IDM UID
2LZJHB

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EXTERNAL REFERENCE / VERSION

MQP Procedure

Procedure for the management of Deviation Request

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," andDeviation Request issued by IO, hereinafter "IO-DR" Roles and/or responsibilities of each stakeholder are also specified.

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."

Table of Contents

1 Purpose

The purpose of this document is to specify the Deviation Request, DR processes from the initiation to the implementation. Two types of DR's are described:

- DR issued by DA, (Sub-)Contractor and/or Supplier, "DA/CON-DR," and
- DR issued by IO, "IO-DR"

2 Scope

This level-2 MQP procedure complies section 2.8 of QAP [22K4QX], and as a part of the Quality Assurance Process as shown in **Fig. 2.1**.

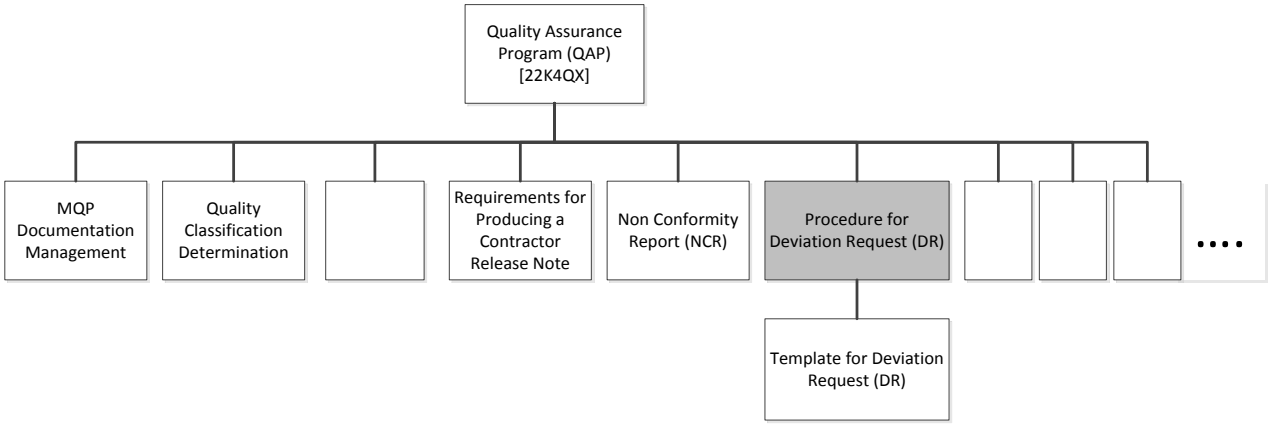

Fig. 2.1 MQP hierarchy structure of Quality Assurance Process

The scopes of the two types of DR's are shown in **Table 2.1**. Design change in Functional Specification PA requested to IO is also comprised in DA/CON-DR.

Table 2.1 Scopes of IO or DA/CON DR's

	Technical Deviation	Non-Technical Deviation, e.g. administrative process
1) IO-DR	N/A*	Yes
2) DA/CON-DR	Yes	Yes

*) IO to issue Project Control Request-Level 3 (PCR-L3)[1] regarding technical aspects.

2.1 Out of Scope

Followings are out of scope from this document:

- Other change control processes, e.g. PCR [22F4E5], NCR [22F53X], PCR-L3
- Review in EPNS Meeting, and
- Close-out of each contract. Where approved DR's are comprised in the close-out dossier, and recognized as the amendments to the formally agreed (contractual) documents.
- Field Change Request, FCR[2]

[1] Under preparation by CIO/CMD as a part of Configuration Management, CM Process.
[2] Procedure for "Field Change Request," which is a kind of first track DR to be happened in the construction site, is to be generated by the process owner, i.e. CST.

3 Definitions and Acronyms

3.1 Definitions

Deviation Request, DR

- Request for deviation from a formal agreement, e.g. signed contract, signed Procurement Arrangements (PA), with alternatives to requirement, specification and/or processes, and full justification by impact assessment, trade-off study, etc. ,
- Where deviation in this project means both a) temporary change without impacting on any baseline document, and b) change on low-level (specific) baseline document, e.g. Manufacturing Drawing, and
- DR's to escalate to the higher level of change control process, e.g. PCR, as necessary, if they impact on:
  1) Regulatory requirements, safety or environmental aspect (EPNS-DH to verify),
  2) ITER system level performance, reliability, operability, interfaces (IO-RO and IO-DIRO to verify).

