

Beamex

Calibration White Paper

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October 2007



Traceable
and efficient
calibrations
in the process
industry

Traceable and efficient calibrations in the process industry

1. Introduction

Today's modern process plants, production processes and quality systems, put new and tight requirements on the accuracy of process instruments and on process control.

Quality systems, such as the ISO9000 and ISO14000 series of quality standards, call for systematic and well-documented calibrations, with regard to accuracy, repeatability, uncertainty, confidence levels etc.

Does this mean that the electricians and instrumentation people should be calibration experts? Not really, but this topic should not be ignored. Fortunately, modern calibration techniques and calibration systems have made it easier to fulfill the requirements on instrumentation calibration and maintenance in a productive way.

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However, some understanding of the techniques, terminology and methods involved in calibration must be known and understood in order to perform according to International Quality Systems.

2. What is calibration and why calibrate

Calibration can be briefly described as an activity where the instrument being tested is compared to a known reference value, i.e. calibrator. The keywords here are 'known reference', which means that the calibrator used should have a valid, traceable calibration certificate.

To be able to answer the question why calibrate, we must first determine what measurement is and why measuring is necessary.

WHAT IS MEASUREMENT?

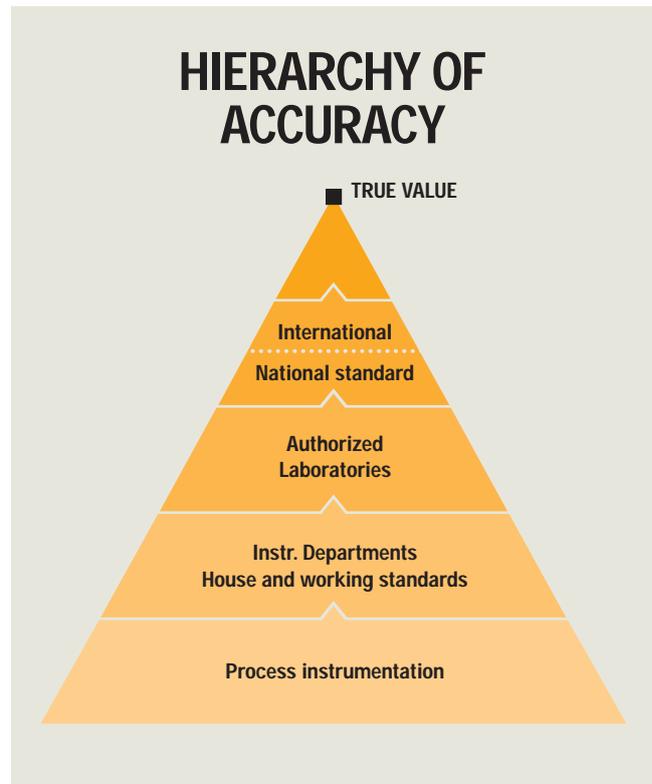
In technical standards terms the word measurement has been defined as:

"A set of experimental operations for the purpose of determining the value of a quantity."

What is then the value of quantity? According to the standards the true value of a quantity is:

"The value which characterizes a quantity perfectly defined during the conditions which exist at the moment when the value is observed. Note: the true value of a quantity is an ideal concept and, in general, it cannot be known."

Therefore all instruments display false indications!



