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Technical Specifications (In-Cash Procurement)

General Management Specification for Service and Supply

The purpose of this General Management Specification for Service & Supply ("GM3S") is to define the main requirements applicable for the implementation of service or supply scope of work. If any part of the scope is taking place at IO Site, it is covered in section 13 of this document, complemented by General Management Specification for Executing Entities at the ITER Site

The GM3S is the reference document for the management of the scope that is to be performed in preparation for, and during ...

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1 Purpose

The purpose of this General Management Specification for Service & Supply ("GM3S") is to define the main requirements applicable for the implementation of service or supply scope of work. If any part of the scope is taking place at the ITER Site, section 13 of this document shall also apply, complemented by Ref [1].

The GM3S is the reference document for the management of the scope that is to be performed in preparation for, and during the implementation of the Contract, in conjunction with the technical specification(s) and the Contract conditions.

The GM3S presents the main principles and requirements which the Contractor must take into account during the implementation of the scope of work and defines the minimum standards expected for the management of the Occupational health, safety ("OHS"), environment, nuclear safety, quality, contact control and all associated deliverables. The Contractor shall comply with all the requirements of the latest instructed version of the GM3S and reference documents.

2 Definitions and acronyms

2.1 Definitions

Service Contract: shall mean any Contract that involves performing and providing value through an action, referred to as a service, rather than providing tangible goods.

Supply Contract: shall mean any Contract for the delivery of a defined set of products, goods or items.

Works Contract: shall mean a Contract for building, construction, fabrication, completion, erection, installation, fitting out, improvement, modification, repair, maintenance, renovation, alteration or commissioning of any immovable property.

Construction Site: Means IO construction site as defined in Appendix I of this document (shaded area)

Areas under Operation: Means IO premises at the ITER Site that is not Construction Site as defined in Appendix I of this document.

Site or ITER Site or IO Site: covers the Construction site and Areas under Operation. By extension, any place where IO staff is operating on a regular basis is to be considered ITER Site, if specified as such by IO.

Off Site: Anywhere that is not ITER Site.

Contractor: the economic operator who have signed the Contract in which this document is referenced, as defined in the Special Conditions of the said Contract.

Subcontractor: shall mean an economic operator who is under contract to a Contractor providing supplies, services or works to the IO, being understood that the subcontractor shall perform, under responsibility of the Contractor, with independence and free from any subordination, a specific part of the obligations of the Contract.

Supplier shall mean a legally registered entity, that can provide standard / catalog goods or material, or standard services to a Contractor, or a subcontractor, that will enable the performance of the scope of work to be provided by the Contractor or subcontractor.

Mandatory Template: model of document provided by IO that the Contractor shall use in order to submit the said document and which cannot be modified without the prior agreement of the IO.

Typical Template: model document provided by IO for information that the Contractor may use in order to submit this type of document.

Logistics Service Provider (LSP): operator contracted by any party who provides logistics services, such as but not limited to: transportation, storage, custom clearance services…

Global Logistics Contractor: Primary IO LSP who operates the logistics for the IO at ITER Site and Off-Site.

2.2 Acronyms

The following acronyms are the main one relevant to this document.

Abbreviation	Description
ANB	Agreed Notified Body
CFSI	Counterfeit Fraudulent Suspect Item
CCN	Contractual Change Notice
CMA	Construction Management as Agent
CRO	IO Contract Responsible Officer
CRN	Contractor Release Note
DR	Deviation Request
DRR	Delivery Readiness Review
EPRO	Environment Protection Responsible Officer
FAT	Factory Acceptance Test
FME	Foreign Material Exclusion
FR	Functional Reference
GLC	Global Logistics Contractor
GM3S	General Management Specification for Service and Supply (this document)
GTD	Generic Document Title
OHS RO	Occupational Health & Safety Responsible Officer
ILM RO	Integrated Logistics & Materials Responsible Officer
IO	ITER Organization
ITP	Inspection & Test Plan
KOM	Kick-Off Meeting
LSP	Logistics Service Provider
LTI	Lost Time Injury
MIP	Manufacturing Inspection Plan
MOM	Minutes Of Meeting
NCR	Non Conformity Report
NB	Notified Body
PE/NPE RO	Pressure Equipment / Nuclear Pressure Equipment Responsible Officer
PNI	Part Number of ITER
PPE	Personal Protective Equipment
PRE	Environmental Respect Plan
PRO	Procurement Responsible Officer

QARO	Quality Assurance Responsible Officer
RFI	Request For Information
SAF	Subcontractor Acceptance Form
SAT	Site Acceptance Test
SLP	Service Logistic Provider
SRO	Safety Responsible Officer
TDF	Technical Document Family

3 Applicable documents

It is the responsibility of the Contractor to identify and request any documents that would not have been transmitted by IO, including the below list of applicable documents.

The Contractor must comply with the reference documents listed below.

This GM3S takes precedence over the applicable documents listed in this section. In case of conflicting information, it is the responsibility of the Contractor to seek clarification from IO.

Upon notification of any revision of the applicable documents transmitted officially to the Contractor, the Contractor shall advise within 4 weeks of any impact on the implementation of the Contract. Without any formal response after this period, no impact will be considered.

You can download each document from IO trusted source by clicking on the document title

Ref	Title	IDM Doc ID	Version
1	General Management Specification for Executing Entities at the ITER Site[1]	YX55YY	2.3
2	Procedure for the Usage of the ITER CAD Manual	2F6FTX	1.1
3	Contractor Safety Management Procedure	Q2GBJF	1.4
4	Chemical Safety Management Tool - User Manual	W6EREY	1.0
5	Working Instruction for the Delivery Readiness Review (DRR)	X3NEGB	2.0
6	Provisions for Implementation of the Generic Safety Requirements by the External Actors/Interveners	SBSTBM	2.2
7	Procedure for the CAD management plan	2DWU2M	2.2
8	ITER Information Technology (IT) Acceptable Use Principles	27ZPBE	2.8
9	ITER Policy on Safety, Security and Environment Protection Management	43UJN7	3.1
10	AVEVA E3D CAD Manual	8QZS2R	1.0
11	ITER Site Access Procedure	S3893D	3.1

[1] If applicable as defined in section 13 of this document.

12	Environmental requirements	97WRFP	2.2
13	IO / In-Cash Contractor Documentation Exchange and Storage Working Instruction	G8UMB3	4.1
14	List of Deliverables Form	73MVYS	2.0
15	ITER Procurement Quality Requirements	22MFG4	5.1
16	Requirements for Producing a Quality Plan	22MFMW	4.0
17	Quality Classification Determination	24VQES	5.2
18	Software Qualification Policy	KTU8HH	2.0
19	Procedure for the management of Deviation Request	2LZJHB	8.1
20	Procedure for the Import and Export of Goods	LF4QST	2.0
21	Export Control Procedure	JE3N8C	2.2
22	ITER Site Permit to Work Overarching Procedure	3E8289	3.1
23	Procedure for Analyses and Calculations	22MAL7	6.6
24	Specification for CAD data Production in ITER direct contracts	P7Q3J7	2.0
25	CAD Manual 07 - CAD Fact Sheet	249WUL	6.2
26	Procedure related to Information Protection Levels	44GRMV	3.2
27	Procedure for Management of Nonconformities	22F53X	9.1

4 Organization, roles and responsibilities

4.1 Organization

4.1.1 ITER Project

ITER ("The Way" in Latin) is one of the most ambitious energy projects in the world today.

In southern France, Saint Paul-lez-Durance, 33 nations are collaborating to build the world's largest tokamak, a magnetic fusion device that has been designed to prove the feasibility of fusion as a large-scale and carbon-free source of energy based on the same principle that powers our Sun and stars.

The primary objective of ITER is the investigation and demonstration of burning plasmas—plasmas in which the energy of the helium nuclei produced by the fusion reactions is enough to maintain the temperature of the plasma, thereby reducing or eliminating the need for external heating. ITER will also test the availability and integration of technologies essential for a fusion reactor (such as superconducting magnets, remote maintenance, and systems to exhaust power from the plasma) and the validity of tritium breeding module concepts that would lead in a future reactor to tritium self-sufficiency.

Thousands of engineers and scientists have contributed to the design of ITER since the idea for an

international joint experiment in fusion was first launched in 1985. The ITER Members—the Government of the People's Republic of China, the European Atomic Energy Community (Euratom), the Government of the Republic of India, the Government of Japan, the Government of the Republic of Korea, the Government of the Russian Federation and the Government of the United States of America—are now engaged in a 35-year collaboration to build and operate the ITER experimental device in European Union, at Saint Paul lez Durance, in southern France, and together bring fusion to the point where a demonstration fusion reactor can be designed (the "ITER Project"). The ITER Members contribute to the resources of the ITER Organization through appropriate legal entities called Domestic Agencies (DA).

More information about the ITER Project can be found on the ITER website: https://www.iter.org/

4.1.2 ITER Organization

The ITER Organization is an intergovernmental organization governed by international agreements as detailed in the Contract conditions and the nuclear operator of the ITER facilities which are classifies as a Basic Nuclear Installation (INB) under French nuclear laws and regulations and as defined in Section 5.3.1 below.

