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Author	QCore Consulting	Approved By	[Approver]

NONCONFORMANCE MANAGEMENT

Standard Operating Procedure

10 Process Steps | 4 Defined Roles | 8 KPIs | ISO 13485 + FDA 820 + EU MDR + MDSAP + ISO 14971

1. Purpose

This Standard Operating Procedure (SOP) defines the process for identifying, documenting, classifying, investigating, dispositioning, and closing Nonconformities (NCs) to:

- Prevent the use or delivery of nonconforming product
- Ensure appropriate containment, disposition, and corrective action
- Maintain regulatory compliance with ISO 13485, FDA 21 CFR 820, and EU MDR
- Provide data-driven input to trend analysis, CAPA initiation, and Management Review
- Enable systematic root cause analysis to prevent recurrence
- Support post-market surveillance and vigilance obligations

2. Scope

This procedure applies to all nonconformities within the organization, including those arising from:

- Incoming inspection of purchased materials and components
- In-process inspection and manufacturing deviations
- Final inspection and release testing
- Customer complaints and field feedback (post-delivery nonconformities)
- Internal and external audit findings
- Supplier quality issues
- Post-market surveillance and vigilance data (per EU MDR Art. 83–86)
- Environmental monitoring deviations

- Equipment calibration failures
- Document control deviations

i Best Practice

Define clear ownership for each NC source. Incoming NCs are typically owned by Quality/Purchasing, in-process NCs by Production Quality, and customer NCs by Customer Quality or Regulatory Affairs.

What Does the Auditor Ask?

- "Can you show me the scope of your NC process? Does it cover post-delivery issues?"
- "How do field complaints enter your NC system?"
- "Show me an example of an NC from each source category in the last 12 months."

3. Definitions & Abbreviations

Term	Definition
Nonconformity (NC)	Non-fulfillment of a specified requirement. Any product, process, service, or document that does not conform to established specifications, standards, or requirements.
Correction	Immediate action to eliminate a detected nonconformity (e.g., rework, scrap, re-inspection). Does NOT address root cause.
Containment	Immediate action to prevent further impact of a nonconformity while investigation is ongoing (e.g., quarantine, stop shipment, customer notification).
Disposition	Decision on the handling of nonconforming product: Use-as-is (concession), Rework, Repair, Scrap, or Return to Supplier.
Rework	Action on a nonconforming product to make it conform to the original specifications. The product meets its original design requirements after rework.
Repair	Action on a nonconforming product to make it acceptable for intended use, although it may not conform to original specifications. Repair changes the design requirements.
Refurbishment	Restoration or modification of a product after delivery/use. Requires separate documentation and may require new regulatory submission.
Root Cause	The fundamental, systemic reason for a nonconformity, which if eliminated, would prevent recurrence. Must be actionable and specific.
CAPA	Corrective and Preventive Action — systemic action to eliminate root cause and prevent recurrence (corrective) or first occurrence (preventive).
FSCA	Field Safety Corrective Action — action taken to reduce risk of death or serious deterioration in health associated with a medical device already placed on the market.

DHR	Device History Record — record of the manufacture of a specific production unit.
DMR	Device Master Record — compilation of records containing the procedures and specifications for a finished device.
UDI	Unique Device Identification — system to identify medical devices through distribution and use.
SCAR	Supplier Corrective Action Request — formal request to a supplier to investigate and correct quality issues.

4. Responsibilities

4.1 NC Initiator (Any Employee)

- Identify and report nonconformities promptly
- Initiate containment actions within their authority
- Complete Section 1 (NC Description) of the NC Form (FRM-NC-001)

4.2 Quality Assurance (NC Owner)

- Review and classify all reported NCs within 24 hours of receipt
- Assign NC numbers and designate NC Investigators
- Verify containment actions are adequate and documented
- Approve disposition decisions (with Management for Use-as-is/Repair)
- Monitor NC metrics and KPIs (see Section 9)
- Perform trend analysis quarterly (minimum) per Section 5.7
- Initiate CAPA escalation when thresholds are met
- Evaluate FSCA requirement for Critical NCs and post-delivery NCs

4.3 Department Managers

- Ensure personnel report NCs promptly and accurately
- Provide resources for NC investigation and resolution
- Review overdue NCs in their area and ensure timely closure
- Participate in root cause investigations as needed

4.4 Management Representative

- Approve Use-as-is and Repair dispositions
- Review Critical NCs and post-delivery NCs within 24 hours
- Review escalated overdue NCs and allocate resources
- Review NC KPIs and trends in Management Review
- Approve FSCA decisions

What Does the Auditor Ask?