3.2 Acronyms

CON	Contractor. Both IO Direct Contractor and DA Contractor are included.
CCB	Configuration Control Board
CM	Configuration Management
CST	Construction Department
DH	Division Head
DR	Deviation Request
EPNS	Environmental Protection & Nuclear Safety Division
FCR	Field Change Request
INB	Basic Nuclear Installation (from French: "Installation Nucléaire de Base")
IO-DIRO	IO Design Integration Responsible Officer
IO-PARO	IO Procurement Arrangement Responsible Officer
IO-QARO	IO Quality Assurance Responsible Officer
IO-RO	IO Responsible Officer, who can be IO-TRO, IO-PBS-RO, IO-WBS-RO, etc.
IO-SRO	IO Safety Responsible Officer, who is assigned by EPNS-DH, as necessary
NCR	Non-Conformity Report
PA	Procurement Arrangement
PCR	Project Change Request
PCR-L3	Project Change Request Level-3
PIA	Protection Important Activity
PIC	Protection Important Component
RACI	R: Responsible, A: Accountable, C: Consulted (Review), and I: Informed
SIC	Safety Important Class
SL	Section Leader
SSC	Structure, System and Component

4 Applicable and References Documents

4.1 Applicable Documents

[1] ITER Quality Assurance Program	[22K4QX_v8.5]
[2] Sign-Off Authority for Project Documents	[2EXFXU_v4.0]
[3] Document Management Procedure	[22K5JQ_v6.3]
[4] Procedure for Configuration Control, Review and Audit	[TZY7YV_v1.2]
[5] Project Change Procedure	[22F4E5_v7.1]

4.2 Reference Documents

[6] IO Deviation Request Template	[2LRNQP, Latest]
[7] Nuclear safety common definitions	[RLZXMV_v1.9]
[8] Procedure for Management of Nonconformities	[22F53X_v7.0]
[9] Design Change Control Procedure	[U2QPDS_v2.0]

5 Basic Principles

- DR is issued before the deviations from clauses in a signed contract or in a mutual agreement after that, e.g. any implemented change request,
- IO-DR is only for non-technical deviations,
- The deviation to escalate to different change control frameworks, e.g. PCR, EPNS Meeting, as necessary. The escalation criteria are shown in **Table 5.1**,
- From safety point of view, the impact of a DR shall be analysed regarding the risks, etc. linked to the Authorization Basis [RLZXMV] of the ITER INB,
- DR process starts with the **MQP-L3 Template** [2LRNQP]. Eventually, the dedicated IT system to be developed and implemented in order to facilitate all the rules and the process steps specified in this procedure,
- DR should contain or refer to all relevant materials for the justification including impact analysis and trade-off study. Attachments are recommended instead of long sentences in the form,
- 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.
- The deviation shall be implemented only after the approval by IO,
- At the close-out of the activity, e.g. contract, the deliverable package is verified with respect to the approved DR as well as other input documents,
- Reviewers and approvers are specified in **Section 7.2**. Sign-Off Authority for Project Documents [2EXFXU] to be consistent later,
- The term to the closure in RO-level should be no longer than 2 weeks. Additional one week is reserved for the decision by IO-DH level[3],
- In urgent case, it can be shortened through the mutual agreement between IO and DA/CON, and
- Dispute and recording related rules are described in **Sections 8** and **10**, respectively.

[3] DR is used in a contract (including PA) level, which is normally managed by IO-(T)RO. After a dispute longer than two weeks, it automatically escalate to one level the higher, e.g. DH-level. If the IO-RO is DH, immediately after the two weeks of the initiation, it escalates to PCR as specified in Section 8.

5.1 Criteria for Escalation

The general criteria for escalation are shown in **Table 5.1**. Decision maker for escalation is specified in **Section 7**.

Table 5.1 General criteria for escalation to PCR, i.e. CCB-level-2 or the higher[4]

#1	Safety / Regulation	- Deviation from any regulation applicable to IO. - Deviation from Nuclear Safety defined requirements for PIC and/or PIA.
#2	Baseline	- Deviation impacting on a Baseline Document Level 0 / 1 / 2
#3	Interaction[5]	- Deviation impacting other PBS (Level-1) - Deviation impacting other processes related to other PBS (Level-1)
#4	Impact on Performance	- Implication on functional performance
#5	Dispute	- Dispute without successful mutual agreement

6 Work Flow

6.1 Flow Charts

In **Fig. 6.1** and **6.2**, two flowcharts for 1) DA/CON-DR and 2) IO-DR are shown, respectively.

