TRAINING UPDATE

Lab Location:	GEC, SGAH & WAH	**Date Distributed:**	1/24/2014
Department:	Technical Staff	**Due Date:**	2/1/2014
		Implementation:	**2/1/2014**

DESCRIPTION OF PROCEDURE REVISION

Name of procedure:

Temperature and Humidity Quality Control
GEC / SGAH / WAH QA.12 v4

Forms:
MIN / MAX Room Temperature Log AG.F180v1
MIN / MAX Humidity Log AG.F181v1

Description of change(s):

SOP changes -
Section 4: Add definition of hygrometer
Section 5: Add requirement to document humidity
Add requirement to document min/max is reset
Add requirement to block hot spots for heat block/incubator

Form changes –
Add column on both forms to document that min/max device was reset
Change humidity acceptable range to 10 - 80% (*humidity look-back only required if it is below 10 or above 80*)

The revised SOP & forms will be implemented on February 1, 2014

Document your compliance with this training update by taking the quiz in the MTS system.

Approved draft for training all sites (version 4)

Non-Technical SOP

Title	**Temperature and Humidity Quality Control**	
Prepared by	Leslie Barrett	Date: 3/19/2009
Owner	Cynthia Bowman-Gholston	Date: 3/19/2009

Laboratory Approval		
Print Name and Title	**Signature**	**Date**
Refer to the electronic signature page for approval and approval dates.		
Local Issue Date:	Local Effective Date:	

Review:		
Print Name	**Signature**	**Date**

Form revised 3/31/00

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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 all thermometers used by the laboratory.
- The procedure applies to all temperature dependent equipment (refrigerators, freezers, incubators, water baths, ovens and heating blocks) used in the testing process or for the storage of specimens or test reagents.
- Applies to any device or environment where humidity control is required.
- This also applies to room temperature where critical to the testing process,
- This SOP is not applicable to test equipment with self-monitoring temperature controlled reaction areas (e.g., automated analyzers). These are verified by on-board systems with function checks that are addressed per manufacturer's protocol.

3. RESPONSIBILITY

- All 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.
- Blood Bank manager prepares a monthly QC summary for review by the Laboratory Director.
- The QA supervisor is responsible for content and review of this procedure.

4. DEFINITIONS

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

Blood Bank Refrigerator – Used to store blood and blood products used for transfusion. Must be capable of controlling temperature between 1C and 6C and be equipped with an alarm system.

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

High/Low recording device – Records the highest and lowest temperature reached during the period monitored. Also referred to as Min/Max thermometer.

Hygrometer – Records the humidity over time.

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, micobiological 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. See procedure Thermometer Selection and Accuracy Verification for details.
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. The thermometer should be situated where it is easily accessible and most likely to demonstrate an adverse temperature.

6. 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.
7. Refer to the Blood Bank manual for more specific procedures for monitoring blood and blood product storage equipment.

B. Requirements and Acceptance Criteria for Specific Applications

1. Blood Bank Refrigerator
   a. The thermometer must be accurate to 1°C in the range of 2°C to 6°C.
   b. All thermometers (including recording chart) must be calibrated annually.
   c. The probe should be in a container of fluid having heat exchange characteristics similar to those of a unit of blood (suggest 10% glycerol in water).
   d. Refrigerator must be maintained at 2°C - 6°C.
   e. Visual and recording thermometers must agree within 2°C of each other.
   f. Temperatures should be monitored continuously when storing blood products. If a continuous monitoring system is not available, temperatures must be monitored at least every 4 hours to ensure products are stored correctly.

2. Blood Bank Freezer
   a. Plasma must be maintained at < -18°C.
   b. Temperatures must be maintained through defrosting cycles if so equipped.
   c. Temperatures should be monitored continuously when storing blood products. If a continuous monitoring system is not available, temperatures must be monitored at least every 4 hours to ensure products are stored correctly.

3. 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. If an item with a tighter storage requirement is stored in the refrigerator, the refrigerator must be controlled to the tighter requirement.

4. Laboratory Freezer
   a. For best results, the bulb should be immersed in antifreeze solution. Do not use expansion fluid thermometers below –35°C.
   b. Review items stored in freezer to determine appropriate range (use the most stringent requirement for items stored). For freezers that maintain temperatures to -65°C, a tolerance limit of ± 2°C is acceptable.

