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MQP Level 3

MQP L3 Working Instruction for Manufacturing Readiness Review

This procedure defines the procedural requirements and methods for conducting a Manufacturing Readiness Review (MRR). In this document MRR designates both:
- the period of preparation of the review to the Authorization To Proceed (ATP) to manufacturing
- the review itself which supports the ATP at the end of the period

Approval Process			
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Change Log			
MQP L3 Working Instruction for Manufacturing Readiness Review (44SZYP)			
Version	***Latest Status***	***Issue Date***	***Description of Change***
v1.0	In Work	28 Jan 2011	
v1.1	In Work	23 Feb 2011	Minor changes
v1.2	Disapproved	03 Jun 2011	Assigned Reviewers and Approver according to MQP. Added Form of MRR chit and Typical Process of MRR.
v1.3	Signed	26 Jul 2012	- update to comply with MQP Procedure Template - added acronyms list
v1.4	Signed	09 Aug 2012	- update to comply with MQP Procedure Template - added acronyms list
v2.0	Revision Required	08 Feb 2018	Update as per MQP doc Request VQ7WG4. All the document is updated on the latest MQP Documentation Template.
v3.0	Revision Required	09 Apr 2018	Integrated comments from reviewers in particular: - revised section 2: scope: removed reference to Level 2 (not yet approved); clarified scope (limited to manufacturing phase and prior to issue EWP) - revised section 3: definition: removed reference to " installation" - revised section 5: applicable references: rewording for clarifications. In particular relevant to "off-the-shelf" components and design phase status (shall be completed before MRR) - section 7.2.1 (clarification about MRR plan process; to be submitted 6 weeks before (instead of 4) and 7.2.2 (modification/clarification on Panel members with CIO representative added)
v3.1	Approved	11 Jun 2018	This version 3.1 is updated based on comments received from version 3.0 from CIO Deputy Head and from AGN for Design Control Consistency check
v4.0	Approved	18 Nov 2020	As per approved MQP doc Request - 3LGGNB, the main changes are: 1/ Update the chapter scope for the case of IO Works Contractor supplied SSCs 2/ Update the chapters 6 Responsibilities and 7.1 Flow chart about the approver of the MRR report (CAT-2093), 3/ update the chapter 7.2.5 Follow up action to specify the tracking of actions (OFI 2 of 2018 MA Internal audit) 4/ update the appendix 1 to integrate the specific PE/NPE requirements (action from 2020 QIA PE/NPE) 5/ update the list of references The draft with tracked changes is attached to the MQP doc Request - 3LGGNB.
v5.0	Approved	06 Apr 2021	The doc changed based on the doc request https://user.iter.org/default.aspx?uid=4G5HL7, but with the changes as provided by author as following: Section 2 – Deletion of text ; “Any manufacturing activities should be authorized by IO supported by the results of a MRR.” Section 2 – “normal” MRR – text replaced by “MRR” Section 5.2 – “Not-critical systems” replaced by “Non-Critical components” – More accurate Section 6 – text modified; “The MRR Chair is responsible to prepare a MRR Report and propose a decision on start/stop work to the DA and IO.” changed to “The MRR Chair in conjunction with the panel members is responsible to prepare a MRR Report and propose a decision on start/stop work to the DA or IO as appropriate.” – Allows flexibility depending on level of control applied Section 6 – 2nd, 5th & 6th bullet points modified to refer “for Critical components where Full / Partial control by IO has been decided for the MRR

			– brings clarity and allows flexibility where no control applied Section 7.1 – text added below flow chart for clarity as follows ; “Note: The workflow above sets out the general steps to be applied to an MRR. Where necessary the above maybe complemented / further developed by a DA to align with their quality needs. The general provisions however shall be respected in terms of roles and responsibilities where IO has Full or Partial Control for component MRRs, unless specific derogation has been granted by the IO.” Section 7.2.3 & 7.2.4 – MRR Chair responsible for report issuance – text updated accordingly Section 7.2.5 – Responsibility for action follow up – text modified to allow flexibility / bring clarity Section 8 (a) – “Panel” changed to “Chair”
v5.1	Approved	28 Apr 2025	New version includes the following complementary updates, 1. Tidy up of terminology (go ahead, ATP, etc.) 2. Inclusion of text on CFSI 3. Inclusion of reference to a new qualification procedure 4. Inclusion of reference to possible templates for use to organize and record outcomes of MRR 5. Inclusion of SOA for process 6. Update of text considering new Iter organization The general MRR process is unchanged and this update will be communicated to DAs for information and compliance if they wish to take on board this new version, hence the review of this version is limited to IO stakeholders.

Table of Contents

1 Purpose

This procedure defines the procedural requirements and methods for conducting a Manufacturing Readiness Review (MRR).

In this document MRR designates both:

- the period of preparation of the review to the Authorization To Proceed (ATP) to manufacturing;
- the review itself which supports the ATP at the end of the period.

2 Scope

This document is a MQP level 3 procedure and implements the process requirements from section 3.5.1 ‘’Planning’’ [2] related to ‘’Manufacturing, Assembly and Installation Process’’ of QAP [1] as a level 3 document.

This document provides requirements and methods to implement MRRs of the ITER components, and if deemed appropriate system or subsystem. These process requirements are applicable to DAs (for in-kind procurements) and Suppliers (for in-cash contracts) and sub-contractors who perform manufacturing activities.

In particular, in the frame of the ITER project, the ITER Organization (IO) is responsible towards the French Licensing Authorities for the different Protection Important Components (PIC) and, as such, needs to be involved in the approval of all PIC development phases.

Manufacturing Readiness Review (MRR) is the last review before manufacturing and if successful it gives the ATP for start the manufacturing of the components as illustrated in the Figure 1.

