

Nonconformities HL-UK / CERN WP4 Handling, sharing and approval

EDMS 2894857

H. Garcia Gavela on behalf of the HL-LHC PDQR Office



16/05/2023

Outline

- HL-LHC Nonconformities
- Handling of NCRs
- Content
- Conclusions





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HL-LHC Nonconformities

Nonconformity → Non fulfilling of a requirement (of any kind)



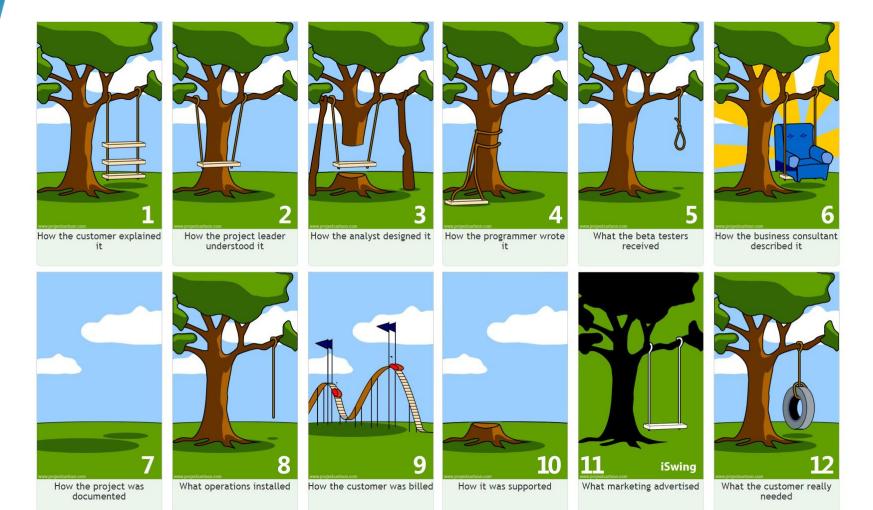
3.6.9 nonconformity non-fulfilment of a requirement (3.6.4)

- Requirements for Cryomodules are specified in the Engineering Specifications, including their annexes (Drawings, Procedures) or are coming from the normative (standards, rules, etc)
- HL Nonconformity Process for Collaborations <u>EDMS 2149457</u>
- Full process on Launching a Nonconformity using EDMS is explained in EDMS 1908145
- NCRs will follow the <u>HL-LHC Template</u> to communicate with CERN in order to comply with HL-LHC NC Policy (class, criticality, decision, corrective/preventive actions...)
- CERN will provide support in the preparation of the NCRs as well with the evaluation. Nevertheless, we expect Collaborations pre-filled the template with the related info as well as with a first assessment





Requirements



Without requirements there are not nonconformities





Requirements

- Without requirements we cannot talk about quality
- Requirements only "exist" if there is a verification method: Each requirement shall be stated in such a way that an objective verification can be defined for it
- Only requirements that are necessary, measurable, achievable, and verifiable shall be included in the specifications
- Requirements are to worded to provide a definitive basis for acceptance or rejection. If no requirements, no nonconformities (to be treated accordingly and to be used for lessons learned and improvement)
- Reviewers allow you to understand how others understand your requirements. Experts will help on defining requirements
- Main goal of the documentation review process is to ensure that requirements (including applicable normative) are clearly defined, revised, agreed and propagated among the different stakeholders. Coordination at Project Level





Project Documentation

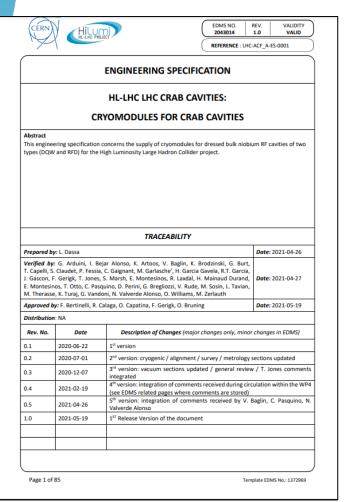
- Documentation is a key player for any project:
 - It provides provision of objective evidence;
 - It proves the conformity of the requirements established by a customer;
 - It enables repeatability and traceability of the work done;
 - It provides provision of appropriate training;
 - In the event of a **nonconformity**, it allows tracing the info back and searching for the **root cause**.
- In projects at large scale, with high personnel turnover (temporary contracts, students, etc) proper documentation (handling, storage, accessibility) becomes critical for an adequate knowledge transfer
- Communication (internal and external)





