



Management and Quality Specification for the supply of the Control Room

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AGENZIA NAZIONALE PER LE NUOVE TECNOLOGIE,
L'ENERGIA E LO SVILUPPO ECONOMICO SOSTENIBILE

Project Details

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Authors & Contributors

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Abstract

This document contains the Management and Quality requirements to be applied by Tenderers and awarded Contractor for the Contract of the Control Room.

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This document is issued for the execution of the ENEA project

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This document contains the Management and Quality requirements to be applied by Tenderers and awarded Contractor for the Contract of the Control Room

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Applicable Documents and Standards

Applicable Documents

RHCR-REF-000: [CR_0] Control Room Technical Specification
RHCR-REF-001: [CR_1] Control Room Technical Requirements
RHCR-REF-002: [CR_2] Control Room Technical and Economical relation
RHCR-REF-003: [CR_3] Interface Control Document
RHCR-REF-004: [CR_4] ControlRoom-IS-001-Power
RHCR-REF-005: [CR_5] ControlRoom-IS-002-Internet
RHCR-REF-006: [CR_6] ControlRoom-IS-003-HYRMAN
RHCR-REF-007: [CR_7] ControlRoom-IS-004-CMM
RHCR-REF-008: [CR_8] Management and Quality Specification

RHK-AD-01: QMS-PRO-20000 - Document Coding and Item Numbering
RHK-AD-02: QMS-PRO-20004 - Management of Documentation issued by Suppliers/Contractors
RHK-AD-03: SPG-HSE-001-DTT (ENG) - HSE Requirements for Supplier and Contractor
RHK-AD-04: HSE-TEC-85009 - Documento Unico di Valutazione dei Rischi delle Interferenze & Allegato 5 - Misure specifiche per ridurre le interferenze

International and National Standards

RHCR-RS-01: ISO 9001:2015 - Quality Management System – Requirements
RHCR-RS-02: ISO 10005:2018 - Quality Management – Guidelines for quality plans
RHCR-RS-03: Italian Legislation – D.Lgs. 81/2008 s.m.i.
RHCR-RS-04: Italian Legislation – D.Lgs. 152/2006 s.m.i.



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Terms and Definitions

Term	Definition	Acronym
Acceptance Data Package	Collection of documents delivered by the Contractor before any payment milestone that declares and demonstrates the conformance of the deliverable in all respect with the applicable specification(s), drawing(s) and all requirements.	ADP
Company	ENEA	-
Contractor	Economic operator which has concluded the contract for the supply of the Control Room	-
Critical Path	The longest sequence of activities in the project that determines the minimum duration to complete all activities in the project.	-
Customer	The entity that shall award the tender for the subject of the present Technical Specification and that shall be in charge of verifying the adherence to the required prescriptions. In this definition Customer should be understood as ENEA.	--
Deliverable	Tangible or intangible good or service produced as a result of a contract signed with ENEA. A deliverable could be hardware, documentation, a software product, etc.	-
Deviation	Permission to depart from the originally specified requirements of a product prior to realization.	-
Divertor Tokamak Test	Tokamak under construction at ENEA Frascati Research Centre (Rome, Italy).	ENEA
Document Management System	ENEA Document Management System (also known as ALFRESCO).	DMS
ENEA Responsible Officer	ENEA's Responsible Officer (<i>Responsabile Unico del Procedimento</i>) in charge for the correct execution of the Contract and related works and for communicating all technical, contractual actions, and decisions to the Contractor.	RUP
ENEA Technical Officer	ENEA's Person in charge for the implementation and monitoring the scope of the works (<i>Direttore dell'esecuzione del Contratto</i>).	DEC
Economic Operator	Any natural or legal person, public entity or group thereof that offers products, services or works on the market.	-
IP	Intellectual Property	IP
Kick-off Meeting	First meeting where ENEA and Contractor project teams define the rules for the execution of the Contract. Mandatory starting points before any other contractual activities are initiated.	KoM
Management and Quality Specification	The present document.	MQS
Manufacturing and Inspection Control Plan	List of activities directly related to the follow-up and verification of the quality and/or safety of the final product(s) and/or service(s) in the frame of prototyping, qualification and manufacturing activities.	MIP



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Term	Definition	Acronym
Nonconformity	Any condition that does not comply with a specified requirement.	NC
Nonconformity Report	Document detailing a nonconformity.	NCR
Progress Meeting	Meeting between ENEA and the Contractor to discuss the Contract status.	-
Project and Quality Management Plan	Document describing the management system developed, implemented and maintained by the Contractor throughout the life-cycle of the Contract to ensure that the Contract Requirements are met and that evidence of such compliance is maintained.	PQMP
Quality Representative	Contractor project team member responsible for the implementation of Quality Assurance Requirements of the Contract.	QR
Release Note	First page of the Acceptance Data Package (duly signed by the Contractor) certifying that the supplied goods or services meet the requirements of contractual specifications and deliverables listed in the Release Note has been previously cleared by ENEA.	-
Remedial Action	Action taken to address the nonconformity condition and to restore the conformance of the item, meanwhile the root cause is identified, and the corrective actions defined.	-
Site	The location where the Control Room facility will be installed (San.Giovanni Barra, Napoli, Italy).	-
Subcontractor	Economic operator, who is not Party to this Contract and who enters into a legal commitment with the Contractor in order to perform a part of the Contract.	-
Supplier	Company or individual that provides materials or products to the Contractor or to the Subcontractors for the production of the Control Room without the need of a legal commitment with the Contractor in performing a part of the Contract.	-
Technical Responsible Officer	Technical Responsible Officer of the Contractor in charge of the Contract.	TRO
Technical Specification	The Contract Technical Specification for the Supply.	TS
Tenderer	Economic operator who has submitted a tender in reply to a call for tender.	-
Tokamak	A fusion device for containing a plasma inside a torus chamber using magnetic fields.	-
Work Breakdown Structure	Deliverable-oriented breakdown of a project into smaller components.	WBS
Work Package	Part of the WBS dividing a large project into smaller related tasks.	WP