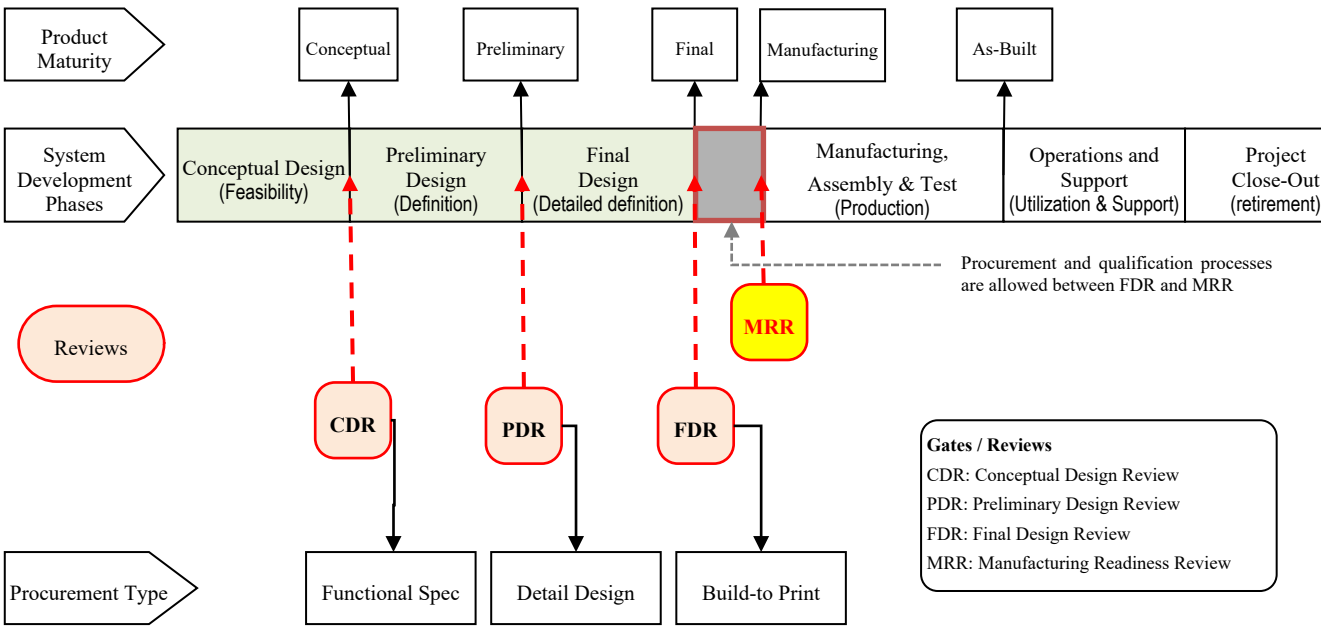


Figure 1 – System life cycle [3]

All MRRs (covering the full Manufacturing scope) should be identified in the IO-Design Review Plan with an indication of their importance (MRR or Simplified MRR), and if it is a Control Point for IO Hold Point (HP) or Authorization To Proceed Point (ATTP).

This procedure describes the general rules for MRRs and specific MRR procedures could be developed to better adapt to specific needs, provided they remain compliant with general provisions from this document including the IO's roles and responsibility.

The process for Review and Acceptance of Site and Buildings Construction Designs developed under PAs 6.2.P2.EU.02 & 05 is described in [4] and therefore is excluded from the present document.

MRR relates to manufacturing phase/fabrication activities undertaken prior to installation works on the IO site.

MRR can relate to any SSC supplied by an IO DA (In-kind Procurement) or an IO Suppliers (In-Cash Procurement).

In the case of IO Suppliers provided SSCs (e.g. fabricated pipework spools intended for installation at the ITER site), the MRR shall be undertaken post issuance of Engineering Work Package (EWP) [5] documentation and review, acceptance / approval of Supplier documentation related to the SSCs to be manufactured.

3 Definitions and acronyms

3.1 Definitions

Component: the product to be manufactured as requested in the procurement documentation and that is subject of the MRR. It may be an individual or a group of components of the ITER Facility, and/or parts of components. It includes all requested spare components or parts.

''Delta'' MRR: a partial authorization to start Manufacturing up to defined manufacturing operations.

Graded Approach:

A Graded Approach is a structured method determining:

• The characteristics of a facility or activity and operational procedures according to the safety significance and complexity.

• The potential impacts of the facility or activity on human life and health and the environment.

• The possible consequences of an unanticipated event or an activity improperly carried out.

Manufacturing activities: all activities to be performed in order to manufacture the requested component until its delivery on site. These activities are:

- The fabrication including the acquisition and/or fabrication of all raw materials and parts to manufacture the components, and their assembly into the requested component;
- The inspection and testing [6] to be performed on the raw materials, parts and the manufactured component in order to demonstrate the compliance of the manufactured component with its technical criteria;
- The conditioning and packaging of the manufactured component for its storage and shipping to site including its preservation and handling.

Manufacturing activities requirements: a set of technical requirements that has been propagated from the technical criteria of the component to manufacture and that must be satisfied by the manufacturing activities to ensure that:

- The manufactured component meets their technical criteria at delivery on site (fabrication of the component).
- The technical criteria of the component are not impacted during the execution of their manufacturing activities (protection of the component).

Manufacturing/Fabrication: the processes (e.g. by machining, assembly, etc.) of converting raw materials, components, or parts into finished component that meet the technical criteria specifying its manufacturing design.

Manufacturing Readiness Review: a set of verification activities to be performed before the start of manufacturing activities in order to assure:

- The required activities are adequately and ready to be effectively performed according to approved documents;

- The relevant technical criteria of the manufactured component are specified in approved documents including for on-site storage, on-site assembly and installation, maintenance and preservation after installation, commissioning, operation and maintenance;

*It should be noted that through this project gate review, the approved documents which are presented will become **applicable** for the manufacturing phase after acceptance and authorization from IO. It is also important to note that even if some approved documents are preliminary version, it will be possible to revise it during the manufacturing process.*

Input Data Package: list of documents with their version number, submitted as input to the MRR (ref. Appendix 1 – MRR Input Data Package)

Procurement documentation: the set of documents transmitted to the manufacturer of the component concerned by the MRR. This set includes:

- For the Domestic Agencies, the Procurement Arrangement Annex A (for project, process and quality assurance requirements), the PA Annex B (for the component technical requirement) and all their applicable documents;
- For IO Suppliers, the Technical Specifications of the "In Cash Contracts" (ICP), and all their applicable documents;
- For the manufacturers (when different from above), the Technical Specifications and all their applicable documents developed by the DA or IO's Suppliers.

Supplier: shall mean a legally registered entity, that provides products or services to another entity.

Technical criteria: a characteristic of the component to be manufactured that has been fully propagated during the manufacturing design phase completed prior to the MRR.

