

ISO 9001 and the Role of Uncertainties in Calibration

Section 7.1.5.2a of ISO 9001:2015 focuses specifically on the importance of performing calibrations and verifications of measuring instruments against standards that are traceable to national or international standards. While these are certainly important, it's also important to understand two critical concepts and how they relate to this requirement: traceability and uncertainties. Both of these principles are vital to ensure the accuracy and reliability of calibrations or measurements, making them fundamental to quality management systems like ISO 9001.

What Is Traceability in Calibration?

Traceability refers to the property of a measurement result allowing it to be connected to a reference standard through a well-documented and unbroken chain of calibrations. This continuous chain ensures that each step in the process is able to be traced back to a recognized and consistent standard.

Historically, traceability involved physical objects that defined the quantity being measured. All weight measurements were traceable back to a physical 1 kg test weight maintained by the United States Department of Commerce at the National Institute of Standards and Technology (NIST). This primary standard was periodically calibrated to the kilogram maintained by the International Bureau of Weights and Measures in France.

Today, units of measure have been defined by inherent physical properties as opposed to physical artifacts. traceability isn't as concerned with these physical objects. In most cases, traceability is realized electro-magnetically and determined through calculations related to the weight itself. As an example, these days there are no physical objects that define SI units, but it is still possible to achieve traceable measurements if the necessary equipment and apparatus are in place.

This clear path from a measurement to a national standard ensures that measurements are accurate and that they agree with the measurements of others that are also traceable. This agreement within the measurement community enables mass production as well as confidence in products and materials purchased.

Why? The lack of physical traceability (ie, artifacts replaced by inherent attributes) does not drive nor necessitate the need for a clear path.

What are Uncertainties in Calibration?

Uncertainties are parameters characterizing the range of values that could reasonably be attributed to the quantity being measured (referred to as the measurand). To put it simply, uncertainties ask "How far off could we be in our measurements?" This concept is central to the accuracy of any measurement system.

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Many operations are ISO 9001 registered without requiring uncertainties to be reported. No where in ISO 9001 is there an explicit requirement relative to uncertainties. However, the VIM (the International Vocabulary of Metrology) defines “calibration” as “operation performed on a measuring instrument or a measuring system that, under specific conditions

1. Establishes a relation between the values with measurement uncertainties provided by measurement standards and corresponding indications with associates measurement uncertainties and
2. Uses this information to establish a relation for obtaining a measurement result from an indication.

This definition is often overlooked by 9001 auditors, and in turn customers.

Factors contributing to the overall uncertainty in a measurement include

- Accuracy of the Measuring Instruments – how closely does the reading on the instrument match the true value?
- Previous Uncertainties – every prior calibration in the chain of traceability contributes to the overall uncertainty of the current measurement
- Resolution of the Instrument – how finely can the instrument read a measurement (ie, how precise is your equipment)?
- Degree of Repeatability – can the measurement be repeated with the same/similar results?
- Degree of Reproducibility – can other operators achieve similar results using similar tools in different environments?
- Environmental Condition Consideration – are numerous external environmental factors such as temperature, humidity, or vibration affecting the result of the measurement?

ISO 9001 and Measurement Uncertainty

ISO 9001 requires measurement traceability be maintained. According to ISO 9001, “the organization shall determine and provide the resources needed to ensure valid and reliable results when monitoring or measuring is used to verify the conformity of products and services to requirements.” This means that the individual instrument (for instance, calipers or micrometers – which are often calibrated internally by operations) is not driving the process. The measurement is. According to ISO 9001:2015, section 7.1.5.2a, organizations must ensure that calibration is performed against standards traceable to recognized measurement systems. If no such standard exists, the basis for calibration must be documented.

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ISO 9001 requires measurement to be traceable utilizing calibrated devices. Calibration, as defined by the measurement community, includes quantifying the measurement uncertainty. This means that organizations must consider factors such as the accuracy of the instrument, the reliability of prior calibrations, and environmental influences. In addition, this makes the calibration process an essential component of quality management under ISO 9001.

Many organizations performing minor calibrations internally may not be aware of the potential for creeping uncertainties to throw off calibrations over time. If an operation is performing delicate calibrations without taking these factors into account, it can result in drifting readings as the instruments become less and less accurate over time. This makes quality control more difficult and can potentially lead to more problems down the line as processes and controls diverge further and further away from the desired standard.

In manufacturing settings, products are built to a specified tolerance. You lose confidence in the measurement being made as the uncertainty of the measurement grows relative to the tolerances of the product being manufactured. For example, say you had a component that needed to be 12" long with a tolerance of $1/16$ ". If you measure it to be 12.00" but your uncertainty of the measurement is $1/4$ ", there is a solid chance the 12" measurement is outside of the $1/16$ " tolerance.

It's hard to overstate the relationship between ISO 9001 and measurement uncertainty. To ensure compliance with ISO 9001:2015, operations need to understand how traceability and uncertainty can impact calibration processes. By accounting for these factors, operations can ensure a higher degree of accuracy, consistency, and reliability in measurements. This is necessary to maintain high standards of quality in manufacturing processes.

The above considerations are also why it is generally recommended to partner with professionals for critical calibrations.

A Note on Selecting the Right Measurement Instrument

When selecting a measurement instrument, it is critical to consider the factors contributing to uncertainty. Ask questions like:

What am I measuring with, and is it the most accurate instrument for the job?

Is my measurement process repeatable and reproducible across different operators and environments?

Is my environment suitable for accurate measurement?

For example, choosing between a micrometer or a tape measure will depend on the precision needed. While a micrometer may offer precision down to 0.001 inches, a tape measure may only measure to 0.0625 inches, and choosing the wrong instrument could significantly affect measurement uncertainty.

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A measurement process also needs to be repeatable, meaning that another operator in similar conditions with similar instruments should be able to get the same reading. This is an indicator of consistency and helps determine product reliability. Poor repeatability can negatively impact product quality.

Some measurements also require specific environmental conditions. Some may also require low humidity. Others may even be sensitive to ambient vibrations (such as trucks driving down a nearby highway). These considerations have to be taken into account to ensure an accurate measurement.

The above considerations are necessary steps in making sure your measurements are accurate, reliable, and repeatable. They're also why it's so important to work with certified and experienced professionals when it comes to calibration and metrology more broadly. If you'd like to learn more about how Cross Company can help your operation with necessary calibration, contact us today.