Clinical and Translational Sciences Institute

STANDARD OPERATING PROCEDURE
Indiana CTSI Specimen Storage Facility

TITLE: STANDARD OPERATING PROCEDURE FOR THERMOMETERS

CHAPTER: 3-Equipment

SOP #: SF-3-7.07

SUPERSEDES SOP #: N/A

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QA APPROVAL: [signature] DATE: 08.16.2021
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1. REVISION
   1.1. Significant changes incorporated in this version include
      1.1.1. Section 10, Collaborating Biobank Training Directives, added to align with SF-1-1 SOP for Writing, Reviewing, and Maintaining SOPs.
      1.1.2. Appendix A revised to remove the necessity of Management review when removing thermometer from service.

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 an 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. All thermometers have a defined instrument range (temperatures the instrument is capable of measuring) and a defined operating range (temperatures in which the instrument can safely be operated) per the manufacturer. It is critical that the SSF ensures that the calibrated range of NIST-traceable devices (or verification of non-NIST devices) does not exceed the manufacturer's defined instrument range. No NIST device should be intentionally used to measure a temperature outside of its calibrated range. In rare instances where an NIST device is utilized and reads a value slightly outside its calibrated range, an extension of calibrated range with a ±10°C or 10% variance

(whichever is smaller) may be calculated and incorporated to allow for such readings. The rationale for this is based on the mathematical principle of linear extrapolation, where it can be stated that a thermometer which has had a three point calibration performed maintains its calibration when reading temperatures of small variances outside of its calibrated range. An extension by the amount defined above is likely to preserve the linearity of the calibrated range, thereby ensuring accuracy while providing some degree of flexibility. However, it is crucial to note that an NIST thermometer being used to read a temperature outside its calibrated range is not ideal, and it is highly recommended that an instrument be recalibrated to a more suitable range as soon as possible should the need arise.

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.
      5.1.2. The NIST glass bottle probe is used for room temperature monitoring.
   5.2. Water bath with NIST-traceable thermometer/probe in container/tub and calibration certificate for NIST-traceable device available. Calibration certificate must confirm NIST-traceable device serial number and a calibration due date on or after the date of use for calibration verification.
   5.3. Thermometers which do not have an NIST-traceable certificate of calibration and which must be compared to an NIST traceable thermometer to confirm calibration.
      5.3.1. Non-NIST thermometers could be liquid-in-glass or digital.
   5.4. Standard grade AA batteries (three)
   5.5. 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 the following:

6.1.1.1. The S/N listed on the certificate matches the S/N of the unit received.

6.1.1.2. The calibration due date meets the expected requirements.

6.1.1.3. The calibrated range does not exceed the instrument range as defined by the manufacturer.

6.1.2. If the calibration certificate is not included or is unacceptable for any reason, contact the vendor for resolution.

6.1.3. Non-NIST units are ordered from an approved vendor.

6.2. **Receipt of Thermometers/Probes**

NOTE: This section applies to the intake of new thermometers as well as those returning from service/calibration.

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 new thermometers: SF-NN where NN is numerical, and a number is not re-used if the unit is taken out of service. Assign an SSF Identification to all new probes: SF-NNP where NN is numerical, and a number is not re-used if the unit is taken out of service. P represents Probe. Probes calibrated to LN_2 temperature are additionally assigned a designation of LN_2 (e.g. SF-12 & SF-3P-LN_2).

6.2.1.1.1. Review the In-Service Thermometer Log (Appendix E), saved on the SSF Shared Drive, to determine the next sequential number to assign new thermometers and probes.

6.2.1.2. As applicable, 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 Appendices A & E. An example of equipment data recorded on the In-Service Thermometer Log follows in the table below:

Type	Thermometer	Probe	Manufacturer (thermometer/ probe)	Unit Model Description	Unit Serial Number	SSF-assigned Unit ID	Original Date in Service	Calibrated Range (°C)	Calibration Date	Calibration Due Date	Date Out of Service	Extension Factor, if applicable
Digital	SF-30		Cole-Parmer	Temp 10T	4009590	SF-30	2/25/2019	-200 to 25.0	2/3/2019	2/3/2021		
Digital	SF-30	SF-16P	Cole-Parmer/PCI	08466-83	N/A	SF-30 + SF-16P	2/25/2019	-80.2 to 25.1	2/14/2019	2/14/2021		±10.0

6.2.1.4. Date in service is defined as the date the certificate is reviewed and considered satisfactory per Section 6.1.1. If no certificate is received, contact the vendor for resolution.

