

ITER DMS Prototype - Lot 1 - Cryogenics Quality Plan for SO#2-3

Contract

SO#2 Ref. 4200005703 & SO#3 Ref. 4200005436

under IO/CT/24/6000000482

T. BOUJET

Date: 12th of September, 2025

Reference: DSBT-AQ-25-76

Issue - Revision: 1-1

	Name	Date / Signature <i>(only one needed per field)</i>
Prepared by	Théo BOUJET Project leader for ITER DMS Project	
Verified by	Christophe MARIETTE Quality Management Responsible for ITER DMS Project	
Approved by	Jean MANZAGOL Head of Cryogenics for Fusion Laboratory	

Keywords: Fusion, Injectors, Quality Assurance, ITER

	CEA - GRENOBLE ITER DMS Prototype - Lot 1 - Cryogenics Quality Plan for SO#2-3	Département des Systèmes Basses Températures Date: 12th of September, 2025 Ref: DSBT-AQ-25-76 Issue – Revision: 1-1 Page: 2 / 35
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Document status

Issue	Revision	Date	Nb of page	Modifications
1	0	28th August, 2025	All document	First version
1	1	12th September, 2025	P.6 P.7 P.10 P.11 P.18 P.19 P.20-21 P.24	- 1.1. Reference and applicable documents - 2. Introduction - 4.2.2. CEA's responsibilities - 5. Contract review - 7.3.6. Inter-Organisational Non-Conformity (I-NC) - 7.3.9. PED Assessment - 9.2. Lists of Deliverable - 11.1. ISO 9001 Certificate – Template [T1].

The last modifications appear in blue in the document

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	ITER DMS Prototype - Lot 1 - Cryogenics Quality Plan for SO#2-3	Date: 12th of September, 2025 Ref: DSBT-AQ-25-76 Issue – Revision: 1-1 Page: 3 / 35

CEA Acronyms list

CEA	Commissariat à l'Energie Atomique et aux Energies Alternatives
DSBT	Département des Systèmes Basses Températures
IRIG	Institut de Recherche Interdisciplinaire de Grenoble
QMS	Quality Management System

ITER Acronyms list

CDB	Cold Distribution Box
CHA	Cold Head Assembly
C-QR	Contractor – Quality Representative
CM	DSBT Contract Manager
DMS	Disruption Mitigation System
DR	Deviation Request
DRR	Deliver Readiness Review
FAT	Factory Acceptance Testing
FCR	Final Contract Review
FWC	Framework Contract
IDM	ITER Document Management
IPC	Injector Prismatic Cryostat
ITER	International Thermonuclear Experimental Reactor
IO	ITER Organisation
IO_CRO	IO – Contract Responsible Officer
IO_QARO	IO – Quality Assurance Responsible Officer
KOM	Kick Off Meeting
MIP	Manufacturing and Inspection Plan
NCR	Non-Conformity Report
PED	European Pressure Equipment Directive
PRM	Progress Review Meeting
QARO	Quality Assurance Responsible Officer
QMS	Quality Management System
RCA	Root Causes Analysis
TC	Technical Coordinator
TS	Technical Specification

	CEA - GRENOBLE Département des Systèmes Basses Températures ITER DMS Prototype - Lot 1 - Cryogenics Quality Plan for SO#2-3	Date: 12th of September, 2025 Ref: DSBT-AQ-25-76 Issue – Revision: 1-1 Page: 4 / 35
---	--	--

CONTENT

1	DOCUMENTATION	6
1.1	Reference Documents	6
1.2	Applicable Documents	6
2	INTRODUCTION	7
3	OBJECTIVES AND ACTIVITIES OF THE CONTRACT	7
3.1	Objectives	7
3.2	Activities	8
4	ORGANISATION AND RESPONSIBILITIES	9
4.1	Organisation.....	9
4.2	General Responsibilities	9
4.2.1	<i>Project responsibilities.....</i>	<i>9</i>
4.2.2	<i>CEA's responsibilities</i>	<i>10</i>
4.2.3	<i>IO's responsibilities.....</i>	<i>10</i>
4.3	Subcontracting Management.....	10
4.3.1	<i>Subcontracting Evaluation.....</i>	<i>10</i>
4.3.2	<i>Subcontracting Controls</i>	<i>10</i>
4.4	Quality Control	11
5	CONTRACT REVIEW.....	11
6	TECHNICAL MANAGEMENT	11
6.1	Design Management.....	11
6.2	Design Control	11
6.3	Manufacturing Control	12
6.3.1	<i>Requirements for the Manufacturing Inspection Plan (MIP)</i>	<i>12</i>
6.3.2	<i>Procedure for the MIP</i>	<i>12</i>
6.4	Measuring & Tests	13
7	ANOMALIES, DEVIATIONS & NON-CONFORMITIES MANAGEMENT	13
7.1	Anomalies	13
7.2	Deviation Request.....	13
7.2.1	<i>Main Principles</i>	<i>14</i>
7.2.2	<i>Main Requirements</i>	<i>14</i>
7.2.3	<i>DR Process.....</i>	<i>14</i>
7.3	Non-Conformity.....	15
7.3.1	<i>Main Principles</i>	<i>16</i>
7.3.2	<i>NCR initiation.....</i>	<i>16</i>
7.3.3	<i>Non-conformity categorization.....</i>	<i>16</i>
7.3.4	<i>Assessment of Non-Conformity.....</i>	<i>17</i>
7.3.5	<i>Root Cause Analysis</i>	<i>17</i>
7.3.6	<i>Inter-Organisational Non-Conformity (I-NC):.....</i>	<i>18</i>
7.3.7	<i>Minor Non-Conformities.....</i>	<i>18</i>
7.3.8	<i>Major Non-Conformities.....</i>	<i>19</i>
7.3.9	<i>PED Assessment.....</i>	<i>19</i>
8	SCHEDULE MANAGEMENT	20
9	MANAGEMENT OF DELIVERABLES & DOCUMENTATION	20
9.1	Deliverables Management	20
9.2	Lists of deliverables	20
9.3	Documentation Management.....	21
9.3.1	<i>Documented Inputs</i>	<i>21</i>
9.3.2	<i>CEA/DSBT's Documentation System.....</i>	<i>21</i>
9.3.3	<i>ITER's Documentation System.....</i>	<i>21</i>
9.3.4	<i>Documentation Flow.....</i>	<i>21</i>
9.3.5	<i>Documentation Formats</i>	<i>21</i>

	CEA - GRENOBLE Département des Systèmes Basses Températures ITER DMS Prototype - Lot 1 - Cryogenics Quality Plan for SO#2-3	Date: 12th of September, 2025 Ref: DSBT-AQ-25-76 Issue – Revision: 1-1 Page: 5 / 35
---	--	--

10	HANDLING, STORAGE, PACKING, AND SHIPPING	22
11	ANNEX	23
11.1	ISO 9001 Certificate – Template [T1].....	23
11.2	Manufacturing & Inspection Plan - Template [T2].....	25
11.3	Anomaly Form - Template [T3]	27
11.4	Deviation Request - Template [T4]	30
11.5	Release Note - Template [T5]	33

	CEA - GRENOBLE Département des Systèmes Basses Températures ITER DMS Prototype - Lot 1 - Cryogenics Quality Plan for SO#2-3	Date: 12th of September, 2025 Ref: DSBT-AQ-25-76 Issue – Revision: 1-1 Page: 6 / 35
---	---	--

1 DOCUMENTATION

1.1 REFERENCE DOCUMENTS

	<i>Title</i>	<i>Reference</i>
RD1	Supply Order N°02 for Cold Distribution Box - SO#2	<i>Ref.4200005703 under IO/CT/24/6000000482</i>
RD2	Supply Order N°03 for Cold Cell and Prismatic Cryostat - SO#3	<i>Ref.4200005436 under IO/CT/24/6000000482</i>
RD3	Framework supply contract for Prototype Design, Development and Testing for the ITER Disruption Mitigation System – LOT 1: Cryogenics	<i>IO/CT/24/6000000482</i>
RD4	Quality Requirements for IO Performers	ITER_D_22MFG4 v6.3
RD5	IO Safety Classification and Hazop	ITER_D_47TEBS v1.0
RD6	IO Quality Classification Determination	ITER_D_24VQES v6.0
RD7	Système de Management de la Qualité du CEA/DSBT – Politique Qualité	DSBT/25-048
RD8	Conditions Générales d'Achat (CGA) du CEA (édition de janvier 2022)	
RD9	ITER Numbering System for Components and Parts	ITER_D_28QDBS v5.1
RD10	Directive Européenne des Equipements Sous Pression (European Pressure Equipment Directive - PED)	PED 2014/68/EU
RD11	Framework Supply Contract for Prototype Design, Development and Testing for The ITER Disruption Mitigation System - Lot 1: Cryogenics: CEA TECHNICAL OFFER	DSBT/PF/23-75 - Version 1.0

