ENVIRONMENTAL LABORATORY STANDARD

INTERIM STANDARD

VOLUME 1 MODULE 2, Section 5.5.13.1

DESCRIPTION:

This Interim Standard is a proposed revision of the 2012 Standard (EL-V1M2-2012). It has been prepared by the Quality Systems Expert Committee. The changes from the Voting Draft Standard (VDS) are shown in red. The response to comments documents has been included with the posting of this Interim Standard.

NOTE: Only those changes shown in red are subject to Interim Standard Voting. The remaining text is final.

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.

b) The laboratory shall maintain all support equipment in proper working order. The records of all repair and maintenance activities, including service calls, shall be kept.

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 verify volumetric measuring devices as follows:

   i) Glass microliter syringes and Class A glassware are exempt from any verification requirements beyond what is stated in Section 4.6.2;
   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~~ Mechanical devices shall be verified prior to first use and on a quarterly basis. Mechanical devices used at more than one volume shall be verified at volumes bracketing the range of use, and at the mid-point of the volumes used by the device;
   iv) All other volumetric support equipment shall be checked for accuracy prior to or in conjunction with its first use.

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.