

STATE OF CONNECTICUT


DEPARTMENT OF PUBLIC HEALTH

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Immunization Program

TO: All CVP Providers
FROM: Mick Bolduc 
Vaccine Coordinator-Connecticut Vaccine Program (CVP)
DATE: July 16, 2019
SUBJECT: Calibration Requirements for all Temperature Monitoring Devices

The purpose of this communication is to remind providers of the calibration requirements for all temperature monitoring devices.

Certificates of Calibration

All providers must use a working, digital, downloadable, continuous temperature monitoring device (e.g. data logger) with a current and valid certificate of calibration in all storage units that are used to store CVP supplied vaccine.

The certificate of calibration must either be issued by an ILAC/MRA accredited laboratory or specify in writing that it meets one or more of the following criteria:

- Conforms to ISO 17025
- Is traceable to standards maintained by the National Institute of Standards and Technology (NIST)
- Meets specifications and testing requirements for the American Society for Testing and Materials (ASTM) Standard E2877 tolerance Class F (≤ 0.5 °C) or better
- Includes reference to another acceptable accuracy validation method, such as comparison to other traceable reference standards or tests at thermometric fixed points.

This certificate of calibration requirement applies to all temperature monitoring devices including centralized systems that can be monitored remotely (e.g. Pyxis, Omnicell).

Manufactures of compliant devices should provide an original certificate of calibration. Providers are responsible for retaining and producing these certificates for their current devices



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when asked to by the CVP. Providers may choose to have existing devices recalibrated when the original certificate expires. If so, they must ensure that a new certificate of calibration is issued and that it meets the criteria above.

Back-up Data Logger Calibration

A valid certificate of calibration is also required for back-up devices. CDC recommends the date of calibration for the back-up device differ from that of the primary to prevent the certificates from expiring at the same time.

If you have any questions, please contact the CVP at (860) 509-7929.