1.2 APPLICABLE DOCUMENTS

	<i>Title</i>	<i>Reference</i>
AD1	Framework contract for DMS Prototypes - Lot 1 framework technical specification – CRYOGENIC Prototypes	ITER_D_9CBP22 v1.3
AD2	SO2 Technical Specification – Cold Distribution Box	ITER_D_9CBVMQ v1.4
AD3	SO3 Technical Specification – Cold Cell and Prismatic Cryostat	ITER_D_9CBXPA v2.4
AD4	Procedure for Management of Nonconformities	ITER_D_22F53X v9.1
AD5	Procedure for the Management of Deviation Request	ITER_D_2LZJHB v9.1

	CEA - GRENOBLE Département des Systèmes Basses Températures ITER DMS Prototype - Lot 1 - Cryogenics Quality Plan for SO#2-3	Date: 12th of September, 2025 Ref: DSBT-AQ-25-76 Issue – Revision: 1-1 Page: 7 / 35
---	---	--

2 INTRODUCTION

This document is the Quality Plan (QP) developed by CEA/DSBT and restricted to the real needs and the content of the **Supply Order #2 “Cold Distribution Box”** [RD1] & **Supply Order #3 “Cold Cell and Prismatic Cryostat”** [RD2] under the Framework Contract **“Prototype Design, Development and Testing for the ITER Disruption Mitigation System – Lot 1: Cryogenics”** [RD3].

This quality plan describes the quality rules in accordance to the IO requirements that are applied to this framework supply contract [RD4]. Beyond IO's requirements, CEA/DSBT applies rules described in its own Quality Management System (QMS). The Quality Policy introduces the CEA/DSBT's QMS [RD7].

Since July 2023, CEA/DSBT has been awarded the ISO 9001-2015 certificate [T1].

The quality plan has the following objectives:

- Give to IO the assurance that the specified quality is effectively reached through the application of systematic and pre-established dispositions,
- Inform the IO's and CEA's project teams about the specific measures being implemented and the associated supports,
- Specify the quality measures to be passed on to CEA's subcontractors.

For all CEA subcontractors, their own Quality Plan will be submitted to IO as soon as the subcontracting contract will be in place. If needed, gate reviews such as FDR, MRR, DRR will be planned and mentioned in the subcontractor Quality Plan. For all SO#3 manufacturing and control activities, SDMS is the foreseen subcontractor. For all SO#2 manufacturing and control activities, no subcontractor is yet determined.

The scope of the Framework Contract [RD3] does not fall under Quality and Safety Classification according to [RD5] and [RD6].

3 OBJECTIVES AND ACTIVITIES OF THE CONTRACT

3.1 OBJECTIVES

The purpose of the **Supply Order #2 “Cold Distribution Box”** [RD1] & **Supply Order #3 “Cold Cell and Prismatic Cryostat”** [RD2] is to design and manufacture the Cold Distribution Box and Cold Cells and Prismatic Cryostats prototypes for the ITER DMS. The prototypes will cover specific components of the DMS design that are at preliminary design maturity, but that require further design development and testing to characterize their performance and to improve the final design.

The IO Framework Technical Specification [FWC-TS, AD1] defines the technical requirements for the final design, manufacturing, procurement, testing and delivery of the ITER-DMS cryogenic prototypes, Lot 1 of the FWC. **The IO Technical Specification [SO#2-TS, AD2] for the Supply Order SO#2 and [SO#3-TS, AD3] for the Supply Order SO#3 under Lot 1 - Cryogenics details the technical requirements for the prototypes.**

The FWC including SO#2 and SO#3 is a Supply Contract: CEA/DSBT is responsible for the supply of a product, its delivery to the ITER Site and for ensuring that the product meets the acceptance criteria defined in the FWC-TS and specifically the SO#2-TS and SO#3-TS. For those, CEA/DSBT is responsible for the supply and the delivery to CEA of the CDB and CCA/IPC as defined in in perspective of cryogenic testing in SO#4.

This is a Detailed Design Specification: The IO is responsible for the Conceptual Design and the Preliminary Design and provides them to CEA/DSBT as an input, the detailed design requirements and related documents, e.g. P&IDs, 3D preliminary models, space constraints, functional requirements, some components selection. Thereafter the responsibility for the final design is taken over by CEA/DSBT. CEA/DSBT is responsible for executing the final design and for providing a system, which is compliant with the IO's TS.

3.2 ACTIVITIES

In order to monitor the activities of this contract, a Work Breakdown Structure (WBS – See herein) is developed and used as a basis for the Schedule.

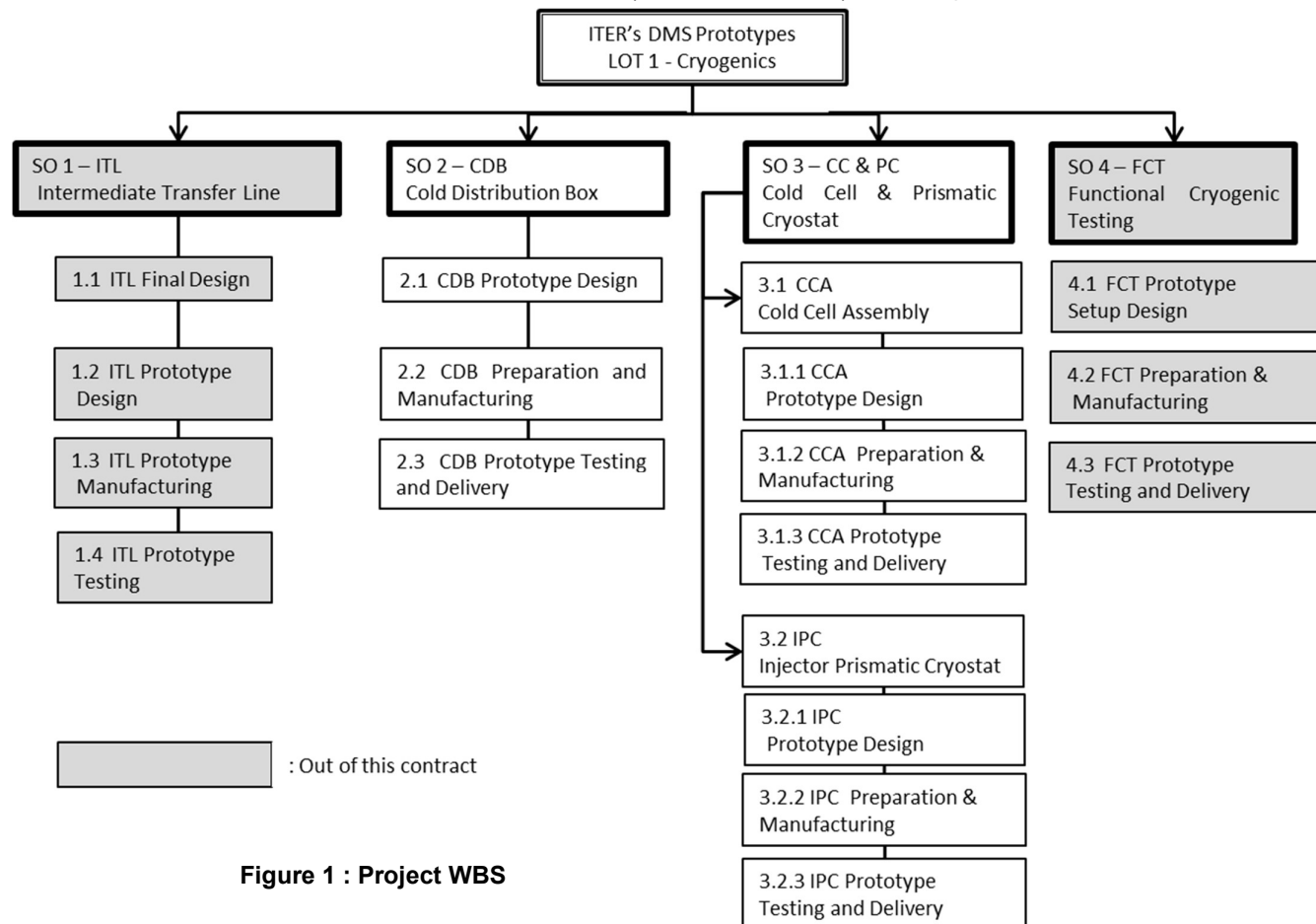


Figure 1 : Project WBS

	CEA - GRENOBLE Département des Systèmes Basses Températures ITER DMS Prototype - Lot 1 - Cryogenics Quality Plan for SO#2-3	Date: 12th of September, 2025 Ref: DSBT-AQ-25-76 Issue – Revision: 1-1 Page: 9 / 35
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4 ORGANISATION AND RESPONSIBILITIES

4.1 ORGANISATION

The contract is performed within the following organization:

- The Contract Manager (CM) is responsible for the contract content.
- The Contractor Quality Representative (C-QR) is responsible for the quality management.
- Verifications and approvals are performed by the IO_CRO, when necessary.

