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Supplier Quality Requirements for the procurement and installation of inlet filters (airlocks) for PRIMA building 1

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Abstract

This document accompanies the Technical Specification for the procurement of and installation of inlet filters (airlocks) for PRIMA building 1 , throughout the launch of the Call for Tender.

This document identifies the project and quality management requirements that the Supplier has to fulfill during the whole supply.

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Terms and Definitions

Term	Definition
MITICA	Megavolt ITer Injector & Concept Advancement.
PRIMA	The overall Neutral Beam test facility hosting the MITICA and SPIDER experiments. Padova Research on Injector Megavolt Accelerated.
Consorzio RFX	Consorzio RFX is a Research Organization promoted by CNR, ENEA, Università di Padova, Acciaierie Venete S.p.A. and INFN.
Site	The location where the system or equipment object of these technical specifications will be installed. The Site considered in this document is the PRIMA Site in Padova (Italy)
Supplier	The successful Bidder (Tenderer or Applicant) is referred in the document as the “Supplier”.
Technical Specification	The Technical Specification of the inlet filters (airlocks) for PRIMA building 1.

Acronyms

ADP	Acceptance Data Package
WBS	Work Breakdown Structure
WP	Work Package

1. Introduction

This management specification applies to the procurement and installation of inlet filters (airlocks) for PRIMA building 1.

The Supplier shall fulfill the requirements specified in this document.

The goal of this specification is to ensure the quality of the supply and a good project and quality management of all the activities involved in the development and realization of the products.

2. General Requirements

GE-010	The requirements in this document shall be fulfilled by the project organization of the Supplier and constitute an integral part of the contract.
GE-020	The Supplier shall have in place a Quality Management System that fulfils all the applicable requirements of ISO 9001 (latest edition) and shall use its Quality Management System to provide the supply (the specified products and services). The certification of Supplier's Quality Management System by a recognized Certification Body is highly recommended.

3. Quality Planning

QP-030	With the offer, the Bidder shall provide a preliminary version of the control plan (with the verifications, validations and reviews to ensure the quality of the supply), preliminary time schedule (with scheduling of activities, milestones and main deliverables) and a preliminary risk / opportunity management plan. Consorzio RFX will consider these preliminary documents for the evaluation of the offer.
QP-040	At the very beginning of its works the Supplier shall review and obtain Consorzio RFX approval on its Control Plan and Time Schedule.

4. Responsibilities

RE-010	The Supplier shall: - identify a person in its organization which is responsible for the Contract, the Supplier Contract Manager; this person shall be the main interface with Consorzio RFX; - identify a person in its organization which is responsible for the project management of the Contract, the Supplier Project Manager, which may be the same as the Supplier Contract Manager; - identify a person in its organization responsible for the quality of the supply i.e. of the deliverables to Consorzio RFX, the Supplier Quality Representative; this person shall report to the Supplier's top management and shall be independent of the Supplier Contract Manager and of the Supplier Project Manager; the Supplier Quality Representative supports the Supplier Contract Manager and the Supplier Project Manager by giving advice and facilitating the processes where needed.

5. Planning of Activities

PA-010	The Supplier shall use a time schedule to:

	- identify the interim and final deliverables (e.g. design documents, reports, records, products, handbooks, services); - identify the project milestones and the work breakdown structure; - plan all the activities and processes needed to satisfy the contract and obtain the deliverables and their quality; this includes for example: design activities, design verifications and validations, design reviews, procurements, process validations, product verifications and others; - communicate the objectives of the project to its interested parties; - launch the planned activities when needed; - monitor the progress of the activities.
PA-020	The Supplier shall identify all the resources needed to perform the activities related to the supply, including the personnel, their responsibilities and competence.

6. Progress Monitoring and Communication

MC-010	At least each month the Supplier shall monitor the project progress, evaluating the project status. When needed the Supplier shall update the time schedule.
MC-020	The Supplier shall plan the meetings between the Supplier and Consorzio RFX in the time schedule; at least the following meetings are required: - kick off meeting, at least for the review of the control plan, the time schedule and the risk (and opportunity) management plan; - design review meetings; - coordination meetings as needed for the progress of the procurement - closure meeting at the completion of the activities and release of all the deliverables.

7. Document Management

DM-010	The documents that represent contract deliverables (e.g. reports of analyses, tests, drawings, etc.) shall be written in English language, except for documentation foreseen by Italian Law.
DM-020	The documentation which is part of a final or interim deliverable shall be internally reviewed and approved by the Supplier and then sent to Consorzio RFX for review and approval.

