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Project and Quality Management Specifications for the Procurement of the Power Supply System for the Divertor (DIV) In-Vessel Coils of the Divertor Tokamak Test (DTT) Facility

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Abstract	This document contains the Project and Quality Management Specifications for the Call for Tender for the Procurement of the DTT Divertor (DIV) coil power supply (PS) system.	

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1 Summary

Acronyms, abbreviations and definitions

Acronyms	Definitions
AC	Alternating Current
ADP	Acceptance Data Package
Alfresco	DMS environment presently used for the DTT project
BOD	Break-over diode
CCON	Central Control Online Network
CODAS	Control and Data Acquisition System
Contractor	Company or organization to which ENEA will entrust the Procurement covered in these Technical Specifications
CP	(Contractor) Control Plan
CPR	EU Construction Products Regulation No 305/2011
CRM	Current regulation mode
DC	Direct Current
DC-Link	Connection system between input and output converters, consisting of a bank of capacities
DEC	Direttore dell'Esecuzione del Contratto, as defined by Italian laws
DIV	Divertor, used to define coils close to DTT divertor
DMS	Document Management System
DTT	Divertor Tokamak Test facility
DTT site	ENEA Frascati Research Center, Via Enrico Fermi 45 – 00044 Frascati (RM), Italy
DTTU	Divertor Tokamak Test facility Upgrade
DUVRI	Documento Unico di Valutazione dei Rischi da Interferenze, as defined by Italian Legislative Decree 81/2008
EDG	Emergency diesel generator
EF	Error field
ELM	Edge-localized mode
EMC	Electromagnetic Compatibility
ENEA	Italian National Agency for New Technologies, Energy and Sustainable Economic Development
ESR	Equivalent series resistance
FAT	Factory acceptance test
FDR	First Design Report
HIL	Hardware-in-the-loop
HMI	Human Machine Interface
HSE, HSEQ	Health, Safety, Environment (and Quality)

ICN	In-vessel coil non-axisymmetric (same as NAS coil)
IEC	International Electrotechnical Commission
IP (code)	International Protection code (Standard IEC 60529)
KOM	Kick-Off Meeting
LCC	Local Control Cubicle
LSM	Local Segregation Mode
LF	Light fault
LSOHFR	Low Smoke, Zero Halogen, Fire Retardant
LTM	Long-Term Maintenance (state)
LV	Low voltage
MV	Medium voltage
NAS	Non-Axisymmetric
NTP	Network Time Protocol
OL	Ordinary Load, loads that require a normal auxiliary power supply
OPC-UA	Open Platform Communications Unified Architecture
PCB	Polychlorinated biphenyl
PCT	Polychlorinated terphenyl
PHIL	Power-hardware-in-the-loop
POS	Plasma Operation (state)
PLC	Programmable Logic Controller
PPE	Personal Protective Equipment
PQMS	Project and Quality Management Specifications
PS	Power supply
QP	(Contractor) Quality Plan
QR	Quality Representative
RSM	Remote Segregation Mode
RMS, rms	Root Mean Square
RUP	Responsabile Unico del Progetto, as defined by the Italian laws
SAT	Site acceptance test
STM	Short-Term Maintenance (state)
SCADA	Supervisory Control and Data Acquisition
Scarl, S. c. a r. l.	DTT S. c. a r. l., Limited liability consortium company (Società consortile a responsabilità limitata) which manages the DTT project
SF	Severe fault
Subcontractor	Company or organization to which the Contractor can entrust a specific part of the Procurement

Terna	The Italian TSO
THD	Total harmonic distortion
TRO	Technical Responsible Officer, person in charge of the contract for the Contractor
TS	Technical Specifications
TSO	Transmission System Operator
UPS	Uninterruptible Power Supply
VRM	Voltage regulation mode
VS	Vertical and radial stabilization
WBS	Work Breakdown Structure
WINCC-OA	WinCC Open Architecture

References

[1] "Technical Specifications for the Procurement of the Power Supply System for the Divertor (DIV) In-Vessel Coils of the Divertor Tokamak Test (DTT) Facility", DTT ID: PSS-SPT-59601.
[2] "DTT HSEQ Policy", DTT ID: PRG-HSEQ-002-DTT_A1, ver. 1.0.
[3] "HSE Requirements for Supplier and Contractor", DTT ID: SPG-HSE-001-DTT, ver. 1.0.
[4] "Document Coding & Item Numbering", DTT ID: QMS-PRO-20000, ver. 2.2.
[5] "Management of Documentation issued by Suppliers/Contractors", DTT ID: QMS-PRO-20004, ver. 1.0.
[6] ISO 9001:2015, "Quality Management System – Requirements".
[7] ISO 10005:2018, "Quality Management – Guidelines for quality plans".

1 Introduction

The goal of the Divertor Tokamak Test (DTT) project is the creation of an experimental research facility to investigate some of the most complex problems along the path to the exploitation of nuclear fusion as an energy source.

The DTT facility will be located inside the Research Center of the Italian National Agency for New Technologies, Energy and Sustainable Economic Development (ENEA) in Frascati, Italy, hereinafter abbreviated as DTT site.

Some technical details of DTT are reported in the Technical Specifications (TS) [1].

The DTT construction is managed by the DTT S. c. a r. l. (Consortium), denoted simply as “Scarl”, including ENEA and other prestigious members. However, the Procurement described in these specifications is managed by ENEA, under the project “Divertor Tokamak Test facility Upgrade (DTTU)”.

The Procurement described in these specifications will be assigned by ENEA in compliance with the present specifications to an entity (“Economic Operator”, according to the Italian law) denoted as “Contractor” in the following.

The present Project and Quality Management Specifications (PQMS) concerns the procurement of a power supply (PS) system to feed the currents in the 3 DTT divertor (DIV) in-vessel coils. The associated TS [1] defines the detailed technical requirements of the Procurement.

The present document defines the project and quality management specification that:

- A Bidder shall comply with during the pre-award phase.
- The Contractor shall comply with during the post-award phase.

