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MQP Level 3

Procedure for the management of Deviation Request

The purpose of this document is to describe the Deviation Request (DR) processes to be followed for the ITER project. This procedure defines the requirements and provides the detailed workflows for management of DRs project wise addressed to and generated by the ITER Organization.

Approval Process			
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Change Log			
Procedure for the management of Deviation Request (2LZJHB)			
Version	***Latest Status***	***Issue Date***	***Description of Change***
v1.0	Signed	02 Jun 2009	
v1.1	Approved	10 Jun 2009	Minor change in para 4.1.2 at the request of SAS DGG
v2.0	In Work	26 Oct 2010	- General revision showing IDM review & approval for Deviation Requests - Incorporated Domestic Agencies in review process for Deviation Requests
v2.1	In Work	27 Oct 2010	New lay-out through IDM auto-generated covering page.
v2.2	Approved	22 Dec 2010	Changed from "DDG/Directorate Head" to "Directorate Head" on para. 4.1.3 , 4.2.2 and Appendix A.
v3.0	Signed	22 Sep 2011	Introduction of a filter for deviations affecting Regulatory Files
v3.1	Approved	22 Sep 2011	Minor change to tidy up role activity chart
v4.0	Approved	04 Sep 2013	- modification of title - modification of the flow chart for DR - addition of a flow chart for NCR - addition of the following steps for NCR: root causse analysis, corrective action (if needed) and closure of NCR
v4.1	Approved	25 Jul 2014	- Scope: include addition of a requirement - WBS RO and TRO change to IO RO and acronym with definition added - Responsibilities: addition of any dispute solved by Head of QA - Flow chart: refer to paragraph listing the reviewer 7.1.4 for DR and 7.2.1.4 for - Flow chart: addition of root cause analysis for NCR - Addition of "Send a link of the signed form to DAs if they are impacted" for DR and NCR - Modification of the paragraphs of the text to be coherent with the flow charts
v4.2	Approved	12 Mar 2015	Changes according to MQP doc Request - QV6CHN: - Update of title “Procedure for IO Deviation Request and Non-conformance Report” - Addition of an explanatory footnote for PIC and PIA - Addition of PIA with PIC - Addition of details for the steps in IDM for the closure of NCRs
v5.0	In Work	01 Sep 2017	The purpose of this document is to specify the Deviation Request, hereinafter DR, processes from the initiation to the implementation. The processes for following two types of DR’s are described: - Deviation Request issued by DA, (Sub-)Contractor and/or Supplier, hereinafter “DA/CON-DR,” and - Deviation Request issued by IO, hereinafter “IO-DR” Roles and/or responsibilities of each stakeholder are also specified.
v5.1	Signed	01 Sep 2017	Compared to the Version 4.2: - DR and NCR processes are separated. - IO technical change request is out of scope. - Work flow and responsibilities are specified clearly. - Criteria for the escalation is specified. - Added all required contents in the new template, MQP Document Template (ITER_D_438T76 v2.5)
v5.2	Signed	20 Sep 2017	Implemented QA Process Owner's comment regarding the approvers. In this version, the approvers are as specified in; Sign-Off_Authority_for_Project_Documents_2EXFXU_v3_3
v5.3	Approved	25 Sep 2017	As commented by CIO/CMD head, rev. nums. of the latest approved versions of the applicable documents are added.
v5.4	Approved	15 Dec 2017	Revision of the flowcharts The flowcharts are revised back into the ones in [2LZJHB v4.2], which had

			been accepted by ASN The specific changes are: 1) “IO-SRO” is replaced by “EPNS-DH” 2) Logic in the flowcharts, e.g. explicit description for escalation to PCR, safety pre-assessment first. Revised user-friendly 1) Basic principle (definition, rule, criteria), process flow and responsibility assignment are separated clearly by section. 2) Deleted needless and/or non-mandatory contents, e.g. some foot notes, KPI. 3) Flowcharts, description of the process steps, and responsibility assignment (RACI matrix) are correlated by paragraph number, #.#.#. 4) Some TYPOs are fixed.
v5.5	Approved	14 Mar 2018	1) "Approval with condition is not allowed" is changed into more realistic statements: • Regarding DA/CON-DR, all conditions shall be documented and agreed between the DA officer representing the initiator and the approver via exchanges in IO-IDM metadata. In case of direct contract between IO and CON, the initiator and the approver shall agree on. • Regarding IO-DR, all conditions shall be documented and agreed between the approver and the accepter, who are IO-CT and DA/CON, respectively. 2) Mandatory and optional reviewers are specified as in Section 7.2. Added some statements telling "SOA [22F4E5] to be consistent later."
v5.6	Revision Required	11 May 2018	As per MQP doc Request - WK73BR Includes Module H needs
v6.0	Revision Required	07 May 2019	Chapter 2.1 to clarify the scope of DR in relationship with MQP procedures changes. CMA audit finding (NC 02) regarding DR scope ITER_D_XYKVBE - Quality Audit Report_IO-QMSA-18-08-CMA Audit Chapter 3.1 - add definition of Equipment, Manufacturer, PE/ NPE and ESPN – maintained as per previous revision of procedure in the scope of PE/ NPE network. Chapter 3.2 – add abbreviation PT- project team Chapter 4.2 – add references - maintained as per previous revision of procedure in the scope of PE/ NPE network. [11] French Order dated 30 December 2015 concerning Nuclear Pressure Equipment [12] Implementation plan for design & manufacture of PE/NPE [VE2DSP] Chapter 5 - add reference to other specific Sign-Off Authority related to PT and construction and PE / NPE responsibilities - maintained as per previous revision of procedure in the scope of PE/ NPE network. Chapter 6.2.2 – add reference to other specific Sign-Off Authority related to PT and construction Chapter 6.3.3 - add reference to other specific Sign-Off Authority related to PT and construction Chapter 7 add reference to other specific Sign-Off Authority related to PT and construction and PE / NPE responsibilities - maintained as per previous revision of procedure in the scope of PE/ NPE network. Table of Mandatory or Optional Reviewers improved - add PT staff review and PE/ NPE review - maintained as per previous revision of procedure in the scope of PE/ NPE network. Eliminate RACI tables.
v7.0	Signed	14 Jun 2019	New version according to additional MQP doc Request - YPKLTV and and essential data YTKAKK, which are documenting list of changes as per reviewers comments.
v7.1	Signed	16 Jul 2019	Revision required for implementation of reviewer comments.

