



STANDARD OPERATING PROCEDURE

Indiana CTSI Specimen Storage Facility

TITLE: STANDARD OPERATING PROCEDURE FOR THERMOMETERS

CHAPTER: 3-Equipment

SOP #: SF-3-7.04

SUPERSEDES SOP #: N/A

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DATE: 7-13-15

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DATE: 13 Jul 2015

See memo to file dated 05 MAR 2015. RD 13 JUL 2015

QA APPROVAL: *[Signature]*

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DATE: 07.13.15

1. REVISION

1.1. Significant changes incorporated in this version include

- 1.1.1. Added distinction between NIST-traceable and non-NIST traceable thermometers in section 3.1.
- 1.1.2. Revised Materials section to include description of batteries needed.
- 1.1.3. Total re-organization of SOP content to improve process flow and ease of use.
- 1.1.4. Revised Appendices A, B and C for process improvement
- 1.1.5. Removed calibration directives from routine procedure and moved these instructions to Appendix D1. Revised Section 9.1 and added Appendix D1 and D2 accordingly.

2. PURPOSE

2.1. This Standard Operating Procedure (SOP) defines the procedures used in the Indiana CTSI Specimen Storage Facility (SSF) to maintain and monitor all thermometers used in the SSF and ensure that temperature readings are accurate. This procedure satisfies guidance set forth in ISBER.

3. PRINCIPLE

3.1. Storage temperature is defined as a critical parameter for storing biorepository specimens. It is the responsibility of the SSF to ensure that the temperature is accurately measured. NIST traceable devices are devices that have been calibrated by the manufacturer or calibration company with calibration certified to be NIST-traceable and documented as such on a certificate of calibration. NIST-traceable devices do not require annual calibration re-certification by SSF personnel. Non-NIST traceable devices do not come with certificates of calibration and the calibration of these devices must be verified by SSF personnel annually against a NIST-traceable device. The SSF strives to utilize only NIST traceable devices with up-to-date certificates of calibration unless it is otherwise not possible to do so.

4. SCOPE

- 4.1. This SOP applies to personnel operating and maintaining the thermometers used in the SSF to monitor critical storage environments. This SOP describes the process for assuring that all thermometers are traceable to NIST standards and incorporates an NIST-Traceable Thermometer as the temperature device to confirm accuracy of the SSF thermometers that are not otherwise NIST traceable.

5. MATERIALS

- 5.1. Thermometers and thermocouples with detachable probes identified with a manufacturer-provided Serial Number and a corresponding NIST-Traceable Certificate of Calibration (NIST Traceable).
 - 5.1.1. A Type T probe is used with the -196°C freezers and warmer. The NIST glass bottle probe is used for room and water bath temperature monitoring.
- 5.2. Thermometers which do not have an NIST-traceable certificate of calibration and which must be compared to an NIST traceable thermometer to confirm calibration.
 - 5.2.1. Non-NIST thermometers could be liquid-in-glass or digital.
- 5.3. Standard grade AA batteries (three)
- 5.4. 1.5 volt G-13 batteries (one).

6. PROCEDURE

6.1. Ordering Thermometers/Probes

- 6.1.1. Contact PCI Calibration Company (www.pci-llc.com) or another approved vendor to order NIST-traceable thermometers/probes. A Calibration Certificate must be included with the NIST-traceable unit upon receipt. Review the calibration certificate to ensure that the S/N listed on the certificate matches the S/N of the unit received and that the calibration due date meets the expected requirements. If the calibration certificate is not included or is unacceptable for any reason, contact the vendor for resolution.
- 6.1.2. Non-NIST units are ordered from an approved vendor.