[4] The same criteria as for NCR are applied for the decision of escalation to "Major"[3E65VE].
[5] If DR impacts on different PBS-Level-2 nodes within the same PBS-Level-1, this can be a case of escalation to SL or DH level (See 6.2.7)

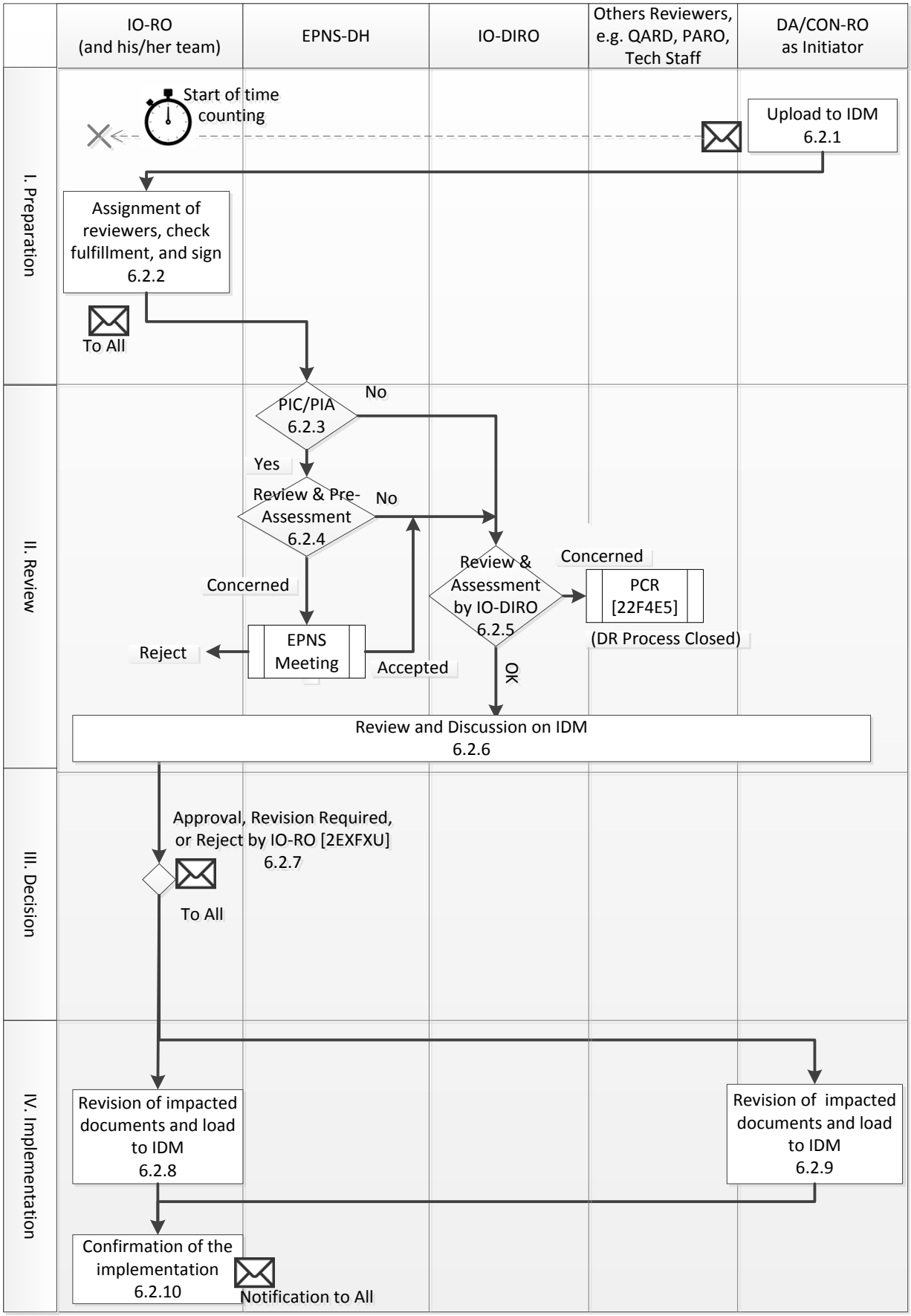

Fig. 6.1 Work Flowchart of DA/CON-DR.

