Calibration **Essentials**

ISA | beamex

Introduction

The proper calibration of instruments is always one of the most essential, yet historically one of the most overlooked processes in today's plants and factories. Even today, with rapidly evolving technology and tools to enhance production and efficiency, the need to calibrate and ensure consistent, reliable measurement is always there.

With innovative new tools and equipment seemingly released every day, how do you know that you're taking the most efficient path towards your facilities calibrated, automated production? To help you find that certainty, the calibration experts at Beamex have teamed with the International Society of Automation (ISA) to provide this in-depth guide to calibration automation, complete with all the information you need to ensure a fully calibrated and reliable facility.

The informative new eBook, Calibration Essentials, comes with 60 detailed pages, covering everything you need to know about today's calibration processes including:

- A comprehensive big picture guide on how to manage a facility-wide calibration program for Industrial Automation and Control Systems.
- Informative overviews of calibration considerations, such as tolerance errors, and calibration uncertainty, as well as practice scenarios and solutions to manage them.
- An in-depth look at some of the new smart instrumentation and WirelessHART instruments and how to effectively calibrate them
- A technical discussion on the pros and cons of an individual instrument calibration strategy versus a loop calibration strategy.
- Detailed guidelines to ensure facility and employee safety and security, as well as compliance with standards, when conducting calibration tasks
- And much more

With this eBook, from Beamex and ISA, you now have the resource you need to ensure that your facility is safely and efficiently getting the most out of your instrumentation. This roadmap to calibration has tools for workers at every level of your facility to standardize your effort and facilitate an advanced, automated production environment.

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Management of a Calibration Program for **Industrial Automation** and **Control Systems**

Introduction

Purpose

The purpose of this recommended practice is to provide the basic framework for developing and maintaining a consistent calibration program for industrial automation and control systems (IACS), including instrumentation used in safety instrumented systems. This recommended practice provides guidance on methodologies for calibration of an IACS by considering the accuracy of each loop required by the process and, if necessary, adjusting a loop component(s) to achieve the desired loop or component accuracy.

Accurate, reliable, and repeatable operation of loops in an IACS is vital to maintaining the safety and reliability of a facility. Where repeatable measurements take place in the monitoring or control of a facility, the measuring instruments and test equipment must have repeatable outputs. A well-considered calibration program, correctly implemented and maintained, can directly contribute to the assurance of the desired operation of the IACS for the facility. A calibration program establishes periodic assessments of loop/component performance over time. Data acquired during these assessments not only aids in the establishment of future calibration intervals, but is also critical in the allocation of capital and operational resources. Clearly defined policy and procedures support the efforts of maintenance planners to schedule adequate labor and equipment for calibration both during and between facility outages. Following established calibration procedures and using correct equipment reduces the likelihood of human errors due to incorrect practices; avoids acting on incorrect information; ensures the desired results of the calibration efforts; and promotes the correct operation of an IACS.

In an IACS, more hardware faults occur in the measuring instrumentation, and control valve components than in the control components of the IACS. A calibration program can aid in early detection of these failures. Inadequate calibration and maintenance of an IACS may increase the likelihood of system problems, including:

- Inaccuracy of measurements and control;
- System not responding correctly or as desired;
- Reduced awareness of instrument performance

and actual need for calibration and maintenance; and
- Potential for reporting of incorrect environmen tal or other data.

However, targeted reduction, or increase, in calibration activities based upon the assessment of data derived from an instrument asset management calibration program can both reduce maintenance costs and improve reliability and safety.

Various definitions of the term calibration can be found:

The formal definition of calibration by the International Bureau of Weights and Measures is: "Operation that, under specified conditions, in a first step, establishes a relation between the quantity values with measurement uncertainties provided by measurement standards and corresponding indications with associated measurement uncertainties (of the calibrated instrument or secondary standard) and, in a second step, uses this information to establish a relation for obtaining a measurement result from an indication." (from International vocabulary of metrology - Basic and general concepts and associated terms (VIM) (JCGM 200:2012, 3rd edition)).

A definition found in the NIST Handbook 150:2001 is: "1.5.8 Calibration: Set of operations that establish, under specified conditions, the relationship between values of quantities indicated by a measuring instrument or measuring system, or values represented by a material measure or a reference material, and the corresponding values realized by standards.

NOTE 1 The result of a calibration permits either the assignment of values measured to the indications or the determination of corrections with respect to indications.

NOTE 2 A calibration may also determine other metrological properties such as the effect of influence quantities.

NOTE 3 The result of a calibration may be recorded in a document, sometimes called a "calibration certificate" or a "calibration report."

According to standards ISO 9001:2008 7.6 and ANSI/NCSL Z540.3-2006, calibration is a comparison of the device being tested against a traceable reference instrument (calibrator) and documentation of this comparison. Although calibration does not formally include any adjustments, in practice, adjustments are possible and often included in the calibration process.

In the absence of a calibration program, maintenance practices for line, vessel or equipment-mounted devices such as pressure, temperature and level indicators, unfortunately, may occur only when the error in reading becomes large enough to be obvious to the operator or technician. Maintenance personnel routinely make decisions based on these devices. A faulty indication on such a device could lead to the release of energy or other unsafe action. A well-considered calibration program that periodically measures actual loop accuracy can provide confidence in the indications and drive the calibration intervals for these devices.

Instrumentation based on newer technology, e.g., "smart" devices, is more accurate than older technology devices and more stable, requiring less frequent calibration monitoring. A calibration program should also accommodate these device types appropriately, such as calibration check frequency and accuracy of calibration equipment required.

Instrumentation worth purchasing and installing is worth calibrating and maintaining. All instrumentation, including the highest quality devices, will drift over time and provide less accurate measurements. Calibration corrects for that drift. Thus, it is critical that all instruments are calibrated on their appropriate intervals.

Companies striving to maintain a safe working environment while ensuring the reliability of their facilities may use calibration as a means of verifying the functionality and accuracy of their equipment.

Like other aspects of maintenance, there are many things to consider when establishing a company

calibration program. Certainly, this is the case with the calibration of monitoring and control loops in a facility IACS. This document presents a recommended approach to developing, implementing and maintaining a calibration program that is intended to increase accuracy and reliability of an IACS, decrease maintenance costs, and improve quality control. More importantly, this approach is also intended to increase safety of operation as the result of increased accuracy and reliability of the instrumentation.

This approach to calibration has proven successful when companies have adhered to the concepts set forth in these guidelines, enabling those companies to realize the full benefits from a standardized approach to calibration.

The intended audience for this document is any company or industry that utilizes instrumentation in the monitoring and control of a process or facility.

Organization

This recommended practice is organized to provide recommendations on:

- Establishing a calibration program;
- Calibration program activities; and
- Calibration program management.

1 Scope

1.1 General applicability

The recommended practice detailed in this document defines a baseline definition and model of a quality management system that can be utilized to implement and maintain a calibration program for industrial automation and control systems. It is applicable to all IACSs.

1.2 Inclusions and exclusions

1.2.1 Manufacturer specific calibration procedures

This document does not provide or recommend manufacturer-specific calibration procedures for specific instruments as these are established by the instrument manufacturer and are outside the scope of this document.

1.2.2 BPCS and SIS functionality

This document does not include any consideration for how instrumentation and control signals are handled within the BPCS or SIS other than including indication of the signal in loop accuracy calculations.

1.2.3 Control valve and other final control devices calibration

This document does not cover the essential maintenance of the mechanical aspects of these and other mechanical devices.

1.2.4 Regulatory requirements

Regulatory requirements related to loop/instrument accuracies are not included in this recommended practice.

1.2.5 SIS instrument calibration

The calibration of monitoring and control loops that are part of safety instrumented systems is included in the scope of this recommended practice. The documentation and management of these instruments as part of safety instrumented systems is excluded. For more information, see ISA-84.00.01 (IEC 61511 Mod) and all its parts.

1.2.6 Instrument criticality

This document mentions criticality as it applies to a calibration program. This document does not modify any guidelines for establishing criticality provided in ISA-TR91.00.02.

1.2.7 Control loop performance

The performance of final control elements and the tuning of control loops are excluded from the scope of this recommended practice.

1.2.8 Hazardous areas

Instruments can be located in hazardous locations. These instruments are to be installed, operated and maintained in accordance with requirements for those hazardous locations. The precautions for working on these instruments are outside the scope of this document. Refer to other codes and standards addressing electrical equipment in hazardous locations for applicable requirements, such as ANSI/ISA-12.01.01-2013, Definitions and Information Pertain-

ing to Electrical Equipment in Hazardous (Classified) Locations.

2 References

ISA-TR91.00.02-2003, *Criticality Classification Guideline for Instrumentation*

ANSI/ISA-5.1-2009, *Instrumentation Symbols and Identification*

ISA-5.4-1991, *Instrument Loop Diagrams*

ANSI/ISA-12.01.01-2013, *Definitions and Information Pertaining to Electrical Equipment in Hazardous (Classified) Locations*

ISA-84.00.01 Parts 1-3 (IEC 61511 Mod), *Functional Safety: Safety Instrumented Systems for the Process Industry Sector*

NIST Handbook 150 Checklist:2001, *National Voluntary Laboratory Accreditation Program (NVLAP)*

Liptak, Bela G., Editor. *Instrument Engineers' Handbook, Process Measurement and Analysis, Fourth Edition*, International Society of Automation, 2003

Ultimate Calibration, 2nd Edition, Beamex, 2009

Cable, Mike. *Calibration: A Technician's Guide*, International Society of Automation, 2005

ISO 9001:2015, *Quality management* systems, Clause "Control of monitoring and measuring equipment", International Organization for Standardization

ANSI/NCSL Z540.3-2006 (R2013), *Requirements for the Calibration of Measuring and Test Equipment*, NCSL International

ANSI/NCSL RP-1-2010, *Establishment and Adjustment of Calibration Intervals*, NCSL International

JCGM 200:2012, 3rd edition. *International vocabulary of metrology - Basic and general concepts and associated terms* (VIM)

3 Establishing a calibration program

3.1 General

A calibration management program includes defined procedures and tasks for the calibration of all relevant instruments. Ongoing calibration is a fundamental part of instrument maintenance, which in turn is a fundamental part of the plant's/facility's maintenance. As such the management and scheduling of maintenance personnel, and other resources such as test equipment, to perform calibration activities is usually executed via work orders from the plant's/facility's maintenance management system (computerized or otherwise). An overarching reliability or asset management program in turn may guide the plant's/facility's maintenance management system. Consequently, consideration should be given to how the calibration program interacts with other programs and systems in the plant/facility.

Where instrument and systems performance certification is mandated by regulating agencies, federal, state or local, the owners should ensure that technicians involved in the calibration process are familiar with those mandatory requirements. Examples in the USA are EPA, NRC or CEMs permits for emissions and discharge to water bodies.

3.2 Calibration program concepts

Monitoring and control instrumentation currently used in an IACS range from pneumatics to "smart" (microprocessor-based) digital electronics. These devices are as varied as the processes they monitor. Devices with moving parts require regular maintenance. These mechanical devices are much more susceptible to mechanical performance issues (e.g., binding and dragging due to environmental contamination) than are other measurement and control instrumentation. Analog electronic instrumentation is subject to drift of settings and output. Digital instrumentation has multitudes of parameter settings that must be set correctly to achieve desired operation. Devices not operating to their manufacturer's specifications and/or not correctly applied or configured for the specific application can result in operational issues, such as off-spec quality, productivity issues, and safety issues. In addition, there is always the instrument failure. All of this results in a need for the loops that are important to safety, quality and correct operation of the facility to be periodically calibrated.

Understanding and adhering to the following guidelines, explained in the sections that follow, is required to achieve the full benefits of the recommended

approach to a calibration program set forth in this document.

3.3 Calibration program

A calibration program for an IACS formalizes a methodology to periodically verify the performance accuracy of the loops/components in that IACS and, when necessary, make adjustments to those components to bring them within their manufacturer-rated accuracy and/or the loop within its required performance tolerance.

Each user company/facility is encouraged to establish a calibration program specific to its needs. This recommended practice discusses the essential features of a calibration program and provides guidance on how to establish such a program.

This proposed approach to a calibration program for an IACS takes into consideration all known loop measurement errors and establishes loop performance tolerances based on the specific process requirements. Successful implementation of this approach requires management's commitment to make this a living process.

3.4 Device calibration

Device calibration focuses on one particular device within a loop and ensures that this discrete component within the loop has been compared and adjusted, if necessary, to a reference standard. This is typically done before the component or instrument is installed, typically by the manufacturer, and is used as an initial benchmark to ensure accuracy and then is periodically checked to ensure device accuracy. The period, or calibration interval, may be set by the authority having jurisdiction, the plant maintenance program, the manufacturer's recommendation, or by another agreed upon method. When this results in multiple periods for a device, the shortest period should be used.

3.5 Loop calibration

A key concept of this recommended practice is establishing required loop tolerance and evaluating, whenever practical, calibration performance of the entire loop, which includes multiple components. The

importance of this concept is that, instead of only looking at the performance of an individual device (e.g., field instrument), it looks at the performance of all of the components (sensor, transmitter, wiring, input card, etc.) that must work together to measure a process parameter. Also, this concept establishes a tolerance requirement for each loop that is based on process needs rather than simply assuming manufacturer ratings. The accuracy of a measurement containing multiple components (a.k.a. a loop) (as a simple example, a sensor, transmitter, and input card) is unknown unless it is calibrated as a system.

For example, a temperature transmitter could be calibrated as a single device but when installed with the sensor, wiring, and indicator, the loop indication might not be within the desired tolerance due to issues with other components of the loop. The key parameter is whether the entire loop is providing a measurement within the tolerance needed for correct operation of the process. Each component in a loop has a rated accuracy. The inaccuracy or error of all components in the loop results in the total loop inaccuracy greater than that of any one component.

3.6 Competency

Trained personnel are essential to the success of a calibration program. This includes understanding the process, regulatory requirements, calibration tools, calibration procedures, and instrument/systems training required by the manufacturer.

4 Calibration program planning

4.1 General

Components and systems require periodic calibration to confirm that they are operating safely, efficiently, and in compliance with regulations. To ensure such calibrations occur as necessary, companies should have a structured calibration program, a formalized methodology, that applies to all components and systems covered by the program, consisting of standards, procedures and tasks for verifying performance accuracy and adjusting or replacing deficient/defective components/systems as necessary to ensure operation occurs in accordance with manufacturer-rated accuracy parameters and/or required loop performance tolerances.

Critical steps in the process of developing a calibration program include:

a) establishing a loop/instrument tagging system;

b) developing a comprehensive list of loops and instrumentation equipment requiring periodic calibration;

c) establishing tolerance requirements for each loop;

d) establishing a loop criticality system and criticali ty ratings for each of those loops;

e) establishing loop calibration verification intervals (frequencies) based on the assigned criticality and manufacturer recommended interval or user experience;

f) establishing calibration equipment requirements, based on loop tolerance and instrument accuracy requirements;

g) establishing loop/instrument calibration record forms and calibration record-keeping systems;

h) establishing necessary calibration procedures;

i) establishing staff qualifications and training re quirements;

j) performing calibration checks at required intervals and documenting results; and

k) establishing a calibration program verification methodology.

4.2 Loops and components in the calibration program

For a meaningful and efficient calibration program to be conducted, it is essential that complete IACS documentation exists from the original design and construction of the plant/facility and that this documentation has been maintained in a current state. As a minimum, this documentation should consist of: 1.) an instrument index/list with all instrument and control devices identified with loop and component functional tagging (e.g., ANSI/ISA-5.1); 2) loop diagrams, e.g., per ISA-5.4, or other instrumentation wiring interconnect drawings showing all components and wiring, including control panels and instrument junction boxes; and 3) instrument location plans for all tagged devices, control panels and junction boxes. Additionally, piping and instrumentation (or similar) drawings (P&ID's), and electrical area classification drawings would be beneficial.

4.3 Component and loop criticality determination

If it does not already exist, establish a loop criticality classification system for loops in the facility. The criticality of each loop is one of the driving factors for establishing calibration intervals. ISA-TR91.00.02 provides a structured technique for establishing criticality classifications. Classification examples from that document include safety, environmental, and asset protection.

Using the criticality classification system established, the applicable criticality classification for each loop and component in the calibration program should be identified and documented.

4.4 Establishing required loop tolerance

Each loop should be evaluated against and calibrated to a specified tolerance, which is the permissible deviation from the actual value, otherwise referred to as the loop tolerance.

The tolerance for each loop may be established in either of two ways: (1) by establishing the required accuracy of the loop necessary to meet safety, quality, and/or production requirements of the process, or (2) by establishing the theoretical tolerance of the

loop based on the rated accuracies of all of its components. In both methods, the theoretical tolerance of the loop should be calculated to demonstrate whether the loop is capable of meeting the required accuracy (in method 1 or to establish the target tolerance for the loop (in method 2). Also, the rangeability of the specific application must be considered. The wider the rangeability (measurement span) required (to accommodate expected/unexpected load variances), the more inaccurate the measurement is likely to be.

Establishing an acceptable tolerance for each loop:

a) clearly defines the level of acceptable perfor mance for each loop;

b) provides a defined measure to use in the periodic check of loop performance;

c) facilitates tracking of loop performance over time;

d) facilitates focusing calibration efforts to the areas that provide the most benefits or have the greatest needs;

e) provides management with a measure for auditing loop performance and calibration work (staff and equipment performance); and

f) clarifies loop performance expectations for opera tions and maintenance, including regulatory re quirements where applicable.

4.5 Calculating theoretical loop tolerance

Theoretical loop tolerance is calculated by using the Root-Sum-Square (RSS) method, which combines the rated accuracy of each component in the loop. Each of the listed effects on accuracy is squared and all squared terms are added together. The square root of this sum provides a combined uncertainty in either percentage or engineering units of the loop. Section 8 provides examples for calculating loop tolerance by

using the manufacturers' data and the RSS method. Each component may have multiple possible sources of error (e.g., accuracy, temperature effect, stability, etc.). Thus, the equation below should include all possible errors for all loop components.

$$Tolerance = \sqrt{(error\ 1)^2+(error\ 2)^2+(error\ 3)^2+(error\ n)^2}$$

Since it is unlikely that each of these components will experience their maximum error at the exact same time, this calculation provides a "typical" error that might be expected from a combination of devices each with its own error statement. If all of the components were to experience their maximum error at the same moment, this would be expressed by the sum of all of the maximum individual errors.

