**[lab name]**

**Use of Continuous Temperature Monitoring Devices**

 **[#]**

**In Compliance with V1M2 4.2.8.5**

**VERSION #1.0 Effective date: January 1, 2024**

**APPROVED BY**

**Signature**

 **[name] Technical Manager**

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**New SOP**

**Revision History**

|  |  |
| --- | --- |
| Version number and effective date | Revisions made |
| V 1.0 January 1, 2024 | Conforms to TNI 2016 standards. |
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# Introduction

Temperature monitoring requirements found in V1M2 sections 5.5.13.1 and V1M5 1.7.3.3 establish simple point monitoring for temperature in ovens, refrigerators, freezers, and incubators. The laboratory has determined that continuous monitoring is necessary in cases where no staff are available to check the temperature. They can operate at temperatures currently not available to standard spirit thermometers and replace mercury thermometers. Continuous monitoring devices are available with digital readouts and are calibrated traceable to the International Standard.

# Procedure Summary

The selected device is placed in the designated autoclave, incubator, oven, refrigerator, or freezer in the same locations as would be a standard thermometer. Only devices that are calibrated to the International Standard and are capable of reading at the desired temperature and allowed temperature range will be used. Annual recalibration or replacement by a calibrated device will be implemented to meet the requirement in V1M2 5.5.13.1.(a).

Any device used as a substitute for a regular thermometer and read at the minimum frequency is not covered by this procedure.

Since these devices measure temperatures over a larger range of time than single point measurements, the purpose of this procedure is to discuss allowed excursions from the allowed temperature range under normal operating conditions. These situations are not observed or recorded due to when the thermometer is read under single point recordings. Any deviations not linked to normal laboratory operations will be treated in the same manner as would any excursion outside of the allowed temperature ranges.

# Temperature Monitoring Devices

Devices may be of any construction if they are suitable for the temperatures to be monitored. They may be a single unit or may be a thermistor or appropriate sensor on a cable connected to an external display. All devices must be able to download to a computer using the manufacturer's software. Files created by downloading are considered original records. The data retained by the device may be deleted once the downloaded information is reviewed.

All devices will be purchased calibrated to the desired temperature and will include a certificate issued by an accredited calibration laboratory (accredited to ISO 17025).

At the annual calibration, the device may be checked against a reference thermometer certified to the International Standard or may be returned be recalibrated by an accredited calibration laboratory. The correction factor, if any was determined, will be made known on all records and when reviewing the downloaded data files.

If the correction factor is greater than 1.5 degrees, the device will be removed for service or replaced.

# Records

All devices will be set to record and store the temperature at least every hour except for any device used to monitor autoclave operations. For those devices the temperature will be recorded at least every minute.

# References

* *Management and Technical Requirements for Laboratories Performing Environmental Analyses*, The NELAC Institute (TNI), Rev 2.1, September 1, 2016

# Definitions and Acronyms

Words specific to this document or used outside of their dictionary definition are defined here. Acronyms can be defined in the text above on their first appearance.

## Definitions

## Acronyms

# Appendices