INFORMATION PAPER

DHA-IHD
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SUBJECT: Digital Data Logger Calibration with the Ice Melting Point Validation Method

1. Overview. Every vaccine storage unit must have a Temperature Monitoring Device (TMD). An accurate temperature history that reflects actual vaccine temperatures is critical for protecting your vaccines. Investing in a reliable device is less expensive than replacing vaccines wasted due to the loss of potency that comes from storage at out-of-range temperatures. The CDC recommends a specific type of TMD called a “digital data logger” (DDL). TMDs can experience “drift” over time, affecting their accuracy. Calibration testing ensures the accuracy of the device continues to conform to nationally accepted standards. Mishandling a TMD can affect its accuracy. If a TMD is dropped, hit against the side of a storage unit, or is potentially damaged in any way, its accuracy should be checked against another calibrated TMD. If there is any question about accuracy, the device should be replaced or recalibrated.

2. Background. The term “NIST certified (with certificate)” is misleading and DHA-IHD has confirmed with the National Institute of Standards and Technology (NIST) they do not calibrate or certify TMD’s. Correct terminology should be “thermometer that has valid certificate of calibration testing.” Appropriate certification methods are listed in Section Three of reference (a).

3. Key Point. NIST recommends utilizing the Ice Melting Point Validation Method as the cheaper, faster, easier way to establish and maintain thermometer traceability. Measurement in an ice melting point is the ideal approach for data logger validation. The melting point of ice is a known physical property that occurs at exactly 0.00 °C. As a result, a properly constructed ice melting point is considered to be an intrinsic, defined standard, and meets the requirements for establishing traceability. This means that end-users can avoid the cost and time delay of outside calibrations by performing their validation processes in-house.

4. Recommendations.

    a. Initial validation must be completed before the device is used to monitor vaccine temperature. At a minimum, all DDL’s used for vaccine temperature monitoring should be measured at the ice melting point on an annual basis, beginning from the initial validation date.

    b. Simple instructions for the Ice Melting Point Validation Method are detailed in the NIST tutorial video (3:40 min) available at the link below. https://www.youtube.com/watch?v=KYOJayWqB3g

Note: recommend following procedures closely as deviations in technique will affect validation accuracy.

c. NIST guidance for the probe-in-bottle type DDL where probe is not removable:

(1) Immerse the entire bottle, ensuring your container is large enough, so that you have ice and water on all sides of the bottle. The bottle should not touch the walls or rest on the bottom of the container holding the ice bath.

(2) Also, it will take longer for the probe-in-bottle to equilibrate with the ice melting point and readings to stabilize near 0 °C. The equilibration time will vary depending on the size of the bottle (approx. 30-90 minutes).

(3) Ensure that the water from the ice bath can't get inside your bottle. If the cap or stopper is sealed with epoxy, then you should be fine. If not, put the bottle inside a (mostly) sealed "Ziploc" with the leads exiting the bag, and then stick this in the ice bath. Equilibration time will take longer if plastic bag is used and more ice may need to be added due too much melting.

d. Immunization sites utilizing this method can document their own Certificate of Calibration which shall include the following elements. These certificates must be maintained throughout the DDL lifecycle following each validation in order to maintain traceability:

(1) Model/device name or number.

(2) Serial number.

(3) Date of calibration.

(4) Confirmation that the instrument passed testing.

(5) Recommended uncertainty of +/-0.5 °C (+/-1 °F) or less.

e. What to do if a thermometer fails its verification.

(1) First, check the instrument to see that you are using it correctly. Is the right probe connected to the readout? Are options for the readout set correctly? Do the batteries need replacing?

(2) Repeat the verification measurement to confirm the first measurement.

(3) If the logger's deviations exceed the manufacturer's specifications, the device is out of tolerance and should be re-calibrated or replaced.

f. An alternate approach to using an ice melting point validation check would be to have a designated "reference thermometer" which is regularly calibrated by an accredited laboratory, or validated by the user with an ice melting point check. Individual data loggers could then be validated by comparison to the reference thermometer. Procedures for this comparison method should be followed in accordance with reference (b).

5. References.

a. Centers for Disease Control and Prevention. Vaccine Storage and Handling Toolkit. March 2021.

b. NISTIR 7899. Data Logger Thermometers for Vaccine Temperature Monitoring. Chojnacky, M., Miller, W., Strouse, G., November 2012.

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