To perform this calculation correctly, all errors should be expressed relative to the actual loop/component application measurement span and in the same manner (e.g., percent of full scale, percent of reading).

4.6 Calibration confirmation intervals

The calibration confirmation interval for a particular loop or component is a function of (a) criticality of the loop/component; (b) the performance history of the loop/component; (c) the ruggedness/stability of the component(s); and (d) the operating environment. Effective calibration programs base calibration intervals on these factors. The user must determine the applicable verification frequency for each loop/component in the calibration program. Historical performance information and/or instrument asset management diagnostics maintained by the user can be very helpful in this effort.

Maintenance records, possibly analyzed using statistical data techniques, can be useful in determining whether or not to modify calibration confirmation intervals. By analyzing instrument drift over time, calibration costs can be reduced and efficiency improved. If no other data is available, initial frequencies may consider manufacturer's recommendations and then be adjusted as calibration performance data is obtained.

If a high calibration fail rate is observed, before changing the calibration interval, check for correct application and specifications of the device, inappropriate test equipment, unqualified calibration personnel, changes to location environment, or other possible causes.

Shown below is an illustrative example of initial calibration intervals being assigned based on some criticality ranking. The example is not intended to be used directly or to assign intervals to criticality rankings.

Table 4-1 – Example criticality ranking (CR) and initial verification frequencies

Critically Ranking	System	Frequency	Notes
CR #4	Safety instrumentation	12 months	See note 1
CR #4	Boiler trip instrumentation	12 months	
CR #4	Turbine trip instrumentation	12 months	
CR #4	Anti-water induction instrumentation	12 months	
CR #4	Regulatory instrumentation		Per regulatory requirements
CR #4	Fire system instrumentation	12 months	
CR #3	Boiler control instrumentation	Outage	
CR #3	Turbine control instrumentation	Outage	
CR #3	Reliability monitoring system instrumentation	Outage	
CR #3	Ash system Instrumentation	Outage	
CR #3	Reclaim System instrumentation	Outage	
CR #2	Boiler transmitters (non-control)	36 months	or as observed
CR #2	Boiler switches (non-control)	36 months	or as observed
CR #2	Turbine transmitters (non-control)	36 months	or as observed
CR #2	Turbine switches (non-control)	36 months	or as observed
CR #2	Performance transmitters	36 months	
CR #2	Performance thermocouples	36 months	
CR #1	Local gauges		as needed or available
CR #1	Recorders		as needed or available
CR #1	Valve positioners (non-control)		as needed or available
CR #1	Indicators		as needed or available

Note 1 to entry: Intervals for SIS-related instruments follow the testing interval required to meet the SIL for the specific SIF, which may be shorter or longer than 12 months

4.7 Calibration equipment

Equipment used to evaluate a loop's performance against its required tolerance or to calibrate a device should be certified, accurate, corrected for local conditions and have adjustments controlled.

Test equipment accuracy requirements are directly related to required loop tolerances. Establishing unreasonably small loop tolerances will result in requiring more accurate test equipment, which in turn can result in increased maintenance costs.

Equipment includes calibration standards, which are traceable to national or international standards. In cases where a national/international standard is not available or practical, a reproducible standard should be established and maintained via an independent entity (preferred) or in-house.

Equipment should be identified with a unique identification number, part number, and range/accuracy. Equipment should be certified, typically by the manufacturer or a third party, on a regular, fixed period (annually or otherwise as recommended by the manufacturer) to be operating correctly and within all manufacturer's specifications. A sticker should be affixed to the equipment documenting the most recent date of re-certification and when it is due for the next re-certification. The device's calibration should be traceable to a national or other acceptable standard. Equipment documentation should include a history of each certification and a traceability statement or uncertainty budget.

Equipment should be of greater accuracy than the device being calibrated and traceable to a higher standard. There are basically two ways to maintain traceability during calibration – the use of an uncertainty budget (performing uncertainty calculations for each measurement), or using a test uncertainty ratio (TUR) of ≥ 4:1. To maintain traceability, without using uncertainty budgets or calculations, ensure standards used for calibration are at least four times (4:1) more accurate than the test equipment being calibrated. (ANSI/NCSL Z540.3- 2006 states: "Where calibrations provide for verification that measurement quantities are within specified tolerances... Where it is not practical to estimate this probability, the TUR shall be equal to or greater than 4:1."). Refer to Example 6 below for an example calculation of TUR. If multiple calibration equipment components are used to perform the calibration of a loop/component, the aggregate uncertainties of the calibration equipment components should be calculated using the RSS method and that aggregate uncertainty be four times greater than the loop/device tolerance.

NOTE A communicator (e.g., HART, fieldbus) is not usually a traceable calibration standard – check the manufacturer's product documentation for intended use of any measurement capability the communicator may have. A communicator is necessary to configure/trim/diagnose certain devices but a traceable standard is also needed to perform a calibration.

Equipment should be corrected for the effects of local conditions (e.g., ambient temperature, atmospheric pressure).

Equipment should have a means to control access to adjustments affecting performance on devices after they have been confirmed or calibrated. These should be sealed or otherwise safeguarded to prevent unauthorized changes. Seals or safeguards should be designed and implemented such that tampering will be detected. The calibration process procedures should include directions to install seals/safeguards and actions to be taken when seals or safeguards are found damaged, broken, bypassed or missing. These recommendations are critical to making an accurate evaluation of loop/component performance and to making any calibration adjustments to a component. Test equipment of insufficient accuracy may result in incorrect evaluation, unnecessary activities, and even leaving a component performing less accurately.

4.8 Calibration record system

A calibration record system is necessary to provide documentation of when calibration activities have been undertaken on which pieces of equipment, what the results were, and what (if any) corrective action was taken. The system should include forms to be used to record the calibration activities and the method for storage of all calibration records to facilitate future access. This system may be paper- or electronic-based. The calibration service record (CSR)

provides essential information on a particular loop/component. This includes the calibration points with the acceptable loop/component tolerances. Using the CSR allows staff to capture the calibration data, which highlights how much drift has occurred in the loop/component since the last calibration. An example of a CSR is provided in the annex.

Recording of calibration activity includes documenting "As Found" and "As Left" readings. Calibration programs serve the dual purpose of checking loops for conformance to tolerance requirements, and if tolerance is not met, making adjustments to equipment to bring it into tolerance. The term "as found" is used to describe the performance (readings and errors) of a device when it is first tested during the calibration activity. If it is found to be within tolerance, no adjustment is made and the performance is recorded as the "as left". However, if an adjustment is made, the equipment is then tested again. This process is repeated until the performance values meet the tolerance criteria. These adjusted values then become the "as left" value for that calibration interval. When the next calibration interval comes up, the calibration activity again starts with reading and recording the "as found" performance, and the cycle completes as before.

When documenting calibration information (as found, as left), calculate and document the accuracy of the observed indications. Ensure that the calculated accuracies are expressed in the same manner as the required loop/device tolerance (e.g. engineering units, percent of full scale, percent of reading, engineering units) to enable direct comparison. Refer to Clause 8 for an example.

Calibrations may be performed using 5 check points (0, 25, 50, 75, and 100%) or 3 check points (0, 50, and 100%). Calibration should be checked and recorded in both directions (inputs increasing from 0 to 100% and inputs decreasing from 100 to 0%) to observe if the loop/device exhibits any hysteresis.

All data should be recorded on a CSR and stored in a centralized location for easy review and audit.

4.9 Calibration procedures

To promote consistent methodology and results, calibration procedures, or calibration work instructions, should be established for each loop/component. These procedures should detail the method, equipment and criteria to be used to check and perform calibration and should be part of a formal procedures management program. Procedures covering on-line, in-situ, or in service calibration of devices will require specifics regarding the process conditions, with

details about the interaction of the instrument being calibrated/tested and the process, interactions such as alarms, interlocks, control points, or other aspects or impacts related to the online instrument being calibrated/tested. In general, calibration procedures should include the following:

a) description of the loop or component to be calibrated;
b) overview of the tasks to be performed;

c) equipment and personnel requirements; and
d) steps to be followed for the calibration.

Persons performing calibration on in-service loops/components, should meet with the appropriate operating personnel to discuss the work to be performed before work is begun.

The latest version of the applicable calibration procedures should be available and referred to during the process to ensure awareness of any recent changes.

Annex A provides an example of a loop calibration procedure document. It is not intended to be a specific recommendation on the calibration procedure itself, as this will depend on the application, the device manufacturer's recommendations, and owner-specific methodology.

NOTE Some instruments require both sensor and output adjustment. Refer to manufacturer's documentation for full calibration instructions.

4.10 Calibration personnel

To ensure the safety and reliability of the measurement and control system, only competent personnel should be allowed to perform calibrations. Suggested areas of knowledge include:

a) general maintenance skills
- operations and process safety
- electrical safety
- troubleshooting

b) instrument maintenance skills
- instrumentation maintenance and repairs, espe cially with the specific instruments involved in the calibration
- loop checking
- calibration
- calibration record-keeping

c) process philosophy, control philosophy, and conditions of process service
- process philosophy and control philosophy
- process conditions (e.g., service, pressure, tem perature, flow, level)
- alarms, cause and effect matrix

Confirming the general qualifications of the personnel involved in calibration can be achieved through the completion of an internal certificate program or through a recognized independent third party certification program. A subject matter expert should then evaluate an individual's ability to perform the various applicable specific types of calibration. The owner should keep a register of qualified individuals by component type. It is important to understand that someone may be fully qualified to calibrate one type of component and not another. In addition, certain regulatory requirements may establish minimum qualification pre-requisites for personnel performing calibrations. Requirements for periodic training and re-certification to ensure continued competency of personnel should also be established.

4.11 Responsibilities

Preferably, a calibration program definition should be an integral part of the initial design and build capital expenditure phases of the plant/facility's life cycle. Whether the calibration program is being created for the initial facility build or created/rejuvenated during the operation phase of the life cycle, given the number of loops in a typical industrial facility, fully implementing an automation and control system calibration program is a major undertaking. It may well be part of a broader scoped instrument asset management or reliability program. As with any significant program, for it to be successful, company management will need to provide sufficient support to the creation and on-going execution of the program. To ensure consistency, a project team should be created to manage the project of establishing the calibration program. The project will require support from the facility technicians, engineers and, most importantly, senior management.

The management of the plant, facility, or automation system should be responsible for establishing and owning the program and ensuring compliance with the IACS calibration program. This would include establishing a process for auditing compliance with, and periodically updating, the program.
All aspects of the calibration program should be completely documented for an effective calibration program, including, but not limited to:

a) calibration procedures (required method);

b) calibration equipment (required accuracies, re-certification frequency and procedures, personnel training, inventory);

c) personnel training and certification;

d) personnel responsibilities and accountabilities;

e) required loop tolerances and manufacturer-supplied device accuracies;

f) required forms;

g) calibration record-keeping system; and

h) required calibration frequencies.

Loop and component performance verification

5.1 General

Performance verifications should be made using the "loop" calibration method whenever possible. In those cases where this is not possible, loop component accuracies should be verified and used to calculate actual loop accuracy, which is then compared to required loop tolerance.

The verification portion of the calibration procedure should define the steps necessary to check the performance of the loop. This should include a task list providing specific steps necessary to perform the check, including equipment and methodology.

If the calibration verification of a loop/component reveals that the loop/component is not within the required tolerance, a calibration adjustment may be required to one or more loop components according to defined procedures. The calibration adjustment procedure for that component defines the overall steps necessary to calibrate the specific device type. A task list provides the specific steps necessary to calibrate the specific component. If the desired device accuracy cannot be achieved, the component should be repaired or replaced.

Calibration confirmation is not achieved until and unless the fitness of the measuring equipment for the intended use has been demonstrated and documented. Calibration confirmation should include calibration verification, any necessary adjustment or repair, subsequent recalibration, and comparison with the loop tolerance requirements for the intended use.

Software used in the calibration processes and calculations of results should be documented, identified and controlled to ensure suitability for continued use. Calibration software, and any revisions to it, should be tested and/or validated prior to initial use, approved for use, and archived.

Calibration program management

6.1 Control

An effective calibration program should include a means to track calibration activity by loop/component, define required interval, forecast calibrations due, document calibrations, and trend results. Many third-party software applications exist that can help automate a calibration program.

6.2 Assurance

An effective calibration program should be periodically monitored for compliance. This includes verification that loop calibration checks are being performed at the required intervals; all calibration activities are being documented, including all calculations; and calibration equipment being used is maintained and has current certification. Management should ensure that this periodic monitoring of the calibration program is consistently performed and results documented.

6.3 Improvement

Calibration programs should be evaluated and updated on a periodic basis or when significant modifications or projects are completed to ensure the program is evergreen. Audits should not only consider if loops/components have been added or removed, but should also include a review of the criticality rating, process conditions, accuracy capability and tolerance requirements for each loop/component.

Calibration results should be trended and reviewed periodically to determine if performance is acceptable or if a modified frequency of calibration or device technology should be considered in order to ensure desired loop performance is maintained.

7 Examples

7.1 Example 1 – Calculating instrument total error

To illustrate calculation of total error of an instrument, assume a differential pressure transmitter application that has been tested/calibrated at a temperature and pressure different from the application temperature and pressure. Total error includes transmitter error and any zero or span shift caused by these temperature and pressure variations. The following are assumptions for this example:

Transmitter accuracy (E) – +/- 0.2% of actual span (under atmospheric ambient conditions)

Maximum range – 0 - 750 inches H2O (0 - 186.82 kPa)

Span – 0 - 100 inches H2O (0 - 24.9 kPa)

Operating pressure – 1000 PSIG (6,894.78 kPa)

Operating temperature – within a 50 ºF (27.8 ºC) difference of the temperature at which it was calibrated

Temperature zero shift – (Tz) – for temperature variation of 100 ºF (55.5 ºC), assumed to be +/-0.5% of maximum range

Temperature span shift – (Ts) – for temperature variation of 100 ºF (55.5 ºC), assumed to be +/-0.5% of actual reading

Pressure zero shift – (Pz) – for pressure of 2000 PSIG (13,789.5 kPa), assumed to be +/-0.25% of maximum range

Pressure span shift – (Ps) – for pressure of 2000 PSIG (13,789.5 kPa), assumed to be +/-0.5% of actual reading

Calculating each error component

E = +/-0.2%

Tz = 0.5(750 in./100 in.) (50 ºF/100 ºF) = +/-1.875%

= (0.5(186.82 kPa/24.9 kPa) (27.78 ºC/55.5 ºC) = +/-1.875%)

Ts = 0.5(50 ºF/100 ºF) = (0.5(27.78 ºC/55.5 ºC)) = +/-0.25%

Pz = 0.25(1000 PSIG/2000 PSIG) (750 in./100 in.) = 0.9375%

= (0.25(6,894.78 kPa/13,789.5 kPa) (186.82 kPa/24.9 kPa) = 0.9375%)

Ps = 0.5(1000 PSIG/2000 PSIG) = (0.5(6,894.78 kPa/13,789.5 kPa)) = +/-0.25%

Calculate the total error, using RSS method, at an assumed actual differential pressure reading of 100 inches H2O (24.9 kPa)

$$Total\ Error = \sqrt{(E)^2+(Tz)^2+(Ts)^2+(Pz)^2+(Ps)^2}$$

$$Total\ Error = \sqrt{(0.2)^2+(1.1875)^2+(0.25)^2+(0.9375)^2+(0.25)^2} = 1.57\%$$

This is the total error associated with the transmitter for this example application. It is not the total loop measurement error, which would include the errors from all other loop components. It is not the maximum possible error associated with the transmitter as that would be the sum of all error components, assuming they all occurred simultaneously.

NOTE This example is taken from the Instrument Engineer's Handbook.

7.2 Example 2 – Calculating theoretical loop tolerance

To illustrate calculation of theoretical loop tolerance, assume a static pressure transmitter application that has been tested/calibrated at a temperature and pressure different from the application temperature and pressure. Total error includes transmitter error and any zero or span shift caused by these temperature and pressure variations. The following are assumptions for this example:

Maximum range – 0 - 3500 PSI (0 - 24,132 kPa)

Span – 0 - 2500 PSI (0 - 17,237 kPa)

Operating temperature – within a 50 ºF (27.8 ºC) difference of the temperature at which it was calibrated

Transmitter accuracy (E): ± 0.075% of full scale

Transmitter stability over 5 years (S): ± 0.125%

Temperature zero shift (Tz) for temperature variation of 100 ºF (55.5 ºC), assumed to be +/-0.036% of maximum range

Temperature span shift (Ts) for temperature variation of 100 ºF (55.5 ºC), assumed to be +/-0.036% of actual reading

Control system analog input card accuracy (C) ± 0.100%

Calculating each error component

E = ± 0.075%

S = ± 0.125%

Tz = 0.036%(3500 PSI/2500 PSI) (50 ºF /100 ºF) = +/-0.025%

= (0.036%(24,132 kPa/17,237 kPa) (27.78ºC/55.5ºC) = +/- 0.025%)

Ts = 0.036%(50 ºF /100 ºF) = +/-0.018%

= 0.036%(27.78 ºC/55.5 ºC) = +/-0.018%

C = 0.100%

$$\textit{Total Error} = \sqrt{(E)^2+(S)^2+(T_z)^2+(T_s)^2+(C)^2}$$

$$\textit{Total Error} = \sqrt{(.075)^2+(0.125)^2+(0.025)^2+(0.018)^2+(0.100)^2}$$

Total Error = ±0.18% of full scale or ±4.5 PSI (31 kPa)

Calculating the theoretical tolerance using the RSS method, the loop is within calibration if the full-scale reading is between 2495.5 and 2504.5 PSI (17,206 and 17,268 kPa)

7.3 Example 3 – Pressure measurement theoretical loop tolerance – pressure switch

To illustrate calculation of theoretical loop tolerance, assume a static pressure switch application that has been tested/calibrated at a temperature and pressure different from the current conditions. Total error includes switch error and zero/span errors due to temperature/pressure variations. The following are assumptions for this example:

Range and span: 0 - 3000 PSI (0 - 20684 kPa)

Operating temperature – within a 50 ºF (27.8 ºC) difference of the temperature at which it was calibrated

Switch accuracy (E): ± 1.0% of full scale

Switch hysteresis (H): ± 0.2%

Switch repeatability (R): ± 0.07%

Transmitter stability (S): ± 0.5% full range per year non-cumulative

Temperature zero shift (Tz) for temperature variation of 50 ºF (27.8 ºC), assumed to be +/-0.04% of maximum range

Temperature span shift (Ts) for temperature variation of 50 ºF (27.8 ºC), assumed to be +/-0.04% of actual reading

Calculating each error component

E: ± 1.0%

H: ± 0.2%

R: ± 0.07%

S: ± 0.5%

Tz = 0.04%(3000 PSI/3000 PSI) (50 ºF/100 ºF) = +/-0.02%

= (0.04%(17236.89 kPa/17236.89 kPa) (27.8 ºC/55.5 ºC) = +/-0.020%)

Ts = (0.04% (50 ºF/100 ºF)
= (0.04% (27.78 ºC/55.5 ºC)) = +/-0.020%

$$Total\ Error = \sqrt{(E)^2+(H)^2+(R)^2+(S)^2+(T_z)^2+(T_s)^2}$$

$$Total\ Error = \sqrt{(1.0)^2+(0.2)^2+(0.070)^2+(0.05)^2+(0.020)^2+(0.020)^2}$$

Total Error = ±1.14% of full scale or ±34.2 PSI (235.8 kPa)

7.4 Example 4 – Pressure measurement theoretical tolerance – pressure gauge

To illustrate calculation of total error of a static pressure gauge application that has been tested/calibrated at a temperature and pressure different from the current conditions. Total error includes gauge error and zero/span errors due to temperature variations. The following are assumptions for this example:

Range and span: 0 - 3000 PSI (0 - 20684 kPa)

Operating temperature: 86 ºF (30.0 ºC)

Gauge accuracy (E): ± 2.0%

Temperature span shift (T_S): ± 0.4% of span per 18 ºF (10 ºC) of temperature change from a reference temperature of 68 ºF (20.0 ºC)

Calculating each error component

E = ± 2.0%

Ts = (0.04%*(86 ºF-68 ºF)/18=±0.04%
= (0.04%*(30 ºC-20 ºC)/10 ºC) = ± 0.04%

$$Total\ Error = \sqrt{(E)^2+(T_s)^2}$$

$$Total\ Error = \sqrt{(2.0)^2+(0.04)^2}$$

Total Error = ±2.0% of full scale or ±60 PSI (413.7 kPa)

These examples highlight the large differences in the uncertainties from system to system and from device to device. Far less accuracy is required to calibrate a switch (combined uncertainties ±1.14%) than is required to calibrate loops on the inputs to a control system (combined uncertainties ±0.18%). It is important to note that there are actually more identifiable factors to uncertainty in the systems. However, none of these factors is typically significant enough to make a recognizable increase in the uncertainty of the loop.