6.2. Receipt of Thermometers/Probes

- 6.2.1. **NIST-traceable thermometers/Probes:** Receive and document (Appendix A: SSF Thermometer Maintenance Log) NIST traceable thermometers and probes (if applicable) used in the SSF as follows. Record one thermometer and probe (if applicable) per form.
 - 6.2.1.1. Assign an SSF Identification to all thermometers: SF-NN where NN is chronological and a number is not re-used if the unit is taken out of service. Assign an SSF Identification to all probes: SF-NNP where NN is chronological and a number is not re-used if the unit is taken out of service. P represents Probe.
 - 6.2.1.2. Label each thermometer and probe with the assigned SSF ID, certification expiration date, and calibration range.
 - 6.2.1.3. Record thermometer and probe (if applicable) information as requested on Appendix A.
 - 6.2.1.4. Date in service is defined as the date the certificate is reviewed and considered satisfactory. If no certificate is received, contact the vendor for resolution.
 - 6.2.1.5. Current calibration due date and calibrated temperature range are located on the calibration certificate. If no certificate is received, contact the vendor for resolution.
 - 6.2.1.6. Select yes that service document and/or calibration certificate is received.
 - 6.2.1.7. If calibration certificate is received, send copies to QA.

6.2.1.8. If calibration certificate was not received, contact the vendor. Do NOT use the thermometer until calibration certificate has been received.

6.2.2. **Non-NIST-traceable thermometers/probes:** Receive and document (Appendix A: SSF Thermometer Maintenance Log) non-NIST traceable thermometers and probes used in the SSF as follows. Record one thermometer and probe (if applicable) per form.

6.2.2.1. Assign an SSF Identification to all thermometers: SF-NN where NN is chronological and a number is not re-used if the unit is taken out of service. Assign an SSF Identification to all probes: SF-NNP where NN is chronological and a number is not re-used if the unit is taken out of service. P represents Probe.

6.2.2.2. Record thermometer information as requested on Appendix A.

6.2.2.3. Date in service is defined as the completion date of a successful calibration verification (refer to section 6.5 for instructions).

6.2.2.4. Current calibration due date is one year from the completion date of the calibration verification. The calibrated temperature range is determined by the temperatures used for the calibration verification.

6.2.2.5. Select “N/A” that service document and/or calibration certificate was not received.

6.3. Thermometer Usage Log

6.3.1. Document usage of all SSF Thermometers/probes on the SSF Thermometer Usage Log (Appendix B) by following the steps listed below. Clarification: **If a thermometer is to be used for room temperature monitoring or any continuous monitoring in a permanent location, an entry must still be made on Appendix B.**

6.3.2. Ensure that the thermometer/probe does not have an expired calibration due date and document on Appendix B.

6.3.2.1. Units with expired calibration dates are removed from service immediately if a replacement unit is available. Document date out of service on Appendix A.

6.3.2.2. When a replacement unit is not available, keep expired unit in service until a replacement is obtained. Document as deviation per SF-1-9 and complete the thermometer calibration verification per section 6.7.

6.3.3. Ensure that the thermometer has an acceptable calibrated temperature range for the desired task and document on Appendix B.

6.3.3.1. If thermometer does not have acceptable calibrated temperature range, use a thermometer calibrated for the appropriate range.

6.3.4. Record the SSF Assigned ID for the thermometer and probe (as applicable) which was assigned as described in sections 6.2.1 and 6.2.2.

6.3.5. Record the date on which the thermometer was used. Alternatively, record the date on which the unit was initially placed for the purpose of providing continuous monitoring.

6.3.6. Record initials of technician using thermometer or placing the unit in the location for the purpose of providing continuous monitoring.

6.3.7. Record the location where the thermometer was used.

6.3.8. In the “Freezer ID w/SN” column, record or place labels denoting the freezer ID and serial number of the applicable freezer. If thermometer is for monitoring

room temperature or any other continuous monitoring in a permanent location, record NA in this column.

- 6.3.9. Select the reason for using the thermometer. If the reason is “Other”, describe in the comment section. For example, if the thermometer is used for room temperature monitoring, record the room ID where the thermometer will be used in the location column and note in the comment section that the reason is room temperature monitoring.
- 6.3.10. Each page is reviewed by SSF management after completion and retained in the SSF Management office.

