TRAINING UPDATE

Lab Location:GEC, SGAH & WAHDepartment:Lab Mgmt, QA & Tech Specialist

 Date Distributed:
 1/28/2014

 Due Date:
 2/15/2014

 Implementation:
 2/15/2014

DESCRIPTION OF PROCEDURE REVISION

Name of procedure:

Thermometer Selection and Accuracy Verification GEC / SGAH/ WAH.QA31 v2

Forms:

Thermometer Accuracy Verification Log AG.F93v1 Thermometer / Hygrometer Inventory Log AG.F92v1

Description of change(s):

SOP:

Change terminology from 'calibrated / calibration' to 'certified / verification'. Reformat section 5.B

Forms:

Change title and add space for hygrometers on Thermometer / Hygrometer Inventory Log

Change title of Thermometer Accuracy Verification Log (was Thermometer Calibration Log)

This revised SOP will be implemented on March 1, 2014

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

Non-Technical SOP

Approved draft for training all sites (version 2)

Title	Thermometer Selection and Accuracy Verification					
Prepared by	Leslie Barrett	Date: 3/22/2010				
Owner	Cynthia Bowman-Gholston	Date: 3/22/2010				

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

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1. PURPOSE

This procedure defines the process for thermometer selection and accuracy verification.

2. SCOPE

This procedure applies to all Laboratory areas in which thermometers are used.

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**

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

NIST-Certified Thermometer: A thermometer certified by the NIST (National Institute of Standards and Technology).

NIST-Traceable Thermometer: A thermometer guaranteed by the manufacturer to meet NIST standards or be traceable to a NIST thermometer.

Non-Certified Thermometer: A thermometer that has not been certified by NIST. calibrated against a NIST Certified Thermometer.

5. **PROCEDURE**

- A. General Requirements
 - 1. All thermometers must be either NIST traceable or calibrated certified against a NIST traceable thermometer.
 - a. When possible Temp-Chex thermometers are utilized. These thermometers have a certificate of accuracy documenting comparison with a standard calibrated at NIST.
 - b. Non-certified thermometers are calibrated verified for accuracy prior to initial use.
 - 2. NIST Certified and traceable thermometers may be put into service immediately, provided the thermometer is labeled with the expiration date of certification. If not labeled as such by the vendor, then attach a label with the expiration date.
 - 3. Documentation of certification and/or verification must be maintained for the life of the thermometer.
 - 4. All thermometers in use are calibrated verified for accuracy annually against a NIST traceable thermometer.
 - 5. Each thermometer must be uniquely identified by an engraved serial number (ideally) or some type of durable label utilizing a lab specific numbering system.
 - 6. Each department must maintain an inventory of each thermometer and serial number along with the location used. The inventory must indicate the disposition of broken thermometers or thermometers which fail calibration verification.
 - 7. Temperature dependent equipment having audible and/or visual alarm systems must have alarm function checks performed when installed and at least semi-annually thereafter to ensure they remain in working condition.
 - 8. Blood Bank regulations have different requirements. Refer to section specific procedures.
- B. Thermometer Selection
 - 1. Liquid Expansion (Liquid-In-Glass):
 - Mercury Filled: Policy is to not use mercury filled thermometers.
 - Alcohol Filled: Maximum usable range of -75C to 120C.
 - Total Immersion: The thermometer must be located completely in the environment being monitored (i.e. entirely in the temperature dependent equipment like a refrigerator or freezer). Not recommended for use with heat blocks or water baths.
 - Partial Immersion: The thermometer must be immersed in the environment or solution up to the line indicated on the barrel of the

thermometer that corresponds to the immersion length (the distance from the tip of the bulb to the line on the barrel).

- 2. Thermocouple / Digital Thermometer:
 - Min/Max thermometers are the thermometers of choice for most applications.
 - The following criteria are used in selecting a thermocouple:
 - Temperature Range
 - Chemical resistance of the thermocouple or sheath material
 - Abrasion and vibration resistance
 - Installation requirement (compatibility with existing equipment, e.g., existing holes may determine probe diameter)
- C. Accuracy Check for Non-certified Thermometers and/or Thermometers with expired certification
 - 1. Verify each thermometer for accuracy at the temperature for which it will be used and compare to a NIST certified or traceable thermometer.
 - a. Place the thermometer(s) to be tested and the NIST certified or traceable thermometer, side by side, in a controlled environment (e.g. freezer, incubator, and ice bath) for 10-15 minutes.
 - b. Read and record the temperature of the certified thermometer and the thermometer (s) being tested.
 - 2. Acceptance Criteria
 - a. All thermometers must measure within 1 degree of the NIST certified thermometer.
 - b. If certain test procedures require more stringent performance criteria, thermometers for those procedures must document acceptable performance meeting those criteria.
 - 3. Corrective Action
 - a. If the new thermometer does not meet established criteria, it is to be returned to the manufacturer.
 - b. Existing thermometers that do not meet established criteria must be discarded and replaced with ones that meet specifications as described in section A.
 - c. Document disposition on the Inventory Log.
 - 4. Frequency

