

MQP Procedure

Requirements for Producing an Inspection Plan

This document describes the requirements for preparing and implementing an Inspection Plan that the ITER Organization (hereinafter IO) will use to monitor quality control and acceptance tests for activities.

Approval Process			
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Read Access	GG: MAC Members and Experts, GG: STAC Members & Experts, AD: ITER, AD: IO_Director-General, AD: EMAB, AD: OBS - Quality Management Division (QMD) - EXT, AD: OBS - Quality Management Division (QMD), AD: Auditors, AD: ITER Management Assessor, project administrator, RO, LG: 5th working group, AD: Exte...		

Change Log			
Requirements for Producing an Inspection Plan (22MDZD)			
Version	Latest Status	Issue Date	Description of Change
v1.0	Signed	13 Dec 2005	
v1.1	Signed	23 Nov 2007	
v1.2	Approved	23 Nov 2007	
v2.0	Signed	30 Mar 2009	
v2.1	Approved	01 Apr 2009	
v3.0	Approved	16 Mar 2015	<p>Changes according to MQP doc Request - QXRE2J:</p> <ul style="list-style-type: none"> - Title changed "Requirements for Producing a Manufacturing and Inspection Plan" - Doc type changed to MQP Detailed Policy - Template changed for MQP Detailed Policy - "should" changed to "shall" throughout the whole document - Addition of conditions for waiving the requirement for MIP in the scope - Addition of the requirement for dual language where applicable - Clarification added on the revision of MIPs - Addition of the requirement for signatures to be by the person who did the intervention. - Clarification added for critical activities - Clarification added that the MIP shall be a shop floor working document - Addition of Third Party Inspectors' interventions. - Suggested template removed and link inserted
v3.1	Signed	19 Dec 2016	<p>Modifications according to MQPWG decision about PT documents (SKJSM8), Lessons Learned Working Group Meeting 2016-04-04 (SVJQGZ), ITER_D_TEBXPK - I-RoD 28th SQA WG meeting on 14th June, 2016., MQPWG presentation Sept 9 2016 (MQP Minutes 2016.09.05 and follow up 2016.09.09- Core team),</p> <p>Overview of main changes:</p> <p>Nuclear Safety : missing PIA and record related Technical Control</p> <p>Nuclear Safety : missing SRO role</p> <p>be more generic than manufacturing (Inspection Plan instead of Manufacturing Inspection Plan / add the definition of Performer)</p> <p>Clarification on changes on MIP before vs. during execution of MIP</p> <p>Precise mechanism in case of NCR impacting the operations</p> <p>Mention of electronic form is OK</p> <p>Merge Level 2 PT specific R6BHPV in this Level 2</p>
v3.2	Signed	06 Jan 2017	<p>New version to include comments from Masanori Onozuka by adding link and reference to the upper Level 1 document, a clear description of which process this procedure belongs to, and the level of the document.</p> <p>New version to include comments from Alessandro Bova about definition of inspection plan, clarification in the chapter "principles" applicable for PIA, Include "inspection report" as example of "records generated during the performance of the particular operation".</p> <p>Others comments had not taken into account this version. As these comments are related to new requirements, another version of this procedure will need first to be reviewed by IO management and DA.</p>
v3.3	Signed	19 Jan 2017	<p>New version including additional comments raised by A.Bova and S.Chiochio (on rev 3.2)</p> <p>N. Fabre and A Bova agreed on version 3.3 including changes:</p> <ul style="list-style-type: none"> • Definition added PIC and (A)NB definition

			<ul style="list-style-type: none"> • 5. Principles: Clarify that Inspection plan shall identify “Documents for traceability and related to verification and completion of these operations”. • 5. Principles: Require that Inspection Plan ‘be kept updated to allow monitoring of operation’s progress.’ • 5. Principles: Clarification in case of PIA / PIC • 6. Roles and Resp: Clarify that ‘An adequate notice period must be agreed with IO (taking into account a reasonable time to organise the inspection mission) to permit IO to send a representative to the performer’s facility if deemed necessary.” <p>We also reviewed the requirements when (A)NB is involved and agreed to keep the wording as in rev 3.2 (A Bova, N Fabre, T Jourdan)</p>
v3.4	Signed	01 Feb 2017	Integration of 3.3 comments from Ken Blackler and Masanori Onozuka
v3.5	Approved	06 Feb 2017	Integrations of comments
v3.6	Signed	11 May 2018	As per MQP doc Request - WK69QX Includes Module H needs
v3.7	Approved	05 Jun 2018	Table of content updated. No other changes

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1 Purpose

This document describes the requirements for preparing and implementing an Inspection Plan that the ITER Organization (hereinafter IO) will use to monitor quality control and acceptance tests for activities.

