

SOP-QA-38 V4

Title: Equipment and Facilities

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GRAMPIAN CLINICAL RESEARCH OFFICE



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Document History

Version	Description of update	Date Effective
1	New SOP	1-4-17
2	Reference to GMP at 1.4 Reference to GMM activities at 3.6, 3.7, 3.8 and 5	1-6-19
3	Change of title to include 'Facilities'.	1-6-22
4	Scheduled review with no updates.	21-5-25



1. Scope

- 1.1 This SOP applies to any individual who uses laboratories, clinical facilities or equipment during a research project which is sponsored or co-sponsored by University of Aberdeen (UoA) and/or NHS Grampian (NHSG). The principles of this SOP may be applied to any work involving laboratories, clinical facilities or equipment to demonstrate best practice; compliant with various quality standards.
- 1.2 This Standard Operating Procedure (SOP) describes the process for ensuring that laboratories, clinical facilities and equipment are maintained in line with good laboratory practice, to ensure the integrity of test results and the safety of staff and visitors.
- 1.3 Any equipment that is loaned to UoA and/or NHSG 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 15189:2022.

2. Responsibilities

- 2.1 It is the responsibility of CI, or PI, 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 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 R&D 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 research.


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- 2.3 It is the responsibility of the CI, or PI, to ensure that effective measures are in place for the segregation of incompatible activities (where required), to prevent cross-contamination, and to ensure that such requirements are documented in the relevant SOPs.
- 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/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 should 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 spillages.
 - 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)

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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.

- 3.7  Any contained use waste from clinical research studies involving Genetically Modified Micro-organisms (GMM) must comply with the requirements of the Genetically Modified Organism (contained use) Regulations 2014 (see SOP-QA-41 – Genetically Modified Micro-organism research).
- 3.8  GMM contained use waste must be identified as such, segregated and disposed of as GMM waste by an approved contractor, or inactivated before disposal through normal waste routes (eg by autoclaving).



Laboratory/clinical facility cleaning and maintenance



- 3.9 Laboratories, clinical facilities, offices and corridor floors are cleaned by specific cleaning personnel.
- 3.10 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.
- 3.11 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

- 3.12 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.
- 3.13 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 of the equipment to a different location.
- 3.14 It is the responsibility of laboratory management 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.
- 3.15 Laboratory Management 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).

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- 3.16  The manufacturer's instructions, or an appropriate User Guide, shall be available at point of use for all critical equipment.
- 3.17  Any equipment withdrawn from use, for whatever reason, shall be suitably identified as such to preclude its use.
- 3.18 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

- 3.19 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:

Autoclaves

Calibration: Annual by approved service agent.

Monitoring: Chart recorder and/or Browne's tube. Regular (eg six monthly) service by approved service agent.

Certification: External certificate of calibration, if required.

Automatic pipettes (including multi-channel pipettors)

Calibration: Three monthly intervals, or as deemed appropriate by laboratory management, 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.

Balances and check weights

Calibration: Annual by approved (ie ISO 17025:2017 accredited) service agent.

Monitoring: 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.



Centrifuges

Service: Annual service by approved service agent.

Monitoring: Visual checks and routine cleaning.

Certification: Annual service.

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

De-ionisers, stills and reverse osmosis units

Service: Annual service by approved service agent.

Monitoring: Daily visual checks.

Certification: Annual service.

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.

Microbiological safety cabinets

Service: Biannual by approved service agent.

Monitoring: Visual checks before use and routine cleaning.

Certification: Biannual service.

Microscopes

Service: Annual by approved service agent.

Monitoring: Visual checks and routine cleaning.

Certification: Annual service.

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.

pH meters

Calibration: Before each use with appropriate calibration buffer (ie pH 4.0, 7.0 and 10.0).

Certification: In-house record of calibration check or participation in EQA scheme.

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: Daily temperature 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 should 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

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temperature map should indicate temperature at various points in each shelf (normally five) and be retained for reference.

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 re-calibrated five yearly to traceable standards by an appropriate service agent.

Timers

Calibration: Annual with calibrated timer or national time signal (if required).

Monitoring: Visual checks

Certification: Internal calibration record

4. Abbreviations and definitions

CI	Chief Investigator
GCP	Good Clinical Practice
GLP	Good Laboratory Practice
GMP	Good Manufacturing Practice
GMM	Genetically Modified Micro-organism
PI	Principal Investigator

5. Related documentation and references

QM-1	Research & Development Quality Manual
SOP-QA-41	Genetically Modified Micro-organism research
TMP-QA-4	SOP Template
TMP-QA-28	Temperature Monitoring Log (MPs)
-	The Genetically Modified Organisms (contained use) Regulations 2014
-	SACGM Compendium of guidance part 6: Guidance on the use of genetically modified micro-organisms in a clinical setting.

⚠ 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.

⚠ For activities involving GMM contained use, researchers should refer to the Genetically Modified Organisms (contained use) Regulations 2014 and SACGM Compendium of guidance part 6: Guidance on the use of genetically modified micro-organisms in a clinical setting. No activities involving GMM must take place until appropriate approval has been received.

Further information and advice should be sought from either the NHSG Biological Safety Officer or UoA Biological Safety Officer, as appropriate.

Further guidance and assistance on general Health and Safety requirements should be sought from the appropriate departmental safety officer or the Health & Safety teams of either NHS Grampian or University of Aberdeen (see QM-1 – Research & Development Quality Manual 6.15).

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