The organization chart of this project is presented in Figure 2. The CVs of the CEA/DSBT core team are present in the CEA offer. The Project Manager is in charge of the training and qualification of the personnel. If any skill or competency is missing, a dedicated training will be put in place through the CEA training Scheme. Specific qualifications will be detailed in the subcontractor's QP when applicable.

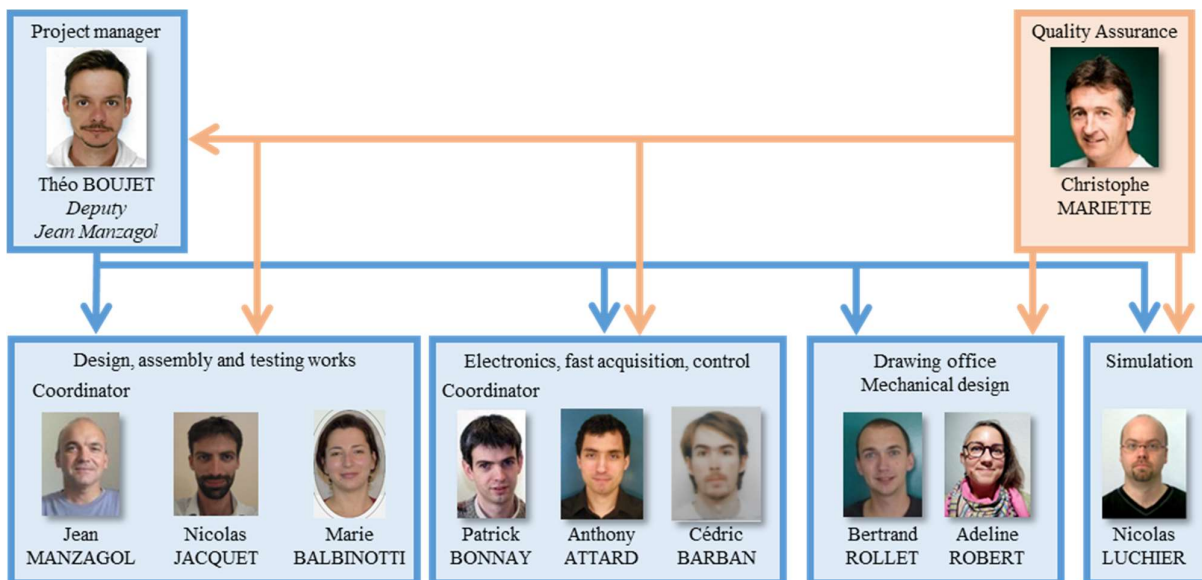


Figure 2: Project Organization

4.2 GENERAL RESPONSIBILITIES

4.2.1 Project responsibilities

- M Théo Boujet is the Contract Manager (CM) and the Project Manager of the Framework contract ITER-DMS Prototype – Lot 1 - Cryogenics. He is responsible for the management of all activities of the contract.
- M Jean Manzagol is responsible for the technical coordination, named Technical Coordinator (TC). He is in charge of the follow-up of the technical activities such as Subcontracting, Schedule, Design, Procurement, Manufacturing, Controls, Factory Tests and Deliverables.
- M Christophe Mariette is responsible for the quality management and named the Contractor Quality Representative (C-QR). He is in charge of the follow-up of all activities in quality terms.

The following chart describes the activities requiring for the supervision and validation.

	CEA - GRENOBLE ITER DMS Prototype - Lot 1 - Cryogenics Quality Plan for SO#2-3	Département des Systèmes Basses Températures Date: 12th of September, 2025 Ref: DSBT-AQ-25-76 Issue – Revision: 1-1 Page: 10 / 35
---	---	---

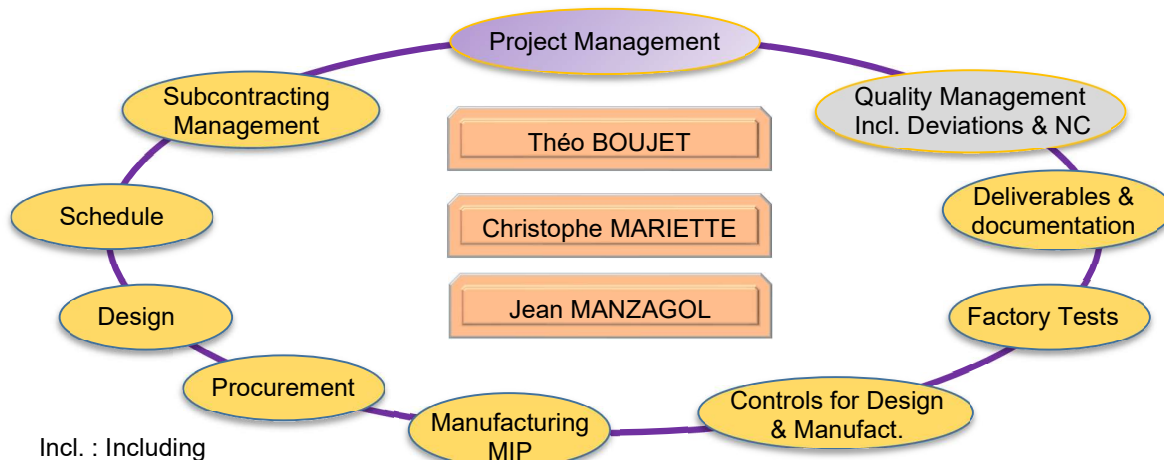


Figure 3: activities of the project

The manufacturing phase includes the MIP filling and update as it goes along. The controls concern the design control and the manufacturing control. Tests are the measurements done at the subcontractor premises and in particular the ones for the final Factory Tests. The quality management includes the management of the deviations and Non-Conformities (NC)

4.2.2 CEA's responsibilities

The CEA/DSBT provides results according to the scope of the work outlined above and agreed between the corresponding Contact Persons, and fulfils the implementation plan and conditions of the present Contract. [IO or his representatives have free access to the CEA and sub-contractor premises for work being executed.](#)

4.2.3 IO's responsibilities

The ITER Organization provides the necessary information and access to the adequate ITER files for executing this work when needed following the implementation plan.

4.3 SUBCONTRACTING MANAGEMENT

4.3.1 Subcontracting Evaluation

All the procurements are done according to the CEA's rules [RD8].

The critical subcontractors involved in this contract, have to implement their own quality Plan. Their quality plan has to be applicable only to the scope of work performed for the related IO activities.

Regarding SO#3, SDMS is the foreseen subcontractor proposed in the CEA Offer (RD11) and accepted by IO for the scope covered by RD1, and RD3, based on the SDMS company documentation submitted during the tender phase, which can be found in Appendix A1.1 from RD11.

The work of the critical subcontractors must not start until their Quality Plan has been approved by CEA/DSBT.

4.3.2 Subcontracting Controls

The CEA/DSBT team managed by the CM and TC assisted by the C-QR follows the subcontractor's performances via frequent inspections. Controls allow knowing how, when and by whom procurements are performed, including:

- any important items or activities that are to be purchased or subcontracted,

	CEA - GRENOBLE Département des Systèmes Basses Températures ITER DMS Prototype - Lot 1 - Cryogenics Quality Plan for SO#2-3	Date: 12th of September, 2025 Ref: DSBT-AQ-25-76 Issue – Revision: 1-1 Page: 11 / 35
---	---	---

- the relevant quality assurance requirements,
- the proposed suppliers or subcontractors,
- the methods to be used to evaluate, select and control subcontractors,
- the methods to be used to satisfy regulatory requirements, which apply to subcontracted products.

4.4 QUALITY CONTROL

The quality control exists at all levels, steps and activities of the contract. The quality control includes all controls, tests and reports required during all the phases of the contract. The traceability is established through the codification of each deliverable.

5 CONTRACT REVIEW

- For SO#3, the Kick-Off Meeting (KOM) was held on October 2024, the 10th (T0),
- For SO#2, the Kick-Off Meeting (KOM) was held on April 2025, the 16th (T0),
- The Regular Progress Review Meetings (PRMs) are organized. A monthly frequency is initially defined.
- The Contract Reviews are organized bi-yearly and defined with IO. Agenda and relevant information have to be sent by the CM at least 2 days before the meeting.
- A Final Contract Review (FCR) has to be organized at the end of the contract.