4.2 Role and Responsibilities

4.2.1 Contractor Representatives

The Contractor shall appoint one or several Contractor representative(s) for contractual, technical and invoicing matters for the duration of the Contract and shall give them all authority necessary to act on the Contractor's behalf under the Contract. As such, they will be the direct contact for the CRO and shall be responsible to (but not limited to):

- Understand the Contract requirement in depth and be fluent in English language
- Disseminate Contract requirements within the Contractor organization and the Contractor supply-chain
- Put in place the appropriate structure and resources to successfully deliver the Contract
- Provide all Contract management plans
- Ensure timely delivery of documentation
- Ensure meeting the contractual deadlines
- Assess any Contract Risk or Opportunities
- Provide the progress reporting
- Organise required meetings (technical, review, ad hoc…)

Any change in Contractor Representative(s) personnel has to be submitted to the IO for approval. The Contractor shall ensure the continuity of the Contractor Representative role in case of any approved change.

In case of consortium, in addition to the consortium leader representative who acts in the name and on behalf of the legal entities forming the Contractor, each consortium member shall also nominate representative(s) with same role and responsibilities for their respective scope in the consortium.

4.2.2 IO Representatives

4.2.2.1 CRO

The CRO is responsible to manage the Contract in relation with the Contractor. As such, the CRO is the primary contact for Contractor Representative. The CRO is coordinating all aspects of the implementation of the Contract with the support of relevant internal stakeholders when deemed necessary, such as but not limited to: OHS responsible officer, QA responsible officer, ILM RO, Technical specialists, PRO…

The CRO is the recipient of the progress reports and take part to the progress meetings organized by the Contractor Representative. The CRO is also in charge of ensuring the deliverables under the Contract are dully submitted by the Contractor and reviewed accordingly. The CRO is following up on the Contractor's invoices.

4.2.2.2 PRO

The PRO has supported the conclusion the Contract with the Contractor and as such is supporting the CRO in any commercial aspect of the implementation of the Contract. This is good practise for the Contractor to keep the PRO informed of any event that could impact the Contract implementation and to a broader level to share the progress of the Contract implementation with the PRO.

4.2.2.3 QARO

The QARO is in charge of reviewing all quality aspects of the Contract, in support to the CRO. QARO is namely involved in reviewing the QA Plan.

4.2.2.4 OHS RO

The OHS RO is in charge of reviewing all Occupational Health & Non Nuclear Safety aspects of the Contract, in support to the CRO. OHS RO is namely involved in reviewing the OHS documentation (Risk assessment, Prevention plan…).

4.2.2.5 SRO

The SRO is in charge of reviewing all Nuclear Safety aspects of the Contract, in support to the CRO.

4.2.2.6 PE/NPE RO

PE/NPE responsible officer has a specific focus on all pressure equipment requirements, nuclear or not.

4.2.2.7 EPRO

The environment protection responsible officer is in charge of reviewing all environmental aspects of the Contract, more specifically the PRE.

4.2.2.8 ILM RO

The ILM RO is involved with coordinating the logistics, delivery, storage at the ITER Site, and preservation of the procured materials. This includes reviewing or approving deliverables such as the contractors release notes, packing lists, delivery reports, packing/handling procedures, storage/preservation documents, and Transportation Quality Plans (if "non conventional" load as defined in section 9.3.).

5 OHS, environmental and nuclear safety requirements

Pursuant to Article 14 of the ITER Agreement, the ITER Organization shall observe the national laws and regulations of France in the fields of nuclear safety, radiation protection, licensing and nuclear substances. The ITER facilities are therefore categorized as a Basic Nuclear Installation under French Law (Installation Nucléaire de Base – INB-174). The IO is the nuclear operator of this INB as defined in the French "Order of 7 February 2012 setting the general rules relative to basic nuclear installations" ("INB Order").

As the nuclear operator, the IO has defined a policy for protecting the interests mentioned under Article L. 593-1 of the Environmental Code: Ref [9]- the ITER Policy on Safety, Security and Environment Protection Management.

5.1 OHS

5.1.1 General OHS requirement

The Contractor shall put in place an OHS Policy and provide this document upon IO request.

The Contractor shall keep the IO informed about any LTI or Near-miss related to OHS matters occurring during the implementation the Contract at the ITER Site, in their premises or at their sub-Contractor premises, within 24 hours of the occurrence. The Contractor shall then provide the associated root cause analysis and corrective action plan no later than 15 working days from the occurrence of the event.

Failing to inform the IO of any OHS incident can be considered as a breach of Contract.

5.1.2 Specific OHS requirement when working at the ITER Site

Refer to section 13 – Additional general requirements for working at the ITER Site.

5.2 Environmental Requirements

5.2.1 Environmental policy

It is expected for the Contractor to have an environmental policy in place and hold an environmental management certification such as ISO 14001 or alternatively an environmental program approved by IO representatives.

5.2.2 Specific Environmental requirement when working at the ITER Site

Refer to section 13 – Additional general requirements for working at the ITER Site.

5.2.3 Hazardous material

It is the responsibility of the Contractor to identify and inform the IO of any hazardous material to be delivered at the ITER Site in the framework of their scope of work under the Contract.

The Contractor is then required to communicate all the relevant documentation (such as but not limited to: Material Safety Datasheet) and expected quantities to be delivered. The CRO will organise this information to be entered in the IO Chemical Product database, either directly or by the Contractor if need be as per Ref [4].

5.3 Nuclear & Beryllium Safety

Regarding Beryllium, this section concerns Beryllium after radiological activation of dust particles. Non activated Beryllium dust material is considered as a Chemical Hazard and covered in section 5.2.3 of this document.

5.3.1 General requirements

If the Contract involves PIC or PIA as defined below, the Contractor shall comply with the all requirements expressed in "Provisions for implementation of the generic safety requirements by the external actors/interveners" Ref [10]. The Contractor shall explain in its quality system or in a dedicated quality plan the measures taken to ensure compliance with these requirements. The Contractor shall ensure the propagation of these requirements to all its subcontractors and/or suppliers involved in PIC or PIA.

5.3.2 Protection Important Component (PIC)

A Protection Important Component ("PIC"), as per INB Order Article 1.3, is defined as "a component which is important for protecting the interests mentioned under Article L. 593-1 of the Environmental Code (nuclear security – i.e. nuclear safety, radiation protection, prevention and fight against malicious acts, and also civil security actions in the event of an accident –, public health and sanitation or protection of nature and the environment), i.e. structure, equipment, system (programmed or not), material, component or software that is present in the Basic Nuclear Installation (INB) or that is under the responsibility of the nuclear operator and that implements a function required for the demonstration mentioned under the second paragraph of Article L. 593-7 of the Environmental Code (safety demonstration) or that ensures that this function is implemented;

The list of PIC applicable to the Contract is provided in the Technical Specifications of the Contract.

5.3.3 Protection Important Activities (PIA)

As per articles 1.3 of the INB Order, a PIA is defined as an "Activity important for protecting the interests mentioned under Article L. 593-1 of the Environmental Code (public safety, health and sanitation, the protection of nature and of the environment), i.e. activity that falls under the technical or organizational provisions mentioned under the second paragraph of Article L. 593-7 of the Environmental Code or that is liable to affect them;"

The Contractor shall put in place a technical control, as defined in Article 2.5.3 of the INB Order, for each PIA. Parties carrying out technical monitoring for a PIA are distinctly separate from the parties who perform the activities.

PIAs and their technical control shall be performed according to procedures (demonstration of compliance a priori) and be properly recorded (demonstration of compliance a posteriori).

The performers of PIAs and of their technical control shall have necessary skill and qualification as per INB order 2.5.5.

The list of PIA carried out under the Contract is provided in the Technical Specifications of the Contract.

5.3.4 Defined Requirements

As defined in Article 1.3 of the INB Order, the Defined Requirements are "requirement assigned to a protection important component so that it fulfils – with the expected characteristics – the function provided for in the demonstration mentioned in the second paragraph of Article L. 593-7 of the Environmental Code, or to a protection important activity so that it fulfils its objectives as regards this demonstration".

In other words, it means any requirement that has been assigned to a PIC or a PIA so that it may perform the function provided for in the safety demonstration.

The applicable "Defined Requirements" are provided by the IO in the Technical Specifications of the Contract. The Contractor shall ensure that these requirements are propagated to the Subcontractors and Suppliers as needed and a demonstration of compliance shall be provided upon request of the CRO or SRO.

5.3.5 Radiation Safety

If the Contract involves the delivery, the storage, the handling or use of any equipment or component containing or producing ionizing radiation on IO site, the Contractor shall get authorization from the radiation competent entity, SQD/NS/RBSE before proceeding. Unless specified differently in the Contract, the request and authorization shall be done via email to radiation competent officer, whose contact detail will be provided by the CRO.

5.4 PE/NPE

Pressure Equipment (PE) are equipment in the scope of the Pressure Equipment Directive 2014/68/UE, Nuclear Pressure Equipment (NPE) are equipment in the scope of the French Order dated 30 December 2015 (also called ESPN Order) and classified as an assembly of Pressure Equipment/Nuclear Pressure Equipment in accordance with Articles L.557-1 and following, Articles R.557-1-1 and following of the French Environmental Code (referring to Directive 2014/68/UE concerning Pressure Equipment) and with amended French Order 30 December 2015 concerning Nuclear Pressure Equipment. They are called ESP/ESPN items. The ESP/ESPN items shall be designed and manufactured in conformity with specific requirements of this Order concerning Pressure Equipment/Nuclear Pressure Equipment and the relevant French laws and regulations.

During the manufacture of PE/NPE, depending on the classification of the equipment an official body (contracted by the manufacturer of the PE/NPE) has to be involved in the conformity assessment, called: Notified Body (NB) for PE and Agreed Notified Body (ANB) for NPE.

