



Traceability of Product affected by Measurements and Validation Processes

ISO 9001:2000, paragraphs 7.6 (Control of Monitoring and measuring equipment) and 7.5.2 (Validation of processes for product and service provisions) both exhibit subtleties that can have a large impact on the integrity of the quality of product and the ability to minimize after delivery problems as well as compliance short falls to your quality management system. [3]

This article will focus on the importance of monitoring and measuring equipment as well as validation processes that can influence the product compliance or decision of compliance to stated specifications and the traceability of product status with respect to monitoring and measuring requirements. The impact of the equipment to product can be complex and the technical aspects within this article have been simplified into basic concepts.

Calibration: Measuring equipment used to accept product must be calibrated (ISO 7.6). Some key areas where calibrated equipment is used are:

- Receiving Inspection
- First Article Inspection
- Final Inspection
- Process Controls
- Process Validations

In ISO9001:2000 7.6(e) addresses when measuring equipment is part of a calibration program *“The organization shall assess and record the validity of the previous measuring results when the equipment is found not to conform to requirements. The organization shall take appropriate action on the equipment and any product affected.”*

Note: All accredited calibration facilities are required to provide as found data before any adjustments are made.

To state another way, you must identify the amount of error from the requirements; make a decision as to action on the equipment which can include;

- a) Increase calibration cycle
- b) Limit equipment use
- c) Replace equipment
- d) Downgrade performance requirements
- e) No action required (evidence OOT condition did not effect product)

Once action has been decided on the OOT equipment, a review of product that may have been affected by this equipment must be considered. To do this, procedures are needed that enable the company to trace the product that was accepted (or rejected) by specific calibrated equipment (see ISO9001:2000 clause 7.5.3 *Identification and Traceability*).

Quality Evolution

During product realization each step where equipment is used for monitoring, controller or testing have an affect and/or influence on the product needs to be identified. Some key area's where calibrated equipment has an influence on the product are;

- Receiving inspection
- First Article
- Final inspection
- Validation processes
- Product Key Characteristics Stages

Equipment accuracy versus product tolerance: It is also important to know the relationship between equipment accuracy and product tolerance so that proper calibration cycles can be established and the impact of an OOT condition to product conformance can be quickly assessed. Knowing the relationship between equipment accuracy and product tolerances also improves the accuracy of process capability studies and process validation activities.

Accuracies of the calibration equipment and relationship to the product specifications are called accuracy ratios. An accuracy ratio is usually thought of as the ratio between the tolerance limits of a parameter being measured and the tolerance limits of another parameter being used as a reference. [4]

For Example:

A product has an output voltage specifications stated at 10 volts ± 0.5 volts per customer requirements. During final testing product the values cannot be ≤ 9.5 volts or ≥ 10.5 volts. The measuring equipment at the 10 volt range has an accuracy of ± 0.25 volts. The ratio of accuracy to product specifications is 2:1. The measuring equipment is twice as accurate as the specification tolerances of the product.

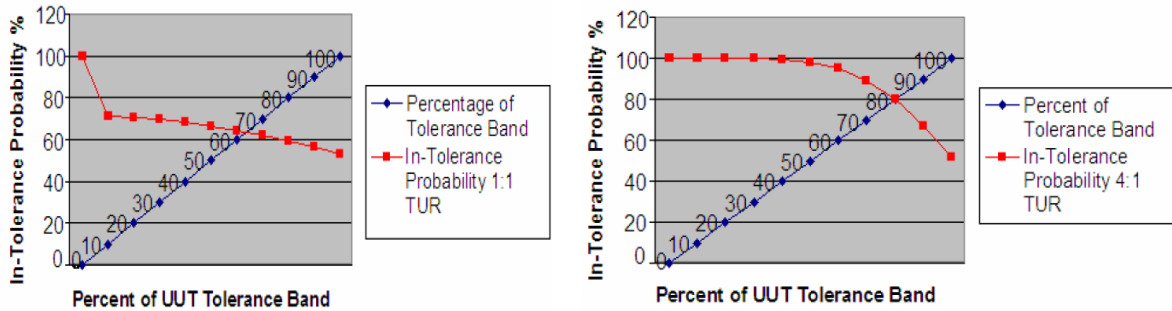
In the above scenario, if the equipment was found to have an OT condition $\geq 100\%$, there is a possibility that during the final testing, product could have been accepted or rejected based on false results. All products that were tested with the equipment would need to be rechecked or if the product has shipped, the customer notified.

With an accuracy ratio of 2:1, the calibration cycles should be more frequent to minimize the risk of false results during the final test phase.

When product tolerances become tighter and accuracy ratio's drop below the 4:1 ratio, overhead costs can increase exponentially as the ratio's decrease. The use of equipment or monitoring devices with accuracies 4 times higher than product specifications is not always cost effective or the specifications maybe pushing technological capabilities. When the ratios drop the risks increase and operations need to compensate to offset for this increased risk.

When the accuracy ratio is less than 4:1, the calibration cycles should be more frequent to minimize the risk of false results during the final test phase.

