Unit Procedure

Thermometers

SOP No./WI No.: CTSI-CRC-PL-306

Department: Processing Laboratory

Version No.: 02

Effective Date: 05 Jan 2017

Supersedes: No.: CTSI-CRC-PL-306-01 Effective Date: 08 May 2014

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Review Period: 2 years

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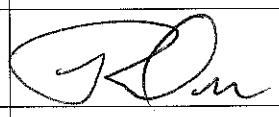
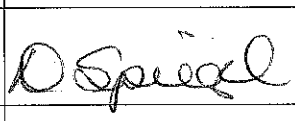
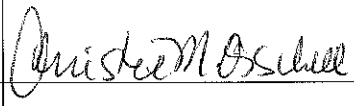
Signature			
Date	28 Dec 2016	28 Dec 2016	Dec 29. 2016

1. OBJECTIVE

This Standard Operating Procedure (SOP) defines the procedures used in the Indiana Clinical and Translational Sciences Institute (CTSI) Clinical and Translational Support Laboratory (CTSL) to maintain and monitor all thermometers used in the CTSL and ensures that temperature readings are accurate.

2. SCOPE

This SOP applies to personnel operating and maintaining the thermometers used in the CTSL 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 CTSL thermometers that are not otherwise NIST traceable.

3. RESPONSIBILITIES

The CTSL staff is responsible for appropriately operating and maintaining thermometers in a safe and compliant manner.

4. DEFINITIONS

4.1. Principle: Storage temperature is defined as a critical parameter for storing biorepository specimens. It is the responsibility of the STSL to ensure that the temperature is accurately measured. Calibration of thermometers used within the CTSL to a NIST-traceable thermometer is required to confirm the accuracy of all thermometers used in the CTSL.

CRC: Clinical Research Center	CTSI: Clinical and Translational Sciences Institute
CTSL: Clinical and Translational Support Laboratory	NIST: National Institute of Standards and Technology
PL: Processing Lab	SOP: Standard Operating Procedure

5. ASSOCIATED DOCUMENTS

5.1. CTSI-CRC-QA-003 "Document Control and Management"
5.2. CTSI-CRC-CLN-030 "Handling of SOP Deviations"
5.3. CTSI-CRC-PL-105 " Out of Specification Condition and Notification Management"

6. PROCEDURE

6.1. Materials

6.1.1. Thermometers with Traceable Certificates of Calibration or Certificates of Conformance and Accuracy (NIST Traceable).

6.1.2. Thermometers to be verified against an NIST traceable thermometer.

6.2. Receive and document (CTSI-CRC-PL-LG610 "CTSL Thermometer Log") thermometers used in the CTSL as follows: (Record one thermometer per log)

6.2.1. Assign a CTSL Identification to all thermometers: CT-NN where NN is chronological and a number is not re-used if the unit is taken out of service.

6.2.2. Record date unit placed in service.

6.2.3. Record thermometer information as requested on CTSI-CRC-PL-LG610 "CTSL Thermometer Log".

6.2.4. If NIST traceable, not Receipt of Traceability or Conformance documents and retain with the receipt log.

6.2.5. Record the date and location for each usage of the thermometer. Update when the location of the unit is changed.

6.2.6. When taken out of service, record Date Out-of-Service, any corrective actions taken, and the date it was returned to service, is applicable.

6.2.7. When permanently removed from service, cross through, initial and date any remaining blank fields and file in equipment file.

6.3. Verify calibration of all non-NIST traceable thermometers annually.

6.3.1. Verify and record the CTSL identification number of the NIST traceable thermometer to be used in the verification process on log CTSI-CRC-PL-LG610 "CTSL Thermometer Log" for the thermometer being verified.

6.3.2. Verify that the NIST traceable thermometer is calibrated and that the calibrated range encompasses the range of the unit under test.

6.3.2.1. Record NIST calibration expiration date on CTSI-CRC-PL-LG610 "CTSL Thermometer Log".

6.3.2.2. If expired, obtain a unit within calibration date to replace defective thermometer. Follow section 6.4 for re-calibration of the unit with expired calibration document.

6.3.3. Determine applicable range for thermometer under test. Choose three different environmental temperature test points, differing by $\geq 10^{\circ}C$ from each other, within that range. For example, the calibration of a thermometer with a range of -1 to 50°C may be checked by using temperatures such a 4°C (refrigerator), 25°C (room temperature), and 37°C (warm water bath). For each of the three points, proceed with the following:

6.3.3.1. Place in the appropriate environmental temperature. For example, the thermometer may be place in a freezer/refrigerator unit, LN2 unit, water bath, or left out at ambient temperature.