5.4.1 IO being the manufacturer

When the IO acts as manufacturer of PE/NPE, the Contractor and all Subcontractors and Suppliers (whatever the level) performing design, manufacturing and/or test activities shall develop procedures describing the activities in compliance with regulatory and IO requirements and submit them to IO for approval and NB/ANB for acceptance (when requested by the regulations), prior to starting the implementation.

All along the manufacturing process, the Contractor shall supply all the necessary documentation, allowing the IO as manufacturer to sign the regulatory declaration of conformity at the end of the manufacturing process.

5.4.2 Contractor being the manufacturer

PE/NPE not manufactured by IO must be delivered with their regulatory Declaration of Conformity and Instruction Notice (or Operation Manual) written in English according to the requirement of the Contract and in French according to the requirements of the regulations.

6 General Contract Requirements

6.1 Contract Management

6.1.1 General

The Contractor shall nominate as a minimum one (1) representative as defined in section 4.2.1. The Contractor representative will act as the project manager of the Contract and as such will have to cover all aspects of the Contract and be responsible to meet all Contract requirements. The Contractor representative can delegate part of her/his responsibilities within their organization but will remain ultimately the main point of contact for the CRO and any other IO stakeholders involved in the management of the Contract. In case of consortium, below requirements are applicable to each consortium member and consortium leader representative shall organise the appropriate level of communication with the IO representatives.

6.1.2 Communication

Communication is key to the success of a Contract implementation.

6.1.2.1 Organisation

Roles for key IO stakeholders are define in 4.2. The Contractor shall define their key personnel and their communication organization for the implementation of the Contract:

- in a dedicated section of the Management Plan,
- in a dedicated section of the QA plan if Management Plan does not apply,
- or for more complex Contract in a dedicated communication plan, as required in the Technical Specifications or agreed during the KOM.

6.1.2.2 Means of communication

Face to face, telephone and email communication are considered informal communication and cannot be contractually bidding. Communication is considered formal only if following the means of submission as defined in section 6.1.2.3 and 6.2.

6.1.2.3 Contractual Letters

In case the Contractor would like to raise any contractual matters, they shall send contractual letter by registered letter attention to the CRO and the PRO and signed by Contractor authorised person. No contractual commitment can be considered until the Contract is dully amended by the Parties for the said commitment.

6.1.3 Contract Management Plan

The Contractor shall provide a contract management plan for any contract above 150,000 euros. The contract management plan is required to cover the description of the organization put in place by the Contractor to serve the Contract, dealing with but not limited to: key personnel, key

responsibilities, milestone dates, escalation, communication and performance management arrangements, subcontracting organization, EU directive management, CFSI management.

The requirement to produce a QA plan as per Ref [16] also call for some of the above topic to be covered for contract below 150,000 Euros where no contract management plan is mandatory. Topics covered in one plan can be referenced in the other.

6.1.4 Contract Control

6.1.4.1 Contract Implementation Schedule

The Contractor shall develop a schedule for their activities covering all the tasks within the Contract and submit this document for review and approval, initial version to be reviewed at the KOM.

The Contractor will show in their schedule all the required tasks to cover their full scope under the Contract, Including but not limited to:

- Contract gates as milestones
- Engineering activities;
- Procurement;
- Subcontracting activities
- Manufacturing
- Assembly & installation
- Works preparation and mobilizations;
- Tests and inspections including mechanical completion milestones.

The schedule for deliverables are not required to show in the Contract Implementation Schedule as this is covered under the Document Schedule.

6.1.4.2 Progress report

The progress report is a key document to follow-up on the Contract implementation by all the Parties.

6.1.4.2.1 Frequency and Template

The Contractor shall prepare on a monthly basis a progress report using the template as per Appendix IV. This report is to be submitted at minimum one (1) week prior to the monthly progress meeting to IO.

6.1.4.2.2 Progress measurement

The calculation of the progress is completed by the Contractor based on agreed deliverable schedule, unless otherwise agreed by the Parties. Each listed document has a relative weight (1 to 5). The progress is calculated for each document as follows: 10% when the slot for document submission is created, 70% when the document is submitted for review, 100% when document is approved. The excel Document Schedule template in Appendix II enables to calculate the aggregated percentage of progress.

The progress measurement is to be reported in the relevant section of the Progress Report.

6.1.4.3 Contract Risk & Opportunities

For contract above 150,000 euros, Contract Representative has to check and maintain a register of the Contract risks and opportunities with any mitigation action put in place to limit the risk(s). Outcome of this analysis is to be reported in the Progress Report.

6.1.5 Contract Gates

The contract gates are milestones that request a formal review and validation through a dedicated meeting. The contract gates are conditioned by the delivery of associated documents as identified in the Document Schedule. If the Contract Specific Terms and Conditions associate a gate to a milestone payment, all documents associated to that gate shall be approved to consider the payment milestone is reached.

6.1.5.1 KOM

The KOM is the first contract gate. The CRO organises the meeting with support of PRO no later than one (1) month after the Contract enters into force, unless agreed differently between the parties.

The Contractor representatives, IO CRO and IO PRO shall prepare the KOM using the KOM template as available in Appendix III. This document will be signed by the attendees and capture the KOM review discussions and decisions if any.

The Contractor Representatives, including Sales representative who participated to the Contract negotiations, IO CRO, IO PRO constitute the minimum attendees to the KOM and shall be completed with (partial) attendance of relevant personnel from both Parties, like but not limited to technical specialist, QA, OHS, SRO, Safety, Logistics, Document Control representatives.

For any contract above 1M euros, the KOM has to take place face to face at ITER premises unless agreed differently by the parties. For any contract below 1 M euros, the KOM can take place remotely.

The Contractor shall submit at minimum one week before the KOM the following document in advanced draft (when applicable but not limited to) : Contract Management plan, Contract implementation Schedule, Documentation Schedule, QA plan, safety risk assessment documents.

6.1.5.2 Contract Gates for Supply

The below gates as defined hereafter call for a dedicated review meeting to validate that the Contract implementation can carry-on. The minimum associated list of document required to be approved prior to each Contract gate review is defined in the technical specification and shall be captured in the Contractor document schedule.

6.1.5.2.1 Design review

The design review might be split in a preliminary design review and final design review depending on the complexity of the design, as either stated in the Technical Specification or further agreed by the parties. If no design by the Contractor is involved, this gate does not apply.

6.1.5.2.2 Procurement review

The procurement review is the review of the Contractor procurement arrangement to complete the scope under the Contract. If no procurement by the Contractor is involved, this gate does not apply.

6.1.5.2.3 Manufacturing Readiness Review

The manufacturing readiness review is key to ensure that all requirements are met prior to start the manufacturing. If the scope of supply only covers for off the shelves items, this gate does not apply.

6.1.5.2.4 FAT readiness review

The FAT readiness review is key to ensure that all the requirements for the factory acceptance test are met. If a SAT is also considered, this meeting shall also cover for this scope unless agreed

differently by the parties. If the scope of supply only covers for off the shelves items, this gate does not apply provided the Contractor is able to provide type test procedure and records.

6.1.5.2.5 Delivery Readiness Review

The purpose of the DRR is to review and validate Contractor's documents, as developed in Ref [5]:

- CRN, template in Appendix VII
- Delivery Report, template in Appendix XIII
- Native-file Packing List, template in Appendix XII
- Storage & Preservation requirements, typical in Appendix XIV
- Customs documents: Packing list and Pro-forma invoice, but other ad-hoc documents may be requested, as developed in Ref [20].
- Transportation Quality Plan (if " non-conventional" load)
- Lifting, handling, and/or Packing procedures or requirements
- and/or any other technical or logistical information that is needed so that the material can be adequately managed through transportation, reception, storage, preservation and ultimately into ITER construction and assembly.

No shipment is allowed without a successful DRR.

Please refer to Section 9 that further develops the logistics requirements.

6.1.5.3 Contract Gates for Service

The gates for Service have to be defined in accordance with the scope of service as developed in the technical specification and formalized at the KOM.

6.1.5.4 Close-out

The close-out is the last contract gate. It is managed is by the PRO in coordination with the CRO, checking that all the contractual aspects of the Contract have been fulfilled by each Party, with the exception of obligations surviving the delivery of the last milestone (such as but not limited to: warranty).

The PRO will send the close-out letter to the Contractor representative as per Appendix IV for validation within 15 calendar days (passed this time, close-out will be considered approved by default by the Contractor).

This last gate does not call for a formal meeting unless agreed differently by the Parties.

6.1.6 Meetings

Meetings can be organised face to face or remotely as agreed by the Parties with the exception of the KOM that has to be face to face at IO site for any contract above one (1) Million euros, unless specified differently in the Technical Specification.

The Contractor representative and CRO have to align prior to any meeting about the expected attendees and the agenda. The Contractor representative has to organise the meeting and provide the MOM to the CRO for review no later than one (1) week after the meeting took place.

6.1.6.1 Progress Meetings

A progress review meeting is to be held on a monthly basis between the Contractor representative and CRO with the appropriate support of relevant stakeholders. The planning of those meetings is to be agreed during the KOM and dates booked accordingly. The Contractor to ensure the timely submission of the Progress Report minimum one (1) week prior to the meeting.

6.1.6.2 Gate review meetings

Gate review meeting are to be planned and showed in the Contract Implementation Schedule as milestones. Those dates are to be reported in the Document Schedule to ensure the appropriate forecast submission dates for the documentation related to each of those gates are known and met.

6.1.6.3 Pre-inspection Meeting

This specific meeting is defined in the below section 7.4.4.

6.1.6.4 Ad hoc Meetings

Upon request of any party, the Contractor or IO, ad hoc meeting can be organized to tackle any specific topics not covered in the planned meetings.

