

Generated from this prompt in Grok: “You are an ISO 9001:2015 expert. Generate a procedure for documenting a non-conformance event.”

Procedure: Documenting and Handling Nonconformance Events

Document Reference: QMS-PROC-010 (Rev 1.0)

ISO 9001:2015 Clauses: 8.7, 10.2, 9.1.3, 7.5

1. Purpose

To establish a consistent, documented process for identifying, recording, evaluating, controlling, and dispositioning nonconforming products, processes, or services so that they do not reach the customer and that root causes are eliminated to prevent recurrence.

2. Scope

This procedure applies to all nonconformities detected at any stage: incoming materials, in-process, final inspection, customer complaints, internal audits, or post-delivery.

3. Responsibilities

- **Any Employee** – Identify and immediately report nonconformances.
- **Quality Manager / Designated Person** – Review, classify, investigate, and close nonconformances.
- **Department Managers** – Contain the issue, perform root cause analysis, and implement corrective actions in their area.
- **Top Management** – Review significant nonconformances in Management Review meetings.

4. Definitions

- **Nonconformity**: Non-fulfilment of a requirement (product, process, or system).
- **Correction**: Action to eliminate a detected nonconformity.
- **Corrective Action**: Action to eliminate the cause of a nonconformity and prevent recurrence.
- **Disposition**: Decision on what to do with the nonconforming item (use-as-is, rework, repair, regrade, scrap, return to supplier).

5. Procedure Steps

1. Identification & Immediate Containment

- Stop the process or segregate the affected product immediately (clearly label/tag with “HOLD – NONCONFORMING” and red tag if physical).
- Record basic details: what, where, when, who discovered it, quantity affected, and reference (order, lot, batch, etc.).

2. Document the Nonconformance

- Complete a **Nonconformance Report (NCR)** form (or equivalent in your QMS software) within 24 hours.
- Minimum required information on the NCR:
 - NCR unique number (e.g., NCR-YYYY-001)
 - Date and time
 - Description of the nonconformity (with photos/evidence where possible)
 - Applicable requirement (drawing, spec, standard, customer requirement)
 - Quantity affected / lot numbers
 - Detected at which process/stage

- Initial containment actions taken
- 3. **Review and Classification**
 - Quality reviews the NCR within 48 hours and classifies it:
 - Minor (isolated, low impact)
 - Major (systemic, high impact, affects customer, safety, regulatory)
 - Determine if it is a product, process, or system nonconformity.
- 4. **Disposition Decision**
 - Responsible authority (Quality + relevant Manager) decides disposition:
 - Rework / Repair
 - Use As Is (with customer approval if required)
 - Scrap / Destroy
 - Return to Supplier
 - Regrade / Alternative use
 - Obtain customer concession/waiver when required and document it.
- 5. **Root Cause Analysis & Corrective Action**
 - For every Major NCR (and selected Minor ones): perform root cause analysis using 5-Why, Fishbone, or equivalent.
 - Identify and document the root cause(s).
 - Define corrective action(s) with responsibility and target completion date.
 - Update risk register (Clause 6.1) if new risks or opportunities are identified.
- 6. **Implementation & Verification**
 - Implement corrective actions.
 - Verify effectiveness (e.g., follow-up inspection, audit, or data review).
 - If ineffective, reopen the NCR and escalate.
- 7. **Closure**
 - Quality Manager reviews and closes the NCR only after:
 - Disposition is complete
 - Corrective actions are implemented and verified
 - All required approvals and records are attached
 - Record the final outcome and lessons learned.
- 8. **Trend Analysis & Improvement**
 - Quality Department analyses NCR trends monthly (by type, process, supplier, etc.).
 - Significant trends are inputs to Management Review and continual improvement.

6. Records (Retained Documented Information)

- Nonconformance Reports (including attachments)
- Root cause analysis and corrective action records
- Customer concessions/waivers
- Evidence of verification of effectiveness

Retention period: Minimum 7 years or as required by customer/regulatory requirements.

7. References

- ISO 9001:2015 Clauses 8.7 & 10.2
- Control of Nonconforming Outputs Procedure (if separate)
- Corrective Action Procedure
- Risk Register

This procedure ensures full traceability, customer protection, and drives continual improvement. It can be integrated into your existing QMS software (e.g., SAP QM, IQMS, or a simple SharePoint/Excel system).

Would you like the corresponding **NCR Form template**, a **flowchart**, or integration instructions with your risk register and corrective action process?