6.2.1.5. Document yes (Y) or no (N) if the calibration certificate is received.

6.2.1.6. If maintenance was performed, document whether or not service documentation was received.

6.2.1.7. Calibrated temperature range and current calibration due date are located on the calibration certificate. If no certificate is received, contact the vendor for resolution.

6.2.1.8. If calibration certificate is received, send copies to QA.

6.2.1.9. 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) 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 new thermometers: SF-NN where NN is numerically, and a number is not re-used if the unit is taken out of service. Assign an SSF Identification to all new probes: SF-NNP where NN is numerically, and a number is not re-used if the unit is taken out of service. P represents Probe. Probes calibrated to LN_2 temperature are additionally assigned a designation of LN_2 (e.g. SF-12 & SF-3P-LN_2).

6.2.2.1.1. Review the In-Service Thermometer Log (Appendix E), saved on the SSF Shared Drive, to determine the next sequential number to assign new thermometers and probes.

6.2.2.2. Record thermometer information as requested on Appendices A & E, referring to example in Step 6.2.1.3.
6.2.2.3. Date in service is defined as the completion date of a successful calibration verification (refer to Section 6.5.2 for instructions).
6.2.2.4. Document N/A for calibration certificate received.
6.2.2.5. If maintenance was performed, document whether or not service documentation was received.
6.2.2.6. Current calibration verification due date is one year from the completion date of the most recent calibration verification (Refer to Section 6.5.2). The calibrated temperature range is determined by the temperatures used for the calibration verification.
6.2.2.7. Send copy of the completed calibration verification documentation (Appendix D2) to QA.

6.3. **Thermometer Usage and 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 thermometer/probe use on Appendix B.
6.3.2.1. NIST-traceable units with expired calibration dates are removed from service immediately if a replacement unit is available. Document date out of service on Appendices A & E.
6.3.2.1.1. When a replacement unit is not available, if necessary, keep expired unit in service until a replacement is obtained. Document as deviation per SF-1-9, and complete the thermometer calibration verification per the Thermometer Calibration Verification procedure (Appendix D1) and document results on Appendix D2.
6.3.2.1.2. As soon as possible, submit unit for calibration described in Section 6.5.
6.3.2.2. If a NIST-traceable unit is found to be approaching calibration expiration and a replacement unit will not be available by expiration, complete the thermometer calibration verification per the Thermometer Calibration Verification procedure (Appendix D1) and document results on Appendix D2.
6.3.2.2.1. As soon as possible, submit unit for calibration described in Section 6.5.
6.3.2.3. For non-NIST traceable units with expired calibration dates, a thermometer calibration verification is performed per Appendix D1, and results are documented on Appendix D2 before use.

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 the thermometer does not have acceptable calibrated temperature range, use a thermometer calibrated for the appropriate range.
6.3.3.2. If there is no thermometer with an acceptable calibrated range available, calculate the extension of calibrated range which will allow the user to accept temperature readings slightly outside of the thermometer's calibrated range as being accurate and therefore acceptable per this SOP.

6.3.3.2.1. Assess the applicability of the extension factor to determine whether to use a ±10% or ±10°C variance. Use whichever variance is smaller. Determine the ±10% variance per the following calculation:

± (|upper limit of calibration minus lower limit of calibration|) x 10%

Example: A particular thermometer/probe unit has a certificate of calibration showing a calibrated range of -80°C to +25°C. Determine the ±10% variance:

± (|+25°C minus -80°C |) x 10%
± 105°C x 10%
± 10.5°C

Since a ±10°C variance is less than a ±10.5°C variance, the ±10°C variance would be used in this case. Therefore, the extension of calibrated range for this unit would be -90°C to +35°C.

6.3.3.3. If there is no thermometer with an acceptable calibrated range nor extension of calibration of range available, it is acceptable to complete thermometer calibration verification per Appendix D1 and document results on Appendix D2, provided that the calibrated range does not exceed the instrument range, and that the verification of calibration is successful at the intended use range.

6.3.3.4. If the unit is to be continuously used at the desired calibrated range, as soon as possible, submit unit for calibration to this new range per Section 6.5.

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. In the "Location / Location ID and SN" column, record the location where the thermometer was used, if in continuous use for room temperature monitoring, for example. Otherwise, record or place labels denoting the freezer location ID and serial number of the applicable freezer.

6.3.8. 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.

6.3.9. 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 with 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 on the thermometer to display an updated ambient temperature reading.

6.4.2.4. The screen will show the current ambient 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 once to update the probe temperature displayed on screen.

