IDM UID
22MFG4

VERSION CREATED ON / VERSION / STATUS
18 Nov 2025 / 6.4 / Approved

EXTERNAL REFERENCE / VERSION

Technical Specifications (In-Cash Procurement)

Quality Requirements for IO Performers

The purpose of this document is to provide IO performers with quality management requirements based on the quality class of structures, systems, and components (SSC).

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1 Purpose

The purpose of this document is to provide IO performers with quality management requirements based on the quality class of structures, systems, and components (SSC).

2 Definitions and acronyms

Term	Acronym	Definition
(Agreed) Notified Body	(A)NB	Notified Body agreed by the French Nuclear Authority (ASN) to perform conformity assessment of Nuclear Pressure Equipment
Acceptance		Acknowledgement that a product or document is in compliance with the Contract requirements
Approval		Formal agreement for the use or application of a product or document. The approver takes responsibility for the use.
Certificate of Conformity	CoC	
Commercial-off-the-shelf (items), Commercial grade item or service	COTS	Item or service commercially available without modification.
Contract		PA, TA or contract
Contractor		An entity that have a contract with IO or DA
Contractor Release Note	CRN	A document to provide a confirmation from a Performer that the products supplied and/or services performed meet the requirements of Contract.
Construction Readiness Review	CRR	
Counterfeit item		Items that are intentionally manufactured, refurbished or altered to imitate original products without authorization in order to pass themselves off as genuine.
Counterfeit / fraudulent / suspect item	CFSI	
Critical quality activity		Any activity or operation that if not performed correctly may affect safety, functionality or reliability.
Domestic Agency	DA	An organization set up under the ITER Framework Agreement to provide goods or services to the IO through Procurement Arrangements (PA) and Task Agreements (TA).
Equipment	PE/NPE	Pressure Equipment or Nuclear Pressure Equipment
Fraudulent items		Items that are intentionally misrepresented with intent to deceive.
ITER Organization	IO	

Inspection Plan	IP	A plan used for the execution and control of Contract activities. It may also be referred to as a Manufacturing and Inspection Plan (MIP), Inspection and Test Plan (ITP), Control Plan (CP), or other similar terms.
Manufacturer		Any natural or legal person who manufactures an equipment or has an equipment designed or manufactured and markets under his name or trademark.
Mechanical Completion Dossier	MCD	
Manufacturing Database	MDB	
Manufacturing Readiness Review	MRR	
Notified Body	NB	Technical organisation approved in an EU state, either for approval and monitoring of the manufacturer's quality assurance system or for direct product inspection for the manufacture of Pressure Equipment.
Performer		An all-inclusive term used to cover DAs, contractors and subcontractors
Procurement Arrangement	PA	
Quality Class	QC	
Quality plan	QP	Document describing the operational quality system to ensure that Contract requirements will be met, and that evidence of such compliance will be maintained. It covers the whole scope of the Contract including work performed by contractors/subcontractors and addresses all activities performed in connection with the Contract.
Protection Important Component	PIC	As per INB Order (French Order of 07/02/2012)
Responsible Officer	RO	IO primary point of contact to manage a Contract.
Structures, systems and components	SSC	
Subcontractor		An entity that performs work for contractors
Suspect items		Items where there is an indication or suspicion that it may not be genuine.
Task Agreement	TA	

3 References

[1]	Quality Classification Determination (24VQES rev. 6.0 or consequent)
[2]	ITER Quality Assurance Program (QAP) (22K4QX)

[3]	Qualification of Protection Important Components (PIC) (XB5ABP)
[4]	Working Instruction for Processing Construction Nonconformities (U8VPSS)
[5]	Procedure for Management of Nonconformities (22F53X)
[6]	Procedure for the management of Deviation Request (2LZJHB)
[7]	Risk and Opportunity Management Procedure (22F4LE)
[8]	Work Instruction for producing an Inspection and Test Plan for construction (UELU9F)
[9]	Working Instruction for Construction Readiness Review (QXW4KQ)
[10]	Working Instruction for Completion Dossier Preparation (UYUSEE)
[11]	Working Instruction for the Delivery Readiness Review (DRR) (X3NEGB)
[12]	Procedure for Transportation of Components to ITER Site (RY5C6Q)
[13]	Procedure for the CAD management plan (2DWU2M)
[14]	Procedure for Analyses and Calculations (22MAL7)
[15]	Design Review Procedure (2832CF)
[16]	Working Instruction for Manufacturing Readiness Review (44SZYP)
[17]	Implementation plan for design & manufacture of PE/NPE (VE2DSP)
[18]	Inspection Plan (IP) Template (QV7GQF)
[19]	Construction Inspection and Test Plan Template (ITP) (TTPQL2)
[20]	Release Note Template (QVEKNQ)

4 Requirement to define quality class (QC)

The quality class of the SSC must be specified in the Contract.

