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| **22F53X** |
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**MQP Level 2**

# 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.

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| *Read Access* | **LG: SQD Managers, GG: MAC Members and Experts, LG: Quality Control Group, AD: ITER, AD: External Collaborators, AD: IO_Director-General, AD: External Management Advisory Board, AD: OBS - Quality Management Division (QMD) - EXT, AD: OBS - Quality Management Division (QMD), AD: Auditors, AD: ITER Mana...** | | |

| *Change Log* | | | |
|---|---|---|---|
| **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 | |
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| 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<br>- add the following steps in the process for non-conformities:<br>- root causse analysis<br>- corrective action (if needed)<br>- closure of NCR |
| v6.1 | Approved | 25 Jun 2013 | Modifications according to approved MQP Doc Request G23MB4:<br>- Changes to allow verbal agreement on remedial actions when the non-conformance does not impact on an external system<br>- 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:<br>- Addition of an explanatory footnote for PIC and PIA<br>- Addition of PIA with PIC<br>- 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).<br><br>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:<br>- Process NC introduced (not product NC as previously understood);<br>- 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.<br>- The workflow and roles rendered generic (e.g. notion of DIRO now extended to 'interaction RO', so that it can encompass Construction Teams).<br>- 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.<br>- 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.<br>- 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<br>Includes Module H needs |
| v8.0 | Revision Required | 10 May 2019 | as per approved MQP doc Request - XYLYX5:<br>- requirements regarding Counterfeit, Fraudulent, and Suspect Items (CFSI) |

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

| | | | |
|---|---|---|---|
| | | | o Add specific section for Inter-Organizational Non-Conformity (I-NC)<br>o Add requirements for application of fast NCR closure – applicable only for minor NCR<br>o Add specific section for Conditional Release of NC.<br>o Add clarification for RCA methodology - ITER_D_2X4E9A - Root Cause Analysis Leaflet<br>o Add clarification for NCR closure<br>o Add interaction with the risk and opportunity process.<br>- Chapter 5.5 – changes to introduce specific requirements for Module H and H1.<br>- Add chapter 5.7 – Internal NC of Performers<br>- Chapter 7 – change the responsibilities for process owner and DH – for IO NCRs<br>- Chapter 9.3 – add requirements for "Nonconformities survey process for PIC and PIA" |
| v9.1 | Approved | 19 Mar 2021 | Technical issue |

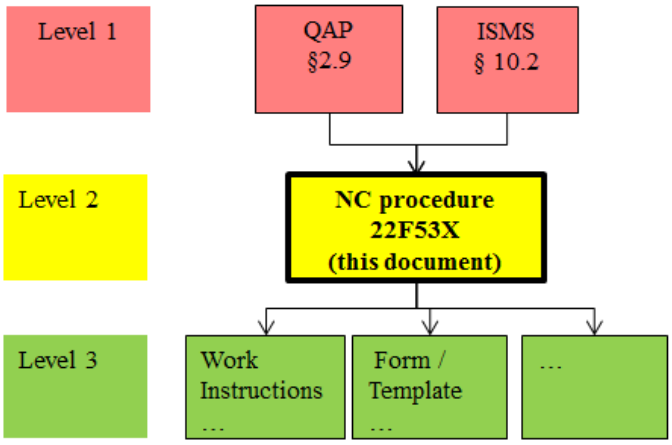
# Table of Contents

# 1 Purpose

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.

# 2 Scope

This MQP Level 2 Procedure belongs to the Process 'Quality Assurance' and propagates the requirements of the chapter 2.9 of the Quality Assurance Program (QAP) [5], and of the chapter 10.2 of the Integrated Safety Management System Manual (ISMS) [6]. Hierarchy of MQP documentation is illustrated below:




This procedure shall be followed for the management of Nonconformities detected during the all ITER project phases (from the design until operation/maintenance).
- for both types of NCs: Product NC and Process NC,
- by both internal and external performers (IO/ DAs/ suppliers / contractors).

## 2.1 Out of Scope

- Management of Deviation Request.
- Cost and schedule issues. To be treated as per contractual requirements.
- The management of Internal Nonconformities [1] of external Performers is not covered by this procedure.
    - However, external Performers shall make lists of their Internal Nonconformities available to IO for information, on request of IO.
- NC of Quality Audit (see link with others processes in **section 9**)

# 3 Definitions and acronyms

## 3.1 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.

**Authorized Body/Authorized 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].

[1] Nonconformities according to the QMS of the external Performers

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

**Corrective vs preventive/risk-based actions** [2]

- **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

**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.

**Deviation Request, DR** (out of Scope)

Request for deviation from a specified requirement in a formal agreement (e.g. signed contract, signed Procurement Arrangements…).

**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 IO NC system (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):**

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

| Definitions ISO 9000 v2015 (QMS - Fundamentals & vocabulary) | Concept of preventive action in ISO9001 v2015 (QMS - 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. |

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-CT, IO-PT, DA, ASN, (A)NB staff members, etc.).

**IO/ DA Specified Requirement:**

- Specified requirements by IO/ DA including:
  - Technical and Quality requirements
  - Regulatory requirements.

**IO NC Owner, hereafter IO-RO:**

- IO staff member nominated as responsible for the coordination and closure of the NC, in the IO NC system (NCR database). Depending on NC scope the IO-RO is :
  - for Product NC, TRO (manufacturing phase) or CRO (construction phase).
  - for Process NC, the IO DH of affected entity.

**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 or RO in Construction Teams…).

**IO NC system**:

- An all-inclusive term used to refer to the agreed system for tracking and recording NCs until closure in IO. Either IO NCR Database (DB) or through IDM system (for specific cases – see the **note**).

**Note:** IDM maybe used only for specific cases when NC database does not provide necessary configurations, ensuring flexibility for recording of such specific NCR (e.g. cases when performers refuse or are not available to apply NCR DB, etc.). The use of IDM instead of NCR database shall be agreed with IO QARO in advance (by email). After NCR approval in IDM, QMD shall ensure the transfer (link) of such NCR from IDM to NCR database (NCR legacy) considering the graded approach established by QMD.

**Long-term actions** – Actions (remedial/ corrective actions) that requires more than one month for implementation and strict follow-up of responsible and due dates.

**Manufacturer** Means 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 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); sometimes referred as NCR.

**Performer**

- An all-inclusive term used to cover both IO internal and external organizations, such as IO-CT, IO-PT, Domestic Agencies, Suppliers, Manufacturers and Contractors… who provide products (SSC…), works or services to ITER project.

**PE Group**

The PE Group 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 – part of EPNS.

