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22K4QX
VERSION CREATED ON / VERSION / STATUS
18 Apr 2017 / 8.5 / Approved
EXTERNAL REFERENCE / VERSION

MQP Top Level Plan

ITER Quality Assurance Program (QAP)

The purpose of this Quality Assurance Program (QAP) is to ensure that ITER activities are performed at a level of quality appropriate to achieving the safety and performance objectives of the Project.It is one of the three highest level documents of the Management and Quality Programme (MQP). The other two documents are the PMP (Project Management Plan) and ISMS (Integrated Safety, Environment and Security Management System Manual).

Approval Process			
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Document Security: Internal Use *RO: Fabre Nadine*			
Read Access	**GG: MAC Members and Experts, GG: STAC Members & Experts, LG: IT Report Team, AD: ITER, AD: IO_Director-General, AD: EMAB, AD: OBS - Quality Assurance and Assessment Division (QAA) - EXT, AD: OBS - Quality Assurance and Assessment Division (QAA), AD: Auditors, AD: ITER Management Assessor, project ad...**		

Change Log			
ITER Quality Assurance Program (QAP) (22K4QX)			
Version	***Latest Status***	***Issue Date***	***Description of Change***
v1.0	In Work	06 Sep 2005	
v2.0	Signed	14 Sep 2005	
v3.0	Signed	30 Nov 2005	
v4.0	Signed	05 Dec 2005	
v5.0	Signed	08 Dec 2005	
v5.1	Signed	08 Dec 2005	
v5.2	Signed	13 Jan 2006	
v6.0	Signed	07 Nov 2006	
v6.1	Signed	13 Nov 2006	
v6.2	Signed	14 Nov 2006	
v6.3	Signed	16 Nov 2006	
v7.0	Signed	19 Jan 2007	
v7.1	Signed	19 Jan 2007	
v7.2	Signed	22 Jan 2007	
v7.3	Approved	26 Jan 2007	
v8.0	Signed	17 Mar 2017	As part of the simplification/ optimization of MQP as approved by MQPWG, this Major revision of QAP reflects progress of project and new MQP process map defined by MQPWG. This includes the merge of 2NS3UH (ITER Management & Quality Programme (MQP)) into this version. This version has been pre-reviewed by QAA, concerned Process Owners-Representatives, DAs (iteration of drafts including review of their comments).
v8.1	In Work	31 Mar 2017	Changes to version 8.0 accepting RCO DDG's comments: (1) Delete DA from the definition of Performer (2) Add DA’s responsibility and the requirement for joint QA/QC work, as well as Project Team establishment when necessary.
v8.2	Signed	31 Mar 2017	Changes from version 8.1 to version 8.0 accepting RCO DDG's comments: (1) Delete DA from the definition of Performer (2) Add DA’s responsibility and the requirement for joint QA/QC work, as well as Project Team establishment when necessary. Changes from version 8.2 to 8.1: change from track mode to a clean mode by accepting the changes from 8.1 to version 8.0
v8.3	In Work	04 Apr 2017	Accepting COO DDG's request to add 'Construction Teams in Construction Organization should be noted as having full responsibility of Assembly and Installation Works, with a specific organization chart with defined specific responsibility' in Section 1.2.
v8.4	Revision Required	05 Apr 2017	integration of Reviewers comments: Section 2.5: Roles and Responsibilities: adding of a dedicated section for DA, strengthening the synergy approach for implementing Quality activities Section 1.2: project organizational structure, adding precision on Construction Teams Section V (reference): complement the list of external Regulation requirements by adding the PE/NPE Regulation references
v8.5	Approved	18 Apr 2017	As per DG's request: Changing 2.5.1 as

			The IO Director General may consult the IO Central Team Management Board (CTMB) before taking his decision to stop work for the ITER Project. Adding to 2.9: The Non-conformities shall be resolved with high priority and that this resolution shall not exceed 9 months in average and 12 months individually, except initial agreement from the IO DG or the QAA Head.

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I Policy Statement

ITER Management and Quality Policy Statement

To ensure that ITER activities are performed at a level of quality appropriate to achieving the safety and performance objectives of the Project, ITER shall establish, maintain and implement a Quality Assurance Program (QAP) under an overall Management and Quality Program (MQP).

The Quality Assurance & Assessment (QAA) Division has the responsibility to coordinate and monitor the implementation and effectiveness of the Management and Quality Program under the authority of the ITER Director General.

ITER Senior Management has the responsibility and authority to ensure the effectiveness, suitability and sufficiency of the Management and Quality Program, and to develop, procure, manufacture, operate and maintain equipment in accordance with the Management and Quality Program.

All ITER personnel shall adhere to the requirements set forth in this Management and Quality Program and support the QAA Division in performing its task.

ITER Director General

II General Introduction

The ITER project activities, through all the stages and/or phases of ITER project (e.g. R&D, Design, Procurement, Manufacturing, Construction or Assembly & Installation, Commissioning, Operation & Maintenance, Deactivation), shall be governed by a Quality Assurance Program (QAP) under an integrated Management and Quality Program (MQP), which makes use of the experience gained in similar projects, takes into account the specific nature of fusion and the multi-national, multi-party and multi-disciplinary characteristics of the ITER Project, and combines applicable requirements of:

- ISO 9001 “Quality Management Systems Requirements” (Reference [1] and [2])
- IAEA General Safety Requirements (Reference [3])
- The French Order dated 7 February 2012 relating to the general technical regulations applicable to INB (Reference [4])
- ISO 14001 International standard for environmental management system (Reference [5])
- OHSAS 18001 Standard for Occupational Health and Safety management system (Reference [6])
- Pressure Equipment directive 2014/68/UE (RZ6PAK)
- French Decree 2015-799 (Transposition of [7] in French law called ESP (U5TKD4)
- ESPN Order dated 30 December 2015 (SMP384)

Overall, the MQP consists of three levels of documents:

- level 1 PMP, ISMS and QAP,
- level 2 processes or procedures and
- level 3 working instructions and guidelines.

The requirements defined in the top level PMP, ISMS and QAP are propagated into level 2 processes documents and finally implemented through level 3 documents executed by the performers. All these MQP documents are subject to continuous improvement by periodic evaluation and updating. By process approach, this ITER QAP defines requirements for common activities affecting quality independent from phases and organizations, thus is applicable to any performing parties involved in ITER project realization processes.

Access to all the MQP structure and the MQP documents is through the MQP web page [10]: https://portal.iter.org/baseline/Pages/MQPmap.aspx. It shall be noted that this is an area under configuration control where only current approved documents are hyperlinked.

III Scope

This ITER QAP applies to all quality-related activities and processes and all performing parties involved in ITER project processes during any phases, regardless of phase or organization.

The individual Performing Parties shall either implement (flow down) the applicable provisions from this program to their own established quality programs, or agree to adopt the ITER QAP as their Quality Assurance Program in the completion of their scope of work on the ITER Project.

The extent of quality program provisions applied to any specific task is proportional to, and appropriate for, the safety and/or project success significance of the task, as determined by the IO Director General. Research and Development, Design, Procurement, Manufacturing and Construction activities shall utilize the quality assurance requirements defined in this ITER QAP.

IV ACRONYMS AND DEFINITIONS

Activities Affecting Quality: Those work activities when performed will affect the safety, reliability and performance of the ITER Facility.

Condition Adverse to Quality: an all-inclusive term used in reference to any of the following: failures, malfunctions, deficiencies, defective items, and non-conformances. A significant condition adverse to quality is one, which, if uncorrected, could have a serious effect on safety or operability.

Configuration Management: process of establishing and maintaining a consistent record of technical, performance and management configurations.

Domestic Agency (DA): This term refers to an organization appropriately formed and appointed within and by each "Party" to the Agreement on the Establishment of the ITER International Fusion Energy Organization of the Joint Implementation of the ITER Project, each of which will be the supplier of in-kind goods and services to the IO, on the basis of defined specifications.

