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EXTERNAL REFERENCE / VERSION

MQP Level 3

MQP L3 WI for Manufacturing and Inspection Plan

This document explains preparation and implementation of Manufacturing and Inspection Plan (MIP).

Approval Process			
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Change Log			
MQP L3 WI for Manufacturing and Inspection Plan (UKQG8M)			
Version	***Latest Status***	***Issue Date***	***Description of Change***
v0.0	In Work	28 Mar 2017	
v1.0	Signed	19 Dec 2017	first version as approved MQP doc request VQ82Y3
v1.1	Signed	19 Dec 2017	Responsibilities are updated: Intervention point markup for TRO from R to A/R as per request in v 1.0
v1.2	Signed	05 Jan 2018	NO IMPACT ON: Nuclear Safety, Environmental Protection, Configuration Management, Project Control, Quality Assurance ADDITIONAL INPUT (alternative template) FOR: Documents and Records, Procurement The changes are: FORM PREPARATION 1. In case the alternative template (not the Form with the operations yet which is to be accepted by TRO) is to be used it is subject to QARO acceptance (7.2). Responsibilities and Outputs matrices are updated accordingly (8, 10). 2. "IO negotiation" of the Form is replaced with "IO review and communication of necessary changes" to avoid extra kindness (7.2). 3. For acceptance of the Form "QARO or QCRO" is replaced with "QARO (and QCRO if dedicated QCRO is assigned in the scope of activity)" to avoid ambiguity (7.2). ACCEPTANCE OF COMPLETE MIP 4. Acceptance by QCRO is replaced with QARO/QCRO as it is systematically QARO (7.3.5). Responsibility table is updated as "C/R" for both QARO/QCRO (8). 5. Encouragement of complete MIP submission ASAP is added (7.3.5). Minor wording changes (following -> next, all -> the, left -> retained). Details are visible in the comments to previous version.
v1.3	Signed	11 Jan 2018	7.2 Form Preparation: Removal of: (and QCRO if dedicated QCRO is assigned in the scope of activity) Addition of: Additional reviewer, e.g. QCRO, might be added by TRO decision in the scope of their expertise. 7.3.5 Acceptance: QARO/QCRO -> just QARO for acceptance 8 Responsibilites Preparation of Form: QCRO - C (Consulted)
v1.4	Signed	11 Jan 2018	Manufacturing Inspection Plan -> Manufacturing and Inspection Plan
v1.5	Approved	26 Jan 2018	Integration of comments as: - MIP definition reworded for clarity - MRR acronym and reference are added to indicate typical scope/trigger of MIP - Some changes for Basic principles - Removal of intervention points description as to be defined in the MIP itself - Some rewording in the chapters 6.3 Marking-up

			- Some rewording in the chapters 6.4 Flexibility in mass production - TRO consulted to the change of template
v1.6	Approved	14 Sep 2021	as per approved MQP doc Request - 5RY6F7, this minor version is to update the chapter 10 Outputs for consinstency with SOA 2EXFXU
v1.7	Approved	03 Oct 2025	- Re-org changes - Alignment with the decision to remove the SRO as mandatory reviewer - Clarification of principles - Flowcharts updated - Definitions limited, acronyms chapter removed - RACI matrix updated - Editorial changes

Table of Contents

1 Purpose

This document develops provisions from QAP [1] and from process documents [2] and [3] providing the requirements and recommendations for preparation and implementation of Manufacturing and Inspection Plan (MIP).

2 Scope

This document is addressed to IO staff and IO representative involved in the preparation, review, acceptance and/or approval, execution and implementation monitoring of the MIPs in ITER project.

3 General principles

In the present document the term MIP is used. Depending on the case this kind of document may have other denominations used from the supply chain, e.g. “control plan”.

The terms of MIP Form (or simply Form) and MIP can be utilized to distinguish the blank form of MIP agreed by the parties from the MIP as working document and eventually record of the performed activities.

A MIP is usually presented in the form of a table. It lists the sequence of manufacturing operations and describes for each operation, what is the control planned and what are the reference acceptance criteria.

The level of detail in a MIP shall be such as to prevent the inadvertent bypassing of critical operations or critical quality activities [3] and to enable their adequate planning, monitoring and verification.

It should start with Pre-Inspection Meeting (PIM) or with reference to Manufacturing Readiness Review (MRR) [4] completion and it should end with ‘’inspection before shipment’’.