8. Requirements Management

RM-040	The supplier shall obtain Consorzio RFX approval on any change in the requirements listed in the Technical Specification.

9. Risks and Opportunities Management

RO-010	The Supplier shall manage the risks and opportunities related to the supply by means of a risk and opportunity management plan (see the section about the forms). NOTE: Often this plan includes: identification of meaningful risks and opportunities; their prioritization; risk mitigation actions and preventive actions; action verification and validation.
RO-020	The following steps shall be followed: - identification of the risks, their root causes and effects on the final user; - identification of the opportunities, with positive effects on the interested parties; - estimation of the impact of the main effects and the probability of each cause; - prioritization of risks and opportunities and identification of a risk threshold under which no preventive or mitigation action is needed; - planning of preventive and mitigation actions or actions to seize the opportunities; - execution of the planned actions recording the results of the actions taken; - review the effectiveness of the actions taken.
RO-030	When a nonconformity occurs, the Supplier shall update the risk and opportunity management plan

10. Design and Development

DD-010	The Supplier shall meet the requirements of ISO 9001:2015 8.3 - Design and development of products and services; in particular: - about design and development planning, the time schedule shall be used to identify the timing of the design stages; - about design and development verifications, validations and reviews, they shall be planned and recorded in the Supplier control plan; the design reviews shall also be recorded in the minutes of the review meeting; - about design and development changes, the Supplier shall ensure their identification, review and control, also by means of an analysis of their impact, by ensuring the Consorzio RFX authorization of the change, where required and by the update of the documents involved in the change (e.g. drawings,

	process documentation, control plan, risk and opportunity management plan, etc.).
DD-020	The Supplier shall plan the design verifications and validations taking into account the requirements, the possible failure modes of the products and the effects, or consequences, of these failures. FMEA, or equivalent risk analysis, is required at all the meaningful levels of the product breakdown structure to identify the needed design verifications and validations.
DD-030	The Supplier shall ensure the participation of Consorzio RFX to its design reviews; Consorzio RFX experts, customers, partners, shall be allowed by the Supplier to participate in the design reviews.

11. Procurements

PR-020	The Supplier shall ensure the quality of externally provided products and services also by means of: - an analysis of the risks related to these products and services; - mitigation actions such as planned verifications on the products.
PR-070	The Supplier shall verify the purchased products according to the applicable requirements, the Supplier control plan, the applicable procedures and in agreement with the requirements in ISO 9001:2015 8.4.
PR-080	The Supplier shall plan in the control plan the verifications on the purchased products taking into account the risks related to the purchase.

12. Production and Manufacturing

MA-010	During the entire development of the contract, the Supplier shall meet the requirements of ISO 9001:2015 – 8.5 (Production and service provision).
MA-040	Validation of the processes, where applicable, shall be planned and recorded in the control plan.

13. Identification and Traceability

IT-010	ISO 9001 requirements (only) apply, there are no other requirements on identification and traceability.

14. Customer Property

CU-010	ISO 9001 requirements (only) apply, there are no other requirements on customer property.

15. Preservation of products

SE-010	Product preservation includes handling, packaging, storage and protection means, assuring appropriate handling of the product to prevent damages and mix-ups. The Supplier shall design and implement the means used for the preservation of product, managing these means as an integral part of the product.

16. Measuring equipment

ME-010	The Supplier shall meet the requirements in ISO 9001:2015 7.1.5 at least on the measuring equipment used for the specific case.
ME-015	The Supplier shall ensure that test equipment used to provide evidence of compliance to a requirement is calibrated.
ME-020	In the measurement reports the Supplier shall record the identification code of the measuring equipment used, its calibration status and its range and resolution.

17. Acceptance data package

DP-010	The Supplier shall provide the requested contractual documents and the requested deliverables as specified in the Technical Specification.
DP-020	The Supplier shall deliver each deliverable together with the relevant Acceptance Data Package (ADP); unless otherwise agreed the ADP consists of: - Manufacturing Design Report - As Built Drawings - Updated “On Site Assembly Plan” - Updated “On Site Acceptance Test Plan” - Test Procedures and Test Reports (e.g. On Site Acceptance Test Report) - Materials/Components certifications where required - Handling and Transportation documents - Nonconformities and Concessions related to the deliverable - Change and Deviation Requests and Approved Changes and Deviations - Updated Control Plan of processes and products involved in the delivery - Updated Risk Management Plan - Updated Time Schedule - Open issues

	- Minutes of the meetings - Use and maintenance manuals - Spare parts list - CE certification - Release Note Where editable versions of the above documentation exist (text documents, spreadsheets, drawings, etc) also editable versions will be provided in the Acceptance Data Package.