- Additional propagation or refinement of these requirements is not required regarding the manufacturing design.
- The criteria include, at the minimum, the component identification and number, classifications, dimensions and weights, materials, surface finish/roughness and cleanliness, handling/lifting features, and marking/label. Each characteristic is complemented as applicable with acceptance criteria and acceptable tolerances.
- Only the relevant technical criteria for the successful manufacture of the component are covered by the MRR, i.e. criteria that:
    - Will be implemented by the manufacturing activities (fabrication of the component);
    - May be impacted during the execution of the manufacturing activities (protection of the component).
- The identification of all the relevant technical criteria classified as ''Defined Requirements'' is mandatory.

3.2 Acronyms

Acronym	Definition
ATP	Authorization To Proceed
ATTP	Authorization To Proceed Point
CFSI	Counterfeit, Fraudulent or Suspect Items
CID	Central Integration Division
CP	Construction Project
DA	Domestic Agency
DR	Deviation Request (as defined in [7])
EWP	Engineering Work Package (as defined in [5])
FDR	Final Design Review (as defined in [8])
HP	Hold Point
ICP	In-Cash Procurement
IO	ITER Organization
MN	Manufacturer Part Number
MRR	Manufacturing Readiness Review
NCR	Non-Conformance Report (as defined in [9])
PBS	Plant Breakdown Structure
PCR	Project Change Request
PE/NPE	Pressure Equipment / Nuclear Pressure Equipment
PIC	Protection Important Component (as defined in [10])
PNI	Part Number of ITER
QMDH	Quality Management Division Head
QARO	Quality Assurance Responsible Officer
QC	Quality Class (as defined in [11])
PA	Procurement Arrangement
PARO	PA Responsible Officer
TRO	Technical Responsible Officer
SSC	Systems, Structures or Components
SysRO	System Responsible Officer
VCM	Verification Compliance Matrix

For a complete list of ITER acronyms and abbreviations see [12].

4 Reference Documents

[1] ITER Quality Assurance Program (QAP) (22K4QX)

[2] Manufacture, Assembly & Construction Planning Procedure (UYULNL)

[3] ITER Systems Engineering Management Plan (SEMP) (2F68EX)

[4] Working Instruction for Review and Acceptance of Site and Buildings Construction Designs developed under PAs 6.2.P2.EU.02 & 05 (S7HRYX)

[5] WI for Construction Preparation (EWP/CWP/IWP) (UYGEDA)

[6] Procedure for Inspection and Testing (TVL3Y5)

[7] Procedure for the management of Deviation Request (2LZJHB)

[8] Design Review Procedure (2832CF)

[9] Procedure for the management of Nonconformities (22F53X)

[10] Safety Important Functions and Components Classification Criteria and Methodology (347SF3)

[11] Quality Classification Determination (24VQES)

[12] ITER D_2MU6W5 - ITER Abbreviations (2MU6W5)

[13] Procedure for Identification and Controls of Items (U344WG)

[14] ITER Numbering System for Components and Parts (28QDBS)

[15] Quality Requirements for IO Performers (22MFG4)Work instruction for Producing the Manufacturing & Inspections Plan (UKQG8M)

[16] PE/NPE - Manufacturing Design Controls for PE/NPE (WSJ6VM)

[17] Management of Counterfeit, Fraudulent or Suspect Items (CFSI) (A52J3Z)

[18] MQP L3 WI to Produce EWP/CWP Verification Compliance Matrices (VCMs) (23GNX7)

[19] Qualification of Protection Important Components (PIC) (XB5ABP)

[20] Template - MRR Plan (DPQ7TN)

[21] Template - MRR Notification (DRVBGD)

[22] Template - MRR Agenda (9759UU)

[23] Template - MRR Panel Report (96QPG6)

5 Basic Principles

IO as Final Customer and Nuclear Operator decides the level of control on the MRRs and ATPs, depending on the criticality of the project and as identified in IO-Design Review Plan, as follow:

- Full control: IO organizes the MRR and gives the ATP on the basis of this procedure;

- Partial control: IO gives the ATP on the basis of the results of an MRR organized by the DA or the IO-Supplier, using this procedure or an equivalent procedure (demonstrated by a compliance matrix), submitted to the IO for Acceptance for use before proceeding.

- No IO control: IO leaves the MRR and the ATP organization to the provider (DA or IO-Supplier)

MRR's goal is to enable IO (in the case of ICP) and, IO and DAs (in the case of PAs):

1. To confirm that the manufacture of the concerned component is ready to start without incurring unacceptable risks;
2. To give the authorization to proceed with manufacturing.

Each DA or IO Supplier for large/complete ICP contracts shall identify the MRRs to be undertaken taking into consideration the following parameters (not exhaustive):

- Size, number and complexity of the component to be manufactured;
- Number of manufacturers used for the PA and ICP contract;
- The Graded Approach defined by IO, the DA and/or Supplier.

The outcome of this activity is:

- The number of MRR to be performed per PA/ICP;
- For each MRR, the concerned component(s) and manufacturer(s);
- Target dates for MRR.

A typical process for the preparation and execution of a MRR is shown in the Flow Chart Section 7.

A MRR shall only be executed after:

- the completion of the design phase of the concerned component, including the development of the manufacturing design with the appropriate integration of information from the selected manufacturer;
- the acceptance of the manufacturing design;
- the approval and authorization for use of all the documentation that constitute the Input Data Package for the MRR (see Appendix 1);
- all resources needed to proceed with manufacturing confirmed as are available.

A MRR shall be performed before fabrication starts and after the completion of the qualification phase unless otherwise agreed between IO and DA (in the case of PAs).
The qualification of PIC is outlined in MQP procedure Qualification of Protection Important Components (PIC) [19].

The MRR shall review the documents of the Input Data Package in order to verify that the appropriate manufacturing activity requirements have been defined in order to ensure that:
- The technical criteria of the component to be manufactured are not impacted during the execution of their manufacturing activities;
- The manufactured component meets its technical criteria at delivery on site.

It shall verify that all manufacturing activities have been planned and prepared to ensure that the work can be accomplished as specified.
The MRR shall also check that:
- Identification of components and parts will be achieved in consistence with MQP identification procedures [13], [14] during manufacturing
- Preservation has been studied (packing, packaging , handling, protection on site procedures)
- Specific procedures and specifications have been prepared to define the installation conditions and tooling as well as maintenance and preservation and spares need after installation

These studies (identification, preservation, installation, maintenance) shall be achieved by the manufacturer with the support of its customer (DA or IO)

In particular the following general points shall be verified during a MRR:

(a) check appropriateness of area and working facilities;

(b) check availability of materials and 'off-the-shelf' datasheets to start work and their compliance to applicable specification and with appropriate traceability;

(c) check availability and approved status of the relevant drawings, including required tolerances, to start work and their compliance to applicable specification;

(d) check availability and approved status of applicable quality and manufacturing documentation (e.g. Quality Plan, Manufacturing Inspection Plans, Non-destructive testing protocols, Welding data package, Process qualification records, etc.)