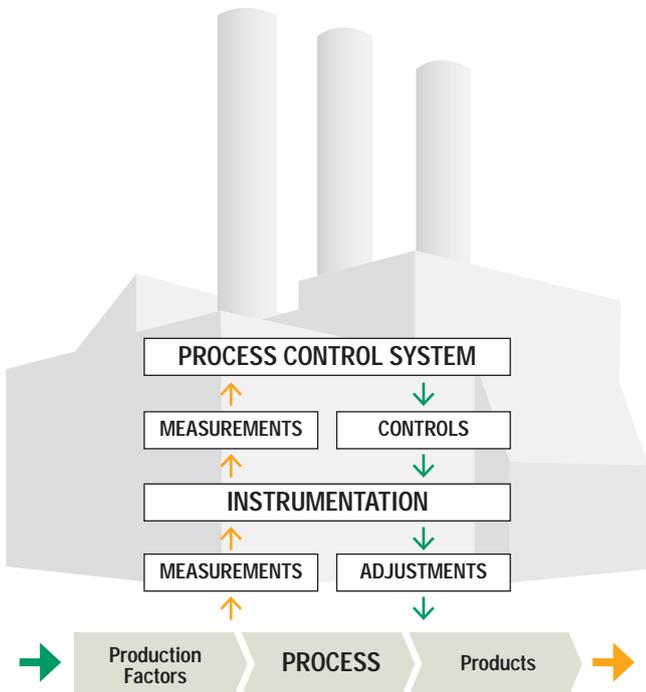
3. Why measure?

The purpose of a process plant is to convert raw material, energy, manpower and capital into products in the best possible way. This conversion always involves optimizing,

which must be done better than the competitors. In practice, optimization is done by means of process automation. Anyhow, regardless of how advanced the process automation system is, the control cannot be better than the quality of measurements from the process.

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EVERYTHING IS BASED ON MEASUREMENTS



4. Why calibrate

The primary reason for calibrating is based on the fact that even the best measuring instruments lack in absolute

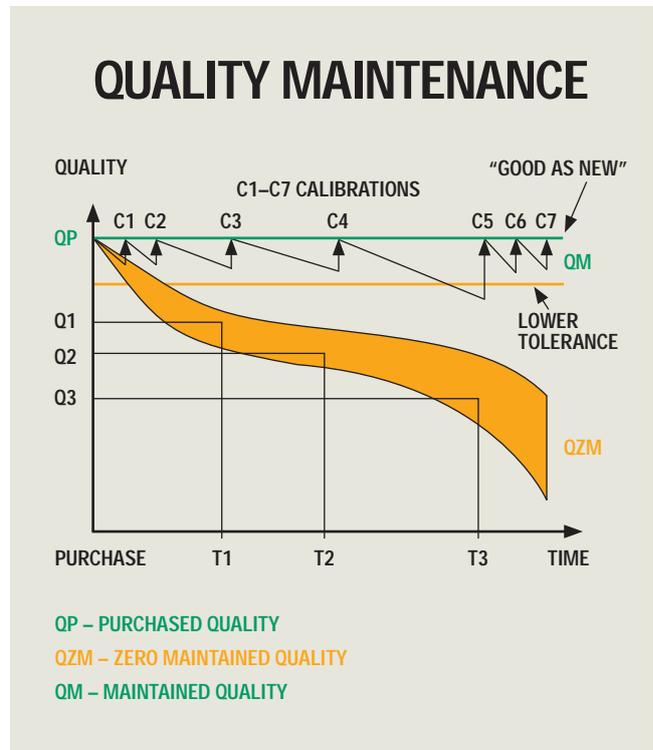
stability, in other words, they drift and lose their ability to give accurate measurements. This drift makes recalibration necessary.

Environment conditions, elapsed time and type of application can all affect the stability of an instrument. Even instruments of the same manufacturer, type and range can show varying performance. One unit can be found to have good stability, while another performs differently.

Other good reasons for calibration are:

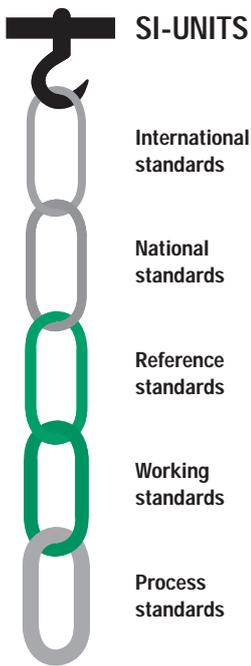
- To maintain the credibility of measurements
- To maintain the quality of process instruments at a good-as-new level
- Safety and environmental regulations
- ISO9000, other quality systems and regulations

The ISO9000 and ISO14000 can assist in guiding regular, systematic calibrations, which produces uniform quality and minimizes the negative impacts on the environment.