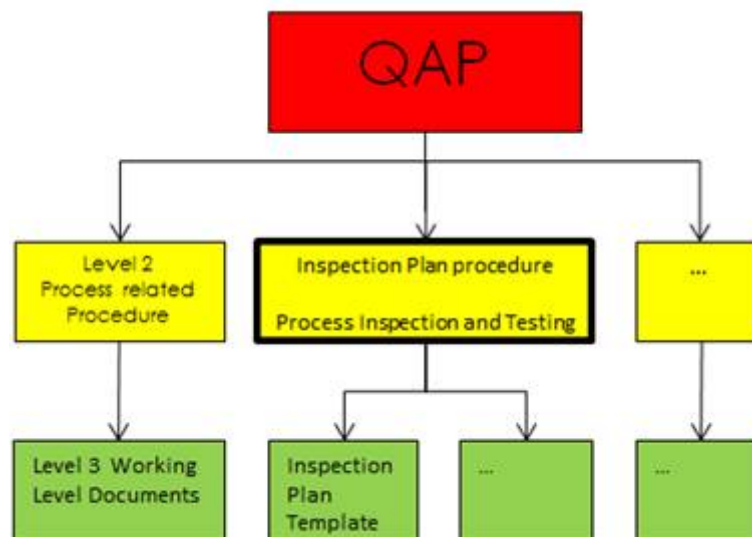
2 Scope

An Inspection Plan must be produced by all Performers to the ITER Organization as defined by the contract. Inspection plan shall encompass the whole scope of the contract and be implemented for both PIC's as well as non-PIC's.

This requirement may be waived if it is agreed by the ITER Organization.

For Inspection Plan accepted by IO before this version of the procedure, no revision of the inspection plan shall be required to reflect the updates.

This procedure implements requirements from section 3.8 of QAP [1] as a Level 2 procedure related to the Process Inspection and Testing:



3 Definitions and acronyms

IO	ITER Organization sometimes referred to as ITER
Domestic Agency (DA)	An organization set up under the ITER Framework Agreement to provide goods or services to the ITER Organisation through Procurement Arrangements (PA) and Task Agreements (TA)
Performer	An all-inclusive term used to cover both IO internal and external organizations such as Specified PA/Contract Execution Teams, IO PT (Project Team established in accordance with 4.ii of IC-Ex/03.15 Record of Decisions QYTZEP), 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.
Contract	An all-inclusive term used to cover Procurement Arrangements, Task Agreements and Contracts placed directly by the IO
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

	<p>control and to verify that applicable requirements from [1][2] [3] and acceptance criteria have been met during execution.</p> <p>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)</p>
PIA Protection Important Activity	<p>As per articles 1.3 of the INB Order:</p> <p>“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;”</p> <p>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).</p>
PIC Protection Important Component	<p>Specific category of systems, structures or components as defined per articles 1.3 of the INB Order:</p> <p>“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.”</p>
NB Notified Body	<p>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.</p>
ANB Agreed Notified Body	<p>Notified Body agreed by the French Nuclear Authority (ASN) to perform conformity assessment of Nuclear Pressure Equipment</p>
Technical Control	<p>In application of the article 2.5.3 of the INB Order, the technical control is the act of verification whether :</p> <ul style="list-style-type: none"> - 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. <p>Parties carrying out technical control are distinct from the parties who accomplish the activities.</p> <p>A technical control is mandatory for each PIA [6]</p> <p>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.</p>
PE	Pressure Equipment in the scope of the Pressure Equipment Directive
NPE	Nuclear Pressure Equipment in the scope of the French ESPN Order
PE/NPE Network	Internal IO network in charge of the surveillance of the implementation of the requirements of the French regulation for PE/NPE inside IO.

PED	Pressure Equipment Directive
ESPN Order	French Regulation for Nuclear Pressure Equipment

4 References

- [1] [ITER Quality Assurance Program \(QAP\)\(22K4QX\)](#)
- [2] [ITER Procurement Quality Requirements \(22MFG4\)](#)
- [3] [Procedure for Inspection and Testing \(TVL3Y5\)](#)
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- [4] [Inspection Plan Template \(QV7GQF\)](#)
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- [5] [Requirements for Nonconformities management \(22F53X\)](#)
- [6] [List of ITER-INB Protections Important Activities \(PSTTZL\)](#)
- [7] [Overall surveillance plan \(4EUQFL\)](#)
- [8] [Sign-Off Authority for Project Documents \(2EXFXU\)](#)

5 Basic Principles

An Inspection Plan is a listing of the sequence of operations affecting quality. For each particular operation, in the Inspection Plan, Inspection Plan shall identify:

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

In case of PIA, the representative of the Nuclear Operator implements a surveillance of the PIAs according to [7].

