Loughborough University **The Centre for Biological Engineering**	**Provision of Resources**			
Document Ref: RM-POL-005	Version Nº:	1.0	Issue Date:	January 2016

Policy

The Centre for Biological Engineering (CBE) laboratories shall provide and maintain a controlled environment and both the physical requirements (infrastructure, equipment & support services) and technical expertise (personnel) to ensure the safety of CBE research staff and the wider environment, to protect research materials and ensure research quality and relevance. It shall determine and provide resources to implement and maintain the Quality Management System (QMS), to ensure effective research product realisation, stakeholder satisfaction and compliance to applicable statutory and regulatory requirements.

1. Buildings, Facilities and Equipment

All research within the CBE Laboratories is conducted at Containment Level 2, as defined under the Control of Substances Hazardous to Health Regulations 2002 and the Genetically Modified Organisms (Contained Use) Regulations 2000 (as amended 2005). This includes research activities that require a lower level of containment (i.e. Containment Level 1), which shall be carried out under the management standards imposed by the higher level (Containment level 2) to impose a quality assurance discipline and ensure research material segregation and protection. This will apply under circumstances in which projects may be divided into several phases, or where more than one project may be under way in the CBE Laboratories simultaneously, or where the CBE Laboratories might be in use for activities requiring higher containment i.e. involving Hazard Group 2 biological agents.

Description of Premises

The CBE Laboratories consists of: A) The CBE facility comprises a purpose built, self-contained, Containment Level 2 Laboratory Unit consisting of 6 laboratories with ancillary rooms such as changing rooms, store rooms and an autoclave room. The CBE Laboratories are a shared multi-user facility and has been located, designed, and constructed to facilitate cleaning, maintenance, and operations as appropriate for its intended use and to ensure that the premises have sufficient space for the orderly placement of equipment and materials to prevent or minimise mix-ups and contamination, with defined areas or other control systems for the following activities:

- Receipt, identification, sampling, quarantine and storage of incoming materials;
- Holding and segregation of waste materials before further treatment and disposal;
- Processing and laboratory operations with biological and chemical materials.

Infrastructure

The CBE has established and shall maintain processes to ensure that:

- Infrastructure and facilities, such as buildings, workspaces and associated utilities, etc., are appropriate and are properly maintained to achieve specified safety and quality requirements;
- The needs for each new project or significant change to an existing project are determined, in terms of workspace, facilities associated with the workspace, equipment and support services;
- The need and requirements for new, and/or modification or repair of existing infrastructure and facilities are identified and that requests for changes and/or expansions of facilities shall be submitted to the CBE Management Committee for review and approval;
- Maintenance of buildings and facilities is performed by appropriate University Facility Management personnel and/or external contractors, including regularly scheduled maintenance of lighting systems, air conditioning and heating systems.

Security and Containment

The CBE has established and shall maintain procedures or measures to ensure that:

- All utilities e.g. ventilation, air filtration and exhaust systems, that could impact quality and safety are maintained, controlled and appropriately monitored to minimise risks of contamination and cross-contamination;
- Premises are subject to a planned cleaning and preventative maintenance programme;
- Premises are secure and that access is restricted to authorised CBE and University personnel, including storage facilities and alarm systems, as applicable;
- Access for essential non-laboratory personnel, such as Contractors and Maintenance Staff, emergency call-out personnel, cleaning staff is controlled.

Storage Areas

The CBE has established and shall maintain procedures or measures to ensure that:

- Dedicated and appropriate areas are identified for the different storage activities, as appropriate;
- Storage areas have equipment, facilities, and temperature/humidity control or HVAC systems in place, appropriate for the different storage activities, and to ensure that all material is stored in such a way that minimises the risk of contamination to the product, personnel and the environment;
- For critical materials, storage environments are subject to continuous temperature monitoring,

- Storage areas and/or equipment are secure and access is controlled;
- Emergency procedures and contingency arrangements for continued operations are available in the event of storage environment or equipment failure, or for the requirement for significant structural change to the building that renders the premises unusable for the storage of biological and/or chemical material, as applicable. .

