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MQP Level 2

MQP L2 Procedure for Management of Nonconformities

The purpose of this document is to specify the Nonconformity Management process, hereinafter NC from the Initiation to the Closure in the IO NC system. The Workflow as well as the Roles and Responsibilities of each stakeholder are specified in a generic way.

Approval Process			
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Change Log			
MQP L2 Procedure for Management of Nonconformities (22F53X)			
Version	***Latest Status***	***Issue Date***	***Description of Change***
v1.0	In Work	25 Feb 2005	
v2.0	In Work	14 Sep 2005	
v3.0	In Work	14 Dec 2005	
v4.0	In Work	28 Feb 2006	
v4.1	Signed	10 Apr 2008	
v4.2	Signed	10 Apr 2008	
v4.3	Signed	11 Apr 2008	
v4.4	Approved	11 Apr 2008	
v5.0	In Work	18 Jun 2012	Definitions of Deviation and Specified Requirement clarified and immediate notification and agreement of classification of non-conformances introduced
v5.1	Approved	18 Jun 2012	Minor editorial change to contents
v6.0	Approved	02 Apr 2013	- modification of the title - add the following steps in the process for non-conformities: - root causse analysis - corrective action (if needed) - closure of NCR
v6.1	Approved	25 Jun 2013	Modifications according to approved MQP Doc Request G23MB4: - Changes to allow verbal agreement on remedial actions when the non-conformance does not impact on an external system - Minor NCR: the section 1, 2.1 and 2.2 need to be filled and sent to IO
v6.2	Approved	13 Mar 2015	Changes according to MQP doc Request - QWRRS2: - Addition of an explanatory footnote for PIC and PIA - Addition of PIA with PIC - Addition of list of internal NCRs to be sent to IO upon request of QARO
v7.0	Approved	18 Aug 2017	Update according to MQP doc request VBFECU (the summary of pre-reviews: MQPWG, SQAWG, SD, Construction Teams... can be found in the MQP doc request VBFECU). The changes consists in clarification, simplification by making the document generic (thus applicable to all phases; not only to Manufacturing but also to Construction), and rework of the document according to the MQP template 438T76: - Process NC introduced (not product NC as previously understood); - Simplification of number of documents (starting situation was 6 documents level2): 22F53X is now the Level 2 MQP for Nonconformity management, e.g. merging RGF2R7 (PT), dealing with both external IO NC and internal IO NC. - The workflow and roles rendered generic (e.g. notion of DIRO now extended to 'interaction RO', so that it can encompass Construction Teams). - Clarified list of criteria (Baseline, Performance,...) to guide in the categorization of NC (major / minor), still keeping the same criteria regarding Regulatory Requirements, Safety, Environmental impact. - The requirement of paragraph 2.9 of revised QAP version 8.5, and GIN007 (General Instruction Note from DG), are propagated: tracking of NC closure; re-enforcement of tracking mechanism of actions until implementation. - KPI of the process and escalation process (in case of dispute) are introduced.
v7.1	Approved	11 May 2018	As per MQP doc Request - WK69F2 Includes Module H needs
v8.0	Revision Required	10 May 2019	as per approved MQP doc Request - XYLYX5: - requirements regarding Counterfeit, Fraudulent, and Suspect Items (CFSI)

			as per Safety Division Action plan (definition CFSI included, clear requirement for SD involvement and responsibilities). - clarify the IO NC approval level (process owner / DH) as per NCR database application - reference of JIRA CAT system to be applied for action follow-up - clarification related to minimum time - frame from NCR detection until NCR recording (maximum two weeks is allowed). - clarifications regarding intermediate / conditional release of NCR that requires further long term actions (further actions and instruction to be recorded in release note).
v8.1	Signed	14 Jun 2019	Revision to implement reviewer comments from previous version. List of changes: - add reference - XKUKAX - add DAs responsibilities (as per NCR database application) - add clarifications regarding baseline levels (see chapter 5.1 and annex 2) - add further clarifications for NCR conditional release. - add annex 2 - Baseline level map as per [11] - add clarifications on appendix 1 - NC form
v8.2	Approved	17 Jun 2019	Revision - Technical IDM issue. Revision as per MQP doc Request - XYLYX5 & to implement reviewer comments from previous version. List of changes: - add reference - XKUKAX - add DAs responsibilities (as per NCR database application) - add clarifications regarding baseline levels (see chapter 5.1 and annex 2) - add further clarifications for NCR conditional release. - add annex 2 - Baseline level map as per [11] - add clarifications on appendix 1 - NC form
v9.0	In Work	19 Mar 2021	- Chapter 3.1 – arrange definition – alphabetic order - Chapter 3.1 – add the following definitions: o Causal Analysis Tree o Contractor o Inter-Organization Non-Conformity (I-NC): o IO NC system (add note for clarification NC database scope) o PE Group o Scrap (remedial action) o Root Cause Analysis (RCA) o Service o Service provider - Chapter 3.2 add the following abbreviations: o CAT; I-NC, PBS, PROR, SCG - Chapter 4.1 add the following references o [31] How to – Long Aging NCRs management 3CZWDX o [32] Risk and Opportunity Management Procedure 22F4LE o [33] Management review procedure 3L7SWX o [34] Lessons Learned meeting Procedure DV4UUH o Add note “The procedures are applicable to the DAs, only if they are listed in the Multi Party Amendment (MPA).” - Chapter 5.1, 5.2, 5.3 and 5.4 o Change the structure of procedure to reflect the NCR stages o For NCR categorization ITER_D_4HCC3W - HOW TO - NCR Categorization was added o Add RCA categories and Causal Analysis Tree (CAT) o Add mandatory requirements to defined expected due dates for decided remedial actions o Add mandatory requirements to defined expected due dates for NCR closure

			o Add specific section for Inter-Organizational Non-Conformity (I-NC) o Add requirements for application of fast NCR closure – applicable only for minor NCR o Add specific section for Conditional Release of NC. o Add clarification for RCA methodology - ITER_D_2X4E9A - Root Cause Analysis Leaflet o Add clarification for NCR closure o Add interaction with the risk and opportunity process. - Chapter 5.5 – changes to introduce specific requirements for Module H and H1. - Add chapter 5.7 – Internal NC of Performers - Chapter 7 – change the responsibilities for process owner and DH – for IO NCRs - Chapter 9.3 – add requirements for "Nonconformities survey process for PIC and PIA"
v9.1	Approved	19 Mar 2021	Technical issue
v10.0	Revision Required	09 Sep 2025	This new version has been issued following the draft review by DA QLT representatives (EAZQRL) and key changes are - Implement IO reorganization changes (include responsibilities for IO program managers and project managers and DIRO / SIRO). - Include the prevision of GIN 007 inside procedure - Simplification of stage 1a - Include NCR prioritization (high priority/ medium priority / low priority) - RCA clarifications (reference to IO How to). - Introduce concept of simplified RCA and complex RCA
v10.1	Signed	15 Oct 2025	Review comments from the previous version have been addressed and reflected in this version.
v10.2	Signed	17 Oct 2025	Typo correction
v10.3	Approved	20 Oct 2025	Clarification regarding the approver of IO internal NCR

Table of Contents

1 Purpose and Scope

The purpose of this document is to specify the Nonconformity Management process, hereinafter NC from the Initiation to the Closure in the IO NCR database.