			The following changes/ clarifications are applied: - Chapter 2 - Scope of procedure - add clarifications to allow IO to raise DR for technical deviations with no impact on cost, schedule and without changing the PAs documentation - Main, annex B , annex A) - Chapter 2.1 - add clarifications to eliminate the discrepancies with DR definition - Chapter 3.1 - Chapter 3.1 - clarify definition of "Equipment". Add clarification for Deviation request definition to eliminate conflicts with chapter 2.1 requirements. - Chapter 5 - first bullet - add clarification regarding deviation to IO requirements. - Chapter 6.2.10 - Confirmation of DR implementation. add clarification regarding criteria for "required" DR implementation confirmation. - Chapter 9 - correction chapter numbering (9.1, 9.2 9.3 and 9.4) - F4E comments regarding interface with Supply process / application of PA change notice are implemented in the chapter 2.1 and chapter 9.
v7.2	Signed	18 Jul 2019	The following minor changes are applied: - Chapter 5 - Basic principle - eliminate 7th bullet regarding IO DR. - Fig 6.2 - Work flowchart of IO -DR - add clarification: Not applicable in the scope of PA changes - Chapter 6.3.3 - IO -DR Decision - Eliminate DA / CON responsibilities for decision since IO-DR is not applicable for PA changes. - Chapter 7 - Mandatory or Optional Reviewers - for IO-DR the responsibility for DA-RO review is Optional instead of Mandatory (IO-DR is not applicable for PA changes)
v7.3	Approved	18 Jul 2019	New version according to additional MQP doc Request - YPKLTV and and essential data YTKAKK, which are documenting list of changes as per reviewers comments The following minor changes are applied: - Chapter 5 - Basic principle - eliminate 7th bullet regarding IO DR. - Fig 6.2 - Work flowchart of IO -DR - add clarification: Not applicable in the scope of PA changes - Chapter 6.3.3 - IO -DR Decision - Eliminate DA / CON responsibilities for decision since IO-DR is not applicable for PA changes. - Chapter 7 - Mandatory or Optional Reviewers - for IO-DR the responsibility
v8.0	In Work	25 Nov 2019	As per approved MQP doc request https://user.iter.org/?uid=27JZVH the main changes are: - Clarification of the DA/CONT DR and IO-DR workflows (even though no major steps were added or removed); - Clarification of the roles of approvers for the DA/CONT DR and IO-DRs; - Inclusion of the IO supplier DR to IO, that follows the same process as the DA DR; - Clarification of the text, notably sects. Main principles and main requirements; - Editorial changes, which make the procedure much easier to understand and implement;
v8.1	Approved	25 Nov 2019	Minor update due to technical problem with pdf conversion. All changes are listed for the previous version 8.0
v9.0	Signed	10 Dec 2024	In accordance with CSAJJV the changes are: - Update due to the ASN Decision 2017-DC-0616 of November 30, 2017 amended by Decision 2023-DC-0770 on noticeable modifications to INBs (C58DCJ): any DR that is categorized as a Noticeable Modification shall trigger a PCR - Update due to the NCR-IO.NCR-0171 - SRO review of Deviation Request (8TZQDH): clarification that the DR review by the SRO is mandatory only

			when PIC/PIA are impacted - New mandatory field introduced: Impacted Requirement Document - Approver for DR purely related to MQP process is changed from the MQP Process Owner to the approver of the MQP document from which the DR requests to deviate. The MQP Process Owner is now a mandatory reviewer - CID Head removed as mandatory reviewer - SIROs added as mandatory reviewers - CMS Section Leader added as observer - The DR Database, which today is used for IO Supplier DR only, is recommended to be used as well for DA-DR and IO-DR - Addition of the section 8.4 Interactions with MQP Process Management Process: it is recommended, but not mandatory, to apply the DR procedure to track any deviation to MQP requirement - Use of the MQP Document Template 438T76 v5.0 - Integration of various needs consolidated in CAT-4915
v9.1	Approved	17 Dec 2024	Changes compared to the last approved version v8.1 are those described in the Version Change Description of the v9.0, plus the following additional changes from v9.0 to v9.1: - In accordance with the MQP Process Management Process, for DRs related to the MQP process, impacted original document's stakeholders are mandatory reviewers of the DR - For IO-DRs related to the MQP process, the first check (step 4) can be done by the MQP Process Representative instead of the MQP Requirement Document Approver

Table of Contents

1 Purpose

The purpose of this document is to describe the Deviation Request (DR) processes to be followed for the ITER project. This procedure defines the requirements and provides the detailed workflows for management of DRs project wise addressed to and generated by the ITER Organisation.

