NC-to-CAPA Escalation Guide

When and How to Escalate Nonconformities to Corrective Action

Purpose

This guide defines the criteria and process for escalating Nonconformities (NC) to Corrective and Preventive Actions (CAPA). Not every NC requires a CAPA, but systematic issues demand formal root cause investigation and corrective action.

KEY DISTINCTION:

NC = Individual event. Immediate fix. Focus: THIS product.
CAPA = Systemic investigation. Root cause. Focus: Prevent recurrence.

Mandatory CAPA Escalation

An NC SHALL be escalated to CAPA when ANY of the following criteria are met:

#	Criterion	Rationale
1	**Critical Classification**	Any NC involving safety, regulatory compliance, or patient risk requires systemic investigation
2	**Repeat NC (≥3 in 12 months)**	Recurring issues indicate systemic problems that disposition alone cannot solve
3	**Customer Complaint / Field Failure**	External impact requires formal investigation and documented corrective action
4	**Systemic Root Cause Identified**	Process, design, or training deficiencies need formal correction
5	**Regulatory Notification Required**	MDR vigilance reports, FDA MDRs require accompanying CAPA documentation
6	**Released Product Affected**	Products in distribution may require field action, recall assessment, or advisory notice

When CAPA is NOT Required

An NC may be closed without CAPA when ALL of the following apply:

- Classification is Minor
- Isolated, first-time occurrence
- Root cause is obvious and non-systemic (e.g., operator error on single unit)
- Disposition effectively addresses the issue
- No customer impact or regulatory implication

⚠ **IMPORTANT:** Even when CAPA is not required, document the justification in Section 6 of the NC Form. Auditors will review your decision rationale.

Escalation Process

Step 1: Evaluate NC Against Criteria

- Complete NC Form Sections 1-5
- Review mandatory escalation criteria in Section 6
- Check NC history for similar occurrences

Step 2: Decision and Documentation

- If CAPA required: Initiate CAPA Form, record CAPA number on NC Form
- If CAPA not required: Document justification in NC Form Section 6
- Obtain QA signature for evaluation

Step 3: Link Records

- Reference NC number in CAPA Form (Source of CAPA)
- Reference CAPA number in NC Log
- Ensure traceability between records

NC-CAPA Traceability

The relationship between NC and CAPA records must be clearly documented:

NC Form	Link	CAPA Form
Section 6: CAPA Reference	↔	Section 1: Source (NC Number)
NC Log: CAPA Ref column	↔	CAPA Log: Source column

Best Practices

✓ **DO:**

• Evaluate every NC against CAPA criteria - document the decision
• Review NC trends monthly - pattern = CAPA trigger
• Link related NCs to a single CAPA when root cause is shared
• Close NC disposition before or parallel to CAPA - they are separate

✗ **DON'T:**

• Open a CAPA for every NC - this dilutes effectiveness
• Leave CAPA decision blank - always document justification
• Accept "human error" as root cause without deeper analysis
• Close NC when CAPA is still open - unless disposition is complete

References

- ISO 13485:2016, Clause 8.3 (NC) and Clause 8.5.2/8.5.3 (CAPA)
- FDA 21 CFR 820.90 (NC) and 820.100 (CAPA)
- NC-SOP - Control of Nonconforming Product
- CAPA-SOP - Corrective and Preventive Action

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