This procedure shall be followed for the management of nonconformities detected during all ITER project phases (from the design, manufacturing, installation, commissioning, until operation/ maintenance).

- for both types of NCs: Product NC and Process NC
- by both internal and external performers (IO/ DAs/ suppliers / contractors).

OUT OF SCOPE

Cost and schedule issues to be treated as per contractual requirements and IO processes requirements.

NC of Quality Audit (applicable procedure is [16]).

Management of OHS nonconformities (applicable procedures is [25]).

Minor NC of Nuclear Safety Inspection (applicable procedures is [10][25])

2 Basic principles

2.1 General principles for NC management

The main steps for the methodology for NC management are as follows:

a) STOP WORK & SEGREGATE the NC
b) RECORD / INITIATE the NCR (Stage 1a)
c) EVALUATION of NC (Stage 1b):
d) CLOSURE of NCR (Stage 2):

2.2 Disputes & resolutions

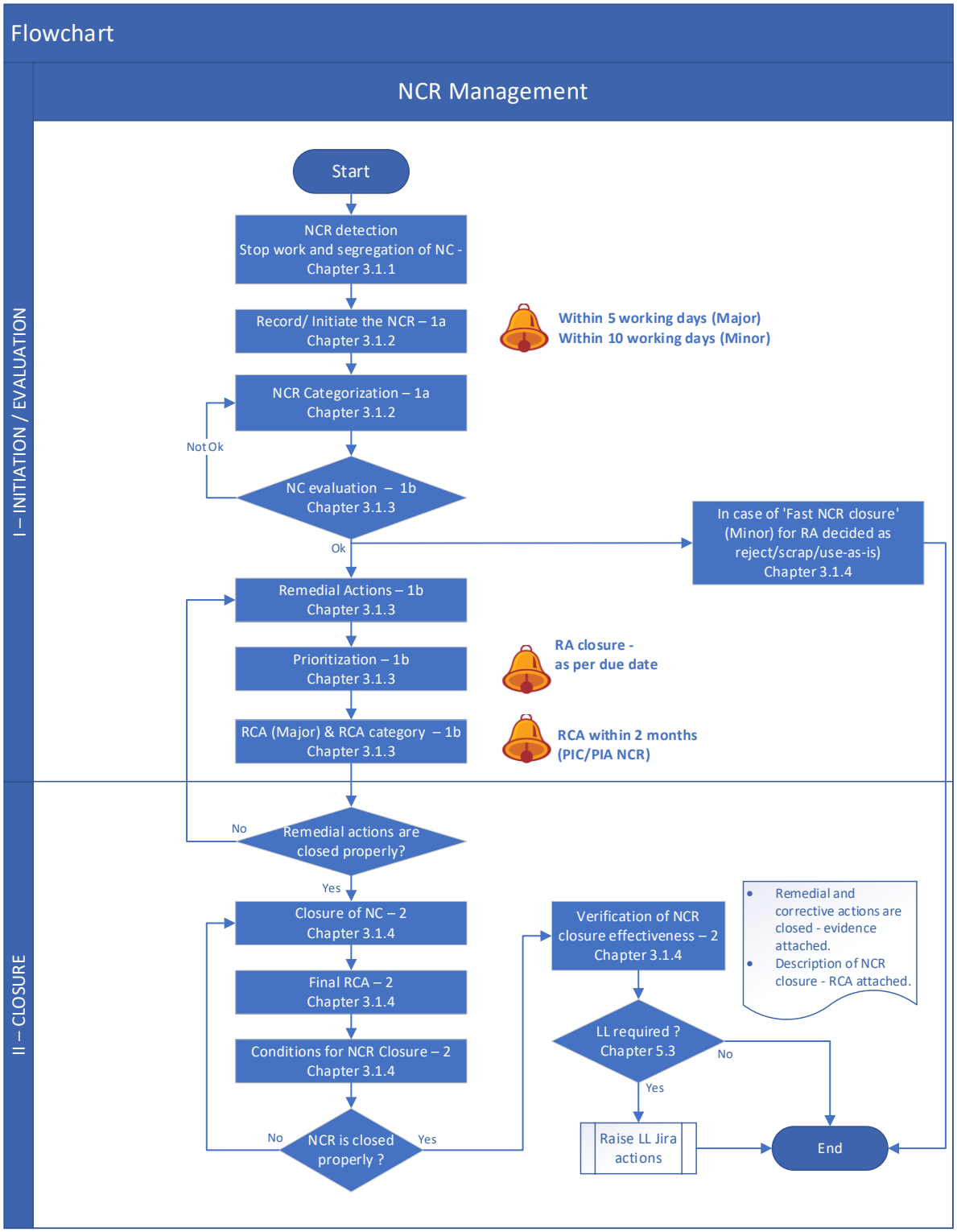
Criteria for triggering escalation includes but is not limited to: dispute on the way to close a NC, dispute on ownership of NC; as an example, when there are multiple interfaces involved (e.g. different systems, multiple Performers and organizations …), dispute regarding resources (costs, staff, contacts) required to close the NCR.

In IO, the mechanism to escalate NCRs is as follows:

- Submission of the NC first to Project Leader / Section Leader level.
- If resolution within IO is not gained at fist level of escalation, then the NC it will be submitted to the Program Manager / Division Head level.
- If still no resolution/ decision is made, then the issue will be escalated on upper level – Department Head or Director General level.

The disputes and resolution regarding costs shall not be overlapped with Inter organization-NC mechanism [21].

3 Workflow – Flowchart



3.1 Description of steps

3.1.1 Stop work & segregation of NC

This step shall be applied before NCR is recorded in NCR DB, just after detection of NC. The entity affected by the NC (performer) shall stop work / isolate the non-conform product immediately. The stop work shall be applied with IO agreement only.

The entity shall inform immediately the IO TRO / IO CRO / IO Management (Project Leader or Program Manager) & DA TRO (for PA implementation). The stop work should be connected with the non-conform product /component within limited area impacted by the respective NC and not with all contractual activities assigned to the performer/contractor.

The performer shall isolate/ segregate the non-conforming items (where practical) by placing them into a clearly identified and designated hold (quarantine) area until completion of remedial actions.

Where impractical, the non-conforming item may remain in the manufacturing/installation area but shall be clearly identified/labelled to avoid misuse.

3.1.2 NCR initiation – 1a

Who can raise/initiate an NCR? Any person who detects a Nonconformity. Can be any stakeholder of the ITER project (IO and DAs staff, supplier/ contractor staff, etc.).