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Scope of the Document

Aim of this document is to provide Project and Quality requirements that:

- Tenderer shall comply with when preparing its offer/proposal.
- Contractor shall comply with during the execution of the Contract.

Some legal, procedural, and financial requirements for the Call for Tender can be found in the Invitation to Tender and in the annexed Contract Form.

The associated Technical Specification RHCR-REF-000 defines the detailed technical requirements for the supply.

The quality management system of the Contractor and its Subcontractors (if any), implemented to complete the work, shall be compliant with the requirements defined in this Management and Quality Specification (MQS) document, and in the Technical Specification RHCR-REF-000.

All requirements of [RS-01] shall be applied to this Contract.



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1 Introduction to the Work

The scope of the work is the procurement, as reported in the Technical Specification RHCR-REF-000 (Section 2: Scope of the supply), of the Control Room.

2 Summary of Documentation Deliverables

Documentation deliverables shall include, as a minimum, all the documents described in the TS RHCR-REF-000 and in the present MQS.

The documentation deliverables shall be developed, maintained, and submitted for acceptance to ENEA.

The main Contract documents are described in the following subsections.

A brief description of the minimum contents of the main documentation deliverables is reported here below:

1. Technical proposal description

The Technical proposal description takes into account the overall scope of the supply and shall be submitted by the Tenderer in the offer phase.

2. Project and Quality Management Plan (PQMP)

Contractor PQMP shall be developed according to requirements and guidelines defined in the present MQS.

3. Work Breakdown Structure

The WBS shall be developed according to the requirements and guidelines defined in the present MQS (refer to Section 4.3).

4. Time Schedule

The Time Schedule shall be developed and maintained in a planning tool accepted by ENEA.

The Time Schedule shall contain all activities performed by the Contractor for the execution of the contract including at least:

- Contractual milestones.
- Technical milestones.
- Payment milestones.
- Stage milestones.
- Contract phase gate reviews (e.g., MRR).
- Control points described in the MIP.
- Issuing of deliverables.
- Subcontracted activities (if any).

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 shall be reliable, robust, and identifiable.

The Critical Path shall run unbroken from the Report Date through to the end of the project.

Time Schedule baseline and forecasted in Progress Report shall be provided in its native, editable form.

5. Risk and Opportunity Management Plan

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



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- 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 risk exposure of the project.

Additional details are provided in Section 4.13 of the present MQS.
Further requirements are specified in [RS-01] (Section 6.1).

6. Project Organization Chart

Tenderers during proposal/offer stage, shall provide information about the proposed structure that will be mobilized for the execution of the Contract.

After the award of the Contract, the Project Organization Chart shall be detailed and re-issued to ENEA for approval.

If during Contract execution, Contractor key roles (i.e., TRO and QR) will be substituted, the new figures shall be submitted to ENEA for approval.

7. Progress Reports and Progress Meeting minutes

Progress Reports shall be prepared and sent on monthly basis to ENEA, or otherwise agreed during KoM, reporting in particular on:

- Main scheduled work packages and milestones.
- Main results, completed activities, achievements and issues encountered in the last month.
- Proposed deviations and raised nonconformities with their acceptance status.
- Main scheduled WPs, Time Schedule, and milestones for the coming month.
- Issues and actions updates.
- Risks and mitigation actions.

The Contractor shall organize the Progress Meetings and shall draft minutes of KoM and Progress Meetings within 3 working days after the meeting and circulate them to all attendees for review and comment prior to upload to DMS.

8. Documentation Schedule

The Documentation Schedule with related requirements and contents is specified in this MQS.

9. Final Technical Report

After the final acceptance, the Contractor shall issue a Final Technical Report, including and updating all the documents, information and drawings provided during the Contract.

The Final Technical Report with related requirements and contents is specified in the TS RHCR-REF-000.

10. Acceptance Data Package (ADP)

The primary objective of this document is to declare the conformance of the item(s) in all respect with the applicable specification(s), drawing(s) and requirement(s).

The Contractor shall deliver to ENEA an ADP before any payment milestone. This package shall include evidence of all activities performed for that milestone.

The Contractor shall provide a complete ADP at the end of the activities included in the Contract.