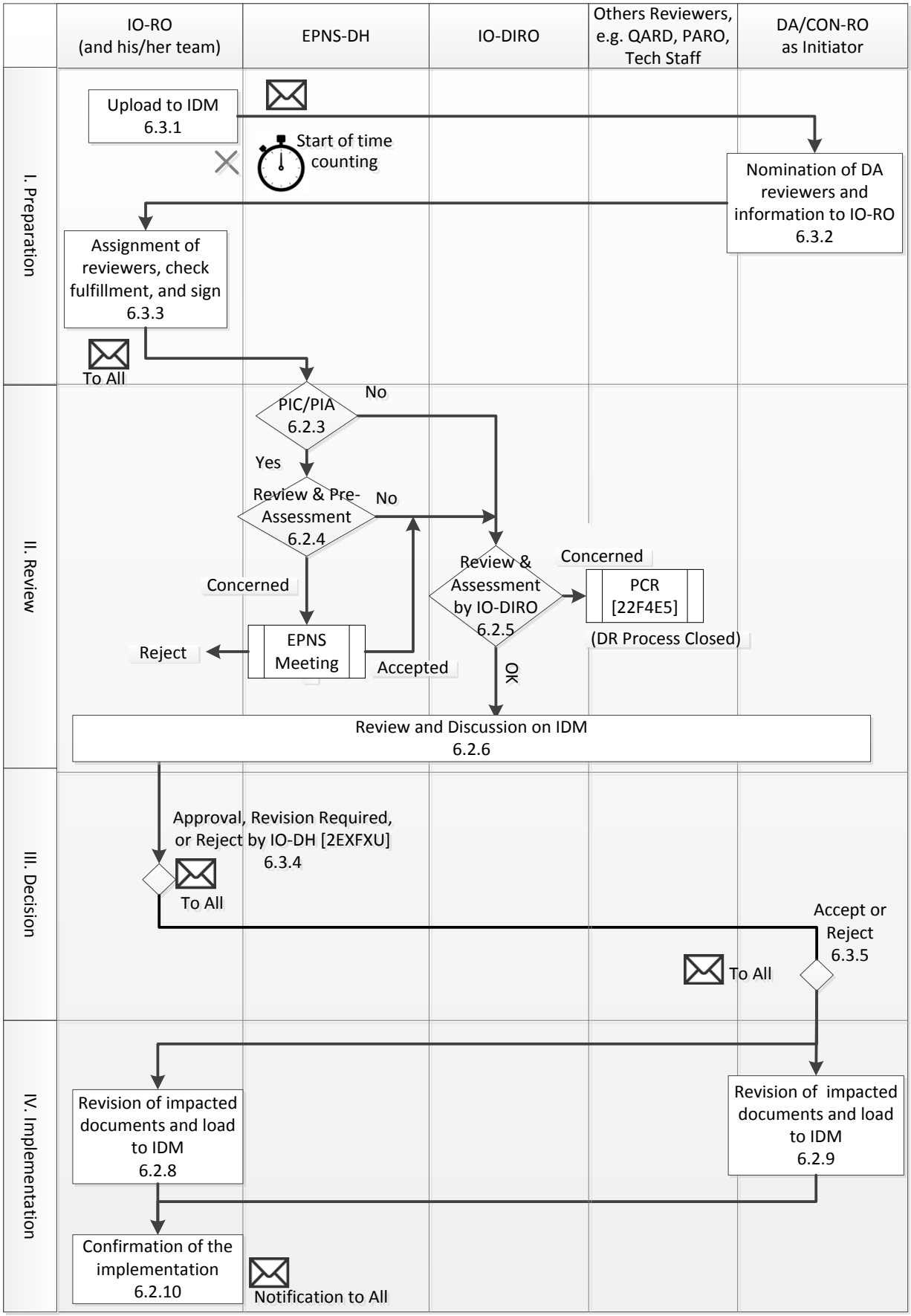

Fig. 6.2 Work Flowchart of IO-DR

6.2 Description for DA/CON-DR Process

The process consists of four phases, namely:

I. Preparation,
II. Review,
III. Decision, and
IV. Implementation

As shown in **Fig. 6.1**, the DA/CON-DR process is executed throughout the following steps.