During NC initiation stage – 1a, the following points need to be addressed (but not limited):

- Recording the NCR (Description of the problem)
- NCR categorization (major / minor)

RECORDING of NCR

Once NC is detected, the initiator will record the NC in the IO NCR database (status "Submit"). NCR shall be submitted in the NCR DB within maximum 5 working days for Major NCRs and 10 working days for Minor NCRs to initiate the NC review/ approval process.

In case of dispute between stakeholders, maximum two weeks from the detection time may be allowed with IO agreement only.

The NCR detection date shall be connected with the date when nonconformity was clarified - the NCR triangle conditions are confirmed:

- Requirements – are clearly identified
- Finding – non-fulfilment of requirements is confirmed
- Evidence – clear evidence of finding are available

The disputes and investigations period required for confirmation of NCR shall be considered as preparatory period and should not be counted as period between detection and NCR recording/submission.

For use of IO NCR database, stakeholders shall apply detailed instructions [27]

The stage 1a (NCR initiation/recording) does not require full IO review cycle in NCR database. The review cycle for stage 1a, will involve the following stakeholders only: initiator, Submission RO (performer – responsible for NCR closure), DA (when applicable), QARO and IO approver.

For specific cases, the NCR approver may request additional IO reviewers if specific expertise and evaluations are required.

The stage 1a (NC initiation) and stage 1b (NC evaluation) can be merged into one stage (1b) - if the initiator or NCR have all the necessary information like: description of NC, categorization, prioritization, remedial actions, RCA and due date for NCR closure.

In case during the review / approval cycle, the NCR is rejected, then the performer is immediately informed and will have the responsibility to restart / re-submit the NCR only after all the conditions are agreed and applied. In case of disputes, the NCR approver shall ensure further escalation as per – section 2.2 of present procedure.

NCR CATEGORIZATION

The NCRs are categorized as MAJOR or MINOR. The NCR categorization shall be agreed between:

- NC initiator (propose the NC categorization), /
- Performer (propose the NC categorization),
- DAs TRO (provide support and agreement for NC categorization) in case of PAs implementation.
- IO approver with support of IO QARO (final confirmation of NC categorization)

Criteria for NCR categorization are presented on **annex 1** of present procedure.

The detailed requirements /clarifications regarding NCR categorization are also described in the [28]

3.1.3 Evaluation of Nonconformity – Stage 1b

During NC evaluation stage – 1b, the following points need to be addressed (but not limited):

- NCR Prioritization
- Remedial actions: recorded in NCR database and agreed with NCR approver
- Root Cause Analysis (RCA): applied for major NCR and propose corrective actions
- RCA categorization: recorded in NCR database – see annex 3 (when required)

For all the decided remedial actions the expected due dates and responsible for closure need to be established and recorded in NCR Database – Stage 1b. Also, during stage 1b, the expected due date for NCR closure needs to be established and approved.

NCR PRIORITIZATION

All the NCRs shall have allocated a priority considering the impact on cost and schedule.

NCR priority is proposed by performer (responsible for NCR closure) and accepted by IO NCR approver. There are 3 NCR priorities:

- High priority – P1
- Medium Priority - P2
- Low priority – P3

NCR prioritization criteria and requirements can be found in detailed instruction [29]. NCR priority is only connected to the target date for NCR closure but not with the NCR criticality/importance.

Once the NCR priority is established, a graded approach will be applied for NCR monitoring and reporting:

- NCR with high priority will be periodically reported (by QMD) to IO management (Program Managers, Project Leaders, and Department Heads) and DAs (when applicable). The NCRs with high priority are categorized as blockers (with impact of project milestones / schedule and costs) and the closure of such NCRs shall be taken as high priority.
- NCR with medium and low priorities does not require reporting to IO management or DAs but normal process of NCR follow-up and on time closure.

REMEDIAL ACTION

The Performer shall propose a final remedial action such as Use as is, Rework, Repair, Reject, Scrap, or Other, and provide a clear justification supporting the proposed remedial action.

ROOT CAUSE ANALYSIS (RCA)

During stage 1b, RCA is required.

The RCA shall be prepared by the performer and recorded in NCR database, during stage 1b (if all the required information and data are available at this stage), otherwise the RCA will be prepared and recorded in the stage 2 (NCR closure) as final RCA.

The RCA is required to be applied for all NCs in accordance with the following criteria:

- For major NCR's, the RCA need to be accepted by IO and shall be recorded in NCR Database.
- For minor NCR's, the RCA does not require IO acceptance and shall be under performer responsibility only. For specific cases decided between performer and NC owner (approver), the RCA may be submitted to IO for acceptance and recorded in NCR Database.

For major PIC / PIA NCRs the RCA shall be prepared within maximum 2 months. For the rest of NCRs, the RCA should be prepared as soon as possible considering also the target date for NCR closure.

For exceptional cases the time required for RCA preparation may be extended with IO acceptance. Considering the criticality and complexity of the NCR, NC-Owner (approver) can request:

- Complex RCA - RCA methodology (5 Why, Ishikawa diagram, etc.) shall be applied and RCA report need to be prepared separately and attached in NCR database – the RCA report shall be reviewed and approved by the same stakeholders involved in the NCR review cycle or
- Simplified RCA (RCA can be recorded directly in the NCR DB and does not require separate RCA report).

For Complex RCA, the performer (responsible for RCA) shall arrange specific RCA meetings. The RCA report should have the following content (but not limited):

I. General information:
- Report title / NCR UID
- RCA team members.

II. NCR description:
- What happened? (Factual / objective description)

- When did it happened? Chronology of the events,
- Who was involved?
- What were the consequences? (impact on cost and schedule, safety, etc).

III. RCA methodology with identification causes, (5 why, Ishikawa diagram, etc)
IV. Corrective and preventive actions plan - with clear identification of responsibilities
V. Conclusions and lessons learned

For all the corrective actions indicated in the RCA, the expected due dates and responsible for closure need to be established and recorded in the RCA report and fully aligned with NCR expected closure date and NCR priority.

For Root Cause Analysis (RCA) application the following guidance may be used by the stakeholders - Root Cause Analysis Leaflet[19].

RCA CATEGORIZATION

with Causal Analysis Tree (CAT) evaluation shall be applied for all NCRs – see annex 3.

For Minor NCR, the application of RCA remains under performer internal responsibility and does not require IO acceptance. This approach regarding minor NCR evaluation does not release the performer from his responsibility to ensure correct evaluation of NCR, establishing the NCR Causes and corrective actions application.

The root-causes of nonconformities are categorized based on Causal Analysis Tree by the type of failure/ problems as following:

RCA category/ level	Description of RCA category by type of failure
A1	Design/ Engineering problem
A2	Equipment/ Material problem
A3	Human Performance problem
A4	Management (procedure/ process/ method) problem
A5	Communications problem
A6	Training Deficiency
A7	Other Problem

Each RCA categories/ levels (A) are also divided in sub-categories/ levels (B) as described in Annex 3 of present procedure. The sub-categories/ levels (B) – see annex 3, shall be recorded in the RCA report only.