**Product NC**: When the requirement related to the characteristic of an item, component or work is not fulfilled. As an example, failure in meeting a specified tolerance of a component.

**Process NC:** 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.

The Process NC related to IO processes, will be treated by IO as internal NC in accordance with detailed IO internal working instructions.

The Process NC related to performers processes, will be treated as Internal NC of performers in accordance their internal procedures – **see chapter 5.7 conditions**

**Remedial action**

- Action 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.

## 3.2 Acronyms

Complementary or as quoted in [23] ITER abbreviations:

| | |
|---|---|
| ASN | French Nuclear Safety Authority (from French: Autorité de Sûreté Nucléaire) |
| (A)NB | (Authorized) Notified Body |
| CAR | Corrective Action Request |
| CAT | Causal Analysis Tree – see annex 3 |
| CCB | Configuration Control Board |
| CFSI | Counterfeit, Fraudulent, and Suspect Items |
| CRO | Contract Responsible Officer |

| | |
|---|---|
| DA | Domestic Agency |
| DH | Division Head |
| DR | Deviation Request |
| EPNS | Environmental Protection & Nuclear Safety Division |
| FR | Functional Reference |
| I-NC | Inter-Organization Non-Conformity |
| IO | ITER Organization (sometimes referred to as ITER) |
| IO-RO | IO Responsible Officer of the work package affected by the NC |
| IO-DIRO | IO Design Integration Responsible Officer |
| IO-QARO | IO Quality Assurance RO |
| IO-SRO | IO Safety Responsible officer |
| IO-CT | ITER Organization Central Team |
| IO-PT | Project Team established in accordance with 4.ii of [QYTZEP] |
| IDM | ITER Document Management(System) |
| ISMS | Integrated Safety Management System Manual |
| KPI | Key Performance Indicator |
| MQP | Management Quality Program |
| MIP/ITP | Manufacturing Inspection Plan / Inspection and Testing Plan |
| NC | Nonconformity |
| NCR | Nonconformity Report |
| NSI | Nuclear Safety Inspection |
| PA | Procurement Arrangement |
| PBS | Plant Breakdown Structure |
| PCR | Project Change Request |
| PIC | Protection Important Component, as defined in [24] 0 |
| PIA | Protection Important Activities, as defined in [24] |
| PIM | Project Issue Management |
| PE/NPE | Pressure Equipment (PE) in the scope of [2] Nuclear Pressure Equipment (NPE) in the scope of [4] |
| PE Group | Pressurized Equipments Group – part of EPNS |
| PNI | Part Number of ITER |
| PROR | Project Risk and Opportunity Register |
| QAP | Quality Assurance Program |
| QMD | Quality Management Division |
| QMS | Quality Management System |
| RCA | Root Cause Analysis |
| RRF | Review of Regulatory Files |
| RO | Responsible Officer |
| SSC | System, Structure and Component |
| SCG | Safety Control Group |
| SOA | Sign-Off Authority |
| SR | Safety Related |
| SQD | Safety and Quality Department |
| TRO | Technical Responsible Officer |

# 4 Applicable and Reference Documents

## 4.1 Applicable documents

| | | | |
|---|---|---|---|
| Regulations | [1] | Order dated 7 February 2012 relating to the general technical regulations applicable to INB - EN | 7M2YKF |
| | [2] | Pressure Equipment directive 2014/68/UE [French version] | RZ6PAK [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 |
| MQP Level 1 | [5] | Level 1 MQP – ITER Quality Assurance Program (QAP) | 22K4QX |
| | [6] | Level 1 MQP - ITER Integrated Safety, Environment and Security Management System Manual (ISMS) | 4HCWJU |
| | [7] | ITER Policy on Safety, Security and Environment Protection Management | 43UJN7 |
| Interacting processes – MQP | [8] | Level 2 MQP - Document & Records process - Sign-Off Authority for Project Documents | 2EXFXU |
| | [9] | Level 2 MQP – Nuclear Safety process - Procedure for the Safety Review of Regulatory Files | 48VD6T |
| | [10] | Level 2 MQP – Nuclear Safety process - Organization of nuclear safety inspections in ITER Organization and its supplier chain | CW8EL3 |
| | [11] | ITER Baseline diagram | 2XWZEK |
| | [12] | Nonconformity and corrective actions Survey Process for PIC and PIA in Application of Articles 2.6.3, 2.7.1 and 2.7.3 of the INB Order | HDAWCU |
| | [13] | Level 3 MQP – Configuration Management process – Project Issue Management | SSU96T |
| | [14] | Level 2 MQP – Inspection and Testing process – Requirements for Producing an Inspection Plan | 22MDZD |
| | [15] | ITER Procurement Quality Requirements | 22MFG4 |
| | [16] | Requirements for Producing a Contractors Release Note | 22F52F |
| | [17] | Release Note Template | QVEKNQ |
| | [18] | Working Instruction for Mechanical Completion Dossier Preparation | UYUSEE |
| GIN | [19] | GIN 007 - Closure of Non-Conformance Reports | UKG3W8 |
| ***Note: The procedures are applicable to the DAs, only if they are listed in the Multi Party Amendment (MPA).*** | | | |

## 4.2 Reference documents

| | | |
|---|---|---|
| [20] | Quality Management System Audits | 2DQTA8 |
| [21] | ITER Corrective Action Procedure (CAR) | 9QELY2 |
| [22] | DA / Supplier / Sub-contractor QA Non-conformance Report Template | A6HRLB |
| [23] | ITER abbreviations | 2MU6W5 |
| [24] | Nuclear safety common definitions | RLZXMV |
| [25] | IO QA Non-conformance Report Template | 2MVY2Z |
| [26] | Project Change Procedure | 22F4E5 |
| [27] | Guideline for identification (Symptoms) of Counterfeit, | |

Fraudulent and Suspect Items (CFSI) XKUKAX

[28] Procedure for Implementation of the Inter-Organizational Non-Conformity Resolution Process YVPWYR
[29] ITER Project Management Plan (PMP) 2NCR3F
[30] Procedure for management of Deviation Request 2LZJHB
[31] How to – Long Aging NCRs management 3CZWDX
[32] Risk and Opportunity Management Procedure 22F4LE
[33] Management review procedure 3L7SWX
[34] Lessons Learned meeting Procedure DV4UUH

# 5 Basic principles

## 5.1 General principles for NC management

- The main steps for the methodology for NC management, are as follows:
  - The organisation, where the NC is detected, shall immediately stop works related to the nonconforming product /service and to inform IO.
  - Immediate actions to segregate *(*labelling and/or physical separation of NC shall be applied) the nonconforming item / work and to ensure safety.
  - Description of the nonconformity - NC report shall be immediately registered in NC system.
  - Agreement and implementation of remedial actions to eliminate the Nonconformity. The remedial action can be implemented only after IO formal agreement.
  - Root cause determination through RCA (Root Cause Analysis) using Causal Analysis Tree and decision on corrective & preventive/risk-based actions
  - Follow-up of actions from their initiation until their implementation
  - Verification of the effectiveness of actions.
  - NCR closure - NCR shall be handled and closed with the priority.

