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EXTERNAL REFERENCE / VERSION

MQP Level 3

Work Instruction for Producing of the Manufacturing and Inspection Plan

This document develops provisions from QAP [1] chapters 3.4, 3.5, 3.8 and from MQP Level 2 document [2] providing the requirements and recommendations for preparation and implementation of Manufacturing and Inspection Plan (MIP).

Approval Process			
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Document Security: Internal Use *RO: Cruz-Mermy Marie-Laure*			
Read Access	**GG: MAC Members and Experts, GG: STAC Members & Experts, AD: ITER, AD: IO_Director-General, AD: External Management Advisory Board, AD: OBS - Quality Management Division (QMD) - EXT, AD: OBS - Quality Management Division (QMD), AD: Auditors, AD: ITER Management Assessor, project administrator, RO, L...**		

Change Log			
Work Instruction for Producing of the 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

Table of Contents

1 Purpose

This document develops provisions from QAP [1] chapters 3.4, 3.5, 3.8 and from MQP Level 2 document [2] providing the requirements and recommendations for preparation and implementation of Manufacturing and Inspection Plan (MIP).

2 Scope

This MQP Level 3 document belongs to the Level 2 Requirements for Producing an Inspection Plan [2] in the scope of the process Inspection and Testing.

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

3 Definitions and acronyms

3.1 Definitions

Agreed Notified Body	Notified Body agreed by the French Nuclear Authority (ASN) to perform conformity assessment of Nuclear Pressure Equipment. [2]
Archive	IO Archive, managed by DOC Section [17]
Contract	An all-inclusive term used to cover Procurement Arrangements, Task Agreements and Contracts placed directly by the IO. [2]
Defined Requirement	Requirement that has been assigned to a PIC or PIA so that it may perform the function provided for in the safety demonstration [3].
Inspection Plan	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). [2]
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.
MIP	Manufacturing and Inspection Plan - the document that the Performer uses to list and execute all manufacturing activities. Other Participants like IO, DAs or PTs use the MIP to assess and follow these manufacturing steps as well as to control the quality of the products and processes during the manufacture. IO exclusively uses the MIP for surveillance in application of the article 2.2.2 of INB order [4]. It shall encompass the whole relevant scope of the Contract and normally it is the range from MRR [18], procurement of materials, manufacturing operations, assembly, inspections, testing, storage, handling, inspection and factory acceptance test to the acceptance of Release Note by IO [5] and packaging.
Notified Body	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. [2]
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, IO PT, 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. [2]
Protection Important Activity	As per articles 1.3 of the INB Order: "Activity important for protecting the interests mentioned under Article L. 593-1 of the Environmental Code (public safety, health and sanitation, the protection of nature and of the environment), i.e. activity that falls under the technical or organizational provisions mentioned under the second paragraph of

	Article L. 593-1 of the Environmental Code or that is liable to affect them;" These activities include design, purchase, fabrication, manufacture, construction, assembly, installation, testing, commissioning, operating, maintenance, modifications and the most of sub activities under these ones (non-exhaustive list). [2]
Protection Important Component	Specific category of systems, structures or components as defined per articles 1.3 of the INB Order: "A component which is important for protecting the interests mentioned under Article L.593-1 of the Environmental Code (public safety, health and sanitation, the protection of nature and of the environment), i.e. structure, equipment, system (programmed or not), material, component or software that is present in the basic nuclear installation or that is under the responsibility of the operator and that implements a function required for the demonstration mentioned under the second paragraph of Article L. 593-1 of the Environmental Code or that ensures that this function is implemented." [2]
Project Team	IO Project Team established in accordance with 4.ii of [6].
Quality Assurance Responsible Officer	IO employee from QAA appointed to the control of quality aspects of certain activity (usually prescribed by [7]).
Quality Control Inspector	The person in charge of the inspection. It could be IO employee or representative of contracted organization.
Quality Control Responsible Officer	IO employee performing quality control supervision activities.
Release Note	Confirmation from the Performer that the goods or equipment being supplied meet the requirements of ITER Technical Specification referenced in the Contract [5].
Safety Responsible Officer	IO employee from SD appointed to the control of nuclear safety aspect of certain activity (usually Contract).
Technical Control	In application of the article 2.5.3 of the INB Order, the technical control is the act of verification whether : - The PIA (Protection Important Activity) has been performed according to the prescriptions and that the result is in compliance with the

	Defined Requirements. - Appropriate corrective and preventive actions have been defined and implemented. Parties carrying out technical control are distinct from the parties who accomplish the activities. A technical control is mandatory for each PIA […]. As per article 2.5.5 of the INB Order, individuals performing technical controls shall have the appropriate skills and qualifications necessary for the performance of their specific duty. [2]
Technical Responsible Officer	IO employee appointed to the control of certain activity (usually technical or overall control of the Contract).