(e) check availability and appropriateness of machine & tooling and the approval status of manufacturing procedure compliant with manufacturing process qualifications as may be applicable;

(f) check availability and appropriateness of personnel in term of qualifications and number, as may be applicable;

(g) verify by direct evaluation of manufacturing process, facilities, and personnel whether manufacturer has capability to ensure quality of product within required schedule;

(h) verify approval status of all documents and records as appropriate, (e.g. manufacturing procedures, qualification report /certificate, etc.) confirming that manufacturing processes conform to specified (PA or ICP) requirements;

(i) check all documents and records are designated properly with contract / job number, concerned product number, etc.

(j) check availability and use of applicable documentation including standards and codes;

(k) verify by examination of plans and documents whether a suitable QA/QC program has been developed to ensure production monitoring;

(l) check Manufacturing Inspection Plans capture all activities requiring inspection and associated control points, e.g. Witness / Hold points have been defined and agreed between Supplier and IO and / or DA depending on the level of control of the MRR. Specific attention shall be paid to all activities defining Factory Acceptance Tests (FAT) and associated control points.

(m) check that all necessary resources have been considered for successful execution of the MIP including all activities related to FAT and associated control points;

(n) check that final inspection before shipping is planned (e.g. packaging, etc.)

(o) check configuration status including NCR and Deviations and Design changes status which should be closed;

(p) check that chits/actions related to design reviews have been resolved / closed and that no issues remain related to design;

(q) check the requirements propagation by VCM fulfilment as specified in 5.1.6

(r) Verify the identification of:

(i) All the manufacturing activities classified as Protection Important Activity, with their Defined Requirements and imposed Technical Controls and criteria/tolerances.

(ii) All the relevant technical criteria classified as Defined Requirements.

(s) check of subcontracted operations.

Objective is to:

(i) Verify approval status of the manufacturing documentation (ref. Annex 1),

(ii) Verify approval status of the preservation documentation (packing, packaging, on-site storage, on site protections),

(iii) Verify approval status of installation and maintenance documentation,

(iv) Making sure that all requirements are considered and that the VCM is populated with reference to evidences,

(v) Authorize (partially / fully) or put On-Hold the start of manufacturing.

The MRR needs to take into account the Graded Approach, so that the products that are considered Critical for the ITER project (e.g. the system contains component PIC and/or QC1 or QC2; components or systems that have a relevant financial impact/cost; products that have a complex manufacturing process and involve the different specialities and special processes; Pressure Equipment and/or Nuclear Pressure Equipment) are given high priority.

The necessity and decision on MRR application shall be established during the contract's preparation (PA's or ICP as applicable) with the definition of Control Points. In case of "off-the-shelf components'' (e.g. raw materials already available from the market / commercial item form manufacturer's catalogue) derogation from MRR execution could be accepted as specified in the relevant contract.

In case a system is not considered Critical (e.g. it does not contains PIC component or QC1 or QC2) implementation of a "Simplified MRR" could be agreed with IO as described in Subsection 5.2.

All MRR meetings shall be conducted in a formal way. The comments from the reviewers shall be recorded and related actions shall be tracked.

In case of any need of change detected during an MRR and depending by criticality of impact of this change on design requirements a DR or a PCR shall be issued.

Note: In case of possible issues identified during the MRR the manufacturing shall be put "On-Hold" or partially authorized highlighting any outstanding obligation.

In some cases MRRs may be split (''Delta'' MRR) in time for schedule optimization due to phased manufacturing. In this case the criteria above could be applied to the partial MRRs.

5.1 MRR General Content

The MRR shall cover:

5.1.1 Material

- Manufacturing environmental conditions meet product technical requirements (e.g. temperature, humidity, cleanliness class, ventilation, segregation from other material, etc.).
- Production materials used for ITER project are correctly procured, qualified, inspected and stored. Compliance with contractual requirement is confirmed and all material (raw, finish goods, nonconforming product, etc.) are well controlled in production line.
- Appropriate procedure/system for assuring material identification and traceability.
- All products designed for manufacturing shall be designated with type reference codes, i.e. PNI and/or MN.

5.1.2 Personnel

- Personnel who work for ITER project have been trained and evidence that IO requirements, as imposed through the contract documents, are understood is available. Personnel are qualified as may be applicable. In particular the qualified operators for special process (e.g. welding, heat treatment, NDE) are available and sufficient number of resource is allocated.

5.1.3 Machines and Tools

- Machines, jigs, measuring and testing equipment are qualified and valid for usage, e.g. the equipment list is in place, the maintenance plan is established, the calibration is kept valid, etc.
- Processes: specific manufacturing processes (e.g. heat treatment, welding, coating, cleaning, bending, forming, etc.) have been qualified as may be applicable.

5.1.4 Manufacturing methods

- Check documents relevant to ITER project are approved or accepted by IO as may be applicable (e.g. Quality Plan, the MIPs, manufacturing procedures, the work instructions, manufacturing drawings, etc. including all changes affecting the system).
- Check documents stating compliance of manufacturing processes, facilities and personnel (including applicable approval and qualifications) and whether manufacturer has capability to ensure quality of product within required schedule.

5.1.5 Transportation and ITER site activities

- Check documents describing packing, packaging, transportation, handling and protection on ITER site
- Check relevant documents detailing installation and maintenance on ITER site and particularly specific tooling and spares when needed.
- Check Planned Delivery List describing all items or groups of items to be delivered. Noting that all items listed in the Delivery List shall have designated PNI's and/or MN.

This specific part of the studies are performed by the IO TRO in case of ICP or DA coordinator in case of PA with the manufacturer inputs.