### 5.2 NCR initiation – 1a

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)
- Preliminary proposal of remedial actions need to be established (if the initiator can provide this information at this stage).

Recording of NCR

Once NCR is detected, the initiator is recording the NC in the IO NCR database (status “Submit”) or equivalent electronic system (e.g. IDM for internal IO NCRs (status “Sign”) recognised by IO.

NC report shall be submitted within maxim 5 working days in the NC system to initiate the NC process (trigger the NCR review / approval cycle). In case of dispute between stakeholders, maximum two weeks from the NC detection time may be allowed with IO agreement only.

For management / use of IO NCR database, stakeholders shall apply detailed instructions:

- ITER_D_SM2JWP - NCR Database - Introduction & How to for IO-DA personnel
- ITER_D_SY6RQ5 - NCR Database - Introduction & How to for Suppliers and Contractors

Immediate actions shall be taken to segregate (*labelling and/ or physical separation of NC shall be applied*) the nonconforming item / work and to ensure safety.

After the NCR is submitted in the NC system, the review and approval cycle will be launched and will allow to the performer and all effected stakeholders to provide their feedback.

In case during the review / approval the NCR is rejected, then the NC owner (approver) 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 NC owner shall ensure further escalation as per - **section 10** of present procedure.

NCR categorization

The preliminary categorisation of NCR shall be done at the initiation stage with the involvement IO RO (confirm) and IO QARO in accordance with the following criteria:

- In ITER project, the way to implement this graded approach for NC management is to categorize NCs either as 'Major' NC or as 'Minor' NC depending on the impact of the NC to the safety, quality or performance.

- The following table provides guidelines to establish the category of the NCR. The final categorization shall be agreed between:

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

| | | |
|---|---|---|
| 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) |
| | Nonconformity not falling under definition of Major NC. | |

*Baseline document levels are defined as per IO procedures [11] and [29].

The detailed requirements /clarifications regarding NCR categorization are described in the ITER_D_4HCC3W - HOW TO - NCR Categorization.

During the NC initiation stage, performer shall propose preliminary remedial actions (if the initiator can provide this information at this stage) and need to be recorded in NC system for IO acceptance.

## 5.3 Assessment of Nonconformity – Stage 1b

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

- Final remedial actions need to be recorded in NC system and agreed with NC owner.
- Preliminary Root Cause Analysis (RCA) need to be applied and propose corrective actions / RCA category need to be established and recorded in NC System (when required)

During the NCR assessment stage, the remedial actions shall be clearly defined and agree by IO-RO.

For all the decided remedial actions the expected due dates and responsible for closure need to be established and recorded in NC system – Sage 1b.

RCA categorization with Causal Analysis Tree (CAT) evaluation shall be applied for all NCRs.

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, need to be recorded in the RCA report only.

The RCA category – level A, shall be recorded by performer in the NC system in the "Preliminary Analysis of Causes" section and confirmed by IO-RO (NC owner).

In IO and DA, the NC owner is primarily the RO of the item or work being affected by the NC.

- In case of NC involving several Performers, an owner in IO (or DA – for the cases when the NC does not have impact on IO requirements) shall be established with the responsibility to coordinate all actions between parties and supervise the overall action plan.

Two options are possible for NC treatment:

- A unique NC is opened covering all aspects and Performers;
- Several NCs are opened for each Performer.

If the NC owner face issues in finding agreement between parties, or if there is no agreement to find an NC owner, issue will be escalated according to **section 10** of present procedure.

For the cases when the DA is NC owner (NC with no impact on IO requirements), the DA shall apply their own specific NCR procedure accepted by IO.

For most of the cases the performer is also assigned for NCR closure. For specific cases when responsible for NC closure is other entity than performer, during the NC evaluation stage the NC owner (IO-RO / DA- RO), shall confirm (indicate) who is responsible entity for NCR closure.

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

For specific situations, stage 1a (NC initiation) and stage 1b (NC evaluation) can be merged into one stage (1b) - if the NC initiator have all the necessary information: description of NC, Categorization, establish remedial actions, NC evaluation, Preliminary RCA, Corrective actions and categories.

Inter-Organizational Non-Conformity (I-NC)

The I-NC is a non-conformity applied in situations when a quality issue is identified late in the items 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 [28]. The NCR can be closed even if the I-NC is not closed and vice versa.

When an I-NC is detected, the NCR title should indicate the mark “I-NC” to raise the attention of stakeholders and initiate application of I-NC mechanism. The mechanism and details for treatment of I-NC is described in the [28].

## 5.4 NCR closure – stage 2

When required (see note 1), a detailed RCA shall be performed with conclusions whether or not launching corrective actions, and should consider as appropriate any preventive/risk-based actions.

Note 1: 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 mandatory recorded in NC system.
- 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 (IO-RO), the RCA may be submitted to IO for acceptance and recorded in NC system.

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 NC system (when Preliminary RCA is finalized -1b stage).

For complex RCA, the performer (responsible for NC closure) shall arrange specific RCA meetings and perform a detailed RCA. The RCA results and conclusions, together with the decided corrective actions shall be recorded in RCA report with the following information: RCA team members, RCA method, chronology of the events, causes of NC, corrective actions and risks required to eliminate and prevent the NC, etc.

For Root Cause Analysis (RCA) application the following guidance may be used ITER_D_2X4E9A - Root Cause Analysis Leaflet by the stakeholders.

The NCRs can be closed only after the following conditions are meet:

- **For minor NCRs:**
  - all remedial actions are closed (respecting the expected due dates – as recorded in the NCR stage 1) and evidences for remedial actions closure are recorded (attached to NCR for closure stage) in IO NC system.
  - For minor NCRs, the RCA application together with corrective actions implementation are under performer responsibility only and does not required IO acceptance.
  - in case the decided remedial actions (ex: "reject", "scrap") will not remain part of (will not affect) the final product or activity that will be delivered to IO and the related corrective actions (if necessary) will be implemented internally by performers without affecting IO products and activities, the NC can be closed immediately – fast NCR closure**. For such cases, the NC owner shall agree on fast NCR closure mode.

