Quality Assurance Procedure

HANDLING OF NONCONFORMING EQUIPMENT

Abstract
This document establishes a policy and provides guidelines for the handling of nonconforming equipment produced by Contractors, collaborating Institute, and CERN Divisions or Groups. The objectives are to ensure that nonconforming equipment is segregated from conforming equipment, and is prevented from being installed in the LHC; to eliminate or minimise the reoccurrence of problems leading to nonconformance by implementing appropriate corrective and preventive actions; to ensure that all nonconformities are properly documented and traceable.

Prepared by:
M Mottier
EST/ISS
Marcel.Mottier@cern.ch

Checked by:
LHC Quality Assurance Working Group

Approved by:
Paul Faugeras
Deputy to LHC Project Leader for Quality Assurance


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1. PURPOSE

To establish a policy, and to provide guidelines, for the handling of nonconforming equipment produced by Contractors, Institutes and CERN Divisions and Groups, to ensure that nonconforming equipment is segregated from conforming equipment and is prevented from being installed in the LHC.

To provide guidelines for establishing appropriate corrective actions aimed at eliminating or minimising the recurrence of problems leading to nonconformities.

To ensure that all nonconformities are properly documented and traceable.

2. POLICY

Procedures for the tracking of nonconformities detected during the production of LHC systems, assemblies, sub-assemblies and parts shall be established and documented.

Equipment that does not conform to any specified requirements shall be marked as nonconforming, and the occurrence shall be recorded in a nonconformity report.

Nonconforming equipment shall be segregated from conforming equipment and equipment awaiting inspection or test, to prevent further unintended use until the appropriate disposition is decided.

Nonconforming equipment shall be reviewed by authorised personnel to determine whether it can be accepted "as-is", or whether it should be repaired, reworked or rejected.

Repaired or reworked equipment shall be re-inspected and re-tested to verify conformance with specified requirements.

Nonconformance markings shall be removed by authorised personnel only, after the review has determined that the uncorrected equipment may be used "as-is", or after repair or rework is complete. The decision to use a nonconforming equipment shall be documented.

The causes of nonconformities shall be analysed and appropriate action taken to avoid recurrence of problems.

3. SCOPE

The policy and guidelines apply to all materials, parts and equipment to be installed in the LHC and manufactured and/or assembled by:

- Contractors,
- Collaborating Institutes,
- CERN Divisions and Groups.

They apply to all stages of fabrication and assembly, from raw material procurement until final inspection and test.

For the construction of the LHC a number of collaborations have been organised between CERN and other Institutes. These collaborations are of different types depending on the degree of financial and technical responsibility delegated by CERN to the Institutes. As the ultimate responsibility for the successful completion of the LHC rests with CERN, it follows that the policy and guidelines described in this document are applicable whether the client organisation is CERN or a collaborating Institute.
4. RESPONSIBILITIES

Project Engineers (PE) in charge of the procurement of LHC systems, assemblies, sub- assemblies and parts shall:

- Ensure that procedures established by the supplier for the handling of nonconformities fulfil the requirements of this document and are followed.
- Make sure that all personnel involved with production of equipment, at CERN, Institutes and Contractors, is aware of the nonconformities procedures.
- Review the disposition of nonconformities.
- Participate in the analysis of the causes of nonconformities and initiate appropriate corrective and preventive actions.

Authorised inspectors in charge of inspection and test are responsible for identifying, segregating and reporting all nonconformities.

Supplier's Contract Engineers are responsible for the documentation of all nonconformities and for notification of the client organisation.

The LHC Project Management is responsible for:

- The approval or rejection of the use without repair or rework ("use as-is") of nonconforming equipment where the nonconformity is critical.
- The approval or rejection of proposed corrective action in cases where that action might affect the required performance of the LHC, its ability to operate safely, or its construction.

5. DEFINITIONS

- Authorised Inspector: A person authorised by the client organisation to carry- out defined inspection and test activities in the framework of a contract or other procurement agreement.
- Client organisation: The organisation responsible for a contract. It can be CERN or an Institute collaborating to the LHC Project.
- Conformity: Fulfilment of all specified requirements.
- Contract engineer: The engineer designated by the supplier to be responsible for the contract and its follow-up, including all contacts with the client organisation throughout the duration of the contract.
- Critical nonconformity: Nonfulfilment of a specified requirement that may impair the ability of the equipment to achieve the required performance or may impair its ability to perform safely.
- Deviation: Written authorisation to depart from the originally specified requirements for a product prior to its production.
- Disposition: Action to be taken to deal with an existing nonconforming equipment in order to resolve the nonconformity.
- Equipment: Any material, part, sub-assembly, assembly, sub-system, or system designed or provided for use in the LHC.
- Nonconformity: Nonfulfilment of a specified requirement.
- Product: The result of activities or processes. A product can be tangible (e.g. assemblies or processed materials) or intangible (e.g. knowledge or concepts), or a combination thereof.
Rejected  Unacceptable use of a nonconforming equipment.
Repair  Action taken on a nonconforming equipment so that it will fulfill the intended usage requirements although it may not conform to the originally specified requirements.
Rework  Action taken on a nonconforming equipment so that it will fulfill the specified requirements.
Supplier  In the context of this document the term supplier is used to designate an organisation manufacturing and/or assembling materials, parts and equipment for the LHC. Such organisation may be:
  • A company
  • A collaborating Institute
  • A CERN Division or Group
Traveller dossier  The set of printed reports documenting the inspections and tests performed on a product. The traveller dossier follows the product through its production, inspection, delivery and installation.
Use-As-Is  Acceptable use of a nonconforming equipment.
Waiver  Written authorisation to use or release an equipment which does not conform to all specified requirements.