11. Plan for Factory Assembly & Acceptance Tests

The Contractor shall submit the list of Factory Assembly & Acceptance Tests (FAT) to ENEA. The Contractor shall provide a detailed description of the test procedures to be performed, the acceptance criteria, and the time schedule for each test. Technical requirements are given in the TS RHCR-REF-000.



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The overall test schedule shall include, if any, tests that are performed outside the Contractor premises.

12. Plan for Site Assembly & Acceptance Tests

The Contractor shall submit the list of Site Assembly & Acceptance Tests (SAT) to ENEA. The Contractor shall provide a detailed description of the test procedures to be performed, the acceptance criteria, and the time schedule for each test. Technical requirements are given in the TS RHCR-REF-000.

The overall test schedule shall include, if any, tests that are performed outside the Contractor premises.

13. Technical Documentation

The Contractor shall submit documentation regarding the list of hardware components intended for the control room, along with all the documentation related to the development of software modules and their respective tests.

14. Test Reports

The Contractor shall provide written records of all the performed tests by means of Test Reports.

The Test Reports shall be provided within 15 working days after the relevant tests have been performed.

The Test Reports shall clearly report the results of the tests, which shall be compared with the requirements given in the TS RHCR-REF-000.

15. Handling and Instruction Manuals

Refer to TS RHCR-REF-000, Section 9.2.2.3 “ Operation and Maintenance Manual”

The documents listed above with delivery stages and update requirements are summarized in Table 1. Table 1 shall not be considered exhaustive and does not include the legal and financial documents prescribed by the Invitation to Tender and by the Italian laws to participate to the Call for Tender procedure and to sign the Contract with ENEA.

The Contractor shall comply with any other applicable Italian and European law, prescription or regulation.



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Table 1: List of main Contract documents with deadline/periodicity

Document Title	Provisional	Preliminary	Detailed	Update
Technical proposal description	Tender			
Project and Quality Management Plan (PQMP)	Tender	15 working days before KoM	15 working days after KoM	To be detailed as needed
WBS	Tender	15 working days before KoM	15 working days after KoM	To be updated as needed
Time Schedule	Tender	15 working days before KoM	15 working days after KoM	<ul style="list-style-type: none">• Together with Progress Report• Achievement of each milestone and issuing of each deliverable
Risk and Opportunity Management Plan	Tender	15 working days before KoM	15 working days after KoM	Together with Progress Report
Project Organization Chart	Tender	15 working days before KoM	15 working days after KoM	To be detailed and updated as needed
Progress Report		7 working days before Progress Meeting	5 working days after the Progress Meeting	Monthly or otherwise agreed during KoM
Documentation Schedule		Completion of MRR (TS RHCR-REF-000 milestone M.02)	<ul style="list-style-type: none">• Completion of the engineering documentation required for WP.1 including MRR documentation (Sec. 2.4.1 of TS RHCR-REF-000 for each component/block	<ul style="list-style-type: none">• As needed• Monthly
Final Technical Report			1 month after the end of activities	
Acceptance Data Package (ADP)			End of the activities related to each deliverable and 2 weeks before each payment milestone	
Plan and Report for Factory Assembly & Acceptance Tests (FAT)			2 months before starting of Factory Assembly & Acceptance Tests	



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Document Title	Provisional	Preliminary	Detailed	Update
Test Reports			15 working days after completion of the tests. Each Milestone should also contain the test report document.	
Operation and Maintenance Manuals			To be issued with the Final Technical Report	



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3 Ownership and Responsibilities

3.1 ENEA responsibilities

ENEA is responsible for:

- Providing supply parameters, specifications and requirements reported in the Contract TS RHCR-REF-000, ensuring that they comply with the needs of ENEA and with the related documentation.
- Providing and updating (if any) the information for the HW installation.
- The approval of the Executive Design.
- The approval of the Subcontractors (if any) selected by the Contractor, when such option is allowed by the Call for Tender requirements, by the Contract documentation and by the Italian laws.
- The review and approval of the documentation issued by the Contractor within the Contract.
- Monitoring the status of the Contract through the established meetings, inspections, visits, audits, teleconferences and reports.
- Witnessing the prescribed and agreed tests according to the agreed MIP.
- The acceptance of the supply and related documentation, provided that they fully comply with the Contract TS RHCR-REF-000 the MQS, the contractual documentation, the Call for Tender rules, and the applicable international standards.

3.2 Contractor responsibilities

The Contractor is responsible for:

- The procurement of components and materials.
- The testing and delivery of supply components.
- Providing all documentation, in accordance with the Contract TS RHCR-REF-000 and the requirements included in the present MQS.

The responsibility of Contractor includes the following items and activities:

- Preparation, issue, update, and implementation of a PQMP for the Contract to ensure the project success and the quality of the deliverables.
- Preparation, issue and implementation of a Risk Management Plan effectively reducing the Project risks.
- Guarantee that any activity of its Subcontractors (if any) complies with the quality and management requirements written in this MQS and in the TS RHCR-REF-000.