**note: Fast NCR closure is applicable for minor NCRs where the remedial actions ("reject" or "scrap") will not affect the final products / activities that will be delivered to IO. Fast NCR closure means, immediate NCR closure after initial stage of NCR is reviewed and approved – does not require a new review / approval cycle for NCR closure by all stakeholders.

- **For Major NCRs:**
  - all remedial actions are closed (respecting the expected due dates – as recorded in the NCR stage 1) and the evidences for remedial actions closure are recorded (attached to NCR for closure stage) in IO NCR database (or IDM).
  - all corrective actions (CA) decided as per RCA are closed (respecting the expected due dates – as recorded in RCA) and the evidences for CA closure are recorded in IO NC System (attached to NCR for closure stage).

The final closure of NC is confirmed if all related actions are implemented to guarantee the IO requirements of the item or work at the handover to IO.

For NCR closure, the performer (responsible for NCR closure) issues the update of NCR (NC report) in the IO NC system, to ensure NCR is reviewed & accepted /approved by all relevant stakeholders.

As a basic principle, the delivery of the items shall be released only if all the related NCR's are closed.

The IO NC system record the actions (remedial/corrective actions) agreed with Performers and also the internal actions in IO. If it is decided to follow some long-term actions (remedial/ corrective actions) in a separate system (JIRA CAT system or equivalent electronic system), traceability of the actions and tracking system shall be demonstrated to monitor the progress. The NCR shall not be closed if the related remedial actions / corrective actions are still open (see previous paragraphs for NC closure conditions.)

If during the NCR treatment, the risk and opportunities are identified then the IO-RO shall record the risk and opportunity in IO register (PROR) as per procedure [32].

Conditional Release of NC.

For exceptional cases, intermediate/ conditional release of the NCRs can be accepted only after agreement between IO (NC owner) and DA's / performers.

For such cases when conditional release of the NC is agreed to allow the shipment of components, 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. The continuous follow-up of NCRs status will ensure on the same time the follow-up of such conditionally released NCRs.

For such cases when conditional release of NC is applied, clear further instructions/ actions shall be also indicated in the NCR and in the final delivery documentation (section 6 of [17] - Release Note template – QVEKNQ or section 12 – Punch list of Mechanical Completion Dossier prepared as per [18] - UYUSEE) to be taken into account on the next phases of the project.

The performer shall record the NC conditional release in NC system and NC owner will communicate this information to the corresponding IO team (IO construction team, PT, PBS team etc.) if any impact on the next phases of the project.

## 5.5 PE/NPE Assessment

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

Nonconformity shall be close out following relevant paragraph 5.3.

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.

### 5.5.1 Nonconformity related to Equipment manufactured by IO in the scope of Module H/H1

#### 5.5.1.1 Process Nonconformity

IO describes and presents to ANB[3] 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[4] before they are implemented.

#### 5.5.1.2 Product NCR

Product Non-Conformances are classified as Major or Minor according to the criteria defined in chapter 5.2 above.

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

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

#### 5.5.2.1 Major Product Nonconformity

Only major product NCR affecting regulations [1], [2], [3] & [4] shall be sent to ANB.

IO describes and presents to ANB[3] the solutions it intends to adopt to remedy the major product NCR and shall obtain ANB validation[4] 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 [1], [2], [3] or [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).

5.5.2.2 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 evidences 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).

## 5.6 Case of NC related to CFSI

In case the Non-Conformity deals with a Counterfeit, Fraudulent and Suspect Item (CFSI), the Head of the EPNS Division informs the ASN using the template Déclaration d'évènement significatif à l'ASN (SKKSP3), after validation by the Director General. Such cases will be treated and reported as significant event following the regulatory requirements.

The template ITER_D_SRVZKZ - Compte-rendu d'évènement significatif is used for this analysis. After validation by the Director General, the analysis report is sent by the Head of the EPNS Division to the ASN within 2 months after the detection of the CFSI.

For identification (symptoms) of CFSI items the following guideline need to be followed and consulted by the stakeholders: [27] - XKUKAX - Guideline for identification (Symptoms) of Counterfeit, Fraudulent and Suspect Items (CFSI).

All the non-conformities dealing with a CFSI shall be evaluated by IO QARO and IO SRO to:

- ensure confirmation of CFSI case,
- initiate and perform RCA and
- ensure further escalation to EPNS Head.

### 5.7 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 by external performers in accordance with their internal NCR procedures.

The performers shall maintain fully traceability and evidences for internal NCR closure, to be available during the IO/ DAs audits and inspections.

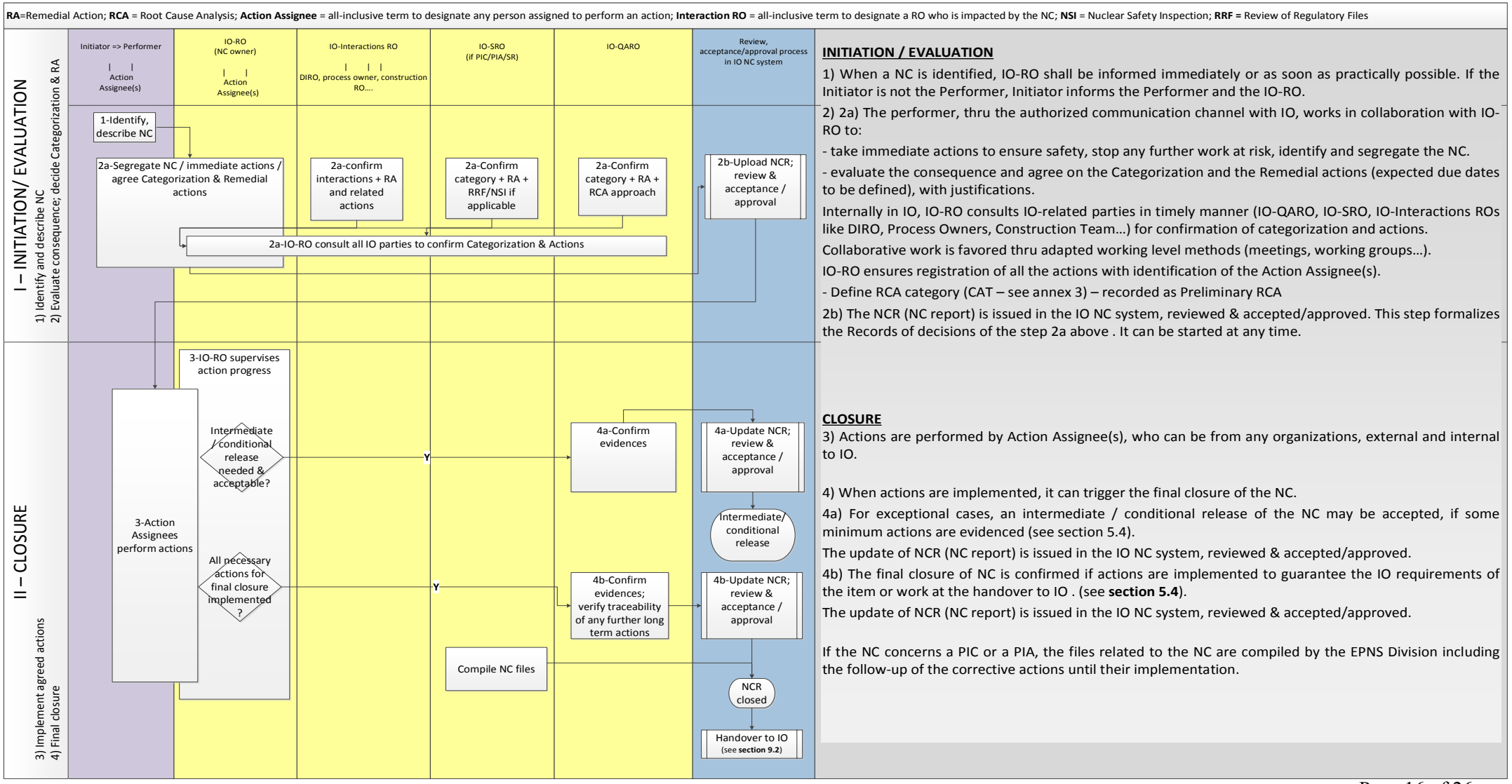
Internal NC of performers shall be recorded using performer's NCR templates and internal database (if applicable). A list (log/ register) of internal NCRs need to be maintained by the performer to allow strict control of NCR stages, trend reports and analyses. This internal NCR log shall be available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

