



Quality Digest - Webinar

5 Areas of Focus *before* **Your Next Audit**



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Overview

Organizations adhere to many standards/certifications:

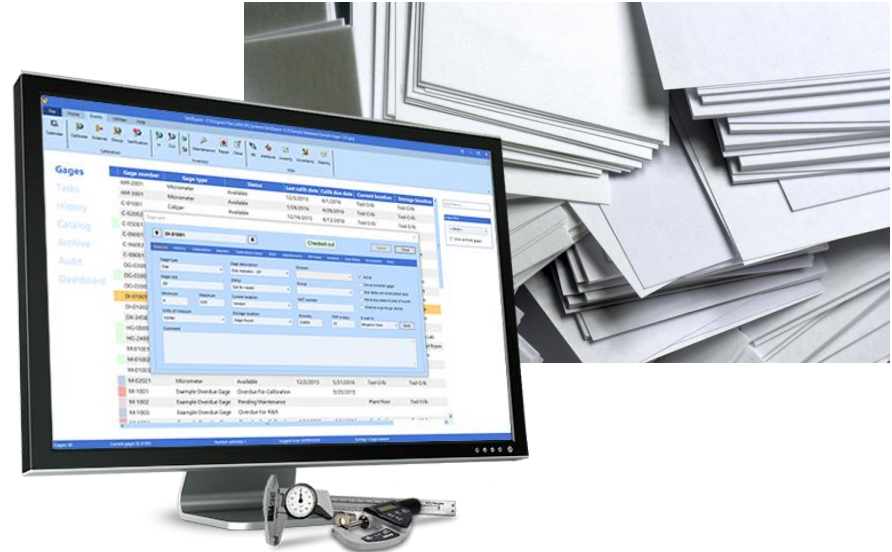
- ISO 17025
- IATF 16949
- AS9100
- FDA

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



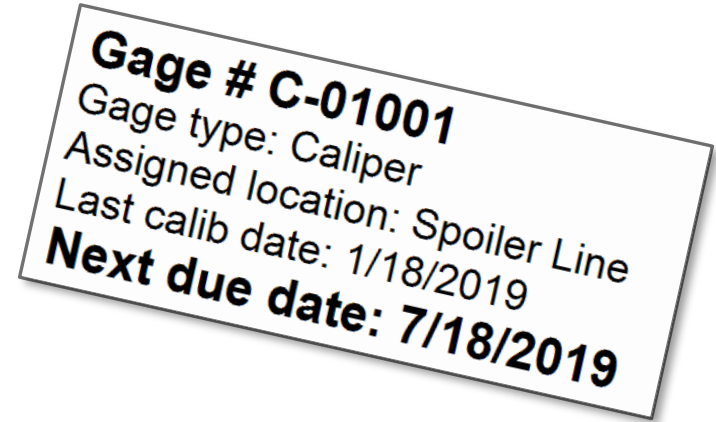


Inventory control

Locate

Identification

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



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



Calibration certificates

Certificate storage

Printed

- Cabinet → Folder → Files (each gage)

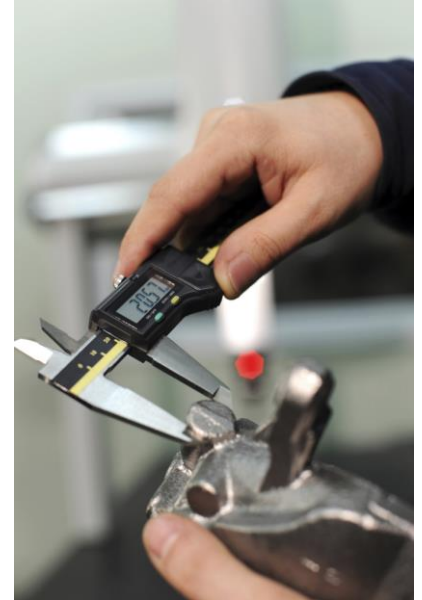
Electronic

- Network / Server
- Accessibility and backups

Training

Operators and calibrators

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





Process

Training

Create training program

- Schedule periodically
- Document completions



Security

Protection of critical data

Paper / file system

- Secured room and cabinets
- Limited personnel access



Security

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



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