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Reference Management Specification for the contract for the detail design, manufacturing and test of the Magnetic Energy Storage and transfer System

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1. Purpose

This document specifies the quality and management requirements *for this procurement* for Consorzio RFX.
The goal is to ensure the quality of the supply while minimizing the probability of failures and delays by means of the use of good practices in quality and project management.

2. Objectives and deliverables of the contract

If not already defined in other bid or contractual documents, the Bidder/Supplier shall issue a table specifying per collection of items to be supplied:

- number and quantity;
- the level of subcontracting
- all the documents to deliver (ADP) , including the Release Note

The ADP, shall contain, but shall not necessarily be limited to, the following documents:

- The deliverable Quality Plan implementation documentation;
- The Release Note form(s);
- Related technical documentation (as-built, manuals)

2.1. Quality Plan requirements

The Supplier shall define and implement a Quality Plan (see ISO 9000:2015 for a definition of quality plan).The Quality Plan shall define how the Supplier meets the requirements of this document and the subject of the supply.
The Supplier with the offer shall provide a preliminary version of the Quality Plan, together with a preliminary "Time Schedule" (with scheduling of activities, milestones and main deliverables) and a preliminary "Risk & Opportunity Plan". These preliminary documents shall be considered by Consorzio RFX for the evaluation of the offer.
During the contract, the Supplier shall review the Quality Plan and obtain Consorzio RFX approval at the very beginning of the project and whenever needed in order to keep it up-to-date.

2.2. Quality Management System Requirements

The Supplier shall have in place a Quality Management System that fulfils all the applicable requirements of ISO 9001 (latest edition) and shall use the Quality Management System to provide the specified products and services.
The certification of Supplier's Quality Management System by a recognized Certification Body is not mandatory, although highly recommended.

3. Contract Organization

The Supplier shall:

- identify a person in his organization responsible for the Contract, the Supply **Contract Manager**; this person shall be the interface with Consorzio RFX;
- identify a person in his organization responsible for the project management of the Contract, the Supply **Project Manager**, which may be the same as the Contract Manager;
- identify a person in his organization responsible for the quality of the supplies or deliverables to Consorzio RFX (the Supply **Quality Representative**).

This person shall report to the Supplier top management and shall be independent from the Supply Contract Manager and from the Supply Project Manager; the Quality Representative supports the Contract Manager and the Project Manager by giving advice and facilitating the processes where needed.

4. Project Management

4.1. Project organization

The Supplier shall document in the Quality Plan the project organization by means of:

- a project organization chart (Organization Breakdown Structure) with names of the involved persons and their roles
- a description of each role and related responsibilities

4.2. Planning

The Supplier shall:

- identify the project milestones and the develop the Work Breakdown Structure
- identify the deliverables, interim and final (e.g. design documents, reports, quality plan, records, products, handbooks, services)
- develop a reference Time Schedule for the entire project and keeping it regularly updated
- plan all the activities and processes needed to satisfy the contract and obtain the deliverables and their quality; this includes for example design, verifications and validations, product and process inspections, measurements and others;
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4.3. Project Progress Control & Communication

At least each month the Supplier shall measure the project progress, evaluating the project status. Meetings between the Supplier and Consorzio RFX shall be planned in the Time Schedule; the following meetings are required:

- kick off meeting, for the implementation of the quality plan during the project
- progress meetings with a frequency according to Consorzio RFX needs (tentatively on a monthly basis)
- closure meeting at the completion of the activities and release of all the deliverables

RFX and Supplier shall agree which of previous meeting shall be “in person” or in videoconference

4.3.1. Kick off meeting items

It shall take into account that the activities shall commence with an official **kick-off meeting** where the following shall in particular be agreed upon:

- Confirmation of the specifications, specific requirements and contractual input;
- Detailed schedule of the contractual activities, including milestones;
- Frequency of Documentation Schedule and Control Plan review
- Contents of the ADP and Contract Final Report
- Frequency and location of the proposed progress meetings (if not agreed otherwise, at least once a month) (also by videoconference);
- The responsible for preparing the meeting minutes (unless agreed otherwise, minutes of the meetings shall be prepared by the supplier);
- Content and frequency of the progress report, (if not agreed otherwise, once a quarter)
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4.3.2. Progress meeting