3.2 Acronyms

ANB	Agreed Notified Body
CP	Control Plan
DR	Deviation Request
IDM	ITER Documentation Management System
IO	ITER Organization (legal entity)
IP	Inspection Plan
ITP	Inspection and Testing Plan
MIP	Manufacturing and Inspection Plan
MRR	Manufacturing Readiness Review
NB	Notified Body
NC	Non-conformity
NCR	Non-conformity Report
NPE	Nuclear Pressure Equipment
PE	Pressure Equipment
PIA	Protection Important Activity
PIC	Protection Important Component
PT	Project Team
QAA	Quality Assurance and Assessment Division
QARO	Quality Assurance Responsible Officer
QCRO	Quality Control Responsible Officer
SD	Safety Department
SRO	Safety Responsible Officer
TRO	Technical Responsible Officer

4 Applicable Documents

[1] ITER Quality Assurance Program (QAP) (22K4QX)
[2] Requirements for Producing an Inspection Plan (22MDZD)
[3] Nuclear safety common definitions (RLZXMV)
[4] Order dated 7 February 2012 relating to the general technical regulations applicable to INB – EN (7M2YKF), hereinafter INB Order
[5] Requirements for Producing a Contractors Release Note (22F52F)
[6] IC-Ex/03.15 Record of Decisions (QYTZEP)
[7] List of QA RO (N3NLUX)
[8] Procedure for Inspection and Testing (TVL3Y5)
[9] Notification for intervention points (UKUCG9)
[10] Inspection Report Template (TVUQWY)
[11] ITER Procurement Quality Requirements (22MFG4)
[12] Sign-Off Authority for Project Documents (2EXFXU)
[13] Document Management Procedure (22K5JQ)
[14] IO Archive and Records Management Procedure (353X9Z)
[15] List of ITER-INB Protections Important Activities (PSTTZL)
[16] Inspection Plan (IP) Template (QV7GQF)
[17] MQP IO Archive and Records Management Procedure (353X9Z)
[18] Working Instruction of Manufacturing Readiness Review (44SZYP)

5 Basic 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.

The level of detail in a MIP should be such as to prevent the inadvertent bypassing of critical operations and to enable adequate planning, monitoring and verification of critical operations.

The MIP is not necessarily paper document. It might be, for example, implemented as a set of interfaces of the dedicated software. 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.

For each operation Participants have to mark-up 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 [2].

6 Intervention points

6.1 Background

The interventions points that are marked up in the MIP are used by several parties for different purposes, which are not to be mixed:

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)	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. Usually, the technical control is done within the company in charge of the PIA, by another person.
Spot check verifications	Article 2.5.4 of the INB Order	Only the nuclear operator (IO staff)
Surveillance	Article 2.2.2 of the INB Order	Only the nuclear operator (IO staff)
(A)NB surveillance	Specific regulation such as PE/NPE	(A)NB

6.2 Types

All definitions of different intervention points and according requirements shall be given in the MIP to be properly used.

6.3 Marking-up

In order to optimize the list of intervention points quality control level is to be taken into account [8].

Selection of intervention points should take into account:

- Work specificity and complexity
- Accessibility for inspections and sampling
- Consequences due to failures
- Consequential damage to other elements
- Availability of resources
- Intervention already covered by other Participants to avoid duplication

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

The type and frequency of other intervention point should be reasonable as once intervention points are marked up they mostly 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 [16] is used).

In most of the cases for PE or NPE the first operation 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.

