CONSORZIO RFX Ricerca Formazione Innovazione — FUSION FOR ENERGY	**Page:** 1/16
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Supplier Quality Requirements for the procurement of the MITICA Cryopump Assembly Tool

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Abstract

This document accompanies the Technical Specification for the procurement of MITICA Cryopump Assembly Tool, 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 development and the realization of the Tool.

Table of contents

Terms and Definitions

Term	Definition
MITICA	Megavolt ITer Injector & Concept Advancement.
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 MITICA Cryopump Assembly Tool.

Acronyms

ADP	Acceptance Data Package
WBS	Work Breakdown Structure
WP	Work Package
WPM	Work Package Manager

1. Introduction

This management specification applies to the Supply of the Assembly Tool that will be used to install two large Cryopumps inside the Vacuum Vessel of MITICA experiment.

The Supplier of the MITICA Cryopump Assembly Tool 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 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-010	For the scope of this supply, the Supplier shall define and implement a Quality Plan; ISO 9000:2015 definition of quality plan apply. NOTE: Often the quality plan includes procedures, processes and resources applied by the Supplier to meet the requirements of the product / service.
QP-020	The Quality Plan shall define how the Supplier meets all the quality requirements of this document and the requirements of the subject of the supply. NOTE: the use of a Quality Plan is intended to sustain a project management approach to ensure the quality of the supply, minimizing the probability of failures and delays by means of the use of good practices in quality and project management; the project management approach is encouraged as the Supplier has to perform unique activities such as design and development of new products or validation of new processes.
QP-030	A preliminary version of the Quality Plan shall be provided by the Supplier with the offer, together with a preliminary 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. These preliminary documents shall be considered by Consorzio RFX for the evaluation of the offer.
QP-040	The Quality Plan is part of the contract between the Supplier and Consorzio RFX. At the very beginning of its works the Supplier shall review and obtain Consorzio RFX approval on its Quality Plan and its Control Plan. During the execution of the contract, the Supplier shall keep the Quality Plan and the related documents (see requirements QP-030 and MC-040) continuously up-to-date; the approval of Consorzio RFX is required at each update for the Supplier Quality Plan and the Supplier Control Plan.

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 from the Supplier Contract Manager and from 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.
RE-020	The supplier shall make available to Consorzio RFX the Curriculum Vitae of the personnel with responsibilities in project and quality management.
RE-030	The Supplier shall determine the project organization in charge of the supply and document it in its Quality Plan, by means of: - a project organization chart with names of the involved persons and their roles; - a description of each role and related responsibilities.

5. Planning of Activities

PA-010	The Supplier shall use a time schedule to: - identify the interim and final deliverables (e.g. quality plan, design documents, reports, records, products, handbooks, services); - identify the project milestones and the work breakdown structure; - identify a responsible manager for each work package or each element of 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; - record and 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.

	The Supplier shall ensure the resources needed for the activities related to the supply providing evidence to Consorzio RFX of the availability of these resources.

6. Progress Monitoring and Communication

MC-010	At least each month the Supplier shall monitor and measure 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 implementation of the quality plan during the project; - progress meetings with a frequency according to Consorzio RFX needs, on a monthly basis if not agreed otherwise; - design review meetings; - closure meeting at the completion of the activities and release of all the deliverables.
MC-030	If not otherwise agreed, the Supplier shall propose an agenda of each meeting. Each meeting agenda shall be agreed between the Supplier and Consorzio RFX in advance so that the meeting can be prepared by both parties. If not otherwise agreed, the minutes of the meetings are prepared by the Supplier and submitted to the meeting participants for acceptance.
MC-040	During the progress meetings the following points shall be addressed by the Supplier: 1. updated time schedule with progress of activities, including subcontracting, and forthcoming work schedule 2. updated risk / opportunity management plan with status of mitigation actions 3. updated control plan with status of verifications, reviews, etc. 4. updates in the subcontracting schedule 5. identification and description of issues encountered during the latest time period 6. status of deviations and nonconformities 7. status of pending actions The outcomes of the discussion on these points shall be documented in the minutes of the meeting.

7. Document Management

DM-010	The documents that represent contract deliverables (e.g. reports of analyses, tests, drawings, progress reports, 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.
DM-030	The documents issued by the Supplier for the contract, shall be listed in a Documentation Schedule, continuously updated. NOTE: the documentation schedule is a complete list of documents issued by the Supplier in the course of the contract.
DM-040	The Supplier shall keep the documents issued for the contract at least for 10 years after the final balance of the contract price.

8. Requirements Management

RM-010	The supplier shall identify, develop and document the requirements to be met for the specific case.
RM-020	The supplier shall take into consideration also the interface requirements.
RM-030	The supplier shall manage the documents containing requirements as (interim) deliverables and obtain Consorzio RFX approval on these documents.
RM-040	The supplier shall obtain Consorzio RFX approval on any change in the agreed requirements.