Graded Approach: The scope, depth, and rigor of the quality management systems application of requirements to a specific activity should be determined by selecting the controls and verifications to be applied to various items and activities consistent with their importance to safety, reliability, performance, and success of the program. The grading process provides the flexibility to design controls that best suit the ITER facility or activity and is a requirement of INB Order [4].

Item: an all-inclusive term used in place of any of the following: appurtenance, assembly, component, equipment, material, module, part, structure, subassembly, subsystem, system, or unit.

ITER Organization (IO): the organization that is legally responsible for the construction and operation of the ITER facility including but not limited to one who has applied for, or who has been granted, a construction permit or operating license by the regulatory authority having lawful jurisdiction.

Non-Conformance: non-fulfilment of a requirement **(**a deficiency in characteristic, documentation, or procedure that renders the quality of an item or activity unacceptable or indeterminate).

Performing Parties (Performers): An all-inclusive term used to cover both IO internal and external organizations such as Specified PA/Contract Execution Teams (i.e. TCWS, VV, BIPS, and CMA), Suppliers, Contractors, Manufacturers (in the sense of Pressure Equipment Regulation), Fabricators who provide products, works or services to the ITER project.

Process: a set of interrelated or interacting activities that use inputs to deliver an intended result.

Procurement Arrangement (PA): an agreement signed between the IO and a DA and governing the implementation of procurement in kind.

Prototype: A prototype is designed to test and trial a new design to enhance precision by system analysts and users. A common strategy is to design, test, evaluate and then modify the design based on analysis of the prototype. Final production design detail is generally unwarranted for prototypes as some refinement to the design is to be expected. Often prototypes are built using very limited engineering detail as compared to final production intent, which often uses statistical process controls and rigorous testing.

Special Process: a process, the results of which are highly dependent on the control of the process or the skill of the operators, or both, and in which the specified quality cannot be readily determined by inspection or test of the product**.**

Task Agreement (TA): agreement signed between IO and a DA, by which IO outsources IO work scope to a DA.

Service: The performance of activities such as design, fabrication, inspection, non-destructive examination, repair, or installation or support activities for the ITER Facility.

Validation: confirmation, through the provision of objective evidence, that the requirements for a specific intended use or application have been fulfilled.

Verification: confirmation, through the provision of objective evidence that specified requirements have been fulfilled.

V Reference

The references are categorized as external and internal documents. Applicable versions of documents are under configuration control.

V.I External Documents

[1] ISO 9000 (2015): Quality Management Systems - Fundamentals and Vocabulary.
[2] ISO 9001 (2015): Quality Management Systems, Requirements
[3] IAEA GSR part 2 (2016): Leadership and Management for Safety – General Safety Requirements
[4] Order dated 7 February 2012 relating to the general technical regulations applicable to INB - EN (7M2YKF)
[5] ISO 14001 (2015): Environmental Management Systems -- Requirements with guidance for use.
[6] OHSAS 18001 (2007): Occupational Health And Safety Management System, British Standard Institute
[7] Pressure Equipment directive 2014/68/UE (RZ6PAK)
[8] French Decree 2015-799 (Transposition of [7] in French law called ESP (U5TKD4)
[9] ESPN Order dated 30 December 2015 (SMP384)

V.II Internal Documents

[10] MQP Process Map and Documents: https://portal.iter.org/qa/SitePages/Home.aspx
[11] ITER Organization Chart (2FQ5YR)
[12] PMP – Project Management Plan (2NCR3F)
[13] ISMS - ITER Integrated Safety, Environment and Security Management System Manual (4HCWJU)
[14] MQPWG Terms of Reference (262GYN)
[15] SQAWG (Safety and Quality Assurance Working Group) Terms of reference (2ACL4E)

1 Purpose and Organizational Structure

The purpose of the ITER MQP is to describe and establish the overall framework for the execution of the ITER Project. The QAP lies beneath the overall framework of the MQP and addresses the organization for implementation of the MQP.

The goal of the MQP is:

- to assure the safe operation of the ITER Facility
- to use ITER resources in an effective way
- to ensure that the level of quality considered necessary to achieve ITER objectives is specified and implemented using Useful Usable and Used MQP Documents

- to ensure that sufficient documentation is maintained to demonstrate achievement of the required objectives.

It is the goal of ITER management to provide assurances that the activities associated with fusion research and development as well as the design, procurement and construction activities for the ITER Project, yield data, designs, procurements and other activities with results for facilities, structures, systems, components, equipment, and materials that:

- conform to established requirements
- are fully traceable to valid data
- capable of withstanding detailed technical reviews

This MQP shall:

- cover all items or activities important to the safety, reliability and performance of the ITER Facility
- conform to all applicable regulations
- encompass all the activities that are necessary for verifying that the required quality is achieved and that objective evidence is produced to that effect

This shall include in particular items whose failure would result in a significant:

- safety problem to the public and/or workers
- loss of time and investment
- unscheduled shutdown of the machine
- reduction of the quality of data which could be acquired during operation
- impact on the environment.

1.1 Assigned and Delegated Work

All activities of the ITER Project are managed and controlled by the IO Director General. These activities may be executed by project staff or Performing Parties (Performers) such as laboratories, universities, industrial firms of participating countries, and integrated Project Teams that are formally delegated under the management of IO Director General.

The IO Director General specifies work activities performed outside the ITER organization by procurement arrangement or contract documents. Applicable quality requirements shall be passed on to subcontractors, but the responsibility for meeting the necessary quality requirements remains with the contracted organization. The organization responsible for the quality compliance of the ITER facility is the IO, whereas the organizations responsible for the quality compliance of the items & activities are the respective Performing Parties or Performers of both internal and external. Surveillance activities shall be performed by IO and shall not be delegated. When any part of IO acts as manufacturer of Pressure Equipment or Nuclear Pressure Equipment, it is considered the Performing Party.

1.2 Project Organizational Structure

The current ITER Project Overall structure is described in the ITER Organization Chart [11].

When an integrated Project Team is established to facilitate project execution, or when any part of IO acts as Manufacturer of Pressure Equipment or Nuclear Pressure Equipment, a specific organization chart shall be in place to define the specific responsibility.

Construction Teams in Construction Organization should be noted as having full responsibility of Assembly and Installation Works, with a specific organization chart with defined specific responsibility.

2 Management Responsibilities and Quality Requirements

2.1 ITER Management

The IO Director General (DG) has ultimate responsibility for the quality of the Project. The DG may delegate to Deputy Director General authority (DDG) on all matters pertaining to quality. The QAA Division, under the authority of the IO Director General, shall be responsible for developing and maintaining the QAP, which is part of the MQP, and for monitoring its implementation and effectiveness.

Responsibilities shall be assigned such that:

- attainment of quality and performance objectives is accomplished by the ITER relevant "Responsible Officer", who has been assigned responsibility for performing the work;
- verification of conformance with the MQP is carried out by the QAA Division under the authority of the IO Director General; and
- development and implementation of the MQP is overseen by the MQPWG (Terms of Reference [14]) and/or the Safety and Quality Assurance Working Group (SQWAG) (Terms of Reference [15]) if DA related.

Achieving the objectives of this plan requires the support of all participating personnel. Adherence to the ITER MQP provisions and to applicable plans, implementation procedures, and instructions is mandatory for all IO personnel who are performing activities related to ITER.

Each person performing work is responsible for the quality of the work they perform, meeting the project requirements, and consistently striving for improvement.

2.2 Quality Assurance & Assessment Division

The Head of the QAA Division reports to the Director General and shall be responsible for:

- coordination of quality assurance with Domestic Agencies
- developing training programs in quality assurance and quality systems management and verifying training materials are up to date
- coordinating the preparation of standards, specifications, requirements, procedures, instructions and guidelines, as may be necessary to implement the MQP
- maintaining and implementing quality procedures including but not limited to MQP documents & records control, Non-conformance control, Quality Audit, Corrective & Preventive or Improvement Actions control, and Management Review, that form a part of the Management and Quality Program (MQP)

- advising Responsible Officers on matters affecting risk, performance and quality, identifying significant quality problems and assisting in their resolution
- ensuring the communication of information related to the implementation and effectiveness of the management system appropriate to IO employees and other interested parties.

