

MQP Level 2

Quality Classification Determination

A quality classification is introduced to provide a basis upon which a graded approach is used to implement the ITER Quality Assurance Program and ITER Procurement Quality requirements.

This document defines: the quality classes, the criteria for assigning quality classes, the quality requirements applicable for each quality classes.

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Version	Latest Status	Issue Date	Description of Change
v1.0	Signed	24 Oct 2006	
v1.1	Approved	24 Oct 2006	
v1.2	Approved	22 Nov 2006	
v1.3	Signed	06 Jun 2007	
v1.4	Approved	22 Jan 2008	
v2.0	Approved	22 Jun 2009	1) Classifications updated to remove terms “significant” and “major”; 2) Inspections requirements clarified; 3) Re-definition of Class 4; 4) The above incorporate comments from the Safety & Quality Working Group 5) Reviewers and approver changed to reflect MQP review
v3.0	Approved	13 Oct 2010	General revision, incorporating safety classification as per document ITER_D_347SF3 Version 1.5 titled SAFETY IMPORTANT FUNCTIONS AND COMPONENTS CLASSIFICATION CRITERIA AND METHODOLOGY
v4.0	In Work	27 Jun 2012	1) Document re-formatted to comply with detailed policy template 2) Attachments re-named as appendixes 3) Inspection Requirements in Appendix 2 relaxed
v4.1	Approved	27 Jun 2012	Replaced attachments with appendixes in text Clarified Quality Class 4 criteria
v4.2	Revision Required	14 Feb 2017	New methodology for determination of quality class was included in the procedure. Improvement of Appendix 1 and Appendix 2 of procedure.
v4.3	Approved	03 Aug 2017	The new version was created to include the requirements related to construction, assembly and installation phase. The present version was not recirculated to DA's representatives taking into consideration that the new added requirements does not have impact on DA activities.
v5.0	In Work	07 May 2019	Chapter 6.2 - replace QAA Division with QMD Appendix 2: Quality classes application: - add note 6 for each referred procedure - responding to USIPO comments: Procedures versions: The procedures referred in the present document shall be applied at the latest version indicated in the PA Applicable Documents (PA AD) list - latest agreed version between IO and DA's. For the procedures not considered PA AD, the latest approved version shall be applied. Any modification of referred procedures, shall be applies following the requirements and workflow indicated in the MQP Document Change Control procedure (VDVFHY) - latest agreed version between IO and DA's. - add reference to Working Instruction for Construction Readiness Review (QXW4KQ) - quality audit section - for In kind - add clarifications regarding suppliers quality audits "unless otherwise agreed between IO / DA's. Alternative suppliers evaluation methods shall be applied in case audits are not performed." similar approach with In cash procurement. - close all the comments from previous version review cycle.
v5.1	Signed	07 May 2019	Technical issue, some spaces deleted for better view. The key changes are listed for the major version 5.0.
v5.2	Approved	04 Jul 2019	Revision to implement the USDA and JADA comments as following: - Appendix 2 - Design control section - clarification regarding application of ITER_D_R3KD8C - Design Verification and Validation Procedure (applicable for IO only)

			<ul style="list-style-type: none"> - Appendix 2 - Procurement / Documents and Records section - clarification regarding application of Working Instruction for Completion Dossier Preparation (UYUSEE) (applicable for IO only - not in the scope of PA) - Appendix 2 - NCR & DR control section - clarification regarding Minor NCR application as per USDA comments.
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1 Purpose

A quality classification is introduced to provide a basis upon which a graded approach is used to implement the ITER Quality Assurance Program [1] and ITER Procurement Quality requirements [3].

This document defines:

- the quality classes,
- the criteria for assigning quality classes,
- the quality requirements applicable for each quality classes.

Quality Classification applies to all structures, systems and components (SSC), spare parts and activities necessary for ITER operation or for supporting ITER operation.

2 Scope

The requirements of this document apply to the ITER Project and all performers.

Specific technical and documentation requirements may be included in PA's/Contracts or in other contractual documents.

This document, in the scope of the Quality Assurance Process, propagates the requirements from the Quality Assurance Program chapter 2.3 [1]

3 Definitions and acronyms

All the acronyms used in the present procedure are defined in the [ITER Abbreviations \(2MU6W5\)](#) and [Nuclear safety common definition RLZXMV](#).