6 TECHNICAL MANAGEMENT

6.1 DESIGN MANAGEMENT

From the very beginning, Design Reviews are integrated in the KOM and the PRMs. However, some specific design review meetings could occur additionally.

All design solutions are identified, reviewed, tracked and checked throughout the contract life. Compliance with these requirements have to be demonstrated via design reports and/or project reviews. These reviews are documented in accordance with the contractual specifications.

All design documents dedicated to IO are reviewed by a competent person in the domain and different from the author and by the C-QR also. The final submission of the CEA documents is done by the CM or the TC. The CM or the TC ensures that selected solutions cope with the technical specifications of the customer.

IO has to approve documents in IDM as, minutes of PRM, design reports.

6.2 DESIGN CONTROL

The design control is based on:

- Proper documents management to verify the good version of the deliverables (see "Documentation Management" presented in chapter 0),
- Subcontracting specifications including quality requirements (see "Subcontracting Management", §4.3),
- Identification of individual items to insure traceability of the quality activities for appropriated items.
- The ITER TAG numbering and PNI is applied for the main components and all material, that is to say the Cold Distribution Box and the Cold Cell Assemblies / Injector Prismatic Cryostat, following RD9, in compliance to FWC.CRYO.064 from RD3.

Verifications are done either by the subcontractor under the CEA/DSBT's control or by the CEA/DSBT directly.

  	CEA - GRENOBLE Département des Systèmes Basses Températures ITER DMS Prototype - Lot 1 - Cryogenics Quality Plan for SO#2-3	Date: 12th of September, 2025 Ref: DSBT-AQ-25-76 Issue – Revision: 1-1 Page: 12 / 35
---	--	---

6.3 MANUFACTURING CONTROL

The manufacturing control will be based on:

- Proper documents management to verify the good version of the manufacturing documents (see §0),
- Subcontracting specifications including quality requirements (see §4.3),
- Manufacturing and Inspection Plans (MIP) defining the manufacturing steps and allowing also to control the progress of the work (see Template T2 in §11),
- Identification of individual items to insure traceability of the quality activities for appropriated items.
- The ITER TAG numbering and PNI is applied for the main components and all material, that is to say the Cold Cell Assembly and the Injector Prismatic Cryostat, following RD9, in compliance to FWC.CRYO.064 from RD3.

For deliverables, verifications will be done either by the subcontractor under the CEA/DSBT's control or by the CEA/DSBT directly.

6.3.1 Requirements for the Manufacturing Inspection Plan (MIP)

The Manufacturing Inspection Plan (MIP) is a listing of the sequence of operations affecting quality. For each particular operation, the MIP shall identify:

- Requirements and instructions applicable to those operations,
- Operations to be inspected or witnessed by IO,
- Reference document providing traceability and recording of the verification and completion of these operations.

The level of detail in a MIP should be such as to prevent the inadvertent by passing of critical operations and to enable adequate planning, monitoring and verification of critical operations. To ensure that operations are performed as directed in this plan, the document should be directly accessible to those carrying out the work.

A MIP must be written in English for IO record purpose and acceptance, and be easily understood by those carrying out the work. When English is not the mother tongue, the document must be in dual language to facilitate CEA/DSBT and subcontractor workforce understanding.

Work shall not start until the MIP has been accepted by IO Responsible Officer (or his duly appointed representative).

Acceptance of the MIP shall not relieve the performer of any contractual obligation and responsibilities.

6.3.2 Procedure for the MIP

All suppliers and subcontractors who perform activities of this contract shall submit a MIP through CEA/DSBT CM to the IO Responsible Officer (or his duly appointed representative of that activity) for acceptance and mark-up IO intervention point.

After internal review, IO will return the MIP to the CEA/DSBT CM with a mark-up of IO intervention points. If the IO_TRO decides that essential operations are missing on the submitted MIP, the MIP will be returned to the CEA/DSBT for correction. Evidence of IO acceptance of the MIP shall be maintained. A revised MIP shall be subject to the same acceptance procedure as the original MIP.

It is the CEA/DSBT's responsibility to notify the IO of any forthcoming intervention points: Hold Points, Notification Points, Witness. After having been informed about these different points, IO will be informed about relevant meetings and will be able to attend the meetings.

The intervention points present on the MIP must be signed off and dated by the person performing the intervention. Compliance with this plan shall be checked and recorded as work progresses.

	CEA - GRENOBLE Département des Systèmes Basses Températures ITER DMS Prototype - Lot 1 - Cryogenics Quality Plan for SO#2-3	Date: 12th of September, 2025 Ref: DSBT-AQ-25-76 Issue – Revision: 1-1 Page: 13 / 35
---	--	---

- Each completed operation must be dated and signed off at the time of completion by the performer or his direct supervisor,
- The identification of records generated during the performance of the particular operation (e.g. test report, non-conformance report, etc.) must be recorded on the MIP.

6.4 MEASURING & TESTS

This chapter is presently not applicable to this Supplier Order. Indeed, the SO#2 and SO#3 is dedicated to the Cold Distribution Box and the Cold Cell Assemblies / Injector Prismatic Cryostat Manufacturing. All measuring and testing will only be performed at the subcontractor premises, under the supervision of CEA/DSBT.

The measuring and tests description will be fully applicable to the CEA/DSBT activities performed in the Supplier Order SO#4 dedicated to the Prototype testing at CEA as well as in the subcontractor Quality Plan.

During experiments, some measuring & test apparatus are required. All used apparatus are identified and all measurements and tests are detailed and recorded.

More particularly, all the measurements are named and stored in a specific folder. In order to identify measurements in time, they are dated correctly and measurements are synchronized. These measurements include all the data from instrumentation (pressure, temperature, ...) to allow re-running any test in the same experimental conditions. A master list of instruments with calibration validity and serial number are provided and calibration stickers are present on the instruments.

7 ANOMALIES, DEVIATIONS & NON-CONFORMITIES MANAGEMENT

Anomalies, Deviations & non-conformities are managed in accordance with IO's requirements based on the IO's document [AD4, AD5].

When a default appears, it is identified as anomaly. According to importance of its impact, the anomaly is classified as "Immediate action", deviation or non-conformance.

The management of internal nonconformities of external performers is not covered by the IO's procedure. However, external performers shall make lists of their internal nonconformities available to IO for information, on request of IO. Internal nonconformities are managed by the CEA/DSBT's QMS and/or the QMS of critical subcontractor.

A deviation is managed differently since it is an accepted default that becomes a deviation to former IO specifications.

7.1 ANOMALIES

An anomaly is a sudden default detected during a project activity. It is identified in a dedicated template, the anomaly form [T3 in ANNEX]. If the performer masters the anomaly and can correct it with no consequence, the subcontractor can implement an immediate action. In this only case, the anomaly is classified as "Immediate Action".

If the anomaly is not mastered or corrected with consequence, it is then classified as a deviation or non-conformity depending on the impact and the choice on IO's requirements as described below.

7.2 DEVIATION REQUEST

A deviation is an accepted alternative to a specified IO's requirement relating to Technical or Quality requirements. Each identified deviation is the object of a Deviation Request (DR). Each DR sent to CEA/DSBT by the subcontractor has to be forwarded to IO for discussion and approval (See Template T4 in ANNEX).

	CEA - GRENOBLE Département des Systèmes Basses Températures ITER DMS Prototype - Lot 1 - Cryogenics Quality Plan for SO#2-3	Date: 12th of September, 2025 Ref: DSBT-AQ-25-76 Issue – Revision: 1-1 Page: 14 / 35
---	--	---

A deviation request can be initiated either by CEA/DSBT, its subcontractors or by IO itself. The request shall contain or refer to all relevant material available to enable an informed decision to be taken by CEA/DSBT_CM and IO_CRO.

When a deviation to IO specifications is anticipated, CEA/DSBT shall discuss it with IO_CRO and a DR shall be sent to IO for approval. A deviation to IO specifications means a deviation after an operating control. In the case of a manufactured part, that does not include a manufacture default, which is the direct responsibility of the subcontractor. Such a manufacture default leads the subcontractor to manufacture a new part according to IO's requirements.

7.2.1 Main Principles

Following the IO Procedure [AD5], the main principles that shall be respected for Deviation Request are as follows:

1. CEA/DSBT and IO staff can issue DRs for IO approval,
2. DRs are punctual departures from a particular requirement from the current authorized configuration documentation and prior to the execution of the actions that have an impact on meeting the original specified requirements.
3. The DR process is composed of four main steps:
 - Submission,
 - Review,
 - Decision, dispute and resolution,
 - Closure
4. DRs can impact different authorized configuration documentation, depending on the DR submitter,
5. DRs shall be managed using a dedicated ITER Template from initial submission to closure, as per guidelines given in the procedure AD5.

