Plan for the performance of the Qualification activities (functional, environmental, etc.), which ensures that all of the requirements are covered and identifies the verification method for each requirement (Analysis, Demonstration, Visual Inspection and Testing).

The supplier shall also define, document and have approved by Leonardo-SDI the procedures for carrying out the planned tests.

The results of the tests carried out on the prototype shall be recorded, together with any corrective actions that may result. Test results shall be traceable against the requirements specified for the product.

If necessary, the supplier shall update the design documentation and/or the Manufacturing and Control Plan in accordance with the indications arising from the verification activities.

5.6 Design validation

The product resulting from the Design and Development (the prototype) shall be validated by Leonardo-SDI and/or its customer to ensure that it is able to meet the requirements of the intended use or specified application.

The supplier is required to provide the necessary technical assistance and support during the validation activities, in accordance with the provisions of the supply specification and the PO.

If necessary, the supplier shall update the design documentation according to the results of the validation.

Validation may also include Type Approval activities.

5.7 Control of changes to the design

The supplier shall record and monitor all design changes throughout the product lifecycle in accordance with the Configuration Management requirements applicable to the project.

Changes shall be reviewed and approved by the supplier prior to implementation, documented, verified and subjected to non-regression tests and additionally validated if necessary.

Major changes, which concern aspects relating to the interchangeability[1] of the product, shall be approved by Leonardo-SDI before they are incorporated into the configuration.

5.8 Control of design and development

The supplier shall organize the design and development according to successive stages, and carry out appropriate reviews (Design Review) to keep the planned activities and their results under control.

Depending on contractual agreements, Design Reviews may be internal (carried out independently by the supplier) or joint (carried out by the supplier in the presence of Leonardo-SDI and potentially its customer).

Design Reviews shall be included in the planning documents and, in the case of joint reviews, shall be called by the supplier at least fifteen days prior to the scheduled date, submitting at the same time the documents to be reviewed to Leonardo-SDI.

All documents submitted for review shall be previously approved by the supplier and placed under configuration management.

The result of Design Reviews shall be recorded by the supplier, together with any actions considered necessary for it to be passed.

[1] These are the changes that have an impact on at least one of the Form, Fit and Function of the product.

If the result is negative, a Design Review can be considered “Not Passed” (and therefore shall be repeated after completion of necessary actions) or "Passed under Reserve" (in this case the reserve will be removed at completion of corrective actions with no need to repeat the review).

Joint design reviews need to be approved by Leonardo-SDI.

As part of the TRR and FQR Design Reviews, the supplier shall also conduct functional configuration (FCA) and physical configuration (PCA) audits.

Unless otherwise provided for in the PO, the supplier shall conduct as a minimum the design reviews indicated in Appendix C.

If deemed necessary, Leonardo-SDI reserves the right to request further Design Reviews in addition to those planned.

6 DOCUMENTATION

General requirements

The general requirements set out in the document PQA004-L (paragraph 6.2) shall apply.

Specific requirements

The list of documents required from the supplier is defined in Appendix B. Any further details or different requirements will be transmitted to the supplier through the PO.

If not explicitly defined in the PO, the supplier shall agree with Leonardo-SDI the methods for identifying the documents (revision codes and indexes) and the forms to be used for drawing them up.

All documents submitted for review or presented as delivery items shall be formally approved by the supplier prior to delivery to Leonardo-SDI.

Any changes made by the supplier to documents already approved by Leonardo-SDI require the approval of Leonardo-SDI.

The delivery documentation shall be delivered to Leonardo-SDI accompanied by a Cover Letter containing the following information as a minimum:

- Reference to the PO number,
- Delivery date,
- List of documents delivered,

7 INDUSTRIAL CONFIDENTIALITY

The supplier shall respect the industrial confidentiality restrictions specified in the PO.

8 RIGHT OF ACCESS AND SUPPORT FOR QUALITY ASSURANCE ACTIVITIES

The requirements set out in the document PQA004-L (paragraph 8) shall apply.

9 ACCEPTANCE OF THE SUPPLY

General requirements

The requirements set out in the document PQA004-L (paragraph 7.8) shall apply.

Specific requirements

Unless otherwise agreed, the acceptance activities shall include the successful completion of a final Design Review for the project (FQR or another specifically planned review) to be carried out in the presence of Leonardo-SDI personnel and if necessary its customer.

The review shall be carried out in accordance with the indications in paragraph 0.

Design and Development supplies are considered complete only if all of the required documentation has been delivered by the supplier and accepted by Leonardo-SDI.

10 MANAGEMENT OF SUB-TIERS

It is prohibited to subcontract in full Design and Development activities.

Any partial sub-tier supply of Design and Development shall be authorized in advance by Leonardo-SDI and declared by the supplier in the Quality Plan; in this case the requirements set out in the document PQA004-L (paragraph 7.4) shall apply.

11 CONFIGURATION MANAGEMENT

General requirements

The requirements set out in the document PQA004-L (paragraph 7.7) shall apply.

Specific requirements

- For NATO supplies, the supplier shall produce and submit to Leonardo-SDI for approval a Configuration Management Plan in accordance with the requirements of AQAP 2110 (EN 9100 for Aerospace supplies), as indicated in Appendix B.

- In correspondence with the planned Design Reviews, the supplier shall document the Configuration Status of the design/product and submit it to Leonardo-SDI for approval.

- If not explicitly defined in the PO, the supplier shall agree with Leonardo-SDI:
  - the procedures for identifying the Part Numbers, documents and related revision indexes;
  - the methods for physically identifying the items;
  - how the proposed changes are to be classified and the criteria for assessing their impact on the change in P/N when they affect interchangeability;
  - the strategy for the logistic structure of the product and the list of Configuration Items;
  - the configuration management methods for COTS components;
  - the obsolescence management strategies.