I. Preparation:

6.2.1 Upload to IDM

- DA/CON-RO:
  - To upload the DA/CON-DR to IDM,
  - To use the form in **MQP-L3 Template** [2LRNQP],
  - To sign on IDM as the initiator,
- From the sign on the DR, the time to the due is counted.

6.2.2 Assignment of Reviewers and Fulfilment Check

- IO-RO:
  - To assign the reviewers on IDM including their specific responsibilities according to **Section 7.2** ([2EXFXU] to be consistent later),
  - To invite PA-RO for PA-related DR's,
  - To check the DA/CON-DR in terms of fulfilment,
  - To be consulted by the initiator regarding Safety-Tags,
  - To sign, as necessary
  - To inform ready for review to all the assigned reviewers using the Email-function of IDM.

II. Review:

6.2.3 Check on Safety-Tags for PIC/PIA

- If the safety tag is ticked, EPNS-DH to verify regarding safety related aspects, in order to judge the necessity of escalation.

6.2.4 Review and Pre-Assessment

- If the DR is found a potential impact on the Authorization Basis [RLZXMV] by EPNS-DH, EPNS Meeting is to be organized,
- Where EPNS-DH to decide Accept, Reject and/or Escalation,
- Section 4 in the template to be fulfilled, and
- Once accepted by EPNS-DH, the process moves forward to 6.2.5.

6.2.5 Review and Assessment by IO-DIRO

- IO-DIRO to assess the technical aspects from system integration point of view,
- If IO-DI-RO finds the necessity of escalation respecting #2 to #4 in **Table 5.1**, the DR escalates to PCR, and
- Section 5 in the template to be fulfilled.

6.2.6 Review and Discussion on IDM

- All assigned reviewers to review and to discuss on IDM,
- Note that escalation to the higher level of change control mechanism can happen at any time during the review process[6], and
- Other reviewers from EPNS-DH and IO-DIRO can start to review and to comment without waiting for the assessment results by them (6.2.3 to 6.2.5).

III. Decision

6.2.7 Decision by IO-RO

- IO-RO to decide Approval, Revision Required, or Rejection,
- If the impact-level is recognized higher than IO-RO level, then IO-RO to consult with SL and/or DH in order to change the approver into a higher level of manager, i.e. SL or DH (See the footnote of **Table 5.1**),
- At rejection, the DR returns back to 6.2.1 after the revision, dispute for the escalation or withdrawn,
- If DA/CON does not agree, the DA/CON can appeal for the decision change to the higher level, as explained in **Section 8**,
- At any decision, IO-RO to inform all the reviewers, using the Email-function of IDM, and
- IO-RO to distribute the link to the one level higher line-management, e.g. SL, DH, in CC, as necessary.

IV. Implementation

6.2.8 Revision of Impacted Documents and Load to IDM by IO-RO

- The DR should appear in revision histories of all impacted documents.

6.2.9 Revision of Impacted Documents and Load to IDM by DA/CON-RO

- The DR should appear in revision histories of all impacted documents.

6.2.10 Confirmation of The Implementation

- IO-RO to notify the implementation to all the stakeholders by the Email feature of IDM,
- Configuration Status Report [TZY7YV] is also used in order to ensure the implementation with new version of the documents.

All revised documents shall be included in the close-out dossier, e.g. as-built dossier, in order to ensure their implementation.

6.3 Description for IO-DR Process

As shown in **Fig. 6.2**, the IO-DR process is executed through the following steps. **I. Preparation** and **III. Decision Phases** are different from the DA/CON-DR process.

I. Preparation

6.3.1 Upload to IDM

- IO-RO to issue DR after internal discussion, using the same template [2LRNQP].

6.3.2 Nomination of DA/CON Reviewers and Information to IO-RO

- DA/CON-RO to nominate reviewers from the DA/CON side, and to inform them to IO-RO

[6] However, early decision for escalation is recommended in order to shorten the process time to the close out.

6.3.3 Assignment of Reviewers

- IO-RO:
  - To assign all reviewers on IDM, according to **Section 7.2** ([2EXFXU] to be consistent later),
  - To assess the fulfilment,
  - To sign on IDM, and
  - To inform the link to all stakeholders.