5. 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 a reading exceeds the acceptable performance range, the location must be taken out of service by placing tape over the hole or otherwise blocking it.

6. Laboratory Water bath
   a. Acceptable temperature range as defined by technical SOP or target temperature ± 1°C.

7. 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.

8. Relative Humidity in the core laboratory
   a. Record the relative humidity of the Core laboratory area.
   b. The relative humidity fluctuates in response to the room temperature; humidity limits are specified on the QC form.
   c. The temperature must be taken and recorded concurrent with the humidity.

C. Documentation Requirements

1. The temperature / humidity record must be kept at or near the equipment.

2. The temperature/ humidity record must include:
   - identity of the equipment or area being monitored
   - identity of the thermometer / hygrometer used for monitoring (the identifier must be traceable)
   - acceptable performance range
   - date
   - temperature / humidity reading (both Min and Max required for Min/Max devices)
   - when Reset occurred for Min/Max devices
   - tech's initials or other identifier
   - 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 supervisory review

3. All employees responsible for taking the temperature / humidity reading must be trained in the proper reading of the type of thermometer / hygrometer used.

4. Total / Partial Immersion Thermometer temperatures must be recorded daily. If the temperature cannot be recorded daily, then Min/Max thermometers are required to record out of range temperatures when the department is not staffed.

5. Min/Max Thermometer or Hygrometer:
   - Record both the min/max reading daily unless the department is not staffed.
   - The min/max must be reset daily unless the department is not staffed. If the department is not staffed, the device must be reset the last day worked.
   - When staff returns:
     - Min/max readings are taken and documented on the first working day.
     - There must be documentation indicating that readings did not adversely change from the last time recorded.
     - There must be a means to document that staff were not present when no readings were recorded.

6. Record Review
   - If unacceptable ~~temperatures~~ readings are observed during the month, ensure acceptable corrective actions were taken and recorded. Sign and date record as reviewed.
   - If unacceptable ~~temperatures~~ readings are observed and no corrective actions were taken, determine if any adverse effects have occurred for the items tested on or stored in the equipment and document findings. Sign and date record as reviewed.
   - If gaps occur in the record, the reviewer must determine the cause by interviewing the person responsible for overlooking the ~~temperature~~ monitoring. Documentation must include the cause of the unacceptable ~~temperatures~~ readings and the corrective action taken.

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 ~~temperature~~ reading exceeds the acceptable performance range. Documentation must include the date and description of the corrective action and the ~~temperature~~ reading after corrective action has been performed.

3. Examples of appropriate corrective action are listed below.
   a. If the temperature is out of range while recording daily temperatures 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 temperature/humidity log noting the circumstances and what has been done to resolve the out-of-range temperature (notify biomedical engineering, move the contents to another location, monitor the temperature more frequently, etc. Include tech's identification.)
      2) Monitor the temperature until it returns to the acceptable range.
      3) Record the temperature reading after corrective action has been performed.

b. If the temperature is markedly out of acceptable, **or** the cause of the unacceptable temperature/humidity is not identified, **or** there is a power failure, **or** the circulating fan stops or some other type of malfunction
   1) Notify service personnel and the supervisor/designee immediately (if it requires immediate attention)
   2) Transfer the supplies to another refrigerator/freezer. Attach signage to the refrigerator/freezer describing the temporary location of the supplies that have been moved.
   3) Make a note on the reverse side of the temperature recording log noting the circumstances and what has been done to resolve the out-of-range situation, include tech's initials.
   4) Take the device out of service and/or use an alternate device.
   5) When the problem is resolved and the temperature/humidity returns to the acceptable range, return the supplies to the original refrigerator/freezer or put the device back in use. Documentation must include date and time of return to service.

c. If the humidity reading is outside of the acceptable range, refer to the SOP Humidity Look Back for the corrective action process.

d. Supplies that may be unusable due to improper storage
   1) If the temperature has been out-of-range for an undetermined amount of time and the contents have been stored outside their recommended temperature, then the contents of the refrigerator/freezer/storage area must be quarantined until it can be determined if they have deteriorated.
   2) The supervisor/designee will determine when and if the contents can be used.
   3) If supplies/products are deemed suitable for use, documentation must include the basis for that determination.
   4) If supplies/products are unsuitable for use, they must be discarded. Documentation must include products and quantities discarded.