6.4. Operation

Note: The operation of two specific types of thermometers/thermocouples is described below. The SSF is not limited to these two types of thermometers. If additional units are deemed acceptable for use, the SSF may utilize these units while referencing the respective user manuals supplied with the devices until such time as a description of the operation can be added to this SOP at the time of the next SOP revision.

- 6.4.1. Cole-Parmer Oakton Thermocouple NIST-Traceable Thermometer with Type T Probe
 - 6.4.1.1. Thermocouples and probes are very fragile. If the delicate wires in the probes become loose, frayed, or broken, they generally cannot be repaired and must be replaced. Handle with care.
 - 6.4.1.2. Ensure that the probe (calibrated with the thermometer) is plugged into the thermometer before use.
 - 6.4.1.3. It is optional to deactivate the auto off function by pressing and holding the “min/max” and “on/off light” button at the same time. “A. OFF nO” will appear on the screen indicating that the auto off function is disabled. At this point the thermometer should be on.
 - 6.4.1.4. Be sure the temperature scale is set to °C. If not, press the button labeled “°C/°F” to change it to °C.
 - 6.4.1.5. Place probe in desired temperature environment.
 - 6.4.1.6. Once task is complete, remove probe from temperature environment.
 - 6.4.1.7. Turn off thermometer by pressing and holding the “on/off light” button.
- 6.4.2. Control Company NIST Traceable Sentry Thermometer Glass Bottle Probe
 - 6.4.2.1. Prior to initial use, remove the insulating tape from the battery compartment.
 - 6.4.2.2. If use of detachable probe is necessary, plug the probe into the jack on the side of the unit.
 - 6.4.2.3. Press the RESET button once to update the probe temperature displayed on screen.
 - 6.4.2.4. Screen will display current probe temperature, minimum, and maximum temperatures.
 - 6.4.2.5. If thermometer is to be used for room temperature, the probe is not necessary.
 - 6.4.2.6. Press the RESET button on the thermometer to display an updated ambient temperature reading.
 - 6.4.2.7. The screen will show the current ambient temperature, minimum, and maximum temperatures.

6.5. Calibration/Inspection

6.5.1. Routine Calibration of NIST-traceable thermometers and probes:

- 6.5.1.1. Have digital NIST-traceable thermometers calibrated bi-annually on or before the expiration date listed on the current certificate. Document this event on Appendix A per Section 6.2.1. (Completion of the Out-of-Specification investigation is not required).

NOTE: Any probes to be used with a specific thermometer MUST be sent in to the calibration company with the thermometer and be calibrated together. There should be a separate certificate each for the thermometer by itself as well as the thermometer and probe combination/s.

- 6.5.1.1.1. Access the calibration company's website per Appendix C.
- 6.5.1.1.2. Contact the calibration company to request quote for calibration and ship unit to PCI or other approved calibration company.
 - 6.5.1.1.2.1. Be sure to specify the thermometer brand, probe type, the requested calibration temperature range, request "As-found"/"As-left" calibration data, the length of calibration period desired, and indicate if there are any probes to be calibrated with the thermometer.
- 6.5.1.1.3. Package and ship NIST thermometer per Appendix C.
- 6.5.1.1.4. The calibration company returns the NIST thermometer with a NIST Traceable Certificate of Calibration.
 - 6.5.1.1.4.1. If a calibration certificate is not received, contact the calibration company and request the certificate.
 - 6.5.1.1.4.2. Upon receipt, verify that the calibration certificate includes the information requested in step 6.5.1.1.2.1. If any requested information is missing contact the calibration company. Record actions and results on Appendix C.
- 6.5.1.2. Record results and actions in Appendix C. After reviewing the calibration certificate, if "As Found" values are out- of- specification, notify SSF Director and initiate an OOS investigation per SF1-10. Alternatively, thermometers/probes may be discarded if past their calibration due date or when it is determined appropriate to do so.
 - 6.5.1.2.1. If thermometers and/ or probes are discarded, retire the assigned SSF ID for the thermometers and/or probes and do not re-use numbers. Document rationale for taking out-of-service on Appendix A.

