

Quality Digest Webinar

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4 Steps to an **Audit-Proof** Measurement System

Presenters

Guest Moderator



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Overview

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Organizations adhere to many standards/certifications:

- ISO 17025
- TS 16949
- AS9100
- FDA

Overview

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Today we will focus our attention on:

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

Inventory control

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Companies maintain records relating to their measurement systems.

1. Paper system
2. Software
 - Homemade
 - Commercial



Inventory control

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Locate

Identification

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

Gage #: C-01001
 Gage type: Caliper
 Assigned location: Spoiler Line
 Last calib date: 5/5/2016
Next due date: 11/5/2016

Inventory control

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Locate

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...

MISSING



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

Calibration certificates

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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

Calibration certificates

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Certificate storage

Printed

- Cabinet → Folder → Files (each gage)

Electronic

- Network / Server
- Accessibility and backups


Process

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Training

Operators and calibrators

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

A close-up photograph showing a person's hands using a digital depth gauge to measure a metal component. The gauge has a digital display showing '0.00'. The background is a blurred industrial setting.

Process

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Training

Create training program

- Scheduled periodically
- Document completions

Security

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Protection of critical data

Paper / file system

- Secured room and cabinets
- Limited personnel access

Security


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Protection of critical data

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




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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

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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!

Thank you!

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Questions?

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