The MIP is not necessarily paper document. It might be, for example, implemented as a set of interfaces of the dedicated software (e.g. Manufacturing Data Base – MDB tool) which may allow more effective and timely follow up during its execution. Nevertheless, any kind of MIP should have a capability to be represented as paper document which can be reviewed by usual means e.g. built-in viewers or freeware software. There should also be a mechanism to refer other documents whatever the kind of MIP is used.

MIP’s participants (or interveners) are: the performers, executing an operation listed in the MIP; any entity (e.g. the contractor – in case performer is a subcontractor, DA, IO as final client, Notified Body or other involved third parties)), which must control that the operation is executed in compliance with applicable requirements.

Participants must select what are the operations that shall be controlled by them and mark-up consistently intervention points, so they are able to control the progress of the operations.

The MIP shall be agreed between Performer and Participants prior to work commencement and once accepted shall be followed.

The MIP shall meet the general requirements applicable to any IP [3].

4 Intervention points

4.1 Purpose

The interventions points that are marked up in the MIP are used by different interveners (e.g. performer, contractor, final client and nuclear operator, third party) for different purposes:

Type	Origin	Actor
Supervision	Quality control from industrial practice	Anyone in the supply chain, according to the rules of the companies.
Technical control (mandatory for each PIA) [8]	Article 2.5.3 of the INB Order	Any individual that both: - Have appropriate skills and qualification - Is different from the individual performing the PIA.
Surveillance [8]	Article 2.2.2 of the INB Order	Only the nuclear operator (IO representative)
(A)NB surveillance	Specific regulation such as PE/NPE	(A)NB

4.2 Types

Typical Control points are:

1) Hold Point (HP): Identifies an operation that must be signed off before work proceeds beyond this point. HP can be used by all interveners.
2) Notification Point (NP): Identifies an operation that must be notified by an appropriate notification tool. This notification gives the representative the opportunity to arrange an inspection visit if deemed necessary.
3) Witness (W): identifies an operation that must be witnessed.
4) Review (R): identifies a document or report that must be reviewed.

Combination of more control points could be used to detail type of intervention and control.

Different control points definitions may be agreed in the frame of the contract, and they shall be described in the MIP Form.

4.3 Marking-up

In order to optimize the list of intervention points quality supervision level is to be taken into account [2].

Selection of intervention points should take into account:

1) Work specificity and complexity
2) Accessibility for inspections and sampling
3) Consequences due to failures
4) Consequential damage to other elements
5) Availability of resources

6) Intervention already covered by other Participants to avoid duplication

SRO, if assigned, shall mark-up the interventions points related to a PIC and/or containing PIA [8] to implement his/her surveillance, in application of the article 2.2.2 of the INB Order [6].

Once intervention points are marked up they can be waived with written notification only. To keep higher flexibility and have possibility to participate on additional control points it is recommended to use control points not requiring mandatory participation from its owner (e.g. Notification Points if IO template [7] is used).

In most of the cases for PE or NPE, one of the first operations in the MIP should be check of the NB/ANB approval of the design. The manufacture started without such approval, whereas requested, will not allow the Manufacturer to comply with the regulation.