IO internal NCRs: For such NC (with no impact on other organizations), the involved stakeholders will be IO staff only and review / approval cycle will respect present procedure requirements. A dedicated working instruction – MQP level 3 (with no impact on DAs) will be prepared for detailing the instructions for treatment of IO internal NCRs.

## 6. Workflow

The work flow focuses on Roles and Responsibilities in a generic way. Two main stages of the process are defined, for both Product NC and Process NC:

I. **Initiation / evaluation:** This stage consists in taking immediate actions, describing the NC, evaluating the impact and agreeing on categorization and remedial actions.
II. **Closure:** This stage consists in implementing the actions agreed and in closing the NC with the required evidences.




**INITIATION / EVALUATION**

1) When a NC is identified, IO-RO shall be informed immediately or as soon as practically possible. If the Initiator is not the Performer, Initiator informs the Performer and the IO-RO.

2) 2a) The performer, thru the authorized communication channel with IO, works in collaboration with IO-RO to:

- take immediate actions to ensure safety, stop any further work at risk, identify and segregate the NC.
- evaluate the consequence and agree on the Categorization and the Remedial actions (expected due dates to be defined), with justifications.

Internally in IO, IO-RO consults IO-related parties in timely manner (IO-QARO, IO-SRO, IO-Interactions ROs like DIRO, Process Owners, Construction Team…) for confirmation of categorization and actions.

Collaborative work is favored thru adapted working level methods (meetings, working groups…).

IO-RO ensures registration of all the actions with identification of the Action Assignee(s).

- Define RCA category (CAT – see annex 3) – recorded as Preliminary RCA

2b) The NCR (NC report) is issued in the IO NC system, reviewed & accepted/approved. This step formalizes the Records of decisions of the step 2a above . It can be started at any time.

**CLOSURE**

3) Actions are performed by Action Assignee(s), who can be from any organizations, external and internal to IO.

4) When actions are implemented, it can trigger the final closure of the NC.

4a) For exceptional cases, an intermediate / conditional release of the NC may be accepted, if some minimum actions are evidenced (see section 5.4).

The update of NCR (NC report) is issued in the IO NC system, reviewed & accepted/approved.

4b) The final closure of NC is confirmed if actions are implemented to guarantee the IO requirements of the item or work at the handover to IO . (see **section 5.4**).

The update of NCR (NC report) is issued in the IO NC system, reviewed & accepted/approved.

If the NC concerns a PIC or a PIA, the files related to the NC are compiled by the EPNS Division including the follow-up of the corrective actions until their implementation.

# 7. Responsibilities

- The Performers shall ensure the implementation of the requirements of this document to control nonconformities.
- For NC under performers responsibility, the final acceptance by IO of Nonconformity Reports:
  a) Is limited to the particular contract and item referred in the report;
  b) Does not relieve the performer of any contractual obligations and responsibilities.
- Detailed stakeholders and their roles and responsibilities are listed in the following table.

| # | Stakeholder | Responsibilities |
|---|---|---|
| 1 | Initiator | • Detect and identifies NC and notifies IO;<br>• Alerts the involved parties, primarily the affected IO-RO as soon as practically possible (within one week) and with necessary details; The IO-RO may decide that the NC is actually an "Internal Non-conformity" and stop the initiation of the NC in IO NC system.<br>• Notify the Performer, if different from the Initiator;<br>• Responsible for registering or triggering the registration of the NC into the IO NC system; Sometimes, it can be directly the IO-RO who detects and identifies NC. |
| 2 | Performer | When Performer is the person detecting the NC, executes actions of Initiator as above;<br>• 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;<br>• Make initial written proposal of the RCA categorization, using CAT and remedial actions.<br>Initiates problem-solving technique to treat the NC, including as appropriate RCA and preliminary analysis of causes as soon as practically possible (typically within a couple of weeks). Performer can seek assistance from IO-QARO in the methodology of NC problem solving techniques.<br>• Through the authorized communication channel with IO and DA' (in case of PA implementation), collaborates with IO-RO/ DA-RO to achieve the appropriate conclusion on NC categorization and actions (remedial actions and corrective actions).<br>• Provides evidence of progress of the NC treatment to the IO-RO in a pro-active and timely manner.<br>• Complementary to the required information by IO, manage comprehensively the NC in NC system.<br>• The performer is the designated entity for NCR closure, responsible for implementation of remedial/corrective actions and trigger the NCR closure stage in NC System. |
| 3 | IO-RO<br>NC-Owner | • IO Person assigned responsible :<br>o For the coordination and control of the activities in the NC treatment;<br>o Ensuring that the NC is documented and recorded in the IO NC system correctly.<br>o Triggering and guarantying the closure of the NC. For that , the IO-RO shall:<br>• Consult all related-parties, including IO-Interactions RO, IO-SRO (for NC concerning PIC and/or PIA), PE/NPE expert (as required) and IO-QARO to confirm categorization and actions decided.<br>• Agree with the Performer and DA-RO (in case of PA implementation) on the apparent cause analysis tree and remedial actions; Participate and conclude on the impact assessment, including impact on IO Baseline documentation.<br>• In case there is any change action(s) on IO Baseline documentation, manage the implementation according to [11], manage the initiation of a Project Change Request (PCR), if so requested by the DIRO.<br>• Shall ensure that the NC is issued and registered in the IO NC system correctly.<br>• Track the NC and related actions until the final closure of the NC in IO NC system. |

