**SUBJECT: Measurement of Temperatures/Humidity, Dependent Areas**

1. **Scope:**
   1. This policy applies to all temperature/humidity dependent areas in the lab and lab related locations. This would include OP draw areas, MOB, CPH, MEDC locations. The lab will also assist in monitoring other specific fridges located in other Grand Lake Health offices. These will be assigned using the electronic software monitoring program.
2. **Policy:**
   1. All temperature/humidity dependent instruments, equipment and spaces in the Laboratory will be checked and temperatures recorded daily, electronically and on manual charts as indicated.
   2. If the temperature reading is out of the acceptable range stated on the documentation form or temperature node, investigate alarm and perform corrective action including adjusting of temperature if needed. Call the Facilities department immediately if the temperature does not correct back in range.
      1. Document temperature range issues in computer log or manual form along with action taken.
      2. Document the actual temperature reading on node or thermometer and the corrective action and when the temp was rechecked with the temperature documented.
   3. All SensoScientific thermometers are to be calibrated against a certified National Institute of Standards and Technology (NIST) traceable thermometer annually to ensure the accuracy of all laboratory thermometers. This will be done by the manufacture through facilities.
   4. Any manual temperature recording not assigned a node will still need to have thermometers calibrated against a certified National Institute of Standards and Technology (NIST) traceable thermometer annually to ensure the accuracy of all laboratory thermometers. These records are kept in a thermometer binder with certificates in the lab. Temps will be documented on paper forms in a daily task binder located in the core lab.
   5. If SensoScientific nodes are not able to be used, traditional manual monitoring shall take place and manual recordings shall be taken and kept on file. NIST thermometers will be used and validated yearly where necessary using a certified thermometer. This is also considered our back up method if necessary.
   6. Data will be reviewed by assigned staff and reports made available as necessary for verification of action items and exceptions are being documented.
3. **Procedure:**
   1. Acceptable refrigerator temperature specification is (2 - 8 degrees C) unless noted on unit or in software. Some blood bank requirements list (1-6 C)
   2. Acceptable room temperature specification (20- 25 degrees C). This should be in rooms with doors that store reagents or supplies that are temperature sensitive.
   3. Acceptable freezer temperature specification can vary from <-5C to -70 degrees Celsius, depending on storage need. Refer to department policy and SensoScientific settings for actual ranges in lab departments.
   4. Cryostat -17 to -230 C. Temperatures are recorded daily Pathology Clerk on the Histology Daily Maintenance Log. Instrument Service will be called if any temperature is outside of specified range.
   5. When temperature dependent areas fall outside the acceptable range:
      1. Document when the condition was identified and act if items need to be moved to stable temperature unit.
      2. Document the action taken to correct the problem.
      3. Document relocation of supplies, etc. to maintain appropriate storage conditions.
      4. Document if reagents could be compromised by labelling them as such and that qc must be verified before they are placed into use.
4. **Thermometer Verification (Manual Method only)**
   1. EQUIPMENT: NIST certified thermometer
   2. PROCEDURE:
      1. To be performed on an annual basis.
      2. List each thermometer in use according to location and use.
      3. Each thermometer is placed simultaneously in the operational temperature with the certified thermometer for an hour.
      4. Read and record the temperature of both thermometers.
      5. If a thermometer fails acceptable performance, the calibration is repeated. In the event a subsequent test demonstrates unacceptable performance, the failed thermometer shall be discarded and replaced.
   3. PROCEDURAL NOTES:
      1. If a thermometer falls slightly outside the temperature range of the certified thermometer, the laboratory thermometer will be calibrated in that operational temperature that most closely resembles the temperature for which it is used.
      2. Proper attention should be given to immersion of thermometer bulbs. There are three types of thermometers: total immersion (bulb + entire liquid column), partial immersion (bulb + specified portion of stem), and complete immersion (entire thermometer).
      3. Locate both thermometers in same area of operating temperature, preferably side by side. Great variability can result if care is not taken. (e.g. one thermometer touches metal shelf of refrigerator and one is suspended in air. One thermometer is measuring air temperature and one shelf temp.)
      4. Broad ranges in temperature should not be calibrated in close succession. A waiting period of 72 hours is recommended to overcome any secular changes in bulb volume caused by temperature extremes.
      5. EXPECTED VALUE: Acceptable performance= + 2 degrees of NIST thermometer
5. **Humidity:**
   1. The Hospital has adopted as policy the ASHRAE industry standards of 20% to 60% effective December 28, 2010.
   2. The lab humidity is documented daily in:
      1. Lab Storeroom, Core Lab, Blood Bank and Micro by 3rd Shift
   3. If humidity falls outside acceptable limits, notify maintenance dept. and document action.
6. **References:**
   1. Clinical Diagnosis & Management by Laboratory Methods, Henry,
   2. "Care and Use of Liquid-in-Glass Laboratory Thermometers", Sidney Ween, ISA Transactions, latest editions.
   3. ACHC standards 03.02.07 Quality control for waived tests.
      1. Standard 05.01.00 Specimen Identification and integrity
      2. Standard 06.02.00 Test Systems.
      3. Standard 06.02.01 Essential Conditions.
      4. Standard 06.02.02 Reagent Labeling and Storage
      5. Standard 08.20.00 Blood and Blood Product Storage.
   4. FDA guidelines for blood and blood products storage are found at 21 CFR 610 and 21 CFR 640

**Policy Approved:**

**Dr. Patrick Feasel**

**Laboratory Medical Director**

**DATE: \_4.19.24\_\_\_\_\_\_\_\_\_\_\_**

**Thomas Geis, MT(ASCP)**

**Laboratory Manager**

**DATE: 4-15-24**