4.4 Flexibility in series/batch production

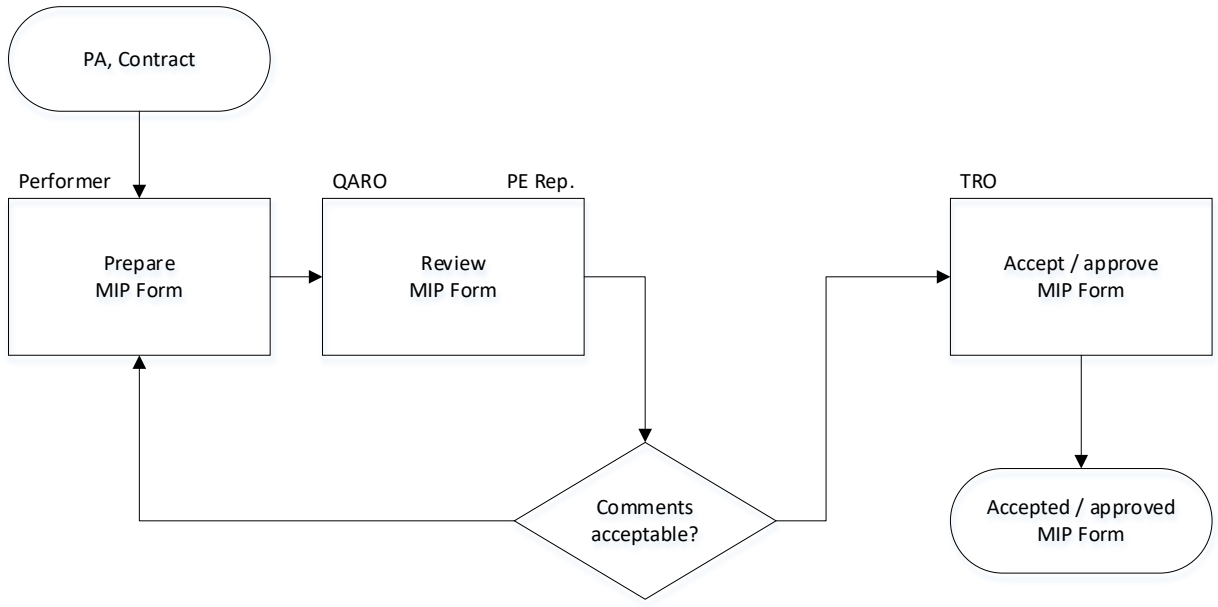
For the series production, where identical or similar items are to be produced, the necessary amount of quality control may vary to balance the appropriate quality and required resources.

The possible approach to provide this flexibility is to initially limit the scope of accepted MIP Form with a certain small value, e.g. 5 items. When the results of control for these initial items are available the Form might be revised to account for the confidence level achieved in the manufacturing process. In the case of systematic acceptable quality, the level of the quality control might be decreased (intervention point's type change or removal). Oppositely, in case of inappropriate quality or identification of additional risks, quality activities might be increased.

Another possible solution without revision of the Form could be establishment of conditional intervention points, where intervention point could take place or not, depending on certain conditions like quality level of the previous items, operator change, tool change, environmental conditions, significant pause in the production etc.

5 Workflow

5.1 Form preparation



The Form shall be prepared and approved by the Performer in charge of the operations and accepted by Participants. IO IP template [5] might be used or alternative. In case alternative template is proposed for the Form preparation it is subject to QARO acceptance prior to the preparation of the Form.

The MIPs should include identification of all Operations defining the factory acceptance tests (FAT). It shall ensure traceability of:

1) Materials
2) Work activities to be undertaken, inspection and tests required under the Contract and in the works specifications
3) Criteria applied against each activity
4) Control methods to be applied
5) Approvals and acceptances
6) Standards, procedures, checklists, method statements, technical and work specifications etc. and revision numbers
7) Records for results of the operations

IO reviews the details of the Form (head fields, operations, applicable standards etc.), communicates the necessary changes to the Performer and mark-up intervention points to be able to control the manufacturing progress.

In most of the cases for PE or NPE, NB and/or ANB assess the regulatory conformity and therefore Manufacturer shall send the MIP Form to NB/ANB for review and mark-up of intervention points. Non-inclusion of these control points in the MIP will not allow the Manufacturer to comply with the regulation. IO PE/NPE network representative shall be consulted in case of the activities related to PE/NPE.

For each operation in the sequence there shall be an indication if the operation is to be considered as PIA ([8], [9]) thus Technical Control is required.

TRO shall make sure that requirements of the Technical Control are properly propagated in the quality systems of the Performer and supply chain in the scope of MIP.