The RCA category – level A, shall be recorded by performer in the NCR Database in the "Causal Analysis Category" section and confirmed by NCR approver.

Also, during the NC evaluation stage, after identification of NCR impact analyse, the NCR has to be linked (IDM, etc.) to the applicable documents (drawings, specification, procedure, etc.) that are affected by the NCR and requires future update. This task is under NCR approver responsibility.

3.1.4 NCR closure – stage 2

During NC closure stage 2, the following points need to be addressed (but not limited):

- Conditions for NCR closure

- Final Root Cause Analysis
- Actions management
- Conditional release of NC

CONDITIONS FOR NCRs CLOSURE

NCR category	Conditions for NCR closure
Major NCRs	All remedial actions and corrective actions are closed (respecting the expected due dates) and the evidence for remedial and corrective actions closure are recorded (attached to NCR for closure stage) in NCR database. (see note below) Final RCA is recorded in NCR database.
Minor NCRs	All remedial actions are closed (respecting the expected due dates) and evidence for remedial actions closure are recorded (attached to NCR for closure stage) in NCR Database. The RCA application for minor NCRs together with corrective actions implementation are under performer responsibility only and does not require IO acceptance (unless it is required by NCR approver).

Note : For specific cases, the major NCRs can be closed if the associated corrective actions are initiated and are strictly followed to a different controlled process (e.g. PCR, FCR, etc.). For such cases the performer shall provide evidence for corrective actions initiation and justifications for application of this exceptional rule.

Fast NCR closure may be applied for minor NCRs only, if the following conditions are meet:

- Fast NCR closure can be applied for minor NCRs where remedial actions are decided as:
    - reject,
    - scrap,
    - use as is – with no impact on products / systems functionality and/or no impact on activities/ services applied in the scope of ITER project.
- The related corrective actions (if necessary) for such NCRs, will be implemented internally by performers without affecting IO products and activities.

Fast NCR closure means, immediate NCR closure after stage 1b is reviewed and approved – does not require a new review / approval cycle for NCR closure by all stakeholders.

For major NCRs, that requires long period (more than one year) for closure, the performer may be requested by NCR approver to record intermediary progress of NCR and remedial/ corrective actions status.

FINAL ROOT CAUSE ANALYSIS (RCA)

Final RCA may be the same with the initial RCA if no additional information and no new corrective and preventive actions identified. Final RCA is applied when the initial RCA is not available during stage 1b.

ACTIONS MANAGEMENT

The IO NCR database records the actions (remedial/corrective actions) agreed with performers and the internal IO actions. For better follow-up of long-term actions (remedial/ corrective actions) assigned to IO staff, a separate system (JIRA CAT system) can be used following applicable procedure [17]. The link of JIRA CAT actions shall be recorded in NCR database for traceability.

If during the NCR treatment, risks and opportunities are identified then the NCR approver shall record them in IO register (PROR) as per procedure [22].

CONDITIONAL RELEASE OF NC

As a basic principle, the delivery of the items and/or reception or the activities shall be performed only if all the related NCRs are closed.

For exceptional cases, conditional release of NCR is allowed. Conditional release of NCR means that the products can be delivered / activities can be released with NCRs still open.

Conditional release of the NCRs can be accepted only after agreement between IO (NC approver) and DA's / performers. For such cases tracking and checking of remaining points/ actions is required, until the final closure of the NC and handover.

To ensure proper follow-up of conditional release of NCRs, the performer shall maintain the NCR open until all the decided remaining conditions / actions are closed.

For such cases when conditional release is applied, clear instructions/ actions shall be also indicated in the NCR and in the final delivery documentation (Release Note template – QVEKNQ or Punch list of Mechanical Completion Dossier – UYUSEE prepared as per [14] or [15]), to be taken into account on the next phases of the project.

If any impact on the next phases of the project, the NCR approver (or delegated) will communicate this information to the corresponding impacted entities (DAs, IO programs/ projects, etc).

Also, conditional release section in NCR DB, can be used to indicate the conditions and required actions to restart the works related to the NCRs that triggers stop work decision.

3.2 Case of NCR related to CFSI

All the NCRs related to CFSI cases shall be categorized as major NCRs.

All the NCRs related to confirmed CFSI case should have a specific flag (CFSI) in the NCR title to ensure easy identification and alert for the involved stakeholders.

The detailed requirements and responsibilities for treatment of CFSI cases are described in the IO procedure [12].

3.3 Internal NC of performers

During contracts / PAs implementation, the performers (DAs, Suppliers, contractors, sub-contractors) may identify internal NC that need to be managed internally within the performers organization without involving IO and other external entities.

Such internal nonconformities (NC) has the following characteristics:

- NC will not affect the final products and activities delivered to IO or different other entities (other DAs, supplier, contractor) in the scope of ITER project,
- NC will not have impact on contractual/ PAs requirements

- NC will not have impact on cost and schedule related to ITER project and
- NC will not have impact on regulatory requirements applicable for ITER project

The performer internal NCRs shall be managed in accordance with their internal NCR procedures.

The performers shall maintain full traceability and evidence for internal NCR closure, to be available during the IO/ DAs audits and inspections. Internal NC of performers shall be recorded using performer's NCR templates and internal database (if applicable). A list (log/ register) of internal NCRs needs to be maintained by the performer to allow strict control of NCR stages, trend reports and analyses. This internal NCR log shall be available at IO/ DAs request during the audits and inspections.

IO internal NCRs: For such NCR, the involved stakeholders will be mainly IO staff and review / approval cycle will respect present procedure requirements.

For IO internal NCRs the following specific requirements shall be applied:

- IO internal NCRs are the nonconformities that will have no impact and interfaces with other external entities (suppliers/ contractors, regulatory bodies) and /or DAs.
- Initiator – anybody who detects a nonconformity (IO, DAs, supplier / contractor staff).
- Performer – IO staff identified as responsible for NCR treatment / closure. Performer is recorded as NCR Submission RO.
- For IO internal NCRs the approver of NCR shall be Project Leader of the performer (Submission RO) or higher level. In case the NCR is not related to the construction Programs the approver is Section Leader of the performer (Submission RO) or higher level.

3.4 NCR follow-up till closure & KPIs

For each NCR, the expected due date for closure shall be established and recorded in NCR database – stage 1b (by the performer) and agreed with IO.

All the involved stakeholders shall respect the committed due dates for NCR closure[1] as one of the highest priority according to the [30].

For the NCR with due date more than 2 years, the NCR can be put on status "on hold" by the NCR approver provided that all the remedial actions, corrective actions are defined and initial RCA is finalized, and it can be resumed by the QMD when the target date for closure is less than 6 months away.

It is therefore requested to all entities involved in a NCR to anticipate and allow enough time for the IO to close NCRs by strictly applying the processes as defined the present procedures.