5. Traceability

Calibrations must be traceable. Traceability is a declaration stating to which national standard a certain instrument has been compared.



6. Regulatory requirements for calibration

6.1 ISO9001: 2000

The organization determines the monitoring and measurements to be performed, as well as the measuring devices needed to provide evidence of a product's conformity to determined standards.

The organization establishes the processes for ensuring that measurements and monitoring are carried out and are carried out in a manner consistent with the monitoring and measurement requirements.

Where necessary, to ensure valid results, measuring equipment is calibrated or verified with measurement standards traceable to national or international standards at specified intervals. If no such standards exist, the basis used for calibration or verification is recorded; adjusted or re-adjusted as necessary; identified for the determining of

the calibration status; safeguarded against adjustments that would invalidate the measurement result; protected from damage and deterioration during handling, maintenance and storage.

In addition, the organization assesses and records the validity of the previous measuring results when the equipment is found not to conform to requirements. The organization then takes appropriate action on the equipment and any product affected. Records of the calibration and verification results are then maintained.

When used in the monitoring and measurement of specified requirements, the ability of computer software to satisfy the intended application is confirmed. This is done prior to initial use and reconfirmed as necessary.

NOTE: See ISO 10012 for further information.

6.2 PHARMACEUTICAL (FDA, U.S. Food and Drug Administration)

Any pharmaceutical company that sells their products in the USA must comply with FDA regulations regardless where the products are manufactured.

- Calibration records must be maintained.
- Calibrations must be done according to written, approved procedures.
- Each instrument should have a master history record.
- All instrumentation should have a unique ID; all product, process and safety instruments should be physically tagged.
- A calibration period and error limits should be defined for each instrument.
- Standards should be traceable to national and international standards.
- Standards must be more accurate than the required accuracy of the equipment being calibrated.
- All instruments used must be fit for purpose.

- There must be documented evidence that personnel involved in the calibration process have been trained and are competent.
- Documented change management system must be in place.
- All electronic systems must comply with FDA's regulation 21 CFR Part 11.
- All of the above should be implemented in conjunction with following regulations:
 - 21 CFR Part 211: "Current Good Manufacturing Practice for Finished Pharmaceuticals"
 - 21 CFR Part 11: "Electronic Records; Electronic Signatures"

Software systems need features such as Electronic Signature, Audit Trail, User Management, and Security System to be able to comply with these regulations.

In such a system, the Electronic Signature is considered equivalent to a hand-written signature. Users must understand their responsibilities once they give an electronic signature. The Audit Trail is required for change management. It must be a tool that records all modifications, which add, edit, or delete data from an electronic record.

7. DEFINITIONS OF METROLOGICAL TERMS

Some metrological terms in association with the concept of calibration are described in this section.

Quite a few of the following terms are also used on specification sheets for calibrators. Please note that the definitions listed here are simplified.

Calibration

An unknown measured signal is compared to a known reference signal.

Validation

Validation of measurement and test methods (procedures) is generally necessary to prove that the methods are suitable for the intended use.

Non-linearity

Non-linearity is the maximum deviation of a transducer's output from a defined straight line.

Non-linearity is specified by the Terminal Based method or the Best Fit Straight Line method.

Resolution

Resolution is the smallest interval that can be read between two readings.

Sensitivity

Sensitivity is the smallest variation in input, which can be detected as an output. Good resolution is required in order to detect sensitivity.

Hysteresis

The deviation in output at any point within the instrument's sensing range, when first approaching this point with increasing values, and then with decreasing values.