7.5 Example 5 – Calculating calibration accuracy

When documenting readings during calibration, accuracy of the readings should be calculated and documented. The calculated accuracy should be expressed in the same manner as the stated loop tolerance or device accuracy (e.g., % of full scale, % of reading).

For this example, assume a pressure measurement loop with a required tolerance of +/-1% of reading and a measurement span of 0 - 20 PSIG.

Test Input (% span)	Reading (PSIG)	Accuracy (% of reading)
0	0	
25	4.95	(0.05/5) = 1%
50	9.92	(0.08/10) = 0.8%
75	14.93	(0.07/15) = 0.47%
100	19.9	(0.1/20) = 0.5%

This loop would meet its required tolerance of +/- 1% of reading.

7.6 Example 6 – Calculating calibration TUR

For this example, assume a device is being calibrated at 10 EU (engineering units). The required tolerance is +/- 1% of reading. The reference standard being used in the calibration has an uncertainty $\frac{(USL-LSL)}{(2u)}$ of 0.5 EU.

TUR =

USL = Upper specification Limit = 10 + (1% x 10) = 11 EU

LSL= Lower Specification Limit = 10 – (1% x 10) = 9 EU

u=uncertainty = $\frac{11-9}{2*0.5} = \frac{2}{1}$ = 0.5 EU

TUR

The TUR must be calculated using identical parameters and units for both terms. Accuracy statements expressed in percentages or other ratios must be converted to absolute values of the basic measurement units. The uncertainty of a calibration standard is not necessarily the same as its accuracy specification. The uncertainty in the equation must include the uncertainties of all test equipment involved in the measurement process used for the calibration.

In this example, the TUR is 2:1, which would not achieve the recommended 4:1 ratio for traceability.

Annex A – Example documentation

A.1 On-line testing procedure of differential pressure transmitter

Unit 2 Point C2 104, PDT-211

Description

The loop consists of the differential pressure transmitter (HART), operator interface computer (OIC), recorder XR-211A-3, and the data acquisition system (DAS). This loop is indication only and uses the 4-20 mA signal for the process variable (rather than the HART digital PV).

Preparation

1) Inform shift supervisor and Unit 2 control operator of the work to be performed.
2) Determine what, if any, affect this work will have on the other systems.
3) Review calibration procedures.
4) Conduct a "job briefing" with all personnel assigned to the work before the job begins.
5) When all tasks are complete, validate that the system has been correctly returned to service.

General

The tasks shall be performed by a fully trained I&C technician working with either an apprentice I&C technician, a calibration technician, or control operator. Each step is initiated by the I&C technician. The calibration technician, apprentice I&C technician, or CO will record data and track the procedure.

The following items are required to perform the work:

1) Reference standard, which must have a current certificate traceable to NIST or equivalent national standard
    a) Pressure source (0-100 PSIG) (0 – 689.5 kPa)
    b) Milliamp measurement (0-25 mA)
2) Other equipment
    a) HART communicator
3) Calibration record sheet
4) Task list for calibrating the static pressure transmitter

Procedure:

1. ___ Proceed with the differential pressure calibration task list.
2. ___ Notify the shift supervisor and or control operator when the calibration process is complete and the device is returned to service.
3. ___ Sign the completed calibration service record and file

Comments: _____
_____
_____
_____

Worker Signatures: _____ _____
Date: _____

A.2 Differential pressure (DP) calibration task list (HART transmitter)

1) Obtain the calibration record sheet for the differential pressure transmitter being calibrated.

2) Locate and verify the identity of the transmitter.

3) Close primary high side isolation valve (process isolation). Close high side isolation valve (transmitter isolation).

4) Open equalizing valve.

5) Close low side isolation valve (transmitter isolation). Close primary low side isolation valve (process isolation).

6) Vent high and low sides of the transmitter.

7) Purge transmitter with instrument air to remove water.

8) Connect HART communicator.

9) Connect pressure source (reference standard).

10) Record the operator interface computer reading in "as found" on the CSR at 0%, 50%, and 100% input range, both increasing and decreasing.

11) Evaluate whether the readings are within the required loop/device tolerance.

12) If the readings are within the required tolerance, record those readings again under "as left" and proceed to step 15.

13) Adjust the device as necessary using the HART communicator and the device manufacturer's instructions to bring the OIC readings with tolerance.

NOTE The method described here is for a loop calibration. If a device calibration is found to be necessary that adjusts the device 4-20 mA output, the reference milliamp measurement must be used to measure device output, the HART communicator is not a reference standard.

14) Repeat steps 10 and 11 until the readings are within the required tolerance, then record those readings under "as adjusted" and "as left".

15) Remove the HART communicator and milliamp measurement (if used).

16) Remove pressure source (reference standard).

17) Verify that the equalizing valve is open.

18) Open primary low isolation valve (process isolation). Open the low side isolation valve (transmitter isolation).

19) Bleed air from the transmitter and close vents.

20) Verify that there are no leaks.

21) Close equalizing valve.

22) Open high side isolation valve (transmitter isolation). Open the primary high side isolation valve (process isolation).

23) Confirm that the operator interface computer reading reflects current process conditions.

A.3 Calibration service record example form

beamex
www.beamex.com

CALIBRATION CERTIFICATE

Certificate Number: BX-11163-CAL

Printed: 31.05.2013 15:02:51
Printed by: Ned Espy

TAG ID: TT-175

TAG INFORMATION

Tag Name:	Dryer 175 Temp
Work Order Number:	A123456
Location:	2nd Floor, Grid 12 - next to control panel
Plant Structure:	Butte Power Plant /Unit 1 /1N (Boiler 1)/1NG (Primary and secondary air)/1NG10 (Primary air)/

ASSET

Asset ID:	TT-175		
Serial Number:	171684		
Manufacturer Model:	Rosemount 248		
Rangeability:	T/C, mV, RTD/Ohm Inputs		
Operating Temp.:	-40 to 185 degF	Humidity:	0 to 99% RH

FUNCTION

Function:	Temperature Transmitter (tt)		
Transfer Function:	Linear		
Range (I/O):	0 to 175 °F	4 to 20 mA	

CALIBRATION EVENT

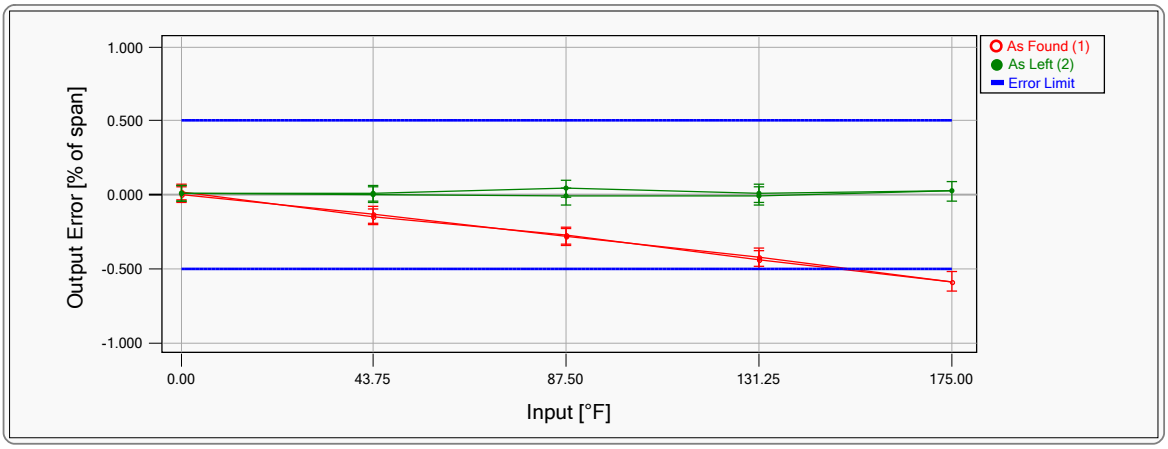
Calibration Date:	5/31/2013 3:00:08 PM		
Next Cal. Date:	11/30/2013		
Environment Temp.:	72 °F	Humidity:	40 %

PROCEDURE

Due Date:	11/29/2013	Interval:	6 months
Reject if Error >:	0.5 % of span	Adjust To <:	% of span
Classification:	Safety		
Calibration Strategy:	OSHA1910		

CALIBRATORS

Input Calibrator:	MC6 s/n: 602057	Due Date: 3/5/2014
Input Module:	TC-R-OUT/ R1 s/n: 61735	Due Date: 3/7/2014
Output Calibrator:	MC6 s/n: 602057	Due Date: 3/5/2014
Output Module:	IN s/n: 21773	Due Date: 3/6/2014



1. As Found — FAILED

Max Error: -0.5888 % of span

Nominal Input [°F]	Actual Input [°F]	Nominal Output [mA]	Actual Output [mA]	Found Error [% of span]
0.00	0.000	4.0	3.9995	-0.0031
43.75	43.750	8.000	7.9782	-0.1362
87.50	87.500	12.00	11.9545	-0.2844
131.25	131.250	16.000	15.9327	-0.4206
175.00	175.000	20.000	19.9058	-0.5888
131.25	131.250	16.000	15.9299	-0.4381
87.50	87.500	12.00	11.9557	-0.2769
43.75	43.750	8.000	7.9761	-0.1494
0.00	0.000	4.0	4.0023	0.0144

2. As Left — PASSED

Max Error: 0.0400 % of span

Nominal Input [°F]	Actual Input [°F]	Nominal Output [mA]	Actual Output [mA]	Found Error [% of span]
0.00	0.000	4.0	4.0016	0.0100
43.75	43.750	8.000	8.0000	0.0000
87.50	87.500	12.00	11.9985	-0.0094
131.25	131.250	16.000	15.9983	-0.0106
175.00	175.000	20.000	20.0041	0.0256
131.25	131.250	16.000	16.0011	0.0069
87.50	87.500	12.00	12.0064	0.0400
43.75	43.750	8.000	8.0019	0.0119
0.00	0.000	4.0	4.0014	0.0088

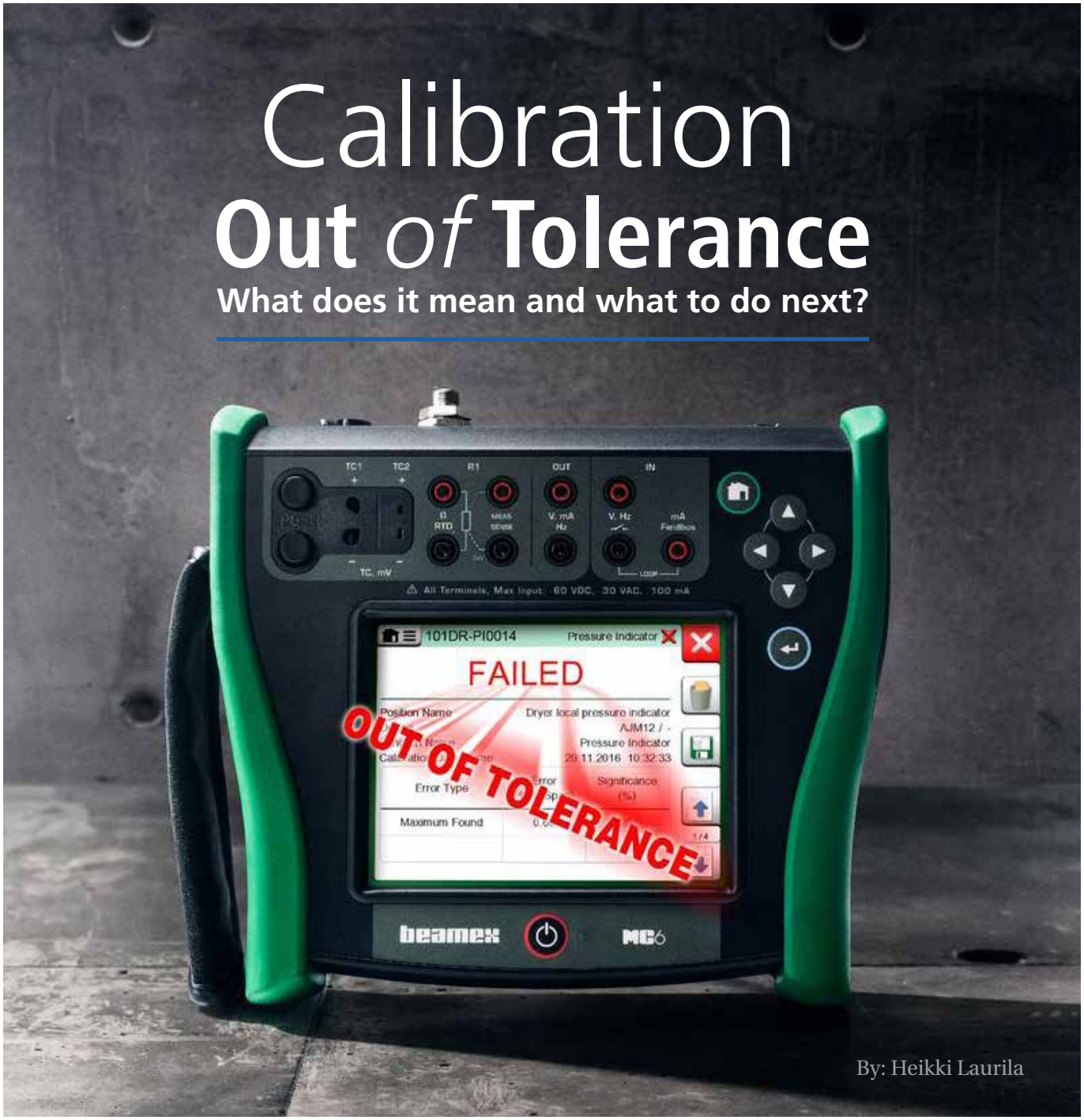
Calibration Note: For more information, call Beamex at 800.888.9892 (www.beamex.com)

Calibrated by: Peter Parker
5/31/2013 3:00:08 PM

Approved: Clark Kent, Calibration Supervisor
5/31/2013 3:02:42 PM

Page: 1/ 1

Calibration
Out *of* Tolerance
What does it mean and what to do next?



By: Heikki Laurila

Sometimes we hear of a calibration being ***Out of Tolerance (OoT).*** What does this mean in practice? How do we know if it really happened, what the impact is and what we should do next? These are the main topics discussed in this article. The focus of this article is mainly for the world of process industry, but most of the principles are valid everywhere you run into an OoT situation. For a process plant, it can be an actual process instrument that is out of tolerance, or it can also be a calibration standard, or any other measuring device.

What does "Out of Tolerance" (OoT) mean?

Let's start by discussing what out of tolerance means. In summary, it means that during a calibration some calibration point(s) failed to meet the required tolerance level. This causes the result of the calibration to be out of tolerance, or also referred to as a failed calibration. This definition sounds pretty simple, but when we start to look deeper, it turns out to be more complicated. So let's continue…

What does out of tolerance mean? In summary, it means that during a calibration some calibration point(s) failed to meet the required tolerance level.

What is the tolerance level used?

For a calibration, we normally specify a tolerance level (maximum permitted error) that a given test result is compared against. If we say that the instrument failed to meet the required tolerance level, it becomes an out of tolerance case and specific follow-up procedures may be initiated.

Whenever a tolerance limit is not met, the next logical question should be; ***what is the tolerance level that was used?*** Or maybe the question should be that ***what tolerance level should be used?***

For a process instrument, it is very typical that the tolerance level used is the manufacturer's accuracy specification of the installed process instrument (as specified by the manufacturer). It means that if you buy 100 similar transmitters and install them into 100 different locations in your plant, all of these locations will have the same tolerance level. However, in most cases, many of these ***installation locations have different criticality and therefore they should also have different tolerance levels.*** A critical process location needs to have a smaller tolerance level and many times it is also calibrated more often. Likewise, in a non-critical location, it is a waste of resources, time and money to calibrate as often and to use the same tolerance level. Personnel who have the best knowledge of the actual requirements of the process in question, should be involved when deciding tolerance levels for given locations.