Key Performance Indicators - KPIs

The process KPIs and targets are annually established and reported during IO management review performed in accordance with applicable procedure [23].

Main process KPIs are connected with process implementation and shall cover:

- NCR submission time.
- Respect of target dates for NCR closure / on time NCRs.
- Required period for RCA release

[1] In case the expected due dates cannot be respected (with clear justifications), a graded approach shall be applied for extension of due dates for NCR closure as indicated in Annex 2.

Other specific KPIs may be established by QMD to ensure process performance measurement.

3.5 Responsibilities

#	Stakeholder	Responsibilities
1	Initiator	• Detect /identifies NC and notifies IO; • Alerts the involved parties, primarily the NCR approver as soon as practically possible and with necessary details; • Notify the Performer, if different from the Initiator; • Responsible for registration of the NC into the NCR database;
2	Performer/ Submission RO[2]	When Performer detects the NC, executes actions of Initiator as above; • Segregates NC, take immediate remedial actions. Stop (as per IO agreement) any further related work on the item until a decision on the NC is taken; • Ensure NCR evaluation. Perform RCA, as soon as practically possible (typically within maximum 2 month). • Propose remedial actions, propose NC categorization, NC priority and actions (remedial actions and corrective actions). • Provides evidence of progress of the NC treatment to the NCR approver in a pro-active and timely manner. • The performer is the designated entity for NCR closure, responsible for implementation of remedial/corrective actions and trigger the NCR closure stage in NCR database.
3	NCR approver	• IO Person responsible for the approval of NCR on all stages. • Initiate / trigger Project Change Request (PCR), if so requested by the DIRO/ SIRO during NCR review. • Verify the effectiveness of remedial and corrective actions. • In case of dispute to find and designate an approver, see section 2.2 of present procedure. • Approve the due date for NCR closure considering the NCR priority. • Agree on further needed Lessons Learned.
4	DA-RO	• DA Person assigned responsible: o For the coordination and control of the activities in the NC treatment within DA; o Ensuring that the NC is documented and recorded in the IO NCR Database correctly. o Triggering and guarantying the closure of the NC ensuring continuously interface/ communication with performer.
Mandatory reviewers		

[2]

Submission RO for IO internal NCR	NCR type
TRO / CRO	Product NCR
Entity/Individual affected by NCR	Process NCR

#	Stakeholder	Responsibilities
5	IO-SRO	• SRO review is only required for PIC/ PIA NCRs. • Checks if PIC, PIA, SR, are properly designated. • Agrees on the NC categorization (for NC concerning PIC and/or PIA). • Assess Safety impact and validates action proposal. • Confirms if there is a need for Safety Review of Regulatory Files [9] and / or Nuclear Safety Inspection [10], and call for those processes as necessary.
6	PE Group	• Checks if PE/ NPE are properly designated. • Agrees on the NC categorization (if the NC is PE/NPE relevant). • Consult (A)NB for major product NCR and process NCR • Assess statutory & regulatory impact and validates action proposal • Review with respect to Regulations [2], [3] & [4].
7	IO-Interactions RO (including DIRO / SIRO) For Major NC only	• Checks the NC potential impact on other areas than the original scope of the NC, review and confirm apparent cause analysis using CAT and remedial action proposal. • For NC at manufacturing stage, it includes the assessment of impact on Assembly, Installation and Operations. • Is part of the review process of the NC reports, as appropriate. • Analyze the NCR considering the design impact and if PCR is required to trigger further upper-level project changes as per [20].
8	IO-QARO	• Review the NCR and ensure compliance with the NC process • Review NCR categorization and NCR prioritization. • Verifies that a proper RCA has been conducted, and proper corrective actions and remedial actions are established • Checks the evidence required for NC closure, ensuring traceability of actions until implemented. • Detailed criteria for QARO review are included in the [31]
Additional reviewers		
9	IO-Tech Staff	• Person is designated by NCR approver as appropriate. • Review the NC regarding the technical aspects - added as additional reviewers of NC.

RESPONSIBLE FOR NCR CLOSURE/ TREATMENT

For each NCR, the responsible for closure (treatment) need to be identified. The responsible for NCR closure (treatment) is the performer who is identified as submission RO in NCR database.

If during NCR evaluation (stage 1b), the approver identifies that the responsible for NCR closure (performer) is a different entity/individual then he shall request to NCR admin to change the Submission RO name.

The changes of NCR Submission RO (responsible for NCR closure) shall be agreed in advance with the staff involved / supplier/ contractor. For IO internal NCRs, the line manager of NCR Submission RO shall be also informed. If the performer (submission RO) does not agree with the NCR, then he

can reject the NCR with clear justifications. In case of disputes, issue will be escalated according to section 2.2 of this procedure.

4 Records

All the NCRs are recorded and treated in the NCR database [32].

5 Interactions with other processes

5.1 Link with 'Quality Assurance' processes (QA audit, Corrective action)

The following procedures have the same goal of addressing nonconformities and having proper corrective actions implemented. These procedures are governed by the same principles based on standard quality practices: problem description, Root Cause Analysis (RCA), corrective actions implementation and verification of effectiveness. They are complementary to address all types of inputs.

- Nonconformities resulting from QA audits are managed through detailed steps described in [16].
- The Compliance actions management procedure [17] describes the process to manage Corrective Actions Requests as a result of other sources (for example DG decision, ASNR request, a management review…).
- What is important is that actions are implemented by one of the above process, and that there is no duplication. This verification is done by Quality Management Division QMD.

5.2 Link with 'Procurement' processes

As elements governing Quality Requirements for IO Performers [13]

NCs are an integral part of a contract. Upon completion of the work, NC reports together with relevant documentary evidence shall be included in the data package handed over to IO.

- For Manufacturing, it is governed by the Contractors Release Note template [14] and Manufacturing Dossier
- For Assembly & Installation, it is governed by the process for Mechanical Completion Dossier [15]

During execution of Inspection Plans governed by [13], if modifications appear to be necessary due to Nonconformity (such as repair…), the NC report should be referred in the Inspection Plan.

The products / activities shall be released for delivery only if all the related NCR's are closed.

The release of the PAs credits / contracts termination shall be applied if all the related NCRs are closed. For exceptional cases, please see conditional release - section 3.1.4.

5.3 Link with 'Nuclear Safety' processes

In the treatment of NC, SRO may trigger the need for the Review of Regulatory File (RRF) [9] or / and for a Nuclear Safety Inspection (NSI) [10].

Nonconformities survey process for PIC and PIA shall be performed by Nuclear Licensing & Oversight (NLO) in accordance with Articles 2.6.3, 2.7.1 and 2.7.3 of the INB Order.

On proposal of the NCR approver (see chapter 3.5 Responsibilities), learning from the NCR can be exported and further disseminated as defined in the Lessons Learned Procedure [24].