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
RO-040	The Supplier shall review the risk and opportunity management plan actions at least at each progress meeting

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.
DD-040	The numerical models (e.g. analysis code) used by the Supplier to perform design verifications (e.g. analyses) shall be validated and the validation process shall be approved by Consorzio RFX in the Supplier Control Plan.
DD-055	The Supplier shall submit to Consorzio RFX for acceptance a Manufacturing Plan for the operations of manufacturing, assembly, integration and inspection, including: - sequence of operations - associated inspections and tests - execution methods for all critical activities (procedures, work instructions, etc.)

	- site/premises where the activities are performed - equipment to be used - resources to be employed - site mobilization plan (if applicable)

11. Procurements

PR-010	The Supplier shall document the requirements for its procurements and ensure they are properly transmitted to its sub-suppliers.
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-030	The Supplier shall transfer to his subcontractors all the applicable requirements of this document.
PR-040	The Supplier shall select its sub-suppliers and subcontractors by evaluating their ability to supply products in accordance with the identified requirements.
PR-050	The Supplier shall explain in its quality plan: - how the Suppliers meets ISO 9001:2015 - 8.4 requirements (Control of externally provided processes, products, and services) and - which are the records of the results of evaluations and actions that can be made available to Consorzio RFX on request.
PR-060	The Supplier shall identify major or critical subcontractor in a subcontracting schedule (see the section about the forms). The Supplier shall keep its subcontracting schedule continuously updated and approved by Consorzio RFX.
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.
PR-090	When applicable, the Supplier can accept the purchased products only with the proper certificate of conformity. With reference to Italian Law and relevant standards, in case of incompleteness of the certificates accompanying purchased components or materials, it is the Supplier's responsibility to execute all the necessary tests for product qualification.

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-015	The Supplier can proceed in the Manufacturing, according to the Manufacturing Plan (req. DD-055), only after Consorzio RFX acceptance of this plan. The acceptance shall be managed in the Supplier Control Plan as an Hold Point.
MA-020	For each production process the supplier shall make available to Consorzio RFX a process flow chart (or similar document) detailing all the production process steps. NOTE: this requirements applies only if the manufacturing plan of req. DD-055 and MA-015 does not provide the above mentioned information or if the manufacturing plan does not exist.
MA-030	The Supplier shall meet the requirements on specific manufacturing processes, tests and delivery reported in the Technical Specification, ensuring: - the availability of work instructions; - the use of suitable equipment; - the availability and use of monitoring and measuring equipment; - the implementation of product release and delivery activities.
MA-035	The Supplier shall ensure that no testing activity starts before Consorzio RFX acceptance of the related test procedure.
MA-040	Validation of the processes, where applicable, shall be planned and recorded in the control plan.
MA-050	If applicable, the Supplier shall initiate a specified reaction plan when the process becomes unstable or not statistically capable.
MA-060	The Supplier shall: - review and control changes for production as per ISO 9001:2015 8.5.6 (Control of Changes); - obtain a new process validation in case of changes in validated processes; - retain documented information describing the results of the review of changes, the person(s) authorizing the change, and any necessary actions arising from the review. The Supplier shall manage any change in the validated process as specified in the Configuration Management section.

13. Identification and Traceability

IT-010	The Supplier shall fulfil the requirements about Identification and traceability stated in this document and in the Technical Specification.

IT-020	The Supplier shall identify the products at its premises, during shipment and delivery. The Supplier shall ensure identification and traceability of the engineering changes, at least for configuration management purposes. Material traceability requirements shall be fulfilled as prescribed in the Technical Specification.

14. Customer Property

CU-010	The Supplier shall identify, verify and protect the property that belongs to Consorzio RFX or its customer, according to ISO 9001 requirements (ISO 9001:2015 8.5.3). This applies to the intellectual property too.

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. Further requirements are in the Technical Specification.

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. Further requirements are in the Technical Specification.
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: - Documentation Schedule

	- Final Design Report - Test Procedures and Reports - Materials/Components certifications where required - Handling and Transportation documents - Component traceability - Nonconformities and Concessions related to the deliverable - Change and Deviation Requests and Approved Changes and Deviations - Control Plan of processes and products involved in the delivery - Updated Quality Plan, Risk Management Plan, Time Schedule - Open issues - Minutes of the meetings - 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 FMEA(s) and/or 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 and of the FMEA 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 forms to be used are: - Progress Report - Documentation Schedule - Risk & Opportunit Management Plan - FMEA - Control Plan - Subcontracting Schedule - Change / Deviation Request - Nonconformity Report - Release Note (certificate of conformity) On Supplier request Consorzio RFX can provide examples and templates of the above mentioned forms.

- End of the Document -