- "Who is responsible for classifying NCs? How quickly?"
- "Who approves Use-as-is dispositions? Is Management involved?"
- "How do you ensure all employees know how to report an NC?"

5. Procedure

5.1 NC Detection & Reporting

5.1.1 Any employee who identifies a nonconformity shall report it immediately using the NC Form (FRM-NC-001) or equivalent electronic system.

5.1.2 The NC Initiator shall document:

- What was found (description of the nonconformity)
- Where it was found (location, process step, inspection point)
- When it was found (date, time, shift)
- Affected product identification (part number, lot/batch, serial/UDI if applicable)
- Quantity affected (known or estimated)

5.1.3 Assign a unique NC number using format: NC-YYYY-XXX (e.g., NC-2026-001).

5.1.4 Quality Assurance shall review and acknowledge receipt within 24 hours.

i Best Practice

Establish multiple NC reporting channels: paper forms on the shopfloor, electronic forms in the QMS, and verbal escalation for critical issues. The barrier to reporting should be as low as possible.

5.2 Immediate Containment Actions

Containment actions shall be implemented immediately to limit the impact of the nonconformity:

5.2.1 Evaluate the scope of affected product: in-process, finished goods, and distributed product.

5.2.2 Implement appropriate containment:

- Quarantine/segregation of nonconforming material (physical or system-based)
- Stop shipment of affected lots/batches
- Production hold on affected processes
- Customer notification if product already delivered
- Labeling hold if labeling is affected

5.2.3 Document containment actions in Section 2 of the NC Form, including:

- Actions taken and responsible person
- Date and time of implementation
- Scope of affected product (quantity, lots, serial numbers)
- Containment verification: confirm effectiveness before proceeding

⚠ CRITICAL: Released Product Assessment

For every NC where product has already been released or shipped: assess whether a Field Safety Corrective Action (FSCA) is required per EU MDR Art. 83 and FDA 21 CFR 806. Document the FSCA decision (Yes/No with justification) in Section 2 of the NC Form. Failure to assess FSCA is a regulatory violation.

What Does the Auditor Ask?

- "Show me how you quarantine nonconforming material. Is it physically separated or system-based?"
- "How do you assess whether product already shipped is affected?"
- "Show me the last NC where released product was affected. What was your FSCA decision?"

5.3 NC Classification

Quality Assurance shall classify each NC based on risk impact using the NC Assessment Matrix (FRM-NC-003):

Classification	Risk Level	Response Time	CAPA Required?	Approval Level
CRITICAL	High	Immediate (<24h)	Mandatory	QA + Management + Regulatory
MAJOR	Medium	48 hours	Evaluation Required	QA + Department Head

MINOR	Low	5 business days	Not Required	QA
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5.3.1 Classification Decision Criteria

1. Could this NC cause patient harm or safety risk? → CRITICAL
2. Does this NC violate regulatory requirements? → CRITICAL
3. Will this NC require a product recall or field action? → CRITICAL
4. Does this NC breach product specifications? → MAJOR
5. Could this NC result in a customer complaint? → MAJOR
6. Has this same NC type occurred before (repeat)? → MAJOR
7. Is this a cosmetic or documentation issue only? → MINOR

5.3.2 Risk Management Integration (ISO 14971)

For every NC classified as CRITICAL or MAJOR, perform a Risk Assessment Impact Check:

- Does this NC represent a new hazard or hazardous situation not previously identified in the Risk Management File?
- Does the NC change the risk profile of an existing identified hazard?
- Is an update to the Risk Management File (FMEA/FTA) required?

Document the assessment in Section 3 of the NC Form. If yes, reference the updated Risk Management document.