The Performer may grade the SSC quality class specified in the Contract down to the component levels in accordance with reference [1].

The Performer shall inform the IO RO about any downgrade in the quality classification of components.

The Performer may request the IO RO to determine or change the quality class of SSC.

5 Common requirements for QC 1-4

5.1 Quality management system

The Performer shall establish and implement a quality system based on a recognized quality standard and shall meet the requirements outlined in reference [2].

This quality system shall be capable of ensuring that Contract requirements are met, and that evidence of such compliance is maintained.

In case of PA or TA, the Performer shall submit a description of the quality management system for the DA's acceptance. The DA shall forward the accepted description to the IO RO for information.

In the case of a direct contract with IO, the Performer shall submit a description of the quality management system for acceptance by the IO RO.

5.2 Counterfeit, Fraudulent or Suspect Items (CFSI)

The Performer shall prevent CFSI at all levels of operations including

a) selection of subcontractors

b) control of externally provided processes, products and services

d) monitoring and measurement activities

When CFSI are detected, they shall be managed as nonconformities (6.1.3).

5.3 Commercial-off-the-shelf / COTS items

To procure and utilize COTS, controls through dedication method(s) shall be implemented to ensure that the item or service is adequate for its intended function. In particular, for PIC minimum requirements according to reference [3] shall be applied, including requested documentary traceability as applicable.

5.4 Propagation of requirements

The Performer shall ensure that the relevant requirements outlined in this document are communicated throughout their supply chain.

6 Common requirements for QC 1-3

6.1 Contract management (common QC 1-3)

6.1.1 Responsible Officer

The Performer shall appoint a Responsible Officer to:

- communicate with the IO
- coordinate the planning and performance of the work, including work assigned to subcontractors
- maintain time schedules and issue monthly progress reports
- verify that the quality systems are consistently followed during the execution of the Contract
- assess and oversee quality in subcontractor's premises
- monitor the implementation of IO requirements
- provide IO with periodic assessment of quality performance

6.1.2 Quality plan (QP)

The requirements and guidance for the content of QPs are provided in the Annex 1.

The Performer shall prepare a QP for all Contracts when all contractors and subcontractors are identified. Unless specified otherwise, for research and development activities not used for qualification purposes, only the DA (for TA) or the Contractor (for direct contracts) shall prepare a QP.

Subcontractors shall submit QPs to the Contractor for acceptance.

In the case of PA/TA, the Contractor shall submit its own QP and QPs of the subcontractors to the DA for acceptance, and the DA shall then submit all QPs for the IO RO's acceptance.

In the case of direct contract, the Contractor shall submit its own QP and QPs of the subcontractors to the IO RO for acceptance.

The Performer shall revise the QP if changes occur that require it and submit it for acceptance in the same manner as the original plan.

At the IO RO's request, the Performer shall provide the documents referenced in the QP.

The Performer shall carry out the activities in accordance with the QP accepted by IO RO.

6.1.3 Management of nonconformities

For work on the ITER construction site, the Performer shall manage nonconformities in accordance with reference [4].

Otherwise, the Performer shall manage nonconformities in accordance with reference [5].

6.1.4 Management of deviations

To deviate from Contract requirements the Performer shall initiate a deviation request and follow the process in accordance with reference [6].

6.1.5 Risk management

The Performer shall manage risks in accordance with reference [7].

6.1.6 Access to Performer's premises

The Performer shall ensure that the IO/DA representatives and representatives or regulatory bodies have access to the premises when required to oversee or support the work being executed.

6.2 Engineering (common QC 1-3)

The Performer shall have the design approved by design authorities established through controlled procedures.

The Performer shall submit the final design for the IO RO's acceptance.

6.3 Manufacturing, assembly and installation (common QC 1-3)

6.3.1 Inspection and Test Plan (ITP)

For work on the ITER construction site, the Performer shall plan and implement control measures using the Inspection and Test Plan (ITP) in accordance with reference [8].

6.3.2 Readiness Review (CRR)

For work on the ITER construction site, the Performer shall conduct a Construction Readiness Review (CRR) in accordance with reference [9].

6.3.3 Material certificates

The Performer shall submit material certificates to the IO RO for acceptance.

6.3.4 Manufacturing

If the design is included in the Performer's scope of work, the Performer shall not begin manufacturing until the final design has been accepted by the IO RO.