- 6.5.2. Non-NIST traceable thermometers are not calibrated, but the calibration is verified at time of receipt using the Thermometer Calibration Verification AppendixD1/D2. Re-calibration for Non-NIST traceable thermometers is due one year from the date of the last successful calibration.

- 6.5.2.1. Additionally, Column/Glass Thermometers are visually inspected annually. The annual re-calibration is due one year from the date the

Thermometer Calibration Verification and inspection was completed. Record results and actions taken on Appendix A and Appendix B.

- 6.5.3. Non-routine Calibration of NIST-traceable thermometers and probes (performed if the calibration period for an NIST thermometer/probe has expired (and use of the unit is critical) or for any other approved reason.
- 6.5.4. Perform calibration as indicated in Appendix D1. Document unit as being Out-of-Service on Appendix A and document results of calibration on Appendix D2.
- 6.5.5. As soon as possible, submit unit for NIST calibration procedure as described in section 6.5.1

6.6. Cleaning

- 6.6.1. Only clean with a damp cloth. Do not clean with abrasives or solvents. Use mild detergents, never immerse or use excessive fluid.

6.7. Maintenance

- 6.7.1. Routine Maintenance: as indicated by low-battery indicators on units, or as needed, change batteries as follows:
 - 6.7.1.1. Cole-Parmer Oakton Thermocouple Thermometer Type T
 - 6.7.1.1.1. Ensure the thermometer is off and probe is removed.
 - 6.7.1.1.2. Loosen screw to remove battery cover from the back of case.
 - 6.7.1.1.3. Remove the three AA batteries.
 - 6.7.1.1.4. Insert new batteries.
 - 6.7.1.1.5. Screw cover on to back of thermometer.
 - 6.7.1.2. Control Company Traceable Sentry Thermometer
 - 6.7.1.3. Unscrew the round battery cover on the back of thermometer.
 - 6.7.1.4. Remove battery.
 - 6.7.1.5. Replace with a new 1.5 volt, G-13 size battery.
 - 6.7.1.6. Replace the battery cover.
- 6.7.2. Non-routine Maintenance: For all thermometers: If unit is not operating properly:
 - 6.7.2.1. Take out of Service. Record date and reason for removing unit from service on Appendix A. Also complete information on Appendix C if unit is NIST traceable. If unit being sent for repair is NIST-traceable, request that the unit be calibrated. Complete an Out-of-Specification per SF 1-10.
 - 6.7.2.1.1. If unit is non-NIST traceable, actions must be recorded on Appendix A. Actions are not to be recorded on Appendix C, since re-calibration will not be requested. Upon receipt of the non-NIST unit returning to the SSF facility, calibration verification must be completed to ensure unit is still functioning properly.
 - 6.7.2.2. Refer to outside vendor for repair or calibration, or destroy the unit.
 - 6.7.2.3. If unit is returned to service, record the following on Appendix A:
 - 6.7.2.3.1. Date returned to facility
 - 6.7.2.3.2. Indicate if service and/or calibration certificate was received
 - 6.7.2.3.3. Record date in service

- 6.7.2.3.4. Attach service and/or calibration certificate to Appendix A if received.
- 6.7.2.3.5. Send a copy of the new certificate or the calibration verification worksheet (Appendix D2) to QA and document on Appendix A.
- 6.7.2.4. If unit is not returned to service, record “N/A” on Appendix A and document an explanation in the comment section. Retire the SSF Assigned ID for the thermometer and/or probe and do not re-use the number.