⚠ FDA & ISO 14971 Requirement

NC classification MUST be aligned with the organization's risk management process per ISO 14971:2019. The connection between NC severity and risk analysis must be documented and traceable. Auditors specifically look for this linkage.

5.4 Investigation & Root Cause Analysis

5.4.1 For CRITICAL and MAJOR NCs, a documented investigation shall be conducted to identify the root cause.

5.4.2 Assemble a cross-functional investigation team appropriate to the issue complexity.

5.4.3 Apply appropriate root cause analysis techniques:

- 5-Why Analysis — recommended for most investigations
- Fishbone (Ishikawa) Diagram — for complex, multi-factor issues

- Fault Tree Analysis — for safety-critical events
- Pareto Analysis — for trend-based investigations

5.4.4 Document the investigation in Section 4 of the NC Form, including: evidence reviewed, analysis method, data collected, and root cause statement.

5.4.5 The root cause statement must be specific enough to derive targeted corrective actions.

⚠ CRITICAL: Human Error is NEVER a Root Cause

"Human error" alone is never an acceptable root cause. Always identify the systemic reason WHY the error occurred: inadequate training, unclear procedure, missing verification step, poor ergonomics, excessive workload, insufficient competence assessment, etc. Auditors will always ask "Why did the person make the error?"

What Does the Auditor Ask?

- "Show me the root cause analysis for this NC. How did you determine the root cause?"
- "What data or evidence supports this root cause conclusion?"
- "I see the root cause is stated as 'operator error' — what systemic factor caused this?"

5.5 Disposition

Quality Assurance shall determine the disposition of nonconforming product based on investigation findings:

Disposition	When to Use	Requirements	Approval	DHR/Records
USE-AS-IS (Concession)	NC does not affect safety, function, or regulatory compliance	• Documented justification • Risk assessment • No patient safety impact	QA + Management (+ Customer if contractual)	• Concession record • DHR notation
REWORK	Product can be corrected to meet ORIGINAL specifications	• Rework instructions • Re-inspection after rework • Verify against original spec	QA	• Rework record in DHR • Re-inspection results
REPAIR	Product can be made acceptable but will NOT meet original specifications	• Repair procedure • Updated risk assessment • Design change evaluation • May require regulatory notification	QA + Management + Regulatory (if design change)	• Repair record in DHR • Updated DMR if applicable
SCRAP / DESTROY	Product cannot be corrected; risk of mix-up or misuse	• Physical destruction • Witnessed disposal • Environmental compliance	QA	• Disposal record • Witness signature

RETURN TO SUPPLIER	Incoming material NC; supplier responsible	<ul style="list-style-type: none"> • RMA documentation • SCAR if repeat issue • Replacement tracking 	QA + Purchasing	<ul style="list-style-type: none"> • Return documentation • Supplier notification
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5.5.1 Rework vs. Repair vs. Refurbishment

It is critical to distinguish between these three terms:

- **REWORK:** Product is brought back to ORIGINAL specifications. No design change. Standard DHR documentation.
- **REPAIR:** Product is made acceptable but does NOT meet original specifications. This constitutes a DESIGN CHANGE and may require regulatory notification per 21 CFR 820.30 and EU MDR Annex IX.
- **REFURBISHMENT:** Restoration after delivery/use. Requires separate documentation and potentially new regulatory submission.

5.5.2 Rework Verification

After rework, the following verification steps are mandatory:

1. Re-inspect against original specification (same acceptance criteria)
2. Document re-inspection results in the DHR
3. Verify no additional nonconformities were introduced by the rework process
4. Release by Quality Assurance

Use the NC Rework Verification Checklist (FRM-NC-006) for standardized documentation.

⚠ **FDA Audit Focus: Rework vs. Repair**

FDA auditors under QSIT specifically ask about the distinction between rework and repair. If your disposition says "rework" but the product does not meet original specifications after the action, it is actually a "repair" and requires design change evaluation. This is a common Major finding.

What Does the Auditor Ask?

- "Show me the re-inspection results for the last 3 reworked products."
- "How do you distinguish between rework and repair in your system?"
- "For this Use-as-is decision: where is the risk assessment and management approval?"