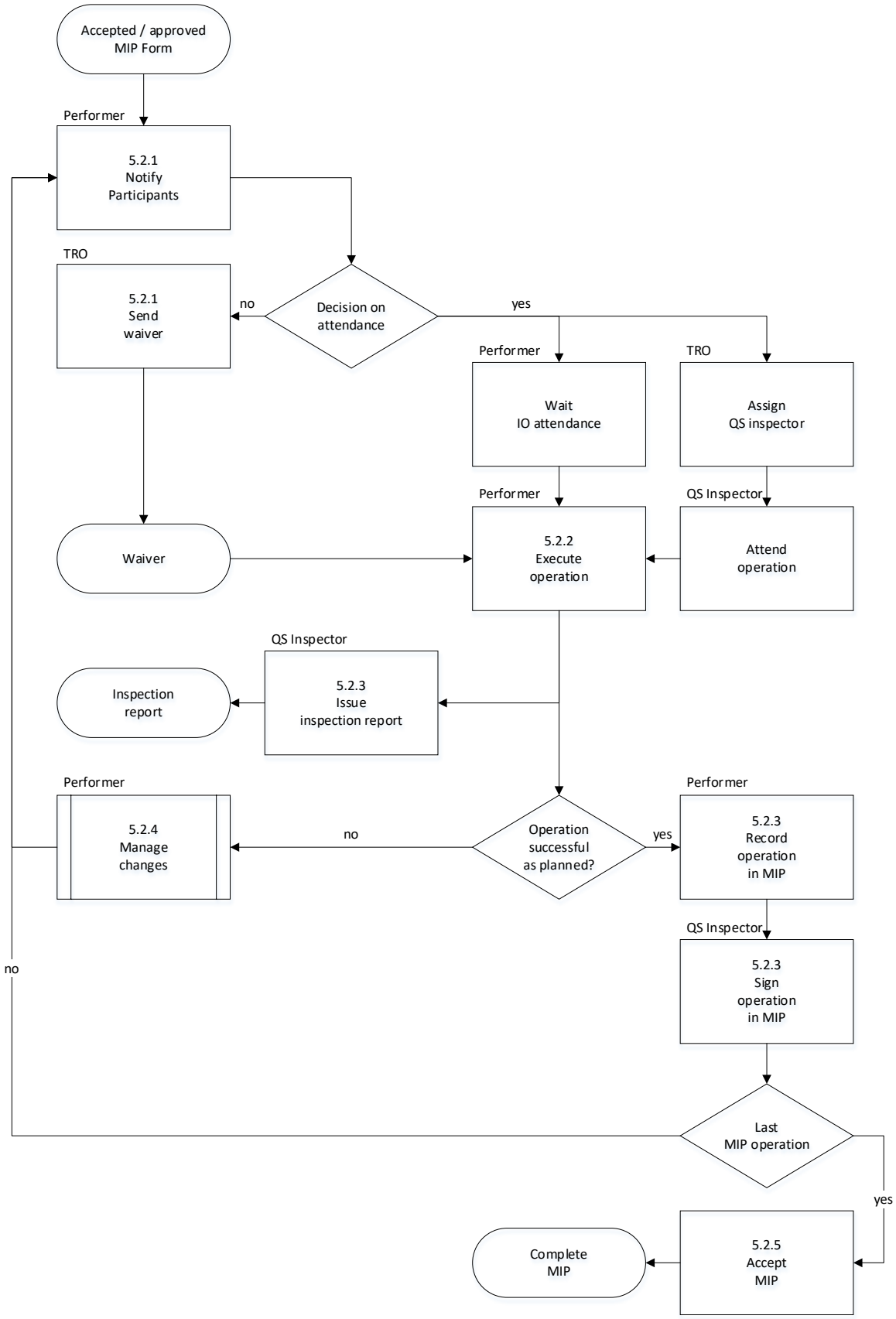
TRO may assign SRO to check and confirm that the PIAs have been properly identified by Performer, with appropriate defined requirements [8], and that a technical control has been defined.

TRO is responsible for the acceptance of the MIP Form by IO. Eventually responsibility for acceptance by IO must be defined by the Contract. Mandatory IO reviewers of the MIP Form shall be QARO [10] and PE/NPE network representative in case shall be additional reviewer for PE/NPE when IO is Manufacturer. Additional reviewers (e.g. Quality supervision inspector, SRO, technical specialists) might be added by TRO for support in the scope of their expertise.

The Form shall not be accepted or approved without mandatory reviews.

N.B.: As the approval/acceptance loop could be long and complicated process, especially for PE/NPE components “manufactured” by IO it is crucial to communicate all the questions, remarks and comments at the stage of review.

5.2 Execution



Prior to the execution of MIP TRO should check:

- That all documents required for the performance are identified and in approved status or if any exception, this is duly addressed in MRR records.
- Allocation of resources to execute controls as selected, in particular for witnessing points which require mission at manufacturing facilities by assigned Quality supervision inspectors ([11], [12])
- If additional verification of the Performers capabilities is required (e.g. Quality Audit or any additional quality supervision activities)

Manufacture shall not be started before the Form has been accepted by IO.

