



Level



Pressure



Flow



Temperature



Liquid
Analysis



Registration



Systems
Components



Services



Solutions

Do you have a calibration plan?

Implementing a calibration plan can help increase profit



Many companies are now in the habit of calibrating their instruments once a year, although there is perhaps no need to pay the same degree of attention to every measuring point. In many cases, it is sufficient to focus on the instruments that play a critical role.

Endress+Hauser has helped customers implement a calibration plan on many occasions. What are the factors to bear in mind when defining which measuring points to include?

To start out, you should begin by noting every measuring instrument in the plant. Identify and make a list of all the equipment parts and all the instrument-related systems. This list should also include details such as description, local information, working range and history, and any other points that provide a better understanding of the part's function.

The first stage in any analysis of the data gathered is to identify which instruments

are critical to the application, the production environment, and operator safety. This calls for teamwork. We will set up a meeting with the Head of Metrology (or Quality), the Head of Production - who has in-depth knowledge of the process and the related instruments - and the Head of Maintenance. Besides generally being the person in charge of calibration, the Head of Maintenance will also be able to contribute what they know about the process environment, the condition of the installed instruments, the type of maintenance work carried out and, finally, any limitations imposed by the plant in terms of servicing.

With this working group, we will start from the finished product - and the tolerance permitted in relation to its quality - and go back through the various stages in the production process. At each stage, we will look at the instruments in place and ask ourselves: 'Does this instrument have an impact on the quality of the product (or any intermediary product), on process functioning, or on operator safety?'

Four categories of critical importance

Instruments should be classified according to one of the four categories of critical importance below:

- **Instruments critical for the product:** instruments that, if defective, may have a direct impact on product quality
- **Instruments critical for the process/system:** instruments that, if defective, may have a direct impact on process or system performance, without affecting the quality of the final product, or safety
- **Instruments critical for safety/the environment:** instruments that, if defective, may have a direct impact on operator safety, or the environment
- **Non-critical instruments:** instruments that, if defective, are thought not to have any impact on product quality, process or system performance, safety, or the environment.

Why start with the finished product?

Users frequently define Maximum Permissible Errors (MPE) on the basis of the instruments they purchase, when what should be most important are the application specifications in relation to the quality of the finished product. Tolerances at all levels of the process should be defined in relation to desired results. In the context of instrumentation, MPEs express defined tolerances for the function being monitored. Taking it a step further, MPEs should provide a basis for deciding what instruments to install, not vice versa!

Let's take a simple example to illustrate this thinking: a good cookie should be baked to just the right degree, taste good and be the right size. The first thing to look at, then, is the cooking phase and the parameters impacting the result: essentially cooking time and oven temperature in this case. The next stage is to try to identify the elements likely to influence the quality of the pastry, e.g. quality and quantity of ingredients and adherence to the recipe.

The relative importance of some of these parameters will help identify measuring points that merit particular attention in relation to metrology. Having defined parameters in terms of their importance for the product, this step is repeated with regard to the process, and then with regard to operator safety. On completion of this first stage of analysis, the working group will have compiled a list of instruments ranked in order of critical importance, i.e. 'high', 'average', 'low', and a list of non-critical instruments.

The primary benefit of this work? Instruments classified as non-critical do not require any metrological monitoring in particular, hence there is no need to continue periodic calibration. As long as the user can prove to the auditor that these instruments have no impact whatsoever on the quality of the finished product, they are entirely at liberty to decide they no longer require calibration.

In many cases, the second benefit is a re-appraisal of the choice of instruments in the context of the application. A Ferrari is not the ideal car for an uphill race, and may even cause lots of problems. The same goes for the instruments you employ."

How to define the calibration frequency of instruments deemed 'critical'?

The ideal calibration frequency should be 'just what it takes' to guarantee the instrument specifications in the context of the production process. To achieve that, we will consider both the factors in favor of frequent calibration and those against it.

The key factor, of course, is the desired measuring precision – which is closely linked to the Maximum Permissible Error tolerated in order to guarantee the quality of the final product. But decisions will also be influenced by the varying nature or condition of the product in contact with the instrument, the continuity (or discontinuity) of the process, the relative severity of the ambient conditions or the presence of CIP (Cleaning in Place). Similarly, considerations such as whether the instrument is used continuously or at intervals, time available for calibration, ease of disassembly and possibility of on-site calibration will also influence calibration plans. And an analysis of calibration history will obviously allow frequency to be adjusted in relation to any non-conformities that are identified.

Inventory of critical devices in a pharmaceutical plant



A final parameter to consider when deciding whether to reduce the frequency of calibration is the risk associated with an excessively long period without calibration. It is useful at this point to remember that the purpose of calibration is to certify the quality of the products that have already been manufactured, not of those yet to be manufactured. Will non-conformities be detected if the instrument is not calibrated for a certain time? Will the production operator, wanting to compensate for a production non-conformity, add too much raw material or modify the process, thereby causing additional costs? This is why the interval between two calibrations rarely exceeds two or three years in the case of critical apparatus.

Why do companies tend to opt for a one-year interval?

It must be something to do with a natural biological rhythm that suits everyone, more or less, auditors included! Because there is rarely any mention of one-year intervals in any regulations. The only stipulation is that the calibration interval must be determined as a function of statistical factors. And as auditors are not necessarily calibration specialists, no one will ask any questions if you calibrate once a year. But if you opt for a longer interval, you will need arguments in support of your decision.

Despite being the usual practice, one-year intervals are not necessarily a good thing. Whereas a flowmeter can go for two or even three years without calibration

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- **CompuCal™** is a high performance system to efficiently maintain and calibrate your on-site instrumentation
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www.us.endress.com/installed_base_audit



Endress+Hauser's calibration and maintenance management software "CompuCal"

(depending on the application), a year is generally too long in the life of a pH measuring device.

What can Endress+Hauser do for companies with a metrology department?

As an instrument manufacturer, we apply our measuring systems' know-how to our client's application conditions. And we have tools to implement, in the initial phase, our method for drawing up a metrological

plan, then for implementing the plan itself. We help our customers achieve dynamic management of their installed instruments, i.e. we ensure they are capable of planning, triggering and documenting maintenance and calibration operations.

At the operational level, we utilize our skills, mobile equipment and accredited laboratories in carrying out calibration, in combination with customers' own resources.

Finally, our contribution helps the Head of Metrology to emphasize the importance of process optimization to their team. For in many cases, metrology is still perceived as a burden, even if those in the life sciences or the food & beverage industry are more aware than others of its benefits in terms of process control. And with the current context making it more necessary than ever to economize raw materials, energy and water, an ever growing number of industry

practitioners now have a better appreciation of the role of metrology in cost control.

Total calibration competence

Endress+Hauser performs instrument calibration across a variety of measuring principles—flow, pressure and temperature. Calibration can be performed at our calibration laboratories or at your facility via our mobile calibration labs. Endress+Hauser

calibration laboratories are located at multiple locations in the US and around the globe. Due to new EPA regulations regarding Greenhouse Gas reporting, traceable calibration is more critical than ever before. Our network of highly trained service professionals, equipped with innovative mobile tools and software, is available to support your critical calibration requirements.

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