For work on the ITER construction site, the Performer shall treat the mechanical completion dossier (MCD) in accordance with reference [10].

6.4 IO Acceptance (common QC 1-3)

6.4.1 Contractor release note (CRN)

The requirements and guidance for the content of CRNs are provided in the Annex 3.

Prior to factory acceptance, or shipment, if there is no factory acceptance, of products and/or services, the Performer shall certify in the Contractor Release Note (CRN) that all required verifications, inspections, and tests are complete and satisfactory, and that all necessary documentation is available, and shall submit the CRN to the IO RO for acceptance.

6.4.2 Mechanical Completion Dossier (MCD)

For work on the ITER construction site, the Performer shall submit the MCD in accordance with reference [10].

6.5 Storage and shipping (common QC 1-3)

6.5.1 Conditions to ship - CRN and shipping notification

The Performer shall not ship the products prior to the acceptance of the CRN by the IO RO.

The Performer shall submit a shipping notification to the IO RO and shall not ship the products prior to their acceptance by the IO RO.

6.5.2 Conditions to ship - Delivery Readiness Review (DRR)

The Performer shall not ship the products until the Delivery Readiness Review (DRR) is completed in accordance with reference [11].

6.5.3 Shipping

The Performer shall ship the products in accordance with reference [12].

7 Specific requirements for QC 1-2

7.1 Engineering (extras for QC 1-2)

The Performer shall submit a request to use software and/or models for design and operations to the IO RO.

The Performer shall manage CAD works and data in accordance with the reference [13].

The Performer shall perform analyses and calculations in accordance with the reference [14].

The Performer shall conduct design reviews in accordance with the reference [15].

7.2 Manufacturing, assembly and installation (extras for QC 1-2)

7.2.1 Special processes

For special processes, the Performer shall submit qualification documents and records for the IO RO's acceptance.

7.2.2 Preparation and change of inspection plan (IP, MIP/ITP)

For work on the ITER construction site, the Performer plans control measures using the Inspection and Test Plan (ITP) in accordance with chapter 6.3.1 (reference [8]).

Otherwise, the Performer shall plan control measures using generic Inspection Plans (IP) as follows:

The requirements and guidance for the content of IPs are provided in the Annex 2.

When an (Agreed) Notified Body ((A)NB) is involved, the Performer shall submit the IP to the (A)NB before submitting it to DA or IO.

In the case of PA, the Performer shall submit the IP to the DA for marking intervention points. The DA shall then submit the IP to the IO RO for marking interventions and acceptance.

In case of IO direct contracts, the Performer shall directly submit the IP to the IO RO for marking intervention points and acceptance.

At the IO RO's request, the Performer shall provide the documents referenced in the IP.

The Performer may revise the IP if changes are required and shall submit it for acceptance in the same manner as the original plan, unless instructed otherwise in writing by IO RO.

7.2.3 Readiness review (CRR, MRR)

For work on the construction site, the Performer conducts a Construction Readiness Review (CRR) in accordance with chapter 6.3.2 (reference [9]).

Otherwise, the Performer shall conduct manufacturing readiness review (MRR) in accordance with the reference [16].

7.2.4 Execution of IP (MIP/ITP)

For work on the ITER construction site, the Performer implements control measures using the Inspection and Test Plan (ITP) in accordance with chapter 6.3.1 (reference [8]).

Otherwise, the Performer implements control measures using generic Inspection Plans (IP) as follows:

The Performer shall not begin executing activities until the IP is accepted by the IO RO and shall carry out the activities in accordance with the IP once it is accepted.

The Performer shall not begin executing activities until the MRR has been completed.

The Performer shall notify DA and IO of the intervention points before executing the relevant operations as defined in the IP.

The Performer shall ensure that the IP is readily accessible to those performing the work.

The Performer shall ensure that the IP is updated in a timely manner - each operation shall be recorded at least before the next concerned intervention point so that to allow tracking by IO and DAs of IP execution during operation’s progress (e.g. by using MDB or other equivalent digitalized tools).

The Performer shall ensure that each operation is signed off and dated by the person in charge of the operation.

The Performer shall ensure that records associated with operations (inspection reports, test reports, nonconformity reports etc.) are properly referenced in the IP and made available by suitable means to the party responsible for the intervention.

The Performer shall ensure that each intervention point is signed off and dated by the person carrying out the intervention.IO Acceptance (extras for QC 1)

7.2.5 Manufacturing dossier

Prior to factory acceptance or shipment (in the absence of factory acceptance) of products, the Performer shall submit the manufacturing dossier to the IO RO.