2 Scope

This procedure is a MQP Level-3 document within the process of Configuration Management (QAP sect. 3.1, ref. [1]), as shown in the Management and Quality Programme (MQP) map:

https://portal.iter.org/qa/SitePages/Home.aspx.

This procedure shall be applicable for managing the following DRs:

- **Deviation Requests from DAs to IO:** e.g. deviations from the PA baseline. To be noted that DAs follow their internal processes to manage the first steps of this procedure as well as their Supplier Deviation Requests;
- **Deviation requests from IO suppliers to IO:** e.g. deviations from IO supplier contract baseline for In-Cash contracts;

  Note: Hereby, the deviation requests from DA to IO, and IO suppliers to IO, are commonly defined as the DA/CONT-DR process, see sect. 6.3.1.
- **IO Deviation Requests**: deviations from defined requirement(s) or punctual departures from the authorized high level configuration documentation belonging to the ITER Technical and/or Management baselines (e.g. ASN approved safety files, Project Requirements (PR)).

  Note: This DR process is known as IO-DR, for the remaining of the document, see sect. 6.3.2.

3 Definitions and acronyms

The definitions of the configuration management terms used in this procedure are given in the Configuration Management Glossary, ref. [2].

Acronym	Definition
ANB	Agreed Notified Body
CID	Central Integration Division
CONT	Contractor (i.e. supplier of IO, excluding DAs)
CMS	Configuration Management Section
DA/CONT-DR	Domestic Agency/Contractor – Deviation request
DA PA TRO	DA Procurement Arrangement Technical Responsible Officer
DR	Deviation Request
ESR	Essential Safety Requirement
IO Contract RO	ITER Organization Contract Responsible Officer
IO-DIRO	IO Design Integration Responsible Officer
IO-DR	ITER Organization Deviation Request
IO-PARO	IO Procurement Arrangement Responsible Officer
IO PA TRO	ITER Organization Procurement Arrangement Technical Responsible Officer
IO-QARO	IO Quality Assurance Responsible Officer

IO-SIRO	IO System Integration Responsible Officer
IO-SRO	IO Safety Responsible Officer
IO-TRO	IO Technical Responsible Officer
MQP	Management and Quality Programme
PA	Procurement Arrangement
PA-CN	Procurement Arrangement Change Notice
PIA	Protection Important Activity
PIC	Protection Important Component
PCR	Project Change Request
PT	Project Team
QAP	Quality Assurance Program
SIC	Safety Important Class
SL	Section Leader

4 References

[1]	ITER Quality Assurance Program (QAP) (22K4QX)
[2]	Configuration Management Glossary (X2SH46)
[3]	Procedure for the Preparation, Review, Approval, Award and Amendment of Procurement Arrangements (2W4F7A)
[4]	IO Deviation Request Template (2LRNQP)
[5]	Project Change Procedure (22F4E5)
[6]	Procedure for Configuration Control, Review and Audit (TZY7YV)
[7]	Sign-Off Authority (SOA) for Project Documents (2EXFXU)
[8]	Procedure for the Management of Safety Modifications (U34EB9)
[9]	Pressure Equipment Directive 2014/68/UE (RZ6PAK)
[10]	French Order dated 30 December 2015 concerning Nuclear Pressure Equipment (SMP384)
[11]	Implementation plan for design & manufacture of PE/NPE (VE2DSP)
[12]	Design Planning Procedure (U34ACR)
[13]	Design Change Control Procedure (U2QPDS)
[14]	ITER Integrated Safety, Environment and Security Management System (ISMS) Manual (4HCWJU)
[15]	In-Cash Procurement Procedure (658PD4)
[16]	MQP Process Management Procedure (7M445D)

5 General principles

5.1 Main principles

The main principles that shall be respected for management of a DR are as follows:

i. The DAs, suppliers of IO, and IO staff, can issue DRs for IO Approval.

ii. As per ref. [2], DRs are punctual departures from a particular requirement(s) from the current authorized configuration documentation and prior to the execution of the actions that have an impact on meeting the original specified requirement(s).

Note: A deviation permit is generally given for a limited quantity of items, period of time, and for a specific use.

iii. The DR process for both DA/CONT-DR and IO-DRs is composed of four main steps:

1) **Submission**, see sect. 6.3.1.1 and 6.3.2.1
2) **Review**, see sect. 6.3.1.2 and 6.3.2.2
3) **Decision, dispute and resolution**, see sect. 6.3.1.3 and 6.3.2.3
4) **Closure**, see sect. 6.3.1.4 and 6.3.2.4.

iv. DRs can impact different authorized configuration documentation (e.g. the PA baseline, the ITER technical baseline, etc.) depending on the DR submitter (see chapter 6).

v. DRs shall be managed using a dedicated IT system (DR Database[1] or IDM) from initial submission to closure, as per guidelines given in this procedure.

