

Temperature-Measuring Devices used for Laboratory Operations Policy (NC WW/GW LCB 08/30/2021)

The purpose of this policy is to expand upon and explain the requirements described in 15A NCAC 02H .0805 (a) (7) (N).

NOTE: This policy does not apply to temperature-measuring devices used for compliance monitoring. Those devices are addressed in the *Approved Procedure for the Analysis of Temperature* document.

Traceability is defined by the National Institute of Standards and Technology (NIST) in “NIST Special Publication 1088, *Maintenance, Validation, and Recalibration of Liquid-in-Glass Thermometers*, January 2009” as the linkage of a measurement back to primary temperature standards (also referred to as metrological traceability). Traceability to the standards maintained by NIST consists of:

- Maintaining an unbroken chain of measurements back to NIST standards, with documented measurement uncertainties, and
- Assuring the continued quality of the measurement artifacts used.

Temperature-measuring device calibrations are performed by NIST, the manufacturer or any International Organization for Standardization (ISO) 17025 compliant vendor and results in the issuance of a new certificate of traceability to NIST standards.

Temperature-measuring device verifications are comparisons of temperature-measuring devices to a Reference Temperature-Measuring Device and may be performed by the user. (NOTE: Vendors or other Certified laboratories may provide assistance in meeting this requirement. When a vendor or other Certified laboratory provides this assistance, they must provide a copy of their certificate of traceability to NIST standards or the serial number, accuracy and calibration expiration date of the Reference Temperature-Measuring Device used.)

Tolerance is the amount of allowable difference from the target temperature. For example, the temperature requirement for a fecal coliform incubator is 44.5 ± 0.2 °C. The target temperature is 44.5 °C. The tolerance is 0.2 °C.

Accuracy is an expression of the reliability of the measured temperature. For example, if a temperature-measuring device with a stated accuracy of ± 0.5 °C displayed a reading of 44.5 °C, the reading could be considered, with reasonable confidence, to be between 44.0 and 45.0 °C. The stated accuracy of a temperature-measuring device across the range of use is documented on the certificate of traceability to NIST standards. When a statement of accuracy is documented for individual calibration points rather than for the entire range of use, the test points above and below the intended temperature of use must be within the accuracy requirement for the intended use of temperature-measuring device.

Reference Temperature-Measuring Device

A Reference Temperature-Measuring Device is an NIST traceable temperature-measuring device used only to verify the calibration of other temperature-measuring devices (i.e., limited use only). This device must be able to distinguish temperature changes of 0.1°C and equilibrate rapidly. It must be recalibrated in accordance with the manufacturer's recalibration date (not to exceed five years). If no recalibration date is given, the Reference Temperature-Measuring Device must be recalibrated, at a minimum, every five years. A new certificate of traceability must be issued and maintained for inspection upon request. Recalibrate sooner if the device has been exposed to temperatures beyond the manufacturer's recommended range of use.

The Reference Temperature-Measuring Device used to verify the calibration of any device used in a microbiological incubator must have a stated accuracy of at least ± 0.1 °C. The Reference Temperature-

Measuring Device used to verify the calibration of any device used in a BOD incubator must have a stated accuracy of at least $\pm 0.3^{\circ}\text{C}$. The Reference Temperature-Measuring Device used to verify the calibrations of any device used in laboratory equipment; other than incubators, must have a stated accuracy of at least $\pm 0.5^{\circ}\text{C}$.

Liquid-in-Glass Temperature-Measuring Devices

(excludes digital, incubator and infrared temperature-measuring devices)

Excluding digital, incubator and infrared temperature-measuring devices, all non-Reference Temperature-Measuring Devices must be verified at least **every 12 months** (or sooner if the temperature-measuring device has been exposed to temperature extremes or other stresses) against a Reference Temperature-Measuring Device and the process documented. These devices must have markings at intervals of 1°C or less. To verify a temperature-measuring device, read the temperature of the temperature-measuring device against a Reference Temperature-Measuring Device and record the two temperatures, the serial number (or other unique identifier) of each device, the date the calibration was verified and the signature/initials of the analyst. The verification must be performed at the temperature of use. When used to measure temperature readings for multiple applications, the device must be verified at each temperature of use and the appropriate correction applied at each of those temperatures. If the temperature-measuring device reading differs from the Reference Temperature-Measuring Device reading by more than 1.0°C , the temperature-measuring device must be replaced. The laboratory must maintain records of established correction factors to correct all measurements. Document any correction that applies (e.g., add 0.2°C , subtract 0.3°C , or if no correction needed; 0.0°C) on both the temperature-measuring device and in a format that can be retained for a minimum of five years. Routine temperature measurements must be documented with any applicable correction factor applied.