Consorzio RFX will propose the agenda and the supplier prepare the minutes of the meetings and will submit them to RFX for acceptance. A different arrangement may be agreed upon at the kick off meeting

During the progress meeting, the following points shall be addressed by the Supplier:

- Updated Time Schedule: progress of activities, including any sub-contracting, and forthcoming work schedule
- Updated Risk & Opportunity Plan (status of preventive actions)
- Updated Control Plan
- Description of issues encountered during that period of time (if any)
- Status of deviations and non-conformities (if any)
- Status of generic actions

The outcomes of the previous points shall be documented in the minute of the meeting.

4.3.3. Closure meeting

At the end of the Contract, after delivery of all items, the Supplier shall issue a **Final Report** of the Contract.

The Final Report shall contain, but shall not necessarily be limited to, the following information:

- Final Contract schedule;
- Final Contract Quality Plan;
- ADP
- Final foreground IPR declaration (Background declaration form, as supplied in the contract documentation).
- Full photographic record of the manufacture

5. Manufacturing and Inspection Plan

The Supplier shall use the Manufacturing and Inspection Plan (Control Plan) to plan and record the controls used for the manufacturing process. Form provided by Consorzio RFX are available

The Manufacturing and Inspection Plan shall be reviewed and updated according to the changes on product, manufacturing process, measurements, logistics, and supply sources.

Consorzio RFX shall approve the Manufacturing and Inspection Plan and its changes before their use.

The Supplier shall ensure that his personnel know and use the Manufacturing and Inspection Plan, operating according to what is planned.

The Manufacturing and Inspection Plan shall be used to record the results of the controls, verifications, tests, inspections, validations. The Manufacturing and Inspection Plan can refer to other documents, e.g. a test report or a standard to be used in a verification.

Consorzio RFX shall accept products and services only with the evidence that they come from a Process controlled by an approved Manufacturing and Inspection Plan.

6. Resource Management

In this section, the Supplier shall provide a resources management system, or at minimum a description of the available resources, detailing where applicable:

- The number and type and field of competence of personnel involved in each of the Contract phases
- Specific training for personnel
- Specific qualification for particular operations (special processes and their control)

The Supplier shall provide proof that all workers are properly qualified

6.1. Special Processes Qualification

Qualification tests of manufacturing processes, if any, shall be included in the Manufacturing and Inspection Plan.
The provisions of this section shall be also applicable to the operator's qualification (welders, etc.) of this processes when so required by the corresponding standards.

6.2. Staff Qualification

In addition to the above, staff both the Supplier' staff and his Subcontractors who participate in quality related activities shall be appropriately qualified. Staff qualification shall be done according to applicable standards for each case.
In addition to the special processes, other activities such as tests, miscellaneous inspections, audits and NDTs need staff qualification.

7. CONFIGURATION MANAGEMENT

Efforts shall be planned and spent by the Supplier in order to implement suitable configuration management within the project.
The Supplier shall manage the changes in the product requirements with respect to Tender configuration, tracking all the required information about changes, such as, but not limiting to:

- rational for change request
- impact of the change request on other project constraints
- benefits or advantages coming from proposed change

7.1. Management of change and deviations

The Supplier shall use the form provided by Consorzio RFX for managing Deviation Requests.
Two scenarios shall be taken into account:

- Deviation Request coming from the Customer
- Deviation Request coming from the Supplier

The Supplier shall use the form provided by Consorzio RFX to manage deviations within this Contract.
The management of the configuration in both the aforementioned situations is described in the next sections

7.2. Deviation Request coming from the Customer: Deviation Notice

The following process shall be followed in case a modification to the reference requirements in Annex B is proposed by the Customer:

- STEP 1: The Customer fill in the form describing the original requirements affected by the requested deviation, the new modified or additional requirements, the justification for the deviation request and attaching necessary supporting documentation
- STEP 2: The Supplier fill in the form including an impact analysis, indicating impact on time schedule and costs, identifying potential risks linked to the requested deviation and attaching necessary supporting documentation
- STEP 3: the Customer fill in the form providing contractual decision (acceptance/rejection) about the proposed deviation, possibly, after negotiation with the Supplier, if necessary

- STEP 4: the Supplier fill in the form declaring agreement with the proposed contractual decision

7.3. Deviation Request coming from the Supplier: Supplier Deviation Request

The following process shall be followed in case a modification to the reference requirements in Annex B is proposed by the Supplier:

- STEP 1: the Supplier fill in the form describing the original requirements affected by the requested deviation, the modified requirements, the justification for the deviation request, the impact analysis and attaching necessary supporting documentation.
- STEP 2: the Customer, after internal evaluation, fill in the form providing contractual decision (acceptance/rejection) about the proposed deviation, possibly, after negotiation with the Supplier, if necessary

7.4. Non Conformity management

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.
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.
The nonconformities that cannot be corrected and that have effects on contractual, technical, management requirements shall be transmitted to Consorzio RFX, together with proposals of how to solve the problems resulting from the nonconformity and together with a concession request, by mean of 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.

- REWORKS

Reworks 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 (the requirements of the conforming product apply also to the reworked product).

- REPAIRS

Repairs shall be executed according to previously defined documented procedures or instructions with Consorzio RFX authorization; the requirements and the procedures to test, inspect, and verify the repaired product shall be preventively agreed upon with Consorzio RFX.

7.5. Configuration Management Records

8. The formats for the "Nonconformity Report", "Deviation Notice" and "Supplier Deviation Request" are provided by Consorzio RFX

The Supplier shall:

- sequentially number the Nonconformity Reports, Deviation Notices and Supplier Deviation Requests, and issued for the Contract
- maintain a Nonconformity Reports, Deviation Notices and Supplier Deviation Requests electronic register with indication of distribution and acceptance status

These documents and any relevant documentary evidence shall be included or referred to in the Acceptance data package handed over Consorzio RFX.

8. Information and Documentation Management

The documents shall be in English language, except for documentation foreseen by Italian Law.
The documentation, which is part of a final or interim deliverable, shall be internally reviewed approved by the Supplier, and then sent to Consorzio RFX for review and approval.
The documents shall be listed in a Documentation Schedule.
The documentation shall be kept at least for 10 years.

9. Subcontracting Management

9.1. Purchasing

The Supplier is responsible for the quality of sub-supplier
The Supplier shall ensure the quality of purchased products by means of planned controls.
The Supplier shall transfer to his subcontractors all the applicable requirements of this document and Supplier Quality Requirement [1]

9.2. Sub-supplier selection

The Supplier shall select his suppliers (subcontractors) by evaluating their ability to supply products in accordance with the identified requirements.
The Supplier shall explain in the quality plan:

- how he 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

The Supplier shall identify major or critical Subcontractor in a Subcontracting Schedule. Form provided by Consorzio RFX are available.

9.3. Verification of purchased product

The Supplier shall verify the product according to this specification, the supplier Control Plan, the applicable procedures of the supplier and in agreement with the requirements in ISO 9001:2015 8.4.
The Supplier shall plan in the Control Plan the verifications on the purchased products taking into account the risks related to the purchase.
The Supplier can accept the purchased products only with the proper certificate of conformity to applicable requirements.
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.

10. Design and development

For specific design activities to be developed by the Supplier, the Supplier shall meet the requirements of ISO 9001:2015 8.3 - Design and development of products and services with special attention to:

- Design and development planning (the time schedule should be used to identify the timing of the design stages and the control plan shall be used to determine the required design verifications, validations and reviews);
- Design and development verifications (to be planned and recorded in the control plan)
- Design and development review (to be planned in the control plan and recorded in the minutes of the review meeting)
- Design and development changes.

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/or validations.