5.4 Link with 'Configuration Management' processes

In the NC categorization, one of the criteria is the level of control (level 0/1/2/3) of the IO Baseline Documentation impacted. Those levels are governed by IO procedure [11].

If the treatment of NC implies the modification of IO Baseline Documentation, the proper Change Action(s) shall be managed according to [20].

5.5 Link with 'Documents and Records' processes

In section 3.5 of the present procedure describes, the roles of IO Stakeholders as reviewers of the NC reports, as an input to SOA (Sign-Off Authority) [8].

The SOA [8] being document-based does not give indication of the status of a document within a workflow. The present procedure develops the each stage of NC treatment, each of them grading the required minimum list of reviewers.

5.6 Link with 'Finance & Budget' processes

Management of I-NC is part of finance & budget process and shall be applied in accordance with [21].

The I-NC is a Non-Conformity that may be resolved more efficiently or in the best interests of the ITER Project by a party (DA or IO) other than by the Sending DA or its contractors. It applies in situations when a quality issue is identified late in the item's manufacturing process when there is a time criticality associated with the onward availability of this item, causing consequential impacts on later work.

The NC identification is the trigger event of the I-NC but the close out of each process does not depend on the same elements.

The NCR should be kept open for technical corrective and remedial actions whereas the I-NC is kept open for financial actions as per applicable procedure [21]. The NCR can be closed even if the I-NC is not closed and vice versa.

6 Definitions and acronyms

6.1 Definitions

Action assignee: An all-inclusive term to designate any person assigned to perform an action in the course of the NC treatment. This person can be from any organization.

Agreed Notified Body: Organisation authorized by a member state to carry out conformity assessment of pressure equipment and /or nuclear pressure equipment.

Baseline documents (level 0, 1, 2 and 3) – to be used for NC categorization – definition as per [11]. The ITER baseline is the set of all configuration items with all of its applicable documents approved at one of the project's key milestones that serve as a reference for activities throughout the lifecycle of a product. The scope of a baseline shall be unique and not overlapping with any other.

Causal Analysis Tree: The Causal Analysis Tree is shown in Appendix 3 ("B"-Level) of the procedure. The Causal Analysis Tree is a result of a benchmarking study of industry causal analysis systems. The lowest level of the Causal Analysis Tree is typically referred to as the "B" Level. The

Causal Analysis Tree allows for a tailored approach to developing corrective actions

Contractor: legal entity/ organization who has entered into a contract with the IO.

Counterfeit, Fraudulent, and Suspect Items (CFSI):

A counterfeit item is a copy or substitute without legal right or authority to do so or one whose material, performance, or characteristics are knowingly misrepresented by the vendor, supplier, distributor, or manufacturer.

A fraudulent item that items which is intentionally misrepresented to be something they are not.

A suspect item is one in which there is an indication by visual inspection, testing, or other information that it may not conform to established industry-accepted specifications or national/international standards.

Corrective vs preventive/risk-based actions[3]:

- **Corrective action:** action to eliminate the cause of Nonconformity
- **Preventive/risk-based action:** an all-inclusive term to refer to an action to eliminate the cause of a potential nonconformity – see [22]

Definitions ISO 9000 v2015 (Fundamentals & vocabulary)	Concept of preventive action in ISO9001 v2015 (Requirements):	Terminology INB order [1]	Terminology IAEA GSR part 2 / 2016
3.12.1 preventive action action to eliminate the cause of a potential nonconformity or other potential undesirable situation … Note: **Preventive action** is taken to prevent occurrence whereas *corrective* action is taken to prevent recurrence.	**0.3.3 Risk-based thinking** The concept of risk-based thinking has been implicit in previous editions of ISO 9001, including for example carrying out preventive action to eliminate potential nonconformities … One of the key purposes of a quality management system is to act as a **preventive** tool. Consequently, ISO 9001 v2015 does not have a separate clause or sub clause on preventive action.	**Art. 2.6.3. − I.** – The operator ensures discrepancies are managed within a time-frame adapted to the issues concerned, in particular by … defining the appropriate remedial, **preventive** and corrective actions	**6.3.** The causes of non-conformances of processes … shall be evaluated and any consequences shall be managed and shall be mitigated … The status and effectiveness of all corrective actions and **preventive** actions taken shall be monitored and shall be reported to the management at an appropriate level in the organization.

DA RO:

- DA staff member nominated as responsible for the coordination of NC process within DA and ensuring continuous interfaces with IO and performers (initiation and closure of the NC).
- For the NCR related to PA implementation, the NCR database shall be used. For NCRs where the NC ownership will be under DA responsibility, the DA RO will apply DA specific NCR procedure.

Inter-Organization Non-Conformity (I-NC): Nonconformity with multiple interfaces between different entities DAs / IO and suppliers. A non- conformity that may be resolved more efficiently or in the best interests of the ITER Project by a party (DA or IO) other than by the Sending DA or its contractors. It applies in situations when a quality issue is identified late in the item's manufacturing process when there is a time criticality associated with the onward availability of this item, causing consequential impacts on later work.

Initiator of a NC: Entity or person who detect the Nonconformity and triggers its' registration. Mainly the performer but can be any stakeholder of the ITER project (e.g. IO, DA, ASNR, (A)NB

[3] Clarification on the term 'preventive' in this document: depending on Standards, various terminologies exist:

staff members, suppliers, contractors, etc.).

IO/ DA Specified Requirement: Specified requirements by IO/ DA including

- Technical and Quality requirements
- Regulatory requirements

IO NC Owner, hereafter NCR approver: IO staff member nominated as responsible for the coordination and closure of the NC, in the IO NCR database. Depending on NC scope the IO-RO is

- for Product NC, TRO (manufacturing phase) / CRO (construction phase)
- for Process NC, the line manager of process owner of affected entity
- for IO internal NC, Project Leader/Section Leader, or higher level of the performer

IO-Interactions RO: An all-inclusive term to designate a RO who is managing the project / contract affected by the original NC and related interactions with other systems (e.g. DIRO/ SIRO or RO in Construction Teams…).

Long-term actions: Actions (remedial/ corrective actions) that requires more than 3 months for implementation and strict follow-up of responsible and due dates

Manufacturer: any organization or legal person who manufactures a product or has a product designed or manufactured and markets that product under his name or trademark.

Nonconformity, herein NC:

- Non-fulfilment of a specified requirement
- Product or Process, which does not fulfil or fail in meeting IO / DA, specified requirements

NC report: Nonconformity Report, i.e. the record of each Nonconformity (NC) - referred as NCR

Performer: An all-inclusive term used to cover both IO internal and external organizations, such as IO, Domestic Agencies, Suppliers, Manufacturers and Contractors… who provide products, works or services to ITER project. Performer is the entity/individual responsible for NCR closure identified and submission RO in NCR Database.

PE Group: The PE Group [26] is responsible for all matters related to the proper and efficient implementation of Pressure Equipment and Nuclear Pressure Equipment regulations within the whole ITER Project.