6.4.2.7. Screen will display current probe temperature, minimum, and maximum temperatures.

6.5. **Calibration/Verification/Inspection**

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

6.5.1.1. Have digital NIST-traceable thermometers calibrated biennially on or before the expiration date listed on the current certificate. Document this event on Appendices A & E, with the date out of service and reason. (Completion of the Out-of-Specification Event Report 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, a process defined as loop calibration. There should be a separate certificate each for the thermometer by itself as well as the thermometer and probe combination/s.

NOTE: NIST-traceable thermometers utilized for continuous room temperature monitoring are generally replaced not recalibrated. Typically utilized for room temperature monitoring are Control Company Model 15-077-941 thermometers. Replacement is more cost effective than recalibration.

6.5.1.1.1. Access the calibration company's website per Appendix C.

6.5.1.1.2. Calibration Request:

6.5.1.1.2.1. Complete the Calibration Request Template (Appendix F), located on the SSF Shared Drive. An example is provided on Page 2 of Appendix F. Submit only page 1 to the vendor.

To ensure individual and loop calibration for each thermometer (meter) and probe (coupler), list one meter or probe per line/Item Number, and direct vendor to complete appropriate loop calibration by indicating in the "Loop Calibration Required" column which meters and probes are to be calibrated together.

6.5.1.1.2.2. Contact the calibration company to request quote for calibration, providing an uneditable copy of the completed Calibration Request.

6.5.1.1.3. Package and ship NIST thermometer to PCI or other approved calibration company per Appendix C. Include copy of Calibration Request.

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 complies with requirements provided in the Calibration Request Template. NOTE: Completion of loop calibration is often denoted in the "Calibration Notes" section of the probe's calibration certificate/ report.

6.5.1.1.4.3. 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 SF-1-10. 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. Document out of service on Appendix E.

6.5.1.3. Document thermometer receipt on Appendices A & E per Section 6.2.

6.5.2. Non-NIST traceable thermometers are not calibrated, but the accuracy is verified at time of receipt using the Thermometer Calibration Verification Appendix D1/D2. Document completion on Appendix E. Re-calibration verification for Non-NIST traceable thermometers is due one year from the date of the last successful verification.

6.5.2.1. Additionally, Column/Glass Thermometers are visually inspected annually. The annual re-calibration verification is due one year from the date the Thermometer Calibration Verification and inspection was completed. Record results and actions taken on Appendices A, B, and E.

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

6.7.1.2.1. Unscrew the round battery cover on the back of thermometer.
6.7.1.2.2. Remove battery.
6.7.1.2.3. Replace with a new 1.5 volt, G-13 size battery.
6.7.1.2.4. Replace the battery cover.

6.7.2. Non-routine Maintenance, for all thermometers:

6.7.2.1. If unit is not operating properly, Remove from Service (NIST-Traceable units):

6.7.2.1.1. Refer to outside vendor for repair or calibration, or destroy the unit.
6.7.2.1.2. Record date and reason for removing unit from service on Appendix A, and document date out of service on Appendix E.
6.7.2.1.3. Document actions on Appendix C
6.7.2.1.4. If sending out for repair, request recalibration per Section 6.5.1.
6.7.2.1.5. Complete an Out-of-Specification Event Report per SF-1-10.

6.7.2.2. If non-NIST traceable unit is not operating properly, Remove from Service:

6.7.2.2.1. Refer to outside vendor for repair or calibration, or destroy the unit.
6.7.2.2.2. Record actions on Appendix A, and document date out service on Appendix E.
6.7.2.2.3. Actions are not to be recorded on Appendix C, since re-calibration will not be requested.
6.7.2.2.4. Upon receipt of the non-NIST unit returning to the SSF facility, calibration verification must be completed to ensure unit is still functioning properly.
6.7.2.2.5. Complete an Out-of-Specification Event Report per SF-1-10.

6.7.2.3. If unit is returned to service, document thermometer receipt on Appendices A & E per Section 6.2.

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. Document actions on Appendix E.

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 SOP for Controlled Document Management.
8.4. OOS results are documented as defined in SF-1-10 SOP or OOS Response and Management.
8.5. Deviations are managed per SF-1-9 SOP for Deviation Management.

