Unit Procedure

Water Bath- Operation and Maintenance

SOP No./WI No.: CTSI-CRC-PL-308

Department: Processing Laboratory

Version No.: 02

Effective Date: 05 Jan 2017

Supersedes: No.: CTSI-CRC-PL-308-01 Effective Date: 08 May 2014

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Review Period: 2 years

	Written by	Reviewed by	Approved by
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Signature			
Date	04 JAN 2017	04 Jan 2017	Jan 4, 2017

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	Written by	Reviewed by	Approved by
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Job Title	Operations Manager	Quality Assurance Manager	ATP Director
Signature			
Date	28 Dec 2016	28 Dec 2016	Dec 29. 2016

1. OBJECTIVE

This Standard Operating Procedure (SOP) describes the process for the operation and maintenance of water baths in a manner which complies with all appropriate regulatory and protocol specific requirements and to ensure that all personnel are consistently using baths at the Indiana Clinical and Translational Sciences Institute (CTSI) Clinical and Translational Support Laboratory (CTSL).

2. SCOPE

This procedure applies to all CTSL and Clinical Research Center (CRC) staff providing lab processing activities requiring the use of water baths. This procedure is intended to provide the basic procedure for operating and maintaining water baths and does not over-ride protocol specific directives.

3. RESPONSIBILITIES

All Clinical and Translational Support Laboratory staff is responsible for appropriately operating and maintaining water bath in a compliant manner.

4. DEFINITIONS

CRC: Clinical Research Center	CTSI: Clinical and Translational Sciences Institute
CTSL: Clinical and Translational Support Laboratory	NIST:
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-121 " General Safety"

6. PROCEDURE

6.1. Operation

6.1.1. Ensure that the water level is at least 2" above the bottom of the tank and not higher than 1" from the top. This applies for empty baths or one with maximum contents.

6.1.2. When placing flat bottom vessels in the bath, always use the base tray to avoid possible damage to the heater.
6.1.3. When a temperature setting above 60°C the use of the gable lid is recommended to optimize the temperature control.
6.1.4. Setting the temperature:
6.1.4.1. Set the power switch to the on position.
6.1.4.2. Set the desired temperature units, Fahrenheit or Centigrade by pressing and holding the set while pressing the Increase or Decrease until the desired C or F are displayed.
6.1.4.3. Release all controls and the display should return to normal display with the correct C or F indicator lit to the left of the display.
6.1.4.4. Turn the safety controller knob fully clockwise.
6.1.4.5. Press and hold the set button to see the current set point.
6.1.4.6. Release the controls if the set point does not need to be changed.
6.1.4.7. Press and hold the set button while pressing the increasing or decreasing button to increase or decrease the set point temperature.
6.1.4.8. Release the controls to return the display to normal once the desired set point temperature is reached.

6.2. Maintenance
6.2.1. Empty and clean the water bath basin with warm mild soap solution and 10% bleach solution on a monthly basis when in use regularly. It is not necessary to clean the water bath during prolonged periods of non-use. Document all activities on the Log No. CTSI-CRC-PL-LG611 for "Water Bath Maintenance and Service Log".
6.2.2. Use an NIST traceable thermometer to verify the accuracy of the digital read out on an annual basis.
6.2.3. Recalibration may be necessary if digital read out is not within ±1°C of the NIST thermometer.
6.2.3.1. Follow recalibration instructions in the user's manual.

6.3. Documents:
6.3.1. NIST Traceability calibration certifications and certificates of conformance are maintained with thermometer calibration verification documents.
6.3.2. Records of annual verification of calibration are maintained in the equipment file.
6.3.3. OOS results are documented as defined in CTSI-CRC-PL-105 "Out of Specification Condition and Notification Management".
6.3.4. Deviations are managed per CTSI-CRC-CLN-030 "Handling of SOP Deviations".

7. REFERENCES

7.1. Thermo Fisher Precision Waterbath user manual.

8. APPENDICES

None

9. AMENDMENT HISTORY

Date of Amendment:	23 Dec 2016
Amendment Request by:	Robert Orr
Change Control No, if applicable:	CTSI-CRC-PL-DC-2016-017
Details of Amendment:	Updated to footer file location; updated the SOPs in 5.2 and 6.3.5; Removed step 6.3.1 as review process is not defined or tracked