

## MQP Level 2

# Procedure for management of Nonconformities

This document specifies the Nonconformity Management process, hereinafter NC, from the Initiation to the Closure in the IO system.

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v5.1	Approved	18 Jun 2012	Minor editorial change to contents
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v6.1	Approved	25 Jun 2013	Modifications according to approved MQP Doc Request G23MB4: <ul style="list-style-type: none"> <li>- Changes to allow verbal agreement on remedial actions when the non-conformance does not impact on an external system</li> <li>- Minor NCR: the section 1, 2.1 and 2.2 need to be filled and sent to IO</li> </ul>
v6.2	Approved	13 Mar 2015	Changes according to MQP doc Request - QWRRS2: <ul style="list-style-type: none"> <li>- Addition of an explanatory footnote for PIC and PIA</li> <li>- Addition of PIA with PIC</li> <li>- Addition of list of internal NCRs to be sent to IO upon request of QARO</li> </ul>
v7.0	Approved	18 Aug 2017	Update according to MQP doc request VBFECU (the summary of pre-reviews: MQPWG, SQA WG, 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: <ul style="list-style-type: none"> <li>- Process NC introduced (not product NC as previously understood);</li> <li>- 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.</li> <li>- The workflow and roles rendered generic (e.g. notion of DIRO now extended to 'interaction RO', so that it can encompass Construction Teams).</li> <li>- 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.</li> <li>- 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.</li> <li>- KPI of the process and escalation process (in case of dispute) are introduced.</li> </ul>
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)

			<p>as per Safety Division Action plan (definition CFSI included, clear requirement for SD involvement and responsibilities).</p> <ul style="list-style-type: none"> <li>- clarify the IO NC approval level (process owner / DH) as per NCR database application</li> <li>- reference of JIRA CAT system to be applied for action follow-up</li> <li>- clarification related to minimum time - frame from NCR detection until NCR recording (maximum two weeks is allowed).</li> <li>- clarifications regarding intermediate / conditional release of NCR that requires further long term actions (further actions and instruction to be recorded in release note).</li> </ul>
v8.1	Signed	14 Jun 2019	<p>Revision to implement reviewer comments from previous version. List of changes:</p> <ul style="list-style-type: none"> <li>- add reference - XKUKAX</li> <li>- add DAs responsibilities (as per NCR database application)</li> <li>- add clarifications regarding baseline levels (see chapter 5.1 and annex 2)</li> <li>- add further clarifications for NCR conditional release.</li> <li>- add annex 2 - Baseline level map as per [11]</li> <li>- add clarifications on appendix 1 - NC form</li> </ul>
v8.2	Approved	17 Jun 2019	<p>Revision - Technical IDM issue.</p> <p>Revision as per MQP doc Request - XYLYX5 &amp; to implement reviewer comments from previous version.</p> <p>List of changes:</p> <ul style="list-style-type: none"> <li>- add reference - XKUKAX</li> <li>- add DAs responsibilities (as per NCR database application)</li> <li>- add clarifications regarding baseline levels (see chapter 5.1 and annex 2)</li> <li>- add further clarifications for NCR conditional release.</li> <li>- add annex 2 - Baseline level map as per [11]</li> <li>- add clarifications on appendix 1 - NC form</li> </ul>

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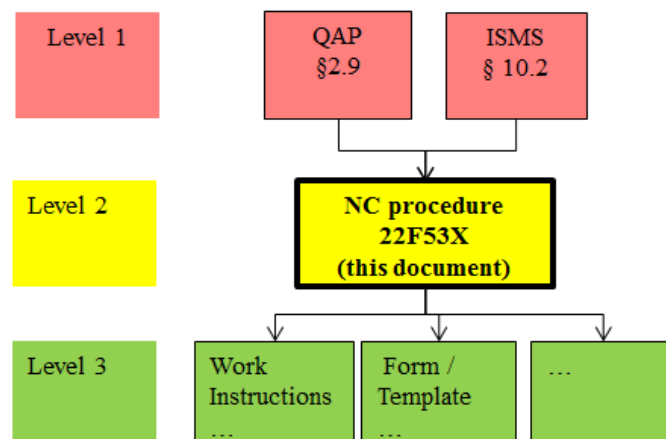
# 1 Purpose

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

The standard form for NC management is provided to list the minimum information required for managing a NC report.

# 2 Scope

This MQP Level 2 Procedure is belonging 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 covers Nonconformities detected in the course of execution of activities:

- for both types of NCs: Product NC and Process NC,
- for both internal and external IO Performers.

It covers the case of DAs and IO-PTs.