Requirements

WP4 Engineering Specifications issued for Cryomodule and Cryomodule components
They are the main basis to check applicable requirements

















HL-LHC Nonconformities

- Nonconformities are part of the any kind of production and it does not mean the equipment cannot be used
- Nonconformities ≠ Deviation Requests
 - Nonconformity A deviation from an established requirement is detected
 - Deviation Request Request to do something different from an established requirement
- We are NOT here to search for guilties but to learn from these issues and improve.
- Root cause and corrective/preventive actions are of utmost importance (solve the issues found and avoid recurrence so the process is optimized).
- NCRs can lead to overcosts or delays so it is mandatory to trace them properly and apply the lessons learned in the future





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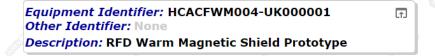
Create EDMS Document via MTF

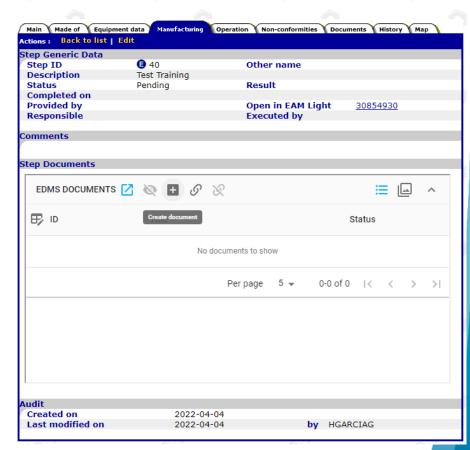
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Equipment Identifier: HCACFWM004-UK000001
Other Identifier: None

Description: RFD Warm Magnetic Shield Prototype

	Made of	E - 1 - 1	Manufacturing Operation Non-conformities Documents	History	Map	
		extra step				
Workflo	ow Dia	_				
			No workflow diagram is defined for this equipment			
Workflo	w Ste	eps			Last Rep	eated
Step 11	R/E	Other name	Description	Status	Result	INC
1		()	Traceability of Materials	Pending		
<u>5</u>		()	Visual inspection after sheet metal and assemble test	Pending		
10		()	Dimensional Control before heat treatment	Pending		
15		()	Final Heat Treatment	Pending		
20		()	Dimensional Control after heat treatment	Pending		
25		()	Magnetic Test	Pending		
30		()	Cleaning, Shipping and Delivery	Pending		
40	(3)	()	Test Training	Pending		