2.3 Quality Classification

The quality assurance activity to be applied to an item shall be commensurate to its importance to the safe, reliable, and performance of the ITER Facility.

A classification scheme shall be used to identify items requiring less stringent quality requirements with consequential cost saving, and to establish a basis on which a stepwise hierarchy of quality requirements can be developed.

To prevent the specification of insufficient or inadequate requirements, Safety and Quality classifications using a graded approach shall be assigned to all items. Requirements shall be defined for those classifications.

2.4 Management and Quality Program Objectives

2.4.1 Quality Performance Objectives

The quality objectives are to ensure:

- Attainment of the level of quality necessary to accomplish the project objectives commensurate with the project's responsibility for protection of the public health and safety, protection of the environment, and reliable facility operation
- That structures, systems, and components designed, procured, fabricated, installed, constructed, and tested for the project shall conform to established and documented requirement.

2.4.2 Performance Monitoring

To monitor achievement of these objectives, the IO shall establish processes for identifying, tracking, and reporting indicators of project performance. These indicators shall be tracked on an ongoing basis and reported to responsible management.

The performance indicators should include but not be limited to items such as:

- Assessment, audit, and surveillance findings
- Non Conformance status
- Licensing status
- Containment action and corrective action status
- Cost and budget status
- Project milestone status
- Reporting and actions status
- Corrective action verifications and effectiveness

2.5 Roles and Responsibilities

2.5.1 ITER Organization (IO)

The IO is responsible for the technical integration, coordination and direction of assigned tasks. The responsibility for the quality of tasks resides with those performing and responsible for those activities.

The IO Director General has delegated technical and management responsibility and authority to the Deputy Director Generals (DDGs), the Chief Operating Officer (COO) and the Relationship Coordinating Officer (RCO). The Responsible Officers are responsible for the tasks and activities assigned to them and performed by contracted organizations under their purview.

The IO Director General has the overall responsibility and authority to stop work for the ITER Project. The IO Director General may consult the IO Central Team Management Board (CTMB) before taking his decision to stop work for the ITER Project.

2.5.2 Domestic Agency (DA)

This term refers to an organization appropriately formed and appointed within and by each "Party" to supply in-kind goods and services to the IO, on the basis of defined specifications.

The DA and the IO shall work together in a cooperative and coordinative way to achieve maximum synergy regarding cost, schedule, safety and quality. Project team will be established consisting of both the DA and the IO staff when it is necessary for more integration to improve the efficiency and effectiveness of the in-kind procurement & manufacturing processes.

To realize the project objectives and to ensure quality of the final products, the following shall be put into place:

- Each DA will have a well-defined management and quality program that will be reviewed and accepted by the IO.
- Each DA will take due consideration of the IO technical opinion with regard to:
  - technical scope of contract
  - subcontractor selection
  - release of payments
  - stop work order
- Each DA will allow and facilitate if requested, IO presence on the premises of any subcontractor.
- Each DA will perform, jointly with the IO, both internal and external QA audits to assess the quality management systems ensuring the propagation of the IO requirements.
- Each DA will perform, jointly with the IO, QC supervision onto its suppliers or contractors checking the quality of the products, i.e. the compliance to the IO requirements in proactive way.

2.5.3 Safety and Quality Assurance Working Group (SQWAG)

The Safety and Quality Assurance Working Group (SQAWG) is established to provide a channel of communication and forum for discussion between IO and DAs in regard to safety and quality concerns. SQAWG is charged with the mission of assisting the IO and the DAs in the development and implementation of ITER safety and quality solutions according to Safety and Quality Assurance Working Group (SQAWG) Term of Reference [15].

SQAWG is chaired by the Relations Coordinating Officer and the secretary provided by IO QAA Division. Others IO members are the Head of IO QAA, the Head of Safety Department and representatives from EPNS Division. Each DA shall appoint a contact person(s) for Licensing, Safety and Quality. This person(s) shall represent the DA in the meetings of the Working Group. SQAWG members shall be empowered by the respective DA Head to represent the DA in terms of Licensing, Quality and Safety. Others staff from IO or the DAs can be invited to attend.

2.5.4 MQP Working Group (MQPWG)

The MQP Working Group (MQPWG) is set up and charged with the mission of assisting the IO in the development and implementation of ITER Management and Quality Program (MQP). The MQP Working Group (MQPWG) through the chairman shall advise ITER Management on the aims and limits of the MQP and hence on the completeness, coherence, comprehension and applicability of the structure and the content of the MQP through MQP WG Term of Reference [14]

MQPWG is chaired by the Relations Coordinating Officer and the secretary provided by IO QAA Division. Others members are the Process Owners (see 2.5.5) and their representatives. The outcome of MQPWG meetings is communicated to DAs through SQAWG where the concerned MQP processes are related to DA's activities.

2.5.5 Process Owner

The MQPWG identifies all Processes and nominates Process Owners for senior management endorsement.

Process Owner ensures that the requirements defined in the three level-1 MQP documents are deployed, implemented, maintained and improved through a Process (a set of interrelated and interacting activities that use inputs to deliver an intended result).

The Process Owner may nominate Process Representative to support the process owner in developing, propagating, maintaining and improving flows, procedures and work instructions to describe how their processes are implemented to comply with the requirements, given assistance by QAA division.

2.5.6 Performing Party (Performer)

The Performing Party or Performer providing products or services to ITER project shall establish and implement a dedicated quality assurance system equivalent to this ITER QAP, with basic elements defined by contract which may include the requirements for Quality Plan, Inspection Plan, Deviations & Non-Conformities and Release Note.

2.5.7 IO as Manufacturer

When any part of IO acts as Manufacturer of Pressure Equipment or Nuclear Pressure Equipment and is considered as a Performing Party, it shall follow the same requirements as defined in 2.5.5.

2.6 Stop Work Authority

Everyone in the IO has the right and responsibility to notify delegated senior management of unsatisfactory work or unapproved practices and, if necessary, recommend the delegated Senior Management to stop or improve unsatisfactory or unsafe work or control further processing, delivery, or installation of nonconforming materials.

Restarting stopped work should be by an established process that is commensurate with the complexity and significance of the stopped work and the reason it was stopped.

For stopped work associated with significant events involving defined safety systems, notification shall be given by IO Safety Department to the French nuclear authority explaining reason for stop work and ITER justification for restarting that work activity in accordance with INB Order 2012 [4].

2.7 Continuous Quality Improvement

The principal practice for quality improvement on IO assigned activities is extensive up-front task planning and timely monitoring of the task performance as defined in the QAP chapter 2.4.2 , in order to improve the suitability, adequacy and effectiveness of the MQP.

The ITER management is convinced that those closest to the working level of an activity are the most knowledgeable of the activity and its problems or shortfalls. The IO management strongly encourages all personnel to offer their recommendations for improvements of its processes and programs. These recommendations should be considered at the lowest appropriate organizational level in order to expedite improvement implementation.

The IO management recognizes that there will be problems during the course of the project. Project personnel are required and encouraged to report problems to appropriate management for correction. Identifying problems is the necessary first step in getting them fixed and preventing their recurrence. This forms the basis for a continuous improvement culture. Root Cause and Corrective Action should be utilized to identify and correct current issues with the knowledge that identifying systems root causes along with resolution of those root causes will prevent reoccurrence. Corrective actions for identified problems are also focused on improvement of management or safety systems.

2.8 Deviation Request

A deviation is a departure from an approved requirement. In order to anticipate a non-conformance a deviation request could be generated by Contractors (ref. QAP chapter 3.4.5). As soon as a deviation request is identified, it shall be issued, documented, evaluated, controlled and recorded. The result of its evaluation could be its acceptance or refusal and shall be documented and recorded.