During the contract execution, the quality management system of the Contractor and its subcontractors shall comply with the requirements defined in this document and in the associated TS. Such quality management system shall be described in a dedicated Quality Plan, specific for the Procurement and compliant with the requirements given in this document.

2 Ownership and responsibilities

2.1 ENEA responsibilities

ENEA is responsible for:

- Parameters, specifications and requirements reported in the TS and their compliance with the needs and documentation of DTT.
- Providing and updating (if any) the information for the manufacturing and the installation.
- Review and possible approval of the documentation issued by the Contractor.
- The approval of subcontractors and vendors selected by the Contractor, when such option is allowed by the documents of the call for tender, by the contract, and by Italian laws.
- The review and approval of the documentation issued by the Contractor within the contract.
- Monitoring the status of the Procurement through established meetings, inspections, visits, audits, videoconferences and reports.
- Witnessing prescribed and agreed tests.
- Installation and test of the components at the DTT site (probably through a different future Contract).
- Accepting the deliverables, if they comply with the TS, the PQMS, the contract, the call for tender rules, the applicable international standards, and the Italian laws.

2.2 Contractor responsibilities

For all goods covered by the Procurement Contract, the Contractor is responsible for the activities outlined in the TS [1]. Contractor responsibilities also include:

- Preparation, issue, update, and implementation of a specific Quality Plan (QP) for the Procurement with all relevant documents and activities.
- To ensure that any activity of subcontractors and vendors complies with the TS, the PQMS, and the QP.

In the QP, the Contractor shall identify the key roles for contract accomplishment and detail the breakdown of responsibilities. In particular, the Contractor shall provide the name and contact details of:

1. The Technical Responsible Officer (TRO) in charge of the contract who shall:
   - Coordinate the planning, performance, and control of the work, including the work assigned to subcontractors.
   - Keep the time schedule.
   - Prepare and issue the Progress Reports.
2. The Quality Representative (QR) for the contract who shall:
   - Be independent from the TRO.
   - Ensure that the QP, quality procedures, and detailed work instructions are observed during the execution of the contract in order to guarantee that all contractual quality requirements are met.
   - Assess and control the quality management of subcontractors.

ENEA shall be promptly informed of any change concerning the TRO or the QR.

2.3 Ownership

After the delivery of a given contract asset to the DTT site, the ownership of that asset will be transferred from the Contractor to ENEA. The ownership transfer does not relieve the Contractor from its obligations and responsibilities towards the contract and the warranty.

3 Procurement schedule and deliverables

The official Procurement schedule and main deliverables are summarized in Table 1. The Procurement schedule shall be compliant also with the Procurement Contract that is issued as scheme/draft in the Call for Tender. The Procurement Contract is split in phases.

The Contract documentation is addressed in Section 4.

Table 1. Summary of Procurement schedule with main milestones and deliverables.

Phase	Milestone/Deliverable	Maximum time from contract signature
1	Issue of First Design Report (FDR)	3 months
2	Completion of FATs of step-down transformer(s)	12 months
3	Procurement of the protection coils	15 months
4	Completion of manufacturing of converters	16 months
5	Completion of FATs on the whole PS system	17 months
6	Delivery of Procurement to DTT site	18 months
–	**Total duration of the Procurement**	**18 months**

4 Documentation

4.1 Summary of main Procurement documents

Procurement documentation shall include all documents listed in Table 2, also in compliance to the time schedule in the Procurement Contract. Table 2 is not exhaustive; for example, it does not include all legal and financial documents prescribed by the Call for Tender, the Contract, the Italian laws and the applicable European directives. Unless already defined in the TS or the present specification, the review lead times for documents requiring approval will be agreed at the KOM. Documents approved by ENEA will be an integral part of contract documentation.

Table 2. Summary of Procurement documentation to be issued with deadline/periodicity.

Document	Reference	Deadline/periodicity
Related to the Call for Tender procedure		
Technical Proposal including: Tender Design Report Tender Test Plan	Section 4.2.3 Section 4.2.4 Section 4.2.5	In the response to the Call for Tender
Quality and Management Proposal including: Preliminary QP	Section 4.2.1	In the response to the Call for Tender
Related to the Kick-off Meeting (KOM)		
Temporary QP	Section 4.2.1	Before the KOM
QP	Section 4.2.1	30 days after the KOM
Related to the First Design Report (FDR)		
First Design Report (FDR)	Section 4.2.4	As in Table 1
Test Plan	Section 4.2.5	As issue of FDR in Table 1
Related to each Factory Acceptance Tests (FATs)		
Invitation to test attendance (with final dates and place)	–	2 weeks before the test
Test Report	Section 4.2.6	2 weeks before the test
Related to transportation, installation and commissioning		
Transportation Manual	Section 4.2.8	30 days before delivery
Long-Term Storage Manual	Section 0	30 days before delivery
Installation and Commissioning Manual	Section 4.2.10	30 days before delivery
List of spare parts	See TS [1]	30 days before delivery
Related to Acceptance Data Package (ADP)		
Updated and Final Design Report	Section 4.2.4	By delivery to DTT site
Operation and Maintenance Manual	Section 4.2.4	By delivery to DTT site
ADP	Section 4.2.12	By delivery to DTT site
Throughout the duration of the contract		
Progress Reports	Section 4.2.2	Every month
Meeting Minutes	Section 4.2.2	1 week after the meeting
Update of the QP and/or attachments	Section 4.2.1	Whenever necessary
Transportation and customs documents	–	At every transportation
Invoices and other financial documentation	–	As per contract

4.2 Contents of the main documents

4.2.1 Quality Plan (QP)

The guidelines for the preparation of the QP are given in Sections 5 and 6.

The QP shall undergo different stages of development. The first QP is presented in the response to the Call for Tender and is subjected to evaluation for the selection of the Contractor. It is a meaningful outline of the quality plan, where the plans, schedules and explanation of the provisions to comply with contract requirements are provided. It shall include at least a preliminary version of:

- Working Breakdown Structure (see Section 5.3).
- Organization Chart (see Section 5.4).
- Control Plan (see Section 0).
- Time Schedule (see Section 5.6).
- Risk Management Plan (see Section 5.15).
- Documentation Schedule (see Section 6.4.1).