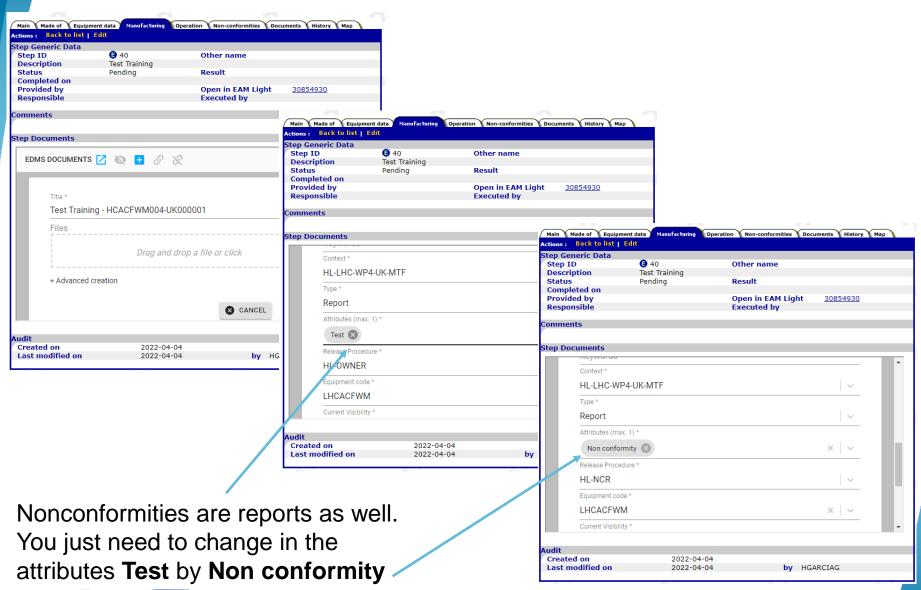








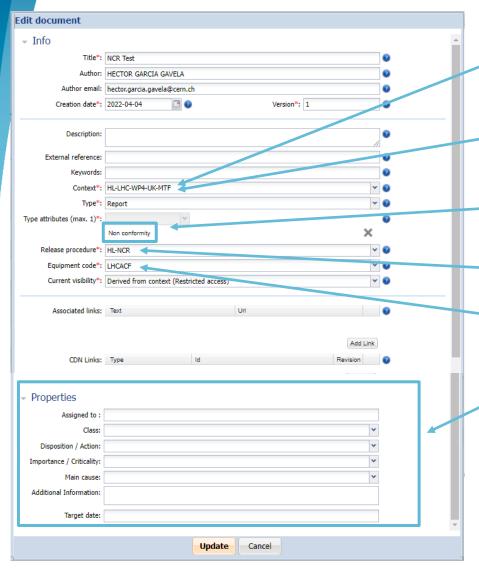
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Create EDMS Document

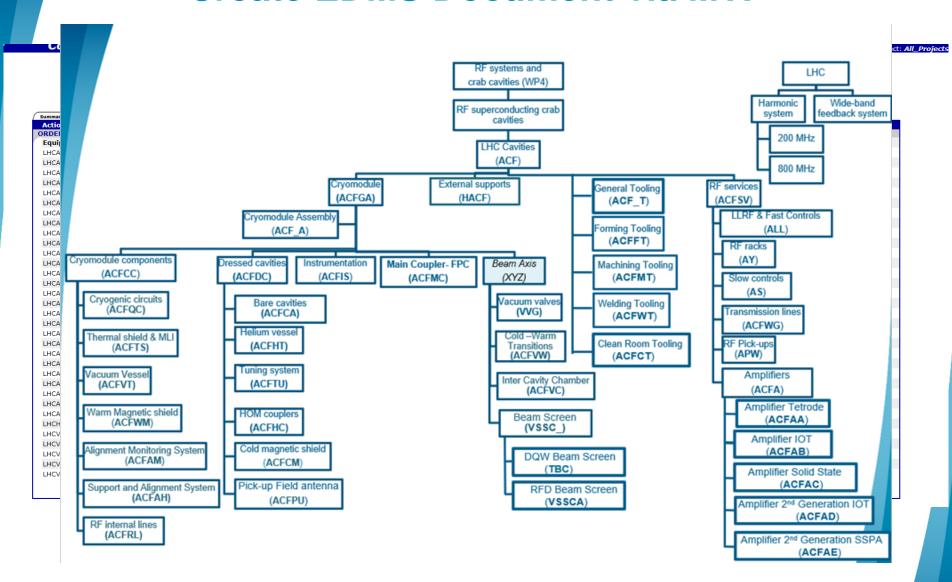


- If you create the NCR directly in MTF, the context by default is already set (HL-LHC-WP4-CANADA-MTF).
- If you create the file in EDMS, choose the context
 HL-LHC-WP4-CANADA-MTF
- Type of Document Report and Type Attribute Non conformity
 - Release Procedure **HL-NCR** (important!!)
 - **Equipment Codes (See next Slide)**
- Once you issue the document, please fill in all the associated EDMS metadata (Info and Properties). Same info that will appear in the Template
- Always start with the version 0.1
- The HL-LHC NCR Template correctly filled in shall be added to the EDMS document





Create EDMS Document via MTF







Attach NCR in EDMS Document to MTF

The NCR shall be attached to the applicable MTF Step (where the deviation is found)

Equipment Identifier: HCACFCA005-UP000001

Other Identifier: None

Description: AUP RFD Bare Cavity Prototype



- If the document is already created in EDMS then we can attach it to MTF
- If it is not created in EDMS yet, the document can be created directly in EDMS by using MTF