In the Project Organization Chart the Contractor shall identify the key roles for Contract accomplishment and detail the breakdown of responsibilities. In particular, the Contractor shall provide information about the name and contact details of:

- The Technical Responsible Officer (TRO) in charge of the Contract, responsible for:
 - Coordinating the planning, performances and control of the work according to the PQMP dispositions, including the work assigned to Subcontractors (if any).
 - Keeping Time Schedules and issuing Progress Reports.
- The Quality Representative (QR), independent from the TRO, who shall:
 - Ensure that the PQMP, quality procedures, and detailed work instructions are followed during the course of the Contract in order to guarantee that all contractual quality requirements are met.
 - Assess and control the quality management at the Subcontractor's premises.

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



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4 Project Management Requirements

The following paragraphs provide details about Project Management Requirements, to be fulfilled by the Contractor, aimed at defining the Project and Quality Management Plan (PQMP).

4.1 Scope of the Contract

The Contractor shall clearly describe in the PQMP its understanding of the subject of the Contract. This description shall include all items covered in its offer/proposal agreed with ENEA. Detailed information about the supply are provided in the Contract TS RHCR-REF-000.

The Contractor shall provide in the PQMP a table including all items to be supplied, specifying:

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

4.2 Contract Management

During the official KoM the following items, but not limited to, shall be discussed and agreed between the Contractor and ENEA:

- Confirmation of the specifications, specific requirements and contractual input.
- Discussion and revision of the preliminary PQMP.
- Presentation of Contractor preliminary MIP.
- Documentation Schedule including ENEA involvement in the review of documents, and a review Lead Time.
- Frequency of review of the Documentation Schedule (if not agreed otherwise, at least once a month during the Progress meeting).
- Plans for implementations of the Contract.
- Contents of the Progress Reports to be prepared and submitted by the Contractor to ENEA.
- Contents of the ADP.
- Detailed schedule of the contractual activities, including milestones as described in Section 2 (Time Schedule).
- Frequency, agenda, and location of the proposed meetings (they can be held face-to-face or by teleconference/videoconference).

The Contractor shall be responsible for issuing the minutes of the KoM and of any other official meeting with ENEA. The minutes of the meeting shall be submitted to ENEA for approval within 3 working days.

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

4.3 Project Work Breakdown Structure

The Contractor shall organize the supply according to the Work Breakdown Structure (WBS) and groups of activities called Work Packages (WPs) given in the TS RHCR-REF-000 with correspondent milestones and deliverables defined in the TS RHCR-REF-000

The WBS shall be presented and accepted as part of the PQMP.

4.3.1 Testing and Approval Requirements

The supply shall be subjected to inspections and tests to prove its compliance, as outlined in the TS RHCR-REF-000.



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4.4 Resource Management and Staff Qualification

Contractor shall provide a resource management system document, detailing:

- The list of competences needed for the main Contract stages with associated available Contractor resources.
- The number and type of personnel involved in each particular stage defined in the MIP.
- Specific experience and training for personnel.
- Specific qualifications for special operations (if any), in particular in accordance with the standard required in the TS RHCR-REF-000.

The Contractor shall provide proof that all workers are properly qualified.

Staff, both from the Contractor and from its Subcontractors (if any), participating in quality-related activities shall be appropriately qualified.

Staff qualification shall be done according to applicable standards for each case.

In addition to qualification requirements for the staff in charge for tests, miscellaneous inspections, and audits, the Contractor shall implement an internal qualification program for the staff involved in critical activities and not already qualified.

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

4.5 Material Resources

The Contractor shall guarantee the availability of the machines or process equipment that will be used during Contract execution.

4.6 Assessment and Validation Management

The Contractor shall demonstrate how the compliance with the MIP is controlled and recorded throughout the Contract. This includes the following subjects:

- Issue, signature, and dating of records for each completed operation to assure ENEA that all operations foreseen in the MIP have been properly performed and controlled.
- Identification and record of each report generated during the performance of any special operation (e.g., Test Reports or Nonconformity Reports) identifying, where possible, improvement opportunities.
- Access to the Contractor premises, Contractor personnel, and Contractor completed work activities for third party audit or inspection.

4.7 Acceptance and Delivery Requirements

4.7.1 Contractor Review of the Acceptance Data Package (ADP) and Release Note

Prior to deliveries, the Contractor shall organize a deliverables 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.
- Processes to be qualified and personnel qualification proof review.
- Review of the records and justification of all changes and derogations (Nonconformity Reports, and Deviation Requests).
- Configuration status.
- Information about the management of Intellectual Property.

This review is formalized with a formal Contractor Release Note signed by TRO, approved by ENEA representative, and included in the ADP.



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The ADP will only be complete after the completion of all components.

The Contractor is asked to supply a complete documentation related to all the aspects of the production process as well as a proper set of documents accompanying each set of Components delivered.

The ADP, including the Release Note, shall be stored in ENEA DMS.

ENEA signature of the Release Note shall not relieve the Contractor from any contractual obligations and responsibilities.

4.7.2 Acceptance of Documentation

ENEA approval of documentation shall not relieve the Contractor from contractual obligations and responsibilities.

4.8 Subcontracting management

For the management of Subcontractors, the Contractor shall refer to the requirements included in the Invitation to Tender and in the Contract.

The Contractor shall ensure that each of its Subcontractors have a quality system compliant to the present MQS and an assessment report shall be issued for each Subcontractor.