6.4 Flexibility in mass production

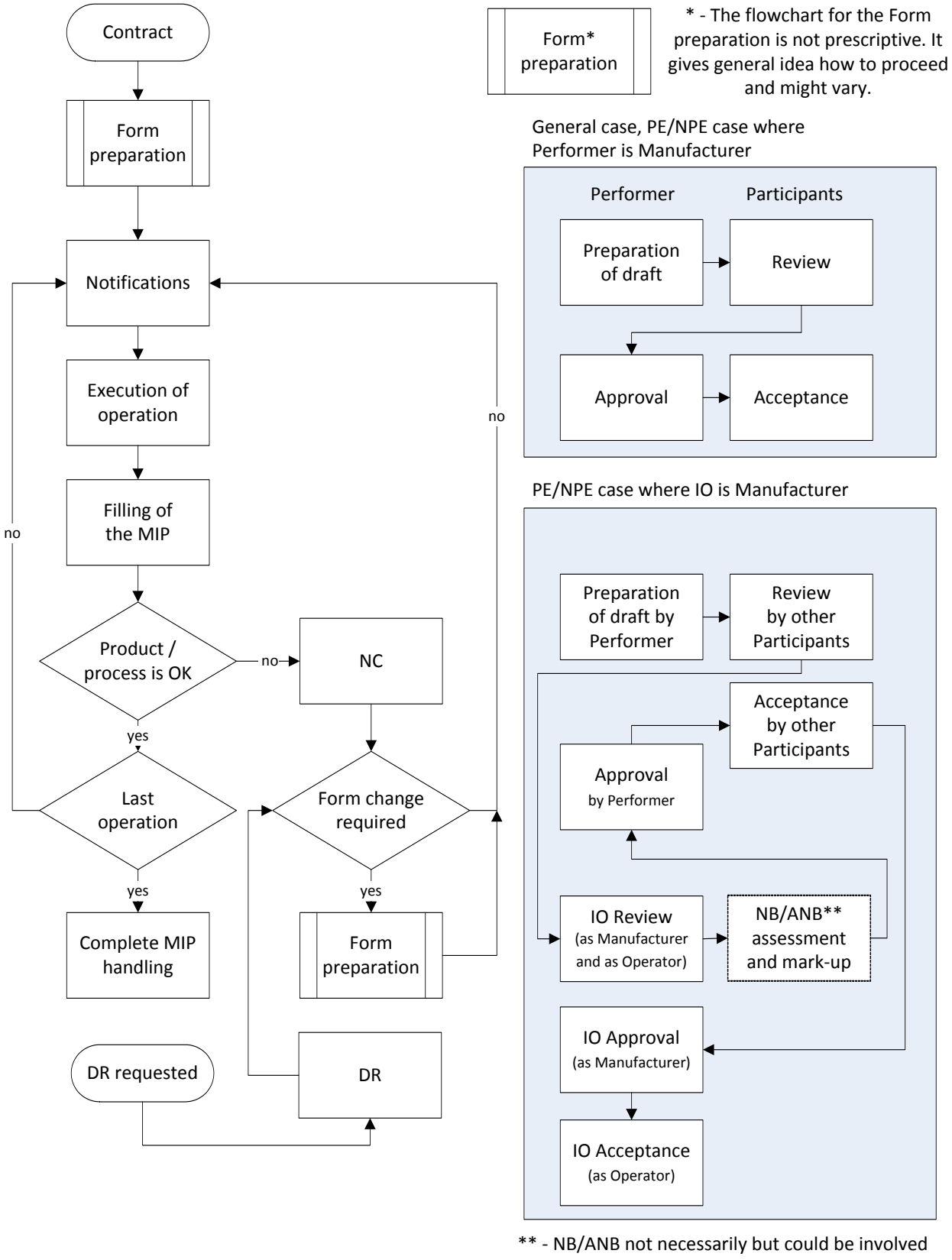
For the mass production, where identical or similar items are to be produced, the necessary amount of quality control may vary to balance the appropriate quality and required resources.

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 from certain conditions like quality level of the previous items, operator change, tool change, environmental conditions, significant pause in the production etc.

7 Workflow

7.1 Flow chart



7.2 Form preparation

The Form shall be prepared and approved by the Performer in charge of the operations and accepted by Participants. IO IP template [16] 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:

- Approvals and acceptances
- Materials
- Work activities to be undertaken, inspection and tests required under the Contract and in the works specifications
- Control methods to be applied denoted as different intervention points
- Criteria applied against each activity
- Standards, procedures, checklists, method statements, technical and work specifications etc. and revision numbers
- 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 particular operation in the sequence there shall be an indication if the operation is to be considered as PIA [15] 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.