5.6 Post-Delivery Nonconformity Process

When a nonconformity is detected after product has been delivered to customers or placed on the market, the following additional process steps apply:

5.6.1 Detection & Initial Assessment

- Customer complaints, field reports, and post-market surveillance data shall be evaluated for NC relevance
- Initial risk assessment within 24 hours of receipt
- Assign NC number and classify per Section 5.3

5.6.2 FSCA Decision Gate

For every post-delivery NC, a mandatory FSCA assessment shall be performed:

- Could this NC cause or contribute to death or serious deterioration in health?
- Is the NC a previously unidentified safety hazard?
- Has the risk-benefit assessment changed?

Document the FSCA decision (Yes/No with detailed justification) in the NC Form.

5.6.3 If FSCA Required

- Notify Competent Authority within required timeframes (serious threat: 2 days; other: 10 days per EU MDR Art. 87)
- Initiate Field Safety Notice to healthcare professionals and users
- Coordinate with Regulatory Affairs for FDA MDR/MedWatch reporting
- Mandatory CAPA initiation (per SOP-CAPA-001)

5.6.4 Post-Delivery NC Linkages

- Link to Complaint record (per SOP-CC-001)
- Link to Vigilance report if applicable
- Link to PMS/PMCF report (per SOP-PMS-001)
- Update Risk Management File if new hazard identified

⚠ EU MDR & FDA Vigilance Requirement

Post-delivery NCs with potential safety impact MUST be reported to the Competent Authority. Failure to report is a serious regulatory violation. When in doubt, report. Under-reporting is always worse than over-reporting.

What Does the Auditor Ask?

- "Show me the last field NC. How did you assess whether an FSCA was required?"
- "What is your timeline for FSCA assessment after receiving a field complaint?"
- "How do post-delivery NCs feed into your PMS system?"

5.7 Trend Analysis & Quantitative Triggers

The Quality Manager shall perform trend analysis of NC data at minimum quarterly. The following quantitative thresholds define mandatory escalation actions:

Data Source	Threshold	Mandatory Action
NC Log	≥3 NCs of same root cause category within 6 months	Mandatory CAPA initiation
NC Log	≥5 NCs from same source (e.g., supplier) within 6 months	Supplier review + potential CAPA
NC Log	≥2 Critical NCs in same product line within 12 months	Management Review escalation + CAPA
Customer Complaints	≥2 complaints on same failure mode within 12 months	Mandatory CAPA initiation
Incoming Inspection	Reject rate >5% for any supplier over rolling 6 months	Supplier SCAR + evaluation
Post-Market Surveillance	Any reportable event; adverse trend per PMS thresholds	Mandatory CAPA + vigilance assessment
Internal Audit	Any Major finding; repeat Minor within 2 audit cycles	Mandatory CAPA initiation

i Best Practice

These are minimum requirements. Organizations should adjust thresholds based on risk profile, product portfolio, production volume, and regulatory environment. Thresholds should be reviewed during annual Management Review and updated as the organization matures.

What Does the Auditor Ask?

- "What are your defined thresholds for NC trending?"
- "Show me the last trend analysis. When was it performed and what did it show?"
- "How many CAPAs were initiated from trend data in the last 12 months?"

5.8 NC-to-CAPA Escalation Decision

Not every nonconformity requires a CAPA. The following criteria guide the escalation decision:

CAPA Required (Corrective Action)	Correction Only (No CAPA)
Recurring NC (same root cause ≥ 2 times)	Isolated, one-time NC with clear assignable cause
Systemic issue affecting multiple products/processes	Contained to single lot/batch with no systemic implication
Patient safety or regulatory compliance impact	Minor cosmetic or administrative deviation
Audit finding classified as Major or repeat Minor	First-time Minor audit observation with obvious correction
Trend threshold exceeded (see Section 5.7)	Below trend threshold, no pattern identified
Supplier-related issue affecting product quality	Supplier administrative deviation (e.g., late CoC)
NC classification is CRITICAL	All containment actions verified effective

i Decision Guidance

When in doubt, escalate to CAPA. It is always preferable to investigate and close a CAPA with "root cause confirmed as isolated event" than to miss a systemic issue. Document the decision rationale in the NC record regardless of the outcome.