The Contractor shall undertake all the necessary actions to establish and maintain the quality in the Subcontractors' premises in conformity with the present MQS and TS RHCR-REF-000.

The Contractor shall ensure that its Subcontractors (if any) implement the same procedure to control acceptance and delivery.

A Subcontracting Schedule Form is provided in Template [A4].

4.9 HSE Management Requirements

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 supply will be installed (i.e., Italian legislation).

Contractor shall carefully analyze and apply all safety requirements to guarantee that the supply will be in compliance with the national regulation/technical standard for the supply.

For the activities on-Site (i.e., SAT and technical assistance during qualification and assembling phases, according to contractual scope of work) the Contractor shall act in accordance with local health, environmental and safety regulation RHCR-REF-003 and RHCR-REF-004.

The Contractor is in charge of ensuring that all its personnel, including those of any Subcontractors (if any), 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 on-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), that shall be kept up to date and easily accessible by all employees.



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- Inform the workforce of risk control measures and HSE procedures, work instructions and plans.
- Train all personnel appointed for safety critical job (e.g., First Aid, work 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).

Detailed Health Safety and Environmental requirements are included in RHK-AD-03 attached to the Contract. Such document shall be read in conjunction with TS RHCR-REF-000, the present MQS requirements and considering the applicable scope of work assigned to the Contractor. Moreover, this document does not replace the obligations imposed by current legislation on health, safety, and environment in the context of public procurement and the provisions of the Contract.

The supply required in the TS RHCR-REF-000 can be framed within the provision of RHCR-REF-003 (art. 26, comma 3). Therefore, attached to the Contract the Applicable Document RHK-AD-04 is provided to the Contractor.

The purpose of this document is to indicate the measures taken by ENEA to reduce or, where possible, eliminate the interference risks due to the supply's activities and other activities carried out in the areas designated for the ENEA Project.

The Annex-5 (*Allegato-5*) of [RHK-AD-04], will provide the following main information:

- Description of the activity and related works.
- Access Information.
- Specific measures to reduce interferences.
- Management of interferences.
- Safety cost due to the interferences.

At the start of on-Site activities (i.e., SAT and technical assistance during qualification and assembling phases, according to contractual scope of work), a dedicated coordination meeting, between ENEA, the Contractor, and the Organization appointed for assembling activities, is required ([RHCR-RS-03], art. 26, comma 2) to verify and identify prevention and protection measures to be taken for interferences management.

4.10 Intellectual Property management

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 Acceptance Data Package 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 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.

4.11 Risk and Opportunity Management

Contractor shall describe in the PQMP the risk and opportunity management process. Contractor shall use the Risk Register to record the Risks and Opportunities.



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Contractor shall develop detailed risk response plans for each risk/opportunity and shall follow up their implementation.

4.12 Lessons learned

The Contractor shall maintain a list of the lessons learned.



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5 Quality Management Requirements

The following paragraphs provide details about Quality Management Requirements to be fulfilled by Contractor for the definition of the Project and Quality Management Plan (PQMP).

5.1 Project and Quality Management Plan

5.1.1 Scope of the Contractor PQMP

The PQMP shall describe the operational quality system implemented by the Contractor to ensure that:

- Contract requirements will be met.
- Evidence of such compliance will be maintained.

The PQMP shall cover the whole scope of the Contract, including work performed by Subcontractors (if any). The level of detail of PQMP shall be consistent with:

- The technical and management requirements of the Contract applying Section 8.2 of [RHCR-RS-01].
- The complexity of economic operators, functions, and activities involved.
- The degree of design innovation.
- The involvement of innovative processes.
- The involvement of processes which cannot be fully verified by an inspection or test.
- The degree to which functional compliance can be demonstrated by inspection or test.

The approval by ENEA of the PQMP is needed before the beginning of the implementation. Any change in the content of the PQMP shall be subject to the ENEA approval.

The Contractor shall update the PQMP (or parts of it) every time that is needed and shall submit it to ENEA for approval. The updates shall be approved by ENEA prior to their implementation.

The PQMP shall be structured in accordance with [RHCR-RS-02] and shall comply with [RHCR-RS-01] requirements applicable to the Contract.

Upon completion of the Contract, the PQMP shall be included in the ADP handed over to ENEA.

5.1.2 PQMP at tender/proposal level

Tenderer, during tender stage, shall provide in its offer a meaningful provisional outline of the PQMP where the plans, schedules, and explanation of the provisions to comply with the requirements will be assembled. The basic structure and contents shall be adequate to assess the compliance of the final PQMP with the requirements.

During offer, due to the nature of the process, the Contractor might not have all the necessary information. As result of this limitation, at this stage, the PQMP cannot be a "complete" version and is referenced as an "outline" version in which some information will be addressed as a description of the proposed system.

5.1.3 PQMP after Contract award

After the Contract signature, the PQMP shall encompass the following sequential stages:

- 15 working days before KoM, the Contractor shall transmit the preliminary PQMP to ENEA for review.
- at the KoM the parties shall agree on the improvement of the preliminary PQMP and on the particular provisions to include on it.
- 15 working days after the KoM the Contractor shall issue a detailed PQMP to ENEA for approval.
- the Contractor shall not begin any purchase activity without ENEA written approval of the PQMP.
- during Contract implementation, the Contractor shall detail the PQMP (or parts of it) as required and shall submit it for approval to ENEA.



