

Auditing excellence into calibration and testing labs

Follow these check points to ensure accurate measurement systems.

When an organization's calibration and testing laboratory is well maintained and controlled, then the company usually can rest assured that its measurement systems throughout the facility are also well maintained and will provide the most accurate and precise readings possible.

To help verify that a measurement system has been carefully considered and well planned, auditors can use the following list of considerations as a resource. Some of the checkpoints listed are within scope of the minimum technical requirements of their relevant standards (these are referenced in parentheses following the checkpoints); other items represent opportunities for improvement that can be implemented without substantial investment in equipment. The points are worded broadly within the scope of system design so a laboratory can adapt the methodologies to suit applicable regulations, its own corporate policy, or customer requirements. Taken together, the checkpoints can easily be implemented internally to improve calibration and measurement systems.

This checklist is by no means a comprehensive survey of all measurement system requirements. Given its generalized nature, readers will no doubt be able to think of many more items that could be added—particularly industry- or product-specific requirements. It's therefore a good idea to establish your own criteria and select questions that will suit your industry and provide the most value as you meet the intent of the audit. For more complete technical requirements, please refer to the measurement system analysis sections of the standard being audited (e.g., ISO 9001:2000 or ISO/TS 16949:2002).

The calibration and testing lab

- **Laboratory certification**
 - Is the laboratory certified separately to a national standard (e.g., ISO 17025, ISO 9001:2000)? [This isn't required if the laboratory is calibrating only its own company's gages.]
- **Laboratory scope**
 - Does the laboratory have a scope that clearly identifies the lab's capabilities? The laboratory scope is a document listing calibration equipment and the gages that can be calibrated with it. Ideally, ranges of measurement capability should be listed as well (e.g., temperature measurements from -20 to +40 degrees Celsius). [This is a requirement of the Measurement System Analysis (MSA) manual, which is part of ISO/TS 16949.]

the AUDITOR

This article originally appeared in *The Auditor*, a bimonthly newsletter created to provide full-time or part-time auditors with information required to conduct effective audits.

You can subscribe to the magazine by visiting the following web address:
www.theauditoronline.com



INTERNATIONAL
REGISTER OF
CERTIFICATED
AUDITORS

CQI The Chartered Quality Institute

www.irca.org

The Auditor

- **Knowledge and training requirements of calibration personnel**
 - Is there a knowledge requirement for calibration personnel?
 - Is there a training matrix or proof of that knowledge? Personnel responsible for calibration should have a prerequisite set of skills. [This is part of the training requirement for ISO 9001:2000 and associated quality systems standards.]

- **Laboratory environment (e.g., temperature, humidity, and cleanliness)**
 - Is the laboratory temperature and humidity controlled?
 - What are the stated ranges?
 - Is the laboratory free of contamination sources? Temperature, humidity, and contamination are major sources of variation that should be controlled and documented to achieve accurate calibration measurements.
 - [These are MSA requirements.]

- **Calibration tracking system**
 - Is there a calibration schedule?
 - Are there gages that are currently past due for calibration (i.e., the next calibration date has already past)?
 - Does the system cover all the requirements of calibration (e.g., gage histories, calibration results, storage locations, calibration procedures, calibration, and due dates)?
 - [These are MSA requirements.]

- **Calibration stickers, including key information**
 - Do calibration stickers include the due date for the next calibration?
 - Is the gage number identified?
 - Does the sticker indicate the name of the person who calibrated the gage?
 - [These are MSA requirements.]

- **Gage calibration certificates retrievable**

When new gages are purchased, most come with a certificate of calibration. Some gages are sent out to be calibrated at another lab, and those should have certificates of calibration also.

 - Are gage certificates retained?
 - Can personnel retrieve certificates in a timely manner?
 - Are certificates identified by gage ID?
 - Are the certificates from accredited laboratories or at least the original equipment manufacturer (OEM)?
 - Do the certificates show traceability to the National Institute of Standards and Technology (NIST)?
 - [These are MSA requirements.]