2.9 Non-conformance Reporting

Any item, process or work that does not fulfil its specified requirements shall be identified and segregated as being nonconforming. A non-conformance report shall then be issued to document the departure from the specified requirement. Each nonconforming item or work shall be prominently identified, tagged, or uniquely identified and, when practical, segregated to prevent its use. The non-conformance report shall be issued by the appropriate organization specifying the requirement and evaluated and resolved by the quality assurance personnel and the IO Responsible Officer as defined in contract documents and applicable scopes of work.

Non-conformities shall be recorded and documented in a systematic manner and relevant treatment for their resolution, including evidence of implemented corrective actions, shall be traceable and allow progress reviews. Because of the time and effort involved in the evaluation of non-conformances, a graded approach which classifies the non-conformance as major or minor and where the safety and quality is considered should be applied to ensure that the most intensive evaluation is reserved for the problems of highest significance.

Following the review and dispositioning of the non-conformance, the item or work shall be placed back in service, repaired, reworked, or rejected. If an item is repaired or reworked to return it to a satisfactory condition, it shall be inspected or reviewed to confirm its fitness for use. After the item has been determined to be acceptable, it may be released for normal processing or use after a determination of 'use-as-is' or after remedial action is performed.
Any personnel who are involved with the dispositioning of non-conformances shall be competent in the technical areas in question and knowledgeable of the intended application of the item or work being dispositioned.

To ensure improvement and prevent reoccurrence, the root causes of such non-conformances shall be determined and action taken to prevent their recurrence. Item characteristics (such as reliability), process implementation, experience and other quality related information (including management processes) shall be reviewed and the data analyzed to identify improvements and needed corrective actions to prevent reoccurrence, and to decide if any preventive (risk-based) actions should be planned to eliminate the cause of a potential nonconformity.

The Non-conformities shall be resolved with high priority and that this resolution shall not exceed 9 months in average and 12 months individually, except initial agreement from the IO DG or the QAA Head.

2.10 Personnel Training and Qualification

2.10.1 Competence Requirements

Line managers shall ensure that the work is performed by competent people. Line Managers shall ensure that their staff is appointed on the basis of an assessment of his/her suitability for the position. This suitability shall consider ability to apply skills, knowledge, processes and attitudes to perform the job to specified standards in an effective and efficient manner. This necessary competence may be developed through education, experience and formal training.

Documented procedures for selecting, evaluate the competence of and training the personnel doing work that affects the performance and effectiveness of QAP processes shall be available.

Staff education, training, experience, competence and qualification requirements should be consistent with the complexity of the design, the hazard potential and other functions that might be assigned to the personnel.

Documented information as evidence of competence shall be retained and where applicable, actions shall be taken to acquire the necessary competence, and evaluate the effectiveness of the actions taken (like training, hiring or contracting of competent persons).

2.10.2 Training Requirements

Personnel shall be trained, as appropriate, on their organization's specific policies, plans, and procedures for performing assigned tasks, and a process for ensuring effectiveness of training and maintenance of competence should be defined. Documentation of personnel training shall be established and include such items as attendance lists, training outlines, and read-and-acknowledgment sheets, as appropriate, for the training given.

Training needs and their fulfilment shall be assessed in order to evaluate the grading process for implementation of training of the staff. Training for a significant activity may require application of a systematic approach to training, including needs analysis, training design, training development, training delivery and evaluation. Training for an activity of lower significance may not require full application of the systematic approach to training or a specific qualification for performance.

Further items to be considered for grading include:

* Type and content of training
* Amount of detail and degree of review of reference procedures

2.10.3 Qualification

The IO shall control qualification of people performing critical functions within the supplier chain, including critical process. Performance of a significant activity may require specific qualification and training such as welding, non-destructive examination, and beryllium handling or reactor operations.
Whereas special processes are performed by other organization assigned for the work activity, these organizations shall establish and maintain appropriate procedures and the documentation of personnel qualifications as applicable and in accordance with specifications supplied by the IO.
In case that special arrangement is to be established with IO-DAs and others for a joint work at the IO-CT (for example, Project Teams), a proper qualification of people shall be performed for Nuclear Operator to validate the assigned staffs' competence for the work they have been assigned.

2.11 Control of Activities affecting quality (thru MQP documents)

Activities in project realization processes throughout ITER project phases that affect the quality of items and services shall be controlled by the development and use of MQP documents i.e. specific procedures and by training personnel in these procedures.

These MQP documents:

- Shall provide for a disciplined and systematic approach to organize activities affecting quality and for production of objective evidence to demonstrate that the required quality has been achieved.
- Shall detail requirements, assign responsibilities and authorities and facilitate the performance and assessment of work.

Typically process procedures address the following elements, as applicable:

- References to applicable standards for special processes such as welding and non-destructive examination (NDE)
- Establishment of suitable environmental conditions, including periodic monitoring
- Specific roles and responsibilities in accomplishing the activities
- Qualification and certification of personnel
- Specification of acceptance criteria (specifically called out, not just a reference to applicable codes or standards)
- Specification of equipment to be used, calibration requirements, and controlled parameters
- Description of the records that are to be generated and maintained
- Provisions for recording data or denoting acceptance or rejection, as appropriate.

Procedures for performing processes shall be followed to ensure the consistency of the process. When process improvements are identified, they should be incorporated into procedures using the established formal document management procedure. Procedures should be reviewed on a periodic cycle by appropriate management for continued applicability and validity. Necessary changes shall be formally processed.

3 Project Realization Process

3.1 Configuration Management

Configuration Management (CM) is the process that shall ensure:

- The characteristics of the structures, systems and components (SSCs) comprising the ITER plant are identified and documented and changes and/or deviations to these characteristics are properly developed, assessed, approved, issued, implemented, verified, validated, recorded and incorporated into the project documentation.
- The activities, and their associated cost and schedule data, to achieve the objectives of the project are identified, documented and changes or deviation to these are properly developed, assessed, approved, issued, implemented, verified, validated, recorded and incorporated into the project documentation.
- The management and technical processes required to support these activities are identified, documented and changes or deviation to these are properly developed,

assessed, approved, issued, implemented, verified, validated, recorded and incorporated into the project documentation.
- Consistency is maintained between the parameters, the requirements, the physical and functional configuration of ITER and its documentation, particularly as changes and/or deviations are made throughout the ITER life-cycle. CM extends beyond the design, ultimately controlling all documentation referred to in construction, operation, and decommissioning.

CM shall be applied to the parameters, systems, components, instructions and procedures whose failure to satisfy requirements could lead to inconsistencies of design, violations of safety requirements, non-compliance with regulations, significant loss of operational capability, or significant changes in cost or schedule.

At ITER, CM shall be organized into three activities:

1 - Configuration identification and configuration status accounting
2 - Configuration control and configuration review and audit
3 - Configuration management planning

3.2 Documents and Records

3.2.1 Control of Documents

The IO Document Control process shall be established to control the preparation, review, approval, issuance, distribution, revision and validation of documents, which prescribe all activities affecting quality, essential to the management, performance and assessment of work in the ITER Organization. An electronic document management system shall be used to aid in document control and management.

A system for control of documents and data to assure appropriate review and approval for use shall also be established and implemented by all organizations performing ITER-related activities, using clearly established protocols for which documents shall be reviewed, by whom, and in what time period. These systems shall include procedures to be used to implement quality program requirements, thus to ensuring that all activities affecting quality are planned, controlled, and documented. The document control systems shall assure only correct and current information is available for the performance of ITER activities.

Types of documents subject to controls include, but are not limited to:

- Procurement and contract documents, including document deliverables
- Management plans
- Quality regulation and plans
- Technical documents (i.e., design drawings, safety documentation, technical specifications, etc.)
- Licensing Documents
- Process procedures, instructions, etc.

Documents prepared, used, and maintained for each work activity shall be controlled from preparation through to distribution. The control shall assure that documents, including changes, are reviewed for adequacy and approved for release by authorized personnel and are distributed to and used at the location where the prescribed activity is performed. The control also includes change notice and revision controls for documents to ensure the timely issuance of the revisions of the controlled documents. Changes to documents shall be reviewed and approved by the same organizations that performed the original review and approval unless the applicant designates another responsible organization.