Product NC: When the requirement related to the characteristic of an item, component or work (e.g. construction, installation) is not fulfilled as specified. As an example, failure in meeting a specified tolerance of a component.

Process NC: Violation of a process. When the MQP procedural requirement are not fulfilled is relative to the specified way of working. As examples, failure in the propagation of requirements in the Supply Chain; failure in the execution of Design process, failure in the notification of a contractual hold point.

Remedial actions: Immediate actions to eliminate a detected Nonconformity

- **Use as-is**: the item deviates from requirements but is declared fit for the intended use.
- **Rework**: compliance with the original requirements can be restored.
- **Repair**: fitness for the intended use can be restored although the repaired item may not conform to the original requirements.

- **Reject**: the item is not fit for the intended use.
- **Scrap**: the item is not fit for the intended use (cannot be restored) and it cannot be used for different other scope.
- **Other**

For process NC, the remedial actions will be specifically defined as per NC evaluation and RCA.

Root Cause Analysis (RCA): Set of problem-solving techniques targeted at identifying the actual root cause or the reason that caused the problem. The need for RCA stems from the fact that the elimination of the symptoms of the problems is not alone sufficient to address the problem, it has to be addressed at the cause level.

Service: output of an organization (service provider) with at least one activity necessarily performed between the organization and the IO. The dominant elements of a service are generally intangible. Service often involves activities at the interface between IO (responsible for establishing the requirements) and service provider, as well as upon delivery of the service and can involve a continuing relationship.

Service provider: organization that provides a service. In a contractual situation, a service provider is sometimes called contractor

6.2 Acronyms

Complementary or as quoted in ITER abbreviations [18]:

ASNR	French Nuclear Safety and Radiation Protection Authority (from French: Autorité de Surety Nucléaire et de Radioprotection)
ANB	Agreed Notified Body
CAT	Causal Analysis Tree – see annex 3
CCB	Configuration Control Board
CFSI	Counterfeit, Fraudulent, and Suspect Items
CRO	Contract Responsible Officer
DA	Domestic Agency
FCR	Filed Change Request
I-NC	Inter-Organization Non-Conformity
DIRO	IO Design Integration Responsible Officer
IDM	ITER Document Management (System)
KPI	Key Performance Indicator
MQP	Management and Quality Program
MIP/ITP	Manufacturing Inspection Plan / Inspection and Testing Plan
NCR	Nonconformity Report
PA	Procurement Arrangement
PCR	Project Change Request
PIC/PIA	Protection Important Component / Protection Important Activities, as defined in [1]
PE/NPE	Pressure Equipment (PE) in the scope of [2] Nuclear Pressure Equipment (NPE) in the scope of [4]
PE Group	Pressurized Equipments Group
PROR	Project Risk and Opportunity Register
QARO	IO Quality Assurance RO
QMD	Quality Management Division

RCA	Root Cause Analysis
RRF	Review of Regulatory Files
SRO	Safety Responsible Officer
SIRO	System Integration Responsible Officer
TRO	Technical Responsible Officer

7 Applicable and Reference Documents

7.1 Applicable documents

[1]	Order dated 7 February 2012 relating to the general technical regulations applicable to INB - EN (7M2YKF)
[2]	Pressure Equipment directive 2014/68/UE_EN (RZ6PAK) / FR (RZ5PGG)
[3]	Environmental code mainly art L557 and art R557 – Décret n° 2015-799 du 1er juillet 2015 relatif aux produits et équipements à risques - EN (U5TKD4)
[4]	ESPN Order dated 30 December 2015 modified – Arrêté du 30 décembre 2015 relatif aux équipements sous pression nucléaires - [EN] (SMP384)
[5]	ITER Quality Assurance Program (2EXFXU)
[6]	ITER Integrated Safety, Environment and Security Management System Manual (4HCWJU)
[7]	ITER Policy on Safety, Security, Quality and Environment Protection Management (43UJN7)
[8]	Sign-Off Authority (SOA) for Project Documents (2EXFXU)
[9]	Procedure for the Safety Review of Regulatory Files (48VD6T)
[10]	Organization of nuclear safety inspections in ITER Organization and its supplier chain (CW8EL3)
[11]	ITER Configuration Management Implementation Plan (CMIP) (27LHHE)
[12]	Management of Counterfeit, Fraudulent and Suspect Items (CFSI) (A52J3Z)
[13]	Quality Requirements for IO performers (22MFG4)
[14]	Release Note Template (QVEKNQ)
[15]	Working Instruction for Mechanical Completion Dossier Preparation (UYUSEE)

7.2 Reference documents

[16]	Quality Management System Audits (2DQTA8)
[17]	Compliance actions management procedure (9QELY2)
[18]	ITER abbreviations (2MU6W5)
[19]	Root Cause Analysis Leaflet (2X4E9A)
[20]	Project Change Procedure (22F4E5)
[21]	Procedure for Implementation of the Inter-Organizational Non-Conformity Resolution Process (YVPWYR)

[22]	Risk and Opportunity Management Procedure (22F4LE)
[23]	Management Review procedure (3L7SWX)
[24]	Lessons Learned Procedure (DV4UUH)
[25]	Management of NCR related to OHS Regulatory, Standard and Technical Requirements (S28TDV)
[26]	List of PE/NPE Representative (2F99GX)
[27]	HOW TO - NCR Database - Introduction (SM2JWP)
[28]	HOW TO - NCR Categorization (4HCC3W)
[29]	HOW TO - NCR Prioritization (DA337C)
[30]	HOW TO - NCRs follow-up till Closure (3CZWDX)
[31]	Template - NCR Checklist (ASH2BP)
[32]	https://user.iter.org/?action=IODashboard&uid=4GES4A