10.1. Validation and Analysis Code

If and when required, the use of a specific analysis code shall be proposed to Consorzio RFX before the beginning of the analysis.
The analysis shall start only after agreement (release) from Consorzio RFX.

11. Production and Service Provision

During the entire development of the contract, the Supplier shall meet the requirements of ISO 9001:2015 – 8.5 (Production and service provision).
In addition, the Supplier shall meet the requirements on specific manufacturing processes, tests and delivery reported in this Technical Specification and concerning:

- 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.

If applicable, the Supplier shall initiate a specified reaction plan when the process becomes unstable or not statistically capable.

11.1. Process validation

Validation of the processes, where applicable, shall be planned and recorded in the control plan.
The supplier shall manage any change in the validated process as specified in the Configuration Management section

11.2. Identification and traceability

The supplier shall fulfil the requirements about Identification and traceability stated in the Technical Specification

11.3. Customer Property

The supplier shall identify, verify and protect the property that belongs to Consorzio RFX, according to ISO 9001 requirements.

11.4. Preservation of product

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.

11.5. Measuring and test equipment

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 could be in the Technical Specification.

12. Delivery and acceptance requirements

In this section, the Supplier shall indicate how, when and by whom delivery and acceptance will be controlled

It is under the responsibility of the Supplier to take any measure to ensure safety and protection of the quality of the product during packaging, transportation, delivery to Site and unloading, installation and test on Site if not otherwise specified
The Supplier shall prepare a "Delivery plan" for handling, storage, packing, shipping and delivery of components and sub-assemblies. The documents shall be submitted to Consorzio RFX for approval before release of delivery.

12.1. Packing and protection during transport

The Supply and its complementary parts shall be delivered to Consorzio RFX suitably packed to minimize the risk of damage and contamination. The Supplier shall propose the delivery specification for approval by Consorzio RFX.
Protection elements are to be compliant or designed and manufactured to protect the assemblies and all other components during transport and storage against weather effects and mechanical damage.

12.2. Delivery to site

It is the Supplier's responsibility to organize the delivery to Site.
The precise building location for delivery and installation, the name of the contact person on-Site and access formalities will be communicated in advance to the Supplier.
The Supplier shall inform in time Consorzio RFX of the approaching delivery. Communication of the oncoming delivery shall be given at least 10 working days before the occurrence of delivery.
The whole Supply for the MITICA experiment shall be delivered to the PRIMA Site at the following address:

Consorzio RFX
Area della Ricerca del CNR
Corso Stati Uniti, 4
I-35127 Padova
ITALY

12.3. Acceptance of the supply

At the delivery, the completeness of the Supply shall be demonstrated by the Supplier in the presence of Consorzio RFX.
The Supplier in the presence of Consorzio RFX, verify the general condition of components and/or subassemblies and to identify any possible damage occurred during transportation and handling shall carry out the visual inspection of all components.
The final acceptance of the supply shall be done after test on site if forecast.
The Supplier within the relevant deliverable shall record all the activities for the acceptance of the Supply, for instance measurements, alignment, verifications, etc.

13. Contract Risk and Opportunity management

The Supplier shall manage the risks and opportunities related to the supply by means of a Risk and Opportunity Plan Form provided by Consorzio RFX is available
The following steps are recommended as guidelines:

- identification of the risks, their root causes and effects on the final user;
- identification of 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.

When a nonconformity occurs, the Supplier shall update the risk and opportunity plan.
The Supplier shall review the Risk and Opportunity Plan actions at least at each progress meeting.

14. Health & Safety

In this section the Supplier shall demonstrate that he fulfils the health and safety regulations of the country(ies) where the activities will be developed as well as any specific health safety regulations laid down by the Organization(s) in charge of the facilities in which the Supply will be installed (PRIMA Organization for the Test facility in Padua, Italy

15. Codes (Regulatory Documents) and Standards

The Supplier shall draw up a document in which all the applicable Laws, Codes, Directives, Regulations are referenced, to be included in the "Final report".
It is the responsibility of the Supplier to comply with existing and applicable Regulations and Directives.