7.2.2 Main Requirements

1. The Deviation Request shall be submitted for IO review and approval or rejection before implementation of related activity.
2. Before submission to IO, any DR at CEA/DSBT shall be internally reviewed by competent and authorized specialist, and approved for the submission to IO.
3. The DRs shall be issued using the dedicated template (see template T4 in ANNEX).
4. The DR template shall contain some information as indicated in RD9. If the deviation concerns a pressure equipment, the submitter shall also fill the DR by referring to RD10.

7.2.3 DR Process

Below are described the tasks to be executed for each of the four main steps mentioned to the chapter 7.2.1.

7.2.3.1 Submission

The submitter shall:

- ✓ Identify the necessity for a DR from a Procurement Arrangement or contract baseline,
- ✓ Initiate the request by following the DR template (Template T4 in ANNEX),
- ✓ Review the DR for technical coherence, completeness and clarity, prior to the submission to IO,
- ✓ The CM shall approve the DR before submission to IO
- ✓ Upload the DR into the IDM.

7.2.3.2 Review

- ✓ IO shall provide the first check by reviewing the DR submitted form for completeness and appropriateness, and verify that it is in agreement with the main requirement (Chapter 7.2.2 above).

	CEA - GRENOBLE Département des Systèmes Basses Températures ITER DMS Prototype - Lot 1 - Cryogenics Quality Plan for SO#2-3	Date: 12th of September, 2025 Ref: DSBT-AQ-25-76 Issue – Revision: 1-1 Page: 15 / 35
---	--	---

- ✓ IO shall review the DR in order to:
 - Ensure that the DR is technically justified and all requirements mentioned chapter 7.2.2 are respected,
 - Assess the technical aspects from system integration / configuration management point of view and provide the System/Design Integration assessment as needed,
 - Verify if the DR impacts on ITER system level performance, reliability, operability and interfaces as needed,
 - Verify if the submitter's DR impacts permanently any configuration document from the ITER configuration baselines.
- ✓ IO-QARO shall check the compliances of the submitter's DR against the requirements mentioned in this chapter "Deviation Request", the assignment of Quality Classification as per the assigned reviewer or IO approver and other concerned quality documents.
- ✓ Each reviewer shall have ten business days to approve/disapprove the DR, with a clear explanation. If after 10 days, the reviewer has not signed the DR (either approving or disapproving), IO shall query as to its status.

7.2.3.3 Decision, Dispute and Resolution

- ✓ The Division Head of EPNS shall decide on the acceptance or rejection of the DR from Safety and environmental point of view,
- ✓ For all DRs accepted by the Division Head of EPNS, IO shall decide on the approval or rejection of the DR, and provide a rationale to the DR submitter and all involved parties.
- ✓ The MQP process owner shall be the approver for DSBT DR related to the MQP
- ✓ If the DR is rejected, the CM:
 - Shall try to develop an alternative plan that does not require deviation in order to fulfil requirements. If the alternative solution involves a departure from the requirements, the IO CRO shall analyze the request and inform the submitter if this alternative solution can be considered for acceptance.
 - If an alternative solution is not suggested, the IO CRO can dispute the decision and liaises with the involved parties for solution seeking.
- ✓ If the DR is rejected, or a reviewer disapproval rationale is disputed by the initiator and cannot be resolved at the IO CRO level, they shall initiate a resolution process to solve the dispute.

7.2.3.4 Closure

CEA/DSBT or IO Staff, as submitters of the DR, shall:

- ✓ Ensure that the DR decision was disseminated to all stakeholders and provide corrective action as needed.
- ✓ Ensure that all impacted documentation (including, document UID) is registered in the DR submitting form.
- ✓ Confirm the DR implementation (optional), for cases when further critical actions are triggered by DR approval and/or related documentation need to be revised to reflect the implementation of the deviation. For cases when DR implementation confirmation is required, the DR submitter shall attach all the necessary evidence to justify the implementation.

7.3 NON-CONFORMITY

A non-conformance is any condition that does not comply with a specific IO requirement. A non-conformance is identified by means of the Non-Conformity Report.

A Non-Conformity (NC) shall be followed during all phases of the project:

- For both types of NC: Product NC and Process NC
- By both internal and external performers (CEA/DSBT and IO Staff).

  	CEA - GRENOBLE Département des Systèmes Basses Températures ITER DMS Prototype - Lot 1 - Cryogenics Quality Plan for SO#2-3	Date: 12th of September, 2025 Ref: DSBT-AQ-25-76 Issue – Revision: 1-1 Page: 16 / 35
---	---	---

- **Product NC:** When the requirement related to the characteristic of an item, component or work is not fulfilled. As an example, a failure in meeting a specified tolerance of a component.
- **Process NC:** When the MQP procedural requirements are not fulfilled is relative to the specified way of working. As examples, failure in the propagation of requirements in the supply chain; failure in the execution of design process, failure in the notification of a contractual hold point.
 - Process NC related to IO processes will be treated by IO as internal NC in accordance with detailed IO internal working instructions.
 - Process NC related to CEA/DSBT processes will be treated as internal NC in accordance to IO procedures.

7.3.1 Main Principles

The main steps for NC management are as follow:

- ✓ The organization shall immediately stop works related to the non-conforming product / service and inform IO.
- ✓ Immediate actions to segregate (labelling and/or physical separation of NC shall be applied) the non-conforming item / work and to ensure safety.
- ✓ Description of the NC – NC report shall be immediately registered in NC system.
- ✓ Agreement and implementation of remedial actions to eliminate the Non-Conformity. 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 and 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 priority.

7.3.2 NCR initiation

During NC initiation stage, the following points need to be addressed in the NC Report (but not limited):

- Recording the NCR with description of problem.
- NCR categorization (major / minor).
- Preliminary proposal of remedial actions need to be established (if the initiator can provide this information at this stage).

NCR Recording: Once the NCR is detected, the initiator records the NC in the IO NCR database (status "Submit") or equivalent system recognized by IO.

The NCR shall be submitted within maximum 5 working days in the NC system to initiate the NC process. In case of dispute between stakeholders, maximum 2 weeks from the NC detection time may be allowed with IO agreement only.

After the NCR submission in the NC system, the review and approval cycle, will be launched and will allow to all effected stakeholders to provide their feedback.

7.3.3 Non-conformity categorization

The preliminary categorization of NCR shall be done at the initial stage with the involvement IO RO and IO QARO in accordance with the following criteria:

- In ITER project, the way to implement this graded approach for NC management is to categorize any NC either as 'Major' NC or as 'Minor' NC depending on the impact of the NC to the safety, quality or performance.

	CEA - GRENOBLE Département des Systèmes Basses Températures ITER DMS Prototype - Lot 1 - Cryogenics Quality Plan for SO#2-3	Date: 12th of September, 2025 Ref: DSBT-AQ-25-76 Issue – Revision: 1-1 Page: 17 / 35
---	---	---

- The following Table 1 provides guidelines to establish the category of the NCR. The final category shall be agreed between:
 - The NC initiator proposes the NC categorization,
 - The CM or TC with support of C-QR proposes the NC categorization if initiator or modifies/confirms the initiator one,
 - The IO_CRO with support of IO QARO confirms the final NC categorization.

Table 1: Category of a NC

Major NC	Safety / Regulation	Nonconformity with an IO specified requirement affecting Regulatory Requirements, Safety, Environmental impact
	Baseline	Nonconformity with an impact on a Baseline document Level 0 / 1 / 2
	Interactions	Nonconformity with interaction with other PBS, Construction and/or other Process
	Impact on Performance	Implication on Functional performance
	Repetitive NC	More than 2 similar NCRs can trigger one major NC to investigate root cause of recurrence.
Minor NC	Safety / Regulation	Nonconformity with a specified IO requirement not affecting Regulatory Requirements, Safety, Environmental impact
	Baseline	Nonconformity with an impact on a Baseline document Level 3
	Interaction	Nonconformity with no interaction with other PBS, Construction and/or other Process
	Impact on Performance	Implication on layout (within the same space reservation of concerned system/ PBS)
	Nonconformity not falling under definition of Major NC.	

7.3.4 Assessment of Non-Conformity

During the NC evaluation stage, the following points need to be addressed (but not limited):

- Final remedial actions need to be recorded in the NC system and agreed with the NC owner.
- The Preliminary Root Cause Analysis need to be provided and proposed corrective actions / RCA category need to be established and recorded in the NC system (when required).

During this assessment stage, the remedial actions shall be clearly defined and agreed by IO. For all the decided remedial actions, the expected due dates and responsible for NC closure need to be established and recorded in the NC system.

7.3.5 Root Cause Analysis

When the RCA is required, a detailed RCA shall be performed with conclusions whether or not launching corrective actions, and should consider as appropriate any preventive / risk-based actions.