## 2.1 Out of Scope

- Deviation Request.
- Cost and schedule issues.
- Internal Nonconformities <sup>1</sup> from external Performers are 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 in **section 9.1**)

<sup>1</sup> Nonconformities according to the QMS of the external Performers

### 3 Definitions and acronyms

#### 3.1 Definitions

##### Performer

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

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

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

##### Nonconformity, herein NC

- 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.

##### IO Specified Requirement:

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

##### Product NC and Process NC

Product NC	Process NC
<ul style="list-style-type: none"> <li>• When the requirement not fulfilled is relative to the characteristic of an item, component, work, it is called Product NC               <ul style="list-style-type: none"> <li>➢ As an example, failure in meeting a specified tolerance of a component.</li> </ul> </li> </ul>	<ul style="list-style-type: none"> <li>• When the requirement not fulfilled is relative to the specified way of working, it is called Process NC.               <ul style="list-style-type: none"> <li>➢ 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.</li> </ul> </li> </ul>
<p>Note1: NC identified first at Product level, after investigation of root causes, may trigger the need for opening a Process NC.</p> <p>Note2: The final and exact classification (product or process) will be consolidated in IO and shall not slow down the process of NC treatment, since the methodology is the same.</p>	

##### Initiator of a NC:

- Entity or person who identifies Nonconformity and triggers the registration of the NC. Usually, it is the Performer, but it can be detected and raised by any person involved in ITER project (e.g. IO-CT, IO-PT, DA, Management, ASN, (A)NB, QC inspector, ...).

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

- IO person assigned responsible for the coordination and closure of the NC, in the IO NC system (NCR database). In majority of cases, IO-RO is:
  - for Product NC, TRO or CRO.
  - for Process NC, the Process owner.

##### DA RO

DA person assigned 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) is used. For NCRs where the NC ownership will be under DA responsibility, the DA RO will apply DA specific NCR procedure accepted by IO.

### **IO-Interactions RO**

- An all-inclusive term to designate a RO who is impacted by the original NC (e.g. DIRO or RO in Construction Teams...).

### **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.

**Baseline documents (level 0, 1, 2 and 3)** – to be used for NC categorization – definition as per [10].

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.

### **IO NC system:**

- An all-inclusive term used to refer to the agreed system for tracking and recording NCs until closure in IO. It can be through IDM documents or through NCR Database (DB).

### **Remedial action**

- Action to eliminate a detected Nonconformity
  - For Product NC:
    - **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.
  - For process NC:
    - **Use as-is:** the process deviates from specification but the result is declared fit for the intended use.
    - **Reject:** the process deviates from the specification and the result does not fit for the intended use and shall be redone according to the process specification.
  - For both Product and Process NC:
    - **Modification or issue of documentation:** it includes at minimum the documents under configuration control which are to be modified or created in IO baseline.

### **Corrective vs preventive/risk-based actions <sup>2</sup>**

<sup>2</sup> 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
<b>3.12.1 preventive action</b> action to eliminate the cause of a potential nonconformity or other potential undesirable situation ... Note : <b>Preventive action</b> is taken to prevent occurrence whereas <i>corrective</i> action is taken to prevent recurrence.	<b>0.3.3 Risk-based thinking</b> 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 <b>preventive</b> tool. Consequently, IOS9001 v2015 does not have a separate clause or sub clause on preventive action. <b>The concept of preventive action is expressed through the use of risk-based thinking</b>	<b>Art. 2.6.3. – I. –</b> The operator ensures discrepancies are managed within a time-frame adapted to the issues concerned, in particular by ... defining the appropriate remedial, <b>preventive</b> and corrective actions	<b>6.3.</b> 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 <b>preventive</b> actions taken shall be monitored and shall be reported to the management at an appropriate level in the organization.

In conclusion, this document uses the all-inclusive term **preventive/risk-based action** to cope with various terminologies, always referring to the same concept of anticipating and mitigating risks.

- **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.

### **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.

### **Authorized Body/Authorized Notified Body**

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

### **Manufacturer**

Means any natural or legal person who manufactures a product or has a product designed or manufactured, and markets that product under his name or trademark

### **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.



### 3.2 Acronyms

Complementary or as quoted in [22] ITER abbreviations:

ASN	French Nuclear Safety Authority (from French Autorité de Sûreté Nucléaire)
(A)NB	(Authorized) Notified Body
CAR	Corrective Action Request
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
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 <a href="#">[QYTZEP]</a>
IDM	ITER Documentation (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
OFI	Opportunity For Improvement
PA	Procurement Arrangement
PBS	Plant Breakdown Structure
PCR	Project Change Request
PIC	Protection Important Component, as defined in [23]
PIA	Protection Important Activities, as defined in [23]
PIM	Project Issue Management
PE/NPE	Pressure Equipment (PE) in the scope of [2] Nuclear Pressure Equipment (NPE) in the scope of [4]
PNI	Part Number of ITER
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
SOA	Sign-Off Authority
SR	Safety Related
TRO	Technical Responsible Officer