| # | Stakeholder | Responsibilities |
|---|---|---|
| | | • In the review and approval cycle of the NC reports, is either the person **Approving**[3] or is **Reviewer** (if acceptance/approval is done by higher level of organisation).<br>• IO-RO can seek assistance from IO-QARO in the methodology of NC problem solving and RCA techniques. In case of dispute to find and designate an IO-RO, see **section 10** |
| 4 | IO-SRO | • Checks if PIC, PIA, Safety Related (SR), are properly designated.<br>• Agrees on the NC categorization (for NC concerning PIC and/or PIA).<br>• Assess Safety impact and validates action proposal.<br>• Reviews with respect to Regulations [1], [2], [3] & [4]<br>• Is part of the review process of the NC reports, as appropriate for NC concerning PIC and/or PIA.<br>• Confirms if there is a need for Safety Review of Regulatory Files [9]0 and / or Nuclear Safety Inspection [10]0 , and call for those processes as necessary. |
| 5 | PE Group | • Checks if PE/ NPE are properly designated.<br>• Agrees on the NC categorization (if the NC is PE/NPE relevant).<br>• Consult (A)NB for major product NCR and process NCR<br>• Assess statutory & regulatory impact and validates action proposal<br>• Review with respect to Regulations [1], [2], [3] & [4].<br>• Is part of the review process of the NC reports, as appropriate. |
| 6 | IO-Interactions RO (DIRO)<br><br><u>For Major NC only</u> | • 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.<br>• For NC at manufacturing stage, it includes the assessment of impact on Assembly, Installation and Operations.<br>• Is part of the review process of the NC reports, as appropriate.<br>• In case there is any change action(s) on IO Baseline documentation, ensure it is implemented according to [11].<br>• Analyse the NCR considering the design impact and if PCR is required to trigger further upper level project changes as per [26]. |
| 7 | IO-QARO | • Checks the compliance of the NC process<br>• Checks if proper RCA is undertaken, commensurate to the impact and risk of the NC, along with the necessary action(s).<br>• Can provide a support to the stakeholders, as necessary, in the methodology of NC problem solving techniques.<br>• Is part of the review process of the NC reports, as appropriate.<br>• Checks the evidences required to grant the closure of NC. It involves traceability of the actions until implementation.<br>• Confirms if any long-term corrective actions can be tracked in a separate system, to allow final closure of the NC on the individual item or work, and verifies the traceability of those actions.<br>• In IO, provide assistance to sort what are internal IO actions and what are external IO actions. Indeed, an NC by an external performer may reveal the need for actions within IO. In that case IO-QARO ensures opening of the relevant NC/CAR in the appropriate IO system.<br>• Facilitate the coordination between the stakeholders, and may become the IO NC |

[3] The <u>approval level of NC can be delegated to a different IO stakeholder</u> (upper level or similar level) if agreed with Department Head of requester and approved by process owner. Such delegation regarding approval level of NC shall be documented with clear justifications using <u>deviation request</u> applied as per [30].

| # | Stakeholder | Responsibilities |
|---|---|---|
| | | owner, in case of complex NC, involving different processes. |
| 8 | QMD | • In application of GIN007 [19], QMD ensures that NCs are closed in due time.<br>• Provide NC statistics and KPIs to monitor the effectiveness of the NC process. |
| 9 | IO-Tech Staff | • Person is designated by IO-RO as appropriate.<br>• Review the NC regarding the technical aspects - added as additional reviewers of NC. |
| 10 | IO Process owner | • For IO internal NC, related IO processes and procedures deficiencies (need for improvements), the process owner is responsible for NCR review for confirmation of RCA and remedial and corrective actions implementation.<br>• Ensure the process improvement (if needed) revising the affected procedures and working instruction as per decided actions triggered by NC evaluation. |
| 11 | IO DH or upper level | • For IO internal NCs, the approval shall be under DH of affected entity (or appointed representative) responsibility. |
| 12 | DA-RO | • DA Person assigned responsible :<br>o For the coordination and control of the activities in the NC treatment within DA;<br>o Ensuring that the NC is documented and recorded in the IO NC system correctly.<br>o Triggering and guarantying the closure of the NC ensuring continuously interface/ communication with performer.<br>Ensure continuous communication / interface with IO-RO to achieve the appropriate conclusion on NCR categorization, agree on related actions, remedial, and corrective actions (as required) and NCR closure. |

# 8. Records/Outputs

- The form in Appendix 1 lists the minimum information required for managing a NC report.
  - The template [22] or template [25] is proposed to address this minimum information. Alternative formats (including in electronic form – NCR database) which include the essential metadata may be acceptable. They shall be subject to IO Quality Management Division acceptance in advance of their intended use.
- NCs are an integral part of a contract and PAs. Upon completion of the work, NC reports shall be included in the data package handed over to IO (**see chapter 9.2**).
- In IO, a NC register shall be maintained including all relevant metadata. The IO-RO is the Responsible person to ensure record of NC reports in the IO NC system, for the whole lifetime of the ITER project.

# 9. Link with other processes

## 9.1. Link with other 'Quality Assurance' processes (QA audit, CAR)

- The 3 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 [20]0
  - The CAR procedure [21]0 describes the process to manage Corrective Actions Requests as a result of other sources (for example DG decision, ASN 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.

## 9.2. Link with 'Procurement'

As elements governing ITER Procurement Quality Requirements0:

- 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 process for Producing a Contractors Release Note 0 and Manufacturing Dossier.
    - For Assembly&Installation, it is is governed by the process for Mechanical Completion Dossier 0.
- During execution of Inspection Plans governed by [14], if modifications appears 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 - chapter 5.4.

## 9.3. Link with 'Nuclear safety'

- In the treatment of NC, SRO may trigger the need for the Review of Regulatory File (RRF) [9]0 or / and for a Nuclear Safety Inspection (NSI) [10]0. See **chapter 7** (role of IO-SRO).