Equipment Identifier: HCACFCA005-UP000001
Other Identifier: None
Description: AUP RFD Bare Cavity Prototype





1 Select Document ... 2 Confirm data

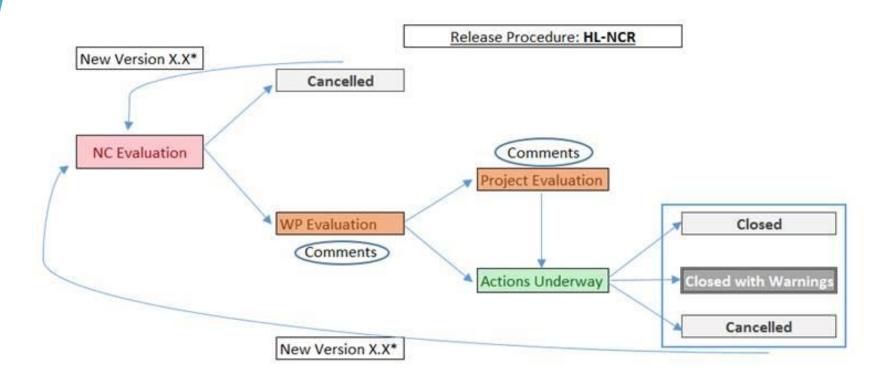
Select the existing EDMS Document

Input the Document Number (in case you know it) or click on the first blue arrow to jump to the EDMS Search page or click on the second blue arrow to jump to EDMS create document wizard

EDMS Document Number
or
Click to search for documents in EDMS
or
Click to create a new document in EDMS

HL-LHC Nonconformatics Continue

Document life-cycle

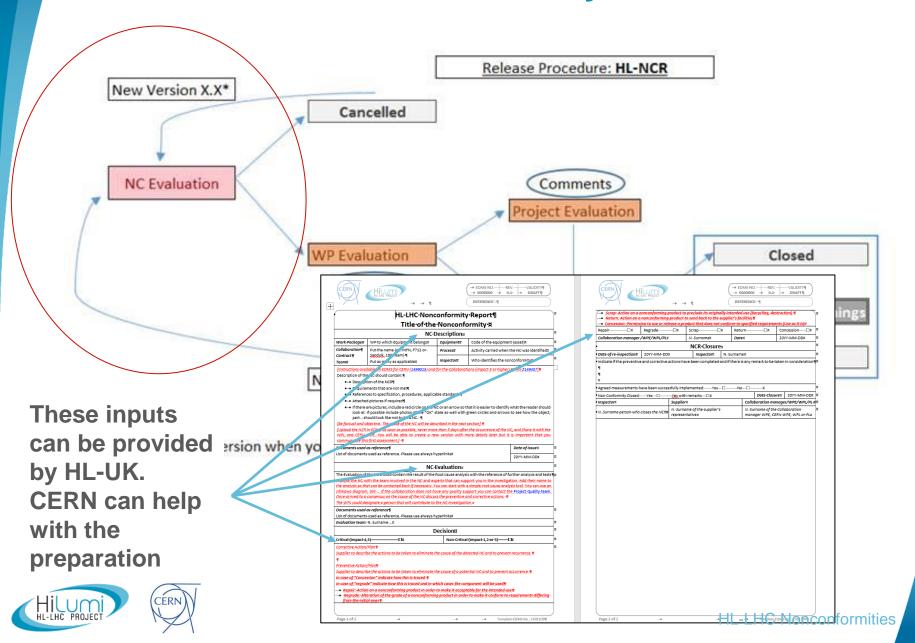


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Document life-cycle



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NC Description

HL-LHC·Nonconformity·Report¶ Title-of-the-Nonconformity-X NC·Descriptionx Work-Package**¤** WP·to·which·Equipment·belongs¤ Equipment¤ Code-of-the-equipment-(asset)¤ Collaboration¶ Put·the·name·(ex.·INFN,·F712·or·· Activity-carried-when-the-NC-was-identified¤ Process¤ Contract¶ Sandvik, 180 Team) 9 Inspectorx Who-identifies-the-nonconformity¤ Put-as-many-as-applicable¤ Team¤