The RCA is required to be applied for all NC in accordance with the following criteria:

- ✓ For major NC, the RCA need to be accepted by IO and shall be mandatory recorded in NC system,

	CEA - GRENOBLE Département des Systèmes Basses Températures ITER DMS Prototype - Lot 1 - Cryogenics Quality Plan for SO#2-3	Date: 12th of September, 2025 Ref: DSBT-AQ-25-76 Issue – Revision: 1-1 Page: 18 / 35
---	--	---

- ✓ For minor NC, the RCA does not require IO acceptance and shall be under CEA/DSBT's responsibility only. For specific cases decided between CEA/DSBT and IO, the RCA may be submitted to IO for acceptance and recorded in NC system.

The RCA categorization with Causal Analysis Tree (CAT) evaluation shall be applied for all NCRs.

For minor NCs, the application of RCA remains under performer internal responsibility and does not require IO acceptance. This minor NC approach does not release the performer from his responsibility to ensure correct evaluation of NC, establishing the NC Causes and Corrective actions application.

The root causes of NC are categorized as following in Table 2:

Table 2: Category of RCA

RCA category/level	Description of RCA category by type of failure
A1	Design / Engineering problem
A2	Equipment / Material problem
A3	Human performance problem
A4	Management (procedure / process / method) problem
A5	Communications problem
A6	Training Deficiency
A7	Other problem

The RCA category/level shall be recorded by the performer in the NC system in the "Preliminary Analysis Causes" section and confirm by IO.

7.3.6 Inter-Organisational Non-Conformity (I-NC):

It is a Non-Conformity between CEA/DSBT and IO. This NC may be resolved more efficiently or in the interests of the ITER project by IO or CEA/DSBT. The I-NC is a non-conformity applied in situations when a quality issue is identified late in the items manufacturing process, when there is a time criticality associated with the onward availability of this item, causing consequential impacts on later work.

When an I-NC is detected, the NCR title should indicate the mark "I-NC" to raise the attention of stakeholders and initiate the application of the I-NC mechanism. [NCR are handled through IO NCR database.](#)

7.3.7 Minor Non-Conformities

The minor NCRs can be closed only after the following conditions are met:

- ✓ All remedial actions are closed (respecting the expected due dates – as recorded in the NCR, initial stage) and evidences for remedial actions closure are recorded (attached to NCR for closure stage) in IO NC system.
- ✓ The RCA application together with corrective actions implementation are under performer responsibility only and does not require IO's acceptance.
- ✓ In case of the decided remedial actions (ex: "reject", "scrap") will not remain part of (will not affect) the final product or activity that will be delivered to IO and the related corrective actions (if necessary) will be implemented internally by performers without affecting IO's products and activities, the NC can be closed immediately – fast NCR closure. For such cases, the NC owner shall agree on fast NCR closure mode.

	CEA - GRENOBLE Département des Systèmes Basses Températures ITER DMS Prototype - Lot 1 - Cryogenics Quality Plan for SO#2-3	Date: 12th of September, 2025 Ref: DSBT-AQ-25-76 Issue – Revision: 1-1 Page: 19 / 35
---	--	---

Fast NCR closure is applicable for minor NCRs where the remedial actions (“reject” or “scrap”) will not affect the final products / activities that will be delivered to IO. Fast NCR closure means, immediate NCR closure after initial stage of NCR is reviewed and approved – does not require a new review / approval cycle for NCR closure by all stakeholders.

In case of a minor non-conformance, the subcontractor shall take actions to resolve the non-conformance within its own quality system and implement remedial actions. The subcontractor shall send it to CEA/DSBT and CEA/DSBT will send it to IO_CRO for information.

Closure: Once the non-conformance is closed, the subcontractor shall send to CEA/DSBT the Non-Conformance Report with the closure information. CEA/DSBT will send it to IO_CRO for information.

7.3.8 Major Non-Conformities

The major NCRs can be closed only after the following conditions are met:

- ✓ All remedial actions are closed (respecting the expected due dates – as recorded in the NCR, initial stage) and the evidences for remedial actions closure are recorded (attached to NCR for closure stage) in IO NCR database (or IDM).
- ✓ All corrective actions (CA) decided as per RCA are closed (respecting the expected due dates – as recorded in RCA) and the evidences for CA closure are recorded in IO's NC System (attached to NCR for closure stage).

The final closure of NC is confirmed if all related actions are implemented to guarantee the IO's requirements of the item or work at the handover to IO.

For NCR closure, the performer (responsible for NCR closure) issues the update of NCR (NC report) in the IO's NC system, to ensure NCR is reviewed & accepted /approved by all relevant stakeholders.

As a basic principle, the delivery of the items shall be released only if all the related NCR's are closed

The Non-Conformance Report shall contain or refer to all relevant material available to enable an informed decision on the definite course of action to be taken. The CEA/DSBT or its subcontractor makes a preliminary RCA and potential consequences, and records it on the non-conformance report. Once the Non-conformance Report written, the subcontractor shall send it to CEA/DSBT and CEA/DSBT will send it to IO for discussion and decision. The remedial action is implemented only after IO's written acceptance. In the cases of Remedial Actions agreed verbally, the actions have to be implemented after receipt of an email from the IO_CRO.

Conditional Release of NC:

For exceptional cases, intermediate / conditional release of NCR can be accepted only after agreement between IO and CEA/DSBT.

For such cases, conditional release of the NC is agreed to allow the shipment of components, tracking and checking of remaining points / actions is required, until the final closure of the NC and handover.

To ensure proper follow-up of conditional release, CEA/DSBT shall maintain the NCR open until all the decided remaining conditions / actions are closed. The continuous follow-up of NCR status will ensure on the same time the follow-up of such conditionally released NCRs.

7.3.9 PED Assessment

According to the IO's NC procedure, this section is useable only when IO is acting as Pressure Equipment (PE) manufacturer. It does not concern the present CEA/DSBT activities. [However, if the NC concerns a pressure Equipment, CEA/DSBT shall fulfil the European Pressure Equipment Directive, PED \[RD10\].](#)

	CEA - GRENOBLE Département des Systèmes Basses Températures ITER DMS Prototype - Lot 1 - Cryogenics Quality Plan for SO#2-3	Date: 12th of September, 2025 Ref: DSBT-AQ-25-76 Issue – Revision: 1-1 Page: 20 / 35
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8 SCHEDULE MANAGEMENT

The management is based from activities identified in the WBS and their dependencies. It is organized with the following processes:

- Estimating the resources and their availabilities,
- Estimating the time to complete each activity,
- Analyze the sequencing, resources, the duration = Schedule baseline,
- Assure the schedule control (performance and deviation control).

The schedule is in progress and available in a specific file. The up-to-date schedule version is presented at each PRM.

9 MANAGEMENT OF DELIVERABLES & DOCUMENTATION

9.1 DELIVERABLES MANAGEMENT

Each contractual deliverable contains on the cover page the IO contract number, the deliverable number, its description as stated in [RD3][RD3] and an Identification File Numbering.

Deliverables are submitted to the IO for approval. After each modification and/or each IO's approval, the document is recorded in a new document with a new revision index.

The ITER Organization shall make its approval or comment decision within a reasonable delay. If the IO's decision is returned late, neither CEA nor the subcontractor would be held responsible for consequences in terms of overall delay and financial aspect.

9.2 LISTS OF DELIVERABLES

The Supplier shall submit all relevant data necessary to demonstrate the performance and outcome of its deliverables to the IO upon request by the IO-CRO anytime during the course of the tasks but the latest with the last deliverable.

The deliverables for the Supply Orders SO#2 and SO#3 shall be in agreement with Appendix 1 of [AD-01] and due dates are given in Table 3. [As mentioned in §5:](#)

- For SO#3, T0 refers to the Kick-Off Meeting (KOM), held on the 10th of October 2024,
- For SO#2, T0 refers to the Kick-Off Meeting (KOM), held on the 16th of April 2025.