6.1.7 Specificity for Framework Contract

In case of Framework Contract, the above 6.1 Contract management requirements are applicable to each Task Order unless agreed differently by the CRO. It means that each Task Order is to be managed as a contract of its own.

But the Contractor Representative of the Framework Contract shall also provide a global Progress report and organise a monthly review for the Framework Contract activities that include a summary of all on-going Task Orders.

6.2 Data and Documentation Management

6.2.1 Document Schedule

The document schedule is a key document to execute the Contract.

The Contractor shall build their document schedule using the template available in Appendix II, in accordance with the minimum required documentation identified in the Technical Specifications while complying with the applicable rules & regulations as well as any other requirements covered in the Contract.

6.2.2 Documentation transmittal and review

The Contractor shall transmit their document via the IDM system using the IDM Exchange folder area, with the exception of and when applicable:

- Computer-Aided Design (CAD) files that have to be transmitted in the CAD database (SMDD).
- Non-Conformity Report (NCR) that have to be transmitted via the NCR Database.

Specific documents may be transmitted via other IO tools as defined in the Technical Specifications or as further agreed in written by the Parties.

6.2.2.1 IDM

Detailed instructions on IDM document management is defined in Ref [13].

6.2.2.1.1 Document folder and slot creation

The definition of document type and the associated creation of the IDM folders are defined in Ref [13] paragraphs 5.2 to 5.4 and 5.10.

The creation of the slot for the document submission shall be organised using the template in Ref [14]] as explained in Ref [13] paragraph 6.2.1.

6.2.2.1.2 Document requirement

The requirement for the document cover page are defined in Ref [13] section 5.11.5. The overall requirements to comply with are further developed in all other sections of Ref [13] paragraph 5.11, including document formatting.

6.2.2.1.3 Document Submission

The process for document submission is defined in Ref [13] paragraphs 5.6, 5.7 & 5.8 and further developed in Section 6.2 thereof. This includes all incoming and outgoing documents as well as communication related to the execution of the Contract.

Unless otherwise specified, the Contractor's documentation must be reviewed by the IO representative within 28 calendar days as follows:

- The review duration shall start after receipt of the Contractor's documentation in the documentation system exchange area.
- Upon receipt of the acceptor's decision that the document is not acceptable, the Contractor shall update and submit their revised document within 10 calendar days.

6.2.2.1.4 Submission of Non Conformance Reports

The Contractor shall use the IO NCR database for the submission of any NCR. Access and training on how to use the database will be organized by the QARO upon request from the Contractor.

If an exceptional deviation to that requirement is granted, the Contractor could then submit any NCR as a standard document. Then, and only then, section 5.6.3 of Ref [13] would not apply.

6.2.2.2 CAD

The Contractor shall ensure that all CAD Data (Schematics, Models and Drawings) delivered to IO comply with Ref [7] - Procedure for CAD Management Plan, and with Ref [2] for Mechanical design activities and with Ref [10] for Plant design activities.

The reference scheme is for the Contractor to work in a fully synchronous manner on the ITER CAD platform as described in Ref [24]. This implies the usage of the CAD software versions as indicated in Ref [25] and the connection to one of the ITER project CAD data-bases. Alternatively and if agreed by the parties, other IO CAD repositories can be used.

IO may reference a Design Collaboration Implementation Form (DCIF) in the Technical Specification and/ or in the Contract to define any specific requirement associated to CAD implementation.

If Contractor deviates from contractual CAD requirement, they expose themselves to cost recovery for any corrective work performed by IO.

6.2.3 Contractor Document Record Keeping

6.2.3.1 General

It is requested that all documents produced by the Contractor in the implementation of the Contract are recorded safely at Contractor end based on their Quality Assurance process and IT security policy.

6.2.3.2 Radiographic record keeping

When applicable, the Contractor is required to deliver the radiographic record primarily in digital format that allows the same accurate interpretation as a Physical radiographic record and answer to traceability requirements to ensure re-interpretation as defined in applicable Code and Standard. If for technical reason digital recording is not possible, the Contractor will have to arrange delivery of the original documents to Iter site (including the preservation during the transportation).

The date of delivery of those records and any other relevant conditions will have to be approved by the CRO and mutually agreed at the KOM in compliance with the Contract.

It is of the utmost importance that for PIC/PIA components, QC1 and/or PE/NPE, radiographic records are dully identified and transmitted.

6.2.3.3 Pressure Equipment record keeping

If Pressure Equipment Directive (Directive 2014/68/EU dated 15/05/2014) is applicable for scope of Contract, the Contractor has to keep related documents for 10 years after releasing their pressure equipment on the market.

6.3 Information protection

Certain types of information within the ITER Organization shall be identified and protected from unauthorized access, misuse, modification, disclosure and/ or destruction. Implementing the right level of protection allows the best protection of the information and informs people accordingly, further guidance can be found in Ref [26] - Procedure related to Information Protection Levels.

By default and except if mentioned differently in the Contract or in the Technical Specifications, the information used within the IO (i.e. not produced expressly for public information and nor for official use nor specifically designated) is “non-public” information and “unclassified”. The documents listed in the document schedule shall identify the information protection level in line with the Technical Specifications requirements, defaulted to “non-classified”.

The “need-to-know” principle shall be applied to ensure that information is accessible only to those who need such information in order to carry out their work or their mission efficiently. The Contractor undertakes to do everything necessary to ensure that the IO's data is in no way accessible or visible to the Individuals who do not have the need to know or any third party.

6.4 Subcontracting

6.4.1 General

6.4.1.1 IO Prior consent on subcontracting.

The Contractor shall not subcontract any part of the Contract without prior written authorisation from the IO. To that respect, the Contractor shall provide the ITER Organization a Subcontractor

Acceptance Form (including the list of documents mentioned in the said document, see template in Appendix VI).

The SAF and the associated documents shall be submitted to the IO as a unique document. The information included in the SAF shall be submitted in the official language of the country where the subcontractor is established. Where the language of such documents is not English, an official translation in English shall be provided by the Contractor. Such official translation shall be certified unless otherwise agreed with the IO.

No commencement of subcontracted works or services is allowed before IO prior written consent.

6.4.1.2 Management of subcontractors

The Contractor is the interlocutor of their sub-Contractor(s). The Contractor shall define in their Contract Implementation Plan (or QA plan if Contract implementation plan does not apply) the communication set-up between all the parties including IO. In any case shall IO representative provide direct instruction to sub-Contractor with the exception of breach of HSE rule.

6.4.1.3 Critical activities

The Contractor shall identify all their subcontractors, with special focus on any subcontractor which scope involve critical activities, such as PIC or PIA components, PE or NPE components, QC1 components or any scope that the Contractor identifies as key in their supply chain.

6.4.1.4 Subcontracting limits

If duly authorised as 6.4.1.1 above, sub-contracting is allowed up to one level of subcontracting only, except otherwise provided in the Special Conditions.

The Contractor shall not subcontract more than 30% of the total Contract Price or of the Maximum Amount of the Contract, except otherwise formally provided in the Special Conditions.

The Contractor shall not subcontract the management of the Contract.

6.4.2 Subcontractor Follow-up

The Contractor shall have a process for subcontractors' selection through assessment and analysis of their competencies, facilities and equipment to ensure that they have the capability to conform to the Contract requirements, delivering products and services safely, to schedule, of the correct quality and to the agreed cost. The Contractor shall ensure that each of its subcontractors has a quality system compliant with this document and if applicable, the requirements are cascaded to low-tier subcontractors.

The Contractor shall implement a process for ongoing verification and monitoring of its subcontractors to ensure that they are delivering products and services safely, to schedule, to the specified requirements and to the agreed cost.

For each proposed subcontractor whose scope of work is identified as a Critical Activity or upon the IO's request, the Contractor shall submit the subcontractor's quality plan as a separate document.

The Contractor shall describe in their Contract Management Plan or QA plan the above.

The Contractor shall submit with the SAF a Subcontractor's statement of compliance with the Contractor's quality plan, the quality manual of the subcontractor and an organization note describing at least the following items:

- ✓ A full and clear definition of the subcontractor's scope of work.
- ✓ The organization of the subcontractor and his links with the Contractor's organization.
- ✓ The communication (in particular documentation) exchanges between the subcontractor and the Contractor.
- ✓ The way the subcontractor will control his activities and the way the Contractor will supervise the activities performed by the subcontractor.

For subcontractor whose scope involves critical activities, a dedicated QA plan shall be provided.

The contractor shall report subcontracting activities in their reporting to IO in the relevant section.

6.4.3 Change in Subcontractor

Any change of subcontractor shall be agreed by IO CRO prior to implementation. The Contractor to use the SAF as per Appendix VI for this purpose.

6.4.4 Subcontractor operating at IO Site

The Contractor shall ensure that any subcontractor operating at IO site on behalf of the Contractor does comply with Section 11 of this document. The Contractor is especially responsible to coordinate the site access requirement for their subcontractors.

6.5 CFSI (Counterfeit Fraudulent Suspect Item)

The Contractor has to have a special focus on CFSI. The Contractor shall have a process in place to identify CFSI and develop this in their Contract Management Plan or QA plan.

Upon IO information about CFSI warning, Contractor shall also be able to check if their subcontractor(s) and/or supplier(s) might be impacted in their supply chain.

7 Design Requirements

7.1 General

Whenever the scope is for the supply of a system, part or piece of equipment that is to be designed by Contractor or is for a service that covers for the design of a system, part of piece of equipment, or more generally the scope requires analysis and calculation tasks, the Contractor shall apply the below unless specified otherwise in the Technical Specification.