If it is a matter for your calibrator or your reference standards, then it is more common to use the manufacturer's specification as the tolerance level (at least to begin with). Comparison to the manufacturer's specifications during re-calibration or certification will indicate how reliable the equipment is for performing field calibration. Calibrator tolerances should also consider local needs and be adjusted accordingly over time.

How was it found to be out of tolerance?

Assuming tolerance levels are set correctly, when someone says that during a calibration an instrument failed to meet its tolerance level, the next logical question is: ***are you sure?*** And to continue, ***how sure are you?***

This leads to the question; which calibrator was used to make the calibration, and what is the total uncertainty of the calibration? If the situation is where the calibration was outsourced to an external calibration laboratory, what are the calibration uncertainties of that laboratory?

For every measurement and calibration, the total uncertainty of the calibration is critical. Whenever you make the ***compliance statement*** that something passes or fails a calibration, or that it is inside or outside of the tolerance, ***you must consider the uncertainty*** of the calibration, in order to be able make a proper decision.

How critical is it?

What is the next step when we have found an instrument to be out of tolerance and our tolerance levels are valid and the calibration was done with appropriate uncertainty? This means that we must admit that this really in an out of tolerance case, and action needs to be taken. Before hitting the "Panic" button, it is important to see ***how critical*** the case is.

Before hitting the "Panic" button, it is important to see how critical the case is.

For a process instrument, it is good practice to have the calibration tolerance a bit tighter than the actual process requirement. By doing this, even if the instrument fails slightly against the tolerance in calibration, it does not have a dramatic effect on the actual process. Generally, if the results are just slightly out of tolerance, this may not be critical for the measurements that have been done with it. An analysis needs to be done in order to see if a failure is critical or not.

During a criticality analysis, you should analyze what

is the impact of this out of tolerance case. If it is a process instrument, what effect does this amount of error in the process measurement have to the actual process and for process control? Also, ***what effect does this have to the actual end product being produced?***

In case of a calibration standard or calibrator, what effect does the error in the calibrator have to all the various measurements and calibrations that have been done with that calibrator?

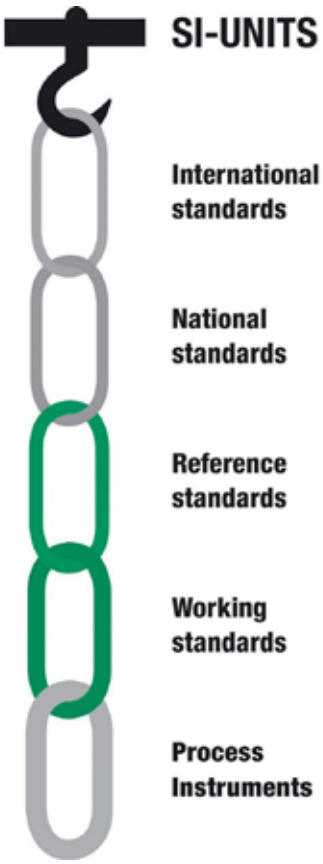
For an extremely critical process or safety measurement, redundancy may be added with two or more simultaneous measurement instruments being installed. In this case, a failure in one instrument's capability to measure correctly does not cause a critical failure.

For some measurements, the process instrument can be checked before each measurement is made with it. For example, a weighing scale can be checked with reference weight(s) before making measurements, or on a regular daily basis. A calibrator can also be cross-checked against another similar level reference instrument periodically (between the regular recalibrations). The calibration interval can also be adjusted according to the criticality of the measurements made with a given instrument. Depending on the application, ***if the cost of an out of tolerance calibration is very high, that will also affect the calibration interval and strategy.***

Where in the traceability chain did an OoT occur?

The criticality and the consequences of a failed calibration depend on ***where in the traceability chain*** it occurred.

A general rule for any calibration is that it needs to be traceable to a higher level standard. The traceability chain goes to a national standard or the equivalent, and there are normally several steps in between. A process transmitter is normally not sent to a national calibration center for calibration. Instead, the process instrument is typically calibrated with a process calibrator that is calibrated with a higher level standard, either in-house or in an outside calibration laboratory. The highest level reference standards/calibrators in the plant should be calibrated by an accredited calibration laboratory, to assure proper traceability coming into the plant.



The higher in the traceability chain an out of tolerance situation occurs, the larger effect it has on all the instruments below that instrument in the chain.

The accredited calibration laboratories are responsible for ensuring that their standards have been calibrated properly, and are traceable to national standards or the equivalent.

The higher in the traceability chain an out of tolerance situation occurs, the larger effect it has on all the instruments below that instrument in the chain. Imagine a situation where a National Laboratory finds out that one of its reference standards is out of tolerance, and that reference has been used to calibrate customers' reference standards/calibrators for a long period. This means that all instruments of all customers are affected! Of course that is a worst case scenario, and not very likely, but it gives you some perspective of the traceability chain.

Wherever in the traceability chain the OoT happened, all instruments below that are affected.

But back to the process plant…typically there are limited levels of instruments in the traceability chain within a plant. The vast majority of calibrated instruments are the actual process instruments, which

are at the bottom of the traceability chain. There are typically process calibrators used to calibrate the process instruments, as most of the process instruments are not sent out for calibration. At some plants there can be also higher level reference standards that are used in-house to calibrate the process calibrators. So, there can be a few levels and the impact is different in each level. Whatever the highest level instrument is inside the plant's traceability chain, it needs to be calibrated regularly by a traceable, preferably accredited, calibration laboratory, in order to get the traceability into the plant.

It is good to remember that ***wherever in the traceability chain the OoT happened, all instruments below that are affected.***

When did it happen?

When an OoT is noticed during a calibration, note this is not the moment when the instrument started to measure incorrectly or went out of tolerance. But when did it happen? It is important to determine when it happened because any measurements done after that moment are suspect. In case of a critical process measurement that failed, any products produced after that moment are affected and may need to be recalled, in the worst case.

It is not an easy task to determine the moment when the instrument went out of tolerance. By checking the previous calibration data, and assuming the instrument was left in acceptable condition, you can start from there. However, if there are no records between the previous good calibration and the new fail calibration, you should take a look at everything done in between. You can study the measurement results and any relevant data in between the OoT and the previous good calibration to see if there is anything that would indicate when the instrument drifted out of specification. For example, there could be a sudden rise in reported issues in the process, or in the case of a calibrator - a time period where more failed calibrations began to appear. You may also analyze the history of that instrument to see if there is an indication of any typical drift for that instrument, and possibly interpolate the data to find the most likely moment when it went out of tolerance.

It can be difficult to determine the actual moment when an instrument failed to meet its tolerance. It may be the case there is no option but to assume that all calibrations done after the previous successful calibration are affected and suspect to be failed.

Impact analysis - what are the consequences?

Once we know that the out of tolerance really happened and we have analyzed how much it was and have an idea when it had occurred, the next step is to evaluate the impact. You need to find out ***where this failed instrument has been used*** and what measurements are suspect.

In the case of a process transmitter, it is obvious where it has been used, but in case of portable measuring equipment, or a portable calibrator, it is different situation. One powerful option for a calibration management program is a ***"reverse traceability"*** report. This kind of report should list all the calibrations where a specific instrument has been used, over a certain time period. This report is most helpful when you need to analyze, for example, where a portable calibrator has been used. If you do not have an automated reverse traceability report and need to manually go through calibration reports to see where that certain calibrator was used, it may take many man hours to complete. However you do it, it needs to be done.

In the case of a ***process instrument*** being out of tolerance, you need to have your process specialist analyze what the impact of this failure is for the actual process and to your end product. In best case scenario, if the effect to the process measurement was so small, it will not cause any significant damage. However, in the worst case, if the analysis tells you that the effects to the process, and to the products being produced, are so big that the products produced do not meet their specifications, then costs can be huge.

You need to find out where this failed instrument has been used and what measurements are suspect.

In many processes, the quality of the end product cannot be simply tested in the final product, but the process conditions must be correct during the manufacturing process. If this example involves food/medicine or the heat treatment process of critical aerospace/automobile parts, then you are obligated to inform your clients/customers, or even withdraw products form market. Product withdrawal is a dramatic consequence; it will get you into the news, it will be very expensive, and it will have a negative effect to your company brand, reputation and stock value.

In the case of a ***process calibrator*** that fails to meet its tolerance, you will need to evaluate how much the failure had effect to all the measurements made with in since its last known good calibration. Many times, the calibrator is significantly more accurate than the process instruments calibrated by it, so there is some safety margin. In the best case scenario, even if the calibrator failed recalibration, the failure can be so small that it does not have significant effect to the calibrations that have been done with it. But in the worst case, if all the calibration work that has been done with that calibrator are suspect, then you need to analyze the effect for each process measurement that has been calibrated. As previously mentioned, this can be a really big task as you need to do the analysis for all the process measurements being affected.

Quality assurance considerations

You may have heard your quality professionals talking about ***CaPa***, being an abbreviation of ***Corrective Actions and Preventive Actions***. This is something that is stipulated by most quality standards, such as the very common ISO/IEC 9001 quality standard as well as ISO/IEC 17025 used in accredited calibration laboratories. Corrective actions are obviously the actions you take to correct the situation, while preventive actions are all the actions you take to prevent the same situation from happening again in the future. The effectiveness of corrective and preventive actions is important to review. Also, all other similar instances should be considered to see if there is any possibility for similar occurrences elsewhere. Quality standards also require that these processes are documented and that responsibilities are specified.

A ***root cause analysis*** is typically required by quality standards to find out what caused an OoT to occur. A ***risk analysis***, or generally, ***risk-based thinking***, is something required by the modern quality system standards. ***Continuous improvement*** is also a common quality requirement to ensure that you continuously improve your quality system and learn from any mistakes, so that problems do not happen again.

Many companies, especially in regulated industries, are using some form of a ***"deviation management software system"*** where all OoT calibration cases are recorded in order to control and document the process of handling these cases.

SUMMARY

Summarizing the key points in this paper, if you get an out of tolerance calibration, you need to do the following:

- Verify what tolerance level was used and that it is a correct level.
- Verify the uncertainty used in making any decisions that a measurement is out of tolerance and that the uncertainty is appropriate.
- How critical is this out of tolerance observation?
- Where in the traceability chain did this occur?
- When did it occur?
- Make an impact analysis to find out what the consequences are.
- Make quality assurance considerations.

RELATED ARTICLE

How often should instruments be calibrated?
https://hubs.ly/H09rXwL0

Calibration Uncertainty

For Non-mathematicians

By: Heikki Laurila

This paper discusses the basics of uncertainty in measurement and calibration. It is not made for mathematicians or metrology experts, but rather for those of you who are planning and making practical measurements and calibrations in industrial applications.

Being aware of the uncertainty related to the measurement is a very fundamental concept. ***You should not really make any measurements unless you are aware of the related uncertainty.*** Generally speaking, it seems that the awareness and interest of uncertainty is growing, which is great.

The uncertainty of measurements can come from various sources, such as the reference measurement device used for making the measurement, from environmental conditions, from the operator making the measurements, and from many other sources.

Being aware of the uncertainty related to the measurement is a very fundamental concept. You should not really make any measurements unless you are aware of the related uncertainty.

Classic "piece of string" example

Let's start with an example to illustrate the measurement uncertainty in practice; the example is to give the same piece of a string to three persons (one at a time) and ask them to measure the length of that string. With no additional instructions given. They can all use their own tools and methods to measure it.

More than likely, as a result, you will get three somewhat different answers, such as:

- The first person says it is about 60 cm. He used a 10 cm plastic ruler, measured the string once and came to this conclusion.
- The second person says it is 70 cm. He used a three meter measuring tape and checked the results a couple of times to make sure he was right.
- The third person says it is 67.5 cm, with an uncertainty of ±0.5 cm. He used an accurate measuring tape and measured the string multiple times to get an average and standard deviation. Also, he tested how much the string stretches when it is pulled and noticed that this had a small effect on the result.

Even this simplified example shows that there are many things that affect the result of a measurement; the measurement tools that were used, the method/process that was used and the way the person did the job.
So, the question you should be asking yourself is:
When calibration work is performed at your plant,

which of these three examples sound the most familiar to you?
What kind of "rulers" are being used at your site and what are the measuring methods/processes?
If you just measure something once without knowing the related uncertainty, the result is not worth much.

Very short terminology course

Let's take a very brief consider the essential terms related to this subject.

So, what is the ***uncertainty*** of measurement? We can simply say that it is the "doubt" of our measurement, meaning that it tells us how good our measurement is. Every measurement we make has some "doubt", and we should know how much this "doubt" is to decide if the measurement is good enough for the purpose.

It is good to remember that ***error is not the same as uncertainty.*** When we compare our device to be calibrated against the reference standard, the error is the difference between these two measurements. But the error does not have any meaning unless we know the uncertainty of the measurement.

So, I would like to say that:

If you don't know the uncertainty of the measurement, don't make the measurement at all!

Too often we have seen, for example, that when a person is making an important temperature measurement in his process with, say, ±1.0 °C acceptance limit, and finds a maximum error of 0.5 °C, he is happy and says it "passes" and accepts the result. Although, after analyzing the calibration process, he could find that the total uncertainty of his measurement process is ±2.0 °C. Therefore, the way the calibration was done was not good enough for this application.

But ***as long as he did not know/care about the uncertainty, he could claim that it was a good "passing" calibration,*** although in reality, it failed.

From making a single measurement to knowing your standard deviation

So, what should you do to start the journey towards being aware of all the related uncertainties?

The first simple, yet good, practice is that when you normally make a measurement/calibration once, try instead to repeat the same measurement several times. Most likely you will discover small differences in the measurements between the repeats. But which measurement is the correct one?

Without diving too deep into statistics, we can say that it is not enough to measure only once. If you repeat the same measurement several times, you can find the average and the standard deviation of the measurement. So you will learn how much the results can differ between repeats. This means that you can find out what is the normal difference between measurements.

It is suggested to make a measurement multiple times, even up to ten times, for it to be statistically enough reliable to calculate the standard deviation. These kind of uncertainty components, that you get by calculating the standard deviation, are called the

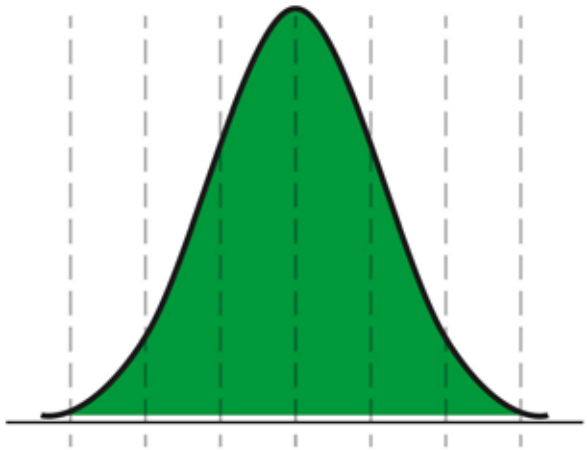


Diagram: Standard deviation

A-type uncertainty.

You may say: ***What???*** - Always repeating the same measurement ten times is just not possible in practice!

Luckily you don't always need to make ten repeats, but you should still experiment with your measurement process by sometimes making several repeats of the same measurement. This will tell you what the

typical deviation of that whole measurement process is and you can use this knowledge in the future as an uncertainty component related to that measurement, even if you just make the measurement once during your normal calibration.

Imagine that you would perform a temperature measurement/calibration multiple times and you would learn that there could be a ±0.2 °C difference between the repeats. Next time you would make the same measurement, even if you would then make it just once, you would be aware that there is this ±0.2 °C possible difference, so you could take it into account and don't let the measurement go too close to the acceptance limit.

So if you keep calibrating similar kinds of instruments over and over again, it is often enough to make the measurement just once and use the typical experimental standard deviation. Of course you need to do your homework and make the measurements and the calculations to find out the typical standard deviation of that instrument type and that calibration process.

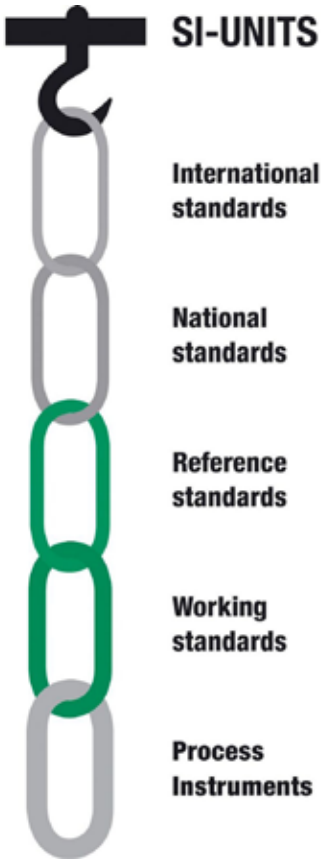
In summary, ***you should always be aware of the standard deviation of your calibration process – it is one part of the total uncertainty.***

Your reference standard (calibrator) and its traceability

Often, ***one of the biggest sources of uncertainty comes from the reference standard*** (or calibrator) that you are using in your measurements/calibrations. Naturally to start with, ***you should select a suitable reference standard*** for each measurement. It is also important to remember that it is not enough to use the manufacturer's accuracy specification for the reference standard and keep using that as the uncertainty of the reference standards for years. Instead ***you must have your reference standards calibrated regularly*** in a calibration laboratory that has ***sufficient capabilities (uncertainty small enough)*** to calibrate the standard and to make it traceable. Pay attention to the total uncertainty of the calibration that the laboratory documented for your reference standard. Also, you should ***follow the stability of your reference standards*** between its regular calibrations. After some time, you will learn the true uncertainty of your reference standard and you can use that information as the uncertainty of your reference standard in your calibrations.

Other uncertainty sources

In the previous section I suggested that you repeat the measurement several times. But how about if you ask a ***few of your colleagues to repeat that same measurement?*** Do you all get the exact same results? Often there are some differences between the different persons making the measurement. So, does it mean that the person making the measurement also have an effect to uncertainty? – yes, it does. This is especially the case if the instructions are not at an appropriate level.



What if you make the same test and this time you ***use different kind of reference standards (calibrators) to make the measurement?*** Again, most likely you will find differences. And if the reference standards have different levels of accuracy (uncertainty) you may even see relatively big differences. Often the reference standard (or calibrator) used to make the measurement can be ***one of the biggest sources of uncertainty!*** Different environmental conditions may add additional uncertainty in certain calibrations.

If you need to read some form of analog display (analog gauge, temperature meter), you have limited ***readability***, i.e. you can only read it to certain accuracy and there is a possibility to read it incorrectly (wrong viewing angle) which ads uncertainty. In case of digital readouts, the ***resolution*** (number of decimals) is always limited, which causes uncertainty (you can only read to the last decimal).