18. Delivery

DE-010	All the deliverables shall be reviewed and approved by Consorzio RFX.

19. Configuration Management

CM-010	The supplier shall manage the product and process configuration. The Supplier shall manage the changes in the requirements, in the design, in the product and in the process: - by identifying the change and its reasons; - by obtaining the Consorzio RFX approval for each change that could affect contractual aspects or the quality of the product. A specific form (change/deviation request) is available at Consorzio RFX for change management (see the section about the forms).

20. Control Plan

CP-010	The Supplier shall use the Control Plan to plan and record the controls used for its main processes involved in the supply, such as: - the design process; - the procurement process; - the manufacturing process. See the section about the forms. NOTE: Typical content of the control plan includes: requirements reviews, design verifications, design reviews, design validations, manufacturing process controls (process validation, product verifications), purchased product verifications.
CP-020	The control plan shall use the results of the risk analysis. In general the verifications, validations, reviews planned in the control plan shall be considered as actions to mitigate some risk.

	The updates of the risk management plan shall be reviewed by the Supplier as starting point for possible updates of the control plan.
CP-030	The Control Plan shall be reviewed and updated according to the changes on products, processes, measurements, logistics, and supply sources.
CP-040	The Control Plan shall be used by the Supplier to record the results of the controls, verifications, tests, inspections, validations. The Supplier shall ensure that his personnel know and use the Control Plan, operating according to what is planned. The Control Plan can refer to other documents, e.g. a test report or a standard to be used in a verification.
CP-050	The Control Plan and its changes shall be approved by Consorzio RFX before their use. Consorzio RFX accepts products and services only with the evidence that they come from processes controlled by an approved Control Plan.

21. Access Rights

AR-010	The Supplier shall allow Consorzio RFX access to the Supplier premises, facilities, personnel, subcontractors and documentation for business purposes such as quality audits, witness to verifications and validations planned in the control plan, help in solving quality issues, participation to design reviews, etc. In case of quality audits Consorzio RFX gives the Supplier at least 1 week's notice.

22. Audits

AU-010	Consorzio RFX guarantees that the information collected during the audit (photos included) remains confidential.
AU-020	The Supplier shall prepare a correction and corrective action plan based on the audit findings and reports. The correction and corrective action plan shall specify: - the nonconformity or improvement opportunity - the causes of the nonconformity - the person responsible for the actions - the target date for the closure of the actions - the actions to remove the nonconformity or to reduce its effects - the actions to remove the causes of the nonconformity or to improve - the validation of the actions results in terms of removal of the causes of the nonconformities

	- the actual date for the closure of the actions - the status of the nonconformity or improvement opportunity (open or closed)
AU-030	The Supplier management, responsible for the audited area, shall ensure that any necessary corrections and corrective actions are taken without undue delay to eliminate detected nonconformities and their causes.

23. Nonconformity Management

NC-010	The Supplier shall meet the requirements in ISO 9001:2015 8.7 - Control of nonconforming outputs and 10.2 - Nonconformity and corrective action. In particular the Supplier shall "update risks and opportunities determined during planning".
NC-020	The Supplier shall record the product and process nonconformities, and the information useful for the research and identification of the causes of the nonconformities. The process owners shall receive these records. These records shall be made available to Consorzio RFX on request and in the course of the audits.
NC-030	The nonconformities that have effects on contractual, technical, management requirements shall be reported to Consorzio RFX together with proposals of how to solve the problems resulting from the nonconformity or together with a concession request, using the "Non Conformity Report" form; the management of the corrective actions to avoid the problem recurrence, and/or to avoid similar problems, is integral part of this procedure, as indicated in the Nonconformity Report form (see the section about the forms).
NC-040	Reworks and repairs shall be executed according to previously defined documented procedures or instructions that specify tests, inspections, verifications to be performed to ensure the quality of the product. These procedures or instructions shall be prepared by the Supplier and approved by Consorzio RFX before their execution.
NC-050	The original requirements of the (conforming) product apply also to the reworked product; instead for the repaired product the original requirements could be not applicable, and in this case other requirements will be defined by Consorzio RFX or proposed by the Supplier and accepted by Consorzio RFX.

24. Forms

FO-010	The Supplier shall use Consorzio RFX forms or its own forms, provided that they contain at least the same information.
FO-020	The Consorzio RFX's forms are listed below and provided as attachments in this document: - Risk & Opportunit Management Plan

	- Control Plan - Change / Deviation Request - Nonconformity Report - Release Note (certificate of conformity)

- End of the Document -