7.2 Applicable instruction and templates

The Contractor shall apply Ref [23], Procedure for Analyses and Calculations as well as all lower level Instructions, Templates and Checklists made applicable by the Procedure and summarized in the below table:

Analysis Type	Instructions	Report Template	Reviewer Checklist	Technical Checker Checklist	Independent Peer Reviewer Checklist
Structural	35BVV3	VQVTQW	RYATXV	TK33SU	VQVFEN
Seismic	VT29D6	VAET99	Q6FH53	V5ZWSB	V5Z65L
Nuclear	R7XRXB	n/a	VP6G35	RSJ9CS	T8K5CG

Electromagnetic	TSZ9KQ	6NVTVK	PRAT8Q	SYCCLR	VNYHRB
Computational Fluid Dynamics	VUEEDB	TL7H73	VJJSZ3	VJJVFJ	VJJUDV
Contamination	XQVZKS	n/a	V96NYH	X7RR2N	X8CS4Z

Structural Integrity Reports shall be written following the requirements in (22MAL7). Guidance for how to meet these requirements is provided in the Guideline for Structural Integrity Report (35QTKD).

Whenever applicable, the Contractor to liaise with CRO to get the relevant documents based on above mentioned references if not already provided as part of the Technical Specification.

7.3 Checks and Reviews

Unless otherwise specified in the Technical Specification, analysis reports shall be delivered with completed Reviewer and Technical Checker checklists. Note that unless otherwise specified in the Technical Specification, completed Independent Peer Reviewer checklists do not need to be delivered. Checks and reviews are defined in the relevant document as listed in section 7.2

7.4 Submission of Analysis Models

The Contractor shall transmit Analysis models to IO via electronic transfer. The Contractor to liaise with CRO to set-up a file sharing (like but not limited to: FTP folder)

The Contractor shall ensure that all the files necessary to rerun the analyses and get all the results presented in the report are delivered, including the following (when applicable): geometry, specific software & subroutines, Excel files. Due to potential file size limitation and after agreement by both parties, the full result files can be excluded if the time of re-computing is considered acceptable.

All models shall be delivered in accordance with the below:

- The analysis models in the database shall be in a ready-to-run state. In other words, the number of manual operations required to rerun the analyses shall be reduced to the strict minimum. Any manual operation that is required to rerun the analyses shall be described either in the analysis report or in a document attached to the model.
- The analysis models shall be as clearly and quickly as possibly understandable by a third party to facilitate their review and re-appropriation. All text shall be written in English: Names (parameters, models, files…), comments (scripts, source code…) etc.
- When multiple formats are available to save/archive a model, the user shall choose:
  - The one that future versions of the software is most likely to be able to open.
  - The one that is the most exhaustive in terms of what is stored.
  - The one that eases the most its modification later on.

8 Quality requirements

8.1 General

The Contractor shall have an ISO 9001 certified quality system or alternatively a QA Program approved by QARO. In addition, the quality management system shall comply with the IO quality requirements as per Ref [15].

8.2 Quality Plan

The Contractor shall produce a Quality Plan in accordance with Ref [16] and transmit the document at minimum 2 weeks prior to the KOM. If some of the required topics of the Quality plan are covered in the Contract Management Plan, the Contractor to organise cross reference between those plans.

The quality plan shall cover all critical quality activities as well as any activity identified with risk to quality, cost or schedule. As such, CRO and QARO reserve the right to request for update of the Quality Plan to cover for any quality issue and/or risk arising at any time of the Contract execution.

8.3 Quality Classification

The quality Classification of the scope of work is a key driver to identify the applicable requirement for the implementation of the Contract. Those requirements are identified in Ref [17] Appendix 2: Quality Classes application.

If Quality Classification is not defined in the Technical Specification or if the Contractor require for quality class determination change of systems components and/or spare parts, Ref [17] provides guidance on how to determinate the Quality Classification, that is to be submitted for approval to CRO.

8.4 Inspection Plan

8.4.1 General

Inspection plans are used to monitor quality control and acceptance tests during the implementation of the Contract: Manufacturing and Inspection Plan (MIP) for manufacturing activities, Inspection and Test Plan (ITP) for works. It should be noted that interventions additional to those required in the Contract document may be included in the inspection plan by the IO. The rights of the IO listed above shall apply in relation to any subcontractor and in this case the IO will operate through the Contractor. The overseeing of the quality control operation by the IO shall not release the Contractor from his responsibility in meeting any aspect of their obligations under the Contract.

The Contractor shall ensure a close follow-up across their supply-chain, which include their activities as well as their Subcontractors', and Suppliers' when it comes to PIC/PIA. As such, the Contractor shall ensure propagation of requirements to its Subcontractors and Suppliers as needed and define in their QA plan how the Contractor manage the follow-up and inspection of their supply-chain.

This monitoring shall include control points at critical steps in the Contractors' plans. The control points shall be integrated into the agreed schedule. Inspection plan shall clearly highlight the PIAs and PICs.

Drawings, standards, specification, instructions, codes and the Contractor quality control procedures which are applicable to the inspection plan shall be clearly identified as to their source, title, number and applicable revision. All drawings, codes and standards referred in the test plan shall be listed in a separate document section. Reference to a standard and/or code shall indicate the pertinent chapter, section clause or paragraph and edition. Flow diagrams or a separate sequential plan that would enable to clearly define some completion stages, if needed. The applicable procedures shall be mentioned for each inspection and testing phase.

The Contractor shall not commence manufacturing activities prior to confirmation of inspection plan's acceptance by the CRO.

Any change to an approved inspection plan shall be resubmitted to the CRO for acceptance.

8.4.2 Requirement for Manufacturing Inspection plan

For manufacturing scope of work, a MIP is required for scope under Quality Class 1, Quality Class 2 and Quality Class 3. Manufacturing is here to be understood at large and also cover for service scope with the exception of software development that are covered under Ref [18].

Typical Manufacturing Inspection Plan is available in Annex VIII.

MIP shall list all operations that are critical from a quality point of view. As such, QARO and CRO reserve the rights to request for MIP revision if any activity becomes critical and is not listed in MIP.

8.4.3 Requirement for Inspection plan

For any operation taking place on IO Site, inspection and test plan - ITP is required for any Quality Class. Typical Inspection Plan is available in Annex XII.

ITP shall list all operations that are critical from a quality point of view. As such, QARO and CRO reserve the rights to request for ITP revision if any activity becomes critical and is not listed in ITP.

8.4.4 Control Points

Several control points shall identified in each Inspection and Test Plan:

HP (Hold Point) identifies an operation that must be formally sign-off by an IO or third party representative mandated by the IO before the work continues beyond this point. The work must not continue until the release delivered by IO or/and the Third Party. Where physical witnessing is required for a HP, this must be clearly indicated in the inspection plan for the associated task. IO or Third Party may add a Hold Point to a specific activity at any time during implementation of the work by the Contractor.

NP (Notification Point) identifies an operation/task that must be notified to the IO or a Third Party. IO or Third Party are invited to attend to the operation/task but if they don't attend at the notified time, the work can be proceeded by the Contractor.

RP (Registration Point) identifies an activity where the IO or Third Party not invited to attend but they need to be informed immediately of the results by the Contractor. The information is delivered by the relevant record signed-off by the Contractor. The work can continue when the record has been delivered to IO.

W (Witness): identifies an operation that must be witnessed.

S1 (Surveillance 1): identifies an operation that requires 100% inspection.

S2 (Surveillance 2): identifies an operation that requires random inspection or spot checks.

R (Review) identifies a document that must be reviewed by the IO or Third Party.

The Contractor may use any additional complementary Control Points they need to support their activity (specific inspection …)

IO reserve the right to waive partially or in full their attendance, and will inform Contractor via their response to Contractor notification for inspection.

For **Hold Points**, **Notification Points and Witness Points** the Contractor shall notify the inspection body representative at least 12 calendar days prior to the implementation of the activity

for any operation. Upon mutual agreement between the different stakeholders, the notification period may be reduced.

8.4.5 Pre-Inspection Meeting

The Pre-Inspection Meeting shall be the first sequence of each ITP. The Contractor representative shall notify IO and regulatory bodies and lead the Pre-Inspection meeting. This meeting can be organized at the Contractor office, on site or remotely. The following the Contractor representatives shall attend the meeting:

- Quality control department,
- Contractor Responsible officer,
- Contractor stakeholders as required by the ITP content.

The main objectives of this meeting are to:

- Verify that all the documents referred in the ITP are approved with the expected revision before to commence the work. Otherwise, conditions on the commencement shall be defined.
- Verify that all the tools planned to be used during implementation of the ITP are calibrated
- Verify that all personnel involved in the implementation of the ITP are demonstrated qualified (welders, NDT etc.)
- Ensure that the Contractor stakeholders know the IO quality expectations and processes. Especially the invitation process for control points, the main QC interfaces between the Contractor and the IO; NCR; specific risk on quality of the works, any other relevant subject.

8.4.6 Invitation Process

During the implementation of its works, the Contractor is in charge of inviting all the involved parties to a Control Point as per its ITP, with a minimum of a 2 week notice. When inspection requires overseas travel of IO representative, this notice is extended to 3 weeks. The Contractor shall use the invitation template as available in Appendix XVI.

8.4.7 Inspection

When an inspection is organised at the Contractor or subcontractor premises, the Contractor shall ensure the inspection is operated in full safety and shall provide relevant safety induction and PPE to the inspectors (or else notify in advance of any PPE to be brought by Inspectors).