The representative of the Nuclear Operator is authorised and responsible to release the Hold Points that he will define according to his marked Interventions in the Inspection Plan and his specific surveillance plan. He has the duty to alert the IO of any issue occurring during any execution of a PIA.

The level of detail in an Inspection Plan shall be such as to prevent the inadvertent bypassing of Quality Activities and to enable adequate planning, monitoring and verification of operations.

To ensure that operations are performed as directed in this plan, the document shall be directly accessible to those carrying out the work (i.e. it shall be a shop floor working document) and shall be kept updated to allow monitoring of operation's progress.

An Inspection Plan must be written in English for IO record purpose and acceptance, and be easily understood by those carrying out the work. Where English is not the mother language, the document must be in dual language to facilitate Performer workforce understanding.

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

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

6 Roles and Responsibilities for Preparation and acceptance of Inspection Plan

All performers who perform ITER Project activities shall submit an Inspection Plan to the IO Responsible Officer (RO) (or to his duly appointed representative of that activity) for acceptance and to mark-up IO intervention points.

Where Domestic Agencies (DAs) are involved, the Inspection Plan submission shall involve the relevant DA to enable them to mark up any DA intervention points and to approve it.

The Inspection Plan shall clearly identify who is performing each intervention point (Performer, DA, IO...).

In case the plan concerns Protection important Component (PIC) and/or contains operations identified as Protection Important Activities (PIA), the IO RO shall consult Safety Responsible Officer (SRO) for advice on intervention mark-up and who shall perform the relevant IO interventions.

Inspection Plan shall be accepted according to Sign Off Authority [8].

Where an (Agreed) Notified Body ((A)NB) is involved, the manufacturer sends the Inspection Plan to them for review and mark-up prior to IO decision of its interventions.

Where IO acts as manufacturer of Pressure Equipment or Nuclear pressure Equipment in the scope of Module H, a specific column of the Inspection Plan shall be dedicated to the PE / NPE Network in order to define control points related to the implementation of Module H IO procedures. The column dedicated to the PE / NPE Network can be the column called Third Party or other in the templates [4] or IDM_D_TTPQL2.

After internal review, IO (or his duly appointed representative) will return the Inspection Plan to the performer (through the DA for in-kind procurement,) with a mark-up of IO intervention points.

If the (A)NB, PE/NPE Network or IO RO decides that essential operations are missing on the submitted Inspection Plan, the Inspection Plan will be returned to the performer (through the DA for in-kind procurement) for correction.

Evidence of IO (or his duly appointed representative) acceptance of the Inspection Plan shall be maintained.

During execution of the Inspection Plan, if modifications appears to be necessary (such as adding an unexpected operation or repair, changing the order of the operation, etc.), there shall be a mechanism in place to obtain formal acceptance by the IO (or his duly appointed representative). If this modification is due to Nonconformity, NCR shall be managed according to [5] and should be referred in the Inspection Plan.

It is the performer's responsibility to notify the IO (or his duly appointed representative) (through the DA for in-kind procurements) of any forthcoming intervention points. An adequate notice period must be agreed with IO (taking into account a reasonable time to organise the inspection mission) to permit IO to send a representative to the performer's facility if deemed necessary.

Intervention points marked on the Inspection Plan must be signed off and dated by the person performing the intervention.

Compliance with this plan shall be checked and recorded as work progresses.

- 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. inspection report, test report, non-conformance report, etc.) must be recorded on the Inspection Plan.

7 Template

A suggested format for the Inspection Plan can be found at the [Inspection Plan Template](#) [4]

Alternative formats (including in electronic form) may be acceptable provided they contain the essential data required and shall be subject to IO Quality Assurance & Assessment Division acceptance in advance of their intended use.

For Inspection Plan accepted by IO before this version of the procedure, no revision of the inspection plan shall be required to reflect the updates.

8 Records

An Inspection Plan is an integral part of the contract. Upon completion of the work, completed Inspection Plans and records relevant to the operations shall be included in the data package handed over to IO.