



# Quality Digest - Webinar

## **5 Focus Zones** *Before* **Your Gage Audit**



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Organizations adhere to many standards/certifications:

- ISO 17025
- IATF 16949
- AS9100
- ISO 13485
- FDA

## 5 zones for our attention:

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





# 1. Inventory control

Locate

Identification (labels)

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



# 1. 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...



# 1. 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



# 1. 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





## 2. 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



## 2. Calibration certificates

### Certificate storage

#### Printed

- Cabinet → Folder → Files (each gage)

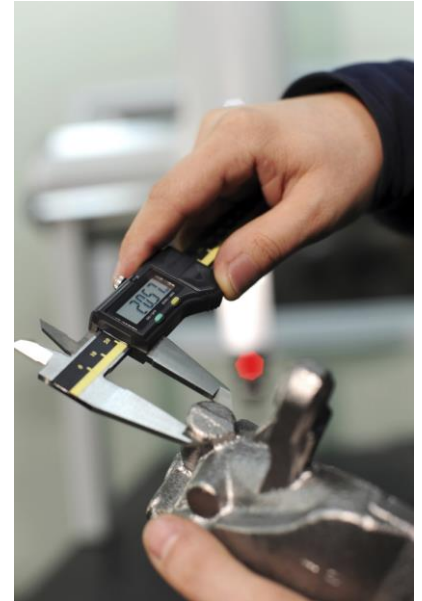
#### Electronic

- Network / Server
- Accessibility and backups

## Training

### Operators and calibrators

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



### 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



## 5. Preparations

Re-read the standard

Plan of attack

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

## Team effort

### Everyone on the same page

- Line up all resources in advance
- Communicate what is needed or expected of everyone





## 5. 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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