

VOTING DRAFT STANDARD

VOLUME 1 MODULE 2, Clause 5.5.13.1

Description

This Voting Draft Standard is a proposed revision of the 2009 standard (EL-V1M4-2009). It has been prepared by the TNI Quality Systems Expert Committee.

5.5.13.1 Support Equipment

This Standard applies to all devices that may not be the actual test instrument, but are necessary to support laboratory operations. These 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 and mechanical volumetric dispensing devices (such as Eppendorf® or automatic dilutor/dispensing devices).

- a) The results of any calibration or verification shall be within the specifications required of the application for which this equipment is used. The laboratory shall define the specifications for acceptability if none exist in method or regulation. If any equipment fails to meet the specifications for acceptability:
 - i) the equipment shall be removed from service until repaired; or
 - ii) the laboratory shall maintain records of established correction factors to correct all measurements.
- ~~a)b) The laboratory shall maintain A~~ all support equipment ~~shall be maintained~~ in proper working order. The records of all repair and maintenance activities, including service calls, shall be kept.
- ~~b)Raw data records shall be retained to document equipment performance.~~
- c) On each day the equipment is used, balances, ovens, refrigerators, freezers, incubators and water baths shall be checked and documented. The acceptability for use or continued use shall be according to the needs of the analysis or application for which the equipment is being used.
- d) Temperature measuring devices shall be calibrated or verified at least annually. Calibration or verification shall be performed using a recognized National Metrology Institute traceable reference, such as NIST, when available.
 - i) If the temperature measuring device is used over a range of 10°C or less, then a single point verification within the range of use is acceptable;
 - ii) If the temperature measuring device is used over a range of greater than 10°C, then the verification must bracket the range of use.
- e) If quantitative results are dependent on their accuracy, such as in standard preparation or dispensing or dilution into a specified volume, the laboratory shall calibrate or verify volumetric measuring devices as follows:
 - i) glasswarecertified to the requirements of ASTM E694 must be permanently labeled as Class A and supplied with a serialized certificate of precision Such glassware isGlass microliter syringes and Class A glassware are exempt from any verification requirements beyond what is stated in Section 4.6.2;
~~If quantitative results are dependent on their accuracy, such as in standard preparation or dispensing or dilution into a specified volume, volumetric dispensing devices shall be checked for accuracy on a quarterly basis;~~
~~Volumetric containers that are used at a single point shall be calibrated or verified at that point prior to or in conjunction with first use;~~
 - ii) Disposable or single-use volumetric equipment shall be verified once per lot, prior to or in conjunction with its first use;
 - iii) Mechanical pipets used at more than one volume shall be checked at 10%, 50%, and 100% of the maximum volume of the pipette. These checks shall be performed prior to first use and on a quarterly basis;

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- ~~iv) All other volumetric support equipment shall be checked for accuracy prior to or in conjunction with its first use on a quarterly basis.~~
- e)f) All other support equipment shall be calibrated or verified at least annually, using a recognized National Metrology Institute, such as NIST, traceable references when available, bracketing the range of use.
- g) Raw data records shall be retained to document equipment performance.
- f) ~~The results of such calibration or verification, whether daily or annually, shall be within the specifications required of the application for which this equipment is used or:~~
 - ~~i) the equipment shall be removed from service until repaired; or~~
 - ~~ii) the laboratory shall maintain records of established correction factors to correct all measurements.~~
- g) ~~If quantitative results are dependent on their accuracy, such as in standard preparation or dispensing or dilution into a specified volume, volumetric dispensing devices (except Class A glassware and Glass microliter syringes) shall be checked for accuracy on a quarterly basis.~~