5 Areas of Focus before Your Next Audit

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PQ Systems
Organizations adhere to many standards/certifications:

- ISO 17025
- IATF 16949
- AS9100
- FDA
Overview

5 areas to focus our attention on:

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

Locate

Misplaced or borrowed gages
Lost

Present 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 the 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

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
Training

Create training program
– Schedule periodically
– Document completions
Protection of critical data

Paper / file system
  – Secured room and cabinets
  – Limited personnel access
Protection of critical data

Software

- Database on network / server – limited access
- Username and password to gain entry
- Expiring password at set intervals

Demonstrate to auditor that only specific users can access and modify the data
Preparations

Re-read the standard

Plan of attack

– Imagine being asked questions about any section
– Prepare examples or have answers ready
Preparations

Team effort

Everyone on the same page
  – Line up all resources in advance
  – Communicate what is needed or expected of everyone
Preparations

Schedule “prep” time

Lead up to scheduled audit
  – Block out time for your preparations
  – Reschedule non-essential activities or events
  – Put best foot forward