Repeatability

Repeatability is the capability of an instrument to give the same output among repeated inputs of the same value over a period of time. Repeatability is often expressed in the form of standard deviation.

Temperature coefficient

The change in a calibrator's accuracy caused by changes in ambient temperature (deviation from reference conditions). The temperature coefficient is usually expressed as % F.S. / °C or % of RDG / °C.

Stability

Often referred to as drift, stability is expressed as the change in percentage in the calibrated output of an instrument over a specified period, usually 90 days to 12 months, under normal operating conditions. Drift is usually given as a typical value.

Accuracy

Generally accuracy figures state the closeness of a measured value to a known reference value. The accuracy of the reference value is generally not included in the figures. It must also be checked if errors like non-linearity, hysteresis, temperature effects etc. are included in the accuracy figures provided.

Accuracy is usually expressed % F.S. or % of RDG + adder.

The difference between these two expressions is great.

The only way to compare accuracy presented in different ways is to calculate the total error at certain points.

Uncertainty

Uncertainty is an estimate of the limits, at a given cover factor (or confidence level), which contain the true value.

Uncertainty is evaluated according to either a "Type A" or a "Type B" method. Type A involves the statistical analysis of a series of measurements. In this case, uncertainty is calculated using Type A uncertainties, i.e. the effects of these components include measurement errors, which can vary in magnitude and in sign, in an unpredictable manner. The other group of components, Type B, could be said to be of a systematic nature. Systematic errors or effects remain constant during the measurement. Examples of systematic effects include errors in reference value, set-up of the measuring, ambient conditions, etc. Type B uncertainty is used when the uncertainty of a single measurement is expressed.

It should be noted that, in general, errors due to observer fallibility cannot be accommodated within the calculation of uncertainty. Examples of such errors include: errors in recording data, errors in calculation, or the use of inappropriate technology.

Type A uncertainty

The type A method of calculation can be applied when several independent measurements have been made under the same conditions. If there is sufficient resolution in the measurement, there will be an observable difference in the values measured.

The standard deviation, often called the "root-mean-square repeatability error", for a series of measurements under the same conditions, is used for calculation. Standard deviation

is used as a measure of the dispersion of values.

Type B uncertainty

Type B evaluation of uncertainty involves the use of other means to calculate uncertainty, rather than applying statistical analysis of a series of measurements.

It involves the evaluation of uncertainty using scientific judgement based on all available information concerning the possible variables. Values belonging to this category may be derived from:

- Experience with or general knowledge of the behavior and properties of relevant materials and instruments
- Ambient temperature
- Humidity
- Local gravity
- Atmospheric pressure
- Uncertainty of the calibration standard
- Calibration procedures
- Method used to register calibration results
- Method to process calibration results

The proper use of the available information calls for insight based on experience and general knowledge. It is a skill that can be learnt with practice. A well-based Type B evaluation of uncertainty can be as reliable as a Type A evaluation of uncertainty, especially in a measurement situation where a Type A evaluation is based only on a comparatively small number of statistically independent measurements.

Expanded uncertainty

The EA has decided that calibration laboratories accredited by members of the EA shall state an expanded uncertainty of measurement obtained by multiplying the uncertainty by a coverage factor k. In cases where normal (Gaussian) distribution can be assumed, the standard coverage factor, k=2, should be used. The expanded uncertainty corresponds to a coverage probability (or confidence level) of approximately 95 %.

For uncertainty specifications, there must be a clear statement of cover probability or confidence level. Usually one of the following confidence levels are used:

- 1 s = 68 %
- 2 s = 95 %
- 3 s = 99 %

8. CALIBRATION MANAGEMENT

Many companies do not pay enough attention to calibration management although it is a requirement e.g. in ISO9001:2000. The maintenance management system may alert when calibration is needed and then opens up a work order. Once the job has been done, the work order will close and the maintenance system will be satisfied.