Note: DAs can use their internal IT applications/platforms to manage DRs before submission to IO.

5.2 Main requirements

i. Deviation Requests shall be submitted for IO review and approval/rejection before implementation of related activity(ies) (e.g. manufacture of the item).

ii. Before submission to IO, the DA/CONT DRs shall be internally reviewed by competent and authorised specialist(s) of the DA/supplier and approved for the submission to IO.

iii. IO DRs shall not be used to request to deviate from an agreed PA baseline or IO direct contracts (In-Cash contracts).

Note: IO requested changes impacting PAs, shall be managed according to the procedure Preparation, Review, Approval, Award and Amendment of Procurements Arrangements (PA), ref. [3]. In line with this procedure, in most cases the vehicle for changing PA baselines is the PA Change Notice (PA-CN).

Note: IO requested changes impacting IO direct contracts (e.g. In-Cash contracts), shall be managed according to the In-Cash Procurement Procedure, ref. [15].

iv. The DRs shall be issued using the DR Database or the DR Template (ref. [4]). If applicable, the DA/CONTs can provide their DRs using their internal template (ensuring that the file contains the IO cover page), as follows:

- Upload the internally approved DR into IDM so that the DR has a well-defined UID.
- Ensure that the DR respects the mandatory information as per sect. 5.2 v. of this procedure;

v. DR submitted forms shall contain (as a minimum) the information requested in the DR Template (ref. [4])":

- **Type of DR**: either DA, supplier of IO or IO submitter;
- **DR Reference Number**;

[1] A DR Database (https://user.iter.org/default.aspx?uid=FA2VRS) is currently in place to support IO construction sub-contractors DRs. It is strongly recommended that this DR Database be used for DA-DR and IO-DR as well.

- **DR Title**;
- **Type of Impact:** item or MQP process;
- **Quality Class** (QC[2])

  Note: For DRs impacting more than one activity or component with different QC classes, the submitter shall choose the highest QC in the DR Template (ref. [4]). A detailed description of the components impacted with individual QCs shall be provided in sect. 2 (Description of deviation) of the DR template (ref. [4]).
- **Safety Class**: SIC-1, SIC-2, SR, Non-SIC, PIA if applicable; For activities or components with different safety classes, the same approach as for QC applies.
- **IO PE or NPE**: yes/no, incl. PE/NPE, pressure category and radioactive level (N2-N3).
- **Impacted Requirement Document**: provide the reference, with a clear link to the IDM UID, of the document that contains the requirement(s) from which the submitter requests to deviate.

  Note: this can be a technical requirement document (such as a System Requirement Document, a Technical Specification, etc.) or a process requirement document (MQP document).

  Note: there may be several Impacted Requirement Documents, in such case they shall all be listed.
- **Description of Deviation**: provide a clear description (and indicate the document IDM UID) of the original requirement(s) (before), the proposed alternative requirement(s) (after), and a detailed justification for the proposed departure (e.g. impact on critical path, etc.). In addition, provide a detailed safety justification if PIC/PIA are impacted.
- **Impact Assessment**: expected additional technical impacts to the best knowledge of the submitter, including an assessment of other impacted PBS, PAs, performance, maintainability, operability, reliability, etc., if known. All impacts shall be assessed, including cost, schedule, performance and logistics.
- **List of expected impacted documents**: exhaustive list of all documents with a clear link to the document IDM UID to the best knowledge of the submitter, that are expected to be impacted should the DR be approved. The impacted documents are technical documentation that uses as input the requirement(s) that the submitter request to deviate from.

vi. DRs **shall not**:

- Lead to a modification of the Performance Baseline. The ITER Performance Baseline is the authorized configuration that comprises the ITER integrated cost, schedule and scope documentation.
- Constitute a permanent change to a document of the ITER Technical Baseline. If a DR leads to a permanent change of the ITER Technical Baseline, a Project Change Request (PCR, see ref. [5]) shall be triggered prior to acceptance of the change. The rationale for the request of a PCR is detailed in sect. 6.3.1.2.

Note: Changes impacting one of the ITER Project's baselines shall be managed using the Configuration Control procedure, ref. [6].

[2] Quality Class to be determined as per the Quality Classification Determination document.

6 Workflow

6.1 Flowchart

The flowcharts for the DA/CONT-DR and IO-DR processes are shown in Figure 1 and Figure 2 below.

