Title: Critical Equipment

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1. Scope

1.1 This SOP applies to any individual who uses laboratory equipment critical to delivering activities included in the scope of accredited testing.

1.2 This Standard Operating Procedure (SOP) describes the process for ensuring that laboratories and equipment are maintained in line with the requirements of ISO/IEC 17025:2017, to ensure the integrity of test results and the safety of staff and visitors.

1.3 Any equipment that is loaned to UoA for a trial must have the appropriate safety acceptance test completed to ensure that any adverse incident caused by the device is underwritten by the suppliers of the equipment. This may be co-ordinated through the appropriate Technical Support department.

1.4 Following the requirements of this SOP shall ensure compliance with the principles of GCP, GLP and the requirements of ISO 9001:2015, ISO 17025:2017 and ISO 15189:2012.

2. Responsibilities

2.1 It is the responsibility of the Technical Manager to ensure that the environmental conditions in laboratories and clinical facilities are such to facilitate the correct performance of tests at all times. The technical requirements for accommodation and environmental conditions which affect the results of tests shall be documented in the relevant SOPs and/or Study Protocol. Environmental conditions influencing the quality and integrity of tests shall be monitored, controlled and recorded appropriately.

2.2 It is the responsibility of the Quality Assurance Manager (QAM) and Institute of Medical Science (IMS) Director to immediately suspend testing and to withhold test results in the event that environmental conditions affect, or have the potential to affect, the scientific integrity of results.

2.3 It is the responsibility of the Technical Manager to ensure that effective measures are in place for the segregation of incompatible activities (where required) and to prevent cross-contamination and/or interference (microbiological, dust, electromagnetic, radioactive, humidity, electrical, temperature, sound or vibration) and to ensure that such requirements are documented in the relevant SOPs.

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2.4 It is the responsibility of all personnel to maintain good housekeeping in their work area. Specific procedures to ensure good housekeeping must be prepared where necessary.

3. Procedure

3.1 The environmental conditions necessary for the effective performance of tests shall be appropriate to the scientific discipline and the technical requirements of test methods.

3.2 Requirements for good housekeeping in the laboratory/clinical facility include:

- Laboratory coats or suitable protective clothing must be worn (fastened) in all biohazard areas.
- Any internal laboratory notices shall be signed and dated by the Laboratory Manager, QA Manager or Technical Managers as appropriate.
- Samples must always be labelled as detailed in relevant laboratory procedures.
- Samples must not be left unattended unless security/integrity can be guaranteed.
- Facilities and equipment shall not be used for more than one function where this could compromise the test results. Effective segregation (in space or time) must be maintained where required.
- Laboratory personnel performing test methods or preparing test material are responsible for ensuring that the equipment and laboratory areas are cleaned and/or disinfected after use, if required*.
- Test material and reagents must be returned to the appropriate environment after use to ensure their integrity and prevent deterioration.
- All laboratory areas must be cleaned immediately of any spills*.
- To facilitate proper cleaning and/or disinfection all benches and work areas must be kept clear of materials not being used for the current task.

* Sodium hypochlorite, or similar solutions, are frequently used as laboratory disinfectants but may contaminate some analysis (ELISA techniques). 70% alcohol may be used as an alternative.

Wash-up of General Laboratory Equipment

3.3 All reusable glassware and plastics used in laboratories shall be washed immediately after use or moved to the wash-up area at the end of the working day. Follow manufacturer’s instructions for loading, setting and maintenance of machines used for washing glassware and general laboratory equipment.

3.4 Small items to be washed in the machine (eg stoppers) may be collected in a beaker or plastic tub and washed as a batch.

3.5 Glassware may also be sterilised in an autoclave or hot air oven, as appropriate to its intended and previous use. Containers must never be over labelled and previous markings must be removed in the washing or sterilisation process.

