**Temperature Monitoring**

**I. Guidelines**

**Audit:**

Questions pertaining to temperature monitoring may be found under the following sections:

Equipment, Test and Control Articles, Physical Facilities and Vertical Audit.

**CAP Accreditation Checklist**

Limited Service Laboratory Checklist Manual, Thermometer, and Temperature-Dependent Equipment sections.

**Background Information:**

What needs temperature monitoring?

Any environment or equipment that uses temperature to maintain the stability of testing samples, reactions, or materials should be monitored. Examples are: instruments, incubators, refrigerators, freezers and rooms that contain specimens, reagents or active testing. These must be monitored for temperature control on a daily basis at a minimum, including weekends and holidays. By monitoring temperature in accordance with the manufacturer’s instructions, the laboratory protects the integrity of the materials. If temperature is not maintained for reagents and specimens, then the laboratory cannot have confidence in the results obtained. Great expense and patient harm can occur.

Exceptions

If the environment or equipment does not contain reagents or samples and testing is not done on certain days, then monitoring is not required for those times. Enter a notation of “not in use” on the recording chart for that day. An example would be a warm water incubator not used for testing on a particular day.

For refrigerators and freezers only, but not for devices containing specimens or repository samples, a case-by-case exemption can be determined by DAIDS to use a continuous recording device or a min/max thermometer over weekends or short holidays. This practice is not recommended due to the expense and time involved in verifying materials suspected of possible spoilage or loss of materials from temperature range failure. Any time that the temperature is outside the appropriate range and there is a suspected violation of the manufacturer’s recommendations, corrective action must be undertaken to verify the integrity of the materials stored.

How to measure

A constant recording graph or computer monitoring system is ideal. A minimum/maximum thermometer is also a good measuring device, because it will alert the laboratory to temperature variance between monitoring. Otherwise, a thermometer that covers the expected range of temperature can be used. Each measuring device should be uniquely labeled for easy identification. The temperature measuring sensor is often placed in a small sealed tube of glycerin inside a refrigerator or freezer to dampen the effect of opening the door from time to time.

Calibration records

All temperature measuring devices must have calibration verified when placed in service and at least once a year thereafter. These devices should be calibrated against a current National Institute of Standards and Technology (NIST) traceable thermometer or equivalent certified instrument. Temperature readings from the two measuring devices are taken at the same time under the same conditions and compared. The two measurements should be within laboratory established criteria. Each measuring device should have a continuous calibration record for the life of the device. The calibration record should contain an identifier unique to the thermometer, the certified and test thermometer temperature readings, criteria of acceptance, result of the calibration, date performed, initials of the person performing the testing and a comment section for any additional information. This record should be reviewed at least annually, then signed and dated for completeness by the lab director or designee. Those thermometers failing calibration should be removed from service. After the device is no longer used, then this calibration record should be preserved in accordance with study or laboratory guidelines.

Range

The range limitations are determined by the most limiting of the manufacturer’s recommendations for the materials stored or in use in that environment or equipment. An example would be a refrigerator that contained two reagents: one must be stored between 3-8 degrees and the other between 2-6 degrees Centigrade. The acceptable range would be 3-6 degrees Centigrade for this refrigerator.

Recording

A separate recording sheet should be maintained for each device. The record should include temperature, date, staff initials, space for comments and any corrective actions. The recording sheet must also specify the temperature range permitted. To help ensure that temperatures are recorded, temperature log must be kept near where the monitoring is done and accessible to all pertinent personnel.

Corrective Actions

If the temperature is outside of the acceptable range, then corrective action should be taken. It is important to ensure the integrity of the materials and determine if product deterioration has occurred. The length of time, the degree of variance in temperature, and the manufacturer’s recommendations for material storage stability are used to determine what actions are necessary. The affected materials should be marked to indicate possible quality problems and moved, or in some way restored to the correct temperature range. Corrective actions for those materials should at least include parallel testing similarly done when new materials are received in the laboratory.

**Resources**

1. College of American Pathologists (CAP) 2023. Commission on Laboratory Accreditation, Laboratory Accreditation Program; All Commons Checklist manual (Revised 08/24/2023).

**II. SOP**

**Purpose**

To ensure comprehensive and consistent temperature monitoring of (insert name) Laboratory equipment such as water baths, refrigerators, freezers and environment (ambient temperature).

**Pre-analytic Procedure**

Refer to the following procedures:

* List all relevant procedures – like specimen collection, safety, specimen handling, specimen storage, etc.
* *Enter other basic procedures needed for your lab*.

The exceptions to these procedures are listed below:

* *Enter exceptions to the procedures listed above that are needed for this procedure.*
* Or N/A

*Examples*

* Thermometers pose a physical hazard when broken. Do not handle broken thermometers by hand. Use a broom and dust pan only. Clean all breakages using the appropriate PPE as designated in the Laboratory Safety Manual.
* Mercury thermometers pose a health hazard when broken. Minimize exposure to spilled mercury. Do not ingest or handle. Mercury evaporates at room temperature and gives off harmful, invisible odorless vapors. Do not inhale mercury vapors. Evacuate the area immediately. Contain and clean all spills in accordance with the laboratory safety manual.

**Analytic Procedure**

Specimen Information:

N/A

Reagents/Media:

N/A

Equipment and Supplies:

Minimum/maximum thermometers

Certified NIST calibrated thermometer

Freezers – ABC Model number 123456

Refrigerators – DFF Model number 111222

Water Baths – WB Model number565656

Incubators –INC Model number 999555

Heating Blocks –HB Model number 564512

Instruction and Procedure:

1. All sections can either be entered as a table below – as suggested by CLSI – or just listed: This table is just an example. Customize information for this subject.

