

Out-of-Tolerance Decision Flowchart

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Step-by-step procedure when calibration equipment is found out of tolerance. Based on ISO 9001:2015 Clause 7.1.5 requirements.

Equipment found OUT OF TOLERANCE during calibration

1 Quarantine the instrument immediately

- Remove from service — attach a red "DO NOT USE" label
- Record the as-found reading and the expected reading
- Note the date, time, and who discovered the deviation
- Do NOT adjust or recalibrate yet — the as-found data is evidence

2 Assess the impact on previous measurements

- When was the instrument last known to be in tolerance? (last cal date)
- What products/tests were measured between then and now?
- Could the OOT condition have affected any pass/fail decisions?
- Calculate the error magnitude — how far out of tolerance?

DECISION

Did the OOT condition potentially affect product quality or test results?

YES — affected

NO — not affected

3a Raise a Non-Conformance Report (NCR)

- Document the affected products/measurements
- Initiate product recall, re-inspection, or re-test as needed
- Notify the customer if affected product was shipped
- Record corrective actions in your QMS

3b Document the assessment

- Record that impact was assessed and found negligible
- State the rationale (e.g. "error within product tolerance")
- Retain as evidence for audit trail

DECISION

Can the instrument be recalibrated and returned to service?



Quick Reference: OOT Record Checklist

Item	Required Information	Recorded?
Asset ID / serial number	Instrument identification	
As-found reading	The actual reading before adjustment	
Expected reading	What the reference standard shows	
Error magnitude	Difference and direction (over/under)	
Discovery date	When the OOT was found	
Last known good date	Previous calibration date (in-tolerance)	
Products/tests affected	List of items measured in the suspect period	
Impact assessment	Significant / not significant + rationale	
Corrective action	Recalibrated / retired / restricted + details	
Root cause	Why it happened and prevention measures	
As-left reading	Reading after adjustment (if recalibrated)	
New certificate ref	Reference number of new calibration certificate	

ISO 9001:2015 Clause 7.1.5.2: "When measuring equipment is found to be unfit for its intended purpose, the organization shall determine if the validity of previous measurement results has been adversely affected, and shall take appropriate action as necessary." This flowchart implements that requirement. For UKAS-accredited laboratories, ISO 17025:2017 Clause 7.7.1 imposes additional requirements for handling nonconforming work. This document does not constitute legal or certification advice. Consult your certification body for definitive requirements.