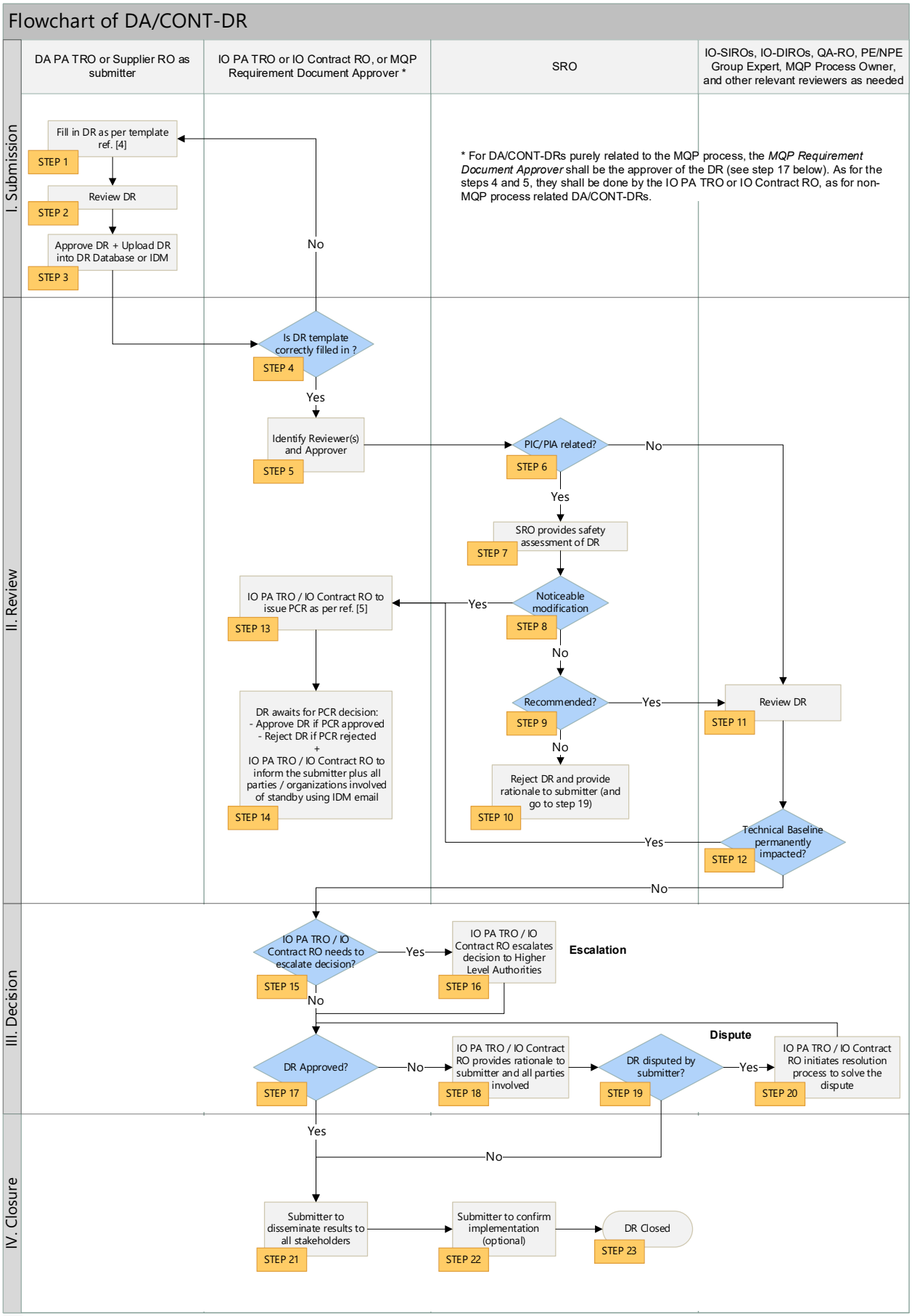

Figure 1 - Flowchart of DA/CONT-DR.

