

4740.2091 REQUIREMENTS FOR CALIBRATION OF SUPPORT EQUIPMENT.

Subpart 1. **Scope.** This part applies to all devices that may not be the actual test instrument, but that are necessary to support laboratory operations, if quantitative results are dependent on their accuracy. Such devices include, but are not limited to, balances; ovens; refrigerators; freezers; incubators; water baths; temperature measuring devices, including thermometers and thermistors; thermal/pressure sample preparation devices; autoclaves; and volumetric dispensing devices, such as Eppendorf or automatic diluter/dispensing devices.

Subp. 2. Requirements.

A. Equipment must be operated by trained personnel. Up-to-date instructions on the use and maintenance of equipment, including any relevant manuals provided by the manufacturer of the equipment, must be readily available for use by the appropriate laboratory personnel.

B. All equipment must be properly maintained, including inspection, calibration, and cleaning. Maintenance procedures must be documented. Calibration of balances, weights, temperature recording devices, light sources, and detectors must be appropriate to the required precision and accuracy of the method. Calibrations must be performed at least annually and must be traceable to appropriate standards.

C. Records must be maintained for each major item of equipment, including software. The records must include:

- (1) the identity of the item of equipment, including software;
- (2) the manufacturer's name, type identification, and serial number or other unique identification;
- (3) documentation that equipment complies with the manufacturer's specification;
- (4) the current location within the laboratory;
- (5) the manufacturer's instructions, if available;
- (6) dates, results, and copies of reports and certificates of all calibrations, adjustments, and acceptance criteria and the due date of the next calibration;
- (7) the maintenance plan and maintenance carried out to date, documentation on all routine and nonroutine maintenance activities, and reference material verifications;
- (8) any damage, malfunction, modification, or repair to the equipment;
- (9) date received and date placed in service or the date on which its first use or repair was recorded; and

(10) if available, condition when received, such as new, used, or reconditioned.

Subp. 3. Frequency of calibration.

A. All support equipment described in subpart 1 must be calibrated or verified at least annually, using National Institute of Standards and Technology (NIST) traceable references when available, over the entire range of use.

B. On each working day, balances, ovens, refrigerators, freezers, and water baths must be checked in the expected use range with NIST traceable references, when available.

C. Mechanical volumetric dispensing devices including burettes, except Class A glassware, must be checked for accuracy at least quarterly. All glassware, including glass microliter syringes used for calibration, must be checked for accuracy and documented before its first use in the laboratory if the glassware does not come with a certificate attesting to established accuracy.

D. For chemical and biological tests using an autoclave, the temperature, cycle time, and pressure of each run must be documented by the use of appropriate chemical indicators, temperature recorders, and pressure gauges.

E. Volumetric equipment must be calibrated as follows:

(1) equipment with movable parts, such as automatic dispensers, dispensers/diluters, and mechanical hand pipettes, must be calibrated quarterly;

(2) equipment such as filter funnels, bottles, non-Class A glassware, and other marked containers must be calibrated once per lot prior to first use; and

(3) the volume of the disposable volumetric equipment such as sample bottles, disposable pipettes, and micropipette tips must be checked once per lot.

F. Dial thermometers must be checked on a quarterly basis. All measurements must be recorded. When the thermometer is used for microbiological methods, all thermometers must be calibrated on an annual basis against a NIST thermometer. When the thermometer is used for nonmicrobiological methods, the thermometer is valid for the time period specified on the vendor's certificate. If a time period is not specified, the thermometer must be calibrated on an annual basis against an NIST thermometer.

Subp. 4. Acceptance criteria.

A. The results of calibrations must be within the specifications required of the application for which the equipment is used.

B. The acceptability for use or continued use must be according to the needs of the analysis or application for which the equipment is being used.

C. When the results of calibration of support equipment are not within the required specifications, the laboratory must remove the equipment from service until repaired.

D. Records must be retained to document equipment performance.

Statutory Authority: *MS s 144.97; 144.98*

History: *31 SR 446*

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