- Nonconformities survey process for PIC and PIA shall be performed by SCG in accordance with Articles 2.6.3, 2.7.1 and 2.7.3 of the INB Order.

- An biannual assessment report shall be prepared by SCG and approved by SQD Head, for global review of non-conformities on the cumulated effect of uncorrected discrepancies on the installation, and identify and analyse the recurrence propensity for similar types of NC as requested by the article 2.7.1 of the INB Order [1]. The SCG is responsible for the annual assessment of trends and the cumulated effect of NCRs and analyse the recurrence propensity for similar types of nonconformities.

- Input data for such report could also come from the lessons-learned feedback as per [34].

## 9.4. Link with 'Configuration Management' process

- In the NC categorization, one of the criteria is the level of control (level 1/2/3/4/5) 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), under the relevant Level of CCB shall be managed according to [11] (**chapter 7)** and PCR [26].
- In **chapter 10** (Dispute and Resolution), the PIM process [13] can be called (Project Issue Management).

## 9.5. Link with 'Documents and Records'

- In **section 0**, the present procedure 22F53X describes the roles of IO Stakeholders as reviewers of the NC reports, as an input to SOA (Sign-Off Authority) [8]0. It can be summarized in following table:

<table>
<tr><th></th><th>IO-RO</th><th>IO-Interactions RO</th><th>IO-QARO</th><th>IO-SRO</th><th>PE Group</th></tr>
<tr><td rowspan="2">Minor NC</td><td rowspan="3">Approve[4] or Review</td><td>-</td><td rowspan="3">Review</td><td rowspan="3">Review<br>(if PIC/PIA/SR)</td><td rowspan="3">Review<br>(if PE/NPE)</td></tr>
<tr><td rowspan="2">At minimum IO-DIRO Review Stage I [5]</td></tr>
<tr><td>Major</td></tr>
</table>

| | | | | | |
|---|---|---|---|---|---|
| **NC** | | | | | |

SOA 0 being document-based does not give indication of the status of a document within a workflow. The present procedure 22F53X develops the stages of NC treatment, each of them grading the required minimum list of reviewers. Therefore, in case of contradiction, this MQP procedure 22F53X, and its derived MQP Level 3 documents, take(s) precedence.

### 9.6. Link with "PE/NPE conformity assessment"

In the treatment of NC, PE Group may trigger the need to update a procedure or any document used as support of the Quality System accepted by ANB.

If during the resolution of an existing nonconformity, a visual examination required for the final assessment of the PE/NPE is impacted, IO will allow ANB to perform a new visual examination.

The pressure test could be performed even if all the nonconformities are not closed if IO provides evidences to ANB that these opened non-conformities will not have an impact on the pressure test.

### 9.7. Link with Finance & budget process

Management of I-NC is part of finance & budget process and shall be applied in accordance with [28].

## 10. Dispute and resolution

Criteria for triggering escalation includes, but is not limited to:

- dispute on the way to close a NC;
- long aging NC - opened for a long time (typically more than 12 months) without any justification;
- dispute on ownership of NC; as an example, when there is multiple interfaces involved (e.g. different systems, multiple Performers and organisations …).

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

- Submission first to Division Head (DH) level;
- If resolution within IO is not gained at the Division Head (DH) level, it will be submitted to the QMD Head and technical Department Head level;
- If still no resolution is made, then the NC will be submitted to ''PIM" (project issue management; issue at PIM [13]).

## 11. KPI

IO has established 2 KPI indicators to assess the efficiency of the process:
1. The time between the detection of the NC and submission of NC (5 working days).
2. The time between the detection date of the NCR and the closure of NCR. – LL NCR

The internal specific KPIs for monitoring of NCR management performance may be established by IO process owner and shall be monitored/reported as per Management Review procedure [33].

In application of QAP [5] section 2.9,

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

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[4] IO-RO is either the person Accepting/Approving (as per contract definition), or is Reviewer (if acceptance/approval by higher level of organisation).
For IO NC the approval shall be obtained from process owner or DH (see chapter 7). The approval level on DAs site shall be applied as per DA NCR procedures

[5] Stage I is the Initiation stage as per **section 0**, with one objective being agreement on remedial actions.

If long time (Long Aging - LL) is necessary to close the NC, justification shall be provided by NCR owner (with performer support) and recorded. The detailed requirements regarding long aging NCRs management are described in the [31].

# Appendix 1: List of related information / data to be provided in NC system template

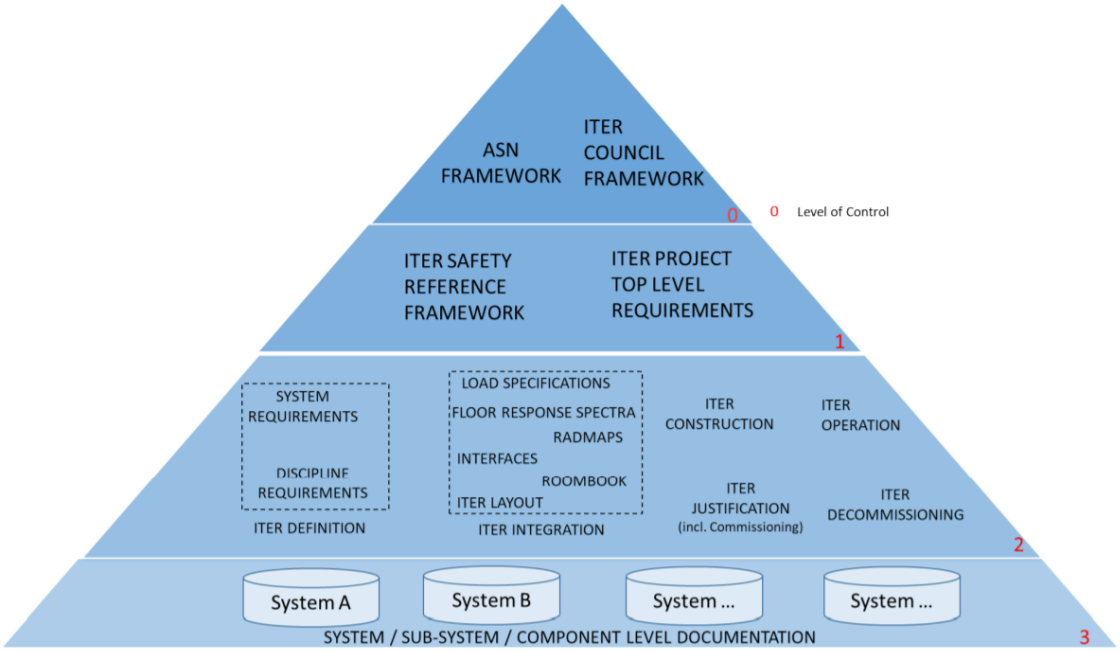
| | Field | M = Mandatory<br>O = Optional |
|---|---|---|
| NC Initiation Stage **I** | Title of Nonconformity | M |
| | External Performer(s) NC Reference(s) | M (if applicable) |
| | ITER Contract reference (PA/Task Agreement / Direct contract as applicable) | M (if applicable) |
| | DA | M (if applicable) |
| | Supplier / Contractor | M (if applicable) |
| | Affected DA (other than related contact) | M |
| | Plant Breakdown Structure (PBS) | M |
| | Item / Work identification and localization (objective is to keep traceability) | M |
| | *FR / PNI/ SN (for product NC only) – see note* ** | *M* |
| | CWP | O |
| | NC Category (Major or Minor) | M |
| | Quality Class | O |
| | Is PIC? PIA? SR? | M |
| | Date of NC detection | M |
| | Requirements | M |
| | Description of the Nonconformity vs. Requirement | M |
| | Proposed preliminary Remedial Action(s) and description | M |
| | Initiator and organization (with signature *) | M |
| NC evaluation Stage **I** | Confirmation of final Remedial Action(s)<br>(*expected completion date for closure)* | M |
| | Justification of Remedial Action (s) | M |
| | Preliminary Root Causes Analysis RCA (following CAT – annex 3) | M |
| | Impacted Documents, including Baseline Documents | M |
| | Target date for NC closure | M |
| | Supporting Documents | O |
| | Is a PCR/CCB Required? (if Y, reference #) | M (MAJOR) |
| | Is an RRF/NSI Required? (if Y, reference #) | M (if PIC/PIA/SR) |
| | Performer(s) RO (with signature*) | M |
| | IO ROs (with signature*) | M |
| | IO Reviewers (with signature*) | M |
| | IO Acceptance/Approval (with signature *) | M |