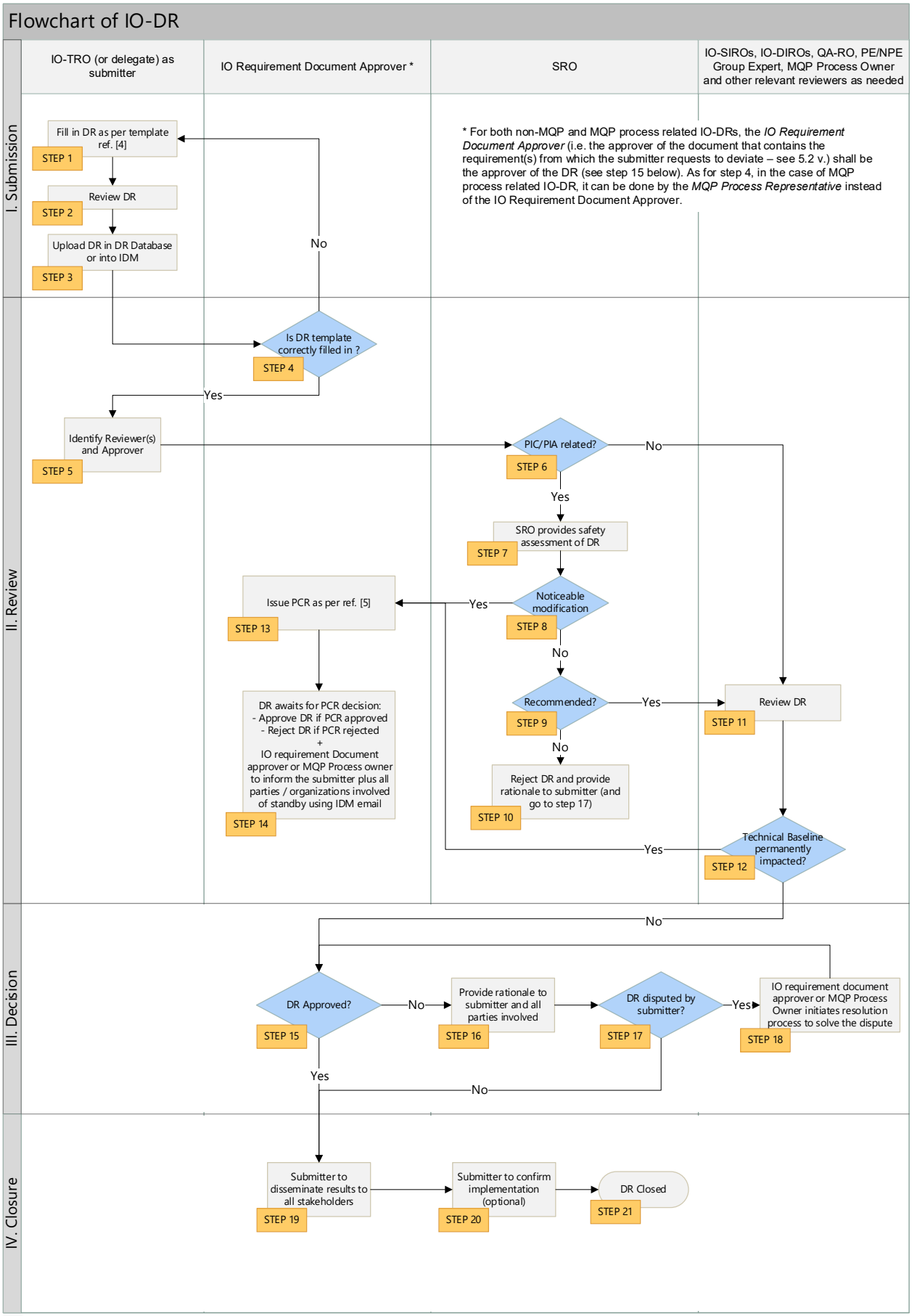

Figure 2 - Flowchart of IO-DR.

6.2 Responsibilities

The main responsibilities for the roles described in this procedure are described in sections 6.3.1 and 6.3.2.

The main roles covered in this procedure are:

- DA PA TRO, Supplier RO or IO TRO (as submitters)
- IO PA TRO or IO Contract RO
- DIRO, SIRO
- IO Expert, PE/NPE Group Expert, etc. as needed
- QARO
- SRO
- IO Requirement Document Approver
- MQP Process Owner, MQP Process Representative and other MQP stakeholders

6.3 Description of steps

6.3.1 DA/CONT-DR Process

Below we describe the tasks to be executed for each of the four main steps of the DA/CONT-DR (see Figure 1).

6.3.1.1 Submission

The DA PA TRO or the Supplier RO (submitters) shall:

- **Step 1:** Identify the necessity for a DR from a PA or contract baseline and initiate the request by using the DR Database or by following the DR template (ref. [4]).

  The DAs or suppliers can provide their DRs using their internal template, as described in sect. 5.2 Main Requirements (iv).
- **Step 2:** Review the DR for technical coherence, completeness and clarity, according to the relevant DA or Supplier internal procedures, prior to the submission to IO.
- **Step 3:** The DA PA TRO or Supplier RO line manager shall approve the DR before submission to IO and shall upload the DR template into the IT tool IDM (if the DR Database was not used).

6.3.1.2 Review

- **Steps 4 and 5: The IO PA TRO or IO Contract RO shall provide the first check by reviewing the DR submitted form for completeness and appropriateness, and verify that it is in agreement with the main requirements as per Sect. 5.2 of this procedure:**
  - If DR submitted form is correctly filled in, the IO PA TRO or Contract RO identifies the appropriate reviewers. The mandatory reviewers are:
    - SRO, if protection important components or activities are impacted (i.e. PIC/PIA ticked in the DR template ref. [4])
    - QARO
    - DIRO
    - SIRO
    - PE/NPE Group Expert (when ITER acts as manufacturer of PE/NPE equipment)

    - IO experts, if the field of concerned expertise is not covered by the mandatory reviewers and the approver
    - MQP process owner (or delegate), as well as the authors & reviewers of the MQP document from which the DR requests to deviate, if the DR is related to an MQP process.
  - Once reviewers are assigned, the IO PA TRO or IO Contract RO shall inform all reviewers that the review process has started using the IDM email function.
  - If the DR is not correctly filled-in, the IO PA TRO or IO Contract RO shall request further processing to the DA PA TRO or Supplier RO submitter.
  - The CMS-SL (or delegate) shall be added as observer.
- **Steps 6, 7, 8 and 9: If protection important components or activities are impacted, the SRO shall review as follows:**
  - Verify all impacts on regulatory, safety or environmental requirements, and provide the safety and environmental assessment in the DR template (ref. [4]). This assessment shall include the determination whether the proposed deviation constitutes a noticeable modification or, on the contrary, a non-noticeable modification, as defined in ref. [8];
  - Either:
    - Inform the IO PA TRO or Contract RO to trigger the PCR process, in case the deviation constitutes a noticeable modification, as follows:
      - Issue a PCR, as per ref. [5]. The PCR decision shall be registered in the DR template form (Step 13);
      - Maintain the DR is standby awaiting PCR decision and provide the rationale for the decision to issue the PCR to the submitter and all involved parties (Step 14);
    - Or recommend the DR;
    - Or reject (unless revised) the DR and provide rationale for the decision (see step 10).
  - If IO acts as a manufacturer of PE/NPE equipment, the PE/NPE Group Expert shall verify impacts on Essential Safety Requirements (ESR) (see ref. [9] and [10]) and quality requirements as defined in ref. [11], and assess if the DR shall be transmitted to the ANB.
- **Steps 11 and 12: The IO DIROs, SIROs and other technical reviewers as needed shall review the DR in order to:**
  - Ensure that the DR is technically justified and all requirements as per sect. 5.2 are respected;
  - Assess the technical aspects from system integration/configuration management point of view and provide the System/Design Integration assessment as needed, in the DR template.