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|-----------------|--|
| • Supplier | Any entity that provide goods or services to ITER organization and DA's |
| • Subcontractor | An entity that perform works or provides goods / services to a supplier |
| • Performer | An all-inclusive term used to cover both IO internal and external organizations such as Specified PA/Contract Execution Teams, IO PT (Project Team established in accordance with 4.ii of IC-Ex/03.15 Record of Decisions QYTZEP, BIPS Team), Domestic Agencies, Suppliers, Subcontractors, Manufacturers (in the sense of Pressure Equipment Regulation), Fabricators, Works Contractors who provide products, works or services to the ITER project. |
| • Contract | An all-inclusive term used to cover Procurement Arrangements, Task Agreements and Contracts placed directly by IO. |
| • Activities | Measurable amount of work performed to convert inputs into outputs. Units of work having four characteristics: (1) definite duration, (2) logic relationships with other activities in the project, (3) resource consumption, and (4) associated cost. Any operation that shall be completed on time and successfully in order to ensure success of ITER project in term of Quality, Safety, Performance and Reliability. |
| • SSC | System Structure Component |

4 References

- [1] ITER Quality Assurance Program (QAP) ([22K4QX](#))
- [2] Safety Important Functions and Components Classification Criteria and Methodology ([347SF3](#))
- [3] ITER Procurement Quality Requirements ([22MFG4](#))

5 Basic principles

Defining ITER Quality Classes is a function of SSCs affecting quality, performance, cost or reliability of the ITER facility and classified as Nuclear Safety Important (PIC/SIC), Safety Relevant (SR) and Non Safety Related (NSR).

Items may belong to one of Quality Classes, as defined in Appendix 1 of present procedure.

Factors to be considered when assessing potential quality class would include:

- Failure Consequence Factors:
 - Factor 1: Functional & operational;
 - Factor 2: Environment, industrial safety and health;
 - Factor 3: Cost /Schedule Impacts and
 - Factor 4: Compliance with applicable laws and regulation.
- Failure Probability Factors:
 - Factor 5: Other Classifications (safety class, vacuum class, tritium class etc.)
 - Factor 6: Design complexity;
 - Factor 7: Complexity of manufacturing process.

Methodology for determination of quality class for SSC

First step:

IO TRO will establish for each factor indicated in Appendix 1, the applicable quality class. (e.g. if Factor 1 has Class 2 then F1QC =2, if Factor 2 has Class 1 then F2QC =1, if Factor 3 has Class 2 then F3QC =2).

Second step:

IO TRO will establish the final quality class applying average the formula:

$$FQC = [(F1QC \times 1.5) + (F2QC \times 1.5) + (F3QC \times 1.5) + (F4QC \times 0.75) + (F5QC \times 0.75) + (F6QC \times 0.5) + (F7QC \times 0.5)] / 7$$

Where: FQC – Final Quality Class;

F1QC – Quality Class for Factor 1;

F2QC – Quality Class for Factor 2;

F3QC – Quality Class for Factor 3

F4QC – Quality Class for Factor 4;

F5QC – Quality Class for Factor 5;

F6QC – Quality Class for Factor 6;

F7QC – Quality Class for Factor 7.

In the average formula, each factor has an individual coefficient that will highlight the importance / criticality (criticality coefficients 1.5, 0.75 and 0.5).

For determination of quality class the following table shall be applied for interpretation of FQC results:

FQC results	Quality class
$1 \leq FQC < 2$	1
$2 \leq FQC \leq 2.5$	2
$2.5 < FQC < 3$	3

Quality Class 4 will be established for systems, structures and components whose failure has:

- no operational, impact;
- no significant cost or schedule impact;
- no others classifications: safety, seismic, vacuum etc.
- no QA Program applicability or specific quality requirements.

However, the following rules shall be considered to keep the correspondence with safety classifications:

- All PIC/SIC-1 systems and component parts shall be Quality Class 1;
- PIC/SIC-2 systems and component parts can be Quality Class 1 or Quality Class 2;
- Commercial Grade or Proprietary Items that are purchased using a manufacturer's catalogue or other commercially available documentation that have been assessed as Quality Class 1, 2 or 3, need only be supplied with a manufacturer's "Certificate of Conformity" whereas applicable and any other documents established in the PA's / Contracts. *Raw materials shall be supplied with material certificate as per standards indicated in the PA's/ contracts (unless otherwise in the contracts).*

Assembly and installation phase.