Access shall be granted by the Contractor to the premises for IO representative and/or any third party inspectors as designated by ITER Organization.

In case of cancellation or re-scheduling , the Contractor shall notify IO representative of such event no later than 3 working before date, 7 for overseas location. Failing to do so exposes The Contractor to cost recovery by IO.

Remote Inspection is supported by IO. The Contractor shall consider this requirement and allow for video capture of specific activities under the Contract and in relation to the test plan. The Contractor shall also ensure that sufficient bandwidth is available in the relevant area to enable direct video diffusion. If limitation exist, the Contractor shall advise IO at last during the KOM.

IO attendance to an inspection and/or test phase shall not relieve the Contractor from their own obligation to perform the control and the Contractor Quality Control team is responsible for endorsing the outcome of the inspection and/or test phase.

8.4.8 Inspection progress follow-up

The Contractor shall provide timely and regular reporting on inspection progress.

If the Contractor has an online tracking system for their inspection, they shall grant access to IO representative for the test plan follow-up under the Contract. Alternatively, the Contractor shall use IO systems, such as but not limited to: manufacturing database (MDB).

In case the Parties agree not to use any system for inspection follow-up, the Contractor shall at least provide the latest test plan dully marked-up as an appendix to their monthly report.

8.5 FME (Foreign Material Exclusion) Management

Foreign Material Exclusion (FME) is a system of arrangements to prevent the uncontrolled introduction of foreign material (materials such as residue, dirt, debris, plastic tools and equipment) into open systems and manufactured components to ensure that those systems and components can function fully and reliably as per their design intent. FME is of particular importance in the nuclear environment because:

- Many systems and components installed in nuclear environments play a direct or indirect role in maintaining the safety of plant and process.
- Many systems and components are installed in areas where access to replace failed components or make repairs to the components is very costly and difficult.

FME management requires that individuals think through activities before they are performed to prevent the introduction of foreign material. In addition to these conscious efforts, a number of other key principles and expectations underlie all work to be performed in the installation.

Workers must recognize when they are about to perform an activity that can generate foreign material. Any drilling, cutting, grinding, machining, filing, lapping, and other such activities generate small particles of foreign material that require attention. All foreign material created must be captured or otherwise contained. Action must be taken to prevent the possibility of spreading the material.

FME management and associated inspection must be early step of the ITPs.

The Contractor needs to develop appropriate arrangements in order to avoid the introduction of uncontrolled “parts” into systems or components.

8.6 Audit and other Inspections

If and when required, audits, inspections (further to the one defined in the MIP or ITP) and surveillance visits of Contractor’s activities or its sub-contractors may be organized by either IO, regulatory bodies or the French Nuclear Authority without prior warning.

The Contractor shall grant access rights to IO, and regulatory body representatives to their offices, facilities and records.

The Contractor shall flow this requirement down to their subcontractors to allow IO, regulatory bodies and the French Nuclear Authority to also perform the above actions in their premises.

8.7 Configuration Management

8.7.1 Configuration management within the Contractor scope

For the delivery of studies or physical items that are under ITER product configuration, the Contractor shall establish provisions for configuration management, either in a dedicated configuration management plan or in their quality assurance program.

The contractor shall establish provisions allowing them to perform configuration control (by the means of their internal technical change procedures), and to perform configuration status accounting on the products they develop and / or manufacture.

Contractor changes, which result in modifying an output already delivered to IO, shall be submitted to the IO for approval via a Deviation Request (DR).

Unless otherwise agreed in written between the Parties, it is not expected from the Contractor to use IO RFI/DR database for their RFI/DR. The Contractor should instead submit any RFI/DR as a standard document as defined in section 6.2.2.

8.7.2 Request for Information (RFI)

The Contractor can raise RFIs to obtain information or clarification on the contractual and technical requirements, using the form as per Appendix IX. This form has to be logged using the Document management system as defined in section 6.2.2.

The RFI may not constitute a design change, nor a contractual change, nor a deviation vehicle. If any of these situations result from the RFI clarification, the adequate process shall be used.

8.7.3 Deviation Request (DR)

The Contractor may raise a Deviation Request to ask for the authorization to depart from a contractual requirement. Deviation Requests shall be approved by IO before implementation of the related activity(ies) (e.g. manufacture of the item).

Deviation Requests shall be managed using IDM IT system (unless agreed differently) from initial submission to closure as defined in section 6.2.2.

The Deviation Request template is available in Appendix X of this document. While filling this template, and to enable the IO configuration control, the contractor shall be precise on:

- The identification of the requirement documents to which the Deviation Request departs from (in The “Initial Requirement” section)
- The identification of the impacted and already delivered documents (in the “Impact assessment” section)

8.7.4 Contractual Change Notice

The IO may issue for assessment to the Contractor a Contractual Change Notice, typically to modify a specific input technical data to the Contract. This Contractual Change Notice must be assessed by the Contractor, and upon formal agreement on the impact, the IO shall instruct the Contractual Change Notice for execution.

The form to be used is as per Appendix XVII.

8.8 Non-conformity

Any item, process or work that does not fulfil its specified requirements shall be identified and segregated as being nonconforming. Each nonconforming item or work shall be prominently tagged, or uniquely identified and, when practical, segregated to prevent its use. Contractor shall comply with Ref [27].

8.8.1 General NCR

The main steps for the methodology for NC management are as follows:

- The organization, where the NC is detected, shall immediately stop works related to the
- nonconforming product /service and to inform IO.
- Immediate actions to segregate (labelling and/or physical separation of NC shall be applied)
- the nonconforming item / work and to ensure safety.
- Description of the nonconformity - NC report shall be immediately registered in NC system.
- Agreement and implementation of remedial actions to eliminate the Nonconformity.
- The remedial action can be implemented only after IO formal agreement.
- Root cause determination through RCA (Root Cause Analysis) using Causal Analysis Tree
- and decision on corrective & preventive/risk-based actions
- Follow-up of actions from their initiation until their implementation
- Verification of the effectiveness of actions.
- NCR closure - NCR shall be handled and closed with the priority.

8.8.2 Recording of NCR

The non-conformity report shall be issued by the Contractor Representative, specifying the requirement and evaluated by the QARO and the IO Responsible Officer.

Non-conformities shall be recorded and documented in a systematic manner and relevant treatment for their resolution, including evidence of implemented corrective actions, shall be traceable and allow progress reviews using the IO Non-Conformity Database system (NCR Database). Upon request, access and training will be organised by QARO to enable Contractor Representative to use the NCR database.

For any reason agreed by the parties, if use of NCR database is not recommended, then Contractor representative will have to issue a non-conformity report using the NCR template is available in Appendix XI and submit their document using the IDM documentation management system as as described in section 6.2.2.

8.8.3 Management of NCR

Because of the time and effort involved in the evaluation of non-conformances, a graded approach which classifies the non-conformance as major or minor and where the safety and quality is considered should be applied to ensure that the most intensive evaluation is reserved for the problems of highest significance. Following the review and dispositioning of the non-conformance, the item or work shall be placed back in service, repaired, reworked, or rejected. If an item is repaired or reworked to return it to a satisfactory condition, it shall be inspected or reviewed to confirm its fitness for use. After the item has been determined to be acceptable, it may be released for normal processing or use after a determination of ‘use-as-is’ or after remedial action is

performed. Any personnel who are involved with the dispositioning of non-conformances shall be competent in the technical areas in question and knowledgeable of the intended application of the item or work being dispositioned. To ensure improvement and prevent reoccurrence, the root causes of such non-conformances shall be determined and action taken to prevent their recurrence. Item characteristics (such as reliability), process implementation, experience and other quality related information (including management processes) shall be reviewed and the data analyzed to identify improvements and needed corrective actions to prevent reoccurrence, and to decide if any preventive (risk-based) actions should be planned to eliminate the cause of a potential nonconformity.

8.8.4 Reporting on NCR

Contractor shall ensure that NCR are manage in a timely manner and report list of NCR and their status in their Progress Report.

8.8.5 *Delivery and NCR*

No delivery is allowed with open NCR, unless otherwise agreed by IO in dully recorded.

9 Coding & Marking

9.1 Coding

If applicable, the Contractor shall receive from the IO the catalogued Part Numbers of ITER (PNI) for the scope of supply. If the ITER component name has been pre-assigned by IO during manufacturing, the Functional Reference (FR) has to be also identified on the component.

The Contractor shall manage a material take-off list completed with their serial number / heat number / batch number or any relevant contractual identification.

In case where the Contractor is in charge of the design of the equipment, the Contractor shall liaise with CRO to determine the applicable IO Part Numbers.

9.2 Marking

9.2.1 General Requirements

All components supplied by the Contractor shall be physically labelled with the minimum contents of the “product label” as specified in below table:

Label	By whom	When	Lifecycle	Mandatory contents	Additional information may be specified in Tech. Spec., etc.	Note
Product (individual Items)	Contractor	After production	Permanent	1) Title of Product, 2) Manufacture Part Number, MN, 3) PNI, 4) SN, 5) Safety Classification, e.g. PIC/SIC, ESPN, 6) Quality Class.	1) Other Ref. Num., 2) Dimensions, 3) Weight, 4) Manufacturer, 5) Production Date (MM/YYYY), 6) CE marking, as required [4].	PNI to be provided by IO.