After the contract signature, the QP shall be upgraded according to the following sequential steps:

1. Prior to the KOM, the Contractor shall issue a preliminary QP; the parties shall discuss the improvements to be implemented and the particular provisions to be included.
2. With the timing given in Table 2, the Contractor shall submit for approval to ENEA an official QP, updating the preliminary QP.
3. The Contractor shall not begin any manufacturing or purchase activity until ENEA approves the official QP in writing.
4. During the execution of the Contract, the Contractor shall update the QP (or parts of it) as/if required and shall submit it for approval to ENEA. No update can be implemented until ENEA approves it in writing.

4.2.2 Progress Report and minutes of the progress meetings

Progress Reports shall be prepared and sent to ENEA on a monthly basis, or otherwise agreed during KOM. In particular, they shall report on:

- Time schedule, planned and ongoing activities, deadlines and milestones, regarding the present and next periodic interval.
- Accomplishment of results and milestones, termination of activities, and validation of solutions.
- Advancement of activities (planned versus actual progress percentages).
- Next expected results.
- Encountered issues or doubts during present periodic interval.
- Proposed corrective actions to return to the baseline schedule in the event of any delay.
- Proposed mitigation for any known risk to the schedule.
- Ongoing and next actions.
- Proposed deviations and non-conformities with their state of acceptance.

The Contractor shall organize periodic progress meetings, either in-person or virtual. Their periodicity shall be agreed during the KOM and can be changed during the Contract to better fit its phases.

The Contractor shall and draw up the minutes of KOM and progress meetings according to the timing given in Table 2 and circulate them to all attendees for review and comment prior to their upload to the DTT DMS. The minutes of progress meetings can replace the Progress Reports.

4.2.3 Technical Proposal

A preliminary Technical Proposal covering the overall scope of the Procurement shall be presented in the response to the Call for Tender and is subjected to evaluation for the selection of the Contractor. The proposed technical solutions are binding for the post-award phase if the Bidder is selected to perform the Procurement, unless different choices are requested by ENEA to meet the TS and the PQMS.

The contents of the Technical Proposal shall comply with the requirements of the TS [1].

4.2.4 Design reports

The design reports are technical documents that shall detail the item(s) to be realized. They may be either a single document or, if useful for clarity, a set of separate and well-identified documents. The most important design reports are the Tender Design Report, issued to participate to the Call for Tender, the First Design Report (FDR), issued to finalize the design after the Contract signature, and the Updated and Final Design Report, included in the ADP at the end of the Contract.

The contents of the design reports shall describe how the Procurement activities comply with the requirements of the TS [1].

4.2.5 Test Plan

The Test Plan provide a detailed description of the tests to be performed during the execution of the contract. If necessary, it can be split into separate documents according to the test typology.

The Test Plan will undergo two stages of development, which are:

1. Test Plan at tender/proposal level that is presented in the response to the call for tender and is subjected to evaluation for the selection of the Contractor. The proposed plan is binding for the post-award phase if the Bidder is selected to perform the Procurement, unless different tests are requested by ENEA to meet the TS.
2. Final Test Plan that shall be approved by ENEA with the same deadlines of the Technical Design Report. The approved Test Plan will be an integral part of the specifications. ENEA approval does not relieve the Contractor from its obligations towards the contract, the TS, the PQMS, and applicable standards. Some details concerning test procedures can be specified later on, but not later than the invitation to test attendance and shall be approved by ENEA.

The contents of the Test Plan are described in the TS.

4.2.6 Test Report

The Contractor shall submit for approval to ENEA written records (i.e., Test Reports) of all performed tests, including those performed outside its premises whether ENEA attended or not, and material certificates. A test is passed only after the approval of the corresponding Test Report by ENEA. No component shall be dispatched to the DTT site until ENEA approves all Test Reports associated with that component.

The contents of the Test Reports are described also in the TS [1].

4.2.7 Manuals

The Contractor shall issue manuals with all useful instructions concerning the use of contract goods, e.g., with reference to installation, handling, transport, storage, operation, maintenance, troubleshooting, calibration, repair, remote interfacing, safety, etc.

All the manual contents shall take into account also the detailed requirements reported in the TS [1].

Some specific manuals are described in the following subsections.

4.2.8 Transportation Manual

The Contractor shall issue a Transportation Manual that contains disassembling and packing procedures as well as any necessary information to ENEA to arrange the reception, authorizations, handling, management, storing, and identification of contract goods.

The Transportation Manual shall be exhaustive to allow any different operator under a new contract to perform transportation and unpacking activities.

No component shall be dispatched to the DTT site until ENEA approves the final version of the Transportation Manual.

4.2.9 Long-Term Storage Manual

The Contractor shall issue a Long-Term Storage Manual analyzing all the aspects concerning the long-term storage in another area before the installation and a long-term inactivity before starting the operations, also in compliance with the TS [1].

The Long-Term Storage Manual shall be exhaustive to allow any different operator under a new contract to perform the suggested activities.

No component shall be dispatched to the DTT site until ENEA approves the final version of the Long-Term Storage Manual.

4.2.10 Installation and Commissioning Manual

The Contractor shall issue an Installation and Commissioning Manual that contains any necessary information to perform installation, commissioning and acceptance tests of the procured system.

The Installation and Commissioning Manual shall be exhaustive to allow any different operator under a new contract to perform installation and commissioning activities.

No components shall be dispatched to the DTT site until ENEA approves the final version of the Installation and Commissioning Manual.

4.2.11 Operation and Maintenance Manual

The Contractor shall draw-up an Operation and Maintenance Manual that contains at least:

- Operation procedures.
- Maintenance instructions.
- Calibration and adjustment procedures.
- Guide to perform check and troubleshooting operations in case of faults or alarms. The guide shall include comprehensive information for each electronic board, sufficient to understand its function and to perform necessary measurements, a list of test points, and the expected value and/or waveform at each test point in normal conditions.
- An assessment of maintenance and check activities that will be reasonably needed during the first ten years of operations.
- A Safety Manual that contains safety documentation. The Safety Manual shall also describes the operational limits of the system, prohibited operations, and safe environmental conditions.