The assembly and installation activities will take into consideration the quality class of the system, structure and components (SSC) that will be assembled / installed.

The assembly and installation activities related to SSC with quality class 1, 2 and 3 will be applied having unique approach and rules as per Appendix 2 of present procedure.

For assembly and installation activities of SSC with Quality class 4, no QA Program applicability or specific quality requirements (no Quality Plan is required, Inspection and Test Plan for construction is not required and no IO Quality Supervision/ Control activities etc.), unless otherwise agreed in the contracts.

Determination of quality class for buildings construction

The quality classes for buildings are already established in procurement documentation (PA's, Quality Plans and Construction Supervision Plans).

In case there is necessary to establish a new quality class for buildings a similar approach with assembly and installation activities shall be applied.

Therefore, the quality class for the building will follow the quality class of the main SSC that will be installed in the building.

6 Responsibilities

6.1 IO Technical Responsible Officers (TRO's)

TRO's are required to indicate the Quality Classes relevant to the systems placed under their responsibility. The selection of Quality Classes and the grading of the QA requirements shall be in accordance with Appendixes 1 and Appendix 2 of present procedure.

The Quality Classes shall be established before PA's / contracts signature and shall be mentioned in the Annex B or technical specification of PA's / contracts.

6.2 IO QMD (QARO)

QARO's shall assist IO TRO if any clarification is needed. Rationale and adequacy of the assigned class shall be reviewed as part of the item design review and recorded by Technical Responsible Officers.

6.3 Performers

Performers are responsible to grade the quality classification down to the component levels (some of which may be lower than the related system classification), however they will be responsible for ensuring the correct classification is applied as defined in the contract. The performer shall inform IO TRO about down grade to component level of quality classification.

Performers can require for quality class determination (change) of systems components and spare parts. In this case, the DA's / contractors shall send a request to IO TRO for quality class determination. IO TRO (with IO QARO assistance) will analyse DA's / contractors requests and will decide if the respective components / spare parts will keep the same quality class that was established for system or is necessary to establish a new quality class as per Appendix 1 requirements.

If it is agreed between the parts (IO-CT / DA's and/or suppliers) and a new quality class is established for the PA's / contracts that are already signed, then IO /DA's TRO will issue a deviation request that will address PA's/ contracts requirement related to quality class.

Performers has the responsibility to cascade to their suppliers / sub-suppliers the quality class of the systems, components and spare parts together with the requirements for application of quality classes as per Appendix 2 of present procedure.

7 Forms and templates and checklists

Not applicable.

8 Records

Not applicable.

The Quality Class shall be established before PA's / contracts signature and shall be recorded in the Annex B or technical specification of PA's / contracts.