Shipping (Package)	Contractor	After packaging	Temp.	1) Title of crate, 2) Purchase Order, PO, Contract Number, PA code, etc., 3) Shipping/Crate Num., 4) Manufacturer Ref. Num., 5) MN, 6) PNI, 7) SN, 8) Safety Classification, e.g. PIC/SIC, ESPN, 9) From (CON-M) / To, 10) Net / gross weight, 11) Responsibility, 12) Packing Date (MM/YYYY).	1) Dimensions, 2) Other Ref. Num., 3) Quantity in the crate	For PNI as mentioned above. Accompanying signs, e.g. sign of handling precaution during transportation.

9.2.2 CE Marking

CE Markings shall be implemented in accordance with European and French legislation requirements.

The list of products for which the CE Marking may be applicable is available on the following web-site: https://ec.europa.eu/growth/single-market/ce-marking/manufacturers_en.

Comprehensive guidance on the implementation of EU product rules can be found in the so-called Blue Guide : https://ec.europa.eu/docsroom/documents/18027/

Except where otherwise specified in the Technical Specification, IO shall not be considered to bear the role of manufacturer.

10 Logistics

10.1 General requirements

The following generic requirements apply for the shipment of any scope of supply (item, component or piece of equipment) from the manufacture/assembly site to the ITER Site or any other location as defined in the Contract. The Contractor shall pack and preserve those in order to prevent any damage during the handling, transportation and storage. The scope of supply shall be subject to control and inspection, as defined below.

During cleaning, particular attention shall be given to the removal of weld spatter, debris and other foreign matter, particularly from the coolant passages and sealing surfaces. Final cleaning shall ensure effective cleaning without damage to the surface finish, material properties or metallurgical structure of the materials. The Contractor shall submit to the IO the proposed cleaning procedure for acceptance. The demonstration of meeting the above cleaning requirements represents a Hold Point (HP) when defined in the Inspection and control plan.

10.2 Packaging & Handling Requirement

Any special IO or regulatory transportation requirements shall be documented and provided by the responsible parties. Subsequent to the Factory Acceptance Test as defined in the Special Conditions or any part of the Contract, the scope of supply shall be partially disassembled to the maximum size that can be shipped.

All components requiring re-assembly at the ITER Site shall be clearly labelled and tagged as per paragraph 8.2. The Contractor shall design and supply appropriate packaging, adequate to prevent damage during shipping lifting and handling operations. Where appropriate, accelerometers or other sensors shall be fitted to ensure that limits have not been exceeded. When accelerometers are used, they shall be fixed onto each box and shall be capable of recording the acceleration along three perpendicular directions. Shock absorbing material shall be used to minimize the risk of component damage during transport.

After packing, each package shall affix a "Shipping Label" as per defined in paragraph 8.2 above.

The document schedule identifies the documents copies that are required to be in the shipment, the Contractor shall ensure those are dully enclosed in the packing.

10.3 Transportation and Delivery Requirements

10.3.1 Transportation categories

Transportation arrangement shall in accordance with the Incoterm applicable per the Contract. Transportation falls in different categories depending on the largest individual package(s) size & weight combination as per below table:

Acronym	Definition	Maximum Length (cm):	Maximum Width (cm):	Maximum Height (cm):	Maximum Weight (kg):
HEL	Highly Exceptional Load	1900	900	910	600000
CEL	Conventional Exceptional Load	1900	500	500	60000
CTL	Conventional Truck Load	1200	250	250	26000

10.3.2 Transportation Quality Plan

For any critical transportation, a Transportation Quality plan shall be approved by the IO before shipment is organised. Critical Transportation includes:

• All HEL and CEL, regardless of safety & quality classification.

• All PIC regardless of size, except bulk raw material (such as piping, fittings (i.e. elbows, tees), steel beams, and steel plates)

• Any additional special or sensitive components (i.e. requiring specific measures for protection and specific handling) as defined in the Technical Specification.

10.3.3Authorization for Shipping

The DRR Gate is an official Hold Point (HP) and therefore must be approved as per paragraph 6.1.5.2.5 prior to the start of transportation. This includes providing the Contract deliverables as per the Technical Specification and listed in above mentioned paragraph with the document names and relevant templates referenced, as per Ref [5]. All of these DRR deliverables shall be approved prior pickup or collection at the Contractor's designated facility for delivery to ITER or other agreed location. After both the Release Note and Delivery Reports are approved, this signifies that the delivery may proceed as planned. The Contractor has to account for sufficient time for submission of the DRR documents (minimum 15 working days).

10.3.4Driver access

When the Contractor is in charge of the final delivery to ITER site, copies of the driver's passport or identity card shall be sent to logistics-planning@iter.org at least 24 hours prior to arrival to the IO site to ensure approval of Driver access.

10.4 Customs and Export Control

10.4.1Customs

If the items supplied are to be transported from non-EU countries to the IO site, the Contractor shall follow the requirements of Ref [20]. Regardless of whom is the LSP chosen by the Contractor, the GLC of IO is responsible to process the customs clearances for all shipments. The LSP chosen by the Contractor shall liaise with the IO GLC and the Contractor shall provide the necessary customs documentation to the GLC at the same time as when the export declaration is being done.

10.4.2Export Control

It is the responsibility of the Contractor to fulfil the requirements of all the applicable export control laws and regulations. The export control classifications shall be those contained in the laws and regulations of the country from where the products/technologies are to be shipped, and those of any other jurisdictions that may apply.

The Contractor is also required to inform the ITER Organization if the item, component or piece of equipment supplied is subject to export control and provide the ITER Organization with the export control classifications of the products and deliverables (if applicable, and, where applicable, the associated technology (copy of any license or other official administrative document obtained in this regard).

The Contactor shall notify the ITER Organization immediately should an export control classification change. All shipping documentation must state the export control classification(s) of the deliverables, together with any applicable export authorisation information. The ITER Organization reserves the right to reject delivery that does not comply with this requirement.

10.5 Procedure for the issue of items, components or pieces of equipment from IO Storage

10.5.1General requirements

In case the Contractor requires a piece of equipment, an item or a component stored in IO storage facilities, the Contractor shall follow the appropriate procedure and complete the relevant forms provided by the CRO.

10.5.2Loan of lifting & handling Equipment

In case the Contractor requires the loan of a lifting or handling equipment owned by the IO, the Contractor shall follow the appropriate procedure and complete the relevant forms provided by the CRO. The Contractor is responsible to ensure the loan equipment is fit for purpose and used by duly qualified people.

11 Start-up & Commissioning, Maintenance

11.1 Installation, Operation & Maintenance Manual

The Contractor shall provide a commissioning plan, a Maintenance and Inspection Plan and an operator training plan unless defined otherwise in the technical specification.

In case the scope of work include the start-up and/or commissioning on site, the Contractor shall provide the reports associated to this activity, such as but not limited to: Site activity report, Performance test report, final acceptance test report.

11.2 Recommended Spare part list

The Contractor shall complete their recommended spare part list using template as per appendix XV.

12 IT Acceptable Use Principles

The IT Acceptable Use Principles apply to all users who have been granted access to IO IT resources, including but not limited to, Intranet/Extranet-related systems, computer equipment, network resources, electronic mail and web browsing.

Contactor who is given access to IO IT services shall comply with Ref [8].

The Contractor will install on their equipment (workstations and servers in particular), malware protection systems, update them regularly, will not deactivate them - even for incident resolution purposes - and will process any alert that may be identified.

13 Additional general requirements for working at the ITER site

13.1 General requirements

Whenever the Contract requires working at the ITER Site, the below requirement applies in conjunction with Ref [1]. Sections 7, 8, 9 10 11, 12, 16, 17, 18 of Ref [1] do not apply as covered in this document. In a more general manner, in case of any conflicting instruction, this document prevails.

The below requirements also apply for any meeting or visit at the ITER site.

13.2 Site HSE

13.2.1 Occupational Health & Safety

Whenever the scope of work or part of it takes place at the ITER non-construction site area, the Contractor shall follow the requirements as described in Ref [3], in compliance with the French regulation.

Ref [3] is defining the applicable documents and processes to follow whenever the Contractor is performing hazardous work on site or work on site for more than 400 hours to carry out their scope of work.

For clarity, when the scope of work or part of it takes place at the ITER site in the construction area, the contractor shall follow the requirements as defined in Ref [1].

13.2.2 Environment

The Contractor shall follow the Ref [12]. However, after environmental impact assessment, if there is no adverse impact expected under their scope of work, the Contractor can submit the deviation request for not submitting the Environmental respect plan (PRE).

13.3 Permit to Work

For work with identified risk, a permit to work is required as per the Ref [22].

Activities not requiring work permit are limited to the following:

- Visual Inspection of Equipment (for low risk inspection, not if includes work at height, or activity on energised equipment, etc…)
- Visual inspection and monitoring of meters, pressure gauges etc for data logging, visual check for leakage, check for lube oil level (lube oil refilling requires a permit)…
- Site visit
- Office work
- Deliveries
- Catering activities and its professional equipment maintenance outside of the ITER platform;
- Services in office environment outside of the ITER platform (e.g. furniture moving, small fixtures fixing, handling works, Minor drillings with compensatory measures of dust emission and removing fire detection impact)
- Check, replacement or repair of extinguishers outside of the ITER platform;
- Cleaning of and waste collection in buildings and areas outside of the ITER platform;
- Road sweeping (including snow removing and salt spreading) outside of the ITER platform;
- Green areas maintenance outside of the ITER platform;

When no permit is required, the Contractor shall ensure the CRO is fully made aware of their intervention at the ITER site.

13.4 Security

Site protection is everyone's responsibility and each person presents on the IO Site shall comply with these security management requirements as defined in Ref [9].

The Command Post shall be called in case of events impacting security or safety and occuring on the IO site. In all cases instructions provided by the security guards shall be followed.

