Admin 117 Temperature and Humidity Quality Control

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Initial version

Approval and Periodic Review Signatures

Type	Description	Date	Version	Performed By	Notes
Approval	Lab Director	4/30/2024	1.0	Ali Mousa Ramadan MD	
Approval	Wendell McMillan approval	4/29/2024	1.0	Wendell McMillan	
Approval	Quality Assurance Manager	4/29/2024	1.0	Lydia Seifu	

Version History

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1.0	Approved and Current	Initial version	4/29/2024	4/30/2024	Indefinite

Non-Technical SOP

Title	**Temperature and Humidity Quality Control**	
Prepared by	Lydia Seifu	Date: 04/29/2024
Owner	Lydia Seifu	Date: 04/29/2024

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1. PURPOSE

This procedure defines the process for manual monitoring of temperature and humidity dependent equipment or spaces.

2. SCOPE

- This procedure applies to thermometers used by the laboratory.
- This procedure applies to refrigerators/freezers containing reagents or patient/client specimens. "Daily" means every day (7 days per week, 52 weeks per year).
- The procedure applies to all temperature dependent equipment (refrigerators, freezers, incubators, water baths, oven and heating blocks) used in the testing process or for the storage of specimens or test reagents.
- Applies to any device or equipment where humidity control is required.

3. RESPONSIBILITY

- The Laboratory staff performing quality control checks must comply with this procedure
- Group Leads perform and document weekly review.
- Section supervisor, manager or designee performs and documents monthly review.

- Lab Manager is responsible for content and review of monthly designee reviews and for this procedure.

4. DEFINITIONS

Alarm – System that emits an audible signal or alert when temperature exceeds defined limits.

Calibrated Thermometer – A NIST (National Institute of Standards and Technology) traceable thermometer or a thermometer that has been calibrated against a NIST thermometer prior to being used.

High/Low recordings – Records the highest and lowest temperature reached during the period monitored.

Laboratory Incubator – Device designed to maintain a constant temperature at or near 37C.

Laboratory Freezer – Freezer capable of reducing and holding temperature at a range that is suitable for the reagents stored within.

Laboratory Refrigerator – Refrigerator capable of reducing and holding temperature at a level that is above the freezing point of water. Used to store reagents, microbiological material, and biological specimens.

Recording thermometer – Records the temperature versus time.

Laboratory Heating Block Incubator – Device that consists of a solid metal block with holes suitable for holding various size test tubes, designed to maintain a constant temperature at or near 37C.

Laboratory Water Baths – Designed to hold water at a constant temperature and used to heat specimens or test samples placed within, as required for certain serological or biochemical reactions.

5. PROCEDURE

A. General Requirements and Information

1. All temperature dependent equipment must have operational temperature monitored and recorded.
2. Temperature must be read and recorded in degrees centigrade.
3. All thermometers must be either NIST traceable or verified against a NIST traceable thermometer.

4. All equipment must have an acceptable temperature range defined, based on the intended use. Reagents, slides, quality controls material, patient specimens and other supplies must be stored at the temperature recommended by the manufacturer.
5. Humidity levels are monitored because some instruments and assays may be affected by humidity fluctuations. The hygrometer must be NIST- certified. Humidity must be read and recorded as percent humidity.

B. Requirements and Acceptance Criteria for Specific Applications

1. Laboratory Refrigerators
   a. The thermometer should be immersed in water or glycerin for stable temperature measurements. The immersion line on the thermometer must be at or below the surface of the liquid used.
   b. The temperature range for most laboratory refrigerators is 2°C to 8°C.

2. Laboratory Freezer
   a. For best results, the bulb should be immersed in antifreeze solution. Do not use expansion fluid thermometers below -35 °C.
   b. Patient specimens, reagents, and controls may be stored in a frost-free freezer only if protected from thawing. Thermal containers within the freezer may be used.
   c. Repeated freeze-thaw cycles contribute to bimolecular degradation and are detrimental to bio specimen quality
   d. It is prudent to avoid freeze-thaw altogether by aliquoting specimens before freezing.

3. Laboratory Heat block/Incubator
   a. In addition to regular or daily monitoring, rotate the thermometer's position/location to ensure that the temperature in each position is monitored twice a year in order to identify "hot spots".
   b. Acceptable temperature range as defined by technical SOP or target temperature ± 1°C.
   c. If reading exceeds the acceptable performance range, the location must be taken out of service by placing tape over the hole or otherwise blocking it.

4. Laboratory Water Bath

   a. Acceptable temperature range as defined by technical SOP or target temperatures ± 1°C.

5. Room temperature in the Laboratory or Supply Storage Areas
   a. Record the room temperature of the Core laboratory area.
   b. Record the room temperature of the areas where temperature-dependent supplies are stored.
   c. Review items stored in each area to determine appropriate range (use the most stringent requirement for items stored).

d. A min/max thermometer is required in areas that are not staffed every day of the week to assure the temperature did not exceed the range since the last recording.

C. Documentation Required

1. The temperature/humidity record must be kept at or near the equipment.
2. The temperature/humidity record must include:
    - Identify of the equipment or area being monitored.
    - Acceptable performance range
    - Date
    - Temperature/humidity reading
    - Tech's initials
    - Corrective action taken when readings exceeds the acceptable limits, impact (e.g. contents of refrigerator) and the acceptable temperature after corrective action was taken
    - Monthly review by supervisor or designee
3. All employees responsible for taking the temperature/humidity reading must be trained in the proper reading of the type of thermometer.

D. Corrective Action

1. If the thermometer liquid has separated causing a break in the column, take the thermometer out of service immediately.
2. Initiate and document appropriate corrective action when the reading exceeds the acceptable performance range. Documentation must include the date and description of corrective action and the reading after corrective action has been performed.
3. Examples of appropriate corrective action listed below:
    a. If the temperature is out of range while recording daily temperature or is discovered during normal use, check for any obvious reasons (door ajar, door open too long, thermostat set incorrectly or unit unplugged) and correct the problem.
    1) Make a note on the reverse side of the log (or at the bottom if space permits) noting the circumstances and what has been done to resolve the out-of-range temperature (notify Facilities by placing a work order on HUH Intranet)
    2) Monitor temperature for an hour, if temperature is still outside of range (for ≥ 5°C then transfer contents of the fridge/freezer into a back-up unit with appropriate storage conditions until the issue has been resolved. If temperature after two hour, is still outside of range (for ≤5°C) then transfer contents of the fridge/freezer into a back-up unit with appropriate storage conditions until the issue has been resolved.
    3) Record the temperature reading after corrective action has been performed.

6. RELATED DOCUMENTS

N/A

7. REFERENCES

N/A

8. ADDENDA AND APPENDICES

N/A