5.1.6 Requirements

- A specific matrix is built for the component to be manufactured (DA coordinator or IO TRO) with all the requirements and the evidences coming from the previous design review (FDR) – that is the Verification Compliance Matrix (VCM) [18]
- Check additional technical criteria generated by the manufacturer studies
- Check ITER site activities requirements (preservation, installation, maintenance)
- Check evidences provided by the manufacturer to fulfil all the requirements

All these verification may be done by documentary review and check and/or through on-site verification at manufacturer's premises as may be more appropriate. Adequate traceability and record shall be ensured.

5.2 Simplified MRR

In case of Non-Critical components (e.g. non-PIC component or QC1 or QC2), a "Simplified MRR" process, with no meeting but only review of documents, could be agreed with the IO:

- MRR Responsible party (DA in case of PA or Supplier in case of ICP) shall issue a MRR Plan containing the list of documents of the Input Data Package and a detailed checklist of elements to be checked.
- Needed elements are requested from and provided by the Manufacturer.
- DA coordinator and/or IO TRO review the elements described in the MRR Plan and issue final MRR Report to give the ATP (partially / fully) or put On-Hold the manufacturing.

6 Counterfeit, Fraudulent or Suspect Items (CFSI) Prevention

As part of the MRR process, CFSI prevention measures shall be evaluated to ensure the integrity and authenticity of all materials, components, and assemblies used in manufacturing.

Suppliers must demonstrate robust controls for the detection, reporting, and mitigation of CFSI are in place including sourcing traceability, supplier qualification, material certification, quality control processes & verification of qualifications of personnel, e.g. welder and NDE inspector certificates etc.

Suppliers Quality Plans shall include a specific chapter related to the measures to be implemented for prevention and control of CFSI cases.

Any identified risk of CFSI shall be addressed through corrective actions, enhanced inspection protocols, or sourcing adjustments prior to proceeding with manufacturing.

Management of Counterfeit, Fraudulent or Suspect Items (CFSI) (A52J3Z) [17] describes the way CFSI cases are managed for the ITER Project and includes guidance and checklists for the identification and prevention of CFSI which may be used in addition to the process to be followed should a CFSI be detected.

7 Responsibilities

DA in case of PA or the Supplier in case of IO direct contract is responsible for preparation, implementation, and follow-up action of MRR.

IO and DA in case of PA or IO in case of ICP shall select MRR Panel Members on key MRR identified by IO and designate a chair and a secretary for each of those MRR.

The MRR Chair in conjunction with the Panel Members is responsible to prepare a MRR Panel Report and propose a decision on start/stop work to the DA or IO as appropriate.

The Manufacturer shall provide all requested information and evidences as requested by the MRR Panel and described in the MRR Plan in order to evaluate and confirm manufacturer readiness including manufacturing area/facilities, machine/tooling, personnel, material, procedure approval status, manufacturing and process qualifications as may be applicable.

In particular the Manufacturer shall provide a detailed manufacturing scheduling and approved Manufacturing Inspection Plan [15].

IO shall be responsible for controlling and supporting DA's or Supplier MRR.

In particular, IO TRO shall:

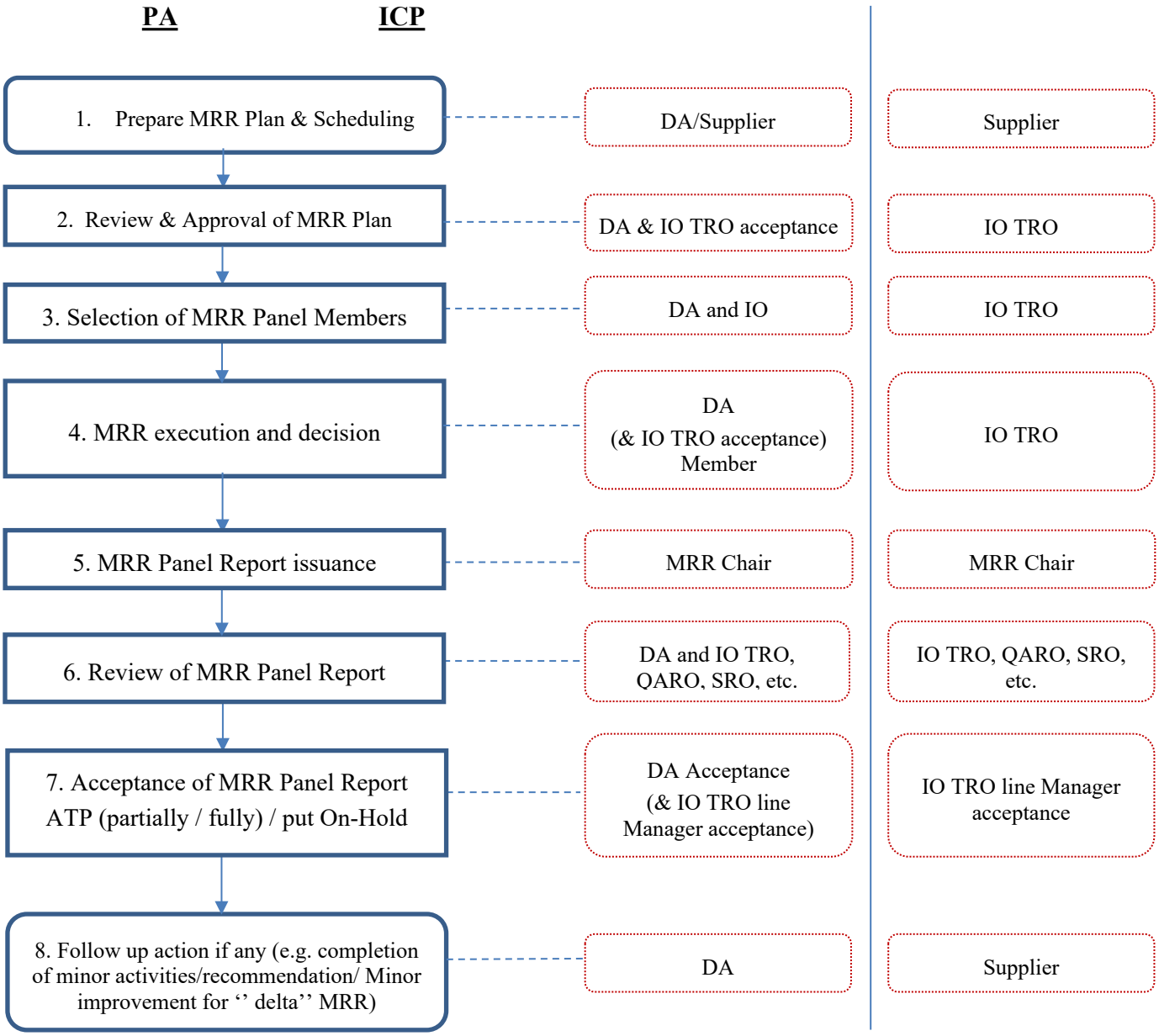
- Participate in MRR meetings for PIC, Quality Class1 and Quality Class 2 SSCs.