7. REFERENCES

- 7.1. ISBER Best Practices (current version)
- 7.2. Cole-Parmer Thermocouple Thermometer Type J, K, T User Manual
- 7.3. Control Company Traceable Sentry Thermometer User Manual

8. DOCUMENTATION

- 8.1. Documents are reviewed annually by SSF Management.
- 8.2. NIST Traceability calibration certificates of conformance are maintained with the SSF Thermometer Maintenance Log (Appendix A).
- 8.3. Records of annual thermometer calibration verification are maintained per SF-1-6 Controlled Document Management SOP.
- 8.4. OOS results are documented as defined in SF-1-10 SOP For OOS Response and Management.
- 8.5. Deviations are managed per SF-1-9 Deviation Management SOP.

9. APPENDICES

- 9.1. The current version of each of the following appendices is used to guide and/or implement this SOP:
 - APPENDIX A: SSF Thermometer Maintenance Log (1 Page)
 - APPENDIX B: SSF Thermometer Usage Log (1 Page)
 - APPENDIX C: Calibration of the NIST Thermometer Form (1 Page)
 - APPENDIX D1: Thermometer Calibration Verification Instructions (2 Pages)
 - APPENDIX D2: Thermometer Calibration Verification Worksheet (2 Pages)

SSF Thermometer Maintenance LogNIST Traceable Thermometer: ☐ Yes ☐ NoAdditional sheets attached? ☐ Yes ☐ No

SSF ID # (Include ID for Probe if applicable)	Manufacturer	Model	S/N	Type (Digital vs. Column)	NIST Traceable (calibration certificate received)?	Operating Range of Unit (From Mfg. supplied information)	Calibrated Temp. Range (from certificate)	New Certificate sent to QA, if applicable? (Y or N or NA)
Thermometer					<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A			<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> NA
Probe					<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A			<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> NA
Comments								

		Service Record					
Date in Service	Current Calibration Due Date	Date Out of Service	Reason Unit is Out of Service	Date Returned (if applicable)	Service document and/or calibration certificate received (yes or no)	New Certificate or Appendix D2 sent to QA? (Y or N)	Comments

SSF Thermometer Location Usage Log

Year: _____

Page ____ of ____

SSF ID # (include ID for Probe if applicable)

Is Calibration Due Date After Today's Date? (Y=Yes) (N=No)	Calibrated Temp Range Acceptable (Y=Yes) (N=No)	Date Used	Used By	Location	Freezer ID w/ SN	Reason	Comment
Y N	Y N					<input type="checkbox"/> SSF MRU Quarterly <input type="checkbox"/> SSF LN2 Annual <input type="checkbox"/> Other <i>(Describe)</i>	
Y N	Y N					<input type="checkbox"/> SSF MRU Quarterly <input type="checkbox"/> SSF LN2 Annual <input type="checkbox"/> Other <i>(Describe)</i>	
Y N	Y N					<input type="checkbox"/> SSF MRU Quarterly <input type="checkbox"/> SSF LN2 Annual <input type="checkbox"/> Other <i>(Describe)</i>	
Y N	Y N					<input type="checkbox"/> SSF MRU Quarterly <input type="checkbox"/> SSF LN2 Annual <input type="checkbox"/> Other <i>(Describe)</i>	
Y N	Y N					<input type="checkbox"/> SSF MRU Quarterly <input type="checkbox"/> SSF LN2 Annual <input type="checkbox"/> Other <i>(Describe)</i>	
Y N	Y N					<input type="checkbox"/> SSF MRU Quarterly <input type="checkbox"/> SSF LN2 Annual <input type="checkbox"/> Other <i>(Describe)</i>	
Y N	Y N					<input type="checkbox"/> SSF MRU Quarterly <input type="checkbox"/> SSF LN2 Annual <input type="checkbox"/> Other <i>(Describe)</i>	
Y N	Y N					<input type="checkbox"/> SSF MRU Quarterly <input type="checkbox"/> SSF LN2 Annual <input type="checkbox"/> Other <i>(Describe)</i>	
Y N	Y N					<input type="checkbox"/> SSF MRU Quarterly <input type="checkbox"/> SSF LN2 Annual <input type="checkbox"/> Other <i>(Describe)</i>	

Reviewed By: _____

NIST-Traceable Unit Calibration Form☐* Calibration Company:

PCI

8100 Brownleigh Dr., Suite 100-A

Raleigh, NC 27617

1-877-724-2257

www.pci-llc.com☐Other Approved Calibration Company:

1) Provide the following information to the calibration company prior to shipping the device:

- a. Thermometer brand
- b. Requested calibrated temperature range
- c. Length of calibration (2 years or other approved time frame)
- d. Probes to be calibrated with thermometer.

