

 **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 ± 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"/> <b>CRITICAL</b> Safety/Regulatory	<input checked="" type="checkbox"/> <b>MAJOR</b> Quality Impact	<input type="checkbox"/> <b>MINOR</b> 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
<b>Disposition Justification:</b>	
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>	
<b>Disposition Decision By:</b>	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.

<b>Evaluated By:</b>	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.

<b>Verified By:</b>	Maria Schmidt   Signature: M. Schmidt   Date: 2025-01-22
<b>NCR CLOSED:</b>	Thomas Weber   Signature: T. Weber   Date: 2025-01-22

### 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)

**EXAMPLE DOCUMENT - FOR TRAINING PURPOSES**

*Template provided by QCore Consulting | qcore-consulting.de*