[Instructions-available-on-EDMS-for-CERN-(1499015)-and-for-the-Collaborations-(impact-3-or-higher)-EDMS-2149457]¶

Description-of-the-NC-should-contain: ¶

- → Description·of·the·NCR¶
- → Requirements·that·are·not·met¶
- → References·to·specification, procedures, applicable·standards¶
- Attached·pictures·if·required¶
- If there are pictures, include a red-circle on the NC-or an arrow-so that it is easier to identify what the reader should look at. If possible include photos of the "OK" state as well with green-circles and arrows to see how the object, part... should look like not to be a NC. If

[Be-factual-and-objective.-The-cause-of-the-NC-will-be-described-in-the-next-section]-¶

[Upload-the-NCR-in-EDMS-as-soon-as-possible, never-more-than-3-days-after-the-occurrence-of-the-NC, and-Share-it-with-the-WPL- and-CERN-WPE.- You- will-be-able-to-create-a-new-version-with-more-details-later-but-it-is-important-that-you-communicate-this-first-assessment.]-¶

- Provide all the available information about the Nonconformity (Description, requirement/s not met, etc.) What, Where, When, Who
- Be factual and objective. We are not assessing the causes and the impact yet. First we need to know what went wrong. The root cause of the NC as well as the consequences will be described in the next section (NC Evaluation)
- Add references to reports and other documentation to be used as reference and supportive documentation of the Nonconformity
- Provide pictures and/or any other relevant material that can be useful for the analysis

NC Evaluation

NC·Evaluation¤

The Evaluation of the NC should contain the result of the Root cause analysis with the reference of further analysis and tests \P Analyse the NC with the team involved in the NC and experts that can support you in the investigation. Add their name to the analysis so that can be contacted back if necessary. You can start with a simple root cause analysis tool. You can use an Ishikawa diagram, $5W \cdot ... \cdot if$ the collaboration does not have any quality support you can contact the Project Quality team. Once arrived to a consensus on the cause of the NC discuss the preventive and corrective actions. \P

 $The \cdot WPL \cdot could \cdot designate \cdot a \cdot person \cdot that \cdot will \cdot contribute \cdot to \cdot the \cdot NC \cdot investigation. \texttt{X}$

Documents-used-as-reference¶

List-of-documents-used-as-reference.-Please-use-always-hyperlinks¤

Evaluation · team : · N. · Surname · ... ¤

- The root cause of the Nonconformity is herein detailed Why, How
- A method statement can be proposed to the evaluation team (if Repair is required)
- The impact of the Nonconformity is to be explained (technical and project level)
- Corrective actions to close this NC and Preventive actions to avoid recurrence are herein proposed. These actions shall be assessed and confirmed during the follow step (WP Evaluation). A new version of the document might be required depending on the decision (more information is requested for completeness, different method statement...)





Handling and Sharing of Nonconformities

The NC Class triggers how it is to be communicated -> Marco is your entry point

Impact assessment	Assessment scale	Financial loss	Reputation	Alignment with Business Objectives (WP Deliverables)	Who I shall inform in the project	When
Catastrophic / Extreme	5	Requiring resources outside the collaboration that can not be covered by the project	Large media (or scientific media) coverage - International coverage	Occurrence of the risk will significantly deter the achievement of all the objectives (ex, delay of the full project, not delivery of a component fully under the responsibility of the collaboration,)	PL, WPL, WPE	As soon as detected
Major	4	Requiring resources outside the collaboration that can be covered by the project	Host MS press coverage - Scientific media - Escalating community activism	Occurrence of the risk will significantly hamper the achievement of the of the objectives (ex, delay beyond the collaboration margin but not yet the WP margin, request of a permanent deviation permit for a component, engineering change request afecting the WP,)	PL, WPL, WPE	As soon as detected
Moderate	3	Requiring resources outside the collaboration but that can covered inside the WP	Local press coverage - Neighbourhood reputation (public, suppliers, etc.)	Occurrence will have some adverse effect on the achievement of the objectives (ex, delay eliminating all the margin, request of a deviation permit for a component, engineering change request,)	WPL, WPE	In the 3 days
Minor	2		No one has heard of the occurrence of risk outside CERN; Problem dealt with at CERN's management level.	Occurrence of the risk will have minimal impact on the achievement of the entity's business objectives (magnet, cold mass, cryoassembly)	WPE	During periodic feedback
Negligible	1		No one has heard of the occurrence of the risk outside he department who owned the risk; problem dealt at department management level	Occurrence of the risk will have very little or no impact on the achievement of the entity's business objectives (magnet, cold mass, cryoassembly)	WPE	During periodic feedback