6. RELATED DOCUMENTS

Technical procedure manuals
Temperature recording logs
Thermometer Selection and Accuracy Verification, QA procedure
Humidity Look Back, Chemistry procedure
Humidity Validation for Adventist Laboratories

7. REFERENCES

- Policy for Monitoring Temperature Dependent Equipment, Quality Assurance Best Practice, QDNQ704
- College of American Pathologist Lab General Inspection and Department Specific Checklists (most current version)
- AABB Standards for Blood Banks and Transfusion Services, 26th edition, 2009.

Form revised 3/31/00

8. REVISION HISTORY

Version	Date	Reason for Revision	Revised By	Approved By
		Supersedes SOPs LIS045.001, LIS046.001, L050.000		
000	3/22/2010	Section 5: Item A.3 added reference to Thermometer SOP; Item B.1 lower range for BB refrigerator changed to 2°C Section 6: added Thermometer SOP Section 7: updated references	L. Barrett	C. Bowman
001	4/21/2011	Section 5: Added corrective action for failed humidity (item D.3.c).	C Bowman	C. Bowman
002	2/11/2013	Section 5: Add min/max thermometer (item B.7.d), Edit corrective action for failed humidity (item D.3.c). Section 6: Add Humidity Look Back SOP	L. Barrett	C. Bowman
003		Section 4: Add hygrometer Section 5: Add humidity and min/max reset to documentation requirements. Add requirement to block hot spots for heat block/incubator Section 6: Add humidity validation Footer: version # leading zero's dropped due to new EDCS in use as of 10/7/13.	L. Barrett	C. Bowman

9. ADDENDA AND APPENDICES

None

Form revised 3/31/00

☐ Shady Grove Adventist Hospital
☐ Washington Adventist Hospital
☐ Germantown Emergency Center

MIN / MAX ROOM TEMPERATURE LOG

Area / ID: _____ **Location:** _____ **Year** _____
Thermometer ID: _____ **Acceptable range:** 20 - 25C

Interp: S = satisfactory, temp w/in acceptable range
U = unsatisfactory, circle result and document corrective action; notify supervisor/Tech Incharge immediately.
Complete Variance form. Additional corrective action should be documented on the back of the sheet.
Check Reset box to document device is reset daily

Month _____

Date	Min	Max	Interp	Reset	Tech	Corrective action	Weekly review
1							
2							
3							
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6							
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Monthly review: Date:

Month _____

Date	Min	Max	Interp	Reset	Tech	Corrective action	Weekly review
1							
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Monthly review: Date:

Corrective Action Codes:

A. Rechecked temperature *(Log repeat temperature)*
B. Adjusted Thermostat *(Retake temperature in 1 hour)*
C. Contacted Plant Ops / Facilities
D. Affected contents relocated
E. Contents quarantined pending evaluation
F. Other: *(Document on reverse side of this sheet)*

☐ Shady Grove Adventist Hospital
☐ Washington Adventist Hospital
☐ Germantown Emergency Center

MIN / MAX HUMIDITY LOG

Area / ID: _____ **Location:** _____ **Year** _____

Hygrometer ID: _____ **Acceptable range:** 10 - 80%

Interp: S = satisfactory, humidity w/in acceptable range
U = unsatisfactory, circle result and document corrective action; notify supervisor/Tech Incharge immediately.
Complete Variance form. Additional corrective action should be documented on the back of the sheet.
Check Reset box to document device is reset daily

Month _____

Date	Min	Max	Interp	Reset	Tech	Corrective action	Weekly review
1							
2							
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Monthly review: _____ Date: _____

Month _____

Date	Min	Max	Interp	Reset	Tech	Corrective action	Weekly review
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Monthly review: _____ Date: _____

Corrective Action Codes:

A. Rechecked *(Log repeat humidity)*
B. Contacted Plant Ops / Facilities
C. Affected contents relocated
D. Contents quarantined pending evaluation
E. Other: *(Document on reverse side of this sheet)*