Appendix 1: Determination of Quality Class for SSC

	Factor / Risk Type	Class 1 Large Impact	Class 2 Adverse Impact	Class 3 Moderate Impact
Failure Consequence Factors	Factor 1 Functional & operational	<i>Failure has potential for a loss of plasma operations for long period or has impact on machine operation activities /performances.</i>	<i>Failure has potential for loss of plasma operations for short period or leads to difficulties in machine operation activities.</i>	Failure has no potential for loss of plasma operation or loss of data essential for machine operation.
	Factor 2 Environment, industrial safety, and health	Failure has potential for: (1) a death or total disability or severe adverse impact on the health or safety of a worker or the public, or (2) Environmental damage that could exceed regulatory limits or involve significant cleanup costs	Failure has potential for: (1) injury or illness requiring hospitalization, temporary or partial disability, or (2) moderately adverse impact on the environment or health or safety of a worker or the public.	Failure has potential for: (1) minimal impact on the health and safety of the public or a worker, such as injury or illness requiring minor supportive treatment but not requiring hospitalization, or (2) a negligible impact on the environment.
	Factor 3 Cost /Schedule Impacts	<i>Failure has potential for a financial loss of 1000K Euro or more.</i>	Failure has potential for: (1) a financial loss of 500K Euro or more or (2) Impact on ITER construction schedule	Failure has potential for a financial loss less than 500K Euro <i>and no impact on construction schedule.</i>
	Factor 4 Compliance	Failure has potential for non-compliance with state, federal or international laws, regulations or requirements	Failure has potential for non-compliance with established IO management practices and procedures.	Failure has potential for minor non-compliance with established management practices.
Failure Probability Factors	Factor 5 Other Classifications	The SSC has other classifications: PIC/ SIC 1 or PIC/ SIC 2 or SR/ seismic class 1/ vacuum class 1/tritium class 1	The SSC has other classifications: PIC /SIC 2 or SR / seismic class 2 / vacuum class 2 / tritium class 2.	The SSC has other classifications: SR / seismic class 3 / vacuum class 3 / tritium class 3.
	Factor 6 Design complexity	<i>The design requires multiple discipline, interfaces, complex verifications, independent validation of the design and special software and models.</i>	<i>The design efforts is normal, it involves different disciplines and independent validation of the design.</i>	<i>The design efforts are minimal.</i>
	Factor 7 Complexity of manufacturing process	<i>The product has multiple critical characteristics and fabrication requires multiple number of manufacturing processes, special process, complex technologies and high qualified personnel that is involved in manufacturing process</i>	<i>The product has critical characteristics and the fabrication requires normal processes, normal fabrication technologies and qualified personnel that are involved in manufacturing process.</i>	<i>The product has characteristics easy to be realised and the product fabrication does not requires a multiple number of manufacturing processes</i>

Class 4: For items whose failure has no operational, significant cost or schedule impact; No others classifications: Non Safety related, seismic etc. No QA Program applicability or specific quality requirements.

Methodology for determination of quality class

First step: IO TRO will establish for each factor indicated in Appendix 1, the applicable quality class.

(e.g. if Factor 1 has Class 1 then F1QC =1, if Factor 2 has Class 1 then F2QC = 1, if Factor 3 has Class 2 then F3QC =2).

Second step: IO TRO will establish the final quality class applying the average formula:

$$FQC = [(F1QC \times 1.5) + (F2QC \times 1.5) + (F3QC \times 1.5) + (F4QC \times 0.75) + (F5QC \times 0.75) + (F6QC \times 0.5) + (F7QC \times 0.5)] / 7$$

Where: FQC – Final Quality Class; **F1QC** – Quality class for Factor 1; **F2QC** – Quality class for Factor 2; **F3QC** – Quality class for Factor 3

F4QC – Quality class for Factor 4; **F5QC** – Quality class for Factor 5; **F6QC** – Quality class for Factor 6; **F7QC** – Quality class for Factor 7

For determination of quality class, the following table shall be applied:

FQC results	Quality class
1 ≤ FQC < 2	1
2 ≤ FQC ≤ 2.5	2
2.5 < FQC < 3	3

Appendix 2: Quality Classes application

Quality activities / processes	Requirements	Class 1	Class 2	Class 3
Design control	Design controls including design reviews and <i>independent</i> ⁽²⁾ verifications ITER_D_R3KD8C - Design Verification and Validation Procedure – applicable for IO only (see note 6).	●	●	○
	Design review process shall be applied by IO, DA's and suppliers as per Design Review Procedure (2832CF) (see note 6). DA's may use equivalent procedure accepted by IO.	●	●	○
Software control & Models Development	IO acceptance of software and models used for design and operation, including life cycle management. IO Identify and validate software and models usage. Procedure for the Management of CAD Work & CAD Data - Models and Drawings (2DWU2M) (see note 6); Procedure for Analyses and Calculations (22MAL7) (see note 6)	●	●	○
Procurement / Documents and Records	Before starting the contractual activities – Necessary procurement documents provided by performers for IO acceptance,			
	Quality Plans Requirements for Producing a Quality Plan (22MFMW) , (see note 6)	●	●	●
	Inspection and Test Plan to be submitted to IO for acceptance Requirements for Producing an Inspection Plan (22MDZD) (see note 6)	●	●	○
	Applicable (manufacturing, testing and inspection, FAT, assembly & construction) procedures shall be reviewed by IO. The applicable procedures will be indicated in the Inspection Plans and contractual documents. Special Process Qualifications reviewed by IO (if applicable)	●	●	○
	At the delivery time - Necessary procurements documents provided by the Performers for IO acceptance, Applicable for manufacturing activities			
	Manufacturing Dossier with completed and approved Contractor Release Note (as indicated in the PA's/ contracts) Requirements for Producing a Contractors Release Note (22F52F) (see note 6)	●	●	○
See note 3	Declaration of compliance to order, material certificates and inspection documents according to the applicable standards indicated in the PA's / contracts, traceable to the component part and equipment (when applicable)	●	●	●