Quality Evolution



The above charts reflect that when the monitoring or test equipment ratios to product (UUT) are 1:1 and during process or testing, should the specification values deviate from nominal values \geq to 30% your confidence in the readings are at 75%, a 1 out of 4 change that the product will reflect a false condition. When the nominal values are \geq 70% of the product tolerance band, the risks of false condition is nearly 50%. With the 4:1 ratio the in tolerance probability stays flat at 100% through 50% of the tolerance range and drops below 90% at the 70% tolerance band. Confidence window is increased with the 4:1 ratio to cover 90% of the specification band. A 10:1 ratio will yield higher confidence but may be impractical. A change from 4:1 to 10:1 ratio will increase the confidence spread only 15%. [1]

Equipment Accuracy ± 5 VDC

Product Specs 100 VDC ± 20

The above bars reflect accuracies of equipment ± 5 VDC and Product specifications ± 20 VDC. The accuracy ratio is 4:1. The overlap area of the two bars represents the actual conditions of both devices. In the event that both devices were at opposite end of the tolerance window the spread would provide false reading.

Process Measurement Controls: Measuring equipment also consists of process controllers for temperature, pressure, flow and time parameters to name a few. When the controller is necessary to realize a measurement process affects product, calibration should be considered.

The accuracy of the equipment related to the process accuracy required to obtain desired results needs to be understood. The accuracies of all of the equipment used within a process are part of the quotient that is used to state a process capability. This is critical when process validation is preformed.

Plating bath uses chemicals that have requirements stated by the supplier that temperature ranges must be maintained for desired results. On some plating bathes if the temperature climbs too high the bath is no longer functional and must be replaced.



Validating Processes: When processes are critical for a desired result on a product that has characteristics that cannot be measured or monitored on the product itself, validation of the process is necessary. Validation is supported by training records, test results for evidence of planned results, revalidation schedule and calibration of measuring process equipment.

Processes subject to validation would include:

Steel and plastic welding, heat treating, painting, sterilization, and curing or any process where the results can not be fully verified through subsequent inspection.

The basic objective of validation is to establish a procedure or in another term, (process recipe) that will provide desired results with high confidence. Periodic testing of samples should still be performed to assure the procedure is being followed properly.

The process recipe would outline all parameters such as temperature ranges, tolerances, specific material type, specifications of the equipment/process, loading conditions and equipment required. The recipe would address the same points we discussed above:

- The instruments used to control the process are calibrated to ensure all key operational parameters are within required tolerances.
- The ratio of the accuracy of the measuring equipment to the product specification tolerances is known. (If the ratios of the equipment tolerances to the process tolerances have ratio of less than 4:1, more frequent calibration should be considered.)
- Procedures are in place that will identify and record product that is subject to the validated process. See ISO9001:2000 clause 7.5.3 *Identification and Traceability*.

Aerospace Material specification AMS-2750 Pyrometry standard is used for the validation of heat treating processes. An example below is part of a requirement within this AMS-2750 specification. [5]

Furnace for Heat Treating Parts

Controller Accuracy $\pm 0.3\%$ Range (1100°F) = 3.3°F

Readability of analog controller $\pm 2^\circ\text{F}$

Readability of Digital controller $\pm 1^\circ\text{F}$

Uniformity of Heat (Process Tolerance) = $\pm 10^\circ\text{F}$

The above specifications identify that the uniformity of the temperature of the working zones within the furnace should be $\pm 10^\circ\text{F}$, the controller accuracy is $\pm 3.3^\circ\text{F}$. This yields an accuracy ratio of 3:1.



As per AMS2750, calibration schedule for the temperature controller can be weekly, monthly or quarterly, which schedule is required is contingent on how many working and/or loading sensors are used within the product during heat treating.

Based on the above scenario the temperature controller would have to experience an OOT condition $\geq 300\%$ before product could be compromised. With a ratio of 3:1, additional protocols have been put into place to limit risk to non-conforming product with tighter calibration cycles, as well as the use of the load sensors.

Temperature uniformity surveys must be performed monthly, quarterly, semi-annually or annually, the schedule required is based on several factors that include; type of material being processed, previous test results of the furnace, as well as number of working sensors for each control zone and load sensors. More frequency schedules are mandated when limited number of working and load sensors are used for monitoring, furnace has poor or little performance history and the type of material being processed.

AMS2750 incorporates several procedural controls that address the calibration cycles for the instrumentation controls, uniformity schedules (Revalidation) and loading sensors to monitor product during the process to insure stated parameters have been satisfied.

Summary

The development of understanding the process or test equipment accuracy to product specifications clarify when and if any action is required when out of tolerance condition is found on calibrated equipment (clause 7.6e). This accuracy to product relationship provides the ability to determine what equipment is required for evidence of conformity and that is carried out in a manner that is consistent with the requirements (clause 7.6). Within the validation of processes the equipment approval process can be quickly identified by accuracy requirements (clause 7.5.2 b). Verifies the suitability of the equipment (clause 7.5.1 c) and supports the infrastructure for the achievement of product conformity (clause 6.3 b).

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