16. Inspection and Quality audits visits

The Supplier shall allow Consorzio RFX access to the Supplier premises, facilities, personnel, subcontractors and documentation for the purpose of quality audits, with 1 week notice.
Consorzio RFX guarantees that the information collected during the audit (photos included) remains confidential.
The supplier shall prepare a correction and corrective action plan based on the audit findings and reports.

17. Summary of Quality Requirements & Action

The following table gives an overview of the Consorzio RFX quality requirements specified in the applicable sections

1. **With the offer / proposal:**
- Submit to Consorzio RFX the meaningful outline of the 'Quality Plan'.
- Relevant 'Documentation Schedule' filled with all contractual documents linked to contractual deliverables
- Relevant Time Schedule

2. **After Contract signature:**
- Submit to Consorzio RFX the proposed 'Quality Plan' and 'Control Plan' and 'Documentation Schedule'
- Obtain from Consorzio RFX acceptance of the relevant 'Quality Plan'.

3. **Prior to design, manufacture, inspection and test:**
- Verify that the 'Control Plan' is up to date
  If changed from accepted, obtain Consorzio RFX acceptance of the updated Plan.

- Obtain Consorzio RFX acceptance of the relevant documents identified in the 'Documentation Schedule'.

4. **During design, manufacture, inspection and test:**

- Notify Consorzio RFX representatives of any pending Hold Point, Authorization-To Proceed Points or Notification Point of the Control Plan.

5. **Prior to acceptance or delivery:**

- Complete the relevant 'Supplier Release Note'.
- Obtain Consorzio RFX written release for dispatch.

6. **After delivery of a deliverable:**

- Complete the 'Acceptance Data Package'.
- Obtain Consorzio RFX 'Acceptance Note'.

7. **During Contract implementation:**

- Issue 'Supplier Deviation Requests' manage 'Deviation Requests' from the Customer and 'Nonconformity Reports' as necessary.

8. **Prior to Contract closing:**

- Issue Contract 'Final Report'

18. Forms

The Supplier shall use Consorzio RFX forms or its own forms,that shall be approved by RFX and shall contain at least the same information.
The forms to be used are:

- Control Plan
- Deviation Request
- Deviation Notice
- Documentation Schedule
- Subcontracting Schedule
- Release Note
- Risk & Opportunity Plan
- Non-conformity report
- Progress Report

Consorzio RFX can provide examples and templates for the above mentioned forms.

19. Quality Plan Outline

This appendix outlines the main items to be included by the Supplier in the Quality Plan. If a particular section is not applicable, the section still has to be outlined and the reason for the non applicability referenced

R1. OBJECTIVES AND DELIVERABLES OF THE CONTRACT
R2. RESPONSIBILITIES REQUIREMENTS
R3. PROJECT MANAGEMENT
R4. CONTROL PLAN
R5. RESOURCE MANAGEMENT
5.1. SPECIAL PROCESS QUALIFICATION
5.2. STAFF QUALIFICATION
R6. CONFIGURATION MANAGEMENT
R6.1. MANAGEMENT OF CHANGES AND DEVIATIONS

R6.2. NONCONFORMITY MANAGEMENT
R7. TIME SCHEDULE MANAGEMENT
R8. INFORMATION AND DOCUMENTATION MANAGEMENT
R9. SUBCONTRACTING MANAGEMENT
R10. ASSESSMENT AND VALIDATION MANAGEMENT
R10.1 MEASURING AND TEST EQUIPMENT
R10.2 VALIDATION OF ANALYSIS CODES
R11. ACCEPTANCE AND DELIVERY REQUIREMENTS
R12. RISK MANAGEMENT
R13. HEALTH AND SAFETY
R14. CODES (REGULATORY DOCUMENTS) AND STANDARDS
R15. [OTHER REQUIREMENTS]
[COMPLEMENT SUPPLIER SECTIONS]
A1. […]
TECHNICAL ANNEXES
T1. [ANNEX …]