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| --- | --- |
| **Step** | **Action** |
| 1 | All temperature sensitive equipment must be temperature monitored. |
| 2 | All equipment should have Temperature Recordings logs. Logs contain the following information:   * Name of temperature-controlled device * Model * Serial Number * Range * Location * Month/Year * Day of the month * Temperature reading * Tech initials |
| 3 | Temperatures must be recorded at least once per day and recorded on the corresponding log with weekends and holidays included. |
| 4 | Any readings which fall outside the demarcated tolerance/safety regions must be reported to the Laboratory Manager or service technician and logged with a record of corrective action taken. |
| 5 | |  |  | | --- | --- | | **If** | **Then** | | Refrigerator cannot be repaired or temperature corrected within 60 minutes | Remove stored items to another refrigerator of desired temperature. | | Freezer cannot be repaired or temperature corrected within 30 minutes | Remove stored items to another freezer of desired temperature. | |
| 6 | Ambient temperature must be monitored with the use of a minimum-maximum thermometer mounted on the wall. |
| 7 | The ambient temperature must be recorded at least once per day and documented on the Temperature log sheet with weekend and holidays included. |
| 8 | Temperature higher than the acceptable range may cause equipment failure or interfere with analytical processes.   |  |  | | --- | --- | | **IF** | **Then** | | Temperature is out of range | Log a fault and take corrective action | |
| 9 | For kits that are affected by relative humidity, it must be measured at least once daily and logged on the Temperature log sheet. (*Kits that are affected by relative humidity should be included in this section.)* |
| 10 | An electronic temperature system can be used to monitor equipment. Documentation must be maintained for such a system and a corrective action procedure in place. |
| 11 | Power sources should be monitored for all temperature equipment and a system in place for outages. |
| 12 | In the event that the temperature reading is outside the permitted range and the problem cannot be rectified immediately, it is the responsibility of the recording laboratory personnel to report this and any other findings to the Lab Manager or Equipment officer immediately. |
| 13 | Corrective action Report should be completed and should include:   * Piece of equipment affected * Items removed/transferred if applicable * New location of items moved * Date and time of the problem * Date and time of the action taken * Date and time the Lab Manager/Equipment Officer was notified * Final resolution of problem. * Initials of staff member taking action |
| 14 | The Laboratory Manager shall assess the reported nonconformity and search for the possible causes. The corrective measures taken shall be recorded in the Corrective Action Report. |

Quality Control:

* All the thermometers used for temperature monitoring should be calibrated against a certified NIST traceable thermometer once per year after maintenance, malfunction or in accordance with manufacturer’s recommendations, whichever is most frequent to ensure the thermometers used in procedures, water baths, incubators, refrigerators and freezers are accurate when compared to a NIST or SANAS traceable thermometer. See the Thermometer Calibration SOP for directions.
* All logs should be reviewed by QA/Charge person on a monthly schedule. All out of range and corrective actions should be documented.

Calculations:

N/A

Expected Values:

Temperature Tolerances:

|  |  |  |
| --- | --- | --- |
| Instrument | Expected Range ◦C | Tolerance ◦C |
| Water bath | +35◦C to 37◦C | ± 2◦C |
| Heating Block | +35◦C to 37◦C | ± 2◦C |
| Refrigerator | + 2◦C to 8◦C | ± 3◦C |
| Freezer ( -20 ◦C) | -15◦C to -25◦C | ± 5◦C |
| Freezer (-70 ◦C) | -60◦C to -80◦C | ±10◦C |
| Room Temperature | +21◦C to 25◦C | ± 2◦C |
| Incubator | +35◦C to 37◦C | ± 2◦C |

Procedure Notes:

* Unacceptable thermometers may be cleaned or serviced and retested. If unable to repair, discard.
* Calibration records should indicate dates of removal or return to service or if thermometer is discarded.
* Thermometers at time of calibration verification should be cleaned and inspected for readability.

Method Limitations:

N/A

**Post-analytic Procedure**

How are Results Prioritized:

N/A

Result Entry into Lab Reporting System:

N/A

Notification of Result to Appropriate Personnel:

N/A

Archiving Results and Report Documents:

* All Thermometer Calibration Verification Record sheets should remain on file as a record, even after the thermometer has been removed permanently from service.
* All Temperature Maintenance logs should be kept on file while equipment is in service and retained indefinitely if used for DAIDS testing.

Specimen Retention:

N/A

**References**:

List sources of information such as instrument manuals that may assist with the procedure.

1. List all relevant references for this procedure. Please always include reference #2. This is where the requirement/suggestions on creating this template can be found.
2. Clinical Laboratory Standards Institute (CLSI). *Clinical Laboratory Technical Procedure Manuals; Fourth Edition*. CLSI Document GP2-A4 (ISBN 1-56238-458-9). Clinical and Laboratory Standards Institute, Wayne, PA

**Appendices***: Attach supporting documents such as package inserts, forms, log sheets or charts. (List any attached Appendices.)*

1. Refrigerator Temperature Log Example
2. Room Temperature and Pressure Log Example

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| **TEMP LOG: REFRIGERATOR RANGE:**  **MODEL: SERIAL NO.:**  **MONTH: YEAR:** | | | | |
| DATE | TEMPERATURE | | **INITALS** | **ACTION TAKEN** |
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| **AMBIENT ROOM TEMPERATURE & PRESSURE LOG** | | | | | |
| **MONTH: YEAR:**  **TEMP. RANGE: PRESSURE MUST BE NEGATIVE!** | | | | | |
| DATE | TEMPERATURE | | **PRESSURE** | **INITIALS** | **ACTION TAKEN** |
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***I acknowledge that I have read, understand and agree to follow this SOP.***

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