The Form shall be used to perform activities in the prescribed sequence and provide the evidence of these activities.

TRO should check the referenced documents (codes, standards, procedures, drawings etc.) for validity before any operation starts.

To ensure that operations are performed as directed, the Form should be directly accessible to those carrying out the work (i.e. it should be a shop floor tool).

N.B.: It is crucial to have sufficient level of communication during execution of MIP. Notifications and confirmations (see chapter 5.2.1) are to be sent in timely manner. In case of any non-conformity (see chapter 5.2.4), abnormality, misunderstanding the parties should communicate the issues as soon as possible to reduce the possibility of quality issues, schedule deviation and financial losses.

5.2.1 Notify Participants

The Performer in charge of the operations sends a Notification to the different Participants that marked-up their intervention points, so they are informed of the upcoming operation and reminded of the intervention points. When appropriate several points might be announced together.

Format of the Notification should be standardized. IO template [7] may be used or alternative form.

Notifications shall be confirmed or waived by TRO provided that the relevant evidence is retained and traceable.

In particular, in case of HP or WP waiving, relevant record should include proper justifications based on risk assessment outcome and may trigger improvement actions like revision of MIP.

Notifications and confirmations (including the ones with waivers) are to be sent in appropriate timeframes which should be prescribed by the Contract, preferably by electronic means: e-mail or dedicated system. To avoid the loss of traceability the notifications from e-mails should be archived in the dedicated folders.

5.2.2 Execute operation

For each operation Participants perform their control functions as prescribed by MIP, assigning a suitable qualified and experienced person (SQEP) for the execution.

SQEP shall be selected according to applicable requirements which could come from codes, standards, regulations and participant's internal procedures.

Successful outcome of the control shall be traceable for release (e.g. signature on the MIP by the SQEP).

If the operation is a PIA and thus a Technical Control for the operation shall be provided. The operation without such Technical Control might not allow the Manufacturer to comply with the regulation.

5.2.3 Record operation

At the time of completion Performer dates and signs off each operation and Participants their intervention points. Responsible persons must be clearly identified. No case containing intervention point shall remain unsigned unless the point is waived (see chapter 5.2.1).

The next manufacture operation shall not start until the current is signed and requirements of intervention points are met, unless they are independent operations that may run in parallel.

In case of witnessing of an operation, the assigned IO QS Inspector [11] shall create an inspection report [13] to record detail of the witnessing and its outcome. The Inspection report shall be uploaded in IDM for review and approval [2].

The documents generated during the performance of the particular operation (e.g. test/inspection report, non-conformance report etc.) shall be identified and recorded in the MIP and traceability shall be provided.

5.2.4 Manage changes

During the manufacturing, normally as consequence of non-conformity or deviation, modification of the process and Form might be required (operation of repair, changing the order of the operation, insertion of some additional operations etc.).

Any changes are to be agreed by additional MIP Form (see chapter5.1). This additional Form shall be managed identically to the original MIP, be referenced in the original MIP and considered as part of it. Other approaches are acceptable provided the original level of approval/acceptance authority is respected and to be agreed in writing prior to any changes done. The evidence of such agreements shall be retrievable. The NCRs/DRs shall be identified in the MIP and managed according to the Contract provisions.

5.2.5 Accept MIP

When the MIP is completed TRO, supported by assigned QARO shall verify that:

- All operations were signed by the Performer.
- All intervention points were signed or correctly waived by Participants.
- All needed reports were issued.
- All NCRs and DRs were identified and closed.

Acceptance of complete MIP shall be done before issuance of Release Note [3]. TRO shall encourage the supply chain to submit the MIP for acceptance as soon as the MIP is completed.

6 Responsibilities

The responsibilities and flexibility are given by the text of procedure. The table below provides quick reference for the typical activities of the parties involved.

	Performer	Participant	TRO	SRO	QARO	Quality Supervisor
Accept alternative template			C		R	
Preparation of Form	R		C		C	
PIA identification	R		A	C		
Intervention points		R	A	C	C	C
Acceptance of Form			R		C	
Operation notification	R	I	I			
Notification confirmation or waiver	I	R	R/I*			
Operation execution	R					
Technical control	R		I			
Supervision		R	A			R
Filling of the Form	R	R				R
Acceptance			R		C	
Managing of the records			R			

R: responsible, A: accountable, C: consulted, I: informed

* - as IO intervention points depend from other intervention points, IO needs to be informed about the waivers of other Participants. It might be done through the Contract provisions (link with process Procurement below) or at least agreed informally.