Along with the final issue of the Operation and Maintenance Manual, the Contractor shall propose a plan for the training classes to the ENEA staff.

4.2.12 Acceptance Data Package

At the end of the SAT of each batch of components, the Contractor shall issue the Acceptance Data Package (ADP), i.e., a dossier including and updating all documents, information and drawings provided during the contract. The ADP declares and demonstrates the compliance of the deliverables in all respects with the applicable specifications, drawings, and requirements.

The contents of the ADP will include also all the information requested by the TS [1].

5 Project management requirements

This section provides the Contractor with guidelines for the preparation of the QP. It gives directions on the project management requirements that the Contractor shall fulfil during the execution of the contract. The subjects of next subsections shall be addressed in the QP. They are not limiting and can be complemented by the Contractor.

Further provisions concerning legal, procedural, and financial aspects are given in the call for tender and in the contract.

5.1 Objectives and deliverables of the contract

The Contractor shall describe the scope and deliverables of the contract.

The deliverables of the Procurement are described in the TS [1] and include the associated documentation. The Contractor shall issue a table including all items to be procured, specifying:

- Deliverable number and quantity.
- Level of subcontracting.
- All associated documents.

5.2 Contract management

The activities of the contract shall begin with an official Kick-Off Meeting (KOM) where the items of the following non-exhaustive list shall be discussed and agreed:

- Confirmation of the specifications, specific requirements and contractual input.
- Discussion and review of the QP.
- Presentation of the preliminary CP.
- Documentation review lead time.
- Plans for contract implementation.
- Frequency of review of Documentation Schedule, Control Plan, and Progress Reports (if not agreed otherwise, at least once a month).
- Contents of the Progress Reports.
- Contents of the Technical Design Report.
- Contents of the Acceptance Data Package (ADP).
- Detailed schedule of contract activities, including milestones.
- Frequency, agenda and location of the proposed meetings.

The Contractor shall be responsible to issue the minutes of the KOM and any other official meeting with ENEA.

5.3 Work Breakdown Structure

The Contractor shall provide a detailed Work Breakdown Structure (WBS) of activities to be performed during the execution of the contract. The level of detail shall allow for a proper control of these activities, including process qualification activities, procurement activities, and manufacturing and measurement activities. The WBS shall describe how subcontracted activities (if any) are linked with internal activities.

5.4 Organization chart

The Contractor shall provide information about the proposed structure that will be mobilized for the execution of the contract. Key roles for contract accomplishment and the breakdown of responsibilities shall be detailed through an organization chart.

5.5 Control Plan

The Contractor shall develop a Control Plan (CP) that describes work sequences, including process validation, quality verifications and intermediate inspections.

The CP shall include at least the following items:

- All activities and tests to be performed to comply with the TS and other applicable requirements.
- List of required hold points, witness points, reviews, notification points and report points.

For each operation, the CP shall:

- Identify applicable requirements and instructions/procedures.
- Identify whether it has to be witnessed or notified.
- Keep track of its verification and completion.

The level of detail in the CP shall be such as:

- To prevent the inadvertent bypassing of critical operations.
- To enable an adequate planning, monitoring and verification of key activities.
- To encompass all contract phases, including the activities performed by subcontractors.
- To ensure that all operations are performed as directed in the CP, the document shall be directly accessible to those carrying out the work.

When updated, the CP shall be sent to ENEA for approval. The acceptance of the CP by ENEA does not relieve the Contractor from any contractual obligation or responsibility.

An example of Control Plan form is attached at the end of the PQMS. The CP will be used to verify the compliance of outputs (documents produced by the Contractor and listed in the column “Records” of the form) with ENEA acceptance criteria (coming from TS and listed in the columns “Specification” and “Criteria” of the form). These outputs/records are produced applying testing procedures, process procedures, instructions, drawings developed by the Contractor (to be specified under the column “Standard, Procedure, DRW” of the form).

5.6 Time schedule

The Contractor shall develop and keep up-to-date a detailed Time Schedule of all activities to be performed during the execution of the contract, including the activities that are subcontracted or acquired from vendors. The Time Schedule shall include at least:

- Contract milestones.
- Technical milestones.
- Payment milestones.
- Contract phase gate reviews.
- Control points described in the CP.
- Issue of deliverables.

It shall be realized in a planning tool accepted by ENEA (see section 6.4.3). All activities in the Time Schedule shall have predecessors and successors, except for start and finish milestones. Any exception shall be promptly justified by the Contractor and accepted by ENEA. The critical path in the Time Schedule, i.e., the longest sequence of activities that determines the minimum duration to complete all contract activities, shall be reliable, robust, and identifiable.

The Contractor shall describe its approach to manage and monitor the Time Schedule. The Contractor shall specify the precise process to report the Time Schedule evolution to ENEA.

5.7 Resource management and staff qualification

The Contractor shall describe its resource management system, detailing where applicable:

- The list of expertise needed during each contract phase with the associated available resources.
- The number and type of personnel involved in each operation defined in the CP.
- Specific experience and training for the personnel.
- Specific qualifications for particular operations.

If requested by ENEA, the Contractor shall provide proof that all workers involved in contract activities are properly qualified.

For the staff that needs qualification, especially if involved in critical activities, the Contractor shall implement an internal qualification program. Staff qualification shall be done according to applicable standards for each case. A file with the documentation relating to the staff that needs qualification and the qualification plan shall be prepared. This file does not need to be submitted to ENEA, but shall be kept by the Contractor/subcontractors for inspection and audit purposes.

Subcontracting shall not exempt the Contractor from its responsibility to supervise and inspect activities requiring qualified staff.

5.8 Qualification for special processes

The Contractor and subcontractors shall be responsible for the qualification tests of the manufacturing processes when qualification is required. In this case, qualification tests shall be carried out before undertaking the corresponding processes. The Contractor shall submit the qualification records to ENEA for approval, along with the corresponding process execution procedures.

Process qualification shall be included in the CP.