Control and Maintenance of Equipment

The CBE has established and shall maintain procedures or measures to ensure that:

- All critical equipment (i.e. that control exposure to hazardous material and/or maintain quality system processes) is of adequate size, appropriate design, and is suitably located for its intended use;
- All critical equipment is subject to regular visual checks, inspection, testing, preventative servicing and remedial work;
- All critical equipment is subject to a cleaning and preventative maintenance programme to enable operators to clean and maintain each type of equipment in a reproducible and effective manner;
- Contaminated equipment is decontaminated regularly and when it leaves the containment area or when it is serviced or maintained;
- Responsibilities for maintenance, calibration, labelling and use of equipment is assigned;
- Personnel are provided with appropriate training for the operation and maintenance, of critical equipment, as appropriate.

Control and Maintenance of Computer Systems

The CBE has established and shall maintain procedures or measures to ensure that:

- Critical computerized systems have sufficient controls to prevent unauthorized access or changes to data;
- Incidents related to computerized systems that could affect the quality or the reliability of data and other records or test results are recorded and investigated;
- Changes to the computerized system are authorized, documented and tested.

Control and Maintenance of Inspection, Measuring and Test Equipment

The CBE has established and shall maintain procedures or measures to ensure that:

- Control, weighing, measuring, monitoring and test equipment critical for assuring quality are calibrated using standards traceable to certified standards, where applicable;
- Calibration, maintenance and servicing records for test equipment are retained;
- Test equipment that does not meet calibration criteria or does not have a documented operating procedure are not used;
- Responsibilities for maintenance, calibration, labelling and use of test equipment are assigned.

2. Provision of Training and Supervision

The CBE has established and shall maintain processes to ensure that:

- All CBE personnel with responsibilities and work activities associated with any of the processes of the QMS are competent on the basis of appropriate education, training, skills and/or experience;
- Current and future training requirements of personnel are identified and appropriate training programmes developed and implemented by qualified personnel to provide information and instruction for all levels of personnel performing activities within the CBE that are associated with any of the processes of the QMS;
- The Research Group Leader/Principal Investigator of a given research group, or the supervisor/manager of a unit or work area, as fits the circumstances, will be responsible for identifying competency requirements and making recommendations on the training needs of their staff, and for ensuring that all employees allocated specific tasks are suitably qualified and experienced to execute those tasks;
- Effectiveness of the training is evaluated and records of training, education, experience, and skills are maintained and periodically assessed by the relevant authority;
- All personnel are aware of the relevance and importance of their activities and how they contribute to the achievement of the quality research objective and conversely business impact when requirements are not achieved.

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Version History

Version Reviewed	Date Revised/ Reviewed	DCN No	Revision Summary	New Version Number
1.0	4th December 2017 By C. Kavanagh	N/A No changes	No Changes Minor editorial changes only	**1.0** No new version number required.
1.0	2nd December 2019 by C.Kavanagh	004	Addition of T208b (Wolfson School) Containment Level 2 Laboratory as a named location for HTA work. However this is a satellite laboratory of the CBE and therefore runs under the same QMS.	2.0
2.0	6th December 2021 by C.Kavanagh	N/A No changes	No Changes Minor editorial changes only	2.0 No new version required.
2.0	4th December 2023 by C.Kavanagh	N/A No changes	No Changes .New Review date only	2.0 No new version required
2.0	8th December 2025 by C.Kavanagh	N/A No changes	Removal of T208b (Wolfson School) as a location as no longer used . Minor change	2.0 No new version required

Document Control

The aster Copy of all Controlled Documents is filed by the Departmental Quality Manager. The latest version M is maintained on the CBE network. This document is not a controlled copy once printed from the network.

Security Statement

Written by: Paul Hourd Date: 25/01/2016
Reviewed by:C.kavanagh Date: 08/12/2025

Reviewed by: R. Thomas

Date:09/12/2025

Approved by N.Medcalf Date: 25/01/2016
Review Approved by: K Coopman

Date: 09/12/2025

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