Quality Control Document:

Calibration of Thermometers

# Purpose

Temperature of areas and equipment which are used to store human tissue for clinical studies or human biomaterials, analytical reagents and clinical sample kit components for Clinical Trials of Investigational Medicinal Products must be monitored to confirm it remains within acceptable limits to ensure integrity of human biomaterials, analytical reagents and reliability of data. See the Laboratory Facilities SOP (UoB-CRL-SOP-002).

Where electronic temperature probes, e.g. Tutela, will be used to continuously monitor temperature, these systems will be calibrated and certified externally and records/certificates must always be kept.

This document provides instructions on how to calibrate thermometers, and a form to capture the calibration. Where thermometer calibration is being performed in house the contents of the Thermometer Calibration Record is mandatory, however the design is optional.

# Instructions

## Source a certified reference thermometer

1. Ensure the certified reference thermometer is directly traceable to national standards.
2. Ensure the certified reference thermometer has a unique ID number that can be matched with its accreditation documentation.
3. Ensure the certified reference thermometer is sent to an accredited calibration facility for recertification and that documentation is retained:
* for electronic thermometers and temperature probes calibration is required each calendar year
* for non-electronic thermometers a calibration check is required every five years.

## Set up the thermometer calibration record

1. Remove these first instruction pages.
2. Update the trial/study ID in the header.
3. Update the footer, retaining the document reference information relating to this quality control document (QCD).
4. Record the thermometer/temperature probe ID number.
5. Record the temperature being monitored.
6. Record the location of the thermometer/temperature probe.
7. Record the last certification date of the reference thermometer being used.
8. Document the action to be followed if the thermometer fails the calibration check.

Thermometer calibration

1. Document in the thermometer calibration record each time a thermometer calibration check is performed.
2. If thermometer/probe calibration checks are being carried out within the cold room ensure the door is fully closed.
3. If calibration checks are being conducted in a water bath/beaker of water, immerse the certified thermometer to the extent required by the individual device, and immerse the test thermometer or probe to the extent marked on the individual device or inferred by the device literature. If heated water baths are used, turn off the heater to read the thermometers to reduce the differential time responses to temperature change that may occur between the test and reference thermometer.
4. Allow temperature readings to equilibrate for 30 minutes or until the temperature read-outs are seen to be stable. Record the actual temperature reading of both the certified reference thermometer, and the in-use thermometer/probe.
5. Record the actual temperature reading of both the certified reference thermometer, and the in-use thermometer/probe.
6. Use the acceptance criteria in the table below to assess whether the calibration check is a pass or fail and document in the thermometer calibration record.
7. If the thermometer/probe fails the calibration check, ensure the action to be followed in if the thermometer fails the calibration check is adhered to.
8. If the thermometer/probe passes the calibration check, label with the date when the next routine calibration check is due.
9. Store the temperature monitoring record in the Laboratory Master File throughout the trial/study and archive with the other trial/study records upon closure. See the Archiving SOP (UoB-ARC-SOP-001).

### Acceptance criteria

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| --- | --- |
| **Temperature of Unit** | **Acceptance criteria** |
| -70°C or colder | ± 5°C |
| -20°C or colder | ± 3°C |
| +4°C to +37°C | ± 1°C |

# Related documents

* UoB-ARC-SOP-001 Archiving
* UoB-CRL-QCD-007 Temperature Monitoring
* UoB-CRL-SOP-001 Laboratory Set-up and Management
* UoB-CRL-SOP-002 Laboratory Facilities
* UoB-CRL-SOP-003 Sample Management
* UoB-CRL-SOP-004 Laboratory Analysis
* UoB-CRL-SOP-005 Reportable Issues

UoB QMS documents can be found on the [CRCT website](https://www.birmingham.ac.uk/research/activity/mds/mds-rkto/governance/index.aspx). Internal work instructions can be obtained from the CRCT (crct@contacts.bham.ac.uk) and/or from the RGT (researchgovernance@contacts.bham.ac.uk).

# Thermometer/temperature probe equipment ID number:

# Temperature being monitored:

# Location:

# Reference Thermometer Unique ID number:

# Last certification date of reference thermometer:

|  |  |
| --- | --- |
| **Action to be followed if thermometer fails calibration check:** |  |

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| --- | --- | --- | --- | --- |
| **Date** | **Temperature reading of reference thermometer (°C)** | **Temperature reading of in-use thermometer or probe (°C)** | **Pass or Fail** | **Initials** |
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