4 Steps to an Audit-Proof Measurement System

Presenters

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Overview

Organizations adhere to many standards/certifications:

- ISO 17025
- TS 16949
- AS9100
- FDA
Overview

Today we will focus our attention on:

1. Inventory control
2. Calibration certificates
3. Process
4. Security

Inventory control

Companies maintain records relating to their measurement systems.

1. Paper system
2. Software
   – Homemade
   – Commercial
Inventory control

Locate

Identification
- Temporary / Permanent
- Handwritten / Label Printer
- Relevant details

Misplaced or borrowed gages

Lost
- Presents a risk
  - Someone finds and uses on a project not designed for that gage
  - Used after the calibration due date…
Inventory control

Use

Gages still in use after calibration date
  – One of the easiest ‘findings’ to avoid
  – Upcoming due reports
  – Quarantine overdue gages until the calibration can be completed

Inventory control

Maintain

All gage and service event records
  – Easily accessible / reviewable
  – Accurate
Archival system
  – Retired gages
  – Keep records for 3, 5, or 10 years
External or internal calibration

Calibration vendor(s)
  – Scope of Accreditation
  – Cert #, Masters used, Uncertainty
  – Review certificates received for accuracy

In-house calibrations
  – Results, Done by, Temp/Humidity

Certificate storage

Printed
  – Cabinet → Folder → Files (each gage)

Electronic
  – Network / Server
  – Accessibility and backups
Training

Operators and calibrators
- Proper use, handling, and maintenance
- Awareness of environmental factors
- Report dropped or damaged gages

Create training program
- Scheduled periodically
- Document completions
Protection of critical data

Paper / file system
– Secured room and cabinets
– Limited personnel access

Software
– Database on server / network – limited access
– Username and password to software
– Expiring password at set intervals
Demonstrate to auditor that only specific users can access and modify the data
Redundancy and backups are great to demonstrate to auditors
    – Attempt to reduce risk
Creating your own system can be desirable if you have clearly defined requirements to meet your industry standards
    – Commercially offered software can reduce stress and risk

Closing

Best advice for your measurement system management:
    – Be proactive
    – Conduct internal audits regularly and prior to external audits

Audits and auditors may seem like the enemy, but remember they are designed to improve the overall quality of your system!
Questions?

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