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: Procedure for Performing Calibration Verification of Thermometers (2 Pages)
APPENDIX D2: Thermometer Calibration Verification Worksheet (2 Pages)
APPENDIX E: In-Service Thermometer Log Template (1 Page)
APPENDIX F: Calibration Request Template and Example (2 Pages)

10. COLLABORATING BIOBANK TRAINING DIRECTIVE

10.1. N/A

SSF Thermometer Maintenance Log Page ____ of ____ ❑ *Check here if additional sheets are attached*

SSF ID # (Include ID for Probe if applicable)	Manufacturer	Model	S/N	Type (Digital vs. Column)	NIST Traceable? Y or N	Instrument Range of Unit (From Mfg. supplied information) in °C	Tech initials / date
Thermometer							
Probe							

Calibration / Service Record

Date in Service	Calibration certificate received Y or N (N/A for non-NIST)	Service documents received (if applicable) Y or N or N/A	Calibrated Temp. Range (from certificate or Appendix D2, as applicable) in °C	Current Calibration or Verification Due Date	Tech initials/date	Certificate or Appendix D2 sent to QA? Initials/Date	Reviewed by/date

Date out of Service	Reason Unit is Out of Service	Tech Initials / Date	Reviewed by *(Initials / Date)*

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? (Yes/No)	Calibrated Temp Range Acceptable (Yes/No)	Date Used	Used By	Location / Location ID and SN (Ex: C135-D9 S/N: 801139-342)	Reason	Comment
Y N	Y N				❑ MRU Quarterly ❑ LN_2 Annual ❑ Other *(Describe)*	
Y N	Y N				❑ MRU Quarterly ❑ LN_2 Annual ❑ Other *(Describe)*	
Y N	Y N				❑ MRU Quarterly ❑ LN_2 Annual ❑ Other *(Describe)*	
Y N	Y N				❑ MRU Quarterly ❑ LN_2 Annual ❑ Other *(Describe)*	
Y N	Y N				❑ MRU Quarterly ❑ LN_2 Annual ❑ Other *(Describe)*	
Y N	Y N				❑ MRU Quarterly ❑ LN_2 Annual ❑ Other *(Describe)*	
Y N	Y N				❑ MRU Quarterly ❑ LN_2 Annual ❑ Other *(Describe)*	
Y N	Y N				❑ MRU Quarterly ❑ LN_2 Annual ❑ Other *(Describe)*	
Y N	Y N				❑ MRU Quarterly ❑ LN_2 Annual ❑ Other *(Describe)*	
Y N	Y N				❑ MRU Quarterly ❑ LN_2 Annual ❑ Other *(Describe)*	
Y N	Y N				❑ MRU Quarterly ❑ LN_2 Annual ❑ Other *(Describe)*	
Y N	Y N				❑ MRU Quarterly ❑ LN_2 Annual ❑ Other *(Describe)*	
Y N	Y N				❑ MRU Quarterly ❑ LN_2 Annual ❑ Other *(Describe)*	
Y N	Y N				❑ MRU Quarterly ❑ LN_2 Annual ❑ Other *(Describe)*	
Y N	Y N				❑ MRU Quarterly ❑ LN_2 Annual ❑ Other *(Describe)*	
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 Calibration Request to the calibration company prior to shipping the device:
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	❑ 2 Years ❑ Other *(List)*	
As Found / As Left Measurements Requested	❑Yes ❑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	❑Yes ❑No** ***request certificate from calibration company*	
S/N of all units received match S/N of units sent	❑Yes ❑No	
Calibrated Temperature Range as desired	❑Yes ❑No	
Calibration Period as requested	❑Yes ❑No	
As-Found / As-Left Values Available on Certificate	❑Yes ❑No	
As-Found / As-Left Values Meet Acceptance Criteria	❑Yes ❑No	
Loop Calibration Completed as Directed	❑Yes ❑No	
Calibration Certificate Sent to QA	❑Yes ❑No	
Comments:		
Reviewed By (Initials/Date):		

Procedure for Performing Calibration Verification of Thermometers

(Use for routine non-NIST device calibration verification, expired device calibration verification, or to verify a range other than the current calibrated/verified range of a device.)

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. Calibration Due Date defines the calibration due date for the thermometer and probe being tested.
      1.1.4. 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. LN_2 – Use a filled dewar or an LN_2 freezer that is filled sufficiently to allow safe access to the LN_2.
            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 LN_2 Freezer display, ensure that the calibrated range of the thermometer/probe unit extends to at least -196° C, including extension factor if necessary per Section 6.3.3.2.
            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 ≥10ºC from each other, within that range. For example, the calibration of a thermometer with a range of -5 to 50ºC may be checked by using temperatures such as ~4ºC (refrigerator), ~25ºC (room temperature), and 50ºC (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, LN_2 unit, water bath, or left out at ambient temperature.
            1.2.2.1.1. Use of water bath requires:

1.2.2.1.1.1. Locating a water bath with a calibrated, NIST-traceable thermometer and probe in service in the water bath container/tub, likely at the CTSI's Processing Laboratory (CTSL).