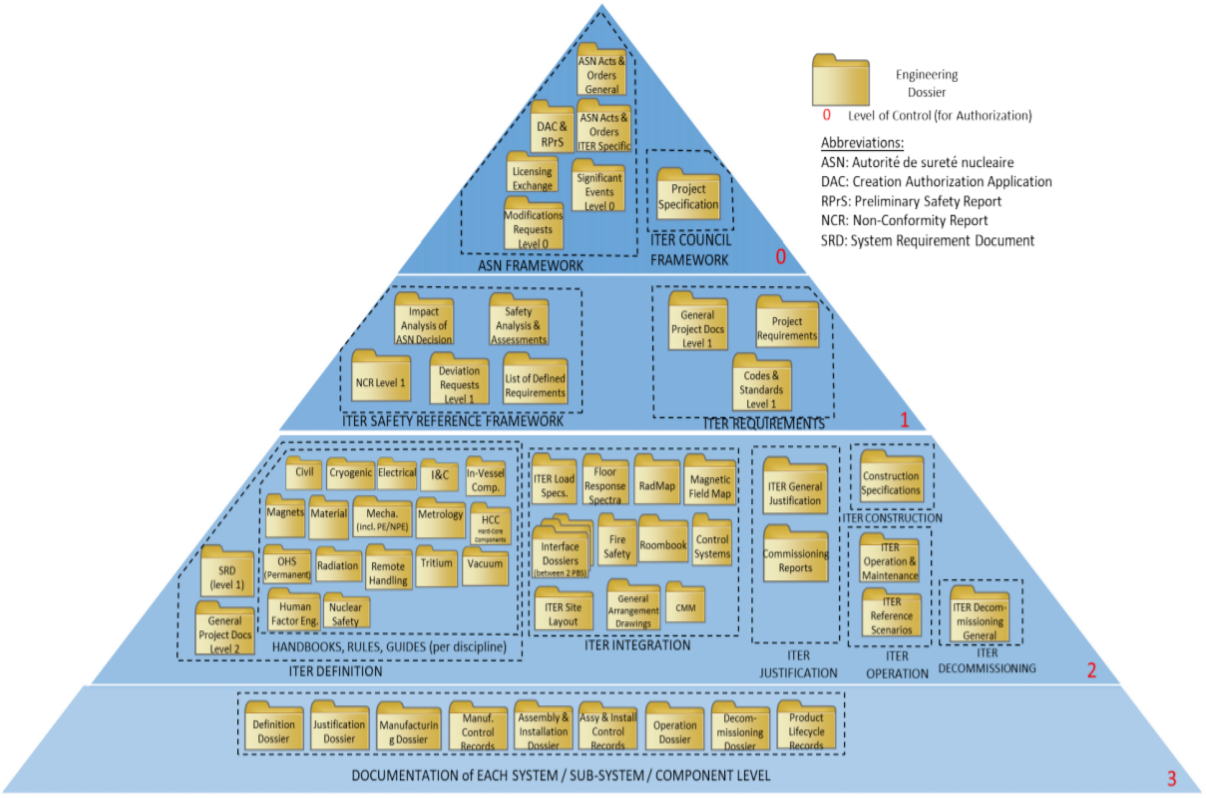
| | | |
|---|---|---|
| NC Closure Stage **II** | Follow-up on remedial action(s): when implemented + evidences | M |
| | Root Cause Analysis | M (Major) |
| | Are Corrective (and Preventive/risk-based) Actions Required? Y/N<br>If Y, description of actions and due date. | M (Major) |
| | Follow-up on Corrective actions required for final NC closure: when implemented + evidences | M (Major) |
| | Performer(s) RO (with signature *) | M |
| | IO ROs (with signature *) | M |
| | IO Reviewers (with signature *) | M |
| | IO Acceptance/Approval (with signature *) | M |

(*) 'with signature' means that there shall be a formal trace (electronic signature –*NCR database*) of the signature of the person.

(**) When the NC affect a single item, the item SN (serial Number), FR (functional reference) and PNI identifier shall be used. When the NC affect an entire batch, the PNI shall be used to identify all concerned items

# Appendix 2 – TECHNICAL BASELINES overview levels as per [11] – see ITER baseline diagram




**Details of ITER baselines with Engineering dossiers type and baseline levels as per [11].**

**MANAGEMENT BASELINES.**

The management baseline requirements are indicated in chapter 9.5 of ITER_D_2NCR3F - ITER Project Management Plan (PMP).

# Appendix 3 – Causal Analysis Tree for Root Cause Analysis (RCA)