GMP 11

Good Measurement Practice
for
Assignment and Adjustment of Calibration Intervals for Laboratory Standards

1 Introduction

1.1 Purpose

Measurement processes are dynamic systems and often deteriorate with time or use. The design of a calibration program is incomplete without some established means of determining how often to calibrate instruments and standards. A calibration performed only once establishes a one-time reference of uncertainty. Periodic recalibration detects uncertainty growth, serves to reset values while keeping a bound on the limits of errors and minimizes the risk of producing poor measurement results. A properly selected interval assures that an item will be recalibrated at the proper time. **Proper calibration intervals allow specified confidence intervals to be selected and they support evidence of metrological traceability**. The following practice establishes calibration intervals for standards and instrumentation used in measurement processes.

Note: This Good Measurement Practice provides a baseline for documenting calibration intervals. This GMP is a template that must be modified beyond Section 4.1 to match the scope[1] and specific measurement parameters and applications in each laboratory. Legal requirements for calibration intervals may be used to supplement this procedure but are generally established as a maximum limit assuming no evidence of problematic data.

For legal metrology (weights and measures) laboratories, no calibration interval may exceed 10 years without exceptional analysis of laboratory measurement assurance data. Associated analyses may include a detailed technical and statistical assessment of historical calibration data, control charts, check standards, internal verification assessments, demonstration of ongoing stability through multiple proficiency tests, and/or other analyses to unquestionably demonstrate adequate stability of the standards for the prescribed interval. Extended calibration intervals in legal metrology laboratories recognized by the NIST Office of Weights and Measures, must approved by NIST OWM. (See also GLP 4).

[1] The laboratory scope is also called calibration and measurement capability (CMC). The CMC includes 1) measurement parameters, 2) range of nominal values, 3) associated expanded uncertainties, and 4) documented and validated calibration methods.

1.2 Prerequisites

1.2.1 Calibration history and valid calibration certificates, with suitable calibration providers and sufficiently small uncertainties, for all laboratory standards.

1.2.2 Up-to-date measurement assurance and uncertainty data, with adequate degrees of freedom, for all measurement processes in the laboratory that match the laboratory Scope.

1.2.3 Expected tolerance limits where applicable.

1.3 Safety

1.3.1 No outstanding safety concerns

2 Methodology

2.1 Summary

Recommended calibration intervals are based on various examples of metrological traceability as described in GMP 13, Good Measurement Practice for Ensuring Metrological Traceability. As data is collected and evaluated, the laboratory technical manager may adjust the calibration intervals to ensure that measurement results are not invalidated by the intervals selected according to this procedure.

2.2 Apparatus

None.

2.3 Procedure

2.3.1 Identification of Parameters

The laboratory must identify all measurement parameters associated with the Scope of calibrations (and tests) that will be performed in the laboratory. All standards used in a calibration process must be assessed to determine their level of significance and to minimize the risk of producing erroneous results on calibration certificates.

2.3.2 Standards are identified as being critical parameters or secondary parameters.

2.3.2.1 Critical Parameters

Components that contribute more than 25 % of a measurement's uncertainty are identified as critical parameters with a higher risk for impacting the measurement results. To ensure an accurate

evaluation of performance, calibration intervals are determined to meet a 99 % reliability target.

2.3.2.2 Secondary Parameters

Components that contribute less than 25 % but more than 1 % of a measurement's uncertainty are identified as secondary parameters. Secondary parameters are assigned calibration intervals designed to meet a 95 % reliability target.

2.3.3 Assignment of Initial Intervals

Assignment of initial intervals is based on examples and recommendations given in this GMP as maximum limits. Otherwise, an initial interval is equivalent to the amount of time that passes before a metrologist makes the first observation of a result lying outside the warning limits of a control chart when the investigation yields no apparent correctable cause or when results from proficiency tests fail the normalized error assessment (or when the observed bias exceeds the laboratory uncertainty), or the maximum authorized through law or technical review.

2.3.4 Initial Intervals – Additional Standards

A calibration program and periodic calibration interval must be documented for all standards used in the laboratory to comply with the definition and interpretation of metrological traceability. Statements such as "as needed" are not acceptable alone without additional qualifications. A statement such as "calibrations are conducted on an annual basis and may be extended based on demonstrated control through technical and statistical analysis of historical calibration data, control charts, surveillance testing, and multiple interlaboratory comparisons, but will not exceed five years" would be acceptable.

2.3.5 Absence of Control Charts or Measurement Assurance Data

If no initial measurement assurance data is available, the laboratory's Technical Manager should assign initial intervals based on guidance and limits provided in this GMP. Intervals may be adjusted based on adequate data and criteria in Section 2.4 and NIST recommendations. Lacking adequate data for setting and adjusting calibration intervals is a risk that must be addressed by the laboratory.

2.3.6 Tracking and Scheduling

The laboratory must have a program of documenting and monitoring calibration status and scheduling calibrations on the defined intervals. Examples include software systems that flag past-due standards prior to use, scheduling on a calendaring system, or periodic reviews to monitor the

calibration status prior to regular management reviews so that adequate resources are available to obtain calibrations in a timely manner and to prevent the use of standards after their calibration due date(s).