Disposal of waste and samples

3.6 Waste shall be disposed of in appropriate local waste streams; Containment Level 2 (CL2), Containment Level 3 (CL3), Radioactive Waste, Genetically Modified Micro-organism (GMM) waste or domestic waste. Consideration should be given to recycling wherever possible but only when safe to do so and where specific permission has been given by the appropriate Health & Safety personnel.
**Laboratory/clinical facility cleaning and maintenance**

3.7 Laboratories, clinical facilities, offices and corridor floors are cleaned by specific cleaning personnel.

3.8 If laboratory/clinical facilities are cleaned at the end of each working day, a log shall be available in which the date and initials of staff responsible for such cleaning are entered.

3.9 Waterbaths must be drained and cleaned at intervals appropriate to the application and the date of cleaning must be entered on the waterbath temperature log/cleaning log. Should sanitizers or biocides be incorporated in the water, the waterbath temperature log/cleaning log must state the date the chemical was added and the next due date.

**Routine calibration and maintenance of laboratory equipment**

3.10 To ensure the scientific integrity of results from laboratory analysis, laboratory equipment used in generating results must be calibrated and serviced at predetermined intervals to demonstrate that they are fit for purpose.

3.11 Critical equipment must be checked, and evidence documented, that it meets the required specification before being put into service. This should be repeated after significant maintenance, repair or a move to a different location.

3.12 It is the responsibility of Technical Manager to ensure that each item of critical laboratory equipment and any software used for testing and internal calibration is uniquely identified and logged on an asset register, as appropriate.

3.13 The Technical Manager is responsible for maintaining records of each item of equipment, its software significant to testing and internal calibration activities. The records maintained for each item of equipment shall include the following:

- The unique identification of the equipment and any software.
- Manufacturer’s name, model number and serial number (or equivalent).
- Checks of the equipment’s compliance with the specification required.
- Current location of the equipment.
- Results of any calibration, maintenance, service or safety inspections and date next due (where possible this should be indicated on the item of equipment for clarity).
- Details of any reference material and acceptance criteria.
- Maintenance plan and details of any malfunction, damage, modifications or repairs.

3.14 The manufacturer’s instructions, or an appropriate User Guide, shall be available at point of use for all critical equipment; to ensure correct operation and prevent unintended adjustment or operation invalidating results.

3.15 Any equipment withdrawn from use, for whatever reason, shall be suitably identified as such to preclude its use.

3.16 The frequency of calibration and performance verification shall be determined by documented experience and be based on the need, type and previous performance of the equipment. The period between calibration and verification shall be shorter than the time the equipment has been found to drift outside accepted limits.
Calibration, monitoring and service
3.17 The following is a list of typical laboratory equipment which may be regarded as ‘critical’ to testing and analysis. Where laboratory equipment is not considered ‘critical’ this must be documented. The list details the recommended calibration, monitoring and certification that the laboratory shall consider:

3.18 Autoclaves
Calibration: Annual by approved service agent.
Monitoring: Chart recorder and/or Browne’s tube. Regular (e.g. six monthly) service by approved service agent.
Certification: External certificate of calibration, if required.

3.19 Automatic pipettes (including multi-channel pipettors)
Calibration: Three monthly intervals, or as deemed appropriate by the Technical Manager, by approved service agent or in-house by suitable trained staff (where less frequent calibration is performed the laboratory shall provide evidence of ‘fitness for purpose’ of the reduced frequency). In-house checks shall use deionised water at three, or more, points using a calibrated balance. Points should be at the maximum (nominal) volume, 50% of the maximum volume and at the lower limit of the pipette range.
Monitoring: Monthly spot check of single pipette.
Certification: External certificate of calibration and/or internal record of calibration.

3.20 Balances and check weights
Calibration: Annual by approved (i.e. ISO 17025:2017 accredited) service agent.
Monitoring: Metrological traceable check weights on a ‘before use’ basis. If the balance has been switched off, a minimum of one hour should be allowed before a weighing is made to ensure temperature equilibrium. All weighing should be done away from draughts, vibration or sources of magnetism and static electricity.
Certification: External certificate of calibration.