Before being placed into service and annually thereafter

- 5. Documentation
 - a. The record must include
 - ID of the thermometer being checked (Test thermometer)
 - ID of the certified thermometer (NIST traceable thermometer)
 - Temperature readings of the thermometer being verified and the certified thermometer
 - Variance observed

- Acceptability criteria (tolerance limit)
- Indication of acceptability
- ID of person performing verification
- Date performed
- Supervisory review
- Corrective Action if verification fails
- b. Attach a tag to the top of the thermometer and label with the verification date, temperature at which it was calibrated, any variation from the reference thermometer, and tech initials.
- c. Corrective action
 - If the thermometer liquid has separated causing a break in the column, take the thermometer out of service immediately.
 - If the thermometer readings are outside the tolerance limits, remove from service and notify supervisor or lead tech.
 - Any thermometer removed from service should be replaced by another properly verified or a certified thermometer. Update the Inventory Log for each thermometer affected.
- D. Broken Thermometers
 - 1. Update the Inventory Log for the appropriate thermometer (column Broken & Discarded) to include date and tech identification. Discard the thermometer by placing into a sharps container.
 - 2. Place another appropriate thermometer into the device (refrigerator, freezer, etc.) and update Inventory Log to reflect new placement of that thermometer.

6. **RELATED DOCUMENTS**

Temperature and Humidity Quality Control, QA procedure Thermometer Accuracy Verification Log (AG.F93) Thermometer / Hygrometer Inventory Log (AG.F92)

7. **REFERENCES**

- Policy for Thermometer Selection and Accuracy Verification, Quality Assurance Best Practice, QDNQ703
- College of American Pathologist Lab General Inspection and Department Specific Checklists (most current version)

8. **REVISION HISTORY**

Version	Date	Reason for Revision	Revised By	Approved By
000	5/12/2011	Section 5: add requirement for annual calibration,	L. Barrett	C. Bowman
		calibrate at temperature of use, label thermometer		
		with certification expiration date or calibration data		

001	Section 5: change terminology from 'calibrated / calibration' to 'certified / verification'. Reformat	L. Barrett	C. Bowman
	section B		
	Section 6: move forms from section 9		
	Footer: version # leading zero's dropped due to new		
	EDCS in use as of $10/7/13$.		

9. ADDENDA AND APPENDICES None



THERMOMETER / HYGROMETER INVENTORY LOG

□ Germantown Emergency Center

□ Shady Grove Adventist Hospital

Washington Adventist Hospital

Thermometer	Thermometer Certified		Domas	Placed in Service				Broken / Discarded	
Serial #	Lot #	Y/N	Range	Date	Tech	Location	Date	Tech	
							+		
							+		
							+		
							+		
							+		
							+		
							+		
							+		
		+					+		
		+					+		
							+		
TT	TT	Contif			DI	1. 0			
Hygrometer	Hygrometer	Certif.	Range	Placed in Service		Broken / I	-		
Serial #	Lot #	Expiration	0	Date	Tech	Location	Date	Tech	
				ļ					
									

All non-certified thermometers **must** be verified before being placed into service

All hygrometers **must** have an indate certification. Replace before expiration date.

Reviewed by:_____



□ Germantown Emergency Center

□ Shady Grove Adventist Hospital

□ Washington Adventist Hospital

Test Thermometer	NIST-Traceable	Thermometer	NIST-Traceable					
Serial # or	Thermometer	Temperature	Thermometer	Variance	Acceptable?	Corrective Action	Tech	Date
Unique ID	Serial #	Reading	Temp Reading		Y/N			
-		0						

THERMOMETER ACCURACY VERIFICATION LOG

Tolerance Limits = +/-1 degree

Reviewed by:_____ Date: _____