6. NONCONFORMANCE GUIDELINES

The procedure for handling nonconforming equipment is shown in annex A.1.

6.1 IDENTIFICATION OF NONCONFORMITY

If, in the course of the execution of an inspection or test procedure, a nonconformity is suspected, the person performing the inspection or test shall first determine that the nonconformity is not due to causes other than the equipment under inspection or test.

Once it is determined that the cause is due to the equipment itself, the inspector shall clearly mark the nonconforming equipment by applying a nonconformity label on the equipment ‘s traveller dossier.

Where practical, nonconforming equipment shall be segregated from conforming equipment and equipment awaiting inspection or test by storing it in a clearly separated area.

6.2 REPORTING

Once identified, a nonconformity shall be documented in a nonconformity report. Important variables affecting the capability of the equipment to meet specified requirements shall be identified. The relationship of cause and effect should be determined, with all potential causes considered. The results of the investigation shall be recorded on the nonconformity report.

The nonconformity report shall contain, as a minimum, the following information:
  • A nonconformity number.
  • The date the nonconformity is open (identified).
  • The number of the inspection or test procedure.
• The step in the inspection or test procedure where the problem occurred.
• The document number of the inspection or test report.
• The identification number of the equipment.
• A description of the nonconformity.
• The name and signature of the inspector.

When complete, the report shall be signed by the inspector and forwarded to the PE in charge of the contract. A copy shall be attached to the traveller dossier.

The nonconformity shall be reported to the Project Engineer in charge of the contract in the client organisation.

6.3 REVIEW AND DISPOSITION

6.3.1 CRITICAL AND NONCRITICAL NONCONFORMITIES

All nonconformities that may have an impact on the equipment performance, durability, interchangeability, interface to other LHC systems, health or safety are categorised as critical nonconformities.

All nonconformities that are not evaluated to be critical as defined above are categorised as noncritical nonconformities.

6.3.2 USE-AS-IS OF THE EQUIPMENT

The PE in charge of the contract, with the assistance of the PE in charge of the LHC system to which the equipment belongs, shall review nonconformities to determine what disposition should apply.

Possible dispositions include:
• Repair.
• Rework.
• Use-as-is.
• Rejected.

The review shall first determine if the equipment may be used "as-is". If that is the case, the criticality of the nonconformity shall be evaluated.

The "use-as-is" of equipment with a noncritical nonconformity shall be approved or rejected by the PE in charge of the contract. The decision shall be recorded on the nonconformity report.

The "use-as-is" of equipment with a critical nonconformity shall be submitted to the LHC Project management for review and approval or rejection. The decision shall be recorded on the nonconformity report.

When the decision taken is to authorise the "use-as-is" of the equipment, the completed nonconformity report is used as a waiver authorising the supplier to go ahead with the further processing of the equipment. The nonconformity is then closed.

6.3.3 REPAIR, REWORK OR REJECTION

Where it is decided that the equipment cannot be "used-as-is", the PE in charge of the contract shall determine whether the equipment may be repaired/reworked or whether it must be rejected.

If it is decided that repair or rework is possible, the impact on cost, performance and schedule has to be evaluated before the final decision is taken.
The decision shall be recorded on the nonconformity report. If the decision is to reject the equipment, the nonconformity is then closed. If the decision is to repair or rework, the nonconformity remains open until the failed inspection or test is successfully repeated.

Repaired or reworked equipment shall be re-inspected or re-tested to verify conformance with specified requirements.

Rejected equipment shall be removed from the production area.

6.3.4 CLOSING THE NONCONFORMITY

Nonconformity labels shall be removed by authorised personnel only, after it has been decided that the uncorrected equipment may be used "as-is", or after repair or rework is complete and the equipment has satisfied all specified requirements.

Appropriate measures shall be taken to prevent unintended use or installation of nonconforming equipment. This may require an assessment of:

- Previously manufactured lots of identical equipment that may be waiting delivery, or stored or already installed.
- Other equipment designed or manufactured in a similar way as the equipment found to be nonconforming.

7. CORRECTIVE AND PREVENTIVE ACTION GUIDELINES

Action shall be taken, as appropriate, to determine the cause of critical, recurring, trend or pattern nonconformities and to develop and implement a remedy that will prevent the recurrence of such nonconformities. This may result in changes to equipment specification, or to production, inspection and test, handling, storage, installation procedures.

The decision to initiate any corrective action shall also be based on an evaluation of the adverse cost and schedule impact of the nonconformity relative to the cost and difficulty of its correction.

Action shall be initiated to a degree appropriate to the magnitude of the problem.

The PE in charge of the contract has the responsibility for initiating appropriate corrective or preventive actions.

Critical cases, such as those that might affect the required performance of the LHC, its ability to operate safely, or its construction schedule shall be referred to the LHC Project Management for review and approval.

8. RELATED DOCUMENTATION

[ 1 ] LHC-PM-QA-309.00 Manufacturing and Inspection of Equipment
Annex A.1 Nonconformance procedure