WBS	Work Breakdown Structure
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## 4 Applicable and References Documents

### 4.1 Applicable documents

Regulations	[1]	Order dated 7 February 2012 relating to the general technical regulations applicable to INB - EN	<a href="#">7M2YKF</a>
	[2]	Pressure Equipment directive 2014/68/UE [French version]	<a href="#">RZ6PAK</a> <a href="#">[RZ5PGG]</a>
	[3]	Environmental code mainly art L557 and art R557	<a href="#">U5TKD4</a>
	[4]	ESPN Order dated 30 December 2015 modified	<a href="#">SMP384</a>
MQP Level 1	[5]	Level1 MQP – ITER Quality Assurance Program (QAP)	<a href="#">22K4QX</a>
	[6]	Level1 MQP - ITER Integrated Safety, Environment and Security Management System Manual (ISMS) ITER Policy on Security, Safety and Environmental	<a href="#">4HCWJU</a> <a href="#">43UJN7</a>
Interacting processes – MQP	[7]	Level2 MQP - Document & Records process - Sign-Off Authority for Project Documents	<a href="#">2EXFXU</a>
	[8]	Level2 MQP – Nuclear Safety process - Procedure for the Safety Review of Regulatory Files	<a href="#">48VD6T</a>
	[9]	Level2 MQP – Nuclear Safety process - Organization of nuclear safety inspections in ITER Organization and its supplier chain	<a href="#">CW8EL3</a>
	[10]	Level2 MQP – Configuration Management process – Procedure for Configuration Identification and Configuration Status Accounting	<a href="#">TZV743</a>
	[11]	Level2 MQP – Configuration Management process – Procedure for Configuration Control, Review and Audit	<a href="#">TZY7YV</a>
	[12]	Level3 MQP – Configuration Management process - Project Issue Management	<a href="#">SSU96T</a>
	[13]	Level2 MQP – Inspection and Testing process – Requirements for Producing an Inspection Plan	<a href="#">22MDZD</a>
	[14]	ITER Procurement Quality Requirements	<a href="#">22MFG4</a>
	[15]	Requirements for Producing a Contractors Release Note	<a href="#">22F52F</a>
	[16]	Release Note Template	<a href="#">QVEKNQ</a>
	[17]	Working Instruction for Mechanical Completion Dossier Preparation	<a href="#">UYUSEE</a>
GIN	[18]	GIN 007 - Closure of Non-Conformance Reports	<a href="#">UKG3W8</a>

### 4.2 Reference documents

[19]	Quality Management System Audits	<a href="#">2DQTA8</a>
[20]	ITER Corrective Action Procedure (CAR)	<a href="#">9QELY2</a>
[21]	NC Report Template	<a href="#">A6HRLB</a>
[22]	ITER abbreviations	<a href="#">2MU6W5</a>
[23]	Nuclear safety common definitions	<a href="#">RLZXMV</a>
[24]	IO NC Report Template	<a href="#">2MVG2Z</a>
[25]	Project Change Procedure	<a href="#">22F4E5</a>
[26]	Guideline for identification (Symptoms) of Counterfeit, Fraudulent and Suspect Items (CFSI)	<a href="#">XKUKAX</a>

## 5 Basic principles

### 5.1 Categorization of NC

- In a graded approach, the depth and rigour of details necessary, and the magnitude of resources required to manage the NC is commensurate with the relative importance of the detected NC in terms of risks on safety, quality and performance.
- 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.
- The following table lists areas of considerations with criteria, to guide the categorization. The final categorization shall be agreed commonly between the Performer (DAs TRO in case of PA implementation) and the IO-RO by consideration of the level of impact. NC will be categorized ‘Major’ if any criteria falls into ‘Major’ category.

Major	Safety / Regulation	- Nonconformity with a specified IO requirement affecting Regulatory Requirements, Safety, Environmental impact
	Baseline*	- Nonconformity with an impact on a Baseline document Level 0 / 1 / 2
	Interaction	- Nonconformity with interaction with other PBS, Construction and/or other Process
	Impact on Performance	- Implication on Functional performance
	Repeated incident	- Several similar NCs can trigger one major NC to investigate root cause of recurrence.
Minor	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 procedure [10] – see extras of ITER Baseline Map - Appendix 2 of present procedure.

### 5.2 General principles for NC management

- The methodology for problem solving, based on standard quality practices, is as follows:
  - 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 problem
  - NC report shall be immediately (typically within few days) raised to record the nonconformity and to initiate the NC process. In case of dispute between stakeholders, two weeks from the NC detection time may be allowed (with IO agreement).
  - Remedial actions to eliminate the Nonconformity
  - Root cause determination through RCA (Root Cause Analysis) and decision on corrective & preventive/risk-based actions
  - Follow-up of actions from their initiation until their implementation
  - Verification of the effectiveness of actions.