- Review the MRR Plan and MRR Panel Report for Critical components where Full / Partial control by IO has been decided for the MRR
- Be involved in preservation, installation, maintenance studies
- Check the VCM to ensure that all requirements are propagated with related evidences
- The IO QARO should be involved in the review of the MRR plan for Critical components where Full / Partial control by IO has been decided for the MRR and shall review MRR Panel Report to verify adequacy of quality requirements.
- The IO TRO line Manager (i.e. the Program Manager or Project Leader) shall accept / approve the MRR Panel Report for Critical components where Full / Partial control by IO has been decided for the MRR.

8 WORKFLOW

8.1 Flow chart

The workflow below presents the steps of the MRR process and identifies the responsibilities for both In-kind Procurement (PA) and In-Cash Contracts (ICP) .



Note: The workflow above sets out the general steps to be applied to a MRR. Where necessary the above maybe complemented / further developed by a DA to align with their quality needs. The general provisions however shall be respected in terms of roles and responsibilities where IO has Full or Partial Control for component MRRs, unless specific derogation has been granted by the IO.

8.2 Description

The main steps for a MRR implementation as listed in the workflow are described below:

8.2.1 MRR Plan and scheduling

In the frame of MRR plan preparation or before, the MRR responsible party (the DA or the Supplier) should perform a visit to the manufacturer facilities and sub-contractor's facilitates where appropriate (e.g. execution of critical operations) in order to verify the manufacturing work area, materials traceability, equipment's and machines, personnel qualifications and resources availability are suitable to accomplish the work in accordance with the applicable requirements.

Prior to performing a MRR, the MRR responsible party, in conjunction with IO, shall prepare a MRR Plan that identifies:

- Scope (list of PBS) of the MRR with applicable PA and/or contract documents
- List of equipment in the scope
- MRR Panel Members and their roles and responsibilities
- Qualification of the Chair
- Supplier organization involved in the MRR
- Input Data Package: list of documents and items needed to be assessed
- Schedule of the MRR
- Previous MRR details, if applicable

A MRR pre-meeting may be held by DA, IO and Suppliers (for in cash contracts) to prepare the MRR outline or to review adequacy and effectiveness of the proposed MRR Plan.

MRR responsible party shall submit the completed MRR Plan to IO for acceptance at least 6 weeks before the MRR scheduled date.

IO shall review the MRR Plan and provide written comments, if any, to MRR responsible party for resolution and agreement with IO before MRR execution.

Upon IO acceptance of the MRR plan, involved organizations and MRR Panel Members shall be notified at least 2 weeks before the MRR is conducted. This notification should be in writing and include information such as the MRR scope and schedule, MRR Panel Members and complete set of documents to be assessed.

If it is found that a scheduled MRR date cannot be met after the approval of the MRR plan, upon written request from DA TRO or Supplier Responsible as may be applicable, IO TRO may authorize a reasonable extension.

8.2.2 Selection of MRR Panel Members

The MRR Panel consists of a Chair and selected members (experts).

MRR Panel Chair shall be a technical and managerial qualified person who is in charge to:

a) Approve the charge for the review by the TRO
b) Propose name of members for the review panel
c) Approve the meeting(s) agenda
d) Ensure that participants understand what is required to them
e) Ensure that sufficient time is allocated for review activities
f) Ensure that the meeting's input package is issued to designated persons;
g) Assign tasks to participants in preparation for meetings;
h) Chair the review meeting, moderate the discussions ensuring that the focus stays on the manufacturing readiness assessment and that all attendees may provide their input and try to reach consensus in the review team in case of differences of opinion. If consensus cannot be reached, forward minority as well as majority view(s) for decision in the MRR Panel Report;
i) Ensure that relevant issues from the meeting are recorded;
j) Ensure that actions and recommendations from earlier meetings have been satisfactorily addressed and closed, as appropriate;
k) Review and approve the minutes of meeting;
l) Ensure that the minutes of meeting are issued to all participants.
m) Coordinate the development of the MRR Panel Report with the Panel Members.

In addition to the Chairperson, appointed members should be SysRO, QARO, SRO, PE/NPE representative, CID representative and and experts as may be proposed by the DA, where applicable, and agreed by IO in accordance with the scope of the review. In case of PAs the IO TRO shall be part of the MRR Panel.

The MRR Panel Members shall be selected considering the type of system or component to be reviewed, its safety and quality classification, and the manufacturing techniques to be used. While selecting MRR Panel Members, a special knowledge, prior experience, and education shall be considered. The nature of the MRR may require the assistance of technical specialists. If so, specialists shall be involved in the MRR.

For MRR on PIC, QC1, and QC2 SSCs, the Chair and the Panel shall be independent from the manufacturing design development i.e. not belonging to the Manufacturer's organization.

8.2.3 MRR execution

The MRR Panel shall conduct the MRR under the direction of the Chair and in accordance with the approved MRR Plan:

- Prior to starting the MRR, each Panel Member shall develop a clear understanding of the scope of the MRR, the reliability aspects of the work scope, the requirements and rules applicable to the work to be reviewed, and the communication and reporting agreements made with the organization responsible for performing the work.
- Checklist shall be used and completed. However, a checklist should not preclude the opportunity to verify manufacturing readiness which may have the potential to yield problem. Nor should the checklist prevent the immediate follow-up of an important or significant concern.

IO external experts may participate in MRR for PIC, QC1, and QC2 SSCs.

The responsibility of an IO external expert is to audit / oversee the process, not to give any Authorization To Proceed.

If any significant conditions adverse to quality are identified, the Chair shall immediately notify to IO TRO of that condition by telephone and / or e-mail. The IO TRO shall consult with the IO QMDH and the appropriate managers as may be the case (e.g. Depending on the pending issue: CP for construction, design and site activities; CID for integration and requirements propagation).

Results of the MRR shall be documented on the checklist by MRR panel, if applicable.

