Title: Calibration of Temperature-Measuring Devices

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1.0 Purpose

This SOP describes the calibration of temperature-measuring devices for the Biopharmaceutical Development Program (BOP).

2.0 Scope

This SOP applies to the calibration of temperature-measuring devices within the BOP.

3.0 Authority and Responsibility

3.1 The Director, Biopharmaceutical Quality Assurance (BQA) has the authority to define this procedure.

3.2 BQA Engineering is responsible for implementing or designating implementation of this procedure and for maintenance of equipment records.

3.3 The individual performing the work is responsible for following this procedure and completing the appropriate documentation.

3.4 BQA is responsible for auditing this procedure (***SOP 21101 - Internal CGMP Compliance Auditing***).

3.5 BQA is responsible for quality oversight of this operation.

4.0 Test Apparatus

4.1 Mineral oil or Dow Corning 21OH fluid in a Pyrex beaker on a hot plate.

4.2 Dry ice/ethanol bath in an insulated container.

4.3 Water bath or oil bath (appropriate as determined by the BQA Engineer, temperature regulated).

4.4 Water in a Pyrex beaker on a hot plate.

4.5 Ice water bath.

4.6 Controlled temperature-heating block (Temperature Reference).

4.7 Cold-Warm room, refrigerator, and freezer: controlled-temperature environment.

4.8 IRTD Probe/Software/Laptop

5.0 Test Setpoints

5.1 The level of calibration of the device determines test setpoints. Blue Mountain Regulatory Asset Manager (BMRAM) and the existing calibration sticker will indicate the level of calibration. BMRAM will also provide the applicable specifications for range and tolerance. Refer to the Equipment Calibration Procedure, ***SOP 21508 - Equipment Calibration Program***, for guidance on appropriate test setpoints and calibration guidance. Any specific guidance in the manual should be provided or referenced in BMRAM.

5.2 Instruments may be checked in either ascending or descending setpoint order unless a directly-specified order is given.

6.0 Procedure

NOTE:

- Thermometers and probes with immersion points must be immersed to that point when possible. If full immersion is not possible due to the length of the probe relative to the well depth, use a dry block and be aware that calculations for deviations may differ.
- Temperature-measuring devices shall be calibrated in the system/loop where they are used. The system/loop must contain a readout device.
- When possible, when calibrating equipment that is used to indicate sterilization temperatures such as controls for autoclaves, fermentors, and water systems, ensure that the temperature indicated on the Unit Under Test (UUT) is less than the reading on the standard. This is to ensure that when the equipment is being sterilized the maximum allowable temperatures are being used. If the temperature on the UUT is above the standard, then adjust it so that it is below the standard but still within specification for the tolerance of the unit.

6.1 Obtain a testing apparatus, which can be heated/cooled to the appropriate temperature range for the instrument requiring calibration. Refer to Section 4.0 of this procedure.

6.2 Obtain an instrument capable of measuring temperature to an acceptable accuracy (herein referred to as the standard), reference **SOP 21508**. Refer to BMRAM for the Calibrated Range and Calibrated Tolerance.

6.3 When removing the device/instrument requiring calibration from the system where it is used, take note of the orientation and insertion depth as applicable and take care when calibration is complete to return it to the proper location. The device/instrument may be marked if needed or a special notation or instruction added to BMRAM.

6.4 Insert the standard into the testing apparatus. The instrument can also be inserted at this time to prevent temperature shock.

6.5 Set the temperature of the testing apparatus to the desired test setpoint. (Refer to Section 5.0 of this procedure).

6.6 When the testing apparatus has reached the test setpoint temperature and stabilized, ensure that the instrument is in close proximity to the standard.

6.7 Allow at least six minutes for the temperature of the instrument to equilibrate.

6.8 Record the temperature of the standard for “As Found-Standard” and the temperature of the instrument requiring calibration for “As Found-Instrument” in BMRAM.

6.9 Repeat steps 6.4 through 6.7 for the required test setpoints. Refer to Section 5.0 of this procedure.

6.10 If the device/instrument requiring calibration is within the calibration tolerances at all setpoints, as determined per the Equipment Calibration Procedure, ***SOP 21508 - Equipment Calibration Program***, it is considered in calibration.

6.10.1 If the instrument is in calibration, record the “As Found” values for the corresponding “As Left” values, and proceed to step 6.13 unless the “As-Found” value was close to the calibration tolerance. Use the guidance of ***SOP 21508*** to determine if adjustment or replacement of a non-adjustable instrument is needed.

6.10.2 If the instrument is not in calibration, proceed to step 6.11.

6.11 Determine from the BMRAM record or manufacturer’s manual if the instrument can be adjusted. If the instrument can be adjusted, proceed to step 6.12. If it cannot be adjusted, seek assistance from the BQA Engineer. The BQA Engineer will determine the disposition of these instruments on an individual basis.

6.12 Adjust the instrument requiring calibration per the manufacturer’s directions, and repeat steps 6.4 through 6.9. Record the standard and instrument temperature values for “As-Left”. If after repeating this step several times, the technician is still unable to achieve calibration, seek assistance from the BQA Engineer who will assign disposition of these instruments on an individual basis. Responsible parties will be notified of all out-of-specification results, per **SOP 21508**.

6.13 Complete and attach the appropriate level of calibration sticker to the instrument in a visible place (reference **SOP 21508**).

7.0 Frequency of Calibration

7.1 All temperature-measuring instruments requiring calibration will be calibrated at intervals established per **SOP 21508**.

This procedure is made available through federal funds from the National Cancer Institute, NIH, under contract [redacted].

8.0 Documentation

8.1 The person performing this procedure shall record pertinent information in BMRAM. All service information, including the vendor's field service reports whenever applicable, shall be filed with the Equipment Calibration Record electronically in BMRAM with the hard copy if applicable in the MEF file.

8.2 An equipment calibration sticker shall be completed and attached to the equipment or instrument in a visible area as per **SOP 21508**.

9.0 Definitions

9.1 **Adjust** - To attempt to bring an instrument to a state of conformance within a set of specifications using instructions provided by the manufacturer of the instrument.

9.2 **Adjusted** - Having made an instrument conform to a set of specifications by adjusting it.

9.3 **BMRAM** – Blue Mountain Regulatory Asset Manager, the software used to manage and capture calibration and other asset activities.

9.4 **Immersion Point** - The point, as specified by the manufacturer, to which an instrument must be immersed in a media in order for the instrument to achieve a valid representation of the temperature. This point can be specified as a specific point or as a minimum point, usually indicated by a line on the instrument.

9.5 **Stability** - An instrument is considered stable when the deviation of three consecutive readings obtained from the instrument at intervals of at least two minutes is less than or equal to the tolerance of the instrument or the range in the least significant digit is equal to or less than ± 2, whichever is smaller.

10.0 References and Related Documents

10.1 **SOP 21101** *Internal CGMP Compliance Auditing*

10.2 **SOP 21508** *Equipment Calibration Program*

10.3 **SOP 21555** *Use and Management of Blue Mountain Regulatory Asset Manager*

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