The provisions of this section also apply to the qualification of specific operators for these processes when required by the corresponding standards.

5.9 Material resources

The Contractor shall provide information on machines and process equipment to be used during the execution of the contract.

5.10 Assessment and validation management

The Contractor shall demonstrate how the compliance with the CP is controlled and recorded during the execution of the contract. This includes the following subjects:

- Issue, signature and dating of records for each completed operation to assure ENEA that all operations of the CP have been properly performed and controlled.
- Identification and record of each report generated during the performance of a particular operation (for example, test reports or non-conformity reports) and, where possible, identification of improvement opportunities.
- Access to Contractor premises, personnel and completed work activities for third-party audit or inspection.

5.11 Acceptance and delivery requirements

The Contractor shall indicate how, when and by whom acceptance and delivery are controlled. The Contractor shall ensure that subcontractors implement the same procedure to control the acceptance and delivery.

5.11.1 Review of the Acceptance Data Package and Release Note

Prior to deliveries, the Contractor shall organize a deliverable status acceptance review in accordance with the contract requirements. This includes at least:

- Review of the documentation (ADP) to be provided in accordance with the Documentation Schedule.
- Achievement of the technical requirements or performance test reports.
- Review of qualification proof for special processes and personnel.
- Review of the records and justification of all changes and dispensations (Non-conformity Reports, Deviation Requests).
- Information regarding the management of intellectual property.

This review is formalized with a Release Note, signed by the TRO, approved by ENEA and included in the ADP. An example of Release Note form is attached at the end of the PQMS. After approving the Release Note, the RUP will give his written approval to the deliverable dispatch.

5.11.2 Acceptance of documentation

The approval of documentation by ENEA does not relieve the Contractor from contractual obligations and responsibilities. The Contractor is responsible for any repair when the failure is directly attributable to its manufacturing and processes.

5.12 Subcontracting management

Concerning the management of subcontractors, the Contractor shall refer to the requirements included in the call for tender and in the contract. The Contractor shall ensure that each subcontractor has a quality system compliant with the present PQMS; an assessment report shall be issued for each subcontractor. The Contractor shall undertake all necessary actions to establish and maintain the quality in subcontractor premises in compliance with the PQMS and the TS.

5.13 Health, safety and environment

The Contractor is obligated to comply with, and operate in accordance with Health, Safety and Environment (HSE) current legislation in force in the country where the system is installed (i.e., Italian legislation).

The Contractor shall carefully analyze and apply all safety requirements in order to guarantee that the goods and activities will be in compliance with the national regulation/technical standard for the manufacturing and procurement.

For the activities at the DTT site (if any), the Contractor shall act in accordance with local health, environmental and safety regulation.

The Contractor shall ensure that its personnel and subcontractor personnel accept and adhere to the highest HSE, radiation protection, and quality standards.

The Contractor shall (where applicable as per assigned scope of work):

- Take all actions necessary to protect all its employees (including those provided by subcontractors) from any exposure to hazardous situation and adopt all measures needed to reduce, as low as reasonably practicable, any injury or damage to people or property in accordance with the HSE risk assessment.
- Ensure that all relevant information regarding HSE and radiation protection aspects are properly handed over from shift to shift through formalized and documented handover notes and meeting in overlapping for the key HSE and technical personnel.
- Immediately notify to ENEA of any incidents (real and/or potential) that occur (or might occur) in the performance of the contracted activities at the DTT site (i.e., SAT and technical assistance during qualification and assembling phases, according to contractual scope of work).
- Provide and maintain in good operating conditions all safety and environmental critical equipment identified in the risk assessment.
- Take all necessary measures to prevent and/or limit, within the levels required by applicable laws, any discharge from any source under its care.
- Provide, in case of use of chemicals/hazardous substances or products, the relevant specific SDS (Safety Data Sheet), which shall be kept up to date and easily accessible by all employees.
- Inform the workforce of risk control measures and HSE procedures, work instructions and plans.
- Train all personnel appointed for safety critical jobs (e.g., first aid, works at height).
- Foresee adequate HSE induction session for all personnel and visitors involved on the worksite.
- Provide adequate Personal Protective Equipment (PPE), in accordance with risk evaluation, so required for the specific type of work being carried out or for the area to be visited. For PPE

requiring specific training, the Contractor shall ensure the evidence that adequate training has been provided (e.g., registers, certifications).

The Contractor shall also follow the applicable HSE requirements of SPG-HSE-001-DTT [2]. Should any conflict arise between the SPG-HSE-001-DTT [2] and the other documentation, the latter prevails.

The present Procurement can be framed within the provision of art. 26, par. 3, Title I, of Legislative Decree 81/08. Therefore, attached to the contract, the DUVRI (Documento Unico di Valutazione dei Rischi da Interferenze) is provided to the Contractor.

At the start of on-site activities (if any), a dedicated coordination meeting, between DTT, the Contractor, and the organizations appointed for on-site activities, is required (art. 26 par. 2, Legislative Decree 81/08) to verify and identify prevention and protection measures and to manage interferences (if any).

5.14 Intellectual property

The Contractor shall identify all results of activities undertaken in the frame of the contract that may take the form of an invention, information, trade secrets, designs, drawings, processes, software, database etc., including the creation of any Intellectual Property (IP).

The Contractor shall inform ENEA in the Progress Reports and in correspondence of the Release Notes about any IP related information.

The declaration of IP foreground shall be submitted to ENEA as a standalone self-explaining document as soon as foreground is created. Each item shall include a short description of the item to allow the easy understanding of its nature.

The Contractor shall inform ENEA about any IP relevant issue, such as requests for access to IP by third parties or any IP issue that may impede the performance of the contract.

The Contractor shall identify in the IP reports any confidential information to ensure the confidentiality and the proper management of strategic IP information such as trade secrets or information on patentable subject matters.

5.15 Risk and opportunity management

The Contractor shall prepare and implement a Risk Management Plan for the Procurement covered by the contract.

