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# Montana Immunization Program

## Data Logger Calibration

## Frequently Asked Questions (FAQ)

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Below are answers to frequently asked questions about data logger calibration in the Vaccines for Children and Vaccines for Adults (VFC/A) programs. Only public and IHS/Tribal/Urban Indian facilities are eligible for our VFA Program. Please direct additional questions to Lori Hutchinson at [lhutchinson@mt.gov](mailto:lhutchinson@mt.gov) or 444-0277.

### Data Logger Calibration

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## Data Logger Calibration

### What is involved in calibrating a data logger?

“Calibration” is checking the data logger’s accuracy by comparing its temperature readings to those of a known standard. Calibration testing must adhere to international standards and be documented with a [certificate of calibration](#). Calibration typically involves shipping the device to a calibration lab. Calibrations can also be performed on-site by a calibration service. You will need to deploy your backup data logger or a loaner from the calibration lab while your data logger is being calibrated.

When arranging a calibration, always confirm:

- The price per device including any shipping charges or loaner options
- The [calibration interval](#) they offer (two years, if possible)
- That the [certificate of calibration](#) meets requirements.

## How often must data loggers be calibrated?

Data loggers in the Montana VFC/A Program must be calibrated at least every two years. Some calibration labs may specify how long the calibration is valid with a “due date” for the next calibration. This is called the calibration interval. Be sure to clarify the calibration interval with the lab and always try to get a calibration valid for two years.

- If the certificate has a due date less than or equal to two years from the testing date, recalibrate by the due date.
- If the certificate has a due date greater than two years from the testing date, recalibrate within two years of the testing date. We do not allow calibration intervals longer than two years regardless of the due date on the certificate.
- If the certificate does not have a due date, recalibrate within two years of the testing date.

## How much does it cost to calibrate a data logger and how long does it take?

Calibrations typically cost from \$40 to \$60 per device. There may be additional charges for shipping and for a “loaner” to use while your data logger is being calibrated (if you choose that option).

The calibration process can take from one week to a month depending on the lab. The calibration lab will provide details on the services they offer, their turn-around time, and instructions on how to ship your data logger.

## What are the requirements of a certificate of calibration?

To show compliance with international standards, the certificate of calibration must either:

- Indicate the testing was done by an ILAC MRA<sup>1</sup> calibration lab OR
- Include a statement saying the testing followed one of the following standards:
  - ISO IEC 17025
  - ASTM Standard E2877 tolerance Class F
  - NIST traceability
  - Other Immunization Program approved accuracy validation method (Contact us).

Certificates also must include:

- The name of the calibration lab or entity
- Device make/model and unique identifier (e.g., device number, serial number etc.)
- Date of calibration testing
- Confirmation that the device passed testing with an accuracy of  $\pm 1^{\circ}\text{F}$  or  $0.5^{\circ}\text{C}$ .
- Optional - [Calibration due date](#). Some calibration labs may include a calibration “due date” indicating how long the calibration is valid (i.e., calibration interval).

Providers are responsible for calibration certificates and must make them available for review during VFC/A site visits.

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<sup>1</sup> International Laboratory Accreditation Cooperative – Mutual Recognition Arrangement

## **How do we find a calibration lab?**

We recommend contacting the manufacturer or distributor of your data logger. They may offer calibration services or be able to recommend a lab. Another option, is to choose a lab from this [list of accredited calibration labs](#) compiled by the California Immunization Program.

## **Can our internal bioengineering/maintenance/facilities department perform the calibrations?**

Yes, as long as they follow international standards and issue a certificate for each data logger with the [required information](#).

## **Can a calibration entity come to our facility to calibrate our data loggers?**

Yes, as long as they follow international standards and issue a certificate for each data logger with the [required information](#).

## **Do we have to notify the Immunization Program when we recalibrate or obtain new data loggers?**

No. Having compliant data loggers on your public vaccine storage units is your responsibility, including keeping them calibrated. We will review your data loggers for compliance during site visits. However, we highly recommend you have us review the specifications on any devices you are considering *before purchase* to make sure they meet requirements. You may be required to replace public vaccine wasted due to negligent cold chain monitoring.