Table 3: List of deliverables and due date for SO#3 and SO#2

SO#3			
	Task description	Deliverable description	Due date
D1	Quality plan	Quality plans for supplier and critical subcontractors	T0 (SO#3) + 1 month (November 2024)
D2	Prototype design (FDR package)	System Design Description Engineering Analysis Reports and calculations Notes – Models and drawings.	T0 (SO#3) + 10 months (August 2025)
D3	Manufacturing Preparation (MRR package)	Manufacturing documentation, drawings (empty MIP to be filled) – Manufacturing procedures – Factory Acceptance Test plan	T0 (SO#3) + 12 months (October 2025)

	CEA - GRENOBLE ITER DMS Prototype - Lot 1 - Cryogenics Quality Plan for SO#2-3	Département des Systèmes Basses Températures Date: 12th of September, 2025 Ref: DSBT-AQ-25-76 Issue – Revision: 1-1 Page: 21 / 35
---	---	---

SO#3			
	Task description	Deliverable description	Due date
D4	Prototype manufacturing testing and delivery	Manufacturing dossier – FAT test reports – Delivery documents.	T0 (SO#3) + 24 months (October 2026)

SO#2			
	Task description	Deliverable description	Due date
D1	Quality plan	Quality plans for supplier and critical subcontractors	T0 (SO#2) + 1 month (May 2025)
D2	Prototype design	- System Design Description, including 3D Models and 2D drawings - Engineering Analysis Reports and calculations Notes	T0 (SO#2) + 7 months (November 2025)
D3	Manufacturing Preparation	- Factory Qualification test Plan - Manufacturing documentation (with approved drawings and manufacturing procedures, empty MIP)	T0 (SO#2) + 9 months (January 2026)
D4	Prototype manufacturing testing and delivery	- Complete manufacturing documentation, including Manufacturing dossier, FAT test reports, CoC, CE marking. - Delivery documentation according to [AD2] Section 10	T0 (SO#2) + 22 months (February 2027 - revised schedule from KoM)

9.3 DOCUMENTATION MANAGEMENT

9.3.1 Documented Inputs

All documented IO inputs are given by the IO_CR to the CEA/DSBT_CM.

9.3.2 CEA/DSBT's Documentation System

All documents are stored in a dedicated specific folder within the CEA/DSBT's server. Quality Control records are maintained in this folder.

9.3.3 ITER's Documentation System

The CEA/DSBT_CM or TC uploads and signs contractual documents (deliverable reports) into the IDM (ITER Document Management). The CEA/DSBT receives from IO the information for this purpose.

9.3.4 Documentation Flow

All documentation and information of the quality and all official documentation and information between the CEA/DSBT and IO are exchanged through the Contractor Responsible (CEA/DSBT_CM) and the Responsible Officer (IO_CRO).

9.3.5 Documentation Formats

Since some file formats are not accepted by the CEA's electronic mail system, file formats of this contract are presented in Table 4:

	CEA - GRENOBLE Département des Systèmes Basses Températures ITER DMS Prototype - Lot 1 - Cryogenics Quality Plan for SO#2-3	Date: 12th of September, 2025 Ref: DSBT-AQ-25-76 Issue – Revision: 1-1 Page: 22 / 35
---	---	---

Table 4: File Formats

Document Type	Editable		Reference Format
	Format	Version	
Engineering Drawings			pdf
Test Documents	docx or pdf	Word (MS-Office 2010) or Adobe pdf	docx or pdf
Spread sheets	xlsx	Excel (MS-Office 2010)	Pdf
Schedules	mpp	Project (MS-Office 2010)	pdf
Scan & Pictures	jpg		pdf
Presentations	pptx	Power Point (MS-Office 2010)	pdf
Document sets	zip		
Issued Documents			pdf
Deliverables		Word (MS-Office 2010) or Adobe pdf	docx or pdf

10 HANDLING, STORAGE, PACKING, AND SHIPPING

Subcontractor shall perform the related transport and delivery, using the most appropriate means in order to guarantee a safe delivery. CEA/DSBT shall follow-up the same rules to send package to IO's site.

The CDB prototype might need to be stored in the CEA/DSBT premises for a period before they are tested and latterly delivered to IO.

CEA/DSBT shall foresee space for storing the prototypes until the end of functional testing and delivery to the IO, for the entire duration of the FWC. The prototype for each SO shall be delivered according to following steps:

- ✓ Prepare Deliver Readiness Review (DRR) documents.
- ✓ Condition, pack and ship the prototype to the address defined by IO within SO.

The prototype shall be transported in the installation orientation and protected from shocks. One or more 3-axis accelerometers shall be attached to the transportation frame/crate, in order to record the maximum acceleration received during transportation. The acceleration limit during transportation shall be defined and verified during the design phase and shall not exceed 10g.

Shipment Hold Point shall only be released after completing the Delivery Readiness Review (DRR).

The following mandatory documents shall be provided in accordance with the working instruction by the DRR:

- a Contractor Release Note [QVEKNQ]
- b Delivery Report [WZPYVZ]
- c Packing List that reflects the content of the CRN [XBZLNG]
- d Equipment Storage & Preservation Requirements Form [WU9636],

The relevant templates will be provided by IO in due time. The DRR documents shall be submitted to IO CRO and to logistics.data@iter.org at least 15 working days prior to the planned shipment date.

	CEA - GRENOBLE Département des Systèmes Basses Températures ITER DMS Prototype - Lot 1 - Cryogenics Quality Plan for SO#2-3	Date: 12th of September, 2025 Ref: DSBT-AQ-25-76 Issue – Revision: 1-1 Page: 23 / 35
---	---	---

The Delivery Report prepared by CEA/DSBT, shall state as a minimum:

- ✓ The packing date;
- ✓ The full address of the place of delivery and the name of the person responsible to receive the package, as well as of the CEA/DSBT's name and full address;
- ✓ Bill of Materials (BoM);
- ✓ Security Measures;
- ✓ Contractor Release Note (see template T5 in appendix);
- ✓ Packing List;
- ✓ Material Safety Sheet;
- ✓ The declaration of integrity of the package;
- ✓ The declaration of integrity of the components;
- ✓ Any additional relevant information on the status of the components.

The packing and packaging list and a delivery report shall also be provided to logistics.data@iter.org in accordance with the working instruction for the DRR.

The delivery address is: ITER Organization
Route de Vinon-sur-Verdon
13115 ST PAUL LEZ DURANCE – France

11 ANNEX

11.1 ISO 9001 CERTIFICATE – TEMPLATE [T1]

	CEA - GRENOBLE ITER DMS Prototype - Lot 1 - Cryogenics Quality Plan for SO#2-3	Département des Systèmes Basses Températures Date: 12th of September, 2025 Ref: DSBT-AQ-25-76 Issue – Revision: 1-1 Page: 24 / 35
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Certificat en cours :
Date d'expiration :
Numéro de certificat :

25 Juillet 2023
24 Juillet 2026
10541954

Première(s) approbation(s) :
ISO 9001 - 25 Juillet 2023

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Certificat d'Approbation

Nous certifions que le Système de Management de la société :

CEA IRIG-DSBT GRENOBLE

17 rue des martyrs, 38054 GRENOBLE cedex 9, France

a été approuvé par la société LRQA selon les normes suivantes :

ISO 9001:2015

Numéro(s) d 'approbation : ISO 9001 – 00041393

Le Système de Management concerne :

Gestion de projets de recherche et développement, de fourniture, mise en service d'équipements et expertise en cryogénie, caractérisation des conductivité et dilatation thermiques des matériaux, stockage et distribution de fluides.



Paul Graaf

Area Operations Manager, Europe

Emis par : LRQA Limited



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--	--	---

11.2 MANUFACTURING & INSPECTION PLAN - TEMPLATE [T2]

	CEA - GRENOBLE	Département des Systèmes Basses Températures
	ITER DMS Prototype - Lot 1 - Cryogenics Quality Plan for SO#2-3	

		MANUFACTURING & INSPECTION PLAN				ITER DMS – Proto Cryo Lot 1 – SO#2-3			
Document Reference :		CEA-DSBT-ITER-DMS-Proto-Cryo-SO2-3-MIP-Item-0.1							
ITER PP Number:		Contract Number:		4200005436 (SO#3) 4200005703 (SO#2) under IO/CT/24/6000000482		Title of Item:			
Name of CEA's Department		DRF / IRIG / DSBT		Supplier:					
Prepared by Subcontractor		Approved by CEA/SBT		ITER Acceptance		Code *			
Name:		Name:		Name:		HP: Hold Point			
Signature		Signature		Signature		ATPP: Authorization to Proceed Point			
						NP: Notification Point			
						W: Witness of Operation			
Position:		Position:		Position:		S1: 100% Inspection, S2: Random Inspection			
Date: 202_ / _ / _		Date: 202_ / _ / _		Date: 202_ / _ / _		R: Review Report			
PP: Procurement Arrangement, (1): Third Party Inspection									
Operations (Manufacture, Inspections & Tests, etc.)	Expected Date	Applicable procedures, drawings, instructions, etc.	Inspection Body				Records (report, non- conformance number, etc.)	Observations	
			Supplier	CEA	ITER	Others (1)			
			Name, Sign & Date	Name, Sign & Date	Name, Sign & Date	Name, Sign & Date			
				*		*		*	

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 	CEA - GRENOBLE Département des Systèmes Basses Températures ITER DMS Prototype - Lot 1 - Cryogenics Quality Plan for SO#2-3	Date: 12th of September, 2025 Ref: DSBT-AQ-25-76 Issue – Revision: 1-1 Page: 27 / 35
--	--	---