II. Review

The work steps shall follow 6.2.3 to 6.2.6 in the **II. Review phase** of the DA/CON-DR process.

III. Decision

6.3.4 Decision by IO-DH

- IO-DH to Approve, Request for Revision, or Reject, and then to inform, as necessary.

6.3.5 Decision by DA/CON-RO

- DA/CON-RO to Accept or Reject the approved change, and then to inform all the stakeholders, as necessary
- The IO-DR cannot be implemented any alternative solution without the acceptance[7] by the concerned DA/CON-RO(s),
- In case of dispute, the resolution should be made in the escalated levels of authority,

IV. Implementation

The work steps shall follow 6.2.8 to 6.2.10 in the **IV. Implementation Phase** of the DA/CON-DR process.

7 Responsibilities

7.1 General Responsivities

- IO-RO, his/her higher line management, EPNS-DH and IO-DIRO have authorities to escalate a DR to the higher change control system, e.g. PCR, as necessary,
- EPNS-DH to ensure that any changes are assessed with respect to the Authorization Basis [RLZXMV] (the criteria #1 in **Table 5.1**.)
- IO-DIRO to confirm that DR does not involve higher level of technical impact than #2 to #4 in **Table 5.1**,
- IO-PARO to review only if the DR relates to a Procurement Arrangement, PA,
- IO-QARO to check the compliances of the DR process respecting this procedure, the assigned reviewers or approver according to **Section 7.2** ([2EXFXU] to be consistent later), and other concerned quality documents, e.g. Quality Plan,
- Some roles in the flow charts can be delegated [2EXFXU]. For instance, the responsibility of EPNS-DH to be delegated to IO-SRO by EPNS-DH, as necessary, and
- Overrule by the higher line-manager is allowed.

[7] The acceptance by the DA/CON is temporary recognized as "Recommendation" in the IDM Review. Eventually, the dedicate IT system with "Acceptance by DA/CON" button after "IO-Approval" to be implemented

7.2 Specific Roles and Responsibilities

Specific roles and responsibilities for DA/CON-DR and IO-DR are shown in **Tables 7.1** and **7.2**, respectively, as RACI Matrices.

Table 7.1 RACI Matrix for DA/CON-DR Process

Step#	Responsibilities	IO-RO	IO-SL	IO-DH	EPNS-DH	IO-DIRO	IO-QARO	IO-PARO	IO-Tech Staff	DA/CON-RO
I. Initiation										
6.2.1	Upload DA/CON-DR to IDM,	I	-	-	-	-	-	-	-	**R**
6.2.2	Assign reviewers and approver, check if all necessary contents are properly fulfilled, and sign. (Regarding safety tag, to be consulted)	**R** (C)	I	I	I	I	I	I	I	I
II. Review										
6.2.3	Check if PIC, PIA and/or SIC are ticked	-	-	-	C	-	-	-	-	-
6.2.4	If yes, review and pre-assess with respect to the Authorization Basis Escalate the DR to an EPNS meeting and/or PCR, as necessary,	-	-	-	C,**A**	-	-	-	-	-
EPNS Meeting	Decide Accept, Reject (unless revision) and/or Escalation	I	(I)	(I)	**A**	(I)	(I)	(I)	(I)	I
6.2.5	Review and assess the technical scope respecting criteria #2 to #4, and decide an escalation to PCR, as necessary	I	(I)	(I)	(I)	C,**A**	(I)	(I)	(I)	I
6.2.6	Review DA/CON-DR as a member of the team of IO-RO	C	(C)	(C)	C	C	C	C	C	C
III Decision										
6.2.7	Decide Approve, Revision Required or Reject of the DA/CON-DR	**A**	I (**A**)	I (**A**)	I	I	I	I	I	I
IV Implementation										
6.2.8	Revise impacted documents to IDM, as required	**R**	-	-	-	-	-	-	-	-
6.2.9	Revise impacted documents to IDM, as required	-	-	-	-	-	-	-	-	**R**
6.2.10	Confirm the implementation and inform all stakeholders	**R**	I	I	I	I	I	I	I	I

*) Parenthesis, () mean “as necessary.”