SRO shall check that the PIAs have been properly identified by Performer, with appropriate defined requirements, and that a technical control has been defined. In case of disagreement about the PIA nature of the operation, the choice of the SRO prevails.

TRO should be responsible for the acceptance of the MIP Form by IO. In the case of PT where TRO is part of it, to avoid the conflict of the interests there should be other responsible from IO, e.g. SRO. Eventually responsibility for acceptance by IO must be defined by the Contract. Mandatory IO reviewers of the MIP Form shall be TRO, QARO, SRO for PIC/PIA. PE/NPE network representative shall be additional reviewer for PE/NPE when IO is Manufacturer. Additional reviewer, e.g. QCRO, might be added by TRO decision 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. Approval and acceptance are formal steps and

any claims requiring revision of the document should generally mean that review was not done properly.

7.3 Execution

Prior to the execution of MIP TRO should check:

- Details of schedule vs overall project schedule
- That all documents and resources required for the performance are identified
- If additional verification of the Performers capabilities is required

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 7.3.1) are to be sent in timely manner. In case of any non-conformity (see chapter 7.3.4), abnormality, misunderstanding the parties should communicate the issues as soon as possible to reduce the possibility of quality issues, schedule deviation and financial losses.

7.3.1 Notifications to 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 [9] might be used or alternative form.

Notifications shall be confirmed or waived by TRO provided that the evidence of such confirmation is retained.

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.

7.3.2 Execution of the operation

For each operation Participants perform their control functions as prescribed by MIP.

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.

7.3.3 Filling the Form

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 7.3.1).

The next manufacture operation shall not start until the current is signed and requirements of intervention points are met.

When required (e.g. when witnessing the operation) the designated IO QC Inspector shall create inspection and test reports [10] to support the status of activities at the time of the review.

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.

7.3.4 Nonconformities, deviations and MIP evolution

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 chapter 7.2). 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 evidences of such agreements shall be retrievable. The NCRs/DRs shall be identified in the MIP and managed according to the Contract provisions.

7.3.5 Acceptance

When the MIP is completed TRO or 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 [5]. TRO shall encourage the supply chain to submit the MIP for acceptance as soon as the MIP is completed.

8 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	QCRO
Alternative template	R		C		A	
Preparation of Form	A/R		C		C	C
PIA identification	R		C	A		
Intervention points		R	A/R	C	C	C
Acceptance of Form			A		C	C
Operation notification	A/R	I	I			
Notification confirmation or waiver	I	A/R	A/R/I*			
Operation execution	A/R					
Technical control	A/R		I			
Supervision		R	A			R
Surveillance			R	A/R		
Filling of the Form	A/R	R	R			R
Acceptance			A/R		C/R	C/R
Managing of the records			A/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.

9 Links with other processes

9.1 Project Control

The overall project schedule could be an input for the MIP preparation. During the execution the MIP and notifications could serve as the inputs for the overall project schedule.

9.2 Procurement

The requirements related to MIP [11, 2, this procedure] should serve as the inputs for the process Procurement in general and particular Contracts.

9.3 Quality Assurance

Complete MIP serves as the input for Release Note [5].

9.4 Configuration Management and 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 [12-14]. Some of the documents might constitute configuration information.

9.5 Nuclear Safety and Environmental Protection

Provisions of the French regulation such as INB Order are the inputs for MIP preparation and execution in the case MIP is related to PIC.

10 Outputs (Records, Deliverables, Implementation plans …)

The execution of this document requires the following outputs:

Type of output	Format	Location	Document type	Identifica-tion	Responsible for managing the output	Retention period
MIP Form	Template [16] or alternative	IDM, dedicated folder	[IN]-DA Manufacturing Inspection Plan 46N6JK [IN]-Contractor QA Manufacturing Inspection Plan 2USZ3T	n/a	TRO	Lifetime of the project
Notifica-tion	Template [9]	IDM, dedicated folder	[IN]-Communication for Notification Point (NP)	n/a	TRO	Lifetime of the project
Inspection Report	Template [10]	IDM, dedicated folder	[IN]-ITER Inspection Report 2YJWSN	As per [8]	TRO	Lifetime of the project
MIP	As per Form agreed	Archive or/and IDM, dedicated folder	[IN]-DA Manufacturing Inspection Plan 46N6JK [IN]-Contractor QA Manufacturing Inspection Plan 2USZ3T	n/a	DOC/TRO	Lifetime of the project