

Beamex

# Calibration White Paper

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## Why calibrate? – Reasons for calibration

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## – Reasons for calibration

**Calibration is an essential activity in the process industries. There are various different reasons and motivations to calibrate. This article explores some of the most common reasons to perform calibrations and to make periodical recalibrations. Also, a short discussion is included on the risks and consequences for not calibrating. In the end, a brief look is taken on how often instruments should be calibrated.**

### What is calibration?

Before considering the various reasons why calibration is required, let's briefly discuss what calibration really means. Very shortly defined, calibration is a comparison of two measurement devices against each other and the documentation of the comparison. The device to be calibrated is compared against a more accurate, traceable reference standard, often referred to as a calibrator. There are many opinions and even extensive research on how much more accurate the reference standard should be, but anyhow, it must be more accurate, and most importantly, it must have valid traceability to national standards. It is vital that the uncertainty of the reference standard and the whole calibration process is evaluated; otherwise the whole calibration is questionable.

Remember the golden rule – all measurement instruments error and calibration tells us how much.

### Why calibrate? – Reasons for calibration

It is pretty obvious that the fundamental reason for calibrating any process instrument is to test and assure that it is measuring correctly. Now it is time to discuss the drivers that make periodical calibrations for process instruments and test equipment essential for effective plant performance, safety, maintenance, sustainability and product quality.

#### All instruments drift

It is a fact that all measurement instruments drift over time. Some instruments drift more, some drift less. Modern instruments typically drift less than older models. The instrument manufacturers may choose the best available

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components and perform aging of the instruments, but still instruments do drift over time. Usually, it is commercially impossible to try to eliminate drift.

Environmental conditions and usage of the instrument may also affect drift. Extreme temperatures, changing seasons, humidity, or lack thereof can cause stress on the instruments. Instruments that are used more often or in critical processes tend to wear out more quickly than those that are used less frequently.

Depending on the accuracy requirement of a measurement location and the selected measurement instrument for that location, the drift may be more or less critical. The most common procedure is to check instruments periodically to see if they have drifted and make adjustments as necessary to bring them into the required accuracy. If you don't calibrate periodically, and the instrument drifts, the instrument is not able to perform the measurement with the accuracy it was aimed for.

Over time, as several calibrations are performed on a particular instrument, an understanding of how much drift has occurred in that specific location helps determine the instrument stability. An intelligent adjustment of the calibration interval based on the needed accuracy of that location and the proven stability of the instrument can be made. There are also other things to consider when adjusting the calibration interval; more on those later in this paper.

In addition to drift, there is always the possibility of an instrument becoming damaged, or something could happen to its connection to the process, causing it to lose its capability to measure accurately. If the instrument totally breaks down, that can be normally seen easily, but if it only starts to measure a little bit wrong over time it is not easy to uncover, until the next calibration.

So, drift is one of the most common reasons to perform periodical calibrations.

**Environmental responsibility, compliance with regulations, standards and quality system**

Other reasons to perform periodical calibration are various regulations, standards and the company quality system. Even if the company itself does not have a quality system, often its customers have them.

In recent years, process plants must constantly monitor their emissions for social corporate responsibility reasons and to meet environmental regulations. In order for the emission monitoring and measuring equipment to prove that the set targets are met, they have to be constantly maintained accurate with regular calibrations. In the worst case, a failure to meet these regulations may cause the plant to shut down or lose their license to operate.

However, most companies do have a quality system and it is often certified. The most common standard to certify the quality system against is the ISO 9000 family of standards. Also, the ISO 14000 environmental standards are popular to follow. Different industries may have different quality system standards to be followed, for example the AMS 2750 for the heat treatment industry.

The pharmaceutical industry needs to follow the various Food and Drug Administration (FDA) regulations, which place very strict rules for many applications, including various calibration related requirements. For example, the FDA 21 CFR Part 11 and Part 211 set many requirements for calibration. Likewise, the food and beverage industry has their own regulations that are set by the FDA as well. Also, the power industry, especially the nuclear and coal generation facilities, have industry specific regulations.

**Safety reasons**

The safety reasons can be split into two main parts; employee/plant safety and customer/consumer safety.

The calibrations of the safety systems in companies are very much regulated and the regulations drive the requirements. In some industries where the risk for explosion is higher due to the use of volatile materials, plant and employee safety is a high priority, including industries such as oil and gas, chemical and petrochemical, power and energy.

In some other industries, like food and beverage and pharmaceutical, customer safety is one big concern and motivation for calibrations. In these industries, poor calibration may cause product failures that have fatal consequences for the customers.

**Product quality**

In some situations, the quality of the final product cannot be proven simply by making measurement of the final product. Instead, various measurements need to be performed during the manufacturing process. These measurements need to be maintained and constantly proven accurate with periodical calibrations. The quality of the final product can be established by verifying that these in-process measurements are within a defined tolerance during the process.