The NC will be assessed by the Collaboration with the team involved in the NC (Production, inspection ...). The first check shall be how this NC affects the project (Impact). If the NC has a relevant impact on the project (delays beyond the margin, additional means beyond the collaboration, damage to the image of the project, etc.), then the WPL shall be informed.

The Collaborations Impact matrix (<u>EDMS 1863763</u>) can be used to evaluate the NC but, in case of doubt, the NC shall be always escalated to the next project level (Share with us!)





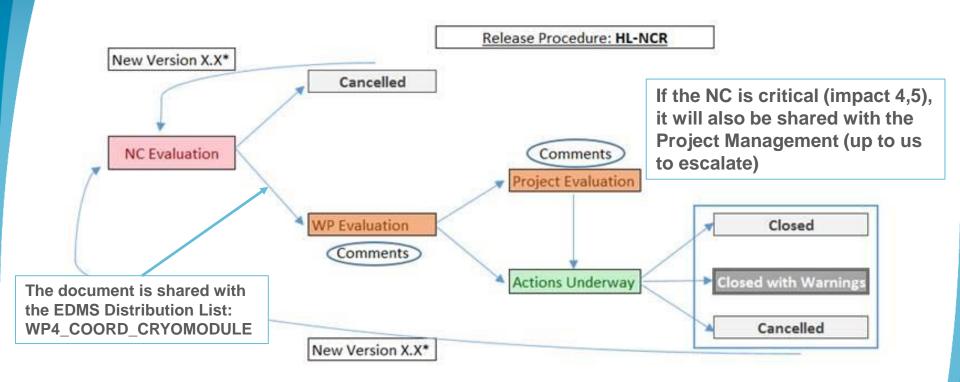
Handling and Sharing of Nonconformities

	Technical impact	Schedule impact	Financial impact	Others
Class 5	 Major implications for the project It requires a clearance from CERN to move fwd. Out of specified performance Potential loss of one full item 	 > 2 months of Delay Time window not respected, and project schedule needs to be updated 		Same issue happens more than timesPotential change in the specification
Class 4	 Major implications for the project It requires a clearance from CERN to move fwd. Potential loss of one partial item Repair to be performed, which requires CERN approval 	 1 month < Delay < 2 months Time window not respected, and project schedule needs to be updated 		Same issue happens up to three timesPotential change in the specification
Class 3	 It requires a clearance from CERN to move fwd. Potential loss of one partial item Repair to be performed, which requires CERN approval 	 1 week < Delay < 1 month Time window not respected but project schedule does not need to be updated 		First time it happensPotential change in the specification
Class 2	Minor implications	• < 1 week of Delay		
Class 1	Minor implications	No delays are accounted		

- Time Reference Delivery of the equipment to CERN
- In case of doubts, inform us! Minor issues may have a later major impact, if they are not properly addressed upon occurrence!
- Of course, a **potential regrade** (change in the specification) needs **CERN Approval** (...and **proper discussion** between HL-UK and CERN-WP4). Regrades will most likely lead to Deviation Requests
- Class 1, Class 2 up to WPE to approve it, Class 3 WPL and Class 4 and 5 to be shared with the PL



Document life-cycle (Share with CERN)



^{*}Create a new version when you have a new file to be uploaded.