Internal check weights shall be checked on the day of balance calibration and their weight recorded and considered stable until the next calibration. Check weights shall be traceable to UK national standard.

3.21 Centrifuges
Service: Annual service by approved service agent.
Monitoring: Visual checks and routine cleaning.
Certification: Annual service.

A traceable calibration, or check against an independent tachometer, may be performed if critical to the centrifugation being carried out by the laboratory.

3.22 De-ionisers, stills and reverse osmosis units
Service: Annual service by approved service agent.
Monitoring: Daily visual checks.
Certification: Annual service.

3.23 Dispensers
Calibration: Three monthly intervals by approved service agent or in-house by suitable trained staff (where less frequent calibration is performed the laboratory shall provide evidence of ‘fitness for purpose’ of the reduced frequency).
Monitoring: As appropriate to use.
Certification: Internal calibration.

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3.24 Microbiological safety cabinets
Service: Six monthly by approved service agent.
Monitoring: Visual checks before use and routine cleaning.
Certification: Six monthly service.

3.25 Microscopes
Service: Annual by approved service agent.
Monitoring: Visual checks and routine cleaning.
Certification: Annual service.

3.26 Volumetric glassware
Calibration: Annual gravimetric to required tolerance (if required).
Monitoring: Visual check.
Certification: Internal calibration.

⚠️ In most laboratories calibration and verification is not necessary for glassware that has been certified to a specific tolerance.

3.27 pH meters
Calibration: Before each use with appropriate calibration buffer (ie pH 4, 7 and 10).
Certification: In-house record of calibration check or participation in EQA scheme.

3.28 Temperature controlled equipment (Fridges, freezers, incubators, ovens, coldstores, waterbaths)
Service: Annual for ultra low temperature (ULT) freezers, and any associated gas pressure system for such freezers or CO₂ incubators.
Monitoring: At least daily temperature (at start of working day) checks and routine cleaning.
Certification: Annual service/gas pressure check by approved service agent as appropriate.

⚠️ If a correction factor requires to be taken into account this should be applied before recording on a temperature log. If the temperature is out of range appropriate action should be taken and recorded ie removal of temperature sensitive items to the correct environment until the temperature is corrected.

⚠️ Temperature mapping shall be considered for temperature controlled equipment (including room temperature storage areas) to identify uniformity of temperature and any areas where temperature may be out of specified range. Such areas may include positions adjacent to motors, heater or cooling elements (or heaters, windows or doors in room temperature storage areas). A temperature map shall indicate temperature at various points in each shelf (normally five) and be retained for reference.

⚠️ Temperature mapping shall be repeated whenever an item of temperature controlled equipment undergoes major repair, is moved to a new location or it is suspected that it may no longer be performing as required. In addition remapping should be considered at scheduled intervals (eg three to five yearly).

3.29 Thermometers/thermocouples
Calibration: Annual to traceable standards (or for duration of manufacturer’s calibration).
Monitoring: Visual check.
Certification: External calibration certificate, or internal if reference thermometer is used.

⚠️ If a reference thermometer is used to calibrate thermometers/thermocouples this shall be recalibrated five yearly to traceable standards by an appropriate service agent.

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3.30 Timers
Calibration: Annual with calibrated timer or national time signal (if required).
Monitoring: Visual checks
Certification: Internal calibration record

4. Abbreviations and definitions

GCP = Good Clinical Practice
GLP = Good Laboratory Practice
GMM = Genetically Modified Micro-organism
QAM = Quality Assurance Manager

5. Related documentation and references


⚠️ All staff using laboratories, clinical facilities or equipment must reference any appropriate Risk Assessments, COSHH or any other relevant safety information prior to commencing work.

Further guidance and assistance on general Health and Safety requirements should be sought from the appropriate departmental safety officer or the Health & Safety teams.