Typical examples for these kind of scenarios are; processes that includes thermal treatment, food and beverage manufacturing, as well as pharmaceutical processing. For example, a thermal heating process may include metal to

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Even a small improvement in the effectiveness often generates far more revenue than what it takes to improve the calibration process.

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be treated in various temperatures to gain certain product characteristics, and it may be very difficult or impossible to measure these characteristics in the final product. So, maintaining records as evidence that the measurements were accurate and correctly calibrated during the process is of utmost importance.

**Optimize processes and improve efficiency**

Most of process plants use some raw material and convert it into the final product. The more effectively a plant is able to do that, the more profit it will generate. Keeping all the critical process measurements accurate with periodical calibrations ensures that the plant is working as effectively as possible. This will help to generate more output and revenue.

For example, in certain types of power plants, keeping critical measurements more accurate with better calibration process, will enable to plant to operate more effectively. Even a small improvement in the effectiveness often generates far more revenue than what it takes to improve the calibration process.

### **Economic reasons**

In some processes, measurements are used as the basis for money transfer or invoicing. In these cases, any error in the measurements will directly cause error in the money transfer so it becomes obvious that the accuracy of these measurements is of critical importance. Often the amounts of money transfers are so large that it is easily justified to make investments for accurate measurements and a proper calibration process.

### **The costs and risks for not calibrating**

In order to maintain the calibration processes as well as to perform and document all the calibrations, it naturally takes resources and investments to be made. It is relatively easy to calculate the annual costs of the calibration process, including equipment and labor. But it is far more difficult calculate the costs of not calibrating correctly or enough, or making bad calibrations. So as a counter side for the investments needed for the calibrations, one should really think about the risks and consequences/costs if calibrations are overlooked.

As mentioned in the previous sections, the consequences of bad calibration or neglecting to maintain calibration process may cause:

- failure to meet the quality system
- safety risks for employees and customers
- poor product quality and loss of reputation
- product recalls
- failure in meeting the regulations, causing the loss of the license to operate
- unexpected downtime
- economic losses

As mentioned, it is easier to calculate the costs for calibration process than it is to estimate the costs and risk for neglecting calibration. In most industries, the costs for calibrations to be neglected, or to let it fail, is distressingly so high that it is cheaper to make sure the calibrations are done as planned. However, still some fail to realize this until it is too late.

### **Risk based approach**

Modern thinking and also the latest quality standards, such as 2015 version of the ISO9000 standard, include the risk based thinking as a fundamental approach. This risk based thinking should also be applied to the company's calibration processes. In a generic risk evaluation, one should think the

impact and likelihood of any risk. Often both impact and likelihood is split into a 1 to 5 rating and the total risk index is the multiplication of these two. ISO 31000 also provides guidance for risk management.

### **In summary**

The bottom line here is that there are numerous reasons to calibrate including verifying instrument performance and accuracy, compliance with both internal and external regulations, safety and product quality. It is important to remember that not all instruments are created equal, which is determined by a multitude of factors, including location in the plant and critically in the process.

Furthermore, even though calibration may seem like a trivial or resource consuming activity at the end of the day it is worth considering the costs of not calibrating that could lead to safety hazards, product quality concerns and lost production time.

## HOW OFTEN TO CALIBRATE?

As we have discussed the reasons to calibrate, the next question is usually: how often you should perform calibrations? Unfortunately, there is no simple answer to this, at least one that would be correct. Instead there is a list of variables that should be taken into account when deciding the calibration period for any measurement device. Let's quickly take a look at these.

Many manufacturers provide a recommendation for the measurement device's calibration period, or they may have stability specifications given for different calibration periods. Following the equipment manufacturer's recommendation is an easy and good starting point.

When installing a measurement instrument into the process, it is important to know what the accuracy requirements for that specific installation location are. Not all the places in a factory are created equal, therefore similar transmitters installed do not always have the same accuracy need. So, criticality of a measurement location is one important factor related to the calibration period. The more critical locations should naturally be calibrated more often than the less critical location. The installed equipment's specifications compared to the need of the installed location also affects the calibration period. If you install a very accurate transmitter into a location that does not have a high accuracy need, it can be calibrated less often. It is not always necessary to follow the

specifications of that installed equipment. The workload or operating conditions of a measurement device will also affect how often it should be recalibrated. If used very often and/or in very harsh operating conditions, it is good to calibrate it more often.

The stability history of a device is also an important aspect. If you have a long history of an instrument and it is found to be very stable, it can be calibrated less often. And on the contrary, if the history shows that the instrument drifts and often fails in calibration, it should logically be calibrated more often. Calibration software can help to easily show the history trend automatically and therefore help to make the analysis, while doing it manually may require a lot of work.

In some areas there are regulatory requirements, standards or quality systems that specify how often instrument should be calibrated. It's tough to argue with them.

In other applications the cost of failed calibration is so high that it becomes cheaper to calibrate more often than to let the instrument fail. This is especially the case in pharmaceuticals, food and beverage, and power and energy, as well as other regulated industries, or in any critical location.

These above principles can be applied for any kind of measurement device, whether it is a process transmitter or a reference standard.