Quality activities / processes	Requirements	Class 1	Class 2	Class 3
Procurement / Documents and Records (cont.) See note 3	At the turnover (reception) time - Necessary procurements documents provided by the Performers for IO acceptance. Applicable for construction and assembly/ installation activities			
	The documentation and procedures requirements shall be applied as per: Requirements for producing a Contractors Release Note (22F52F) (see note 6) Working Instruction for Completion Dossier Preparation (UYUSEE) (see note 6) – applicable for IO and direct contracts only (not in the scope of PAs implementation).	●	●	●
	Mechanical Completion Dossier (MCD) as per appendix D of Working Instruction for Completion Dossier Preparation (UYUSEE) (see note 6) - applicable for IO and direct contracts only (not in the scope of PAs implementation).	●	●	●
Manufacturing, Assembly & Installation / Inspection & Testing	Manufacturing			
	Manufacturing Inspection Plan (MIP) - Requirements for Producing an Inspection Plan (22MDZD) (see note 6)			
	The manufacturing activities shall be performed in accordance with MIP and applicable procedures. No manufacturing activities will start without IO acceptance of MIP and testing / inspections and special process procedures.	●	●	○
	Manufacturing Readiness Review (MRR) - ITER_D_44SZYP - Manufacturing Readiness Review Procedures v.3.1 (see note 6)			
	Manufacturing Readiness Review (MRR) process shall be applied before starting the manufacturing activities	●	●	○
	Quality Control (supervision) applicable for manufacturing phase – Procedure for Inspection and Testing (TVL3Y5) (see note 6)			
	Quality Control level 1 or Quality Control level 2 or Quality Control level 3 or Quality Control level 4 shall be applied. The application and grade approach of quality control levels are described in IO specific procedure	●	●	●
	Construction, Installation and Assembly			
	Inspection & test plan - Requirements for Producing an Inspection Plan (22MDZD) (see note 6)			
	Construction, installation and assembly, inspection and testing activities will start only after IO acceptance of ITP (Inspection and Test Plan) and testing / inspections, special process procedures. Work Instruction for producing an Inspection and Test Plan for construction (UELU9F) (see note 6)	●	●	●
	Construction Readiness Review (CRR) – Working Instruction for Construction Readiness Review (QXW4KQ) (see note 6)			
	Construction Readiness Review (CRR) shall be applied before starting the activities. Applicable for IO and direct contracts only (not in the scope of PA implementation)	●	●	●

Quality activities / processes	Requirements	Class 1	Class 2	Class 3
Quality Audits See note 4	Quality Control (supervision) applicable for construction and assembly & installation phase - Procedure for Inspection and Testing (TVL3Y5) (see note 6)			
	Quality Control level 1 or Quality Control level 2 or Quality Control level 3 or Quality Control level 4 shall be applied. The application of quality control level shall be describe in IO specific procedure.	●	●	●
	Quality audits - Quality Management System Audits (2DQTA8) (see note 6)			
	IO / DA's quality audits to the suppliers/ contractors site – unless otherwise agreed between IO / DA's. Alternative methods for suppliers/ contractors evaluation shall be applied in case audits are not performed.	●	●	○
	The IO and DA auditors shall have the necessary skills / qualifications and experience to perform audit activities. The requirements related to IO and DA auditors' qualification are indicated in IO and DA's audit procedures.	●	●	○
	The quality audits are not mandatory unless otherwise agreed between the parties.	-	-	●
	The evaluation of quality management system of the suppliers / contractors shall be performed base on documents review (ISO 9001 certificate – or equivalent recognized by IO, copy of quality manual). Note: For QC 1 and QC 2 the supplier's evaluation will be done using audits performed by IO/DA's.			
Handling, storage & Transportation	For In-cash procurements the supplier's audits will be on IO responsibility. IO TRO (with QARO assistance) will decide if it is necessary to perform audits to the supplier/ contractor or not. Alternative methods for suppliers/ contractors evaluation shall be applied in case audits are not performed.	●	●	-
	Delivery & transportation of products - Procedure for Transportation of Components to ITER Site (RY5C6Q) (see note 6)			
	The products delivery shall start only after contractors release note and shipping notification are accepted by IO.	●	●	●
	A specific technical specification for transportation and storage activities (issued by IO) shall be applied. Shipping plan for transportation activities shall be applied.	●	●	○
Reception on ITER site - Procedure for Reception of Components at the ITER Site (RXCTBZ) (see note 6)				