5.9 Supplier NC Process

When a nonconformity is attributed to a supplier (incoming material, components, or outsourced processes), the following additional steps apply:

5.9.1 Notify the supplier within 48 hours of NC classification, using the Supplier NC Notification Template (FRM-NC-007).

5.9.2 Issue a Supplier Corrective Action Request (SCAR) when:

- NC is classified as CRITICAL or MAJOR
- Same NC type from same supplier ≥ 2 times in 12 months
- NC affects patient safety or regulatory compliance

5.9.3 Define expected supplier response timeline: 15 business days for initial response with root cause and containment; full corrective action per agreed timeline.

5.9.4 Verify supplier corrective action through incoming inspection data, supplier audit, or documented evidence.

5.9.5 Update the supplier quality record and supplier scorecard. Evaluate impact on approved supplier status.

5.9.6 Link the SCAR to the internal NC record for traceability.

What Does the Auditor Ask?

- "Show me how you communicate NCs to suppliers. What is your response timeline?"
- "How many SCARs were issued in the last 12 months? What was the resolution

rate?"

- "How do supplier NCs feed into your supplier qualification process?"

5.10 NC Closure

An NC may be closed when all of the following conditions are met:

- Disposition has been completed and documented
- Containment actions verified effective
- Root cause analysis completed (for CRITICAL and MAJOR)
- Rework/repair verification completed (if applicable)
- CAPA decision documented (escalated or justified as not required)
- FSCA assessment completed (for post-delivery NCs and Critical NCs)
- Risk Management File updated (if required per Section 5.3.2)
- NC Log updated with all closure information

NC records shall be retained per document retention requirements: minimum product lifetime plus 2 years, or 10 years after last production date (whichever is longer), per EU MDR Art. 10(8) and ISO 13485:2016 Clause 4.2.5.

6. Escalation Procedure

Overdue NCs shall be escalated according to the following schedule. Quality Assurance is responsible for monitoring due dates and initiating escalation.

Overdue Status	Action	Responsible
7 days before due	Automated reminder to NC Owner	Quality Assurance
Overdue 1–14 days	Written escalation to NC Owner and Department Manager; document reason for delay and revised target date	Quality Assurance
Overdue 15–30 days	Escalation to Management Representative; root cause for delay required; revised action plan with weekly status updates	Quality Manager
Overdue >30 days	Escalation to Top Management; inclusion in Management Review agenda as open issue; resource reallocation if necessary	Management Representative

i Implementation Tip

Configure your NC Log (FRM-NC-002) or QMS system to generate automated overdue

alerts. The NC Log v2.0 includes built-in Overdue and Escalation Level columns with automatic calculation.

7. NC KPIs for Management Review

The following Key Performance Indicators shall be reported in each Management Review meeting. Quality Assurance is responsible for data collection and analysis.

KPI	Definition	Target
NC Closure Rate	% of NCs closed within target timeline per classification	≥90% on-time closure
Average Days to Close	Average days from NC initiation to closure, by classification	Critical: ≤10d, Major: ≤30d, Minor: ≤45d
NC Recurrence Rate	% of closed NCs where same root cause recurs within 12 months	≤5% recurrence
Overdue NCs	Number of open NCs exceeding target closure date	0 NCs >30 days overdue
Top Root Cause Categories	Pareto analysis of root cause categories (top 3)	Decreasing trend quarter-over-quarter
Cost of Non-Quality	Total cost associated with NCs (scrap, rework, investigation, returns)	Decreasing trend year-over-year
CAPA Escalation Rate	% of NCs escalated to CAPA	Monitoring (no fixed target)
Supplier NC Rate	NCs per supplier as % of incoming lots	<2% per approved supplier

Additional data for Management Review:

- NC source distribution (incoming, in-process, final inspection, customer, audit, supplier)
- NC by product line and department
- Trend comparison to previous reporting period
- Post-delivery NC summary and FSCA decisions
- Supplier quality performance summary

What Does the Auditor Ask?