- The above principles are deployed in a graded approach, in order to establish action plan commensurate to the extent and impact of the issue. This means that:
  - for Minor NC:
    - Treatment may be limited to defining and implementing remedial actions, though the Performer is not relieved of his responsibility to manage the NC in his own QMS.
  - for Major NC:
    - In case of Rework or Repair as remedial actions (for Product NC), if the rework/repair procedure differs from the procedure agreed with IO, the procedure proposed, describing operations, inspections and tests, shall be agreed with IO before the rework/repair can commence.
    - RCA shall be conducted with conclusions whether or not launching corrective actions, and should consider as appropriate any preventive/risk-based actions.
- As a general principle, the deliveries shall be released only if all the related NCR's are closed. For exceptional cases, intermediate/ conditional release of the NCR may be accepted only after common agreement between IO and DA's / performer.
- For those cases when intermediate/conditional release of the NC is agreed to allow the continuation of work and/or shipment of components, a mechanism for tracking and checking remaining points/ actions is required, until the final closure of the NC and handover. Typical mechanism is through the management of Inspection Plan, as per [13]. For such cases, clear further instructions/ actions shall be also indicated in the final delivery documentation (section 6 of [16] - Release Note template - [QVEKNQ](#)) to be taken into account on the next phases of the project.
- The IO NC system does not only track the actions agreed with external Performers, but also the internal actions in IO. If it is decided to follow some long-term 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.
- Final closure of the NC on the individual item or work shall be granted if all the actions to guarantee the IO specified requirements<sup>3</sup> at the handover to IO, are implemented. This includes at minimum:
  - For minor NC, closure information that evidences the implementation of remedial actions.
  - For major NC, closure information which evidences the implementation of remedial actions, conclusion on RCA and whether or not there is a need for corrective and preventive/risk-based actions, if some corrective actions are decided, evidence that they are implemented.

If it is appropriate that some long-term corrective actions be followed in a separate system (JIRA CAT system or different equivalent system), to allow final closure of the NC on the individual item or work, it is confirmed by IO-QARO who verifies the traceability of those actions.

  - For NCR closure [18] GIN 007 shall be applied by stakeholders.
  - Generally, the NCR timeframe closure shall take into consideration all the remedial and corrective actions due dates, agreed schedule and contractual/ PA requirements / priorities.
- As per KPI **section 11**, a monitoring of the timeline shall be in place to ensure a mechanism of follow-up of NC until final closure.
- The NC report shall contain or refer to all relevant material or information in a usable format to enable an informed decision on the definite course of action to be taken.
- NC management is an essential process which performance directly contributes to the overall ITER Project performance. When establishing categorization and agreeing on relevant actions for problem solving, collaborative work is expected. Any adapted form of working level methods between stakeholders and relevant experts is encouraged (meetings, working groups...).

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<sup>3</sup> or to guarantee that individual item or work is fit for intended use, in the case of Use As-Is or Repair

- In IO, the NC owner is primarily the RO of the item or work being affected by the NC (IO-RO).
  - In case of NC involving several Performers, an owner in IO shall be established with the responsibility to coordinate all actions between parties and supervise the overall action plan.
- 2 options are possible:
  - A unique NC is opened covering all aspects and Performers;
  - Several NCs are opened for each Performer.
- If the NC owner faces issues in finding agreement between parties, or if there is no agreement reached to find an NC owner, issue will be escalated according to **section 10**.
- In DA, the NC owner is primarily the RO of the item or work being affected by the NC. For such situation (NC with no impact on IO requirements) when DA is considers NC owner, the DA shall apply their own specific NCR procedure accepted by IO.

### 5.3 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.

#### 5.3.1 Process Nonconformity

IO describes and presents to ANB<sup>4</sup> the solutions it intends to adopt to remedy the process nonconformity related to the application of [Implementation plan for design & manufacture of PE/NPE](#) and shall obtain ANB validation<sup>5</sup> before they are implemented.

#### 5.3.2 Major Product Nonconformity

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

IO describes and presents to ANB<sup>4</sup> the solutions it intends to adopt to remedy the major product NCR and shall obtain ANB validation<sup>5</sup> 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 have an impact on an essential safety requirement of [1], [2], [3] or [4] and if the hazards and risks analysis should be updated and submit 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).

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<sup>4</sup> Depending on the nature and significance of these non-conformities, the ANB may increase the frequency of audits and unannounced inspections.

<sup>5</sup> ANB acceptance shall be compatible with the production schedule. Reply should not hold the production. If for any reason, ANB need more time to express his opinion, it will be deal with ANB-RO case by case.