11.3 ANOMALY FORM - TEMPLATE [T3]

	CEA - GRENOBLE	Département des Systèmes Basses Températures
	ITER DMS Prototype - Lot 1 - Cryogenics Quality Plan for SO#2-3	
		Date: 12th of September, 2025 Ref: DSBT-AQ-25-76 Issue – Revision: 1-1 Page: 28 / 35

	Réf : CEA-DSBT-ITER_DMS-Proto_Cryo_SO2-3_AF-Name-0-1
	ITER DMS – Proto Cryo Lot 1 – SO#2-3 ANOMALY FORM (AF)
	Version.Revision : 0-1 Date : 202 /mm/dd Page 1/2

Section 1 *To be completed by the subcontractor, if not the CEA.*

1. Date :	2. Subcontractor / Sous-traitant :
3. Anomaly Identification / Identification anomalie :	
4. Equipment information / Information équipement: Model concerned / Modèle concerné (version) : Name Name & Ref / Nom et ref. :	
5. Notification Phase / Phase de la notification : ☐ Manufacturing / Fabrication ☐ Assembly / Assemblage ☐ Test / Test ☐ Delivery / Livraison ☐ Others / Autres	
6. Anomaly Description / Description de l'anomalie:	
7. Analysis / Analyse :	
8. Recommendations / Recommandations :	

	CEA - GRENOBLE	Département des Systèmes Basses Températures
	ITER DMS Prototype - Lot 1 - Cryogenics Quality Plan for SO#2-3	
		Date: 12th of September, 2025 Ref: DSBT-AQ-25-76 Issue – Revision: 1-1 Page: 29 / 35

	Réf : CEA-DSBT-ITER_DMS-Proto_Cryo_SO2-3_AF-Name-0-1
	Version.Revision : 0-1 Date : 202 /mm/dd Page 2/2

1st (1^{ère}) Classification ☐ Anomaly / Anomalie ☐ Non-Conformity / Non-Conformité		
Responsible Subcontractor Officer / Officier sous-traitant Responsable Name / Nom : Date : Signature :	CEA Technical Responsible / Responsable Technique CEA Name / Nom : Date : Signature :	CEA Quality Responsible / Responsable Qualité CEA Name / Nom : Date : Signature :

Section 2 *To be completed if Non-Conformity, inform IO via NCR.*

Non-Conformity Category /: ☐ Minor Non-Conformity / ☐ Major Non-Conformity / Catégorie de la Non-Conformité Non-Conformité Mineure Non-Conformité Majeure	
Non-Conformity Report Attached (reference) : / Rapport Non-Conformité Rattaché (référence)	
CEA Responsible Officer / Officier Responsable CEA Name / Nom : Date : Signature :	CEA Quality Officer / Officier Qualité CEA Comments / Commentaires : Name / Nom : Date : Signature :

 	CEA - GRENOBLE Département des Systèmes Basses Températures ITER DMS Prototype - Lot 1 - Cryogenics Quality Plan for SO#2-3	Date: 12th of September, 2025 Ref: DSBT-AQ-25-76 Issue – Revision: 1-1 Page: 30 / 35
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11.4 DEVIATION REQUEST - TEMPLATE [T4]

	CEA - GRENOBLE	Département des Systèmes Basses Températures
	ITER DMS Prototype - Lot 1 - Cryogenics Quality Plan for SO#2-3	
		Date: 12th of September, 2025 Ref: DSBT-AQ-25-76 Issue – Revision: 1-1 Page: 31 / 35

Deviation Request (DR)

1. General

Type of DR	IO / DA / CON		Issue Date		
DA/ CON / ref. num.					
DR Title					
Item/ Component identification					
Work Activity:					
	PBS description			PBS number	
Main PBS					
Quality class (QC)	QC 1: ☐ QC 2: ☐ QC 3: ☐ QC 4: ☐				
Safety self - assessment by RO	PIC/SIC-1	PIC/SIC-2	Non-SIC		PIA
	☐	☐	☐		☐
IO Manufacturer of the Pressure Equipment or Nuclear pressure Equipment	Yes ☐	PE ☐	Pressure Category		Radioactive level
	No ☐	NPE ☐	☐ 0 ☐ I ☐ II ☐ III ☐ IV	☐ Level N2 ☐ Level N3	

2. Description of Deviation

Introduction	
Description of the original requirements (Before)	
Description of the proposed alternative (After)	
Justification (for PIC and PIA, include safety justification)	

	CEA - GRENOBLE	Département des Systèmes Basses Températures
	ITER DMS Prototype - Lot 1 - Cryogenics Quality Plan for SO#2-3	
		Date: 12th of September, 2025 Ref: DSBT-AQ-25-76 Issue – Revision: 1-1 Page: 32 / 35

Deviation Request (DR)

3. Impact assessment (to be filled by initiator)

Other technical impact	☐
Cost impact	☐
Schedule impact	☐
Impact on interface, other impacted PBS, PA, etc.	☐
Impacted documents	☐ <i>List impacted document title and <u>U</u>id + Rev. Num.</i>
Other impacts	☐
Follow-up of DR implementation (see note 4*)	Required ☐ Not required ☐

4. Safety and Environmental (Assessment by EPNS-DH – see note 2*)

Assessment result and comments	☐ Escalation required to a EPNS meeting required / ☐ Accepted (No escalation) ☐ Rejection unless revised
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5. System / Design Integration (Assessment by IO-DIRO – see note 3*)

Assessment result and comments	☐ Escalation to a PCR required ☐ Accepted (No escalation to PCR required)
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6. Decisions

	Name	Signature*	Date	Decision
Initiator				
CON RO				
DA RO				
IO-Approver				☐ Approve * ☐ Reject *

7. Confirmation of Implementation (if required – see section 3 – impact assessment)

	Name	Signature*	Date
CON-RO			
DA RO			
IO-Approver			

8. List of Attachment

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Note *:

- 1- Signature of DR and confirmation of IO decision (reject/ accepted) are mandatory required. IDM system may be used for DR review and approval signatures (DR shall indicate the reviewers / approver names and date).
- 2- EPNS-DH (delegated SRO) assessment will be recorded in IDM system – with a clear resolution if DR is rejected/escalated.
- 3- DIRO assessment will be recorded in IDM system. If escalation to PCR is required then the section 5 of DR shall be mandatory filled.
- 4- The DR implementation confirmation “is required” typically for the cases when further critical actions are triggered by DR approval and/ or related documentation need to be revised to reflect the deviation implementation.

	CEA - GRENOBLE Département des Systèmes Basses Températures ITER DMS Prototype - Lot 1 - Cryogenics Quality Plan for SO#2-3	Date: 12th of September, 2025 Ref: DSBT-AQ-25-76 Issue – Revision: 1-1 Page: 33 / 35
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11.5 RELEASE NOTE - TEMPLATE [T5]

	CEA - GRENOBLE	Département des Systèmes Basses Températures
	ITER DMS Prototype - Lot 1 - Cryogenics Quality Plan for SO#2-3	
		Date: 12th of September, 2025 Ref: DSBT-AQ-25-76 Issue – Revision: 1-1 Page: 34 / 35

	Ref : CEA-DSBT-ITER_DMS-Proto_Cryo_SO2-3_RN-Item-0-1	
	ITER DMS – Proto Cryo Lot 1 – SO#2-3 Release Note (RN)	Issue.Revision : 0-1 202_/mm/dd Page 1/1

Section 1 *To be completed by CEA*

1. ITER Contract number: 4200005436 (SO#3) & 4200005703 (SO#2) under IO/CT/24/6000000482	
2. With the exception of the deviations listed below (section 6), we certify that the following equipment or service: <i>(describe)</i>	
3. has been manufactured or performed, inspected and tested in accordance with requirements described in the following documents: <i>(documents list)</i>	
4. that the equipment or service is complete, 5. that all relevant verifications, inspections and tests are complete and satisfactory, 6. that the following documents are those required by the technical specifications: <i>(Detailed list)</i>	
7. List of deviation request and non-conformance report: <i>(attached)</i>	
CEA Technical Responsible Name : Date : Signature :	CEA Quality Responsible Name : Date : Signature :

Section 2 *To be completed by ITER*

IO Responsible Officer Decision : Name : Date : Signature :	IO Quality Officer Comments : Name : Date : Signature :
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	CEA - GRENOBLE Département des Systèmes Basses Températures ITER DMS Prototype - Lot 1 - Cryogenics Quality Plan for SO#2-3	Date: 12th of September, 2025 Ref: DSBT-AQ-25-76 Issue – Revision: 1-1 Page: 35 / 35
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End of the document