The control process shall ensure that documents are approved according to a prescribed method before they are issued for use. Applicability of the documents for use shall be clearly defined. The responsibilities for approval shall be clearly defined by senior management. An effective electronic document management system shall be built on and it shall utilize the necessary controls applied for this process. The system shall support clear identification and version control. Documents stored in the system shall be protected by online security and made available through controlled access. In case wide public distribution is requested, documents shall be cleared through a defined publication process.

3.2.2 Records

Records provide objective evidence of activities performed or results achieved. Those activities that result in data, technical reports, drawings, specifications, and analyses for use by the IO shall provide a traceable trail to be preserved to resist deterioration for the necessary retention times. Original items, or documents, should be provided where possible, but a high-quality reproducible (digitalized) copy is acceptable.

Records shall be accessible at all times during the specified retention periods. Retention times of records and associated test materials and specimens shall be established to be consistent with the statutory requirements and knowledge management of obligations of ITER. Access to locations where records are retained should be controlled. Responsibilities for maintaining and operating the records process and the facilities for the storage of records should be clearly defined and documented.

The responsibility to identify, collect, classify, index, file, and maintain records of work performed for the IO shall be specified in contract documents and scopes of work. The indexing system and the filing system should provide proper identification and ability to retrieve requested records. Records shall be filed in a storage system that provides a suitable environment to minimize deterioration or damage and prevent loss.

Special processed records such as radiographic film, electronic media (such as magnetic media, optical media), archival samples, and photographs shall be handled and stored to preclude damage. At a minimum, manufacturer information for proper handling and storage should be used in preparing proper controls for these types of records. When transmitted to IO for final storage, records in special formats should be converted into high-quality digitalized documents to allow long-term storage, retrieval and accessibility.

3.2.3 Sign-Off Authority

The direction for ensuring proper level of review and approval for the key types of documents generated or received by IO-CT for use in the ITER Project shall be specified by considering the significance of the project document and the impact on other project activities.

3.3 Design Control

Design control shall apply through the lifetime of the technical items (Systems, Structures and Components SSCs). The control of design activity shall ensure that specified design requirements are met in the design solution and on the end-product in accordance with the design input. The control of design activity including verification activities shall be done using plans and documented processes which shall ensure a level of control commensurate to the risk, safety role and complexity of the end-product to be developed.

Design control records shall include not only final design documents, such as drawings and specifications, and revisions to those documents, but also documentation that identifies the important steps in the design process, including sources of design inputs that support the final design, calculations, design development computer models, and computer programs used in design.

3.3.1 Design Planning

Design plans shall be prepared for each design work package and for each design stage. The design plans shall be the basis for the execution and control of the design development activities. The plans shall describe objectives, scope, design inputs, tasks to be performed, processes to be used, outputs to be delivered, verification and validation methodology, risks, organization, roles and responsibilities, key milestones, design interfaces necessary to accomplish the design activity, ensuring that the final design meets the specified requirements. The reviews, the verifications and validation stages are defined during the design planning stage. The design plans shall be properly updated as the design evolves.

The design activities shall be assigned to qualified personnel with adequate resources. Organizational and technical interfaces between different groups which provide input to the design process shall be defined, identified and controlled, and the necessary information documented, transmitted and regularly reviewed.

3.3.2 Design Input Control

Design inputs shall be identified, assessed for adequacy to design development, documented, and controlled. The design inputs shall be defined prior to the design development. Any changes in the design inputs shall be identified, assessed and accordingly controlled.
The design input shall include functional and performance requirements, applicable statutory and regulatory requirements (incl. safety), industry codes and standards, and technical requirements including interfaces, and where applicable, information derived from previous similar designs. In particular, the design requirements shall be complete, unambiguous and not in conflict with each other. The design inputs, especially the functional and performance requirements, forms the basis for design verification and validation

3.3.3 Design Development

The purpose of the design development activities is to ensure the propagation of design inputs into the design solution, i.e. design output. Design development shall be carried out in accordance with approved design plan and applicable procedures. The design output which can be technical specification for SSC products and their operation, drawings, results of analysis shall be documented and recorded. At each development stage, the design output shall be traceable to the design input with documentation in sufficient detail to permit design verification. Design analyses and justifications shall be sufficiently detailed so that a competent person in the subject matter can review and understand the content and verify the adequacy of the results without consulting with the originator. The computer programs used for design analysis shall be controlled according to Section 3.10 Software Control and Model Development. Design development procedures shall contain or make reference to acceptance criteria for completion of the actual design work at the end of each design phase and shall ensure that the design outputs meet the design requirements.

3.3.4 Design Interface Control

Design interfaces shall be identified, established documented, and placed under configuration control including coordination among the participating design organizations. Interface controls shall include assignment of responsibility and establishment of procedures among participating design organizations for review, approval, release, distribution, and revision of documents involving design interfaces. Design information transmitted across interfaces shall identify the status and applicability of the design information or design document provided, and identify incomplete items that require further evaluation, review, or approval. All interface requirements shall be associated with their verification requirements.

3.3.5 Design Verification and Validation

Design verification shall be performed in accordance with planned arrangements to ensure the design outputs have met the design inputs. Design verification method(s) shall be determined for each input requirement and planned for each appropriate stages of the design and construction of the SSC. The results of design verification shall be documented with the identification of the verifier clearly indicated.

Design verification shall be performed by competent individual(s) or group(s) other than those who performed the original design but who may be from the same organization. Acceptable verification methods should include, but are not limited to, any one or a combination of the following: (a) design reviews (analysis of documents), (b) alternate calculations, (c) qualification testing, and (d) benchmarking against a similar successful design. The resulting verification outputs should themselves be reviewed to confirm their adequacy, validity, and relevance to the design being verified. Design verification shall be performed before release for procurement (unless done as part of a procurement action), manufacturing, construction, or unconditional release to other organizations for use in associated designs. Any unverified design information shall be identified and controlled during design verification process. However, in all cases, the design verification shall be completed before the design is relied upon to perform its function.

Design validation, such as qualification or final product testing, shall be performed in accordance with planned arrangements to ensure that the resulting product is capable of meeting the requirements for the specified application or intended use, where known. Validation shall follow successful verification and shall be completed prior to the delivery or

implementation/operation of the product. Records of the validation results and any necessary actions shall be maintained.

3.3.6 Design Change Control

Changes to designs and design outputs shall be identified, documented, and controlled. The changes shall be reviewed, verified, and validated as appropriate and approved before implementation. The review of design changes shall include evaluation of the effect of the changes on other designs and/or constituent products already delivered. The changes shall be approved by the same affected groups or organizations that have reviewed and approved the original design outputs. When a design change is approved, the contents of the design change shall be incorporated in all affected documents.

3.4 Procurement Process

Items or services to be contracted by the ITER Project shall be specified in procurement documents either as an In-Cash procurement through a Contract or Purchase Order or as a Procurement Arrangement under In-kind procedures.

Components technical requirements may involve conformance assessments or product compliance requirements such as arising from the French Nuclear Order 2012, the European Pressure Equipment Directive (PED) or Nuclear Pressure Equipment Directive (NPED). Where these requirements exist they shall be considered in addition to other quality requirements contained in this document. Such documents shall be reviewed, approved and controlled.

The Contracts shall be placed according to selection and award criteria derived from the technical requirements. Contractors' Quality Assurance Programs shall be evaluated and approved by the IO or the DAs for the procurement activity for which they will be used.

Items or services relevant documentation shall be reviewed and formally accepted by the IO prior to delivery.

In general, the procurement process consists of the following steps:

(1) Identification of the need to be procured
(2) Establishment of technical and quality requirements
(3) Selection and award of Contractors, signature of the Contract
(4) Monitoring of Contractor's performance
(5) Handling of deviations from requirements
(6) Acceptance of items or services delivered.

3.4.1 Identification of the need to be procured

The need for an item or service is usually identified from a Work Package. A Technical Specification shall be issued describing in detail all the requirements.