7 Interactions with other processes

7.1 Quality Assurance

Complete MIP serves as the input for Release Note [3].

7.2 Documents and Records

Alternative MIP template, MIP Form, notifications, inspection reports and complete MIP are the project records and direct inputs for the process Documents and Records[14].

8 Records

Record	Author	Reviewer	Approver	Informed
MIP Form	Performer	QARO, PE/NPE rep. (for PE/NPE)	TRO (acceptance or approval for PE/NPE)	
Notification	Performer	-	-	TRO

Inspection Report	See [2]	See [2]	See [2]	See [2]
MIP (completed)	Performer	QARO	TRO (acceptance)	

Record	Template, UID	Place to store, UID	Document type(s)	Naming convention	Retention period
MIP Form	[5]or alternative	IDM, dedicated folder	9RTJWC 9RRLRY 9RT9J5	n/a	Project lifecycle
Notification	[7]	IDM, dedicated folder	W8G5UW 9RTEJB	n/a	Project lifecycle
Inspection Report	[13]	IDM, dedicated folder	9RRUV4 9RS87F	As per [2]	Project lifecycle
MIP	As per Form agreed	Archive or/and IDM, dedicated folder	9RTJWC 9RRLRY 9RT9J5	n/a	Project lifecycle

9 Definitions

Agreed Notified Body (ANB)	Notified Body agreed by the French Nuclear Authority (ASNR) to perform conformity assessment of Nuclear Pressure Equipment [15].
Inspection Plan (IP)	Any plan used for any inspection activities on products during the entire lifetime of the project (e.g. procurement, manufacture and testing, prototype, construction … as defined by the contract) used as a tool to monitor quality control and to verify that applicable requirements from […] and acceptance criteria have been met during execution. The inspection plan may be named IP (Inspection Plan), for Manufacturing MIP (Manufacturing and Inspection Plan) or CP (Control Plan) for Construction ITP (Inspection and Test Plan) [3].
Intervention Point	Special mark in a MIP to denote a pre-defined activity for notification, report or control to be used by Participants.
Notification	Hardcopy, scan or other agreed and retrievable kind of the form to inform the involved parties about an intervention point.
Manufacturer	With exception of PE/NPE the party who physically produces the equipment. For the PE including NPE the Manufacturer is the one responsible for designing and manufacturing a product with a view of placing it on the community market (for PE) or selling it to the operator of the INB (for NPE) on his own behalf. For number of components as TCWS, VV and some others IO is the Manufacturer.
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 [15].
Participant	An entity other than Performer involved in the MIP execution by defining operations subjected to its intervention/control, e.g. higher level supplier, DA, IO, NB/ANB.
Performer	An all-inclusive term used to cover both IO internal and external organizations such as Specified PA/Contract Execution Teams, Domestic Agencies, Suppliers, Subcontractors, Manufacturers (in the sense of Pressure Equipment Regulation), Fabricators, Works Contractors who provide

	products, works or services to the ITER project [3].
Release Note	Confirmation from the Performer that the goods or equipment being supplied meet the requirements of ITER Technical Specification referenced in the Contract [3].

10 References

[1] ITER Quality Assurance Program (QAP) (22K4QX)
[2] Procedure for Inspection and Testing (TVL3Y5)
[3] Quality Requirements for IO Performers (22MFG4)
[4] Working Instruction of Manufacturing Readiness Review (44SZYP)
[5] Inspection Plan (IP) Template (QV7GQF)
[6] Order dated 7 February 2012 relating to the general technical regulations applicable to INB – EN (7M2YKF), hereinafter INB Order
[7] Notification for intervention points (UKUCG9)
[8] Nuclear safety common definitions (RLZXMV)
[9] List of ITER-INB Protections Important Activities (PSTTZL)
[10] List of Program/Project QARO (N3NLUX)
[11] IO Quality Supervision Inspectors List (VEZNHG)
[12] Quality Supervision Inspector Certification Working Instruction (TVUJZY)
[13] Inspection Report Template (TVUQWY)
[14] IO Archive and Records Management Procedure (353X9Z)
[15] French ESPN Order dated 30/12/2015 related to Nuclear Pressure Equipment