2.4 Adjustment of Intervals

2.4.1 Intervals may be adjusted when determined to be necessary by the laboratory's Technical Manager based on adequate data, valid technical and statistical analysis, and documentation of the assessment. Subsequent intervals may be adjusted based on documented analysis of adequate measurement assurance data, demonstrated control through surveillance assessments, and ongoing stability as demonstrated through multiple interlaboratory comparisons or proficiency tests.

2.4.2 Calibration intervals may be lengthened or shortened by performing a technical and statistical analysis, taking the following factors into consideration as appropriate, and fully documenting the data and assessment:

- calibration history;
- measurement assurance data;
- interlaboratory comparisons;
- data for the population of similar standards, equipment or technologies;
- NIST recommendations;
- statistical analysis methods; and
- manufacturer′s recommendations.

2.4.3 Inadequate reasons for adjusting intervals might include failure to have an adequate system for tracking due dates, lack of funding for suitable calibrations, loss of competent staff, or other related operational risks. Extending calibration intervals must be based on valid, technically supported, and documented assessments to ensure that metrological traceability is supported for all measurement results provided by the laboratory.

3 Assignment of Uncertainty

The uncertainty associated with the establishment of calibration intervals is not included as a part of the uncertainties associated with the respective measurement SOPs. See SOP 29 for calculating uncertainties for standards and measuring instruments.

4 Calibration Intervals for the Laboratory Scope

4.1 As this document is a template, the laboratory may eliminate all examples in this section and reference another laboratory document that combines metrological traceability information and calibrations in one file if it completely states calibration intervals. It is NOT recommended to include calibration intervals in the laboratory Quality Manual to ensure that updates are regularly implemented when calibrations are performed without excessive document approval requirements. The tables of calibration intervals noted in this GMP may be combined with the tables of reference, working, and check standard tables from the worksheets and hierarchies of GMP 13 to minimize the need for multiple tracking methods in the laboratory.

4.2 In the following sections, where Lab or Accredited Lab is noted, the measurement capability must be noted on the Scope of the laboratory performing the measurements and suitable supplier evaluations must be in place. For each level of calibration, a higher-level calibration is required for check standards.

4.3 Examples for Mass

4.3.1 Mass Critical Parameters

4.3.1.1 Balance and Measurement Process Performance

It is important to keep measuring equipment clean and in good working condition. If problems with the equipment are observed, the device should be evaluated and may require maintenance or repair before being put back into service. Regular service, maintenance, and calibration schedules may prevent equipment problems from occurring. When problems are observed, immediate service is required prior to use.

Balance performance in weighing processes following SOP 5 and SOP 28 (e.g., Echelon I) is evaluated in each measurement series. An F-test ratio evaluates the observed standard deviation of the process against the accepted standard deviation of the process. However, while balance calibration might be considered part of a mass calibration procedure, maintaining equipment in good operating condition that minimizes contamination and prevents deterioration is a requirement for all laboratory balances and comparators as a part of accreditation and recognition. The laboratory may have additional procedures to ensure suitable maintenance of balances that ensures proper functioning and prevents contamination and deterioration.

All other weighing processes have incorporated measurement control procedures and control charts that must be evaluated for balance performance characteristics as data is collected.

Table 1. Recommended intervals for balances used for mass (and gravimetric volume) calibrations.

Equipment	Initial Service and Calibration Interval (months)	Source
Balances and Mass Comparators	12	Approved Provider

4.3.1.2 Mass Standards

Each weighing series in Echelon I also incorporates a check standard with a value that is evaluated using a t-test. The observed value is compared to the accepted reference value to determine if there might be problems. Even with the extreme care in storage and handling required for mass standards at this level, mass standards are dynamic with use. Wear, contamination and other factors can cause drift from accepted values. Thus, the following intervals have been set:

Table 2. Recommended calibration intervals for mass standards where Echelon I or II are in place and standards are used at Echelon I or II.

Standards	Initial Interval (months)	Source
R 1. kg and R 1. kg	48	NIST
S_c 1. kg and S_c 1. kg	(alternating 2 years) 48	NIST
R 100. g and R 100. g	48	NIST
S_c 100. g and S_c 100. g	(alternating 2 years) 48	NIST or Accredited Lab
R 30 kg to R 2 kg	12	Lab (Echelon I) or Accredited Lab (Echelon II)
R 500 g to R1 mg	12	Lab (Echelon I) or Accredited Lab (Echelon II)
S_c 500 g to S_c 1 mg	12	Accredited Lab
W 25 kg to W 1 mg	12	Lab
R 500 lb to 1 µlb	12	Lab
W 5000 lb to 1 µlb	12	Lab
Sensitivity weights and tare weights used as standards	12	Lab
R = Reference; S_c = check/control; W = working standards		
Note: where Echelon I is not in place, all reference standards or working standards may need to be calibrated by a suitable calibration provider.		