3.4.2 Establishment of Technical and Quality Requirements

Technical and quality requirements shall be prepared in the form of technical or equipment specifications. The procurement process covers the technical and quality review of the procurement documentation to ensure that appropriate technical and quality requirements, as well as acceptance criteria, are adequately and clearly stated.

Procured items, works or services shall be in accordance with the governing statements of work and any additional requirements. These documents shall specify the scope to be performed, the required documentation, the qualifications of those performing the work, and the required schedule of performance. These documents shall also include all appropriate technical and quality requirements. The reviews and approvals of these procurements shall be in accordance with the approval process.

3.4.3 Selection and Award of Contractors

The evaluation of the potential Contractors shall include the assessment of their quality capabilities (programmatic and quality of items provided). Qualified suppliers shall have demonstrated relevant financial and technical capacity to supply items or services at the quality level required, substantiated by appropriate documentation.

Domestic Agencies are responsible for the work performed either by them or Contractors in the frame of Procurement Arrangements and Task Agreements signed with the ITER Organization. The ITER Procurement Arrangement Responsible Officer shall agree with the procurement, and should be responsible for the final acceptance of the activities.

Activities or tasks shall not begin prior to the signature of the Contract by both Parties.

3.4.4 Monitoring of Contractors Performance

Contract performance monitoring should be performed as in-process surveillance, inspections, or reviews, as stated in appropriate Inspection Plan that could be performed at the Contractor's facility and/or upon delivery of the completed item or service. Sub-Contractors of critical items should also be monitored to ensure that items and services conform to requirements.

3.4.5 Item Deviation from requirements

Contractors may request to deviate from the technical specifications or quality requirements contained in the contract. The Contractor concerned shall describe in details the proposed deviation identifying the changes, additions, or deletions to the technical requirements. Any deviation request (DR) shall justify the adequacy of the proposed deviation and the potential impact on the technical requirements, as well as how the overall technical requirements will still be satisfied, state the extent to which the original document remains in effect; identify the number of items that will be affected by the proposed deviation; and provide a schedule of actions necessary to complete the proposed changes. Deviation requests shall be reviewed and approved.

3.4.6 Item or Service Acceptance

Items or service acceptance shall occur after evidence that acceptance criteria have been met. Acceptance is predicated on the receipt of contract items or deliverables and inspection reports

as well as evaluations, contractor oversight reports (e.g., audit, surveillance, and inspection), and contractor performance documentation.

Regarding services, contractors shall be required to provide deliverables in the form of reports, studies, progress reports, etc. These shall be reviewed and accepted by Responsible Officers.

3.5 Manufacturing, Assembly and Installation Process

Manufacturing, Assembly and Installation shall be controlled to the extent necessary to ensure items conform to ITER procurement requirements and supervisory authority (ref. QAP chapter 3.4).

All operations shall be controlled to the extent necessary to ensure that the installation of each item shall not compromise the integrity and the safety:

- of the item to be installed,
- of the assembly where item is installed and of the ITER facility.

3.5.1 Planning

Approved planning shall be established and shall define:

- the operations to be performed
- the identification of competent and qualified personnel to perform the task
- the systematic sequential progression of operations
- The work procedures or instructions required to comply with the requirements of the defined work scope.

Planning shall include a review to ensure that:

- all activities have been incorporated
- The work can be accomplished as specified
- the time and resources are sufficient to accomplish the work in accordance with the specified requirements.

3.5.2 Execution

Work shall be carried out under controlled conditions:

- using approved drawings, procedures, standards and other documents (ref. QAP chapter 3.2.1)
- according to approved pre-established checklists of operations (ref. QAP chapter 3.8)
- assigning competent and qualified personnel as appropriate (ref. QAP chapter 2.10)
- using controlled and calibrated measuring and test equipment (ref. QAP chapter 3.7)
- Ensuring that engineering and design changes during operations are documented and controlled (ref. QAP chapter 3.3.6).

Checklists shall identify:

- the sequence of critical operations
- the instructions and requirements applicable to these operations
- the acceptance criteria, as may be appropriate, for these operations
- the operations the IO intends to witness
- The completion status of the operations listed.

Prior to implementation, work documents shall be reviewed for compliance with ITER requirements, approved "for manufacture", and controlled.

Processes that cannot be adequately inspected after completion shall be carried out according to approved procedures implemented by qualified personnel using calibrated equipment, where applicable.

Where examination during final inspection is no longer possible particular attention shall be put on definition of examinations and tests before and during manufacturing, assembly and installation.

Any deviation from procurement requirements shall be recorded and reported to the IO (ref. QAP 2.8).

Documents and records shall be maintained to reflect the progress status of item's configuration, and approved "as built" on item completion (ref. QAP chapter 3.2).

Arrangements to verify the completion of manufacturing, assembly and installation activities shall be defined and implemented.

This verification shall be formally documented and shall confirm that structures, systems and components have been manufactured, assembled and installed to the specified requirements as applicable, including but not limited to:

- procurement requirements
- shipping
- storage
- installation
- accessibility
- post-installation testing
- proof tests and running in plant at reduced loads

3.5.3 Handover

Provisions shall be made to control and coordinate the handover of completed works from one supplier to another and from the manufacturing, assembly and installation to the commissioning and operations phases.

These provisions shall ensure maintaining of the integrity of the completed works and shall include:

- review for completeness and accuracy of documentation relating to transferred items including contractor release notes

- identification of the boundaries of transferred systems and equipment
- proper planning and implementation of record transfer.

3.6 Identification and Control of Items

Identification shall be maintained on the items or in documents traceable to items, or in a manner that assures that identification is established and maintained. The suitable means shall be determined according to the type of item and its conditions: for instance, complexity of the product, unitary or serial products, risk of mixing of material grades, etc.

The traceability system should be proportionate to the risk of mixing items during their life cycle. It shall be maintained by procedural methods that cover receipt, identification, storage, and transfer to production, temporary storage and use in production, availability of correct inspection documents at the final inspection.

Control shall be established to assure that only correct and accepted items are used or installed.

Items of production (batch, lot, component, part) shall be identified from the initial receipt and fabrication of items up to and including installation and use in ITER activities. This identification shall relate an item to an applicable design and other pertinent specifying documents. Physical identification shall be used to the maximum extent possible. Where physical identification in the item is either impractical or insufficient physical separation, procedural control or other appropriate means shall be deployed.

Identification markings shall be applied using material and methods that provide a clear and legible identification and do not degrade the function or service life of the item. Markings shall be transferred to each part of an identified item when subdivided and shall not be obliterated or hidden by surface treatment or coating unless others means of identification are substituted.

When codes, standards, or specifications include specific identification or traceability requirements, this shall be identified and controlled.

Items having limited calendar or operating life or cycles shall be identified and controlled to preclude use of items whose shelf-life or operating life has expired.

Provisions shall be made for the control of item identification consistent with the planned duration and conditions of storage such as:

- provisions for maintenance or replacement of markings and identification records due to damage during handling or aging
- protection of identifications on items subject to excessive deterioration due to environment exposure
- provisions for updating existing plant records.

3.7 Calibration of Monitoring and Data Collection Equipment

Organizations who perform ITER work activity shall define the measurement and data collection equipment that will be used in performing their assigned tasks. All equipment (tools, gages, instruments, and other measuring and testing devices) having significant influence on

results shall be, whereas appropriate, uniquely identified, properly controlled, calibrated, and adjusted at specified periods to maintain accuracy within necessary limits.

The required accuracy and reliability of each item shall be determined, and appropriate maintenance/calibration specifications shall be developed. These specifications shall be satisfied by the manufacturer's measuring equipment calibration protocol.

Equipment shall be calibrated before put into service, and thereafter calibrated according to an established programme at appropriate determined intervals by competent personnel. The calibration of measuring or data-collection equipment shall be traceable typically to a national or internationally recognized measurement standard. When the standard used is not traceable to a national or internationally recognized standard, the basis of its use shall be justified and the calibration results documented and adequacy of such standard shall be demonstrated. .