- *"Show me your NC KPIs from the last Management Review. What actions resulted?"*
- *"What is your NC closure rate? How do you track overdue NCs?"*
- *"Show me the trend analysis for NC root cause categories over the last 12 months."*

8. Regulatory References

Requirement	Standard / Regulation	Clause / Section	How This Document Addresses It
Nonconforming product control	ISO 13485:2016	§8.3	Sections 5.1–5.5: Complete NC lifecycle from detection to disposition
Control of nonconforming product	FDA 21 CFR 820.90	820.90(a)–(b)	Sections 5.2–5.5: Containment, investigation, disposition with DHR linkage
Data analysis and trending	ISO 13485:2016	§8.4	Section 5.7: Quantitative trend triggers with defined thresholds
Risk management	ISO 14971:2019	§7, §9	Section 5.3.2: Risk Assessment Impact Check for every CRITICAL/MAJOR NC
Post-market surveillance	EU MDR 2017/745	Art. 83–86, Art. 87	Section 5.6: Complete post-delivery NC process with FSCA decision gate
CAPA requirements	FDA 21 CFR 820.100	820.100(a)(1–7)	Section 5.8: NC-to-CAPA escalation criteria aligned with CAPA SOP
Supplier controls	ISO 13485:2016	§7.4	Section 5.9: Supplier NC process with SCAR integration
Management review input	ISO 13485:2016	§5.6.2	Section 7: NC KPIs for Management Review with defined targets
Record retention	EU MDR 2017/745	Art. 10(8)	Section 5.10: Retention requirements (lifetime + 2 years or 10 years)
Purchasing controls (MDSAP)	MDSAP	Chapter 5	Section 5.9: Supplier NC management and SCAR process
NC process (MDSAP)	MDSAP	Chapter 6	Sections 5.1–5.10: Full NC lifecycle aligned with MDSAP requirements
Monitoring and measurement	ISO 13485:2016	§8.2.5	Section 7: KPI monitoring and trending

9. Related Documents

Document ID	Document Title	Relevance
FRM-NC-001	NC Form	Primary record for documenting individual NCs

FRM-NC-002	NC Log	Tracking and trending of all NCs with dashboard analytics
FRM-NC-003	NC Assessment Matrix	Risk-based classification and disposition guide
FRM-NC-004	NC Example (Incoming Inspection)	Filled example — incoming material NC
FRM-NC-005	NC Example (Customer/Field NC)	Filled example — post-delivery NC with FSCA assessment
FRM-NC-006	NC Rework Verification Checklist	Standardized rework/repair verification protocol
FRM-NC-007	Supplier NC Notification Template	Supplier notification and SCAR request template
FRM-NC-008	NC Cost Calculator	NC cost tracking and analysis tool
FRM-NC-009	NC Trend Analysis	Trend analysis and Pareto reporting tool
QRC-NC-001	NC Quick Reference Card	Quick reference for NC process on the shopfloor
GDE-NC-001	NC-to-CAPA Guide	Decision guide for NC-to-CAPA escalation
FLC-NC-001	NC Process Flowchart	Visual NC process flow
SOP-CAPA-001	Corrective and Preventive Action	CAPA process for systemic issues
SOP-CC-001	Customer Complaint Handling	Complaint process (NC source)
SOP-RM-001	Risk Management	Risk management per ISO 14971
SOP-PMS-001	Post-Market Surveillance	PMS process per EU MDR

10. Revision History

Rev	Date	Description of Change	Author
1.0	2026-02-15	Initial release	QCore Consulting
2.0	2026-02-15	Major revision: Added post-delivery NC process (5.6), quantitative trend triggers (5.7), NC-to-CAPA escalation criteria (5.8), supplier NC process (5.9), escalation procedure (6), NC KPIs (7). Enhanced containment process with FSCA decision gate (5.2). Added ISO 14971 risk management integration (5.3.2). Added rework vs. repair vs. refurbishment distinction (5.5.1). Expanded regulatory references to include EU MDR vigilance, MDSAP, ISO 14971 (8). Added Note-Boxes, Warning-Boxes, and Auditor Question sections throughout.	QCore Consulting

11. Appendix: NC Process Overview

NC Detection → Containment → Classification → Investigation → Disposition →
Verification → CAPA Decision → Closure

For a complete visual process flow, refer to the NC Process Flowchart (FLC-NC-001).