2) Complete the items below as applicable for unit calibration.

3) *If listed Calibration Company is unable to perform the desired calibration, consult the SSF Director for directives. Document all actions on this form.

4) Retain this form in the SSF and complete Part II of this table upon receipt of until after calibration

Part I: Prior to shipment		
SSF Assigned ID and S/N (include probe ID if applicable):		
Thermometer SSF ID & S/N:	Probe SSF ID:	
Item	Requirements	Initials/Date
Desired Calibrated Temperature Range	_____ °C to _____ °C	
Requested Calibration Period	<input type="checkbox"/> 2 Years <input type="checkbox"/> Other (List)	
As Found / As Left Measurements Requested	<input type="checkbox"/> Yes <input type="checkbox"/> No	
Date Thermometer Shipped		
Date Estimate Received		
Part II: Upon Receipt		
Thermometer SSF ID & S/N:	Probe SSF ID:	
Item	Requirements	Initials/Date
Date Received		
Calibration Certificate Received	<input type="checkbox"/> Yes <input type="checkbox"/> No** <small>**request certificate from calibration company</small>	
S/N of all units received match S/N of units sent	<input type="checkbox"/> Yes <input type="checkbox"/> No	
Calibrated Temperature Range as desired	<input type="checkbox"/> Yes <input type="checkbox"/> No	
As-Found / As-Left Values Available on Certificate	<input type="checkbox"/> Yes <input type="checkbox"/> No	
Calibration Period as requested	<input type="checkbox"/> Yes <input type="checkbox"/> No	
As-Found / As-Left Values Meet Acceptance Criteria	<input type="checkbox"/> Yes <input type="checkbox"/> No	
Calibration Certificate Sent to QA	<input type="checkbox"/> Yes <input type="checkbox"/> No	
Comments:		

Procedure for performing calibration of Thermometers

(See SOP sections 6.5.2 and 6.5.3 for description of when to use this procedure)