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5.2 Nonconformities and Deviation Management

The Contractor shall adopt nonconformity (NC) and Deviation management processes in case of divergences from the Contract requirements.

Reference of the management of NC and Deviation shall be based on the requirements provided in this document and shall be included by Contractor in the PQMP.

Any divergence from Contract requirements needs to be documented, and shall be addressed with one of the following:

- Nonconformity: any condition which does not comply with a specified requirement.
- Deviation: a previously proposed and approved modification to a specified requirement.

Specified requirements include:

- Technical or management specifications requirements of the Contract.
- Requirements of any document issued in connection with the Contract and agreed with ENEA.

The Contractor shall ensure that its Subcontractors (if any) will implement the same procedure to control NCs and Deviations.

Nonconformity Reports (NCRs), Deviation Requests, and deviation consequences assessment reports are an integral part of the Contract.

The sequential number of the NCRs and the Deviation Requests shall be in line with requirements provided in [RHK-AD-011] and [RHK-AD-01].

The Contractor shall maintain an electronic register of all NCRs and Deviation Requests issued in respect of this Contract that must contain an indication of their distribution and acceptance status.

During or before the end of the Contract, all NCRs, Deviation Requests, associated reports, and any relevant documental evidence, must be included in an appendix at the Final Technical Report.

The acceptance of NCRs and Deviation Requests does not relieve the Contractor of any contractual obligation or responsibility.

5.2.1 Management of Nonconformities

The Contractor shall describe the nonconformity management system in the PQMP and shall ensure that:

- any NC is detected, and nonconforming elements are segregated.
- an updated register of all NCs and their associated Remedial or Corrective Actions is maintained and submitted to ENEA within each Progress Report.
- appropriate Remedial or Corrective Actions are implemented to prevent repetition of nonconformity.
- appropriate improvements, in the form of Preventive Actions brought about by the Corrective Actions, are implemented to prevent future nonconformities.
- a NC is raised by means of NCR in case ENEA, or its appointed representatives, issue a NC note after detection of a pertinent discrepancy (normally in the form of a Field Observation Report or in an Audit Report).

Moreover, it shall be guaranteed that if:

- the Contractor considers that a NC has occurred, or
- ENEA notifies the Contractor (in the form of a Field Observation Report or in an Audit Report) that it considers that a NC has occurred, the Contractor, within 5 working days, notifies ENEA to this effect in the form of a NCR, before any remedial action is implemented.

If a NC is found, the Contractor shall issue the NCR, and provide ENEA with a proposal for Remedial Action to remedy the NC.

No Remedial Action suggested by the Contractor is to be implemented until such Remedial Action has been approved by ENEA in writing.



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The NC shall be classified as:

- a. Major NC: divergence with impact on contractual requirements and, in particular, those specified in the contractual TS RHCR-REF-000 and/or MQS.
 - The NCR shall be sent to ENEA with proposed Remedial Actions for approval.
 - Remedial Actions shall be implemented only after ENEA written acceptance.
- b. Minor NC: divergence with no impact on contractual requirements and, in particular, those specified in the contractual TS RHCR-REF-000 and/or MQS.
 - The Contractor shall address suitable Remedial Actions to resolve the NC within its own quality system.
 - The NCR shall be sent to ENEA for information and the Remedial Actions shall be implemented.

The Contractor shall indicate how, when, and by whom NCs will be processed including those originating from its Subcontractors.

Proposed format for NCR is reported in [A3].

5.2.2 Management of Deviations

The Contractor shall describe the Deviation management process in the PQMP including the management of all Deviations initiated by the Contractor, its Subcontractors (if any), and those issued by ENEA.

This process shall ensure that:

- Deviation Requests are approved by ENEA before any implementation.
- Status of Deviations is made available to ENEA when requested.

5.2.2.1 Deviation Request originating from the Contractor

When a modification to an approved requirement is foreseen, the Contractor shall discuss it with ENEA.

If the proposal is considered beneficial, the Contractor shall request ENEA approval by issuing a Deviation Request, in the format provided in [A4].

The Deviation Request shall contain or refer to all relevant material available to enable an informed decision to be taken.

The Deviation Request shall include an assessment of the Deviation consequences in terms of technical performance, cost, delay, and risk.

The deviation shall be implemented only after ENEA formal acceptance.

5.2.2.2 Deviation Request originating from ENEA

The Contractor shall issue an impact assessment report for each Deviation Request received from ENEA.

The report should contain or refer to all relevant material available to enable an informed decision on the definite course of action to be taken and 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 from ENEA of a formal notice.

5.3 Traceability and Identification

The Contractor shall ensure traceability of material(s) as requested in the Contract TS RHCR-REF-000 and/or MQS.

The Contractor shall define in PQMP 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.



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- 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).

Raw materials, sub-assemblies/sub-components and parts shall be identified according to the Contract TS RHCR-REF-000 and MQS.

5.4 Document Management

Official language for the Project is the English language that shall be used for all project documents.

Documents required by Italian laws or prepared for Italian Authorities approval (to be agreed with ENEA RUP) shall be in Italian language.