13.4.1 Site access

Access rules to the IO site, to areas, buildings and premises are detailed Ref [11] which shall be followed. This procedure details the access request process, the associated timeframe to be respected and the ITER badge conditions of use.

Any person requesting access to the IO Site may be subject to a background check by the Host State's relevant authorities under the provisions of French Defence Code.

Any person accessing the IO Site must hold a badge, which must be swiped when the person enters and exits the IO Site.

Luggage and vehicle inspections at the Site Entrances and within the IO site are possible. The following items are prohibited on the IO Site and shall not be brought without prior written authorization from the Director General:

- Animals;
- Drugs;
- Alcohol;
- Dangerous items (needles, knives, sharp items, incendiary devices, broken glass, weapon, improvised weapon, ammunition or explosive materials of any nature).

Access to any area on the IO Site is regulated and restricted. No one can access an area within the IO Site without authorization from the designated authority.

The badge is I.O. property and shall be returned immediately when no longer needed.

Badge shall be worn at all times. In case of dangerous work, the badge shall be in the pocket and not in the vehicle. The badge holder shall take due care of the badge and ensure that it is not lost, stolen, misused or altered. Should a badge be forgotten, lost or stolen, the badge holder shall report it:

- During opening hours: to the Reception Offices at entrances B or C.
- Outside opening hours: to the Security Command Post (+33 4 42 17 20 00).

It is strictly forbidden to lend or transfer a badge to another person and to copy, clone or reproduce badges.

13.4.2 Request for Site Access

The Contractor shall submit its access request for its own employees/workers and for their subcontractor(s)/supplier(s) and their respective employees/workers through the dedicated IO pre-enrolment application unless agreed otherwise between the parties.

The CRO will organise with support of the IO Security team the access and training for the Contractor to IO pre-enrolment application. The CRO will be in charge of access request validation.

13.4.3 Vehicle, circulation and parking

Rules governing site access in a vehicle, circulation and parking on the ITRE Site shall be followed and is based on French circulation rules. The related procedure can be provided upon request.

The patrol road along the site boundary fence is reserved for security purposes and there shall be no walking tour along the site boundary fence.

13.4.4 Camera and security surveillance systems

Installation of camera and security surveillance systems are restricted and subject to authorization given by the IO. The IO reserves the right not to authorize.

13.4.5 Indoor & outdoor flight

Usage of unmanned aerial systems for indoor and outdoor flight are restricted and subject to authorization given by the IO prior to any use of such equipment and systems. Associated procedures can be provided by the IO upon request.

13.4.6 Radio condition of use

Usage of radio hand held, radio systems and some specific frequencies are restricted and subject to authorization given by the IO/Security section who shall be consulted prior to any use of such equipment and systems. Associated procedures can be provided by the IO upon request.

13.4.7 Instructions for photography and videography on the ITER site

Photos and videos are permitted on the ITER Site in the following cases:

a) The photos or videos are required in relation to a technical expert assessment, documentation of the "as-built" or "as-installed" condition of a given system or component, a safety or quality assessment, or other ITER documentation purpose.

b) The photos or videos are useful for internal communication or public relations purposes by ITER Communication (COM).

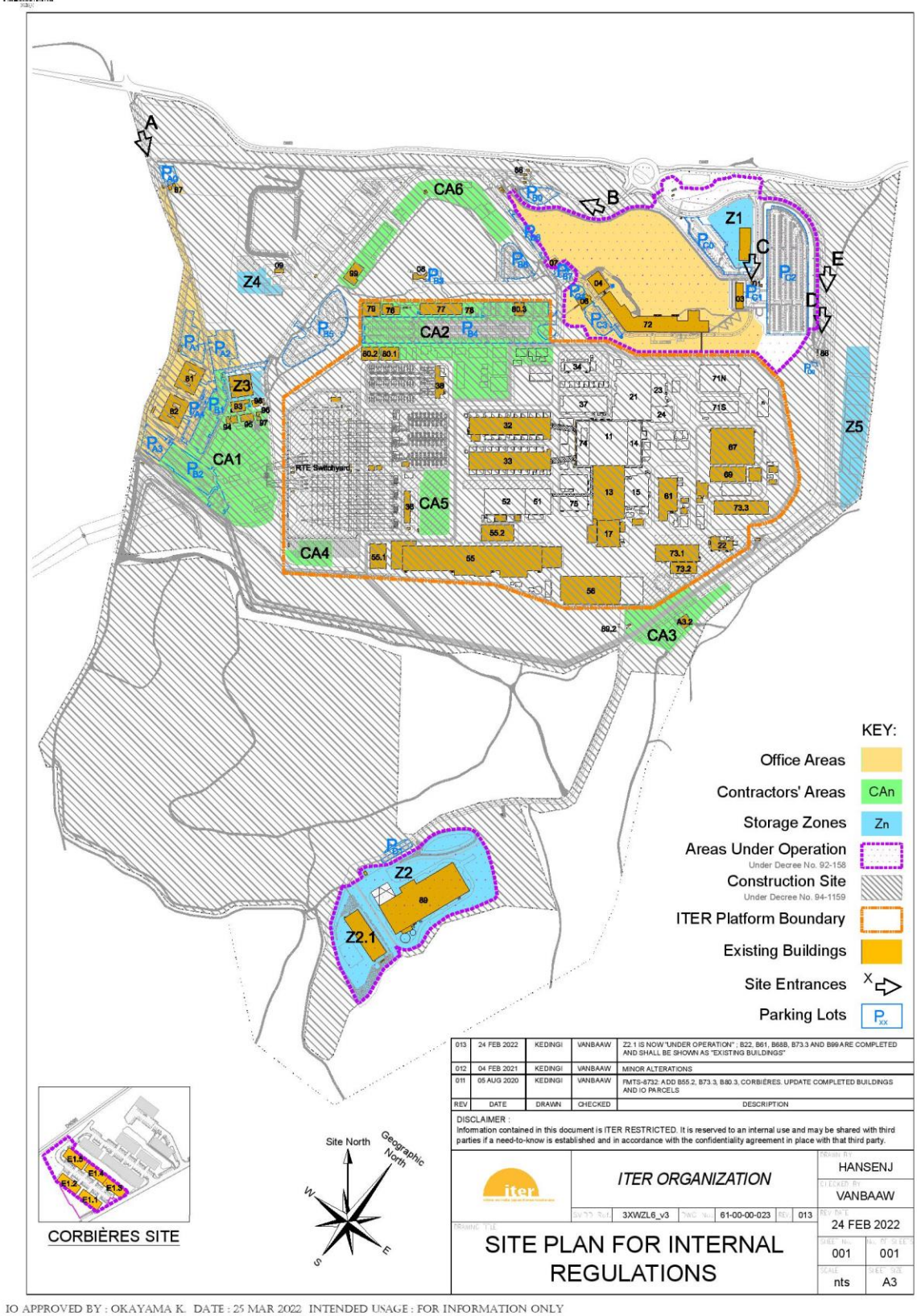
Even in the cases described above, photography and videography may only be performed by individuals who understand the conditions under which photography and videography is authorized, or by individuals under the direct supervision of a COM representative or a certified visit guide (e.g., journalists or authorized visitors).

Photos and videos taken under provision a), above, may be shared within the ITER Project: with stakeholders, Domestic Agencies, Contractors, and other ITER partners, for technical purposes. However, visual images from the IO site, whether they are taken under provision a) or b), above, may only be shared publicly – including on social media – when the images have been pre-approved by the IO.

14 Appendices:

Use the hyperlinks to directly download from IO trusted source the documents listed in this section.

I. IO Worksite and Site Map



II. Document Schedule – Mandatory Template

GM3S-Appendix II-Document Schedule.doc

III. KOM – Mandatory Template

GM3S-Appendix-III_KOM_Template.doc

IV. Progress Report - Mandatory Template

GM3S-Appendix_IV_Contractor_Progress_Report_Template.docx

V. Close-out Letter – Typical Template

GM3S-Appendix-V_Close-out Letter_Template.docx

VI. Subcontractor Acceptance Form – SAF - Mandatory Template

GM3S-Appendix-VI_SAF.xlsx

VII. Contractor Release Note – CRN - Mandatory Template

GM3S-Appendix-VII_Release Note Template.docx

VIII. Inspection & test Plan – Typical Template

GM3S-Appendix-VIII_Inspection_and_Test_Plan_Template.docx

IX. Request for Information form – RFI – Mandatory Template

GM3S-Appendix-IX_RFI_template.docx

X. Deviation Request - Mandatory Template

GM3S-Appendix-X_DR_Template.dotx

XI. Non Conformance Report - Mandatory Template

GM3S-Appendix-XI-NCR_Template.dotx

XII. Package and Packing List - Mandatory Template

GM3S-Appendix-XII Packing List Template.xlsx

XIII. Delivery Report - Mandatory Template

GM3S-Appendix-XIII_Delivery_Report_Template.docx

XIV. Equipment Preservation Procedure – Typical Template

GM3S-Appendix-XIV_Equipment_Preservation_Typical.docx

XV. Spare Part List - Mandatory Template

GM3S-Appendix-XV_Spare Part_List_Template.xls

XVI. Notification of Intervention Point – Mandatory Template

GM3S-Appendix_XVI_Notification_for_intervention_points.docx

XVII. Inspection and Test Plan - Mandatory Template

GM3S-Appendix_XVII_Inpection_and_Test_Plan_template.docx

XVIII. CCN Template

GM3S-Appendix_XVIII_CCN_Template.docx