WP Evaluation (CERN Assessment and feedback)

WP Evaluation

Project Evaluation

 Once the document is shared with WP4_COORD_CRYOMODULE, we will provide Feedback via EDMS

Decision									
Critical (Impact 4,5)				_	Non-Critical	(Impact 1,2 o	r 3) 🗆		
Repair		Regrade		Scrap		Return		Concession	
Collaboration manager /WPE/WPL/PL				N. Surnai	те	Date		20YY-MM-DD)

- Based on the previous income CERN will assess the information and provide a decision (Full process is traced through EDMS).
- The decision about the Nonconformity shall be integrated in the document

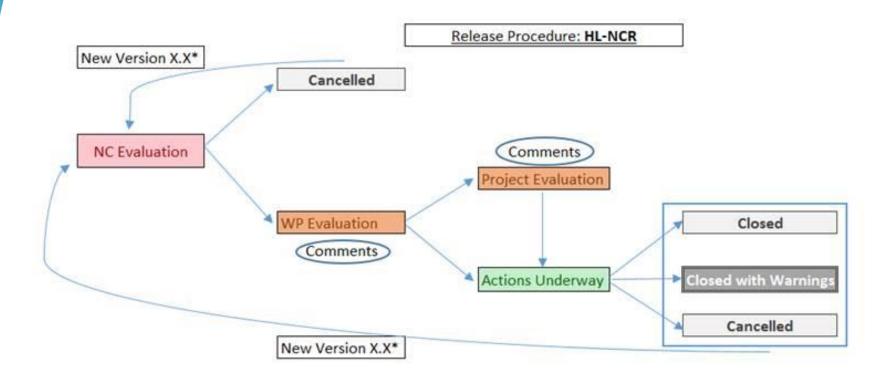
Repair \square	Regrade		Scrap		Return		Concession	
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- Repair: Action on a nonconforming product in order to make it acceptable for the intended use
- Regrade: Alteration of the grade of a nonconforming product in order to make it conform to requirements differing from the initial ones
- **Scrap:** Action on a nonconforming product to preclude its originally intended use (Recycling, destruction).
- Return: Action on a nonconforming product to send back to the supplier's facilities
- Concession: Permission to use or release a product that does not conform to specified requirements (Use as it is)

 HL-LHC Nonconformities

 24

Document life-cycle



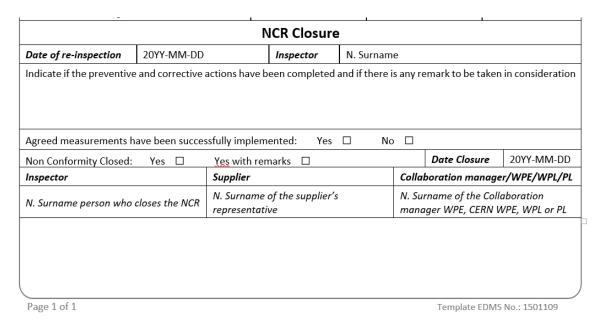
^{*}Create a new version when you have a new file to be uploaded.

The status of the NC will remain in Actions Underway until it is proven that the NC has been solved





NC Closure





- Once the Nonconformity is solved, the document shall be updated (new version to be issued). The reference to the report(s) that proves the Nonconformity is closed is to be added in MTF (additional MTF Step if needed) and the Status of the Nonconformity is changed to Closed or Closed with Warnings
- No measurable actions = No closure of the NC





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Some reasons a problem-solving process often fails

- Jumping from analysis to a solution too quickly
- Using data that are inaccurate or biased
- Failing to include the right people in the problemsolving process
- Mistaking a symptom for the root cause of the problem
- Failing to test a solution before implementing it
- Failing to evaluate the potential benefits and costs of the chosen solution





Conclusions

- Nonconformities are part of the production of any component. When a specified requirement is not fulfilled a Nonconformity is to be issued
- The metadata as well as the information of the NC is to be provided by the Collaboration with support from CERN
- CERN will assess the NCR and provide the feedback (assessment of the proposal and decision)
- Actions are to be implemented (if any) before closing the Nonconformity
- NCR to be attached to the corresponding MTF Step and when necessary the step shall be repeated to prove that the Nonconformity is closed (if repair)
- Every NCR should answer to the 5W-1H (Who, When, Where, What, Why, How) – Otherwise it is most likely incomplete







Q&A





Closing the NC- pre-steps

- Who will verify the actions? (internal auditors or similar)
- Once the actions are implemented, how long until they are verified as effective?
- Where will the verification activities be recorded?
- What verification indicators will be used (reduced scrap rates, reduced nonconformances, reduced customer complaints, trained personnel, and so on)?
- Do the indicators provide evidence that the actions solved the problem and didn't create any new ones?
- Will the actions require ongoing monitoring? If so, what is the frequency of the monitoring?
- Who will the verification results be reported to? How? When?