All communications and official documentation shall be in the standard project language. In particular:

- For monolingual documentation, the language shall be English.
- For double language documentation (regulatory or safety documentation requirements), the original and reference text shall be in English, and all its interpretations will be based on the English text. In the event of a conflict between different translations, the English text will prevail. The layout to be used is a dual-column page, where both versions of the document are in parallel, with English in the left column.

The documentation shall be provided in standard formats and shall be delivered in electronic copy, or otherwise specified in other contractual documents.

All technical and management documentation issued by the Contractor for the Contract, as well as all information exchange between ENEA and Contractor, shall be managed through ENEA RUP/DEC and Contractor TRO.

All official documentation issued by the Contractor, shall be produced and issued in accordance with Applicable Document RHCR-REF-000 & RHCR-REF-001 attached to the Contract.

Applicable Document provides information/requirements about the coding and numbering systems that shall be adopted for the preparation, compilation, and identification of all type of documents to be issued by the Contractor and its Subcontractors during the execution of the Project.

Applicable Document provides also electronic templates that shall be used by the Contractor for the drafting and official issue of Project technical and management documents.

5.4.1 Information and Documentation Management

All project documents to be issued officially by Contractor, shall be managed through ENEA Electronic Document Management System (DMS) named ALFRESCO.

The procedure in [RHCR-AD-02] provides instruction for the management of documentation in ALFRESCO. Contractor personnel will have access to ALFRESCO system and, in case of needs, will be instructed by ENEA about its use.



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The Contractor shall provide a Documentation Schedule (refer to the form in [A1]), detailing all documents and records relevant to the implementation of the Contract, including work performed by Subcontractors (if any), that are planned to be issued during Contract execution.

For all documents listed in the Documentation Schedule, the Contractor shall provide at least the following information:

- Document title and codes (based on instruction provided by [RHK-AD-011] [RHK-AD-01]).
- ENEA involvement in document reviews (i.e., if the document is for approval/review or just for information) based on the instruction provided by ENEA during KoM.
- Document Status.

The Documentation Schedule shall be updated when necessary.

During the contract phase the Documentation Schedule will be the reference for the document management within the Contract.

The Contractor shall keep all necessary documents and technical information related to the Contract for monitoring, quality assurance controls, checks, and audits. If required by ENEA for its convenience, the Contractor shall provide copies of such documents.

The Contractor shall keep the documents for 10 years (or the regulatory period, whichever is longer) after the payment of the final balance of the Contract price or, if requested by ENEA, the Contractor shall transfer the requested documents to ENEA at the end of the Contract.

ENEA acceptance of Documentation Schedule or approval of technical documents such as drawings sketches, specifications, and other, shall not relieve the Contractor of its responsibility of proper execution of the Contract.

The Contractor shall propose to ENEA the acceptance of the format of all the quality records needed to control the design and manufacture (design control, traveler, NCR, etc.).

5.4.2 Documentation control

For all deliverables (including CAD data), the Contractor shall implement a drawing control system for any drawing activities, if applicable. The Contractor shall prepare, review, and approve the drawings through controlled procedures that establish the approval authorities and responsibilities.

The drawing coding system shall be in line with requirements included in the [RHK-AD-011] [RHK-AD-01]).

The following classification shall be applied to changes in drawings::

- A design change, to modify an approved design, is a “change” and shall be controlled according to the above management of deviations (otherwise agreed with ENEA RUP).
- Alteration to drawings, without addressing approved design, are defined as “Drawing Modifications” (namely modifications relating to the different stages of the drawing process, e.g., “as defined”, “as detailed” and “as built” stages).

5.4.3 Electronic Documents

Only the following electronic document file formats are acceptable for project documentation exchange and delivery. All documents must be supplied at all stages of the contract in the formats shown below (Table 2). In the event of additional formats being utilized, for example for specialized engineering calculations, fully useable data input and output files shall be provided (in English language, if available as standard inside the program). Such formats shall be previously authorized by ENEA.



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Table 2: Mandatory Document formats.

Document Type	Editable		Reference	Informative
	Format	Version	Format	Format
Text Document	docx / Rtf	Office Word 2007	pdf	-
Spreadsheet	xlsx	Office Excel 2007	pdf	-
CAD models and drawings	CATPart/ CATProduct	CATIA V5	cat	pdf of typical 3D views
CAD drawings	CATDrawing	CATIA V5	pdf	-
Schedules, Plans	mpp/xer	MS Project/ Primavera	pdf	pdf of all pages
Scans and pictures	jpg	-	pdf	-
Movie	avi	-	avi	-
Presentations	pptx	Office Power Point 2007	pdf	-
Document Sets	7z	-	-	-
Issued documents	-	-	pdf	-
Finite Element Calculations	ANSYS	-	ANSYS	pdf of typical 3D views
Documentation Schedule	docx	Office Word 2007	pdf	-
MIP	docx	Office Word 2007	pdf	-

Where the version is given, this indicates the lower version compatibility requirement.

Where editable versions exist (text documents, spreadsheets, drawings, etc.) editable versions of the deliverables shall be provided to ENEA.