- **Approved contractors**
 - Is an approved contractor list available for calibration labs, gage vendors, laboratory supply vendors, and gage repair centers? This is a list of vendors that are proven to be trustworthy and capable of meeting the laboratory's needs. [This is an MSA requirement.]

the AUDITOR

This article originally appeared in *The Auditor*, a bimonthly newsletter created to provide full-time or part-time auditors with information required to conduct effective audits.

You can subscribe to the magazine by visiting the following web address:

www.theauditoronline.com



- **Gage suppliers**

- Do new gages come with: gage drawings, suggested spare parts, maintenance or service manuals, diagnostic trees and troubleshooting guides, certification reports, and calibration instructions?
- Did the gage have a full dimensional layout and functional test before it was bought?

The requirement is to prove that the gage is accurate before use. It's acceptable if testing is completed after a gage is received but prior to use, but the time that could be saved by doing it prior to receiving is worth consideration.

- **Calibration procedures**

- Are calibration procedures (i.e., instructions) documented? [This is an MSA requirement.]
- Were the procedures written in-house or purchased from a credible source? [This is a continuous improvement opportunity.]
- Do the procedures indicate the proper calibration standards required, additional tools required, and amount of time for gage acclimation? [This is a continuous improvement opportunity.]
- Have the procedures been tested for accuracy and reproducibility of calibration results? [This is a continuous improvement opportunity.]

- **Calibration standard gages**

- Are all calibration standard gages traceable to NIST standards? [This is an MSA requirement.]
- Are standards protected from harm or environmental hazards? [This is an MSA requirement.]
- What is the condition of the standards? [This is a continuous improvement opportunity.]
- Is there a schedule to verify condition of standards between calibrations and use? [This is a continuous improvement opportunity.]
- Are rust-prevention methods utilized? [This is a continuous improvement opportunity.]

Gage standards are the most important instruments of a calibration laboratory. They're the most accurate gages a company has and all other gages are compared to them. They should be handled and maintained with extreme care.

- **Gage care**

- Is gage care and cleaning addressed in the calibration procedures? [This is a continuous improvement opportunity.]
- Does the company have a gage training program for operators? [This is a continuous improvement opportunity.]
- Does the training include cleaning, lubrication, and general care of gages? [This is a continuous improvement opportunity.]
- Do the storage areas protect the gages from potential harm? [This is an MSA requirement.]

This article originally appeared in *The Auditor*, a bimonthly newsletter created to provide full-time or part-time auditors with information required to conduct effective audits.

You can subscribe to the magazine by visiting the following web address:

www.theauditoronline.com



INTERNATIONAL
REGISTER OF
CERTIFICATED
AUDITORS

CQI The Chartered Quality Institute

www.irca.org

The Auditor

- Answers to all the questions above concerning gage care should be "yes." The more care and protection given to the gages, the better.
- **Extra, obsolete, and inactive gages**
 - Are these gages isolated from gages in active use? [This is an MSA requirement.]
 - Are there scheduled intervals for upkeep, cleaning or lubrication of these stored gages? [This is a continuous improvement opportunity.]
 - How are these gages identified? [This is an MSA requirement.]
 - Is a list of these gages maintained?
 - What is the procedure for bringing a gage out of isolation? [This is an MSA requirement.]

Procedures and actions should be in place to prevent extra, obsolete, or inactive gages from getting mixed in with active gages. Because inactive gages are listed as such, there might not be a flag in the system to indicate when they're due for calibration.

- **Contingency measurement plans**
 - Are there contingency plans for missing, broken, or temporarily out-of-service gages or calibration standards?
 - How is it ensured that critical product verifications are completed in these instances?

Contingency plans include spare (or replacement) gages, alternative gages approved to use for measurements, inspection labs or other divisions approved to perform emergency measurements, and OEM support and service for inspection equipment. [This is an MSA requirement.]