Closing the NC

- The independent person's role is to perform a check and balance at the end of the problem-solving process. However, there is nothing wrong with the person(s) who implemented the action being present when the actions are being reviewed. In fact, that is suggested, because that person should be able to clearly describe, as well as show, confirmation of effectiveness of the actions taken.
- The closure dates should be recorded, as it provides the evidence that the problem is now resolved and all steps have been completed. Without completing the verification step, actions will appear in a perpetual state of "openness" and their status difficult to determine. If we bypass the verification step we will never be sure that the solution fixed the problem so it doesn't come back.
- Long-term monitoring of implemented actions ensures that the solutions are working the way they were intended. It also determines whether or not the actions taken were the best long-term solution so that the problem will not occur again





Finding solutions – In the context

Your solutions/actions

- How will the actions affect the customer?
- Will the actions negatively affect other processes within the organization?
- How much will it cost to implement the actions?
- Do we have the necessary resources?
- How long will it take?
- Who is going to do it?
- Due to limited resources, will we need to implement a short-term solution while planning for a more permanent one?





Finding the solution - The Why not principles

Nalebuff and Ayres created four approaches that act as catalysts for developing solutions to problems. Each is represented by a question:

- What would an "unconstrained" person do? Be a bit bolder and more outrageous than you might otherwise be. Typically, solutions prompted by this question will not be feasible in real life, but might represent a core idea that can be expanded upon.
- Why don't you feel my pain? Individual and corporate actions have consequences to others that are not priced in the market. Looking for inefficient behaviour by buyers or sellers is a systematic way both to identify problems and to solve them. Some problems create an external harm that is greater than the internal benefit.
- Where else would it work? Great solution exists for a different problem, one similar enough to your problem that the solution can be an inspiration. This normally requires some translation to fit the context and institutions of the new setting.
- Would flipping it work? There are symmetries all around us and sometimes flipping things around provides a powerful new solution. This is done by breaking down the existing practice into its component parts and writing a description in simple, declarative sentences.





Corrective versus Preventive action

Corrective action

- occurs as a result of a reported problem and is considered a reactive approach.
- should be taken to eliminate the cause of existing problems, thus preventing them from recurring.
- should not be considered disciplinary action or a means in itself, but rather, part of the problem-solving process that analyzes issues with the intent of improving. It is important to note that the mere act of correcting a problem is different than taking corrective action. When correcting a problem, immediate action is taken which may or may not involve the additional steps of determining the root cause of the problem or following up for effectiveness. Correcting alone may not result in resolving the issue.

Preventive action

- Is the response to information or knowledge that indicates that a potential problem might occur. This information or knowledge could come from trend analysis, risk analysis, market analysis, or previous experience. Using this information allows the organization to prevent the problem from happening in the first place.
- Prevention of potential problems may require different thinking, since a
 preventive approach requires us to ask the "what-ifs." One way to start thinking
 about preventive action is to brainstorm the kinds of preventive actions that are
 experienced every day.





Preventive actions

Action to eliminate the cause of a **potential** nonconformity or other potential undesirable situation.

In general is the weakest point of the analysis because requires to go beyond the NC. You should ask yourselves

- There is any similar component where the same NC could happen?
- There is any similar process where the same NC could happen?
- If happened here why did not happen in the similar object/process?
- Did I communicate the NC to colleagues that could be interested?





For all actions

- State clearly:
 - What you want to do,
 - When you want to do it,
 - How long the action will take to be implemented
 - Who will do it,
 - How much will cost
 - Which is the result expected and how you will measure the success of the action
- Obtain endorsement of the stakeholders
- Trace the action and obtain the endorsement on writing





I keep six honest serving men (They taught me all I know);
Their names are What and Why and When And How and Where and Who.

Rudyard Kipling