### 5.3.3 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.

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 can add new control points (Hold points, witness points, reports or notification points) on this new MIP.

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

### 5.3.4 Nonconformity closure

Nonconformity shall be close-out following relevant paragraph 5.2.

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

### 5.4 Case of NC related to CSFI

In case the Non-Conformity deals with a Counterfeit, Fraudulent and Suspect Item (CSFI), 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.

An in-depth analysis is conducted in a second time describing the detection means that were used, the causes, the real or potential consequences and the corrective actions.

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 CSFI.

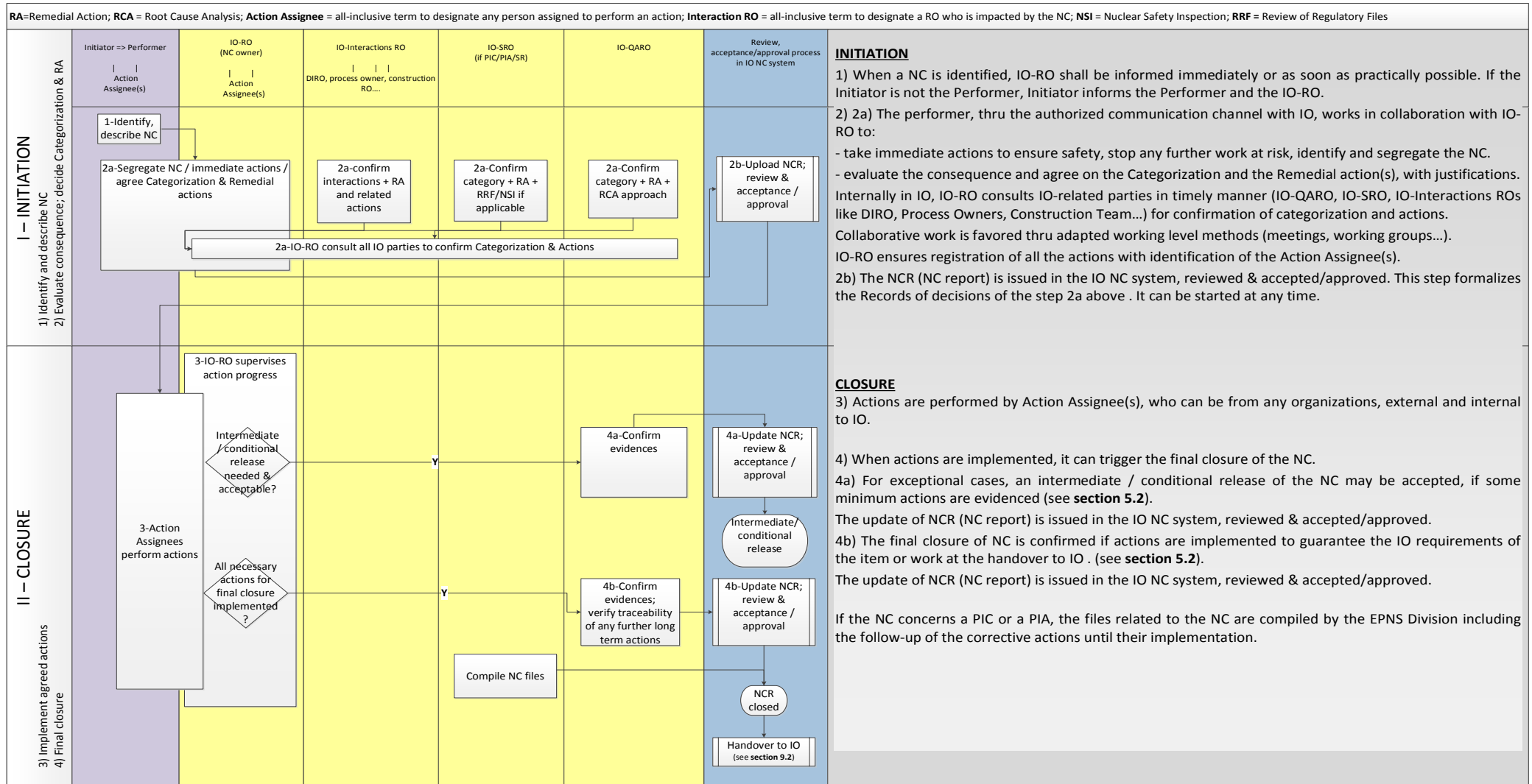
For identification (symptoms) of CFSI items the following guideline need to be followed and consulted by the stakeholders: [25] - [XKUKAX - Guideline for identification \(Symptoms\) of Counterfeit, Fraudulent and Suspect Items \(CFSI\)](#)