1. Record information on the Thermometer Calibration Verification Worksheet, on Appendix D2 as follows:
 - 1.1. Preliminary Information Section:
 - 1.1.1. Thermometer ID defines the specific info for the thermometer being tested. Place labels denoting the assigned SSF ID & Manufacturer Serial Number (S/N). It is acceptable to also record this information by hand.
 - 1.1.2. Probe ID defines the specific info for the probe being tested with the thermometer being tested, if applicable. Place labels denoting the assigned SSF ID & S/N. It is acceptable to also record this information by hand.
 - 1.1.3. Check the box that describes the reason the verification is being conducted. If the reason is not listed, check “other” and describe.
 - 1.2. Select the environmental temperature test points set to be used in the verification (Step # 1 Appendix D2).
 - 1.2.1. Record the comparator NIST traceable Glass / Electronic Thermometer and probe (if applicable) ID # to be used in verification against thermometer under test in Step # 2 Appendix D2. See step 1.2.1.2 for additional NIST device requirements. If a comparator thermometer is not necessary and physical standards are used, select “N/A” in step #2 Appendix D2 for all columns and prepare baths for physical standards as follows.
 - 1.2.1.1. Physical standard baths preparation:
 - 1.2.1.1.1. LN2 – Use a filled dewar or an LN2 freezer that is filled sufficiently to allow safe access to the LN2.
 - 1.2.1.1.2. Dry ice – Place dry ice in a container or use the dry ice bin.
 - 1.2.1.1.3. Wet ice – Fill a cup with ice and water.
 - 1.2.1.2. Note the following NIST-traceable device requirements:
 - 1.2.1.2.1. Prior to using the NIST traceable unit (thermometer/probe) for the calibration of an LN2 Freezer display, ensure that the calibrated range of the thermometer/probe unit extends to at least -196° C.
 - 1.2.1.2.2. Prior to using the NIST traceable unit (glass thermometer or electronic device) as a comparator device at temperatures between -80 °C and 50°C, ensure that the unit is calibrated at the prescribed range.
 - 1.2.2. Determine applicable range for thermometer under test. Choose three different environmental temperature test points, differing by $\geq 10^{\circ}\text{C}$ from each other, within that range. For example, the calibration of a thermometer with a range of -5 to 50°C may be checked by using temperatures such as ~4°C (refrigerator), ~25°C (room temperature), and 50°C (warm water bath). For each of the three points, proceed with the following:
 - 1.2.2.1. Place in the appropriate environmental temperature. For example, the thermometer may be placed in a freezer/refrigerator unit, LN2 unit, water bath, or left out at ambient temperature.
 - 1.2.2.2. Place signage on the unit where test is being conducted (as applicable):
“Thermometer Calibration Verification in Process. Do Not Open.”
 - 1.2.2.3. Place the probe from the NIST-traceable thermometer or the thermometer itself, as applicable, next to the thermometer being tested.
 - 1.2.2.4. Wait until temperature is stabilized (minimum 20 minutes).
 - 1.2.2.5. Read the value from the NIST thermometer and record to the nearest 0.1 degree in Step # 3 on Appendix D2.

- 1.2.2.6. Read the value from the unit under test and record to the nearest 0.1 degree on Step # 3 on Appendix D2.
- 1.2.2.7. Compare NIST thermometer with readout from the unit under test.
- 1.2.2.8. Determine if the variation is acceptable per the following chart:

Temperature Range	-30° C to +56° C	-30° C to -85° C	< -85° C or > +56° C
Acceptable Variation	+/- 2.0° C	+/- 3.0° C	+/- 4.0° C

- 1.2.3. Document determination in Step # 4 of Appendix D2.
- 1.2.4. If the difference between the two readings for any of the three test points exceeds the above, notify SSF management and proceed as follows:
 - 1.2.4.1. Take the thermometer out of service and replace with a unit that satisfies the above NIST comparison standard. Update Appendix A.
 - 1.2.4.2. Initiate an Out-of-Specification (OOS) investigation per SF-1-10.
 - 1.2.4.3. Notify SSF Management to have the unit recalibrated, repaired, or replaced.
 - 1.2.4.4. Post-repair of a non-NIST traceable unit, perform calibration steps as indicated on Appendix D1 and D2 prior to returning to service.
- 1.2.5. Record results and actions on Appendix A.
- 1.2.6. If the thermometer is a column (glass) thermometer, inspect it to ensure that it is not cracked or that the liquid is not separated (evident by air bubbles present). Document inspection on Appendix D2.
 - 1.2.6.1. If the thermometer is cracked or the liquid is separated, document on Appendix A, discard unit and order replacement as applicable.