There are different technical aspects in the calibra-

tion process, applications and quantities that create additional uncertainties. For example in temperature calibration, it is imperative to wait long enough for the temperature to stabilize and to ensure proper probe immersion into temperature block; in flow calibration you need to ensure a stabile flow; in pressure calibration you must avoid any leaks and have a stabile pressure, etc. Generally, any fluctuations or changes in the variable to be measured will cause additional uncertainty.

There are also some ***random variables*** that throw in some additional spices to the soup.

Also, you can use the ***experimental standard deviation*** mentioned earlier as one uncertainty component.

So we can shortly ***summarize*** these additional sources of uncertainty:

- Device under test
- Reference standard (calibrator)
- Method/process for making the measurements/calibrations
- Environmental conditions
- The person(s) making the measurements
- Additional uncertainty components depending on the quantity being measured/calibrated

All of these above listed uncertainty components are referred
as the Type B uncertainty.

Adding uncertainties together => combined uncertainty

The type A (standard deviation) is something you can calculate, but often some of the various type B uncertainties needed to be estimated. Once standard deviation is calculated and the various Type B uncertainties are estimated, it is time to add them together. Before that you need to make sure that all uncertainties are in the same quantity/unit. Also, the uncertainties should be having the same ***coverage factor/confidence level.***

When you add together uncertainty components that are independent from each other, don't just sum them all together, that would make a too pessimistic (worst-case) result. Instead, add the components together using ***the root sum of the squares*** method. That means, square each component, then sum them together and finally take a square root of the total sum. Although I said no formulas, maybe it is anyhow easier to understand this with a relatively simple formula:

Total uncertainty =

$$\sqrt{u_{(1)}^2 + u_{(2)}^2 + \ldots + u_{(n)}^2}$$

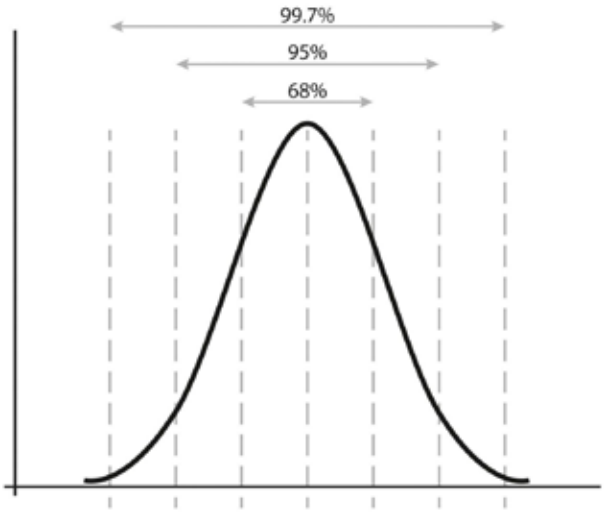
Where each "u" is one independent uncertainty component.

Coverage factor/confidence level

When uncertainty is determined, it is typically multiplied with a ***coverage factor (k).*** Most often the combined uncertainty is multiplied with 2 (k=2 or 2 sigma). This multiplication is done in order to have greater confidence level of the result. When the coverage factor of 2 is used, it equals a ***confidence level*** of 95%. This is done because we are dealing with statistical data and according ***normal (Gaussian) distribution*** 95% of the results are within the 2 sigma range. So in practice, using the 2 sigma, 95% of the results will be within the given uncertainty budget. Different sigma values give the following confidence levels:

- 1 sigma (k=1) = 68% confidence level (68% of the results are within)
- 2 sigma (k=2) = 95% confidence level
- 3 sigma (k=3) = 99.7% confidence level

Normal (Gaussian) distribution



When you add different uncertainty components together, make sure they are all the same 1 sigma values before adding them.

Expanded uncertainty

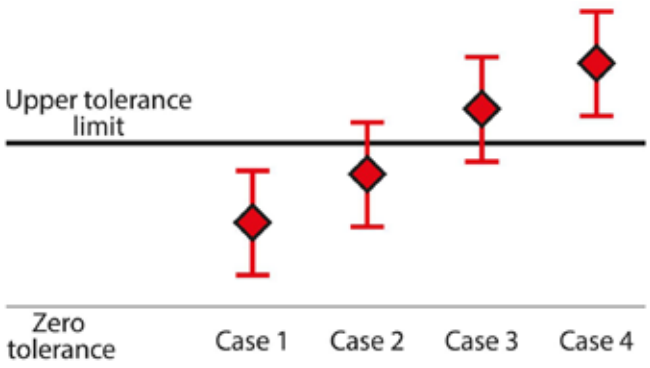
Before the combined uncertainty component is published, you need to multiply the result with the selected sigma value in order to get the required confidence level. After you have done the multiplication, what you get is called ***expanded uncertainty,*** i.e. uncertainty with certain confidence level included.

How to express uncertainty in results or calibration certificate

In your calibration results, you should express the uncertainty as ± value and also mention the coverage factor/confidence level. For example, you can say that the temperature is: 20.5°C
with uncertainty ±0.1 °C (k=2).

Compliance statement – pass or fail

Most often the calibration of an instrument includes an acceptance criteria, i.e. there are limits within which the result is considered being ***passed*** and outside of which it is considered being ***failed***. There are different interpretations if/how the uncertainty should be taken into account when deciding for Pass/Fail. Let's use some examples to study different cases. In the below picture, the diamond shape illustrates the measurement result and the line above and below indicates the total uncertainty for that measurement.



We can interpret these different above cases as following:

- **Case 1**: This is pretty clearly within the tolerance limits, even when uncertainty is taken into account. So we can state this as a good "Pass" result.
- **Case 4**: This is also pretty clear case. The result is outside of the tolerance limits, even when uncertainty is taken into account. So we can state this being a bad or "Fail" result.
- **Case 2** and **Case 3**: These cases are a bit more difficult to judge. Sure it seems that in case 2 the result is within the tolerance while in case 3 it is outside, especially if you don't care about the uncertainty. But taking the uncertainty into account, we can't really say this with confidence.

There are regulations (for example; ILAC G8:1996 - Guidelines on Assessment and Reporting of Compliance with Specification; EURACHEM / CITAC Guide: Use of uncertainty information in compliance assessment, First Edition 2007) for how to state the compliance of calibration. These guides suggest stating a result as passed only when the error added with uncertainty is less than the acceptance limit. Also, they suggest to state failed only when the error added (or subtracted) with the uncertainty is bigger than the acceptance limit. When the result is closer to the acceptance limit than half of the uncertainty, it is suggested to be called an "undefined" situation, i.e. you should not state pass or fail.
We have seen many people interpreting the uncertainty and pass/fail decision in many different ways over the years. In practice, the uncertainty is most often not taken into account in the pass/fail decision, but it is anyway very important to be aware of the uncertainty, when making the decision.

Uncertainty examples

In the graphics below, there are some examples of what different uncertainties can mean in practice. The cases 1 and 2 have the same measurement result, so without uncertainty we would consider these being the same level measurements. But when the uncertainty is taken into account, we can see that case 1

is really terrible because the uncertainty is simply too large to be used for this measurement with the given tolerance limits.
Looking at case 3 and 4 it seems that the case 3 is better, but with uncertainty we can see that it is not good enough for a pass statement, while the case 4 is.

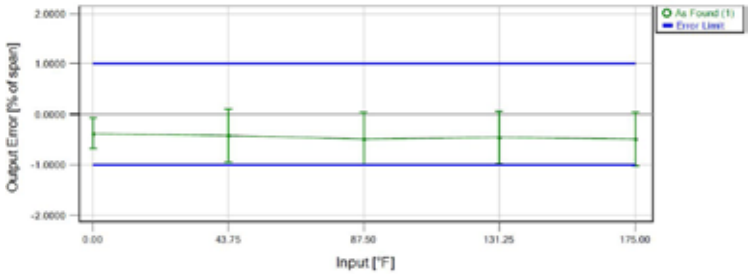
Again, I want to point out that ***we need to know the uncertainty before we can judge a measurement result.*** Without the uncertainty calculation, the above cases 1 and 2 look similar, although with uncertainty taken into account they are very different.

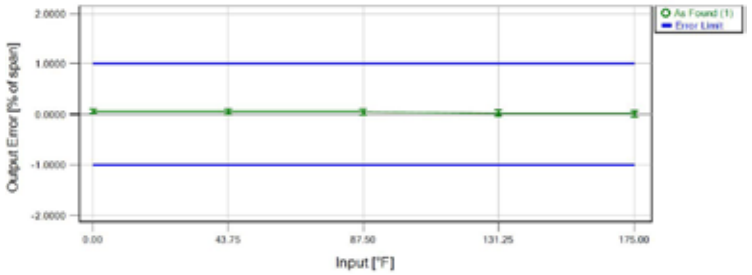
A real-life example

Below is a real-life example where the same RTD temperature transmitter has been calibrated using two different calibrators. This graphics were produced using Beamex CMX calibration management software. You can easily see that in the first case, the results is very good and also the green vertical uncertainty line is very short indicating a very small uncertainty. In the second case you can see that the result is a little bit worse, but the uncertainty of that calibrator is much worse.

Well, needless to say, that the first case is done with a Beamex calibrator… ;-)

Anyhow, when you see the uncertainty graphically it is very easy to notice the significance of it.





TUR / TAR ratio vs. uncertainty calculation

The ***TUR (test uncertainty ratio),*** or ***TAR (test accuracy ratio),*** is often mentioned in various publications. In short, this means that if you want to calibrate a 1% instrument and you want to have 4:1 ratio, your test equipment should be 4 times more accurate, i.e. having 0.25% accuracy, or better. Some publications suggest that having a TUR/TAR ratio large enough, there is no need to worry about uncertainty estimation/calculation. The quite commonly used ratio is 4:1. Some guides/publications do also have recommendations for the ratio.

Most often the ratio is used as in the above example, i.e. just to compare the specifications of the DUT (device under test) and the manufacturer's specifications of the reference standard. ***But in that scenario you only consider the reference standard (test equipment, calibrator) specifications and you neglect all other related uncertainties.*** While this may be "good enough" for some, calibrations, this system does not take some of the biggest uncertainty sources into account. So it is highly recommended to make the uncertainty evaluation/calculation of the whole calibration process.

We also get asked quite regularly: "How many times more accurate should the calibrator be, compared to the device to be calibrated?". While some suggestions could be given, there isn't really a correct answer to that question. Instead you should be aware of the total uncertainty of your calibrations. And of course, it should reflect to ***your needs!***

SOME USEFUL RELATED RESOURCES

- EA-4/02 - Evaluation of the Uncertainty of Measurement in Calibration
- ILAC G8:1996 - Guidelines on Assessment and Reporting of Compliance with Specification
- EURACHEM / CITAC Guide: Use of uncertainty information in compliance assessment, First Edition 2007
- ISO/IEC 17025:2005 - General requirements for the competence of testing and calibration laboratories
- ISO 9001:2015 - Quality management systems -- Requirements
- ISO 10012:2003 - Measurement management systems-- Requirements for measurement processes and measuring equipment
- JCGM 101:2008 - Evaluation of measurement data Guide to the expression of uncertainty in measurement

RELATED WEBINAR

Calibration uncertainty and why technicians need to understand it

https://hubs.ly/H09rYqg0

SUMMARY

I hope this paper helped to give some practical understanding of the uncertainty subject.

To very shortly summarize the key take-outs of some of the main topics:

- Be sure to distinguish "error" and "uncertainty"
- Experiment by making multiple repeats of measurements to gain knowledge of the typical deviation
- Use appropriate reference standards (calibrators) and make sure they have a valid traceability to national standards and that the uncertainty of the calibration is known and suitable for your applications
- Consider if the effect of the environmental conditions have a significant effect to the uncertainty of your measurements
- Be aware of the readability and display resolution of any indicating devices
- Study the specific important factors of the quantities you are calibrating
- Familiarize yourself with the "root sum of the squares" method to add independent uncertainties together
- Be aware of the coverage factor / confidence level / expanded uncertainty, of the uncertainty components
- Instead, or in addition to the TUR/TAR ratio, strive to be more aware of all the related uncertainties
- Pay attention to the total uncertainty of the calibration process before making pass/fail decisions

If you have any comments or questions, and I hope you do, we are very happy to hear from you!

Contact us, www.beamex.com or marketing@beamex.com

Calibration Intervals

By: Mike Cable

Probably the #1 question asked at calibration seminars is "How do I determine the initial calibration intervals?" The answer to this question is difficult at first for someone new to developing a calibration program. It ends up being pretty simple. Initially we try to use a variety of resources which include:

- Manufacturer recommendation
- National Conference of Standards Laboratories Recommended Practice RP-1
- Past experience
- Intervals of similar existing instruments

In reality, it is a combination of all the above, but mostly past experience. As an example, in my experience, electronic transmitters have a calibration interval of 6 months and analog gauges have an interval of a year. Many manufacturers' specifications contain a 6-month stability specification. This stability specification, in effect, only guarantees the accuracy specification for 6 months. Also, electronic transmitters are typically installed in applications that are "more important" to the process. Even though these instruments are more reliable than analog gauges and fail calibration less often, we check the calibration on a more frequent basis. This means we set our calibration intervals based on how much risk we are willing to take. If we wanted an almost 100% assurance that our instruments were within calibration tolerance, we'd have to check the calibration almost every day. Obviously, that would be impracticable. So we assume some risk that every once in a while a calibration is not going to pass. Of course, our managers and quality department don't want to hear that, but it happens and we need to educate other disciplines that it does happen.

Don't be alarmed if you calibrate more or less often than described above. It simply means you're willing to take more or less risk based on the process and quality standards at your facility or you have more history to base your calibration intervals on. Of course, not all instruments fit into the same category. Some instruments, particularly analytical instrumentation, are calibrated more frequently, even to the point that the user performs a calibration check prior to each use. On the other hand, some instruments may have an interval of two years or more.

Calibration intervals may be adjusted over time. Once several calibrations have been performed, the calibration history of the device may be used to adjust the calibration interval. If the as-found calibration data of a particular instrument does not meet the calibration tolerance, the calibration interval may be shortened. If several instruments with a particular manufacturer/model number are always well within the calibration tolerance, the interval is increased.

Criteria for Instrument Selection in Relation to the **Measurement Requirements**

1 Introduction

The organization, in congruence with what is defined, documented, and regulated, must meet:

- The quality objectives for the product
- The contractual requirements of the customer
- The regulatory requirements of the market

It must identify and define which variables or characteristics of the product (process or service) should be considered critical. For example, a variable, characteristic, or measure can be considered critical when:

- The consequences of nonconformity of the measured characteristic are serious and costly (e.g., when it concerns the areas of security, health, and the environment)
- The likelihood of nonconformity is not negligible, because the capacity of the process is not adequate or it has excessive tolerance or insufficient stability
- The likelihood of the onset of such nonconformity is not large enough to be immediately detected and eliminated, if not before delivery to the cus tomer and or use
- The relationship between the amplitude of the tolerance allowed on the product (process or service) and the measuring equipment uncertain ty is too small (e.g., < 3)
- The characteristic measured in a stage of produc tion is mandatory, in that it could compromise its application characteristics (e.g., for a manufac tured mechanical device)
- The characteristic measured in the testing phase is “determining,” it could impair its metrological characteristics (e.g., for a measuring instrument)

Once the organization defines variables, characteristics, and critical measures, it should design the

measurement processes suitable for the control of the product, process, or service, to prevent any nonconformity, in accordance with the requirements prescribed in 7.2 of ISO 10012.

Therefore, it must specify, document, and identify the relative measurement process, at least the following elements:

- The type of product
- The measurement method
- The measuring equipment
- The environmental conditions of measurement
- The ability and qualifications of the operating personnel

In addition, for each measurement process, it must identify and quantify the following characteristics described in point 7.2.2 of ISO 10012:

- Measuring range
- Measurement uncertainty
- Maximum Permissible Error
- Stability, repeatability, and reproducibility
- Any other specific feature of interest

Finally, remember that each individual process must be validated before use and should be checked regularly and continuously during operation to prevent nonconformity over time.

2 Measurement Equipment Selection

The equipment for measuring relative to the designed measurement processes should be first chosen, then calibrated, and then confirmed before being inserted in the measurement process, according to the requirements prescribed in point 7.1 of ISO 10012.

The initial selection must be made according to the metrological characteristics required for the above measurement process, described in the introduction, while the initial calibration can be done directly from the supplier, externally by a qualified laboratory, or even internally at the company's laboratory, but it must always be traceable to the International System (SI). In any case, the measuring equipment must be specified and documented for at least the following elements:

- Manufacturer
- Type and description
- Series or serial number
- Measuring range
- Measuring resolution
- Measurement accuracy
- Measurement uncertainty
- Functional operating conditions
- Environmental operating conditions
- Stability or possible eventual drift
- Sensitivity to any influential quantities

Further, before being inserted into the measurement process, it must be submitted to the calibration process and metrological confirmation provided for in point 7.1 of ISO 10012.

3 Reference Equipment Selection

Calibration of the measurement apparatus (also called instrument) may be made externally or internally within the organization with reference equipment (also called standard) having a measurement uncertainty possibly at least three times lower than the presumed uncertainty of the instrument to be calibrated.

The relationship between the measurement uncertainty between the instrument to be calibrated and the reference standard (also called test uncertainty ratio or TUR) should also be possibly greater than 3, but 3 could be sufficient given the treatment of

uncertainties. In fact, since the treatment of squared uncertainties, the single contribution due to the standard is approximately 1/10 compared to the contribution of any instrument errors, and therefore, it increases the result of the instrument measurement uncertainty < 5% (see point 10).

On the other hand, more ratios between the measurement uncertainties of the instrument and the standard certainly improve the resulting uncertainty. They surely also increase the purchase and maintenance costs of the reference standard, and of its calibration, especially if this is carried out externally to the organization.

Therefore, see the recommended uncertainty ratios of table 9-1, except in the following situations:

- Cases where there is a technical normative or regulation that specifies different minimum requirements
- Cases where it is not possible to observe the adequacy of the minimum acceptable ratio of 3, as it works with measuring instruments with uncertainty slightly lower than the reference standards (this, of course, will increase the result ing uncertainty)

Table 9-1. Adequacy of the Ratio of Instrument Uncertainty to be Calibrated and Standard

$\frac{\text{Intrument uncertainty}}{\text{Standard uncertainty}}$	Adequacy
< 3	INSUFFICIENT
3	ACCEPTABLE
4 – 9	GOOD
10	EXCELLENT
> 10	EXCESSIVE

Table 9-1 may also be the reference for determining the adequacy of the relationship between the tolerance band of the product (process or service) and the measurement uncertainty (U) of the instrument used for the relative measurement (point 9.4).