Table 3. Recommended calibration intervals for mass standards for Echelon III calibrations.

Standards	Initial Interval (months)	Source
W 25 kg to W 1 mg*	24	Accredited Lab
S_c 25 kg to S_c 1 mg*	24	Accredited Lab
R 500 lb	120	Accredited Lab
W 5000 lb to 500 lb	24	Lab or Accredited Lab
Sensitivity weights and tare weights used as standards	12	Lab or Accredited Lab
R = Reference; S_c = check/control; W = working standards		
Note: where Echelon II is not also in place, reference standards and/or working standards may all need to be calibrated by a suitable calibration provider. *When cast iron working and check standards are used, the initial calibration interval is recommended to be 6 months until adequate measurement assurance data is collected showing artifact stability prior to extending the interval.		

4.3.2 Mass Secondary Parameters

Availability of multiple units for environmental equipment enable the laboratory to conduct internal comparisons immediately after a calibration or between calibration cycles and generate internal calibration reports to enable extension of calibration intervals if adequate stability is demonstrated. See procedure for adjusting calibration intervals. The following table contains initial calibration intervals.

Table 4. Recommended calibration intervals for environmental standards used in calibrations.

Standards	Initial Interval (months)	Source
Barometer	12	Accredited Lab
Hygrometer	24	Accredited Lab
Thermometer (digital)	12	Accredited Lab
Data Loggers (when used for calibrations)	12	Accredited Lab

4.4 Examples for Length

4.4.1 Length Critical Parameters

4.4.1.1 Length Standards

Length standards are dynamic with use. Wear, contamination and other factors can cause drift from accepted values. The following intervals have been set due to these factors:

Table 5. Recommended calibration intervals for length standards.

Standards	Initial Interval (months)	Source
100 ft Tape #1	60	NIST
100 ft Tape #2	60	NIST
25 ft or 7 m Tape	60	NIST
18 in Steel Rule	120	NIST
Length Bench	24 (if used or moved)	Lab

4.4.2 Length Secondary Parameters

Table 6. Recommended calibration intervals for length secondary parameters used in calibrations.

Standards	Initial Interval (months)	Source
Thermometer (digital)	12	Accredited Lab

4.5 Examples for Volume

4.5.1 Volume Critical Parameters

4.5.1.1 Volume Standards

Volume standards are dynamic with use. Wear, contamination and other factors can cause drift from accepted values. Seals and valves must regularly be assessed for leaks and stability. Initial calibration intervals are as follows:

Table 7. Recommended calibration intervals for volume standards.

Standards	Initial Interval (months)	Source
R 100 gal standard	60	NIST, Lab, or Accredited Lab
R 25 gal standard *	60	Lab or Accredited Lab
R 5 gal standard *	24	Lab or Accredited Lab
Glassware- Laboratory standard Autopipettes* 5 L to 100 mL	120	Lab or Accredited Lab
*Gravimetric calibration for volumes 5 gallon or smaller, and all “slicker plate” standards. Laboratory must be qualified for performing gravimetric calibrations. Volume transfer is acceptable above 5 gallons. *May be a “slicker plate” type. None are hand-held, “dump” style, test measures. This GMP does not cover calibration intervals for pipettes used in analytical laboratories.		

4.5.2 Volume Secondary Parameters

Table 8. Recommended calibration intervals for volume secondary parameters (gravimetric) used in calibrations.

Standards	Initial Interval (months)	Source
Barometer	12	Accredited Lab
Hygrometer	24	Accredited Lab
Thermometer (digital)	12	Accredited Lab

Table 9. Recommended intervals for volume secondary parameters (transfer) used in calibrations.

Standards	Initial Cal Interval (months)	Source
Thermometer (digital)	12	Accredited Lab

4.6 Example for Thermometry

4.6.1 Thermometry Critical Parameters

4.6.1.1 Temperature Standards

Temperature standards are dynamic with use. Shock, contamination and other factors can cause drift from accepted values. Recalibration intervals are as follows:

Table 10. Recommended intervals for temperature standards.

Standards	Initial Cal Interval (months)	Source
25.5 ohm SPRT	36	NIST
100 ohm PRT′s	12	Accredited Lab
Standard Thermistor	12	Accredited Lab
Check Standards	12	Accredited Lab
Liquid-in-glass standards*	6*	Accredited Lab
**Annual inspection must also ensure that there is no damage or separation in the liquid column. See NIST SP-1088 (2009)[2] for additional maintenance plan requirements. New thermometers should be checked at least once a month at the ice point for a minimum of the first six months of use.*		

Where internal intrinsic or reference standards are available, and the laboratory has the demonstrated competency, the following may be used to set or adjust calibration intervals: triple point cells, melting point cells, and ice baths (using documented and validated procedures).

[2] NIST SP 1088, Maintenance and Validation of Liquid-in-Glass Thermometers, Christina D. Cross, Dean C. Ripple, W. W. Miller, Gregory F. Strouse, January 01, 2009, http://www.nist.gov/manuscript-publication-search.cfm?pub_id=900914.

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