The Contractor shall describe the provisions implemented to reduce the Contract exposure to risks and to seize possible opportunities regarding the expected performance and the time schedule. This includes at least the following subjects:

- Preliminary risk analysis and assessment report in terms of expected performances and time schedule.
- Associated list of actions to implement in order to reduce the exposure of contract execution to risks.
- Plan to upgrade the two previous documents.

Further requirements are specified in Section 6.1 of the standard ISO 9001:2015.

5.16 Lessons learned

The Contractor shall maintain a list of the lessons learned during the Procurement activities.

6 Quality management requirements

This section provides the Contractor with guidelines for the preparation of the QP. It gives directions on the quality management requirements that the Contractor shall fulfil during the execution of the contract. The subjects of next subsections shall be addressed in the QP. They are not limiting and can be complemented by the Contractor.

As far as anything relating to the execution of the contract is concerned, the Contractor shall implement a quality management system in accordance with ISO 9001:2015. The QP shall be structured in accordance with ISO 10005:2018.

6.1 Scope of the Quality Plan

The QP shall describe the quality management system implemented by the Contractor to ensure that:

- Contract requirements are met.
- Evidence of such compliance is maintained.

The QP shall cover the whole scope of the contract, including the work performed by subcontractors. The level of detail of the QP shall be consistent with:

- The technical requirements of the contract.
- The complexity of involved economic operators, functions, and activities.
- The degree of design innovation.
- The involvement of innovative processes.
- The involvement of processes that cannot be fully verified by inspection or test.
- The degree to which the compliance can be demonstrated by inspection or test.
- Design, performance and manufacturing margins.

6.2 Non-conformities and deviation management

Divergences from the contract requirements can be classified as

- Nonconformity: any condition that does not comply with a specified requirement.
- Deviation: a modification to a specified requirement.

Specified requirements include the requirements of the TS, the PQMS, and any document issued in connection with the contract and agreed with ENEA.

The Contractor shall adopt a nonconformity and deviation management system in case of divergences from the contract requirements. Any divergence needs to be documented and its management represented in a process flowchart. The Contractor shall:

- Record the sequential number of Deviation Requests and Non-conformity Reports.
- Maintain an electronic register of all Deviation Notices, Deviation Orders, Deviation Requests and Non-conformity Reports issued in respect of the contract, which must contain an indication of their distribution and acceptance status.

Deviations and remedial actions to non-conformities shall be subjected to ENEA approval, which does not relieve the Contractor from its contractual obligations and responsibilities.

Non-conformity Reports, Deviation Requests, Deviation Orders and assessment reports on deviation consequences are an integral part of the contract and shall be included in the ADP.

The Contractor shall ensure that subcontractors implement the same procedures to control deviations and non-conformities.

6.2.1 Nonconformity management

The Contractor shall describe and implement a nonconformity management system able to

- Detect any non-conformity and segregate the non-conforming element of the Procurement.
- Maintain an up-to-date register of all nonconformities and their associated remedial actions and periodically submit it to ENEA.

- Ensure that, when appropriate, corrective actions are implemented to prevent the repetition of non-conformities.
- Ensure that appropriate improvements, in the form of preventive actions, are implemented to prevent future non-conformities.

If the Contractor considers that a non-conformity has occurred or ENEA notifies the Contractor (in the form of a field observation report or in an audit report) that, in its opinion, a non-conformity has occurred, then the Contractor shall issue, within 5 working days, a non-conformity report. An example of Nonconformity Report form is attached at the end of the PQMS.

The Contractor shall indicate how, when and by whom non-conformities are processed, including those originating from subcontractors.

In the case of a major nonconformity, namely divergence with impact on a requirement of the TS or the PQMS:

- The Nonconformity Report shall be sent to ENEA with a proposal for remedial actions to remedy the non-conformity.
- Remedial actions shall be implemented only after a written acceptance by ENEA.

In the case of a minor nonconformity, namely divergence with no impact on the requirements of the TS and the PQMS:

- The Contractor can take remedial actions to resolve the nonconformity within its own quality system.
- The Nonconformity Report shall be sent to ENEA for information with a description of implemented remedial actions.

The timing for the management of non-conformities will be defined at the KOM.

6.2.2 Deviation management

This section shall describe and implement a deviation management system, which includes deviation processes initiated by the Contractor/subcontractors and by ENEA.

This system shall ensure that:

- Deviation requests are approved by ENEA before any implementation.
- Status of deviations are made available to ENEA when requested.

6.2.2.1 Deviation Requests originating from the Contractor/subcontractors

The Contractor shall discuss with ENEA any modification to a previously approved contract requirement. If the proposal is deemed beneficial, the Contractor shall request the approval by ENEA by issuing a Deviation Request. An example of Deviation Request form is attached at the end of the PQMS. The Deviation Requests shall contain or refer to all relevant information to allow for an informed decision to be taken. In particular, they shall include an assessment of the deviation consequences in terms of technical performance, cost, delay, and risk.

The deviation shall be implemented only after the reception of a deviation order issued by ENEA through the same form of the Deviation Request.

6.2.2.2 Deviation Requests originating from ENEA

The Contractor shall issue an impact assessment report for each deviation notice received from ENEA. The report shall contain or refer to all relevant information to allow for an informed decision on the course of action to be taken. In particular, it shall address the consequences of the deviation in terms of technical performance, cost, delay, and risk.

The deviation shall be implemented only after the reception of a deviation order issued by ENEA through the same form of the Deviation Request.

6.3 Traceability and identification

The Contractor shall ensure traceability of materials and manufacturing processes.

The Contractor shall define in QP the methodology to ensure the traceability, explaining:

- How products and processes requiring traceability are identified.
- Which methods and equipment are selected to ensure traceability.
- How the traceability of items is recorded.
- Which type of traceability has been selected including proper justification: individual items, batch production, etc.

The Contractor shall ensure that a bidirectional and unequivocal relationship between parts, materials or products, assemblies and associated documentation or records is established and maintained.

The Contractor shall be capable to trace data, personnel and equipment related to procurement, manufacturing, inspection, test, assembly, integration and operations activities.

The Contractor shall be capable to trace back and trace forward the locations of materials from raw stock.