Example of Choice of Measuring Instrument in Compliance with Product Requirements

As an example, a typical exemplification of overexposed methods and criteria is illustrated in figure 9-1, concerning the selection, calibration, and metrological confirmation of measuring instruments, used in a typical production process.

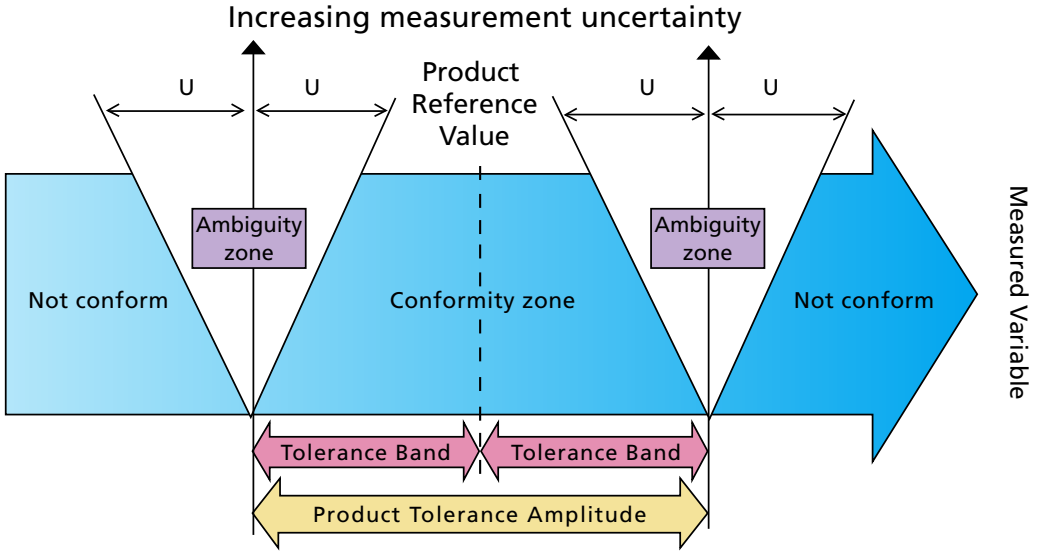


Figure 9-1. Example of Typical Control of a Product (Process or Service)

Consider as an example the one provided in Annex A of ISO 10012:
For a critical operation in a process reactor, it is required that the pressure remains between 200 and 250 kPa. That is then considered a critical variable to be controlled by means of a relative measurement process.

The design of the measurement process that satisfies this critical requirement of the customer can be developed in the following phases:

1. Set a process measuring range more widely between 150 and 300 kPa.
2. Establish a Maximum Permissible Error of the manometer equal to 2 kPa.
3. Choose a suitable manometer accuracy class of 0.5% with a range of 0–400 kPa.
4. Calibrate the manometer with a reference standard with uncertainty of 0.3 kPa.
5. Metrologically confirm the manometer prior to use in the measurement process.

Obviously, the metrological confirmation of the manometer is "passed" if the maximum error found in the calibration is less than or equal to the Maximum Permissible Error of 2 kPa!

This previous example can be schematized in the following way in relation to the critical requirements illustrated in figure 9-1:

Input elements:

- Product Reference Value (PRV) @ 225 kPa
- Product Tolerance Amplitude (PTA) 200 – 250 kPa
- Product Tolerance Band (PTB) ± 25 kPa
- Customer Metrological Requirements (CMR) Err. ≤ 2 kPa
- Measuring Equipment Metrological Characteristics (MEMC) Err. ≤ 2 kPa
- Reference Equipment Metrological Characteristics (REMC) Unc. ≤ 0.3 kPa

Output element:

• Metrological confirmation passed if: MEMC ≤ CMR
Some considerations for the example:

If one compares the specific ratio of the Product Tolerance Band in respect to the Maximum Permissible Error, or PTB/ CMR, and the specific ratio of the instrument Maximum Permissible Error with respect to the reference Maximum Permissible Uncertainty, or MEMC/REMC, with typical ratios presented in table 9-1, one can get the conclusions highlighted in the last column of the following prospectus:

Relations between the input elements:

	Typical	**Annotation**
PTB / CMR = 25 / 2 = 12.5	3 – 10	Excessive
MEMC / REMC = 2 / 0.3 = 6.6	3 – 10	Normal

Obviously, relations between the input elements considered excessive over 10, may still be considered practicable if they do not involve unreasonable additional costs for purchase and management of the measurement. This is because they improve the product and control of the measuring process, and thus minimize the eventual zones of ambiguity corresponding to the measurements of the amplitude limits of the product tolerance (see figure 9-1).

Calibrating *Wireless*HART Transmitters

By: Heikki Laurila

WirelessHART transmitters are becoming more popular. What are they and how do they differ from wired HART transmitters? Why do the WirelessHART transmitters need to be calibrated and how is the calibration done?

A very brief history of HART

The HART (Highway Addressable Remote Transducer) protocol was developed in the mid-1980s by Rosemount Inc. for use with a range of smart measuring instruments. Originally proprietary, the protocol was soon introduced for free use, and in 1990 the HART User Group was formed. In 1993, the registered trademark and all rights in the protocol were transferred to the HART Communication Foundation (HCF). The protocol remains open and free for all to use without royalties (Source: HCF). HART is a digital communication protocol that enables communication with a field device. The communication allows you to read and write settings, read measurement results, receive diagnostic data, etc.

Wired HART signal

The wired HART Protocol uses Frequency Shift Keyed (FSK) digital communication signal superimposed on top of the 4-20mA standard analog signal. The wired HART transmitter is compatible with analog control systems.

HART is a digital communication protocol that enables communication with a field device.

*Wireless*HART

WirelessHART was approved and ratified by the HCF Board of Directors, and introduced to the market in September 2007, becoming the first officially released industrial wireless communication standard. The WirelessHART network uses IEEE 802.15.4 compatible radios operating in the 2.4GHz radio band. Each device in the mesh network can serve as a router for messages from other devices. The WirelessHART transmitter does not have an analog mA signal. It only has the digital signal which is available wirelessly, or through a screw terminal.
Since the transmitter is wireless, power cannot be fed via cables; instead, the transmitter needs a battery for power. The battery life and communication speed are inversely proportional. Sometimes wireless transmitters can be programmed not to send a wireless signal very often which lengthens the lifespan of the batteries. The communication speed can also be increased if necessary. It is possible to use Wire-

lessHART even on a control circuit. In practice, the WirelessHART transmitters are usually used in monitoring applications, which tend to change slowly, as well as in applications that are difficult to wire.
Any existing wired HART transmitter can also be made wireless by adding the wireless adapter available from many instrument manufacturers. If the control system is analog, reading only the mA signal, an additional WirelessHART host system can be built to process all of the additional information available in the HART devices. This can include information that is not available via the analog control system, for example, advanced diagnostics and predictive maintenance.

HART status and the future

Over 30 million HART devices are installed and in service worldwide. The wired HART technology is the most widely used field communication protocol for intelligent process instrumentation. The HART share equals nearly half of the installed base of intelligent transmitters. Various studies estimate growth for HART in the future as well. The new WirelessHART standard seems to be a new booster for the HART protocol. Data from studies predicts exponential growth for WirelessHart over the next 10 years.

What is meant by "calibration"

According to international standards, calibration is a comparison of the device being tested against a traceable reference instrument (calibrator) and documentation of this comparison. Although calibration does not formally include any adjustments, in practice, adjustments are possible and often included in the calibration process.

What is meant by "configuration"

Configuration of a HART transmitter means changing the transmitter settings and parameters. The configuration is typically done with a HART communicator or with configuration software. It is important to remember that although a communicator can be used for configuration, it cannot be used for metrological calibration. Configuring parameters of a HART transmitter with a communicator is not metrological calibration and it does not assure accuracy. For a real metrological calibration, a traceable reference standard (calibrator) is always needed.

How to calibrate a wired HART transmitter

It is good to remember that a HART transmitter has two different outputs that can be used and calibrated: the analog mA output and the digital HART output. In most cases, customers still use the analog output.
To calibrate the analog output, generate or measure the transmitter input and at the same time measure the transmitter output. A dual function calibrator able to handle transmitter input and output at the same time is needed, or alternatively two separate single-function calibrators; for example, if someone wants to generate a pressure input and measure it accurately with a calibrator and at the same time measure the analog mA output with an mA meter.
The calibration process changes slightly if you want to calibrate the digital HART output. Obviously, it is still needed to generate/measure the transmitter input the same way as for an analog transmitter, using a calibrator. To see what the transmitter digital HART output is, some kind of HART communicator with the ability to show the digital HART signal is needed. A HART transmitter can have several digital variables depending on the transmitter type. In the case of analog or digital output, you would progress through the range of the transmitter at a few points and record the input and output signals to document the calibration.

How to calibrate a WirelessHART transmitter

Firstly, it is good to remember that, although the WirelessHART transmitter has a different output than the wired HART transmitter, the WirelessHART transmitter also needs to be calibrated. As the calibration verifies the transmitter accuracy, i.e. the relationship between the physical input and transmitter output, the need for calibration does not change, whether wireless or wired, digital or analog.

The input of a WirelessHART transmitter needs to be generated (or measured) the same way as the analog or wired HART transmitter, using a reference standard or a calibrator. The output of the transmitter needs to be read at the same time. A WirelessHART transmitter does not have any analog output; it only has a digital output. The digital output can be read in two different ways.

One way is to read the output signal wirelessly, but the wireless signal can be very slow. Depending on the transmitter configuration, it may be transmitting its output only once per minute. In any case, the wireless signal is not really suitable for calibration. For example, in the case of a pressure transmitter calibration, there may be small leaks in the pressure connections or hoses, causing the input to change rather frequently. If the output is read very seldom, there could be a significant uncertainty and error between the saved calibration input and output data. Also, if there is any need to trim (adjust) the transmitter, or make any other configurations, these cannot be done wirelessly.

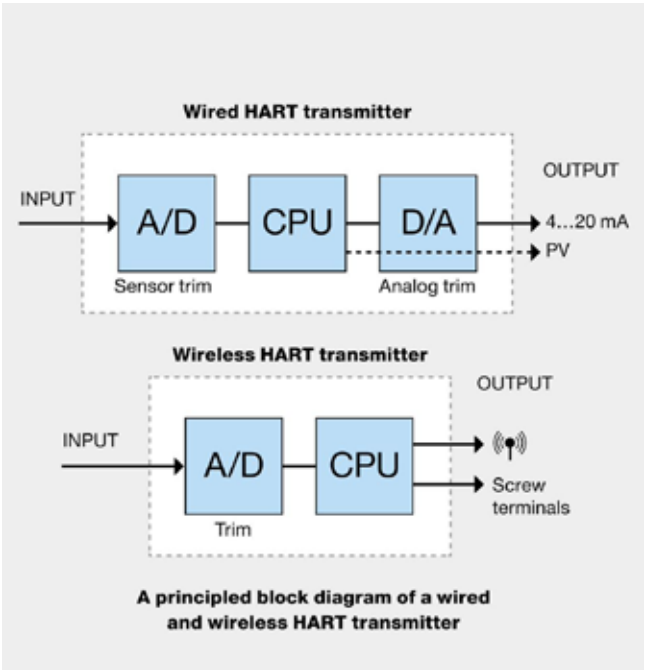
All of the WirelessHART transmitters also have screw terminals allowing a wired connection with the transmitter.

All of the WirelessHART transmitters also have screw terminals allowing a wired connection with the transmitter. While being connected via the screw terminals, the digital output can be read quickly enough for calibration purposes and any configuration or methods, such as trimming methods, are accessible. Therefore, the WirelessHART transmitter should be calibrated with a wired connection to the transmitter's screw terminals.

The input can be generated or measured with a reference calibrator. The output needs to be read with a HART communicator that is able to read the transmitter via the screw terminals. Since the WirelessHART transmitters are made according to the HART7 standard protocol, a communicator able to support the HART7 standard is needed. If there is a separate calibrator for the input and communicator for the output, the readings will need to be manually written down and the calibration documented. However, if there is a calibrator and communicator built into one device, the input and output can be handled simultaneously with the same device. If the device also has a documenting feature, the calibration can be automatically documented without paper.

If a wired HART transmitter needs to be trimmed, the sensor section (A/D conversion), as well as the analog (D/A conversion) section, will also need to be trimmed. In the case of the WirelessHART transmitter, there is no analog section, so it is enough to trim the sensor section.

Wired and *wireless*HART transmitter



A principled block diagram of a wired and wireless HART transmitter

Why calibrate

A modern transmitter is advertised as being smart and very accurate. Sometimes people may say that there is no need for calibration at all because the transmitters are so "smart." Why should smart trans-

mitters be calibrated then?

First of all, changing of the output protocol of a transmitter does not change the fundamental need for calibration.

There are numerous reasons to calibrate instruments initially and periodically. The main reasons are:

- Even the best instruments do drift with time, especially when used in demanding processing conditions.
- Regulatory requirements, such as quality systems, safety systems, environmental systems, standards, etc.
- Economic reasons: any measurement has direct economic effects.
- Safety reasons: employee safety as well as custom er/patient safety.
- To achieve high and consistent product quality and to optimize processes.
- Environmental reasons.

The Beamex MC6 field calibrator and communicator

The new Beamex MC6 is a device that combines a field communicator and an extremely accurate multifunctional process calibrator.

With the Beamex MC6, the smart transmitter's input can be generated/ measured at the same time the digital output is read. Thus, they can be done simultaneously and the results can be automatically stored into the MC6 memory for later viewing or uploading to calibration software.

For configuration of the smart transmitters, the MC6 includes a field communicator for HART, WirelessHART, FOUNDATION Fieldbus H1 and Profibus PA protocols. All required electronics are built-in, including power supply and required impedances for the protocols.

The Beamex MC6 can therefore be used both as a communicator for configuration and as a calibrator to calibrate smart instruments with the supported protocols. While a normal HART communicator can be used to configure and read the HART digital output, it alone cannot be used to calibrate or trim transmitters. You will need an additional calibrator for that purpose, which leads to a situation where you need two separate devices, which lack the automatic calibration procedure and documentation. Therefore, a device such as the Beamex MC6, is superior for calibration of wired or wireless HART transmitters.

Example

■Let's take an example of calibrating an Emerson 648 WirelessHART temperature transmitter. The transmitter is configured for RTD measurement with sensor type Pt100 (Alpha385). Disconnect the RTD sensor and connect the MC6 to simulate the RTD sensor. Connect the MC6's HART terminal to the transmitter's screw terminals and configure the MC6 to read the Primary Variable (PV) of the transmitter, which is the digital output. The range to be calibrated is 0 °C to 100 °C (32 °F to 212 °F). Configure the MC6 to progress the input signal from 0 to 100 °C (32 °F to 212 °F) in steps of 25%, stepping up and down. Then configure the MC6 to wait 10 seconds in each step to allow the transmitter to stabilize. Of course, the transmitters damping should be taken into account when deciding the calibration delay. In completing these steps, we have programmed the maximum error tolerance to 0.5% of the full scale.

When the connections are complete, calibration can begin. The calibration will go through the required input steps fully automatically, stopping for the delay, and then going on to the next step. Once the calibration is completed, a dialog will appear stating whether the calibration was successful or not (Pass/Fail). Next, save the calibration into the MC6's memory. Later on, upload the calibration results to calibration management software to be saved in the database and print a calibration certificate if necessary.

If the As-Found calibration failed, or you want to trim the transmitter, you can use MC6 HART communication. While trimming, it is possible to simultaneously simulate the required input with the MC6, so no other device is needed. Once the calibration is completed, run another automatic calibration procedure to perform an As-Left calibration.

RELATED VIDEO

How to calibrate HART pressure transmitters

https://hubs.ly/H09rYYv0

Configuring and **Calibrating** Smart Instruments

By: Heikki Laurila

So called "smart" instruments are ever more popular in the process industry. The vast majority of delivered instruments today are smart instruments. These new smart instruments bring new challenges to the calibration and configuration processes. But what are these smart instruments and what is the best way to configure and calibrate them?
Beamex has recently introduced a new revolutionary tool, the Beamex MC6 –Advanced Field Communicator and Calibrator, that will help to overcome these challenges.

What is a "Smart" transmitter?

A process transmitter is a device that senses a physical parameter (pressure, temperature, etc.) and generates an output signal proportional to the measured input. The term "smart" is more of a marketing term than a technical definition. There is no standardized technical definition for what smart really means in practice.
Generally, in order for a transmitter to be called smart, it will utilize a microprocessor and should also have a digital communication protocol that can be used for reading the transmitter's measurement values and for configuring various settings in the transmitter. A microprocessor-based smart transmitter has a memory that can perform calculations, produce diagnostics, etc. Furthermore, a modern smart transmitter typically outperforms an older type of conventional transmitter regarding measurement accuracy and stability.

In any case, for the engineers who need to configure and calibrate the transmitter, the digital communication protocol is the biggest difference compared to conventional transmitters. Engineers can no longer simply measure the output analog signal, but they need to have the possibility to communicate with the transmitter and read the digital signal. That brings a whole new challenge - how can the digital output be read?
Thinking of the opposite of a smart transmitter, i.e. a non-smart transmitter, would be a transmitter with a purely analog (or even pneumatic) output signal.

Smart transmitter protocols

There are various digital protocols that exist among transmitters considered smart. Some are proprietary protocols of a certain manufacturer, but these seem to be fading out in popularity and favor is being given to protocols based on Open Standards because of the interoperability that they enable.

Most of the protocols are based on open standards. The most common transmitter protocol today is the HART (Highway Addressable Remote Transducer) protocol. A HART transmitter contains both a conventional analog mA signal and a digital signal superimposed on top of the analog signal. Since it also has the analog signal, it is compatible with conventional installations. Recently the HART protocol seems to be getting more boosts from the newest WirelessHART protocol.

The fieldbuses, such as FOUNDATION Fieldbus and Profibus, contain only a digital output, no analog signal. FOUNDATION Fieldbus and Profibus are gaining a larger foothold on the process transmitter markets.

This article will discuss "smart" transmitters, including HART, WirelessHART, FOUNDATION Fieldbus and Profibus PA protocols.