1.2.2.1.1.2. Calibration verification for the NIST-traceable thermometer in service in the water bath container/tub, including serial number verification and acceptable calibration due date verification.

1.2.2.1.1.3. Document water bath serial number and location on Appendix D2.

1.2.2.1.1.4. Obtain a copy of the NIST-traceable thermometer and probe's calibration certificate, and attach certificate to Appendix D2. Document action on Appendix D2.

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 Appendices A & E.

1.2.4.2. Initiate an Out-of-Specification Event Report 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 Appendices A & E.

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 Appendices A & E, discard unit and order replacement as applicable.

Thermometer Calibration Verification Worksheet

Preliminary Information

Unit and probe under test:	Reason:
Thermometer ID ***(SSF # & S/N:)***	❑ **Expired Calibration Due Date (only perform if thermometer is needed immediately and there is no time to retrieve an updated certificate).**
Probe ID ***(SSF #):***	❑ **Non-NIST Traceable Annual Calibration Verification**
Calibration Due Date:	❑ **Other:** _____

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 required a comparator device. The physical substances that are defined as constant are LN_2, Dry Ice, and Wet Ice. All other temperature points require the use of a comparator device.**	**Environmental Temperature Tests** 1. **Comparator Device Test:** ❑ Refrigerator ❑ Room Temp ❑ ~37°C (warm water bath) Water bath Serial Number _____ Water bath location _____ 2. **Physical Substance Test:** ❑ -196°C (LN_2) ❑ -78.5°C (Dry Ice) ❑ 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		❑ N/A		❑ N/A		❑ N/A

All thermometer values recorded to nearest 0.1 degree.

Check N/A in each section not used per Step 1.

Record temperature environment. Examples of environment would be refrigerator, room temp, warm water bath, LN_2, 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.

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.

3 *Use the table below to determine if the temperature variation between the comparator thermometer or physical substance and the NIST thermometer under test is acceptable.

Comparator Device Test				Physical Substance Test			
❑ **N/A**				❑ **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:			
❑ **N/A**				❑ **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.		❑ N/A				❑ 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. **Document results on Appendices A & E.**	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 ❑ **Column is acceptable-**Unit remains in service ❑ **Column is cracked-**Unit discarded ❑ **Column liquid was separated, but was corrected-**Unit remains in service ❑ **Column liquid is separated and could not be corrected-**Unit discarded ❑ **Other** *(Describe in comment section)* ❑ **Not Applicable**	Initials / Date Comments
6	Attach copy of calibration certificate for NIST-traceable thermometer/probe in service in water bath, if applicable.	❑ Certificate Attached ❑ Not Applicable	Initials / Date:

Comments

**Reviewed By/Date:

****Submit Appendix D2 to QA after approval**

In-Service Thermometer Log Template

Type	Thermometer	Probe	Manufacturer (thermometer / probe)	Unit Model Description	Unit Serial Number	SSF-assigned Unit ID	Original Date In Service	Calibrated Range (˚C)	Calibration Date	Calibration Due Date	Date Out of Service	Extension Factor, if applicable

Calibration Request Template

Account: IUPUI – Specimen Storage Facility

Item #	Request Date	Instrument ID	Instrument Description	Manufacturer	Model	Serial Number	Calibration Interval	Operating Range – High	Operating Range – Low	Loop Calibration Required	"As Found" / "As Left" Calibration Data Required

Calibration Request Example

Account: IUPUI – Specimen Storage Facility

Item #	Request Date	Instrument ID	Instrument Description	Manufacturer	Model	Serial Number	Calibration Interval	Operating Range – High	Operating Range – Low	Loop Calibration Required	"As Found" / "As Left" Calibration Data Required
1	XX/XX/XXXX	SF-XX	Thermometer	Oakton	Temp 10T	XXXXXX	2 Years – Exact Date	25˚C	-200˚C	Yes – SF-XX with SF-XXP	Yes
2	XX/XX/XXXX	SF-XXP	Type T Thermocouple	Digi-Sense	08466-83	N/A	2 Years – Exact Date	25˚C	-85˚C	Yes – SF-XX with SF-XXP	Yes
3	XX/XX/XXX	SF-XXP-LN_2	Type T Thermocouple (LN_2)	JMS SE	Type T	N/A	2 Years – Exact Date	25˚C	-196˚C	Yes – SF-XX with SF-XXP	Yes