Digital and Incubator Temperature-Measuring Devices

(excludes Infrared (IR) temperature-measuring devices)

Digital temperature-measuring devices and temperature-measuring devices used in incubators must be verified at least quarterly (i.e., every 3 months) (or sooner if the temperature-measuring device has been exposed to temperatures beyond the manufacturer's recommended range of use or other stresses) against a Reference Temperature-Measuring Device with the appropriate accuracy and the process documented.

To check a temperature-measuring device, read the temperature of the temperature-measuring device against a Reference Temperature-Measuring Device and record the two temperatures, the serial number (or other unique identifier) of each device, the date the calibration was verified and the signature/initials of the analyst. The verification must be performed at the temperature of use. When used to measure temperature readings for multiple applications, the device must be verified at each temperature of use and the appropriate correction applied at each of those temperatures. The accuracy of the temperature-measuring device depends on the tolerance requirements of the temperature being measured. Routine temperature measurements must be documented with any applicable correction factor applied.

- Digital temperature-measuring devices **not used in an incubator** must verify within 1.0°C of a Reference Temperature-Measuring Device with a stated accuracy of at least $\pm 0.5^{\circ}\text{C}$. These devices must be able to distinguish temperature changes of 1.0°C and equilibrate rapidly. If the temperature-measuring device reading differs from the Reference Temperature-Measuring Device by $\leq 1.0^{\circ}\text{C}$ during subsequent verifications, a correction factor must be applied. If the reading differs by $> 1.0^{\circ}\text{C}$, the temperature-measuring device must be replaced.
- Incubators with an incubation temperature tolerance of $\pm 0.2^{\circ}\text{C}$ (e.g., fecal coliform incubators) must have temperature measuring devices with a stated accuracy of at least $\pm 0.1^{\circ}\text{C}$. These devices must be able to distinguish temperature changes of 0.1°C and equilibrate rapidly. If the temperature-measuring device reading differs from the Reference Temperature-Measuring Device reading by $\leq 1.0^{\circ}\text{C}$ during subsequent verifications, a correction factor must be applied. If the reading differs $> 1.0^{\circ}\text{C}$, the temperature-measuring device must be replaced.

- Incubators with an incubation temperature tolerance of ± 0.5 °C (e.g., total coliform and *E. coli* incubators) must have temperature measuring devices with a stated accuracy of at least ± 0.2 °C. These devices must be able to distinguish temperature changes of 0.1°C and equilibrate rapidly. If the temperature-measuring device reading differs from the Reference Temperature-Measuring Device reading by ≤ 1.0 °C during subsequent verifications, a correction factor must be applied. If the reading differs by > 1.0 °C, the temperature-measuring device must be replaced.
- Incubators with an incubation temperature tolerance of ± 1 °C (e.g., BOD incubators) must have temperature measuring devices with a stated accuracy of at least ± 0.5 °C. These devices must be able to distinguish temperature changes of 1.0 °C and equilibrate rapidly. If the temperature-measuring device reading differs from the Reference Temperature-Measuring Device reading by ≤ 1.0 °C during subsequent verifications, a correction factor must be applied. If the reading differs by > 1.0 °C, the temperature-measuring device must be replaced.

Infrared (IR) Temperature Measuring Devices

Infrared (IR) temperature-measuring devices may only be used to measure the temperature of samples for thermal preservation verification. These devices must be able to distinguish temperature changes of 1.0 °C and equilibrate rapidly. The device must be verified at least quarterly (i.e., every 3 months) using a Reference Temperature-Measuring Device at a minimum of three different temperatures over the full temperature range of use (e.g., 0 °C, 5 °C and 10 °C). Each day of use, perform a verification of the IR temperature-measuring device by checking the temperature of a bottle of water containing another NIST traceable temperature-measuring device (with a demonstrated accuracy of at least 0.5 °C) at a single temperature between 0 and 10 °C. The two measurements must agree within 0.5 °C, or the device must be recalibrated or replaced. Document the quarterly and daily verifications. The correction factor from the quarterly verification must be indicated on the IR temperature-measuring device and applied when documenting temperature measurements. Temperature correction factors are not to be adjusted based on daily temperature verifications. Routine temperature measurements must be documented with any applicable correction factor applied.