12 MANAGEMENT OF MATERIALS BELONGING TO LEONARDO-SDI

The requirements set out in the document PQA004-L (paragraph 7.11) shall apply.

APPENDIX A - Classification Index of Design and Development Supplies

The following table defines the possible values of the Classification Index (CI) for supplies of Design and Development, with the respective characteristics required of the product.

CI	Characteristics of the Supply
1	HIGH COMPLEXITY Development of complex systems that are able to: • Meet specific operating needs and are therefore defined by a specification of requirements; • Are made up of different interdisciplinary components that interact in a very complex way and it is considered necessary to have an architectural design structured on multiple levels (assemblies, sub-assemblies, etc.); • The development involves a certain level of risk (use of advanced technologies, system integration, etc.) which therefore requires a robust planning and control system for the activities.
2	MEDIUM COMPLEXITY Development of moderately complex systems that: • Meet specific functional or operational needs expressed in a requirements specification defined during the design of a higher level system; • Can be characterised by a prevailing discipline (mechanical, electronic, hydraulic, etc.) or require several disciplines simultaneously for the development; • Consist of different components that interact with each other in a moderately complex way so that a single level of architectural design is considered sufficient; • The level of risk inherent in the development of the project is limited.
3	LOW COMPLEXITY Design of single-discipline parts/components, possibly characterised by a very simple architecture, the development of which does not present risks.

Table 1 - Values of the Classification Index

APPENDIX B - Documentation required from the supplier

The following table summarises the activities and documents required from the supplier according to the classification index (CI) of the supply. The table defines a standard that may be overwritten by any information contained in the PO and/or by other special conditions described in this document.

Activity	Documents	CI 1	CI 2	CI 3
Review of Supply Requirements	Minutes/Report of Input Requirements Review	X	X	
Planning	Quality Plan	X	X	
	Activity Planning (GANTT)	X	X	X
	Design and Development Plan	(1)		
	Configuration Management Plan	X	(2)	
	Risk Management Plan	X	X	
Definition of product requirements (if required) and development of the project - Definition Dossier	System Subsystem Specification (SSS)	X		
	System Subsystem Design Description (SSDD)	X		
	Specifications of the System Interface Requirements (ICD/IRS)	X		
	Technical Specifications of Requirements (TS)	(3)	X	
	Interface Requirements Specifications (IRS)	(3)	X	
	Architectural Design Documents (HDD)	(3)	X	
	Project Technical Reports/Descriptions	X	X	
	Drawings, Parts Lists	X	X	X
	Safety Analysis Documentation	(4)		
	Logistic Support Analysis Documentation (see par. 5.1.2)	X	X	
Design Verification Definition Justification Dossier	Requirements Traceability Matrix	X	X	
	Technical Reports, Calculation Notes and other documents justifying the design choices	X	X	
	System Integration Plans, Procedures and Test Reports	X		
	Functional and environmental qualification plans	X	X	
	Functional and environmental qualification procedures and test reports	X	X	X
SW development	*Software documentation - (see PQA011-L)*	(5)	(5)	
Prototype Manufacture	Manufacturing and Control Plan and Procedures	X	X	
Project Control - Reviews/Audits	Design Review Minutes	X	X	
	FCA/PCA audit reports	X	X	
Testing/Acceptance	Test Procedure and Test Data Report (ATP/ATR)	X	X	(1)
	Test Certificate			X
	CoC (and any Waiver Requests)	X	X	X
	CE Declaration of Conformity/Technical File	(6)	(6)	(6)

Table 2 – Documentation vs. Classification Index of the supply

(1) If required in the PO
(2) May be part of the Quality Plan
(3) For Sub-assemblies
(4) If safety requirements have been defined
(5) If SW development is planned
(6) Required for Tools, Equipment, or other products subject to the safety requirements of one or more EU directives for CE marking. If the project is the Industrial Property of Leonardo-SDI, the supplier is required to deliver a Technical File for the project in accordance with applicable directives. If, otherwise, the supplier holds the Industrial Property of the project, the Technical File is not to be delivered but shall be still available for verification at the supplier's premises in accordance with the applicable directives.

APPENDIX C - List of possible Design Reviews

Re-examination of the Requirements - this is carried out before acceptance of the PO in order to ensure complete understanding of the requirements, resolving any shortcomings, misunderstandings and inaccuracies with Leonardo-SDI. The Functional Baseline is comprised of all of the requirement documents.

Preliminary Design Review (PDR) - this takes place at the end of the design phase to analyse the design solutions identified for the supply and to start the executive design phase. At this stage, checks are also made to identify the items configured with their associated interfaces. The documents to be presented during the Design Review are those relating to the architectural design.

Critical Design Review (CDR) - this concludes the executive design phase, to ensure that the project complies with the requirements and all the elements are in place to continue with the activities, including the possible construction of a prototype. Following the CDR, the documents of the Allocated Baseline (for Development) are approved.

Test Readiness Review (TRR) - takes place following the construction of the prototype to ensure that the product produced is ready for the required tests and that the environment and test procedures have been defined and are available.

Final Qualification Review (FQR) - this is performed on completion of qualification activities to verify that the project meets all requirements. The Design Review also ensures that definition documents are up to date, the test plans and procedures have been correctly applied and the tests have been completed and that the traceability of the requirements is properly documented.

Production Readiness Review (PRR) - may be required to verify that all preliminary manufacturing activities have been completed and that all necessary documentation is available. On conclusion of the PRR the Product Baseline is frozen.