Table 7.2 RACI Matrix for IO-DR Process

Step#	Responsibilities	IO-RO	IO-SL	IO-DH	EPNS-DH	IO-DIRO	IO-QARO	IO-PARO	IO-Tech Staff	DA/CON-RO
I. Initiation										
6.3.1	Upload IO-DR to IDM,	**R**	-	-	-	-	-	-	-	I
6.3.2	Nominate necessary reviewer from DA/CON side	I	-	-	-	-	-	-	-	**R**
6.3.3	Assign reviewers / approver, check if all necessary contents, e.g. PIC, PIA, and/or SIC are properly fulfilled, and sign	**R**	I	I	I	I	I	I	I	I
II Review										
6.2.3 to 6.2.6	The process and the responsibilities are the same as for DA/CON-DR									
III Decision										
6.3.4	Decide Approve, Revision Required or Reject of the IO-DR	I	I	**A**	(I)	(I)	(I)	(I)	(I)	I
6.3.5	Accept or Reject the IO-DR after the approval by IO.	I	I	I	I	I	I	I	I	**A**
IV Implementation										
6.2.8 to 6.2.10	The process and the responsibilities are the same as for DA/CON-DR									

Mandatory and optional reviewers are specified in the foot note[8]. SOA [22F4E5] to be consistent with this definition later.

8 Dispute and Resolution

In case of dispute, how to escalate the DR to PCR is as follows:

[8] Mandatory or Optional Reviewers (M: mandatory and O: optional)

	DA/CON-DR (Tech)	DA/CON-DR (Admin)	IO-DR(Admin)
IO-(T)RO	M*[1]		M
IO-SL	O		M
IO-DH	O		M*[1]
IO-Eng-Staff	O		O
DA-RO	M		M
DA-Staff	O		O
IO-EPNS-DH	M		M
IO-DIRO	M*[2]		O
IO-QARO	M		M
IO-PAIO	M*[3]		M*[3]

*[1] Approver as default

*[2] When the DA/CON-DR is found administrative without any technical discussion, DIRO is optional

*[3] Mandatory only for PA-related

- Appeal to the higher management is granted to both IO-RO and DA/CON-RO,
- DR process should be closed no longer than 3 weeks including the additional one week of discussion involving IO-DH, otherwise the request escalates to the PCR, automatically, and
- If it is not settled even after DH-level, the DR to be listed automatically in project issue list, https://jira.iter.org/secure/RapidBoard.jspa?rapidView=45&projectKey=PIM

9 Link with Other Processes

9.1 Interactions with Configuration Management Process

- Change on Configuration Items is based on [TZY7YV].
- After the escalation, it is managed as PCR respecting [22F4E5].

9.2 Interactions with Safety Process

- EPNS-DH and/or IO-SRO to review a DR from safety point of view.

9.3 Interactions with Design Control Process

- DIRO to review a DR from system integration point of view,
- Global design integrity to be ensured respecting Design Change Control Procedure [U2QPDS].

10 Outputs (Records, Deliverables, Implementation Plans….)

- IO-RO, DA/CON-RO, EPNS-DH and IO-DIRO to fill up **MQP-L3 Template** [2LRNQP] [9],
- All the parameters to be fulfilled in order to realize a) cross-references between DR's and impacted documents, hardware, processes, stakeholders, etc., and b) full traceability,
- The approval field shall be signed by IO-RO or IO-DH. The acceptance field to be signed by the impacted party, e.g. DA/CON-RO,
- Decision making process including the escalation history should clearly recorded,
- Alternative formats which include the essential metadata may be acceptable. They should be subject to the acceptances by both the IO-RO's and IO Quality Assurance Division in advance of their intended use,
- Maintain a DR-register with future IT system including all relevant metadata, e.g. status, distribution. Where each rejected DR should be also recorded,
- The implementation to be recorded on each impacted IDM document in the revision history logs, and
- **Table 10-1** summarizes the document management in this DR process.

Table 10-1 Output document of the DR process

Type of output	Format (Template, form, checklist)	Location of output	Document type	Instructions for identification of the output	Responsible for managing the output	Retention period
Deviation Request	Template: [2LRNQP]	As IO-RO specifies	Deviation Request	IDM procedures (in future, the dedicated IT-system)	IO-RO	Project lifecycle.

[9] Tentatively, reviews and assessments by EPNS-DH and IO-DIRO to be carried out with the IDM system with their comments and recommendations.