Equipment shall be safeguarded from adjustment, damage and deterioration that would invalidate the calibration status and subsequent measurements results. Where applicable, the condition of stored items shall be assessed at appropriate intervals to detect deterioration.

In case defective equipment is detected, it shall immediately be removed from service by segregation, prominent labelling or marking. The effect on results from previous measurement shall be examined and, when necessary, appropriate corrective action shall be taken.

All measuring and data collection equipment shall be labelled to identify their identification number from which it shall be possible to check its calibration status on records.

For instruments that obviously do not require calibration, a tag stating that calibration is not required should be attached to ensure the instrument is not used where a calibrated instrument is required.

Instruments used for ITER activities shall have records of calibration retained in project files. Those records should provide the following information to establish the traceability of the instrument's calibration:

- Instrument identification
- Type
    - maker
    - model
    - serial or control number
- Number of calibration certificate and identification of laboratory that issued it
- Name of the performer
- The date of last calibration
- The date the next calibration is due
- Procedure used
- Reference standard used

3.8 Inspection and Testing Activities

3.8.1 Inspection

Inspection activities affecting quality shall:

- ensure that work activity with items and/or materials are performed in accordance with their design requirements
- be performed using an approved inspection process
- be conducted in accordance with inspection planning

Inspection planning shall be developed before the beginning of the operations based on their design requirements (including instructions, procedures and drawings) and address:

- Inspection methods, including specific reference to inspection procedures
- Tests required to be monitored or witnessed
- Characteristics to be inspected
- Identification of mandatory control points to be performed by competent and appropriate person
- Acceptance criteria.

The scope and frequency of inspection programmes should be adapted to the level of risk or importance for safety, health, environmental, security, quality and economical aspects. To this purpose it should be graded based on the Quality Classification (Section 2.3) of the item and on other aspects like the supplier evaluation.

The status and the results of the inspection per item shall be documented and recorded.

Inspection shall be performed by competent individuals other than those who performed the activity being inspected. Examinations, measurements, or tests of material or products processed shall be performed for each work operation where necessary to assure quality. If inspection of processed material or products is impossible or disadvantageous, indirect control by monitoring processing methods, equipment, and personnel shall be provided. Both inspection and process monitoring shall be provided when control is inadequate without both. If mandatory inspection control points, which require witnessing or inspecting by the applicant's designated representative and beyond which work shall not proceed without the consent of its designated representative are required, the specific control points shall be indicated in appropriate documents.

Each inspection shall not be bypassed and that equipment, material, or fabricated assemblies shall not be released for further work activities until all inspections are complete and the results accepted.

When inspection activities identify a non-conformance with a requirement, the person performing the inspection shall initiate a non-conformance report as defined in QAP chapter 2.9.

3.8.2 Testing

Testing activities may be requested in the frame of inspections (e.g. typical testing as per applicable manufacturing standards and criteria) or where critical performance characteristics of an item cannot be verified by design or inspection methods (e.g. validation of a prototype, qualification of special manufacturing processes, and validation of a design).

Testing shall be planned at the same time with the inspection planning and be described in a document defining the type of tests required (e.g., prototype qualification testing, production testing, proof testing before installation, construction testing, and pre-operations testing). Test requirements parameters, methods, test article configuration, and acceptance criteria shall be based on item performance requirements.

Testing shall be conducted in accordance with approved procedures that address, as applicable:

- Instructions on test performance, including control points, as required
- Provisions for assuring that all prerequisites for the given test have been met
- Provisions for test monitoring, calibrated instrumentation, and data acquisition
- Safety of the facility
- Suitable environmental conditions
- Qualification of testing personnel
- Established acceptance criteria

Standard test methods should be used when practical. Use of equipment supplier manuals is also encouraged when testing equipment at a shop or during installation.

Test results shall be documented and evaluated to assure that test requirements have been satisfied. Test records shall be maintained and should identify:

- Item or system tested, including test boundaries
- Date(s) of test
- Test personnel or data recording personnel
- Type of observation (e.g., pressure over time) and results observed
- Conclusion on acceptability of the item(s) tested in accordance with test requirements
- Environmental conditions, where appropriate
- Notation of deviations and subsequent evaluations
- Signature of person accepting results.

3.9 Handling, Storage and Transportation

3.9.1 Handling and Transportation of ITER Items

Special requirements for the handling and transportation of items to prevent damage or deterioration shall be contained in specifications, drawings, or supplier documents that become part of the documentation package for them.

Handling and transportation processes should allow for different methods to provide appropriate care in handling and transportation in accordance with the manufacturer's recommendations. Handling and transportation provisions shall consider types of containers, preservation, and other environmental or safety considerations applicable to the items. Where multiple organizations are involved, procedures shall describe interface and any chain-of-custody requirements.

3.9.2 Storage of Items

Preservation documents shall indicate necessary storage environment, any special protective measures during storage and specific shelf-life if applicable. The requirements and recommendations for preservation, primarily specified by the Suppliers (see 3.4.2), shall then be followed by any party who receives the items.

3.10 Software Control and Model Development

3.10.1 Computer Software Control

Computer software control shall be established to control software used for R&D, design development, manufacturing, installation, construction, commissioning, and operation of ITER facility to provide adequate confidence that a software item or product conforms to established technical requirements. The procedures and work processes used to establish and maintain control of software shall formulate a software management methodology, including authorization control, for software acquisition, and development, the deployment and configuration management of the software used, and change, maintenance, and disposition.

The software to be controlled shall be appropriately authorized and qualified prior to approval for use based on the purpose of the software in accordance with applicable standards, procedures and/or instruction.

The software qualification process shall depend upon the characteristics, importance, and complexity of the software, and be applied to demonstrate that the software, in conjunction with the hardware on which it is running, adequately and correctly performs all intended functions and meets all user requirements.

Where the software cannot be fully validated due to the experimental nature of ITER and the impossibility to create the same ITER conditions, the experimental program of ITER shall take into account this issue by allowing a progressive approach to the full machine performance and by validating the software at the earlier stages of the machine operational program.

3.10.2 Computer Analysis Model Development

Analysis models are used to develop/optimise a design and/or to verify and/or validate the design and/or requirements. The process and its procedures for computer analysis model development are strongly linked with those for design development (see Section 3.3.3), and design verification and validation (see Section 3.3.5).

Development, verification and validation of the analysis models shall be planned according to the purpose of the analysis and executed accordingly. The analysis model including the boundary conditions and applied loads shall be consistent with the design. The analysis model shall be formally reviewed and validated, as the software for which the model is generated. Consistency of the analysis model with the as-built structure shall be demonstrated when construction and assembly is completed. If the as-built structure is somehow different from the design model, a reconciliation of the analysis model as its results with the as-built structure should be performed.

In some cases the complete analysis model validation by experimental testing or other means may not be possible until the final hardware product is created and operated. When this is the situation, operational testing plans should provide the necessary data points to achieve full

validation. Interim benchmarks can and shall be established that provide reasonable interim confidence in the model's validity as part of the formal process planned to fully validate the model.
Where the interim benchmarks or testing cannot be met, such lack of control shall be clearly stated in the technical basis documents of the affected systems. As for the software validation, the experimental program of ITER shall then take into account this issue with the aim of model validation.

3.10.3 CAD Models and Drawing Development

CAD models & drawings representing the components & systems used in the ITER Project shall be unambiguously identified, controlled and verified for validity prior to their publication and use for downstream activities.

The CAD models and drawings development shall be managed based on a CAD work-plan and be implemented based on:

- trained & certified users
- validated CAD infrastructure meeting project requirements (such as complex geometrical interfacing systems requiring common design data management, tools and methods)
- pre-defined project standards & processes
- CAD manual requirements.

The developed CAD data shall be verified to comply with the project standards & processes and CAD manual requirements. Only after the verification, the CAD data can be used for CAD exchange process and/or other downstream processes like publications.

3.11 Research and Development

A need for data may originate from any group or discipline within the ITER project. The data needed shall be clearly defined and planned in order to perform R&D tasks using established technical specifications, requirements and criteria.