    Note: The IO DIRO and SIRO shall ensure that the approved DRs are captured in the system configurations.
  - Verify if the DR impacts on ITER system level performance, reliability, operability, and interfaces, as needed;
  - Verify if the submitted DR impacts permanently any document from the ITER Technical Baseline.

- **If the IO DIRO or SIRO estimates that the requested deviation constitutes a permanent impact to the ITER Technical Baseline, he/she informs the IO PA TRO or Contract RO to trigger the PCR process, as follows:**
    - Issue a PCR, as per ref. [5]. The PCR decision shall be registered in the DR template form (Step 13);
    - Maintain the DR is standby awaiting PCR decision and provide the rationale for the decision to issue the PCR to the submitter and all involved parties (Step 14);

  Note: the DA is also entitled to trigger directly the PCR process.
- IO-QARO shall check the compliance of the submitted DR against the requirements in this procedure, the assignment of QC as per Quality Classification documentation, the assigned reviewers or approver according to this procedure, and the compliance against other concerned quality documents, e.g. Quality Plan, and other specific Sign-of-Authorities related to Project Teams (PT) and construction.
- Each reviewer shall have ten (10) business days to recommend / disapprove the DR, with a clear explanation. If after 10 days the reviewer has not signed the DR (either recommending or disapproving it) the IO PA TRO or Contract RO shall query as to its status and send an email reminding the reviewer(s) of the missing action.

6.3.1.3 Decision, Dispute and Resolution

- **If protection important components or activities are impacted, the SRO shall decide on the recommendation or rejection of the DR from the safety and environmental point of view:**
    - If recommended, the SRO shall notify the DR submitter of the decision and route it to review from the technical aspects system integration point of view (Step 11).
    - If rejected, the SRO shall provide rationale to submitter and all parties involved using the IT management tool IDM email function (Step 10).
- **Steps 15, 17, 18: For all DRs recommended by the SRO or not impacting protection important components or activities, the IO PA TRO or IO Contract RO (after the technical revision is terminated, Step 11), shall decide on the Approval or Rejection of the DR, and provide a rationale to the DR submitter and all involved parties.** DRs shall only be approved after establishing, through technical knowledge, expertise and experience, or by requesting the expertise of other experts, that approval of the request is acceptable with regards to the PA / CONT objectives and overall project needs;
- **For DA/CONT-DRs related to the MQP process, the approver shall be the IO approver of the MQP document from which the DR requests to deviate.**
- **Step 16:** If the decision related to the DR is above the authority of the IO PA TRO or IO Contract RO, the DR shall be escalated to a higher level authority. Higher level Authorities consist of:
    - Impacted Section Leader, or delegate;
    - Impacted Head of Division/Department or delegate, as appropriate;
- If the DR is rejected, the DA PA TRO or Supplier RO:
    - Shall try to develop an alternative plan that does not require deviation in order to fulfil requirements. If the DA PA TRO or Supplier RO devises and alternative solution that (still) involves a departure from the requirement(s), the IO PA TRO or IO Contract RO shall analyse the request and inform the submitter if this alternative solution can be considered for acceptance.

- If an alternative solution is not suggested, the DA PA TRO or Contractor RO can dispute the decision and liaises with the involved parties for solution seeking.

- **Step 20:** If the DR is rejected, or a reviewer disapproval rationale is disputed by the initiator and cannot be resolved at the IO PA TRO or IO Contract RO level, they shall initiate a resolution process to solve the dispute, as follows:
  - Appeal to the higher level management for a solution;
  - If not settled, the DR shall be listed in the Project Issue Management (PIM) list: https://jira.iter.org/secure/RapidBoard.jspa?rapidView=45&projectKey=PIM.
- The decision to approve a DR from a DA/Supplier A impacting the scope of a DA/supplier B, with no impacts to the ITER baseline, shall be taken by a higher level authority that has the full overview to make the decision of approving the DR from the DA/Supplier A and trigger a PA Change Notice (see ref. [3]) for the DA/Supplier B without changing the ITER baseline.

  Upon decision, the DA PA TRO or Supplier RO shall inform the submitter of the DR decision taken by using the IDM email function (as long as IDM is the available tool) and distribute the link to higher-level management (e.g. Section Leader, Head of Division), as necessary.
- Estimated time for decision on a DR is 2 weeks. One additional week to be considered if the decision needs to be escalated.