Alternative formats may be specified at the KoM, with the approval of ENEA, at the sole expense and care of the Contractor.

The formats of the provided electronic files shall be authorized in advance by ENEA. The formats in Table 3 can be accepted without explicit authorization.

5.5 Visits, Inspections and Audits

The Contractor shall provide to ENEA access to the documentation, premises, and personnel, including that of its Subcontractors during all stages of the Contract for the purpose of audit, review, surveillance, and inspection.

ENEA reserves the right to make unscheduled visits to the works of the Contractor or of its Subcontractors (if any) and free access shall be provided at all reasonable times.

ENEA shall have the right to have permanent inspectors working on the Contract inside the Contractor's workshops. In this case, the Contractor shall reserve an office inside its workshops, equipped with a telephone with international access and Internet access.

ENEA can require photographs and record video of anything connected to the pertaining Contract (the obtained material shall remain confidential).

ENEA agrees to keep confidential any other information not related to the Contract that may be accessed during audit and surveillance activities.



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5.5.1 Audits and Surveillance

Planned and documented audits, reviews, surveillance, and inspection of the Contractor quality assurance arrangements may be carried out by ENEA or their appointed representatives to verify compliance with all quality and technical aspects of the Contract.

These activities may be extended to the Contractor's Subcontractors (if any). Regarding any deficiencies found, the Contractor shall implement or ensure that the Subcontractors (if any) implement corrective actions in accordance with an agreed time schedule.

ENEA shall be informed of the Contractor audits, reviews, surveillance, and inspection activities, including those involving Subcontractors. Notifications shall be sent in writing via email at least 2 weeks in advance.

If on-site inspection services exist, the notification shall be sent directly to them well in advance. In this case, only ENEA shall be notified in writing of the points identified as hold points within the time frame stipulated in the above paragraph.

The Contractor shall be responsible for all expenses derived from ENEA inspections or audits, as a result of wrong notifications. When ENEA is not able to witness an activity considered important as 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.

5.5.2 Access of ENEA Observers

ENEA shall have the right to be accompanied by observers to the agreed surveillance and audits visits. These observers will be identified in advance and agreed with the Contractor and will belong to ENEA. All the observers shall be bound by appropriate confidentiality obligations to be agreed in advance.

5.5.3 Third Party Inspection Authority

ENEA may, for the purpose of this Contract, appoint an independent inspection authority to certify that activities are carried out in accordance with the agreed codes and standards.

The Contractor shall arrange free access for the inspector(s) to its works or at the works of its Subcontractor, so that the inspector(s) duties may be carried out. The Contractor shall provide the inspector(s) with copies of all relevant test reports so that he/she is able to certify that deliverables meet the technical requirements.



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6 Templates

- A1:** Documentation Schedule Form
- A2:** Deviation Request Form
- A3:** Nonconformity Report Form
- A4:** Subcontracting Schedule Form
- A5:** Contractor Release Note

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



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A2. DEVIATION REQUEST FORM

Section 1 – to be completed by the Contractor

DR / Number:		Revision Number:		Sheet:		
1. ENEA 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	<input type="checkbox"/> NO	<input type="checkbox"/> YES	Report:			
9.2 SCHEDULE	<input type="checkbox"/> NO	<input type="checkbox"/> YES	Report:			
9.3 PERFORMANCE & COST	<input type="checkbox"/> NO	<input type="checkbox"/> YES	Report:			
9.4 OTHER:	<input type="checkbox"/> NO	<input type="checkbox"/> 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]



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A3. NONCONFORMITY REPORT FORM

Section 1 – to be completed by the Contractor

1. ENEA 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: <input type="checkbox"/> use as is <input type="checkbox"/> rework <input type="checkbox"/> repair <input type="checkbox"/> reject							
8. LIST OF ATTACHMENTS:							
9. PROPOSED NONCONFORMITY CATEGORY: <input type="checkbox"/> MINOR NONCONFORMITY <input type="checkbox"/> 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



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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					
<input type="checkbox"/> POSITIVE <i>Brief description</i>					
<input type="checkbox"/> NEGATIVE <i>Brief description</i>					
4. Notes					
Contractor's Technical Responsible			Contractor's Quality Representative		
<i>Name</i>	<i>Signature</i>	<i>Date</i>	<i>Name</i>	<i>Signature</i>	<i>Date</i>

Section 4 – to be completed by ENEA

ENEA's approval					
ENEA Technical Responsible Officer			ENEA Representative		
1. DECISION:			2. COMMENTS:		
<i>Name</i>	<i>Signature</i>	<i>Date</i>	<i>Name</i>	<i>Signature</i>	<i>Date</i>

[Electronic Template will be made available to the Contractor]



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A5. CONTRACTOR RELEASE NOTE

Section 1 – to be completed by the Contractor

1. ENEA 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

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

Section 3 – to be completed by ENEA

<p>ENEA Technical Responsible Officer</p> <p>1. DECISION:</p>	<p>ENEA Representative</p> <p>2. COMMENTS:</p>				
<i>Name</i>	<i>Signature</i>	<i>Date</i>	<i>Name</i>	<i>Signature</i>	<i>Date</i>

[Electronic Template will be made available to the Contractor]