The Contractor shall establish controls to ensure that:

- Identification numbers are assigned in a systematic and consecutive manner.
- Identification numbers of scrapped or destroyed items are not used again.
- Identification numbers, once allocated, are not changed, unless the change is authorized by ENEA.

The Contractor shall keep trace of any temporary marking which might be removed in further phases (e.g., welding).

6.4 Document management

All quality and technical official documentation as well as all exchanges of information between ENEA and the Contractor shall be via the RUP/DEC and the TRO. All official documentation shall be in electronic format and in English. The documents for Italian authorities shall be in Italian too. Should any conflict or interpretation issue arise, the Italian text will prevail.

As far as document coding and item numbering are concerned, the Contractor shall follow the QMS-PRO-20000 procedure [3]. Such procedure provides directions on the coding and numbering system that shall be adopted for the preparation, compilation and identification of all types of documents to be issued by the Contractor/subcontractors during the execution of the contract. The templates listed therein will be provided to the Contractor before the commencement of the contract.

All issued documents will be property of ENEA.

6.4.1 Information and documentation management

The Contractor shall provide all official documentation via the DTT document management system (DMS), that is presently implemented in the Alfresco environment. Detailed information about the use of Alfresco is given the QMS-PRO-20004 procedure [4]. Contractor personnel will be provided with access to Alfresco.

The Contractor shall provide a Documentation Schedule, detailing all documents and records relevant to the implementation of the contract, including the work performed by subcontractors. An example of Documentation Schedule form is attached at the end of this PQMS. The Documentation Schedule shall list all documents to be uploaded in the DMS for approval or information, depending on the directions provided by ENEA.

During the contract phase the Documentation Schedule will be the reference for the document management within the contract. No activity can start until ENEA approves the Documentation Schedule. The Documentation Schedule shall be updated whenever necessary. The approval of the Documentation Schedule or any technical document by ENEA do not relieve the Contractor from its contractual obligations and responsibilities.

The Contractor shall keep all necessary documents and technical information relating to the contract for monitoring, quality assurance controls, checks and audits. The Contractor shall keep such documents for 5 years (or the regulatory period of time, whichever is longer) after the end of the contract or, if requested by ENEA, the Contractor shall transfer requested documents to ENEA at the end of the contract. The Contractor shall provide copies of the documentation whenever requested by ENEA.

6.4.2 Documentation control

For all deliverables, including schemes and diagrams, the Contractor shall implement a drawing control system. The preparation, review, and approval of drawings shall be accomplished through controlled procedures that establish approval authorities and responsibilities.

The following classification applies to changes in drawings:

1. A change that modifies an approved design is a “drawing change” and shall be controlled according to the abovementioned non-conformity and deviation management system.
2. An alteration that does not affect an approved design is a “drawing modification” (namely a modification relating to the different stages of the drawing process, e.g. “as defined”, “as detailed” and “as built”).

6.4.3 Document format

The formats of provided electronic files shall be authorized in advance by ENEA. The following formats can be accepted without explicit authorization:

- Portable Document Format (.pdf).
- Microsoft Word 2019 (.docx).
- Microsoft Excel 2019 (.xlsx).
- Microsoft PowerPoint 2019 (.pptx).
- Primavera P6 (.xer).
- Catia V5 (.catpart / .catproduct).
- AutoCAD 3D/2D (.dwg / .dxf).
- ISO 10303 (.step / .stp).
- Compressed archives (.zip).
- Scans, pictures and photos (.jpg / .png).
- Movies (.avi).

The use of newer versions of a software shall be agreed with ENEA. The editable/modifiable files shall be also accompanied by the files in Portable Document Format (PDF).

The additional costs necessary to manage a new file format or the new release of a software shall be covered by the Contractor.

6.5 Visits, inspections and audits

ENEA or its representatives may carry out planned and documented visits, audits, and inspections to verify Contractor/subcontractor compliance with all quality and technical aspects of the contract.

ENEA shall be informed of the Contractor/subcontractor audits, reviews, surveillance, and inspection activities. Notifications shall be sent in writing via email at least 2 weeks in advance. The Contractor shall be responsible for all expenses derived from ENEA inspections or audits as a result of a wrong notification. When ENEA cannot witness an important activity, e.g. a hold point, ENEA may request to repeat such activity at its own expense. Moreover, ENEA is responsible for the temporary stops of the activities.

Should any deficiency be found, the Contractor shall implement, or ensure that subcontractors implement, all necessary actions to put this deficiency right in accordance with an agreed time schedule.

The Contractor/subcontractors shall provide ENEA with access to all documentation, premises, and personnel involved in the execution of the contract for the purpose of audit, review, surveillance and inspection. Restrictions can be allowed for reasons relating to security or military secret. ENEA reserves the right to make unannounced visits to Contractor/subcontractor premises and free access shall be provided at all reasonable times. During ENEA visits, the Contractor shall make an office, equipped with Internet access, available to ENEA inside its premises.

ENEA can require photographs and record video of anything connected with the contract (the obtained material shall remain confidential). ENEA agrees to keep confidential any other information not relating to the contract that may be accessed during audit and surveillance activities.

ENEA shall have the right to be accompanied by third-party observers during agreed inspections and audits. For the purpose of the contract, ENEA may appoint an independent inspection authority to certify that activities are carried out in accordance with agreed codes and standards. The third-party observers will be identified in advance and agreed with the Contractor. They shall be regarded as part of ENEA staff. All observers will be bound by appropriate confidentiality obligations to be agreed in advance. The Contractor shall arrange free access for the inspectors so that they can carry out their duties. The Contractor shall provide the inspectors with copies of all relevant test reports to allow them to certify the compliance of deliverables with the technical requirements.

7 Templates and forms

The following forms, shown in next pages, are useful during the execution of the contract:

- A1: Control Plan Form
- A2: Documentation Schedule Form
- A3: Deviation Request Form
- A4: Nonconformity Report Form
- A5: Release Note Form

The Contractor can adopt its own templates provided that at least all fields specified in the annexed Templates are therein included.