6.3.1.4 Closure

The DA PA TRO or Supplier RO (as submitters) shall:

- **Step 21:** Ensure that the DR decision was disseminated to all stakeholders and provide corrective action as needed.
- Ensure that all impacted documentation (including, document UID) is registered in the DR submitting form (as per sect. 5.2).
- **Step 22:** Confirm the DR implementation (optional), for cases when further critical actions are triggered by DR approval and/or related documentation needs to be revised to reflect the implementation of the deviation. For cases when DR implementation confirmation is required, the DR submitter shall attach all the necessary evidences to demonstrate the implementation.

6.3.2 IO-DR Process

As shown in Figure 2, the IO-DR process is similar to the DA/CONT-DR process except for a few steps as shown below.

6.3.2.1 Submission

Steps 1 to 3: The IO-DR submission process shall be performed similarly to the one described in sect. 6.3.1.1, with a few exceptions:

- The IO TRO (or a delegate) is the submitter of the IO-DRs.
- The IO-DR shall be reviewed internally by the IO-TRO (or a delegate) line manager, e.g. Section Leader or Head of Division/Department, using the IT tool.

6.3.2.2 Review

- **Steps 4 and 5: The IO requirement document approver (i.e. the document that contains the requirement(s) from which the submitter requests to deviate – see 5.2 v.) shall provide the first check by reviewing the DR submitted form for completeness and appropriateness, and verify that it is in agreement with the main requirements as per sect. 5.2 of this**

procedure. For IO-DR related to the MQP process, this check can instead be done by the MQP Process Representative.

- If DR submitted form is correctly filled in, the IO TRO identifies the appropriate reviewers. The mandatory reviewers are:
  - SRO, if protection important components or activities are impacted (i.e. PIC/PIA ticked in the DR template ref. [4])
  - QARO, DIRO, SIRO
  - PE/NPE Group Expert (when ITER acts as manufacturer of PE/NPE equipment)
  - IO experts, if the field of concerned expertise is not covered by the mandatory reviewers and the approver
  - MQP process owner (or delegate), as well as the authors & reviewers of the MQP document from which the DR requests to deviate, if the DR is related to an MQP process.
- Once reviewers are assigned, the IO TRO shall inform all reviewers that the review process has started using the IDM email function.
- If the DR is not correctly filled-in, the IO requirement document approver shall request further processing to the IO TRO submitter.
- The CMS-SL (or delegate) shall be added as observer.

- **Steps 6 to 14:** the other reviewers as necessary, shall execute the same steps as described in sect. 6.3.1.2.

6.3.2.3 Decision, Dispute and Resolution

Steps 15 to 18: For the IO-DR, decision, dispute and resolution follow the same steps as given in sect. 6.3.1.3, with the exception that:

- For the IO-DR, a decision shall be taken by the IO Requirement Document Approver (i.e. the document that contains the requirement(s) from which the submitter requests to deviate – see 5.2 v.), both for non-MQP and MQP process related DRs. No escalation is possible.
- If the IO-DR decision is disputed, the IO Document Approver shall initiate a resolution process by following the same steps as given in sect. 6.3.1.3.

6.3.2.4 Closure

Steps 19 to 21: For the IO-DR closure, the submitter shall follow the same steps as for the DA/CONT DR described in sect. 6.3.1.4.

7 Records

The expected records from the DR process are provided below.

Record	Template	Place to store	Doc type	Naming convention	Retention period
Deviation Request	Template in ref. [4], or DA/CONT template	DR Database (*) or IDM	DA QA Deviation Request Contractor QA Deviation Request ITER QA Deviation Request	IDM procedures or DR Database	ITER lifetime

(*) https://user.iter.org/default.aspx?uid=FA2VRS

8 Interactions with other processes

8.1 Interactions with the Design Control Process

This procedure belongs to the process of Configuration Management (QAP, sec. 3.1, see ref. [1]]) and interacts with the process of Design Control (QAP, sect. 3.3, see ref. [1]). The Design Control process provides guidance to the IO PA TRO, IO Contract RO or IO Requirement Document approver for the review of design integration aspects of DRs using the MQP procedures for Design Planning, ref. [12], and Design Change Control, ref. [13], among others.

8.2 Interactions with the Supply Process

This procedure interacts with the Supply process (QAP, sect. 3.4, ref. [1]). IO changes to PAs or IO direct contracts (e.g. In-Cash contracts) shall be managed using the Procedure for the Preparation, Review, Approval, Award and Amendment of Procurement Arrangements (PA), see ref. [3] and the In-Cash Procurement Procedure, see ref. [15].

8.3 Interactions with Nuclear Safety Processes

This process interacts with the Nuclear Safety processes. The Safety RO reviews the DR according to the Procedure for the Management of Safety Modifications (ref. [8]) and to ensure that it complies with the ITER Integrated Safety, Environment and Security Management System (ISMS) Manual (ref. [14]), including the MQP L2 and lower level procedures.

8.4 Interactions with MQP Process Management Process

This process interacts with the MQP Process Management process. As indicated in ref. [16], deviations from MQP should be permissions and not requirements or recommendations. Deviations from MQP shall be reviewed and approved by impacted original document's stakeholders and recorded in IDM.

It is recommended to use the current DR Procedure to track any Deviation to MQP requirement.