## 6 Workflow

The work flow focuses on Roles and Responsibilities in a generic way. 2 main stages of the process are defined, for both Product NC and Process NC:

**I. Initiation:** 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.







## 7 Responsibilities

- The Performers shall ensure that they implement a system compliant with this document to control nonconformities.
- For external IO NC, 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	<ul style="list-style-type: none"> <li>• Detect and identifies NC (provide a NC description vs requirements) and notifies IO;</li> <li>• Alerts the involved parties, primarily the affected IO-RO as soon as practically possible (typically within a few days) and with sufficient details; Note: the IO-RO may judge that the NC is actually an “Internal Non-conformity” and stop the initiation of the NC;</li> <li>• Notify the Performer, if different from the Initiator;</li> <li>• 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.</li> </ul>
2	Performer	<p>When Performer is the person detecting the NC, executes actions of Initiator as above;</p> <ul style="list-style-type: none"> <li>• 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;</li> <li>• Make initial written proposal of the categorization &amp; remedial actions, along with justifications.</li> <li>• 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 categorization and actions (remedial actions and corrective actions).</li> <li>• Provides evidence of progress of the NC treatment to the IO-RO in a pro-active and timely manner.</li> <li>• 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.</li> <li>• Complementary to the required information by IO, manage comprehensively the NC in its own system.</li> </ul>
3	IO-RO (NC Owner)	<ul style="list-style-type: none"> <li>• IO Person assigned responsible :               <ul style="list-style-type: none"> <li>○ For the coordination and control of the activities in the NC treatment;</li> <li>○ Ensuring that the NC is documented and recorded in the IO NC system correctly.</li> <li>○ Triggering and guarantying the closure of the NC.</li> </ul> </li> </ul> <p>For that , the IO-RO shall:</p> <ul style="list-style-type: none"> <li>• 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.</li> <li>• Agree with the Performer and DA RO (in case of PA implementation) on the remedial actions; Participate and conclude on the impact assessment, including impact on IO Baseline documentation.</li> <li>• 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.</li> <li>• Shall ensure that the NC is issued and registered in the IO NC system correctly.</li> <li>• Track the actions until the final closure of the NC in IO NC system.</li> </ul>

#	Stakeholder	Responsibilities
		<ul style="list-style-type: none"> <li>In the review process of the NC reports, is either the person Accepting/Approving<sup>6</sup>, or is Reviewer (if acceptance/approval done by higher level of organisation).</li> <li>IO-RO can seek assistance from IO-QARO in the methodology of NC problem solving techniques.</li> </ul> <p>In case of dispute to find and designate an IO-RO, see <b>section 10</b>.</p>
4	IO-SRO	<ul style="list-style-type: none"> <li>Checks if PIC, PIA, Safety Related (SR), are properly designated.</li> <li>Agrees on the NC categorization (for NC concerning PIC and/or PIA).</li> <li>Assess Safety impact and validates action proposal.</li> <li>Reviews with respect to Regulations [1], [2], [3] &amp; [4]</li> <li>Is part of the review process of the NC reports, as appropriate for NC concerning PIC and/or PIA.</li> <li>Confirms if there is a need for Safety Review of Regulatory Files [8] and / or Nuclear Safety Inspection [9] , and call for those processes as necessary.</li> </ul>
5	PE/NPE Network	<ul style="list-style-type: none"> <li>Checks if PE, NPE are properly designated.</li> <li>Agrees on the NC categorization (if the NC is PE/NPE relevant).</li> <li>Consult (A)NB for major product NCR and process NCR</li> <li>Assess statutory &amp; regulatory impact and validates action proposal</li> <li>Review with respect to Regulations [1], [2], [3] &amp; [4].</li> <li>Is part of the review process of the NC reports, as appropriate.</li> </ul>
6	IO-Interactions RO (DIRO)	<ul style="list-style-type: none"> <li>Checks the NC potential impact on other areas than the original scope of the NC, review and confirm remedial action proposal.</li> <li>For Product NC at manufacturing stage, it includes the assessment of impact on Assembly, Installation and Operations.</li> <li>Is part of the review process of the NC reports, as appropriate.</li> <li>In case there is any change action(s) on IO Baseline documentation, ensure it is implemented according to [11].</li> <li>Analyse the NCR considering the design impact and if PCR is required to trigger further upper level project changes as per [25].</li> </ul>
7	IO-QARO	<ul style="list-style-type: none"> <li>Checks the compliance of the NC process</li> <li>Checks if proper RCA is undertaken, commensurate to the impact and risk of the NC, along with the necessary action(s).</li> <li>Can provide a support to the stakeholders, as necessary, in the methodology of NC problem solving techniques.</li> <li>Is part of the review process of the NC reports, as appropriate.</li> <li>Checks the evidences required to grant the closure of NC. It involves traceability of the actions until implementation.</li> <li>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.</li> <li>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/OFI in the appropriate IO system.</li> <li>Facilitate the coordination between the stakeholders, and may become the IO NC owner, in case of complex NC, involving different processes.</li> </ul>