7.1 Control Plan Form

DTT ID Number:		Revision Number:		Sheet:		of:	
Contractor:		DMS ID Number:					
Contract ID Ref.:		Item:					

Contractor		ENEA	* Code	TPIA: Third Party Inspection Authority
Prepared by:	Approved by:	Acceptance:	D: Document Review R: Report Required M: Monitor N: Notification Point A: Authorisation to proceed point W: Witness Point H: Hold Point	DTT: ENEA or its representative
Name, Sign & Date	*Name, Sign & Date*	*Name, Sign & Date*		

Item No.	Activity (manufacture, inspection, …)	Specification (requirement, DRW, …)	Standard, Procedure, DRW	Criteria	Verification by						Records (report, NCR, …)	Remarks
					Contractor		TPIA		ENEA			
					Name, Sign & Date		*Name, Sign & Date*		*Name, Sign & Date*			
					*		*		*			

[Electronic Template will be made available to the Contractor]

7.2 Documentation Schedule Form

DTT ID Number:		Revision Number:		Sheet:		of	
Contractor:		DMS ID Number:					
Contract ID Ref.:		Item:					

Contractor		ENEA	Notes & acronyms	
Prepared by:	Approved by:	Acceptance:		
Name, Sign & Date	*Name, Sign & Date*	*Name, Sign & Date*	Field:	Distributed for review to the fields of expertise
			Distribution:	A-Approved, I-Information, N-Non Distributed
			Status:	R-Received, W-Waiting, A-Accepted

Document/ Record ID	Rev.	Title	Responsible for			Field	Date / Expected	Distributed ENEA	Archive	Status
			Prep.	Appr.	Distr.					

[Up-to-date list of documents/ records/ drawings/ models/ plans/ schedules/ manuals/ data expected during the contract and/or essential to perform the task and/or part of the ADP]

[Electronic Template will be made available to the Contractor]

7.3 Deviation Request Form

Section 1 – to be completed by the Contractor

DR Number:		Revision Number:		Sheet:		of	
1. DTT ID Number:							
2. Contract ID Ref.:		DMS ID Number:					
3. Contractor:							
4. Item/Subject:							

5. ORIGINAL REQUIREMENT:
[always mention the reference document (title, number, version) where the requirement comes]

6. DEVIATION PROPOSAL:

7. JUSTIFICATION:

8. LIST OF ATTACHMENTS:

9. IMPACT ANALYSIS:

9.1 OTHER ITEMS	☐ **NO** ☐ **YES**	Report:	
9.2 SCHEDULE	☐ **NO** ☐ **YES**	Report:	
9.3 PERFORMANCE & COST	☐ **NO** ☐ **YES**	Report:	
9.4 OTHER:	☐ **NO** ☐ **YES**	Report:	

Contractor's Technical Responsible			Contractor's Quality Representative		
Name	*Signature*	*Date*	*Name*	*Signature*	*Date*

Section 2 – to be completed by ENEA

ENEA Technical Responsible Officer			ENEA Representative		
1. DECISION:			2. COMMENTS:		
Name	*Signature*	*Date*	*Name*	*Signature*	*Date*

[Electronic Template will be made available to the Contractor]

7.4 Nonconformity Report Form

Section 1 – to be completed by the Contractor

1. DTT ID Number:		Rev. Number:		Sheet:		of	
2. Contract ID Ref.:		DMS ID Number:					
3. Contractor:							
4. Item:							
5. REQUIREMENT:							
6. DESCRIPTION OF NONCONFORMITY:							
7. PROPOSED REMEDIAL ACTION: ☐ **use as is** ☐ **rework** ☐ **repair** ☐ **reject**							
8. LIST OF ATTACHMENTS:							
9. PROPOSED NONCONFORMITY CATEGORY:							
☐ **MINOR** NONCONFORMITY							
☐ **MAJOR** NONCONFORMITY							
10. CORRECTIVE / PREVENTIVE ACTION:							

Contractor's Technical Responsible			Contractor's Quality Representative		
Name	*Signature*	*Date*	*Name*	*Signature*	*Date*

Section 2 – to be completed by ENEA

ENEA Technical Responsible Officer			ENEA Representative		
1. DECISION:			2. COMMENTS:		
Name	*Signature*	*Date*	*Name*	*Signature*	*Date*

Section 3 – to be completed by Contractor

Final Result / Closing of NONCONFORMITY					
1. Description of actions performed					
2. List of attachments					
3. Result on product/process					
☐ **POSITIVE** *Brief description* ☐ **NEGATIVE** *Brief description*					
4. Notes					
Contractor's Technical Responsible			Contractor's Quality Representative		
Name	*Signature*	*Date*	*Name*	*Signature*	*Date*

Section 4 – to be completed by ENEA

ENEA approval					
ENEA Technical Responsible Officer			ENEA Representative		
1. DECISION:			2. COMMENTS:		
Name	*Signature*	*Date*	*Name*	*Signature*	*Date*

[Electronic Template will be made available to the Contractor]

7.5 Release Note Form

Section 1 – to be completed by the Contractor

1. DTT ID Number:		Revision Number:		Sheet:		of	
2. Contract ID Ref.:		DMS ID Number:					
3. Contractor:							

Section 2 – Conformity statement to be completed by the Contractor

1. With the exception of the discrepancies listed below (section 2.6), we certify that the following equipment/service: (describe)
2. Has been manufactured/performed, inspected and tested in accordance with the requirements described in the following documents: (Documents list)
3. That the equipment/service is complete.
4. That all relevant verifications, inspections and tests are complete and satisfactory.
5. That the following documents are those required by the Contract: (Detailed list)
6. List of any change proposal, deviation request and nonconformity report: (attached)

Contractor's Technical Responsible			Contractor's Quality Representative		
Name	*Signature*	*Date*	*Name*	*Signature*	*Date*

Section 3 – to be completed by ENEA

ENEA Technical Responsible Officer			ENEA Representative		
1. DECISION:			2. COMMENTS:		
Name	*Signature*	*Date*	*Name*	*Signature*	*Date*

[Electronic Template will be made available to the Contractor]