At the end of the MRR, a time slot should be allocated for the Chairman to debrief MRR meeting's outcome to responsible managers of the applicable organizations and inform if the MRR is successful meaning that nothing is preventing the ATP to be given.

It is the IO's responsibility to grant an ATP in case of an IO Control Point.

Upon the completion of the MRR, the DA in conjunction with the MRR Panel Members shall summarize the MRR results in a formal MRR Panel Report.

The MRR Panel Report shall contain the following,

- Scope of the MRR with applicable PA and/or contract documents;
- MRR Panel Members;
- Input data Package;
- Summary of MRR results and action items to be taken and schedule, if applicable;
- Completed checklists;
- Appraisal of the review by the Chair, and recommendations for ATP.

MRR Chair shall forward the completed MRR Panel Report to IO TRO for acceptance.

The acceptance of the MRR Panel Report constitutes the "Authorization To Proceed''.

IO is in charge for review and acceptance of the MRR Panel Report as follows:

- IO TRO and any other assigned reviewer (e.g. IO QARO, IO SRO) shall review the report and IO TRO shall accept the Report or reject it notifying his comments.
- The report shall be distributed to applicable organizations within IO for information.

8.2.4 MRR conclusion and MRR Panel Report

The scope of a MRR is to confirm or not, the authorization to start manufacturing.

The MRR Chair (supported by the MRR Panel Members) shall issue a MRR Panel Report including recommendations to be carried out along with a clear recommendation on the following possible outcomes:

(i) Successful: there is no objection to deliver the ATP (manufacturing can start).

(ii) Unsuccessful: manufacturing start shall be placed "On-Hold'' until resolution of detected major issues. MRR shall be repeated once available evidences of resolution of detected major issues.

(iii) Conditionally Successful upon the completion of certain minor activities by the Manufacturer in order to comply with a specific recommendation.

(iv) Start of manufacturing activities should neither be stopped nor be put On-Hold unless a major issue is detected. A partial authorization to start could be provided (up to defined manufacturing operation) and a "Delta'' MRR could be considered at a later date in order to give the opportunity to the Manufacturer to improve the maturity of the manufacturing documentation (any contractual impacts are out of scope of this document) and resolve minor issue, if any.

(v) After due consideration of the MRR conclusions, the IO TRO shall decide the start or otherwise of the manufacturing activities. In case of discrepancy between the IO TRO decision and the MRR conclusions, the IO TRO decision shall be endorsed by the IO QARO and by his / her direct line of management.

8.2.5 Follow-up of Actions

Prior to the start manufacturing, the DA and / or Suppliers in case of direct contracts as may be applicable shall resolve unacceptable quality conditions or lack of preservation, installation, and maintenance activities description, resulting from the review. A chit list (actions list) shall be issued in this case to ensure follow-up and closure of all findings. Fabrication shall not start before relevant MRR requested actions are closed, unless otherwise agreed by the DA / IO as applicable depending on the Level of Control applied to the MRR, e.g. differently authorized by the IO TRO following the process described in Sect. 8.2.4 (v).

A Graded Approach needs to be used for documenting the open actions after the MRR. DA and / or Supplier shall notify the DA / IO TRO of status of follow-up actions on a periodic basis. The DA / IO TRO shall ensure follow-up through periodic progress meetings. For Critical components the IO TRO shall be notified in all cases.

9 Outputs and Records

(a) The MRR Chair is responsible for issuing a MRR Panel Report with a clear recommendation on the outcome of the MRR.

(b)The IO TRO is responsible for notifying the MRR Panel and all concerned stakeholders on the final decision taken and for archiving all review records in accordance with project procedures including the charge, the review panel composition, attendees, presentation material, review panel reports, approvals to proceed, and declarations of review closure.

NCR, Actions, Checklist and MRR Plan and MRR Panel Report shall be recorded in IDM in accordance with relevant process and defined tools.

Record	Author(s) (R)	Reviewer(s) (C)	Approver (A)	Informed (I)
MRR Plan	DA/Supplier (PA) (IO support[1])	DA/Supplier appointed reviewers (PA) IO reviewers[1]: QARO, SRO[2], PE/NPE representative[3], Experts[4], SysRO, ….	DA TRO (PA) (IO TRO acceptance)	Participants to MRR plus any other stakeholders
	Supplier/ Contractor (ICP)	QARO, SRO[2], PE/NPE representative[3], Experts[4], SysRO, ….	IO TRO (ICP)	Participants to MRR plus any other stakeholders
MRR Notification	DA/Supplier (PA)	MRR Chair, SysRO, QARO,…	DA TRO (PA) (IO TRO acceptance)	Participants to MRR plus any other stakeholders
	Supplier/ Contractor (ICP)	MRR Chair, SysRO, QARO,…	IO TRO (ICP)	Participants to MRR plus any other stakeholders
MRR Agenda	DA/Supplier (PA)	DA/Supplier appointed reviewers (PA) IO reviewers[1]: TRO, QARO, SRO[2], PE/NPE representative[3], Experts[4], SysRO, …	MRR Chair	Participants to MRR plus any other stakeholders

Record	Author(s) (R)	Reviewer(s) (C)	Approver (A)	Informed (I)
	Supplier/ Contractor (ICP)	TRO, QARO, SRO[2], PE/NPE representative[3], Experts[4], SysRO …	MRR Chair	Participants to MRR plus any other stakeholders
MRR Panel Report	MRR Chair (Panel members support)	Panel Members (including[1], QARO, SRO[2], PE/NPE representative[3], Experts[4], CID RO, SysRO)	DA TRO (PA) IO TRO Line Manager / Project Leader (ICP)	Participants to MRR plus any other stakeholders

Notes:

1. For Critical components where Full / Partial control by IO has been decided for the MRR.
2. Where Nuclear Safety related.
3. Where PE/NPE related.
4. Subject Matter Experts.