7.3 Storage and shipping (extras for QC 1-2)

7.3.1 Storage

The Performer shall store the products in accordance with IO technical specifications provided by the IO RO.

8 Specific requirements for PE/NPE

8.1 Qualification of personnel (PE/NPE)

If IO is the Manufacturer of Equipment, the qualification of Performer's personnel shall be carried out in accordance with the requirements of the reference [17].

8.2 Engineering (extras for PE/NPE)

The Performer shall submit the final design for the IO RO's approval.

8.3 Manufacturing (extras for PE/NPE)

If the design is included in the Performer's scope of work, the Performer shall not begin manufacturing until the final design has been approved by the IO RO.

8.3.1 Special processes

If IO is the Manufacturer of Equipment, the qualification of special processes shall be carried out in accordance with the requirements of the reference [17].

8.3.2 Inspection plan

When IO acts as the manufacturer of Equipment under the scope of Module H, a specific column in the IP shall be dedicated to defining control points related to the implementation of Module H. The column labelled "Third Party" or "Other" in templates [18] or [19] may be used for this purpose.

8.4 Storage and shipping (extras for PE/NPE)

When IO acts as the Manufacturer of Equipment, the procedures related to handling, storage, or shipping shall be approved by the IO RO.

9 Annex 1. Requirements and guidance for the content and structure of Quality Plans (QP)

9.1 Content

Quality Plans shall be brief and to the point, while giving sufficient visibility on the control of the activities to be carried out.

The Quality Plan shall identify:

- the critical quality activities and associated controls
- the specific allocation of resources, duties, responsibilities and authority
- details of all contractors/subcontractors and how interfaces will be managed
- the specific procedures, methods and work instructions to be applied
- the specific methods of communication, both formal and informal, to be established between working groups

The level of detail in the plan shall be consistent with:

- the technical requirements of the Contract
- the safety and operational importance of the items involved
- the complexity of the organizations, functions and activities involved
- the degree of design innovation
- the involvement of innovative processes
- the involvement of processes which cannot be fully verified by inspection or test
- the degree to which functional compliance can be demonstrated by inspection or test
- design, performance or manufacturing margins

Much of the generic documentation needed to prepare the Quality Plan will normally already exist as part of the performer's quality documents and supporting procedures. The Quality Plan need only refer to this documentation and show how it is to be applied to the particular Contract.

The Quality Plan may be a single document that covers the whole scope of the Contract, including work performed by subcontractors. The plan may also be the compilation of coordinated separate and well-defined documents.

9.2 Structure

It is not essential for the Quality Plan to follow the structure outlined below which is given for guidance.

The elements listed in the following sections are neither prescriptive nor exhaustive and shall be addressed only where relevant:

9.2.1 Quality Management

The plan shall:

- identify all critical quality activities and associated controls
- identify the different organizations involved
- detail the breakdown of responsibilities
- identify within the different organizations involved the key individuals responsible for:

- ensuring that the activities performed in connection with the particular Contract are planned, implemented and controlled and their progress monitored
- communicating requirements peculiar to the specific Contract to all affected organizations
- resolving problems that may arise at interfaces between the organisations involved

An organization flow chart could facilitate the understanding.

9.2.2 Contract Review

The plan shall indicate how, when and by whom Contract requirements are to be reviewed and the review recorded.

9.2.3 Document

The plan shall show how, when and by whom documents will be controlled.

9.2.4 Design

The plan shall show how, when and by whom design will be controlled, including:

- when, how and by whom the design process is to be carried out, controlled and documented
- the arrangements for the review, verification and validation of design output conformity to design inputs requirements

Where applicable, the plan shall indicate the extent to which the IO will be involved in design activities, such as participation in design reviews and design verification.

The plan shall reference applicable codes, standards and regulatory requirements.

The plan shall:

- list the computer programs to be used
- indicate how, when and by whom they will be controlled

9.2.5 Procurement

The plan shall show how, when and by whom procurements will be controlled, including:

- any important items or activities that are to be purchased or subcontracted
- the relevant quality assurance requirements
- the proposed contractors or subcontractors
- the methods to be used to evaluate, select and control contractors and subcontractors
- the methods to be used to satisfy regulatory requirements, which apply to, purchased or subcontracted products

9.2.6 Identification and Control of items

Where traceability is a requirement or necessary for the adequate control of the work, the plan shall define its scope and extent, including:

- how affected items are to be identified
- how Contract and regulatory traceability requirements are identified and incorporated into working documents
- what records relating to such traceability are to be generated and how and by whom they are to be controlled

9.2.7 Manufacture

The plan shall indicate how processes, manufacture, assembly, inspections and tests will be controlled.

