4 Steps to an Audit-Proof Measurement System

By Eric Gasper

An upcoming audit can be one of the more stressful times of the year for a quality team. Whether you are pursuing a new certification or retaining your current one, audit preparation can be a daunting challenge to even the most diligent organization. While standards such as ISO 17025, TS 16949, AS9100 and FDA differ in many ways, as it relates to the measurement system, there are more similarities than differences. Here are a few key steps you can take to ensure the audit process goes smoothly, regardless of the standard.

Step 1: Inventory Control

Inventory control is priority one when it comes to managing your gages. Inventory control can be further broken down into three categories to manage.

1. **Locate**
   Lost gages are easy targets for auditors. Gages need to be inventoried, then tracked so that you can easily locate them. A lost gage represents a risk because, if found, it could potentially have been used to measure a part on which it wasn't specified to be used. Lost gages are also an investment from which you are no longer getting value. Missing IDs are a related audit finding. If the device isn't sporting proper identification, how can you know when the device was last calibrated or when it is next due?

2. **Use**
   Using overdue gages may just be the single most common audit finding, and the number one mistake to avoid, but beware of the overdue gages not in use as well. Make sure that gages awaiting calibration are kept in a controlled environment and not at risk for being used.

3. **Maintain**

   Proper inventory control includes maintaining all gage records. Records pertaining to all servicing events, including calibrations, verifications, preventive maintenance, and measurement studies, must be readily available.

Many industries including aerospace, automotive, and food and beverage require retention of gage records for several years; therefore a reliable archiving system is critical to meeting this requirement.

And last but certainly not least, when a gage fails a calibration, you must record what corrective actions have been taken.

Step 2: Calibration Certificates

When gages are being calibrated by an outside vendor, it is critical to check the vendor's scope of accreditation to ensure that it is qualified to calibrate your devices. Check to ensure that the calibration certificate that you receive from the vendor includes the pertinent details required for your industry. Auditors will likely check that all the required info is included on the certificate and that it is completely accurate. Create a safe, reliable system for storing the certificate so that it can be easily located during an audit. A lost certificate is an easily avoidable finding.

Step 3: Process

Lack of proper employee training can lead to the misuse of gages. Personnel need to know which device to use and how to properly measure with the device. If the environment is a factor, they need to be educated on the influence that temperature, humidity, dirt, grease, and other external factors can have on the outcome of the measurements. Ensure that you have a proper training program in place and that you keep accurate training records.

Even with the best trained workers, accidents happen. In the event that a gage is damaged or dropped, workers need to be educated on the process for removing it from use and verifying and/or repairing it. They should also be comfortable reporting the incident. Dr. Deming's point #8, Drive out fear, is relevant here. It is much better to report the incident than to risk measuring with a damaged device.

Step 4: Security

A secure method to prevent tampering is critical. Without it, all the work in Steps 1 through 3 can be compromised.

For electronic systems, you can create permission levels with password protection, but make sure that the passwords have associated expiration dates. Lastly, develop a reliable system for backing up the data.

For paper environments, a locked cabinet in an area with access limited to relevant personnel is needed. Backups are much more difficult in paper environments, but no less critical.

Commercially-supported software systems, such as PQ Systems' GAGEpack, that are designed specifically for gage management can eliminate much of the worry. They offer an easy way to organize and manage your measurement system information so that information that auditors are likely to request is available at the push of a button. GAGEpack is designed based on best practices in gage management so that all four steps are easily covered.

Remember that the audit process, however daunting, is meant to help you improve. A good internal audit system will help you identify any areas in which you have improvement opportunities before the make-or-break audit. Investing the time up front in developing a reliable measurement system will mean less worry when it comes time for the audit.

ABOUT THE AUTHOR

Eric Gasper brings a rich background of technical and business analysis, web development, consulting, and team leadership to his role as trainer-consultant for PQ Systems. Experience in laboratory and office environments has given him a unique perspective on a variety of technical problems as well as insight into customers' unique challenges. Eric holds a bachelor's degree in management information systems from the University of Dayton, where he garnered experience with the university's famed Research Institute prior to entering the work force as a business analyst and development specialist in pharmaceuticals for a major consulting company.

In his role at PQ Systems, he has led regularly-scheduled technical seminars, offered a gage R&R workshop at the 2013 and 2014 Inspection Division Conference sponsored by the American Society for Quality (ASQ), and presented a session on "Better Gage Management" at the 2013 Quality EXPO. Recent consultancy clients include Harley Davidson, Alcoa Howmet, DANA Corporation, Crown Cork & Seal, Eaton, Carpenter Technology, Spraying Systems, and Whirlpool.