Record	Template, UID	Place to store, UID, if available	Doc type	Recommended Naming convention	Retention period
MRR Planning Template	Template - MRR Plan (DPQ7TN)	*PA folder / ICP folder in relevant DMS*	*Plan*	PBS.L1.L2.L3 – SSC description -MRR Plan	Project Life
MRR Notification Template	Template - MRR Notification (DRVBGD)	*PA folder / ICP folder in relevant DMS*	*Communication*	PBS.L1.L2.L3 – SSC description -MRR Notification	Project Life
MRR Agenda Template	Template - MRR Agenda (9759UU)	*PA folder / ICP folder in relevant DMS*	*Agenda*	PBS.L1.L2.L3 – SSC description -MRR Agenda	Project Life
MRR Panel Report	Template - MRR Panel Report (96QPG6)	*PA folder / ICP folder in relevant DMS*	*Report*	PBS.L1.L2.L3 – SSC description -MRR Panel Report	*Project Life*

ANNEX 1 – MRR Input Data Package

The checklists to be used for MRR shall be prepared consistently with importance and complexity of items to be manufactured and may take into account guidance provided in this Annex.

MRR input data package shall include management documents like the following (as a guideline because some documents can be grouped):

- Manufacturing Implementation Plan (covering description points at section 5.1)
- MRR Plan [20]
- Notification [21]
- Agenda [22]
- Presentation,
- Minutes of MRR meeting (record of what has happened during the meeting),
- MRR Panel Report (comments and decisions) [23]

In addition, list of document of the input data package shall be provided. Applicable documents, namely for instance procedure documents, welding documents, Codes, & Standards, tooling related documents, certificate of personnel should be submitted as attachments of Manufacturing Plans.

All documents shall be uploaded in IDM or other agreed document management system allowing for review prior to a MRR meeting, with attendance from IO, DA and Suppliers as may be applicable. All the required documents shall be accepted by IO before manufacturing can commence.

In the frame of PA, the MRR list may be elaborated upon mutual agreement between the DA and the IO and included as part of the review. DA may request MRR Panel members to initiate the checklist relevant to their expert discipline.

Document list below is provided as general guide for required documents to be provided in Data Package for a MRR. This list has to be discussed in the frame of MRR plan review. The list provided here below does not intend to be complete and not all types of documents need to be provided for each MRR depending on item to be reviewed:

1. Engineering	
1.1	List of Deviation Requests if applicable
1.2	Manufacturing drawings (2D) and models (3D) *****
1.3	Assembly drawings at the shop *
1.4	Assembly drawings at the ITER site as may be applicable (e.g. for installation) *****
1.5	Parts and Material list, list of equipment and detailed Bill of material (if necessary)*****
1.6	List of standards, codes and regulations applicable for each step of manufacturing, assembly and integration
1.7	Item Identification & tagging and physical labelling procedure
1.8	Top assembly description and function
1.9	Load analysis as part of the manufacturing process (if necessary)
1.10	Design description and justification of transportation frames
1.11	List of deliverables to be provided by the Manufacturer / Manufacturer Dossier content
1.12	Verification Compliance Matrix (requirements and evidences)
1.13	List of chits / actions from design reviews which are unresolved
2.Manufacturing processes	
2.1	Manufacturing and Inspection Plan (MIP): - All activities requiring inspection shall be captured in a MIP. Control points, e.g. Witness / Hold points shall be defined and agreed between Supplier and IO and / or DA depending on the level of control of the MRR. - Specific attention shall be paid to all activities defining Factory Acceptance Tests (FAT) and associated control points.
2.2	Manufacturing schedule and work flow/assembly sequences
2.3	Material procurement technical specification and sub-orders (including e.g. consumables whereas applicable)
2.4	Material management: - identification and control of material - material certificates - material traceability procedure - Storage conditions - Handling procedures
2.5	Manufacturing procedures including special processes (e.g. machining, forming, wiring, brazing, soldering, welding, cleaning, heat treating, others and non-destructive examination, etc.). E.g.: - components processing and assembly specification - cleanliness program - surface treatment program - pipeline inspection program - non-destructive testing program - labelling program (can be included into the tagging & labelling procedure) - coating program - preservation, packaging, storage and transportation program
2.6	Manufacturing working instructions

2.7	Welding data package - Welding procedures/welding Procedure Specification (WPS) - Welding procedure qualification record (WPQR) - Welding quality inspection and procedure plan (WQIPP) - Welding map - Cleaning procedure and requirements for welded parts / components with particular attention on welded joints forming parts of the vacuum boundary according to requirements of ITER Vacuum Handbook.
3.Test methods	
3.1	Control specifications, Testing plan and Test procedures (e.g. Pressure Test Procedure; Helium Leak test procedure; etc.)
3.2	Qualification through Mock-ups and prototype
3.3	Qualification of special processes
3.4	Manufacturing process qualification procedure
3.5	Manufacturing human resources and quality control procedure
3.6	NDE procedures and templates
3.7	Factory acceptance test program identifying all factory acceptance tests as defined at design stage and including details on extent of the tests, type, examinations and inspections of the Items (verification of requirements for acceptance stage)
4.Quality acceptance	
4.1	Quality Plan
4.2	List of Suppliers/sub-contractors and their attributions
4.3	DA, Suppliers and sub-contractors Quality Plans
4.4	Agreed/Notified Bodies approvals or other third party (where applicable)
4.5	MRR deliverables list (list of documents deliverables to be provided by the Manufacturer)
4.6	Other applicable and/or available documents relevant to manufacturing quality acceptance
5. PIC Qualification [19]	
5.1	Qualification plan
5.2	Qualification Synthesis Report
5.3	Qualification Preservation Sheet
5.4	Reference file
6.Tooling	
6.1	List of machines, test equipment and tools including relevant calibration protocols: - the calibration status and records of the machines and tools - Measuring and test equipment qualification and maintenance - Requirements regarding special tooling / spares and any special pieces of equipment or tools needed for packaging, handling, storage, transportation and installation at ITER site.

7.Training and qualification	
7.1	- list of personnel qualifications to perform a special process as may be applicable - list of qualified welders, welding equipment operators, NDE personnel - training records and certificates
8.Transportation and preservation	
8.1	- Final inspection before shipping plan - Packing and packaging procedure - On site preservation procedure - planned delivery list *
9.Installation and Maintenance	
9.1	- Installation and User manual including tooling - Maintenance plan
10. ITER Manufacturer of PE / NPE	
10.1	When ITER acts as Manufacturer of PE/NPE, in accordance with "*Implementation Plan for design and manufacture of PE/NPE (VE2DSP)*" for the MRR IO shall provide documents demonstrating that the manufacturing design of the equipment fit for use and comply with all requirements (called Equipment Design Review). Exhaustive list of documents constituting this Equipment Design Review are defined in chapter 5 of [16].

* items inside list and drawings shall be properly tagged according to [14] .