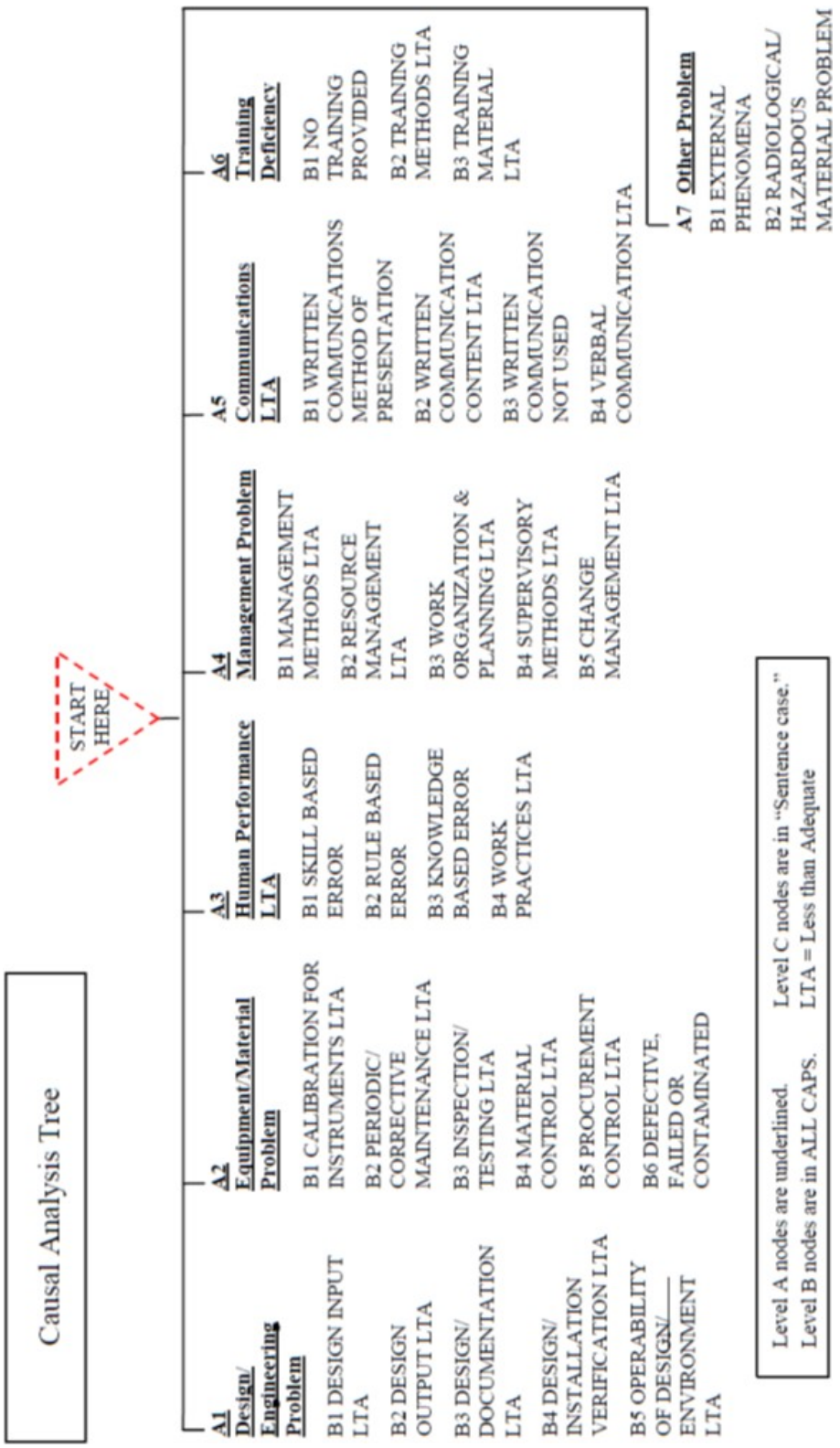
Annex 1: NCR categorization criteria

Major NC	Safety / Regulation	Nonconformity with a IO specified requirement affecting Regulatory Requirements, Safety, Environmental impact
	Baseline	Nonconformity with an impact on a Baseline document Level 0 / 1 / 2
	Interactions	Nonconformity with interaction with other PBS, Construction and/or other Process
	Impact on Performance	Implication on Functional performance
	Repetitive NC	More than 2 similar NCRs can trigger one major NC to investigate root cause of recurrence
Minor NC	Safety / Regulation	Nonconformity with a specified IO requirement not affecting Regulatory Requirements, Safety, Environmental impact
	Baseline	Nonconformity with an impact on a Baseline document Level 3
	Interaction	Nonconformity with no interaction with other PBS, Construction and/or other Process
	Impact on Performance	Implication on layout (within the same space reservation of concerned system/ PBS)

Annex 2: NCR extension request

	Author	Reviewers	Approver	How to record
1st extension of N	Responsible for NCR closure (Performer)	QARO	IO NCR approver	To be recorded directly by TRO/CRO in NCR database (together with justification and impact assessment).
2nd extension (or more) of minor NCR due date		TRO/ CRO/ QARO	Line manager of NC Approver	NCR Extension Request (ER) template (7J6YNG) to be recorded/approved in IDM folder - NCR Extension Request. The approved Extension Request shall be referred in NCR database by QARO or TRO / CRO.
2nd extension (or more) of major NCR due date			Program Manager or Division Head of NC approver (or higher level)	

Annex 3: Causal Analysis Tree for Root Cause Analysis (RCA)



Annex 4: Requirements for PE/ NPE scope

This Annex is useable only when IO is acting as PE/NPE manufacturer, and it explains the process to sort out the nonconformity detected during design and manufacture of pressure equipment or nuclear pressure equipment.

A nonconformity concerning a PE/NPE or Implementation plan for design & manufacture of PE/NPE (VE2DSP) is considered as properly closed by IO if the impact on the other past, current and future productions is performed.

1. Nonconformity related to Equipment manufactured by IO in the scope of Module H/H1

1.1 Process Nonconformity

IO describes and presents to ANB the solutions it intends to adopt to remedy the process nonconformity related to the application of Implementation plan for design & manufacture of PE/NPE – VE2DSP and shall obtain ANB validation before they are implemented.

1.2 Product NCR

Product Non-Conformances are classified as Major or Minor according to the criteria defined in chapter 3.1.2 of present procedure.

IO will describe the solutions it intends to adopt to remedy the non-conformances and will keep the related records available for ANB consultation.

2.2 Nonconformity related to Equipment manufactured by IO out of the scope of Module H/H1

2.2.1 Major Product Nonconformity

Only major product NCR affecting regulations [2], [3] & [4] shall be sent to ANB.

IO describes and presents to ANB the solutions it intends to adopt to remedy the major product NCR and shall obtain ANB validation before they are implemented.

As soon as the NCR is uploaded in NCR database, PE/NPE expert shall send to ANB:

- the NC and all necessary information (report, drawing, picture…),
- remedial actions proposal: Whenever the supplier or subcontractor is able to repair in accordance with the PA documentation and/or selected code, this will be the preferred remedial action,
- Root-cause-Analysis.

If the repair is not following the PA/ contract documentation, contract and/or selected code, IO needs to evaluate if this repair has an impact on an essential safety requirement of [2], [3] & [4] and if the hazards and risks analysis should be updated and submitted to ANB for approval.

To implement the remedial action(s), a revision of original MIP /ITP or new MIP/ITP will be prepared to include the new operations and the needed intervention points from all the parties. IO/ANB could add new control points (Hold points, witness points, reports and notification points).

2.2.2 Minor Product Nonconformity

The supplier or subcontractor is able to repair in accordance with the PA/ Contract documentation or existing repair procedure(s) approved by IO and accepted by ANB.

Minor NC and all evidence or reports are kept by IO in NCR database and are available to ANB on their demand (periodic meeting, ANB visit or audit).

When possible, IO shall accept the action plan without impact on the workshop schedule.

After implementation of the action plan, remedial action(s), corrective action(s) and evidence(s) are approved by IO (if required).