Configuration

One important feature of a smart transmitter is that it can be configured via the digital protocol. Configuration of a smart transmitter refers to the setting of the transmitter parameters. These parameters may include engineering unit, sensor type, etc. The configuration needs to be done via the communication protocol. So in order to do the configuration, you will need to use some form of configuration device, typically also called a communicator, to support the selected protocol.
It is crucial to remember that although a communicator can be used for configuration, it is not a reference standard and therefore cannot be used for metrological calibration. Configuring the parameters of a smart transmitter with a communicator is not in itself a metrological calibration (although it may be part of an Adjustment/Trim task) and it does not assure accuracy. For a real metrological calibration, by definition a traceable reference standard (calibrator) is always needed.

Calibration of a smart transmitter

According to international standards, calibration is a comparison of the device under test against a traceable reference instrument (calibrator) and documenting the comparison. Although the calibration formally does not include any adjustments, potential adjustments are often included when the calibration process is performed. If the calibration is done with a documenting calibrator, it will automatically document the calibration results.
To calibrate a conventional, analog transmitter, you can generate or measure the transmitter input and at the same time measure the transmitter output. In this case calibration is quite easy and straight forward; you need a dual-function calibrator able to process transmitter input and output at the same time, or alternatively two separate single-function calibrators.

But how can a smart transmitter, with output being a digital protocol signal, be calibrated? Obviously the transmitter input still needs to be generated/measured the same way as with a conventional transmitter, i.e. by using a calibrator. However, to see what the transmitter output is, you will need some device or software able to read and interpret the digital protocol. The calibration may, therefore, be a very challenging task; several types of devices may be needed and several people to do the job. Sometimes it is very difficult or even impossible to find a suitable device, especially a mobile one, which can read the digital output.
Wired HART (as opposed to WirelessHART) is a hybrid protocol that includes digital communication superimposed on a conventional analog 4-20mA out-

put signal. The 4-20mA output signal of a wired HART transmitter is calibrated the same way as a conventional transmitter. However, to do any configuration or trimming, or to read the digital output signal (if it is used), a HART communicator is needed.

The solution

The new Beamex MC6 is a device combining a full field communicator and an extremely accurate multifunctional process calibrator. With the Beamex MC6, the smart transmitter's input can be generated/ measured at the same time as reading the digital output. The results can be automatically stored into the memory of the MC6 or uploaded to calibration software.
When it comes to configuration of the smart transmitters, the MC6 includes a full field communicator for HART, WirelessHART, FOUNDATION Fieldbus H1 and Profibus PA protocols. All required electronics are built-in, including power supply and required impedances for the protocols.
The Beamex MC6 can be used both as a communicator for the configuration and as a calibrator for the calibration of smart instruments with the supported protocols. The MC6 supports all of the protocol commands according to the transmitter's Device Description file. Any additional communicator is therefore not needed.
There are some other "smart" process calibrators on the market with limited support for different protocols, typically only for one protocol (mostly HART) and offering very limited support. In practice, a separate communicator is needed in any case.

About Beamex MC6

Beamex® MC6 is an advanced, high-accuracy field calibrator and communicator. It offers calibration capabilities for pressure, temperature and various electrical signals. The MC6 also contains a full fieldbus communicator for HART, FOUNDATION Fieldbus and Profibus PA instruments.

The usability and ease-of-use are among the main features of the MC6. It has a large 5.7" color touchscreen with a multilingual user interface. The robust IP65-rated dust-and water-proof casing, ergonomic design and light weight make it an ideal measurement device for field use in various industries, such as the pharmaceutical, energy, oil and gas, food and beverage, service as well as the petrochemical and chemical industries.

The MC6 is one device with five different operational modes, which means that it is fast and easy to use, and you can carry less equipment in the field. The operation modes are: Meter, Calibrator, Documenting Calibrator, Data Logger and Fieldbus Communicator. In addition, the MC6 communicates with Beamex® CMX Calibration Software, enabling fully automated and paperless calibration and documentation.

In conclusion, the MC6 is more than a calibrator.

WHY CALIBRATE?

■ A modern transmitter is advertised as being smart and extremely accurate and sometimes sales people tell you they don't need to be calibrated at all because they are so "smart". So why would you calibrate them?

First of all, the output protocol of a transmitter does not change the fundamental need for calibration. There are numerous reasons to calibrate instruments initially and periodically. A short summary of the main reasons include:

- Even the best instruments and sensors drift over time, especially when used in demanding process conditions.
- Regulatory requirements, such as quality systems, safety systems, environmental systems, standards, etc.
- Economical reasons – any measurement having direct economical effect.
- Safety reasons- employee safety as well as customer/patient safety.
- To achieve high and consistent product quality and to optimize processes.
- Environmental reasons.

RELATED WEBINAR

Configuring and calibrating smart instruments

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Loop Calibration
VS.
Individual Instrument Calibration

By: Mike Cable

An individual instrument calibration is a calibration performed only on one instrument. The input and output are disconnected. A known source is applied to the input, and the output is measured at various data points throughout the calibration range. The instrument is adjusted, if necessary, and calibration is checked.

A loop calibration is performed from the sensor to all loop indications with all the loop components connected. For example, a temperature sensor connected to a temperature transmitter would be inserted in a temperature bath/block. (Note: Either the bath/block would be calibrated or a temperature standard would be used in the bath/block for traceability.) The temperature of the bath/block would be adjusted to each data point required to perform the calibration. All local and remote indications would be recorded. It is also recommended to record the transmitter output. If all indications and transmitter output are within tolerance, the loop is within tolerance. If any loop component is not within tolerance, then a calibration is performed on that instrument. Do not adjust a transmitter to correct a remote indication.

Individual Calibration

Cons	Pros
1. Entire loop is not verified within tolerance	1. Correct instrument will be adjusted
2. Mistakes on re-connect	2. More compatible with multifunction calibrators
3. Less efficient use of time to do one calibration for each loop instrument as opposed to one calibra tion for the loop	

Loop Calibration

Pros	Cons
1. Entire loop, including sensor, is verified within tolerance	1. Wrong instrument may be adjusted to bring the loop within calibration
2. Mistakes on re-connect minimized	2. Not as compatible with multifunction calibrators used for “paperless” data collection
3. More efficient use of time to do one calibration for loop as opposed to one calibration for each loop instrument	

New Methods for Calibrating Loops

By: Ned Espy

Instrument technicians are following practices that were set up many years ago and it is not uncommon to hear, "this is the way we have always done it." Measurement technology continues to improve and is becoming more accurate.

The typical approach to calibration has been to regularly test instrumentation that influence effective control, safe operation, quality or other relevant criteria. In most cases, scheduling is conservative and methods at a particular site have slowly evolved over time. Instrument technicians are following practices that were set up many years ago and it is not uncommon to hear, "this is the way we have always done it." Measurement technology continues to improve and is becoming more accurate. It is also becoming more complex– why test a fieldbus transmitter with the same approach as a pneumatic transmitter? Performing the standard five-point, up-down test with an error of less than 1% or 2% of span does not always apply to today's more sophisticated applications.

In general, calibration tasks require special skills and an investment in test equipment. Sophisticated, highly accurate and multifunctional calibration equipment, such as the Beamex MC6 advanced field communicator and calibrator, are required to effectively calibrate advanced instrumentation, like multivariable and smart/digital instruments. With the complexity of instrumentation, there is more pressure than ever on the calibration technician. Technicians with 30+ years' experience at a single plant are retiring and cannot easily be replaced by a younger technician or be properly outsourced.

The idea of a loop can mean different things to different people due to their work background and/or industry.

Documentation requirements are becoming much more common for improved quality, environmental monitoring, and for adhering to government regulations. Calibration software, like Beamex CMX calibration management software, is often required to store and analyze detailed data as well as to create calibration certificates and reports. All of these factors should cause scrutiny and evaluation of current practices. Simpler and more efficient test methods need to be considered to ensure proper plant operation.

While not a new concept, there are advanced calibration techniques based on loop testing. In some

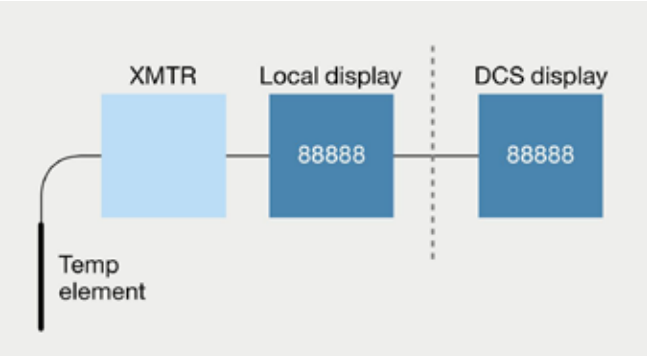
cases, it is best practice to perform individual instrument calibration to achieve maximum accuracy (e.g. custody transfer metering). However, there are viable methods where a loop can be tested end-to-end and if readings are within acceptable tolerances, there is no need to break into the loop for individual instrument testing. To be effective, a common-sense approach is required with the goal to minimize downtime, maximize technician efficiency while ensuring reliable control and maintaining a safe work environment.

What is a loop?

The idea of a loop can mean different things to different people due to their work background and/or industry. In practice, a loop is simply a group of instruments that in combination make a single measurement or effect a control action in a process plant. A typical temperature example would be a temperature element (RTD or T/C) that in turn is connected to a transmitter, which is connected in a series to a local indicator and finally a control system input card (DCS or PLC). The signal is then displayed on one or more control panels and the measurement is ultimately used to control the process. When evaluating a loop for testing, an important distinction to make is whether a closed loop test should be performed or an open loop test?

A closed loop is an end-to-end test; in the temperature loop example (figure 1), the temperature element would need to be removed from the process and placed in a temperature block, such as the Beamex temperature blocks, or temperature bath in order to simulate the process temperature. The final displayed measurement would be compared to the simulated temperature and the error interpreted.

FIGURE 1 – EXAMPLE TEMPERATURE LOOP



A closed loop test is the best practice; if an accurate temperature is made for the control process, it does not matter how the individual instruments are performing. The DCS/PLC value is what is used to make any control changes, alarms, notifications, etc. However, if the loop measurement has a significant error, then the error of each instrument in the loop should be checked and corrected one by one in order to bring the final measurement back into good operation.

In some cases, it is not possible to make a closed loop test. In the example loop, it may be extremely difficult or expensive to remove the probe from the process or the probe cannot be inserted into a temperature block/bath. If this is the situation, then an open loop test can be performed where the temperature element is disconnected from the transmitter and a temperature calibrator is used to simulate a signal into the transmitter. As in the closed loop test, the final displayed measurement would be compared to the simulated temperature and the error interpreted, etc. While the loop is open, it would be good to check the installed temperature element; perhaps a single-point test could be done by temporarily inserting a certified probe/thermometer into the process and comparing that measurement against the element's output when connected to a calibrator.

Analysis of loop error

Error limits can be somewhat difficult to determine and many mistakes are made when it comes to setting error limits. One common judgment is to base process measurement tolerance on a manufacturer's specification. Some manufacturers are better than others, but the marketing department may have as

much to say about an accuracy specification as an R&D engineer. Furthermore, accuracy statements are generally an "off-the-shelf" value that does not include such things as long term stability (typically a significant error component), repeatability, temperature effects and more. Sensor and transmitter accuracy should be a consideration of what the process measurement tolerance should be, not the final value.

The best method is to have a collaborative discussion between the control engineer, quality engineer and/ or the safety engineer with the instrument engineer in setting a realistic and practical tolerance. It is extremely important to keep in mind that the tighter the tolerance, potentially, the more expensive it will be to not only make the measurement, but to maintain the measurement. The balance falls somewhere between the required tolerances to create efficient control, the best quality and maintain the highest safety versus minimizing downtime, maximizing technician efficiency and/ or utilizing optimum test equipment. In practice, it is common to see ±1% of span (or ±2% or even ±5%). However, this does not easily apply to flow measurements (typically a percent of reading or rate) or analytical instruments (pH or ppm, for example).

One good way to look at error is to think in terms of the loop's input engineering units.

One good way to look at error is to think in terms of the loop's input engineering units. As regards the temperature loop example (figure 1), the discussion should focus on what minimum temperature error creates the highest operating efficiency without compromising quality or safety and can be realistically measured by the calibration/test equipment. One other complication for loop error is that a given loop is no more accurate than the least accurate component contributing to the measurement. Today's transmitters are extremely accurate and provide excellent performance. However, temperature sensors are typically not nearly as accurate and, depending on the process, can exhibit significant drift. If a typical RTD is rated to ±0.5 °F, a control engineer cannot expect better than ±0.5 °F to control the process. In reality, even though the transmitter and DCS analog-to-digital conversion can be significantly more accurate, it must be recognized that these components add additional error to the loop measurement. A common practice to compute loop error is to utilize a statistical average or a root mean- square (RMS) calculation. With regard to the temperature loop example, assume the RTD sensor is rated ±0.5 °F, the transmitter is ±0.10% span (span = 50 to 250 °F) and the DCS input card is ±0.25% span (span = 50 to 250 °F). The loop error could be evaluated as follows:

$$\sqrt{0.5^2 + (0.001 \times 200)^2 + (0.0025 \times 200)^2} \approx \pm 0.75°F$$

The most conservative approach would be to simply sum up the errors (0.5 + 0.2 + 0.5 or ±1.2 °F). The final decision should also consider the criticality of the measurement along with evaluation of the impact the error will have on the process and/or the risks involved. The discussion should not end here. The control engineer will strive for the lowest number possible (±0.75 °F), but there are other factors. An

evaluation of the test equipment is required. The typical temperature block has an accuracy anywhere from 0.3 °F to 1.0 °F, and it is good practice to have a 4:1 ratio of test equipment versus process measurement. To make a proper temperature simulation, a reference probe (RPRT or SPRT, reference or secondary primary resistance thermometers) along with an accurate PRT meter, such as a Beamex MC6 with the optional RPRT probe, would both need to be utilized to achieve an improved measurement error of 0.1°F to 0.2 °F. This could impose a significant investment in test equipment, depending on the industry, and it should be noted this will require a higher cost of maintenance for the more accurate test equipment. For example, what if the quality engineer reports that an error of ±5 °F is all that is needed to make a good product? Why impose an unnecessary burden on the instrumentation department? If the control engineer has no objection (along with input from reliability, safety, etc.), a practical approach would be to set a loop tolerance of ±2.0 °F, assuming the temperature block has an accuracy of ±0.5 °F over the range of 50 to 250 °F. While not as accurate as the instrumentation in the loop, it is better than 2:1 for what is required to make a quality product and allows the calibration technician to utilize a simple combination of equipment.

While this is just one scenario, it is good practice to determine the "weakest link" in the loop and not set an unrealistic performance tolerance. When looking at fuel costs or process efficiencies, this type of analysis could easily justify a larger investment in test equipment along with frequent testing if the cost/risk of error is high. With good judgment, striking a balance and avoiding unreasonable testing requests, manufacturing objectives can be met.

LOOP TESTING EXAMPLES

Temperature loop test example

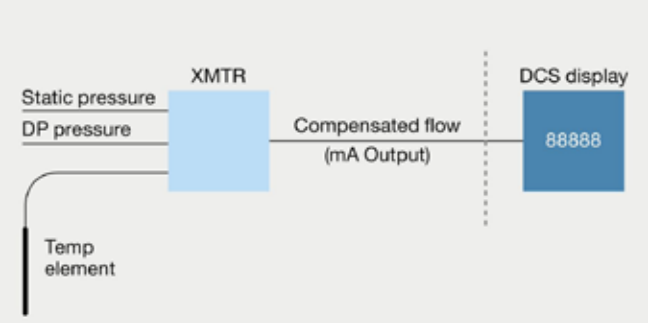
Should a process plant have hundreds of temperature loops like the example (figure 1), there are good benefits with loop testing. While it takes time to make a test with a temperature block, the calibration technician can effectively check 2, 3 or more instruments that make up the loop. With this type of approach, it may make sense to invest in more rugged and/or more accurate probes in order to minimize failures. Depending on the process, more frequent testing may be required, but in any case, management will have a high level of confidence that accurate measurements are being made. With repeatable work methods, technicians will recognize common issues and there should be efficiency gains. If calibrations are being documented, analysis of test cycles can be analyzed and most likely intervals can be extended or at least optimized. The need for troubleshooting and emergency repairs will always be required, but the loop cycle should be reset whenever such an event occurs. This methodical approach effectively provides contact to every instrument in the plant while minimizing disturbances to the loop integrity and delivering the very best measurements to the control system.

Multivariable loop test example

Flow measurements can be very demanding and often require very tight performance tolerances. In the case of natural gas or steam measurements, a small error can amount to significant errors in billing, thus creating extra scrutiny by management. A common example of orifice measurement is to compensate the differential pressure measurement by factoring in the process temperature and static pressure. These three measurements can be processed by the DCS to make an accurate flow calculation. However, there are now DP flow meters (aka, "multivariable") with an integrated process RTD and static pressure measurement that provide a compensated flow measurement output; the flow calculation is built into the smart transmitter.

If the three measurements are independently processed by the control system, typical test procedures apply, but a loop test should be done to verify the accuracy of the compensated flow reading. While multi-

FIGURE 2 – EXAMPLE OF A MULTIVARIABLE LOOP



variable meters appear to be complex, a loop test can be set up to quickly verify that the meter is correctly measuring the flow to a desired per cent of reading accuracy by identifying the measurement components. As an example, consider a steam application:

Specification	Range
Input pressure range:	0 – 250 inH2O
RTD input range:	-200 F – +800 °F
Normal process temperature:	450°F
Static pressure input range:	0 – 800 psi
Ambient barometric pressure:	14.735 psia (average local barometric pressure in 2012)
Output:	4 – 20 mA (typical range of 0 – 1500 lbs/hr, ±1 % of reading)

For this example, a non-linear test should be set up where the expected lbs/ hr output is calculated for specific pressure in put test points assuming a constant, typical 450 ºF temperature and a static pressure of 14.735 psi since the low side of the transmitter is vented to atmosphere for testing. Consulting with the control engineer, expected measurements may look like this:

inH²O	mA	Lbs/Hr
0.00	4.0000	0.0
30.00	7.6250	339.8
60.00	9.2202	489.4
90.00	10.4787	607.4
120.00	11.5717	709.8
150.00	12.5634	802.8
180.00	13.4872	889.4
200.00	14.0738	944.4
225.00	14.7845	1,011.0
250.00	15.4743	1,075.7

The Beamex MC6 offers very unique features for testing multivariable transmitters. The proceeding non-linear table can be entered into the Beamex CMX software for a specific tag and downloaded into the MC6 for testing. Additionally, the three tests can be performed with the process variables versus each HART value that is used in the compensated output calculation. The only additional test tool required would be a Beamex temperature block.