<sup>6</sup> as per contract definition

#	Stakeholder	Responsibilities
8	QMD	<ul style="list-style-type: none"> <li>• In application of GIN007 [18], QMD ensures that NCs are closed in due time.</li> <li>• Provide NC statistics and KPIs to monitor the effectiveness of the NC process.</li> </ul>
9	IO-Tech Staff	<ul style="list-style-type: none"> <li>• He /She is designated by IO-RO as appropriate.</li> <li>• Review the NC regarding the technical aspects.</li> </ul>
10	DH/Process owners	<ul style="list-style-type: none"> <li>• For IO internal <u>product NC</u>, the approval shall be under DH (or appointed representative) responsibility.</li> <li>• For IO process NC, process owner ensure the NCR approval.</li> </ul>
11	DA-RO	<ul style="list-style-type: none"> <li>• DA Person assigned responsible : <ul style="list-style-type: none"> <li>○ For the coordination and control of the activities in the NC treatment within DA;</li> <li>○ Ensuring that the NC is documented and recorded in the IO NC system correctly.</li> <li>○ Triggering and guarantying the closure of the NC ensuring continuously interface/ communication with performer.</li> </ul> </li> </ul> <p>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.</p>

## 8 Records/Outputs

- The form in Appendix lists the minimum information required for managing a NC report.
  - The template [21] or template [24] 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 (**section 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. They 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.
  - The present procedure 22F53X covers Nonconformities detected in the course of execution of activities.
  - Nonconformities resulting from QA audits are managed through detailed steps described in [19] .
  - The CAR procedure [20] 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 Quality’

As elements governing ITER Procurement Quality Requirements[14]:

- 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 [15] and Manufacturing Dossier.
  - For Assembly&Installation, it is is governed by the process for Mechanical Completion Dossier [17].
- During execution of Inspection Plans governed by [13], if modifications appears to be necessary due to Nonconformity (such as repair...), the NC report should be referred in the Inspection Plan.

## 9.3 Link with ‘Nuclear safety’

- In the treatment of NC, SRO may trigger the need for the Review of Regulatory File (RRF) [8] or / and for a Nuclear Safety Inspection (NSI) [9]. See **section 7** (role of IO-SRO).

## 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. (**Section 5.1**). Those levels are governed by [10].
- 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] (**Section 7**) and PCR [25].
- In **section 10** (Dispute and Resolution), the PIM process [12] can be called (Project Issue Management).

## 9.5 Link with ‘Documents and Records’

- In **section 7**, the present procedure 22F53X describes the roles of IO Stakeholders as reviewers of the NC reports, as an input to SOA (Sign-Off Authority) [7]. It can be summarized in following table:

	IO-RO	IO-Interactions RO	IO-QARO	IO-SRO	PE/NPE network
<b>Minor NC</b>	Approve <sup>7</sup> / Accept or Review	-	Review	Review (if PIC/PIA/SR)	Review (if PE/NPE)
<b>Major NC</b>		At minimum IO-DIRO Review Stage I <sup>8</sup>	Review	Review (if PIC/PIA/SR)	Review (if PE/NPE)

SOA [7] 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 Level3 documents<sup>9</sup>, take(s) precedence.

## 9.6 Link with “PE/NPE conformity assessment”

In the treatment of NC, PE/NPE Network 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.

## 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 nine 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 [12]).

<sup>7</sup> 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).

<sup>8</sup> Stage I is the Initiation stage as per **section 6**, with one objective being agreement on remedial actions.

<sup>9</sup> at working level for a given scope

## 11 KPI

- NC management is an essential process which performance directly contributes to the overall ITER Project performance.
- Good NC process management means good treatment of the detected NC. It does not mean few NCs; it means treatment under control, i.e. ability to detect, evaluate and mitigate impact, track and execute the relevant actions in a timely manner, for the respect of the IO Project baseline.
- Indicators (KPIs) of performance of the process shall be in place. KPIs should measure typically, and is not limited to:
  - timeliness between detection and notification to IO,
  - timeliness of closure of NCs.

Timeliness does not mean that NC should be closed quickly; it means the need for controlling the NC from detection, notification to IO, registration in IO NC system until its closure. If long time is necessary to close the NC, justification shall be provided and recorded.