Unfortunately, what happens between opening and closing of the work order is not documented very often. If something is documented, it is usually in the form of a hand-written sheet that is then archived. If the calibration results need to be examined at a later time, finding the sheets requires a lot of effort.

Choosing professional tools for maintaining calibration records and doing the calibrations can save a lot of time, effort and money. An efficient calibration management system consists of calibration management software and documenting calibrators.

Modern calibration management software can be a tool that automates and simplifies calibration work at all levels. It automatically creates a list of instruments waiting to be calibrated in the near future. If the software is able to interface with other systems the scheduling of calibrations can be done in the maintenance system from which the work orders can be automatically loaded into the calibration management software.

When the technician is about to calibrate an instrument, (s)he simply downloads the instrument details from the calibration management software into the memory of a documenting calibrator; no printed notes, etc. are needed. The "As Found" and "As Left" are saved in the calibrator's memory, and there is no need to write down anything with pen.

The instrument's measurement ranges and error limits are defined in the software and also downloaded to the calibrator. Thus the calibrator is able to detect if the calibration was passed or failed immediately after the last calibration point was recorded. There is no need to make tricky calculations manually in the field.

All this saves an extensive amount of time and prevents the user from making mistakes. The increase in work productivity allows for more calibrations to be carried out within the same period of time as before. Depending on what process variable is calibrated and how many calibration points are recorded, using automated tools can be 5 to 10

times faster compared to manual recording.

While the calibration results are uploaded onto the database, the software automatically detects the calibrator that was used, and the traceability chain is documented without requiring any further actions from the user.

Calibration records, including the full calibration history of an instrument, are kept in the database; therefore accessing previous results is also possible in just a few seconds. When an instrument has been calibrated several times, software displays the "History Trend", which assists in determining whether or not the calibration period should be changed.

One of today's trends is to move towards to a paperless office. If the calibration management software includes the right tools, it is possible to manage calibration records on computer without producing any papers. If paper copies of certificates are preferred, printing them must, of course, be possible. When all calibration related data is located in a single database the software is obviously able to create calibration related reports and documents.

Today's documenting calibrators are capable of calibrating many process signals. It is not very uncommon to have a calibrator that calibrates pressure, temperature and electrical signals including frequency and pulses. In addition to the conventional mA output of a transmitter, modern calibrators can also read HART, Foundation Fieldbus or Profibus output of the transmitters, and they can be even used for configuring these "smart" transmitters.

Implementing a modern calibration management system benefits everybody who has anything to do with instrumentation. For instance the maintenance manager can use it as a calibration planning and decision-making tool for tracking and managing all calibration related activities.

When an auditor comes for a visit, QA will find a calibration management system useful. The requested calibration records can be viewed on screen with a couple mouse clicks. If a calibrator drifts out of its specifications, it is possible to use a "reverse traceability report" to get a list of instruments that have been calibrated with that calibrator.

Good calibration tools help technicians work more efficiently and accurately. If the system manufacturer has paid attention usability, the system is easy to learn and use. When many tasks are automated, the users can concentrate on their primary job.

Transferring to a new calibration system may sound like a huge task and it can be a huge task. There are probably thousands of instruments that need to be entered into the

database and all the details must be checked and verified before the system is up and running. Although there is a lot of data involved, it does not mean the job is an enormous one.

Nowadays most companies have instrumentation data in some type of electronic format: as Excel spreadsheets, Maintenance databases, etc. The vendor of the calibration system is most likely able to import most of the existing data to the calibration database saving months of work.

Conclusion

A good, automated calibration system reduces workload because it carries out tasks faster, more accurately and with better results than what could be reached with a manual system. It assists in documenting, scheduling, planning, analyzing and finally optimizing the calibration work.

References

- [1] ISO9001: 2000 "Quality Management Systems. Requirements"
- [2] 21 CFR Part 11: "Electronic Records; Electronic Signatures"
- [3] 21 CFR Part 211: "Current Good Manufacturing Practice for Finished Pharmaceuticals"