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Subject Temperature Monitoring Procedure for HPMG Clinics	**Attachments** ☒ Yes ☐ No
Key words –Min/Max thermometers, QSE 4	**Number** GHI-PC-CLINIC LAB-PROCEDURE-Temperature Monitoring Procedure v. 09-2010
Category Provision of Care	**Effective Date** **September 2009**
Manual HPMG Clinic Laboratory Policy & QA Manual	**Last Review Date** **February 2014**
Issued By Central Laboratory Administration	**Next Review Date** **February 2015**
Applicable Laboratory Technical Consultants, Laboratory Staff	**Origination Date** **October 2007**
	Retired Date
Review Responsibility Laboratory Administration	**Contact** Laboratory Administration

Attachments
Clinic Temperature Log
Well @ Work Temperature Log
Min/Max Thermometer Guide

Purpose/ Principle
This procedure provides instruction for monitoring temperatures for existing or new refrigerators, freezers, incubators, and room temperatures using min/max thermometers or other continuous monitoring system.

Calibration and Maintenance

1. The min/max thermometers are calibrated every two years to standards traceable to NIST. Documentation of calibration verification will be maintained at Central Laboratory. If the min/max thermometer will be used at a different location, a copy will be sent to that location along with the min/max thermometer.
    - A calibration thermometer traceable to NIST will be used to verify thermometer calibrations.
    - Calibrations of all the min/max thermometers will be verified biennially as recommended by the manufacturer.
    - Extra calibrated min/max thermometers for the clinics labs will be kept at the designated clinic.

Procedure – Min/Max Temperature Monitoring

All refrigerators, freezers, incubators, and room temperatures will be monitored with min/max thermometers or other continuous monitoring system. Exceptions are those refrigerators that are for food only.

Clinic laboratories will have the following temperature ranges*:

a. Incubator 34-36 degrees Celsius

b. Refrigerator 2-8 degrees Celsius
c. Freezer (Minimum of -10 degrees Celsius)
d. Ultracold Freezer -65 to -75 degrees Celsius
e. Room 20-25 degrees Celsius

* Temperature range is dependent on the stated reagent requirements.

1. Record the current temperature from the min/max thermometers each day of laboratory operation on the documentation log and **reset.**

2. Record the temperatures after any period of non-hours of operation and **reset**.
   - Document on the temperature logs that during any period of non-hours of operation, the refrigerator, freeze, or incubators remained within the established temperature range.

3. Document on the temperature logs when a refrigerator, freezer, or incubator has been taken out of service and when it has been reinstated.

4. When a temperature exceeds the acceptable range during hours of operation:
   - Recheck and record the temperature approximately every two hours
   - Verify that the Min/Max thermometer is in working order. Erratic readings may indicate problems with the cords, “LL” readings may indicate battery issues.
   - Perform troubleshooting including checking the control panel, checking the door seal. Contact the Laboratory Technical Consultant, Clinic CDS, and building engineer for assistance as necessary.
   - If necessary, contents will be removed and stored in another temperature-controlled location.
   - If normal attempts fail to resolve the problem, repair services will be contacted.
   - The decision to discard reagents, kits, or patient specimens will be made by the Laboratory Technical Consultant.
   - Document all trouble-shooting and the resolution of the problem.

5. Before a refrigerator, freezer, or incubator is put back into service, the unit must have the temperatures monitored to verify the unit is working correctly. See the section below for Temperature Verification of New or Existing Units for more information

6. Corrective action will be documented on the temperature log when temperature monitoring was not performed.

7. Probes or min/max thermometers that are not functioning properly and are not repairable should be discarded.

Min/Max Thermometers

- The Mix/Max probes are identified as “broken” due to broken or frayed wires and cords. These probes need to be disposed of as hazardous chemical through our vendor, Clean Harbors.
- Mark the probes as “broken” and take to the area where the hazardous chemicals are kept for pickup by Clean Harbors.
- The electronic part to the Min/Max Thermometer may be discarded in the regular trash.

Procedure: Temperature Verification of New and Existing Units

This applies to new or existing refrigerators, freezers, and incubators. For new thermometers, follow the Thermometer Calibration Procedure.

1. To verify that new refrigerators, freezer, and incubators are functioning within the intended temperature range, the temperature will be monitored prior to the unit being placed into service and reagents, specimens, and other items are stored within the unit.

2. Place the thermometer on a shelf within the unit and take temperature readings at the following time intervals:
    - 1-2 hours
    - 6-12 hours
    - 12-24 hours

   Record the temperatures on the temperature log.

3. For refrigerators, freezers, and incubators that have been repaired or otherwise taken out of service, the temperature will be verified prior to the unit being placed back into service and reagents, specimens and other items are stored within the unit.
    - Use the temperature monitoring system (min/max) you have established for the refrigerator, freezer, or incubator and record the temperature using the time intervals listed above.

4. Document all temperature readings and indicate when the unit was placed back into service.

Reference Ranges (Expected Values)
See the individual manual log sheet for equipment.

Notification Results Guidelines
- The min/max thermometers record all temperatures, even out-of–range temperatures. Troubleshooting and evaluation will occur when the thermometers are read and an out-of –range event is discovered.

Related Documents
Temperature Calibration Verification Procedure
Temperature Monitoring Policy

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