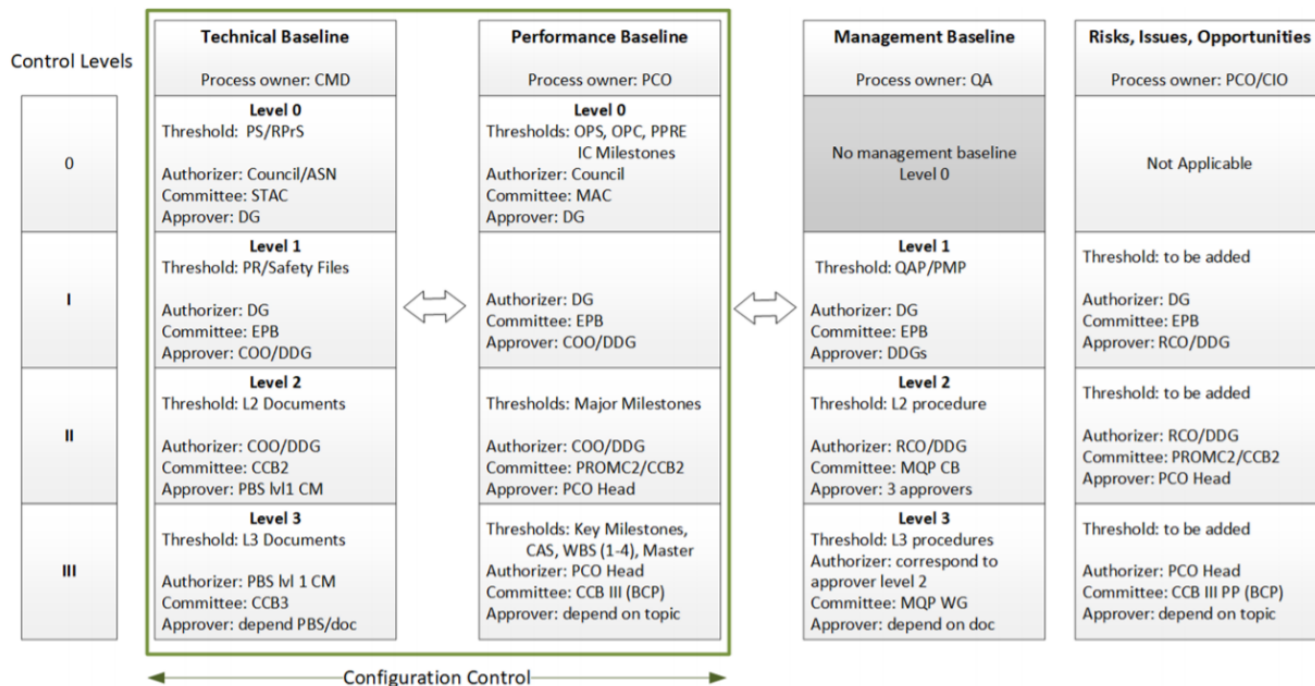
- In application of QAP [5] **section 2.9**, ‘‘ *The Non-conformities shall be resolved with high priority and this resolution shall not exceed 9 months in average and 12 months individually, except initial agreement from the IO DG or the QMD Head.*’’

## Appendix1: NC Form

	Field	M = Mandatory O = Optional
NC description / scope	Title of Nonconformity	M
	ID	M
	Type of NC (process / product)	M
	NC Category (Major or Minor)	M
	External Performer(s) NC Reference(s)	O
	ITER Contract reference (PA/Task Agreement / Direct contract as applicable)	M (if applicable)
	DA	M (if applicable)
	Supplier	M (if applicable)
	Initiator and organization (with signature *)	M
	Work Breakdown (PBS/WBS, Process, Work activity...)	M
	Item / Work identification and localization (objective is to keep traceability)	M
	FR / PNI (for product NC only)	M
	CWP	O
	Affected DA (other than related contact)	M
	Quality Class	O
	Is PIC? PIA? SR?	M
Stage I - Initiation	Date of Detection	M
	Requirements	M
	Description of the Nonconformity vs. the Requirement	M
	Proposed Remedial Action(s) and description	M
	Justification of Proposed Remedial Action (s)	M
	Preliminary Analysis of Causes	M (Major) / O (other)
	Impacted Documents, including Baseline Documents	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
Stage II - Closure	Follow-up on remedial action(s): when implemented + evidences	M
	Root Cause Analysis	M (Major) / O (other)
	Are Corrective (and Preventive/risk-based) Actions Required? Y/N If Y, description of actions	M (Major) / O (other)
	Follow-up on Corrective actions required for final NC closure: when implemented + evidences	M (Major) / O (other)
	For further actions decided: reference # of actions and tracking system	M (Major) / O (other)
	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.

Appendix 2 – Baseline documents levels as per [10] – see ITER baseline map



ITER\_D\_27LHHE - ITER Configuration Management Implementation Plan (CMIP) shall be applied for defining baseline documents level