6.3.3.2. Place signage on the unit where test is being conducted (as applicable): Thermometer Calibration Verification in Process. DO NOT OPEN

6.3.3.3. Place the probe from the NIST-traceable thermometer or the thermometer itself, as applicable, nest to the thermometer being tested.

6.3.3.4. Wait until temperature is stabilized (approximately 1 hour).

6.3.3.5. Read the value from the NIST-traceable thermometer and record to the nearest 0.1 degree on the CTSI-CRC-PL-LG610 "Thermometer Log".

6.3.3.6. Read the value from the unit under test and record to the nearest 0.1 degree on the CTSI-CRC-PL-LG610 "Thermometer Log".

6.3.4. Determine if the variation is acceptable per the following chart. If the difference between the two readings for any of the three test points exceeds the above, notify CTSL management and proceed as follows:

6.3.4.1. Take the thermometer out of service and replace with a unit that satisfies the above NIST comparison standard. Update CTSI-CRC-PL-LG610 "Thermometer Log".

6.3.4.2. Initiate an Out-of-Specification (OOS) investigation per CTSI-CRC-PL-105 " Out of Specification Condition and Notification Management"

6.3.4.3. Notify CTSL management to have the unit recalibrated or replaced.

6.3.4.4. If re-calibrated, document acceptance prior to placing back into service.

6.3.5. Record results and actions on CTSI-CRC-PL-LG610 "Thermometer Log".

6.3.6. 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).

6.3.6.1. If the thermometer is cracked or the liquid is separated, proceed to section 6.4.

6.3.6.2. Document results and actions on CTSI-CRC-PL-LG610 "Thermometer Log".

6.4. Calibrate digital NIST traceable thermometers bi-annually and alcohol (column NIST traceable thermometers annually.

6.4.1. Access the calibration company's website per CTSI-CRC-PL-GM510 "Calibration of Thermometer Form".

6.4.2. Complete Re-calibration/Service form found on website. Request "as found" and "as left" documentation.

6.4.3. Package and ship NIST thermometer per CTSI-CRC-PL-GM510 "Calibration of Thermometer Form".

6.4.4. The calibration company contacts the CTSL with an estimate for re-calibration and approval.

6.4.5. CTSL notifies the calibration company of approval or denial.

6.4.6. The calibration company re-calibrates NIST thermometer if approved.

6.4.7. The calibration company returns the NIST thermometer with a NIST traceable Certificate of Calibration.

6.4.8. Record results and actions in CTSI-CRC-PL-GM510 "Calibration of Thermometer Form". If AS Found is out of specification notify CTSL Director and initiate an OOS investigation per CTSI-CRC-PL-105 "Out of Specification Condition and Notification of Management".

6.5. Maintenance and Repair

6.5.1. For alcohol (column) thermometers:

6.5.1.1. If the thermometer is cracked, proceed to section 6.4.2.

6.5.1.2. If the liquid has separated:

6.5.1.2.1. Tap gently, but firmly, on the thermometer to try to bring the liquid back together.

6.5.1.2.2. If tapping on the thermometer does not work, proceed to section 6.4.2.

6.5.2. For all thermometers: If unit is found to not operate properly:

6.5.2.1. Take out of Service. Record date on the CTSI-CRC-PL-LG610 "Thermometer Log".

6.5.2.2. Refer to outside vendor for repair or destroy the unit.

6.5.2.3. If returned to service, record date and functionality in comment section of CTSI-CRC-PL-LG610 "Thermometer Log".

6.6. Documents:

6.6.1. NIST Traceability calibration certifications and certificates of conformance are maintained with thermometer calibration verification documents.

6.6.2. Records of annual verification of calibration are maintained in the equipment file.

6.6.3. OOS results are documented as defined in CTSI-CRC-PL-105 "Out of Specification Condition and Notification of Management".

6.6.4. Deviations are managed per CTSI-CRC-CLN-030 "Handling of SOP Deviations".

7. REFERENCES

7.1. Thermometer users guide

8. APPENDICES

None

9. AMENDMENT HISTORY

Date of Amendment:	22 DEC 2016
Amendment Request by:	Robert Orr
Change Control No, if applicable:	CTSI-CRC-PL-DC-2016-015

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Details of Amendment:	Updated to footer file location; updated the SOPs in 5.2 and 6.6.4