Where appropriate, the plan shall introduce or refer to:

- relevant documented procedures and work instructions
- the methods to be used to monitor and control processes
- criteria for workmanship
- use of special and qualified processes and associated personnel
- tools, techniques and methods to be used

9.2.8 Inspection and Test

The plan shall show how, when and by whom inspection and test would be controlled, including:

- any inspection and test plan to be used, and how and by whom they are reviewed and approved
- how and by whom inspection and test reports are reviewed and approved
- acceptance criteria to be applied
- acceptance of purchased or subcontracted items
- any specific requirements for the identification of inspections and tests status
- the extent to which the IO and (Agreed) Notified Bodies will be involved, such as witnessing inspection and test

9.2.9 Measuring and Test equipment

The plan shall indicate the control system to be used for measuring and test equipment specifically used in connection with the particular Contract, including:

- identification of such equipment
- method of calibration
- method of indicating and recording calibration status

9.2.10 Handling, Storage, Packing, Shipping and Delivery

The plan shall show how, when and by whom handling, storage, packing, shipping and delivery will be controlled:

- how Contract requirements for handling, storage, packaging and shipping are to be met
- how the item will be delivered to the specified site in a manner that will ensure that its required characteristics are not degraded

9.2.11 Records

The plan shall indicate:

- how records are to be controlled, including how legibility, storage and retrievability will be satisfied
- what records are to be kept
- what records are to be supplied to the IO, when and by what means
- how and by whom the records are reviewed and approved prior to inclusion in the deliverables handed over to the IO
- what form the records will take (such as paper, microfilm, tape, disc or other medium) and in what language the records will be provided

9.2.12 Deviations and Nonconformities

The plan shall indicate how, when and by whom deviations and non-conformances will be processed including those originating from contractors and subcontractors.

9.2.13 Training and Qualification

The plan shall address:

- any specific training requirement for personnel
- how such training is accomplished and recorded

9.2.14 Statistical Techniques

Where statistical techniques are relevant for establishing, controlling and verifying process capability and item characteristics, they shall be indicated in the plan.

9.2.15 Assessment

The plan shall indicate how, when and by whom the implementation and effectiveness of the Quality Plan will be monitored.

10 Annex 2. Requirements and guidance for the content of Inspection Plans (IP)

An IP shall identify:

- Requirements and instructions applicable to those operations
- Operations to be inspected or witnessed by DA, IO and (Agreed) Notified Body ((A)NB).
- Documents providing traceability and recording of the verification and completion of these operations.

The level of detail in the IP shall be such as to prevent the inadvertent bypassing of quality activities and to enable adequate planning, monitoring and verification of operations.

The IP shall be written in English for IO and, if necessary, in Performer's working language to be easily understood by those carrying out the work.

The IP shall identify who is performing each intervention point.

A suggested format for the IP can be found at the IP template [18]. Alternative formats (including in electronic form) may be acceptable at discretion of IO RO in advance of their intended use.

11 Annex 3. Requirements and guidance for the content of Contractor Release Notes (CRN)

The Release Note shall be prepared using the Release Note template [20].

The Release Note shall:

- Certify that the product or service meets the Contract requirements
- List the documents and records constituting the manufacturing dossier and their status
- List any outstanding obligations

The list of documents and records below is non-exhaustive and shall be tailored to meet the Contract requirements.

1. Management Documents:
   - Quality Plan
   - List of contractors/subcontractors
2. Raw Materials - Metals, Ceramics and Other Materials
   - Procurement Specifications
   - Sub-Orders
   - Material Certification traceable to components
3. Manufacturing Documents
   - Fabrication Procedures (machining, forming, soldering, wiring)
   - Welding/Brazing Documents (WPS, PQR, WPQ etc...)
   - Weld Plan
   - Weld Inspection Record
   - Non-Destructive Examination Procedures (VT, PT, MT, RT, UT etc...)
   - Cleaning procedure
   - Surface Treatment Specification
4. Assembly and Test Documents
   - Assembly Sequences, Control Specifications and Procedures
   - Pressure Test Procedure
   - Helium Leak test procedure
   - Function Test Specifications
   - Control Reports (Visual Examination, Non-Destructive Examination, Electrical and
   - Insulation Tests, Leak Tests, Pressure Test, Certification of Cleanliness, etc.).
   - Deviation and Nonconformity Reports
   - Completed Manufacturing & Inspection Plan(s)
   - Drawings marked “As Built”