The loop test should simply be a 5-point check of inH2O vs. lbs/hr at 0%, 50%, 100%, 50% and 0%. If all of the measurements fall within a 1% reading, the technician can pack up his tools and move on to the next instrument. If the loop test result is marginal or a failure, then 3 tests of the DP pressure versus HART, RTD temperature versus HART and static pressure versus HART will need to be performed and adjusted as needed. Upon completion of the three variables that plug into the flow calculation, a quick check of the 4–20 mA output should be done as well. Assuming one or more of the inputs require adjustment, a final As Left loop test of the improved flow output will document indicate that the meter is in good operating condition and make documentation of it. It is a time-saver to focus on the non-linear input vs. flow output for a multivariable loop and this will result in a much simpler maintenance task for the instrument technician.

Other loop examples

A pressure loop can be easily checked by applying a pressure to the input transmitter and comparing it to the DCS or final control reading. This can be done very quickly and can be much more effective than merely testing the transmitter. Any batch control loop should be evaluated for loop testing with the goal to make work more efficient for the technician while verifying that control measurements are as accurate as possible.

This same technique should be considered for control valve testing where an mA input into the I/P is compared to an mA output (feedback). This would also apply to smart control valve positioners using a communicator to step the valve and monitor the digital feedback. By making 10% test points, a quick test on a valve will verify that it is operating correctly. In most cases, the test should pass and the technician can make a quick round of testing of critical control valves.

An overlooked component of a flow loop is the primary element (orifice plates, annubars or averaging pitot tubes). These are critical for a proper flow measurement and while they cannot be calibrated, they should be inspected for damage or wear.
Another critical area where loop testing should be considered is safety instrumented systems (SIS). When the process is down, it is common to follow a script of testing procedures that can include calibration of single instruments. However, whenever possible, consider checking an entire loop where the integrity of a critical measurement can be verified, especially for temperature (utilizing a block/bath) or pressure measurements. Also, it may be possible to perform quick and simple tests on a SIS while the process is up and running to ensure systems are operating properly.

Conclusion

In many, many process plants, calibration is performed by simply checking the transmitter. It takes time to use a temperature block/bath, but consider how important it is to test all the devices that make up a given measurement. Transmitters are not the only devices that drift. Temperature probes drift due to thermal stress/shock and vibration or physical damage. DCS/ PLC input cards drift as much or more than transmitters. If loops are not being tested, how can a good measurement be made? Without good measurements, how can optimum control, safety, reliability and quality be ensured?
As instrumentation and automation evolve, so should the methods for calibrating instrumentation. Loop testing is not a new concept, but it is underutilized as an effective strategy for instrumentation

testing. With the Beamex Integrated Calibration Solution, flexible tests can be designed to meet a variety of applications. The Beamex solution delivers the highest level of automation while providing detailed documentation and electronic reporting.
By approaching the task of calibration with a fresh look, there are plenty of opportunities to “do more with less” and effectively make contact with every instrument in the plant more efficiently using loop calibration strategies. Logical and careful planning of loop testing strategies will result in improved control performance without compromising quality, reliability or safety of plant operations.

RELATED WEBINAR

How to avoid the most common mistakes in field calibration

https://hubs.ly/H09rZ390

Safety Considerations

By: Mike Cable

Obviously, performing calibrations safely is very important. One lapse on safety could cost you or your co-worker your lives. Even if it's not a life lost, minor injuries caused by unsafe work practices are preventable. Safety of the product is also of concern when performing calibrations in a manufacturing environment. There are many resources available from ISA on the topic of safety, including Chapter 1 of Troubleshooting: A Technician's Guide, by William L. Mostia. Here are a few things we, as calibration technicians, can do to improve safety in our day-to-day work activities.

- Include specific safety considerations in each calibration procedure. For example, if we know there is a tank that does not have a thermowell installed for the resistance temperature detector (RTD), highlight this fact. Better yet, if possible, get a thermowell installed.
- Keep the shop and work areas clean and free of trip hazards.
- Work with a partner or at least make sure someone knows where you are working at all times.
- Some instruments are always installed at difficult places to reach. If it's possible to install some permanent platform, have it done. Otherwise use safety harnesses, ladders, and lifts properly.
- Technicians may be exposed to lethal electrical voltages. Know what the high voltage areas are, de-energize electrical circuits that are not required, and use proper electrical safety practices (insulated floor mat, rubber electrical safety gloves, roped off area, safety man outside the area with a rope tied around you).
- Ensure electrical power cords are properly insulated. Ensure equipment is properly grounded.

Data Integrity in Calibration Processes

Calibration in the pharmaceutical industry

By: Heikki Laurila

Although this article primarily focuses on data integrity requirements for the pharmaceutical industry, it is a topic that impacts many other industries as well. Similar requirements are already being implemented into other sectors, such as food and beverage and power generation

As a concept, data integrity is by no means a new one, it has been around for several decades. Anyhow, in this article, we look at the data integrity more from the calibration process point of view, and focus mainly on the pharmaceutical and regulated industry. At first, we look at data integrity generally: what it is, why it is important and what a breach could cause. The ALCOA plus concept is also briefly discussed.

I remember in the early 90's when we had pharmaceutical customers auditing us prior to a calibration software purchase, and data integrity was already then one of the normal topics discussed during such a supplier audit. So, it is not a new topic.

Data integrity is the maintenance of, and the assurance of the accuracy and consistency of the data over its entire life-cycle.

It's all about trust

Often, when we buy an everyday product, we can quickly see if the product is operating properly, or if it is faulty. For example, if you buy a new TV and turn it on, you can quickly see if it is working or not. But with different products it is not so easy to see if you have a proper product. This is especially the case with medicines. When you pick up a medicine, how do know that it is a product working properly according to design specifications? In most cases you can't tell that, so it is all about trust – you must be able to trust that the medicine you take is a proper one.

What is Data Integrity?

Data integrity is fundamental in a pharmaceutical quality system ensuring that products are of the required quality.

In every process, there is a lot of data produced. Data integrity is the maintenance of, and the assurance of the accuracy and consistency of the data over its entire life-cycle. It is a critical aspect to the design, implementation and usage of any system which stores, processes, or retrieves data. The term Data Integrity is pretty widely used and has different meanings in different contexts. The term itself is outdated and was initially used in computing. The integrity of the data collected and recorded by pharmaceutical manufacturers is critical to ensuring that high quality and safe products are produced. To ensure the integrity of data, it should be protected from accidental or intentional modifications, falsification and deletion.

With many processes in the process industry, you cannot just simply test the final product to see if it is a proper one. Instead you must assure that the conditions during the process are correct in order for it to produce the correct product. These critical conditions must naturally be recorded and maintained to assure they were correct. This is certainly the case in many processes in a pharmaceutical plant.

Why is data integrity important at the moment?

Data integrity has recently risen to an even more important topic than before.

Data integrity related violations have led to several regulatory actions such as warning letters and import alerts. Actually, a large number of the recent warning letters issued by FDA are somehow related to data integrity.

As international regulatory agencies have more focus on data integrity, the FDA, WHOA and MHRA auditors have been trained to better recognize data integrity issues.

MHRA (Medicines & Healthcare products Regulatory Agency in UK) has recently released new guide "GMP Data Integrity Definitions and Guidance for Industry" (March 2015). There is a deadline set for pharmaceutical companies to comply at the end of 2017. Also, FDA has released "Data Integrity and Compliance With CGMP - Guidance for Industry" (April 2016). This is still in draft mode but has been

on comment rounds. Both will naturally have effect with the pharmaceutical industry. Sure, previously there has been guidance for the good manufacturing practice (CGMP), such as 21 CFR parts (210, 211, and 212), discussing data integrity related issues, but these mentioned new updates will raise the focus.

One additional reason why more focus has been put to data integrity is the increase of the use of mobile devices in calibration processes. This includes applications used in tablets and mobile phones. It also includes the increase of the use of documenting calibrators, which automatically store the calibration results in their memory during a calibration and transfer this data to calibration software. Since the use of automated documenting calibrators will improve the business case of a calibration system, they are being more widely used.

To learn more on what a documenting calibrator is and how it benefits the calibration process, please check the blog post: What is a documenting calibrator and how do you benefit from using one?

As results of all these, data integrity is getting more and more acute.

Impacts of breach of data integrity

The impact of breach of data integrity can be looked as the impact to customer and impact to the pharmaceutical company.

For the customer, the impact can be that the medicine does not have the required effect, patient safety can be compromised and in a worst case it can cause even loss of lives.

For the pharmaceutical company, the impact can be a warning letter from FDA, bans of license to

produce, negative reputation, loss of customer confidence, reduction of market share, and reduction of share price.

Accidental or Intentional

A breach of data integrity may be accidental or intentional. Often, there are computerized systems involved to handle the data and the users may not be aware of any issues in such systems. Certainly, the majority of data integrity issues are accidental and non-intentional. Anyhow, in looking at some of the FDA warning letters, it indicates that in the very worst cases there have been intentional falsifying of records.

Main steps towards better data integrity

Many pharmaceutical companies seem to agree that the main steps towards better data integrity are:

- Better education and communication
- Detection and mitigation of risks
- Focus on technology and IT systems
- Governance of data integrity

Validation is also something that is a must for any computerized system in the pharmaceutical industry. It is good to remember that ANSI defines systems as: people, machines, and the methods organized to perform specific functions. So, it is not only the computer system that needs to be validated.

ALCOA and ALCOA plus

The acronym ALCOA has been around since the 1990's being used by regulated industries as a framework for ensuring data integrity. It is the key to good documentation practice (GDP). ALCOA relates to data, whether paper or electronic, and is defined by FDA guidance as:

- Attributable
- Legible
- Contemporaneous
- Original
- Accurate

The ALCOA plus ads a few attributes to the list:

- Complete
- Consistent
- Enduring
- Available

A brief description of these attributes are included in the following table:

A	Attributable	Who performed an action and when? If a record is changed, who did it and why? Link to the source data.
L	Legible	Data must be recorded permanently in durable medium and be readable.
C	Contemporaneous	All data should be recorded at the time the work is performed. All date and time stamps should be in order (based upon date and time).
O	Original	Is the document the original (raw) data? This should be the first time the information is recorded. In some cases, the original may not be available, but a "certified true copy" is available e.g., a copy may be from a thermal printer and photocopied to preserve the printing. It should be signed and dated with wording that this is a certified copy.
A	Accurate	This refers to the data being entered without errors or editing. If editing occurred, it must be properly documented, e.g., audit trail, traceable to original data.
+	Complete	All of the data generated is included in the analysis. This includes all runs, whether good or bad. In some cases data may not be used in an analysis, but it is addressed in a deviation or investigation and shown to be invalid.
+	Consistent	This refers to the consistent use of date and time stamps and that the data is collected/reported in the proper sequence (as expected).
+	Enduring	The original data is recorded in controlled records, e.g., controlled (numbered) worksheets, laboratory notebooks (bound) or electronic media.
+	Available	One can access the data throughout the lifetime of the record (and the associated retention period required).

What could cause data integrity issues?

Some practical and general things that could cause data integrity issues in any systems are: lack of training, user privileges, poor or shared passwords, control of a computerized system, incomplete data entry, and lack of audit data records for changes and modifications.

The first trap to avoid for consumers – fraud drugs

Although not really a data integrity issue for the industry, this is an important point for consumers. People are buying more from the internet nowadays and you can also buy medicine from internet, but unfortunately you don't always get what you order. A huge amount of medicine bought online are fraudulent. Sometimes the packaging is obviously inappropriate, so it becomes apparent that the medication is a counterfeit. Unfortunately, that is not always the case and people do, at times, consume fraudulent medicine. It is clear that the fraudulent medication does not provide the expected cure, but it is also a big risk for our safety and at its worse, it may be even lethal.

New regulation for product packaging to avoid frauds

To better control these fake drugs, the European Medicines Agency (EMA) has recently introduced a new regulation that will require all prescription drug makers in all (but three) EU (European Union) countries to incorporate new safety features on their product packaging by February 2019. The regulation, which is part of a broader effort to combat falsified medicines in the EU, will require drug makers to add a unique identifier and an anti-tampering device to the packaging of most centrally authorized products. This naturally adds another burden and cost for the drug manufacturers to build the systems to support this, but this will certainly be beneficial for the customers. Although this specific regulation is for the European Union area, it will have a global effect.

Conclusion

Although the data integrity concept has existed for a long time, it has recently risen to be more acute due to the use of mobile tools and added focus of regulatory agencies. In the end, data integrity is common sense - to ensure the integrity of data throughout its life cycle - in practice with various systems and tools being used, it gets more complicated. Since the impacts of the breach of data integrity can be enormous, it is something that needs to be a high priority.

USEFUL REFERENCES

- 21 CFR Part 11, Electronic Records; Electronic Signatures: www.fda.gov/RegulatoryInformation/Guidances/ucm125067.htm
- MHRA GMP Data Integrity Definitions and Guidance for Industry, March 2015: www.gov.uk/government/uploads/system/uploads/attachment_data/file/412735/Data_integrity_definitions_and_guidance_v2.pdf
- Data Integrity and Compliance with CGMP Guidance for Industry DRAFT GUIDANCE, April 2016: www.fda.gov/downloads/drugs/guidancecomplianceregulatoryinformation/guidancesucm495891.pdf
- FDA warning letters are public and can be found here: www.fda.gov/ICECI/EnforcementActions/WarningLetters/default.htm
- European Medicines Agency (EMA), recent regulation for product packaging: www.raps.org/Regulatory-Focus/News/2016/02/09/24281/EU-Regulation-Requires-New-Safety-features-on-Drug-Packaging-by-2019/

Definition of **Terms** and **Acronyms**

Terms

accuracy
as part of the calibration activity, the degree of conformity of a device's output to its actual input value, typically expressed in terms of the measured variable, for example percent of full scale value or percent of actual reading; usually measured as an inaccuracy and expressed as accuracy

Note 1 to entry: The difference between these expressions can be great. The only way to compare accuracy expressed in different ways is to calculate the total error at certain points in engineering units.

adjustment
as part of a calibration activity, the act of adjusting a device to meet a known standard

calibration
procedure (3.1.18) of checking or adjusting (by comparison with a reference standard) the accuracy of a measuring instrument
[SOURCE: ISO 15378, modified – "process" was replaced with "procedure"]

calibration work instructions
step by step instructions for performing a calibration on a specific device or loop

criticality
criticality ranking or classification of items or events based upon relative significance, importance, or severity.

device
a piece of instrument hardware designed to perform a specific action or function

device calibration
a calibration performed on only one device

error
the difference between an indicated value and the actual value expressed as either

a) percent of full scale – difference between the indicated value and the actual value, expressed as a percentage of the device's full scale (minimum-to-span) range of values or

b) percent of reading – difference between the indicated value and the actual value, expressed as a percentage of the actual value

hysteresis
the deviation in output at any point within the instrument's sensing range, when first approaching this point with increasing input values, and then with decreasing input values (in other words, when a device produces a different output at the same input point based on whether the input is increasing or decreasing)

industrial automation and control system
collection of personnel, hardware, software and policies involved in the operation of the industrial process and that can affect or influence its safe, secure and reliable operation [ANSI/ISA-62443-3-3]
Note 1 to entry: This system includes sensors and final elements and may be either a BPCS or an SIS or a combination of the two.

instrument asset management
coordinated work processes of an organization to ensure the intended capability of assets is available

loop
combination of two or more components (devices or control functions arranged so that signals pass from one to another for the purpose of measurement, indication, or control of a process variable

loop accuracy
the degree of conformity of a loop's measured or controlled variable indicated value to the variable's actual value

loop calibration
a calibration performed on a loop, consisting of two or more devices

loop tolerance
the permissible limit of variation, from a known standard, in the loop indicated process measurement

management program
activity that manages a group of related projects and/or work processes in a way that provides benefits and control not available by managing each activity individually and independently

precision
the repeatability of a measurement over time

procedure
sequence of tasks with a defined beginning and end that is intended to accomplish a specific objective

rangeability
measurement range over which the error statement is guaranteed

repeatability
the variation in outputs/indications of a device/loop under the same conditions, and over a period of time. Often expressed in the form of standard deviation. Also see precision.

task
a single piece of work that needs to be done and does not have interacting elements requiring management

[SOURCE: IEC 62304, modified – "a" was deleted, "and does not have interacting elements requiring management" was added]

test uncertainty ratio
ratio of the span of the tolerance of a measurement quantity subject to calibration to twice the 95% expanded uncertainty of the measurement process used for calibration

SOURCE: ANSI/NCSL Z540.3-2006]

$$TUR = \frac{(USL - LSL)}{(ku)}$$

USL = Upper Specification Limit
LSL= Lower Specification Limit
u=uncertainty
k = 2 approximates 95% of coverage

tolerance
permissible limit or limits of variation in a measurement with respect to the actual value

traceability
the property of the results of a measurement or the value of a standard whereby it can be related to a stated reference, usually national or international standards, through an unbroken chain of calibrations all having stated uncertainties

Note 1 to entry: For example in the US, this is the National Institute of Standards and Technology or ILAC recognized laboratories.

verification
as part of a calibration activity, the act of checking the accuracy of a loop or loop component to determine whether it is performing within required tolerances

work process
set of interrelated or interacting procedure(s) (3.1.18) which transforms inputs into outputs

[SOURCE: ISO 9000, ISO 55000, modified – "activities" was replaced with "procedures"]

Acronyms

ANSI: American National Standards Institute

BPCS: Basic Process Control System

CEM: Continuous Emission Monitoring

CSR: Calibration Service Record

EPA: Environmental Protection Agency

HART: Highway Addressable Remote Transducer

IACS: Industrial Automation and Control System

ILAC: International Laboratory Accreditation Cooperation

ISA: International Society of Automation

ISO: International Organization for Standardization

LRV: Lower Range Value

NCSL: National Conference of Standards Laboratories

NIST: National Institute of Standards and Technology

NRC: Nuclear Regulatory Commission

RP: Recommended Practice

RSS: Root Sum Square

SIS: Safety Instrumented System

TUR: Test Uncertainty Ratio

URV: Upper Range Value