R&D activities shall be fully documented in order to support a critical peer review and provide traceability of the derived data throughout the development process.

Any assumptions used in developing the needed data shall be identified and their use justified. The principal concerns for these R&D activities are the validity and traceability of the resultant data. The results of Research and Development activities are typically input for Design Control Process.

Any data to be used as inputs that were not obtained under a formalized quality program should be reviewed and evaluated for acceptability by the Responsible Officer who is receiving the data. Peer review and/or technical review shall be performed for the qualification of the data.

3.11.1 Experimental Systems

The designs of experimental systems used in the development of data should be formally design reviewed to verify their adequacy for developing the desired data. Critical aspects of the experiment system that affect experimental results shall be fully documented with appropriate records retained. Examples of such aspects could be calibration of the data acquisition systems, confirmation of the system materials, and system operating parameters in accordance with the data development plan.

3.11.2 Data Reduction and Analysis

Derived data are seldom obtained in the exact form needed. Raw data are usually reduced either by manual analysis or through available computer analysis programs. This is a critical step in data development. Reasonable measures should be taken to provide confidence in the reduced data results. Comparisons should be made with alternative calculations where validated alternative techniques are available and accepted. Alternate computer data reduction codes should be used for comparison where practically available. Benchmarks of the data reduction process for areas where the end data are known assist in developing confidence in the data reduction process.

3.12 Operations and Maintenance

Operations and Maintenance Design requirements shall be described for the planning and implementation of all aspects of the operation and maintenance of the ITER facility, according to Project Requirements.
Key systems and infrastructure required for the ITER machine and all aspects of the operation and maintenance of the ITER facility shall be developed and documented that provide direction for maintaining and inspecting structures, systems and components of the ITER plant.
The comprehensive work planning and control system shall be implemented so that work activities can be properly authorized, scheduled and carried out.
The maintenance, supervision, surveillance and in-service inspections tasks shall be implemented via detailed procedures.
A systematic approach shall be defined to identify maintenance activities to be performed on ITER systems including which structures, systems and components (SSCs), to be maintained at specific intervals by qualified resources. The type and frequency of maintenance activity applied to each SSC is commensurate with the SSC's classifications, design function and required performance according to safety analysis, regulatory requirements, performance analysis, and codes and standards.

3.13 Research Program

The activities of specification of research goals, the planning and efficient implementation of the scientific programme by trained staff to achieve these goals, data analysis and archiving, protocols for the reporting of research results shall be defined according to regulatory, environmental and nuclear safety and investment protection requirements.

4 Audits and Assessments

4.1 Audits and assessments

4.1.1 Responsible Officers' Self-Review

The Responsible Officers are responsible for conducting appropriate and timely reviews of assigned tasks. The readiness of an activity or one phase of an activity, to proceed to the next phase or to the next follow-on activity needs to be assessed and agreed upon prior to proceeding. The review will be of varying degrees of formality, as appropriate to the activity being evaluated.

4.1.2 Management Self-Assessment

The IO obtains information on the effectiveness of its quality assurance plan from the following project activities:

- Project coordination efforts
- Project reporting about the status of project tasks in relation to established goals and milestones
- Project performance indicators
- Project-level quality assessments that provide the IO management with information about the overall progress of the project organization in identifying and implementing administrative control systems, the quality of work performed, and areas in which improvement is necessary
- Technical and peer reviews for assigned activities.

Performance information is provided to the IO management from the following sources, as applicable to the institution and the ITER activities being performed:

- The individual performing assigned tasks, which is one of the most effective assessments. The assessments at this level are usually not formally documented but are usually the most detailed in nature. The direct involvement of the performing individual in status reporting and problem solving is often the best opportunity for effective corrective action and quality improvement.
- Procedures with clear acceptance criteria for judging performance provide direct feedback.
- Task readiness reviews conducted to determine the ability of the task participants to start a particular operation. These reviews should be conducted in accordance with established procedures. Readiness reviews are not an audit, but rather a peer check of having performed all necessary prerequisites before starting an activity or continuing from one phase to another.

- Quality audits performed by IO quality assurance personnel. These audits assess the implementation of, and conformance to, the Quality Assurance Program and the Management Quality Program for ITER activities.

- Quality assurance supervision of ongoing work activities (such as design review meetings or research testing) to verify work performance in accordance with established procedures applicable to the work activity. Quality assurance supervision is the act of process monitoring to evaluate in-process work, review corrective action completion status and effectiveness, and review documents and records pertinent to items or activities.

- Responsible Officer meetings that provide regular progress reporting, problem reporting, and adequacy assessments of tests (either ongoing or proposed).

- Procedure deviation reporting by line personnel to identify problems to line management for correction.

The IO QAA Division will investigate conditions adverse to quality, audit findings, schedule corrective action, including measures to prevent recurrence of significant conditions adverse to quality, and notify the appropriate organization in writing of action taken or planned.

4.1.3 Quality Audit

Audit is a systematic, independent and documented process for obtaining objective evidence and evaluating it objectively to determine the extent to which the audit criteria are fulfilled.

Audits shall be performed to evaluate the effectiveness of a quality management system and the application of requirements, in order to identify risks and improvement opportunities, and to determine the fulfilment of requirements. These audits shall be performed in accordance with audit criteria, including regulations, standards, policies, procedures or requirements, by qualified auditors who are independent from the activities being audited.

QAA Division establishes the Annual Audit Program and is reviewed and approved by IO DG. Audits shall be scheduled in a manner to provide coverage and coordination with ongoing activities, based on the status and importance of the activity. Scheduled audits shall be supplemented by additional unplanned audits of specific subjects when necessary.

Auditors shall be qualified and competence shall be maintained according to appropriate requirements. The audit team shall be identified prior to the beginning of each audit. This team shall contain one or more auditors. Auditors participate in an audit as Lead Auditors, auditor and/or technical experts. In any cases, one Lead Auditor in one audit team is mandatory. Auditors shall be granted sufficient authority and organizational freedom to have a value-added and effective audit.

The Audit result shall be documented in a defined audit report format and receive approval by auditee before officially issued. Audit findings shall be recorded in an electronic system for following-up. Audit findings shall be closed when actions are implemented and necessary

evidence is provided to the auditors. The verification of action normally should happen during the subsequent audit.

Audit results shall be reported to the Head of the QAA Division and IO DG who may use this information as the inputs of management review and decision.

4.1.4 Independent Assessments

Independent assessments (other than audits) of ITER activities consist of assessments under the control of the project but performed by organizations and personnel that are independent of the activities being assessed.

The following activities are self-initiated independent assessments of project performance and quality program effectiveness by the Responsible officer:

- Peer reviews or workshops conducted by technically qualified personnel who are independent of the ITER activities to assess the adequacy of project decisions, design bases, and progress in meeting stated performance objectives
- Readiness reviews conducted by independent reviewers to determine readiness to proceed with selected activities.

Self-initiated independent assessments are viewed as constructive and are conducted with the prime goal of improving the work process. Assessment results are reviewed for opportunities for improvements, for needed corrective actions, and to identify observed exemplary performance.

4.2 Audits and assessment responses

Responses to assessments should include, as appropriate, remedial actions to correct the cited deficiency, root cause determination, and actions taken to prevent recurrence, lessons learned, improvement initiatives, and risk-based actions (or preventive actions).
Periodic status reports on the progress of corrective actions should be made to assessing organizations until the action is completed, accepted, and closed.

Responses to external assessments should comply with the instructions provided by the external organization but should, as a minimum, provide the same information as for self-initiated assessments.

4.3 Documentation of results

Each of the assessment processes discussed above shall result in documentation of that activity. Specific overview activities such as audits, reviews, and assessments result in formal documentation of results and corrective actions. Reporting activities such as status reports, award fee reports, and planning efforts usually result in less detailed documentation (e.g., meeting minutes and milestone objectives). Individual performer assessment results may take the form of non-conformance reports if deficiencies are detected.