

 **FILLED EXAMPLE - Sensor Assembly Nonconformance**

This example demonstrates proper NC documentation for a Major incoming inspection failure

NONCONFORMANCE REPORT (NCR)

SECTION 1: IDENTIFICATION

NCR Number:	NC-2025-001	Date Issued:	2025-01-15
Initiated By:	Maria Schmidt	Department:	Quality / Incoming Inspection

SECTION 2: PRODUCT/PROCESS IDENTIFICATION

Product Name:	Temperature Sensor Assembly	Part Number:	TS-4500-A
Lot/Batch No.:	LOT-2025-A12	Quantity Affected:	50 units (entire lot)
Supplier:	TechSensors GmbH	PO Number:	PO-2025-0042
Source of NC:	<input checked="" type="checkbox"/> Incoming Inspection <input type="checkbox"/> In-Process <input type="checkbox"/> Final Inspection <input type="checkbox"/> Customer Complaint <input type="checkbox"/> Audit		
Released product affected?	<input type="checkbox"/> YES <input checked="" type="checkbox"/> NO		Serial/UDI (if appl.): N/A - incoming material

SECTION 3: DESCRIPTION OF NONCONFORMITY

Specification/Requirement Not Met:

Drawing TS-4500-A Rev.3, Dimension A: Housing diameter = 15.0mm \pm 0.05mm (14.95 - 15.05mm acceptable range)

Description of Nonconformity (actual vs. expected results):

During incoming inspection per WI-IQC-001, sample of n=5 units from LOT-2025-A12 was measured using calibrated micrometer (ID: CAL-MIC-042, due: 2025-06-15).

Results:

- Sample 1: 15.18mm (OUT OF SPEC)
- Sample 2: 15.21mm (OUT OF SPEC)
- Sample 3: 15.15mm (OUT OF SPEC)
- Sample 4: 15.19mm (OUT OF SPEC)
- Sample 5: 15.22mm (OUT OF SPEC)

All 5 samples exceed upper specification limit by 0.10-0.17mm. Entire lot rejected and segregated to NC holding area (Shelf NC-03).

Evidence Attached: Photos Test Results Inspection Records Other

SECTION 4: CLASSIFICATION (QA to complete)

<input type="checkbox"/> CRITICAL Safety/Regulatory	<input checked="" type="checkbox"/> MAJOR Quality Impact	<input type="checkbox"/> MINOR Cosmetic/Documentation
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Classification Justification:

MAJOR classification selected because: (1) Dimensional specification is breached - parts cannot fit into housing assembly without rework; (2) 100% of sample failed indicating systemic supplier issue; (3) No immediate safety risk as parts have not entered production. Not CRITICAL because deviation does not affect patient safety or regulatory compliance.

Classified By:	Thomas Weber, QA Manager	Date: 2025-01-15
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SECTION 5: DISPOSITION

<input type="checkbox"/> USE-AS-IS (Concession)	<input type="checkbox"/> REWORK
<input type="checkbox"/> SCRAP/DESTROY	<input checked="" type="checkbox"/> RETURN TO SUPPLIER
Disposition Justification:	
Entire lot (50 units) to be returned to TechSensors GmbH for replacement. RMA initiated (RMA-2025-008). Supplier notified via email 2025-01-15. Replacement lot expected within 10 business days.	
<i>Note: This is the second dimensional NC from this supplier in 6 months. SCAR to be initiated if replacement lot also fails inspection.</i>	
Disposition Decision By:	Thomas Weber Signature: T. Weber Date: 2025-01-15

SECTION 6: CAPA EVALUATION**Does this NC require a CAPA?**

YES → CAPA Number: _____ NO → Justification below

CAPA Escalation Criteria Evaluation:

- NC Classification is Critical
- Same/similar NC occurred 3+ times in 12 months (this is occurrence #2)
- Resulted in or could result in customer complaint
- Root cause indicates systemic issue
- Regulatory notification may be required

If NO CAPA, provide justification:

CAPA not initiated at this time because: (1) This is only the 2nd occurrence from this supplier (threshold is 3); (2) Product caught at incoming inspection - no impact on production or customers; (3) Supplier return disposition adequately addresses immediate issue. However, supplier performance will be monitored. If 3rd NC occurs or replacement lot fails, CAPA will be initiated to address supplier qualification process.

Evaluated By:	Thomas Weber Signature: T. Weber Date: 2025-01-15
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SECTION 7: VERIFICATION & CLOSURE**Verification of Disposition Completion:**

- Disposition action completed as documented
- Product re-inspected and meets specifications (N/A - returned)
- NC Tracking Log updated

Verification Notes:

RMA-2025-008 completed. Lot returned to TechSensors GmbH via DHL (Tracking: 1234567890). Replacement lot LOT-2025-A15 received 2025-01-22 and passed incoming inspection (all samples within spec). NC Log updated with closure.

Verified By:	Maria Schmidt Signature: M. Schmidt Date: 2025-01-22
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NCR CLOSED:	Thomas Weber Signature: T. Weber Date: 2025-01-22
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 **KEY LEARNING POINTS FROM THIS EXAMPLE:**

- ✓ Detailed measurement data provided (actual vs. specification)
- ✓ Calibration status of test equipment documented
- ✓ Classification justified with clear rationale
- ✓ CAPA decision documented with threshold-based logic
- ✓ Verification includes objective evidence (tracking number, replacement lot inspection)
- ✓ Traceability maintained throughout (lot numbers, PO, RMA)