Quality activities / processes	Requirements	Class 1	Class 2	Class 3
See note 5	Minimum inspections and verifications to the products (sampling methods) shall be applied at reception time as per IO procedures and PA's / contracts requirements.	●	●	○
	Storage and preservation - Procedure for the Storage and Preservation of ITER Components at the ITER Site (RWYED5) (see note 6)			
	Storage and preservation activities (in IO site & DA's site) shall be performed in accordance with applicable procedures, TRO request and manufacturer instructions.	●	●	○
NCR & DR control	Nonconformity (NCR) - Procedure for management of Nonconformities (22F53X) (see note 6)			
	All major NCR's related to ITER project issued by the suppliers and DA's shall be submitted to IO for review and acceptance in accordance with IO procedure. For all major NCR's related to ITER project, a root cause analysis shall be issued by the DA's / suppliers / contractors and approved by IO.	●	●	●
	All minor NCR's related to ITER project issued by the suppliers/ contractors and DA's shall be submitted to IO following the requirements of applicable procedure <i>or specific agreements between IO and DA's</i> . For in cash procurements the minor NCR's issued by the suppliers shall be submitted to IO for information and validation of remedial actions.	●	●	○
	Deviation request (DR) - Procedure for the management of Deviation Request (2LZJHB) (see note 6)			
	All the Deviation Request (DR) will be submitted to IO / DA's for review and approval before implementation.	●	●	●
	After DR approval, DA's / IO are responsible for follow-up of DR implementation.	●	●	○
	Risk and opportunity management - Risk and Opportunity Management Procedure (22F4LE) (see note 6)			
Risk and opportunity management	Risk and opportunity management process shall be applied in accordance with applicable IO procedure and contractual requirements	●	●	○
	Project Risk and opportunity Register (PRR)	●	●	●
	Training activities related to risk and opportunity management process	●	●	○

Legend:

● - Fully applicable (Mandatory)

○ - Applied with conditions (agreed between the parties) indicated in

- Not applicable

	the PA's / contracts or other specific documents	
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Notes:

- (1) For systems, component and spare parts with **quality class 4**:
- a. No specific QA requirements.
 - b. For supplier's QA evaluation a copy of ISO 9001 certificate is sufficient.
 - c. No quality control/ supervision (quality control level) activities are required. No specific requirements related to manufacturing process, unless otherwise agreed in the PAs / Contracts.
 - d. The requirements related to delivery & transportation & storage are established in IO and DA's procedures and contractual documents.

Notes (cont.):

- (2) Independent means individual, groups, divisions, departments who were not involved in the original design. 'Independent' can also mean a Third Party organization.
- (3) All the documents necessary before starting the activities and the documents necessary at the delivery time will be established during the procurement process and included on PA's / contracts (chapter – Quality assurance), following the requirements of [ITER_D_22MFG4 - ITER Procurement Quality Requirements](#) procedure. The present Appendix 2 table indicates minimum requirements only.
- (4) The requirements related to quality audits and auditors qualification are established in [ITER_D_2DQTA8 - Quality Management System Audits](#) and DA's/ contractors specific procedures accepted by IO.
- (5) The requirements related to handling, storage & transportation activities will be applied in accordance with IO applicable procedures and PA/ contracts requirements. The present Appendix 2 table indicates minimum requirements only.

(6) Procedures versions:

- a. The procedures referred in the present document shall be applied at the latest version indicated in the PA Applicable Documents (PA AD) list - latest agreed version between IO and DA's. For the procedures not considered PA AD, the latest approved version shall be applied.
- b. Any modification of referred procedures, shall be applies following the requirements and workflow indicated in the MQP Document Change Control procedure (VDVFHY) - latest agreed version between IO and DA's.