- **Gage repeatability and reproducibility (GR&R) system**
 - Are GR&R studies being completed?
 - Is there a customer or internal mandated schedule for repeating the studies?
 - Are the acceptable limits for the total variation defined and documented?
 - Are the results of the studies evaluated to determine the cause of a failed GR&R?
 - If the GR&R is unacceptable, what is the reaction? Is it documented?
 - [These are MSA requirements.]
- **Fixture calibrations**
 - Are calibration measurements that are derived from the fixture aligned to the datum references as specified on the blueprint?
 - If not, why? [This is a continuous improvement opportunity.]
- **Machine controls and automated gages**
 - Are machine controls in the calibration system (e.g., power supplies, oscilloscopes, pressure gauges, torque converters, load cells, voltage, current, rpm, vibration, resistance, and displays)? Any automated gages that measure in-line must be verified. These devices should be calibrated, and there should be some plan to

the AUDITOR

This article originally appeared in *The Auditor*, a bimonthly newsletter created to provide full-time or part-time auditors with information required to conduct effective audits.

You can subscribe to the magazine by visiting the following web address:
www.theauditoronline.com



verify accuracy of any equipment that gives a measurement. [This is an MSA requirement.]

- **Judgment samples**

- Are judgment, limit, boundary, and fool standards, as well as proofs, masters, and working standards controlled in the calibration system? It's not necessary to have these standards controlled in the formal calibration software, but there should be some type of system to verify the correctness of these functional samples periodically. [This is a continuous improvement opportunity.]

- **Uncertainty studies**

- What is the current status of uncertainty studies?
- Are personnel trained to understand and conduct the studies?

The organization presumably has documented what's been done and what still needs to be completed for the laboratory to calculate its uncertainty. [This is an MSA requirement.]

- **Improvement plans**

- Are there improvement plans for the metrology laboratory?
- Who is responsible for continually improving the lab?

Check for a defined plan for future upgrades, training, or improvement initiatives. [This is part of the continuous improvement requirement found in ISO 900:20001 and its associated quality system standards.]

Considerations outside the lab

- **Scheduled measurement system reviews**

- Stability, linearity, bias and GR&R studies should be repeated and reviewed periodically. [This is an MSA requirement.]

- **Overall quality checks**

- Are most inspections visual, or are there more robust systems in place such as fool-proofing, poka-yoke, or in-line sensors? [This is a continuous improvement opportunity.]

- **Measurements defined in control plans**

- Is the frequency, instrument used, and personnel responsible listed on the control plan?
- Are there scheduled audits to confirm that the control plan is being followed?

The responsible personnel should be able to show you the instrument and data sheet used according to the frequency. [This is a requirement of ISO 9001:2000 and its associated quality system standards.]

- **Operator gage training**

- Has the organization implemented a training program to operators on gage care, reporting damage, operator responsibility, checking stickers, and correct gage handling?

the AUDITOR

This article originally appeared in *The Auditor*, a bimonthly newsletter created to provide full-time or part-time auditors with information required to conduct effective audits.

You can subscribe to the magazine by visiting the following web address:
www.theauditoronline.com



INTERNATIONAL
REGISTER OF
CERTIFICATED
AUDITORS

CQI The Chartered Quality Institute

- Has the organization standardized gauging methodologies (e.g., three slow clicks on a micrometer)?
- Do operators have part-specific gage training at their areas of work as defined in their job descriptions?

This training should be documented, and there should be training sign-off sheets. [These are continuous improvement opportunities.]

As an auditor of measurement systems, you must measure to the requirements. As an internal auditor, you should keep mind that your auditing questions can provoke breakthrough thinking and improvements in the measurement systems. In those instances, everyone wins. A company's transition from meeting minimum requirements to continually challenging and improving itself is both exciting and to witness rewarding for those involved. Make the most of your lab's improvement opportunities, and you'll notice the benefits throughout the facility.

Author bios - Dorothy Brown is an ASQ Certified Quality Engineer, with 10 years' experience in automotive component manufacturing. She spent seven years in metrology and supervision, with direct responsibility for calibrating and testing laboratory equipment, developing procedures, and overseeing personnel. She also spent three years working with external suppliers to help improve the quality of their products and systems. Brown is active in several organizations and has trained more than 300 operators in gage use and care.

APRIL 2007

www.irca.org

The Auditor

the AUDITOR

This article originally appeared in *The Auditor*, a bimonthly newsletter created to provide full-time or part-time auditors with information required to conduct effective audits.

You can subscribe to the magazine by visiting the following web address:

www.theauditoronline.com