Thermometer Calibration Verification Worksheet											
Preliminary Information											
Unit and probe under test:				Reason:							
Thermometer ID (SSF # & S/N)				<input type="checkbox"/> Expired Calibration Due Date (only perform if thermometer is needed immediately and there is no time to retrieve an updated certificate). <input type="checkbox"/> Non-NIST Traceable Annual Calibration Verification <input type="checkbox"/> Other: _____							
Probe ID (SSF #)											
Step #	Description			Observation / Measurement				Completed By Initial / Date			
1	A physical substance defined by SSF standards is a substance with a temperature that remains constant and therefore does not require a comparator device. The physical substances that are defined as constant are LN2, Dry Ice, and Wet Ice. All other temperature points require the use of a comparator device.			Environmental Temperature Tests 1. Comparator Device Test: <input type="checkbox"/> Refrigerator <input type="checkbox"/> Room Temp <input type="checkbox"/> ~37°C (warm water bath) 2. Physical Substance Test: <input type="checkbox"/> -196°C (LN2) <input type="checkbox"/> -78.5 (Dry Ice) <input type="checkbox"/> 0°C (Wet Ice) 3. Other: _____							
Step #	Comparator Thermometer and probe (if applicable) ID (If completing a physical substance test, select N/A)			Calibration Expiration Date				Initials / Date			
2	<div style="display: flex; justify-content: space-between;"> <input type="checkbox"/> N/A </div>			<div style="display: flex; justify-content: space-between;"> <input type="checkbox"/> N/A </div>				<div style="display: flex; justify-content: space-between;"> <input type="checkbox"/> N/A </div>			
All thermometer values recorded to nearest 0.1 degree.											
3	Check N/A in each section that will not be used based off of the selection in step #1. Record temperature environment. Examples of environment would be refrigerator, room temp, warm water bath, LN2, Dry Ice, and Wet Ice. Equilibration time is minimum 20 min for the thermometers. After placing thermometer and comparator device into bath, place signage on or near the bath indicating that calibration is in process. Place sign on bath even if there is no comparator device used. <i>If recalibration investigation has been initiated per SF 3-1, it is acceptable to test the one temperature point in question instead of three points. Check N/A on the other temperature environment boxes not used.</i>			Comparator Device Test				Physical Substance Test			
				<input type="checkbox"/> N/A				<input type="checkbox"/> N/A			
	Temperature Environment #1				Temperature Environment #1						
	Comparator Value	Unit under test value	Δ^*	Max Acc. Δ^*	Comparator Value	Unit under test value	Δ^*	Max Acc. Δ^*			
	Pass (circle one)? Yes or No				Pass (circle one)? Yes or No						
	Tech / Date:				Tech / Date:						
	<input type="checkbox"/> N/A				<input type="checkbox"/> N/A						
	Temperature Environment #2				Temperature Environment #2						
	Comparator Value	Unit under test value	Δ^*	Max Acc. Δ^*	Comparator Value	Unit under test value	Δ^*	Max Acc. Δ^*			
	Pass (circle one)? Yes or No				Pass (circle one)? Yes or No						
	Tech / Date:				Tech / Date:						

Thermometer Calibration Verification Worksheet Cont.											
Unit Under Test: Thermometer ID:				Probe ID:							
Step #	Check N/A in each section that will not be used based off of the selection in step #1.			Comparator Device Test				Physical Substance Test			
3 Cont				<input type="checkbox"/> N/A				<input type="checkbox"/> N/A			
				Temperature Environment #3				Temperature Environment #3			
				Comparator Value	Unit under test value	Δ^*	Max Acc. Δ^*	Comparator Value	Unit under test value	Δ^*	Max Acc. Δ^*
				Pass (circle one)? Yes or No				Pass (circle one)? Yes or No			
				Tech / Date:				Tech / Date:			
Temperature Range		-30°C to +56°C		-30°C to -85°C		< -85°C or > +56°C					
Acceptable Variation		+/- 2.0°C		+/- 3.0°C		+/- 4.0°C					
4	Thermometer Temperature Verification successful? If not describe actions in comment section below.			YES or NO				Initials / Date:			
5	If the thermometer is a Column / Glass Thermometer perform the annual visual inspection.			Annual Visual Inspection for Column / Glass Thermometers				Initials / Date	Comments		
				<input type="checkbox"/> Column is acceptable-Unit remains in service <input type="checkbox"/> Column is cracked-Unit discarded <input type="checkbox"/> Column liquid was separated, but was corrected-Unit remains in service <input type="checkbox"/> Column liquid is separated and could not be corrected-Unit discarded <input type="checkbox"/> Other (Describe in comment section) <input type="checkbox"/> Not Applicable							
Comments											
Reviewed By/Date:											