

Beamex

# Calibration White Paper

www.beamex.com  
info@beamex.com

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## Calibrating calibrators

# How often should calibrators be calibrated?

## Calibrating calibrators

For instance, a general rule for Beamex's MC5, is to start with a 1-year calibration period as the MC5 has a 1-year uncertainty specified. The calibration period can be changed in the future as you get cumulated stability history, which is compared with uncertainty requirements. In any case, there are many issues to be considered when deciding the calibration period of a calibrator, or any measuring equipment. This article discusses some of the things to be considered when specifying the calibration period and provides some general guidelines. The same guidelines that apply to a calibrator also apply to other measuring equipment in the traceability chain. These guidelines can even be used for process instrumentation.

While maintaining a traceable calibration system, an important aspect is to determine how often the calibration equipment should be recalibrated. International standards (such as ISO9000, ISO10012, ISO17025, CFRs by FDA, GMP, etc.) require the creation of documented calibration programs. Among other things, this means that measuring equipment should be calibrated traceably at suitable periods and that the basis for calibration periods should be evaluated and documented.

When specifying a suitable calibration period for any measuring equipment, there are several things to be considered.

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Uncertainty need is also one of the most important issues when specifying the calibration period.

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### Uncertainty need

One of the first things to consider is the uncertainty need of the customer for the measurement device. Actually, the initial selection of the measurement device should be also done based on this evaluation. Uncertainty need is also one of the most important issues when specifying the calibration period.

### Stability history

When the customer has considered his/her needs and purchased suitable measuring equipment, then (s)he should follow the stability history of the measuring equipment.

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In critical applications, the costs for an out-of-tolerance situation can be extremely high (e.g. pharmaceutical applications) and therefore it is safer to calibrate the equipment more often.

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The stability history is an important criteria when deciding upon any changes to be made to the calibration period. Comparing the stability history of measuring equipment to the specified limits and uncertainty needs will already give good tools for evaluating the calibration period. Naturally, calibration management software with history analysis is a great help in making this kind of analysis.

### The cost of recalibration vs. consequences of an out-of-tolerance situation

One important thing is to optimize between the recalibration costs and the consequences of an out-of-tolerance situation. In critical applications, the costs for an out-of-tolerance situation can be extremely high (e.g. pharmaceutical applications) and therefore it is safer to calibrate the equipment more often. Then again, calibrations may be made less frequently with less critical applications in which out-of-tolerance consequences are not considered serious. Therefore, considering the consequences of an out-of-tolerance situation is important. The corrective actions in such a case should also be procedurized.

Some of the measurements taken in a factory, for example, affect the quality of a particular product to a greater extent than with other products. Therefore, some measurements are more critical than others and should be performed more often.

## Initial calibration period

When you purchase calibration equipment that is unfamiliar to you, you must in any case decide what the initial calibration period will be, in which case using the manufacturer's recommendation is common. With critical applications, we recommend using a shorter calibration at first.

## Other things to be considered

There are also other issues to be considered when specifying calibration period, such as the workload of the equipment, the environmental conditions where the equipment is being used, the amount of transportation and does the equipment look like being damaged.

In some cases, cross-checking against other similar measuring equipment may be used as a check to detect need for calibration. This kind of crosschecking may be done even before every measurement in some critical applications.

Naturally only appropriate metrological responsible personnel in the company can do any changes to calibration equipment's calibration period.

## Summary

The main things to be considered when specifying calibration period for measuring equipment should include at least the following:

- The uncertainty needs of the measurements
- The stability history of the measuring equipment
- Equipment manufacturer's recommendations
- The risk and consequences of an out-of-tolerance situation
- Significance of the measurements