Loughborough University **The Centre for Biological Engineering**	**Organisation and Governance**			
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Organisation and Management Framework

The Centre for Biological Engineering (CBE) management shall demonstrate its commitment to the development and implementation of the Quality Management System (QMS) and improving its effectiveness by:

- Communicating the importance of meeting stakeholder as well as statutory & regulatory requirements,
- Establishing a quality policy and quality objectives,
- Conducting management reviews,
- Ensuring the availability of resources,
- Ensuring the organisation and management of the CBE is defined and the responsibilities and authorities are specified.

Governance Framework

Authorities and responsibilities for specific processes of the Quality Management System (QMS) shall be defined in the procedures where the specific QMS process or activity is documented. An organisational management structure has been established to show the interrelation of the personnel in the CBE who implement, manage, perform and verify work activities affecting the QMS and associated quality and safety assurance and the interface with groups in the University responsible for Health & Safety and Ethical compliance (Figure 1).

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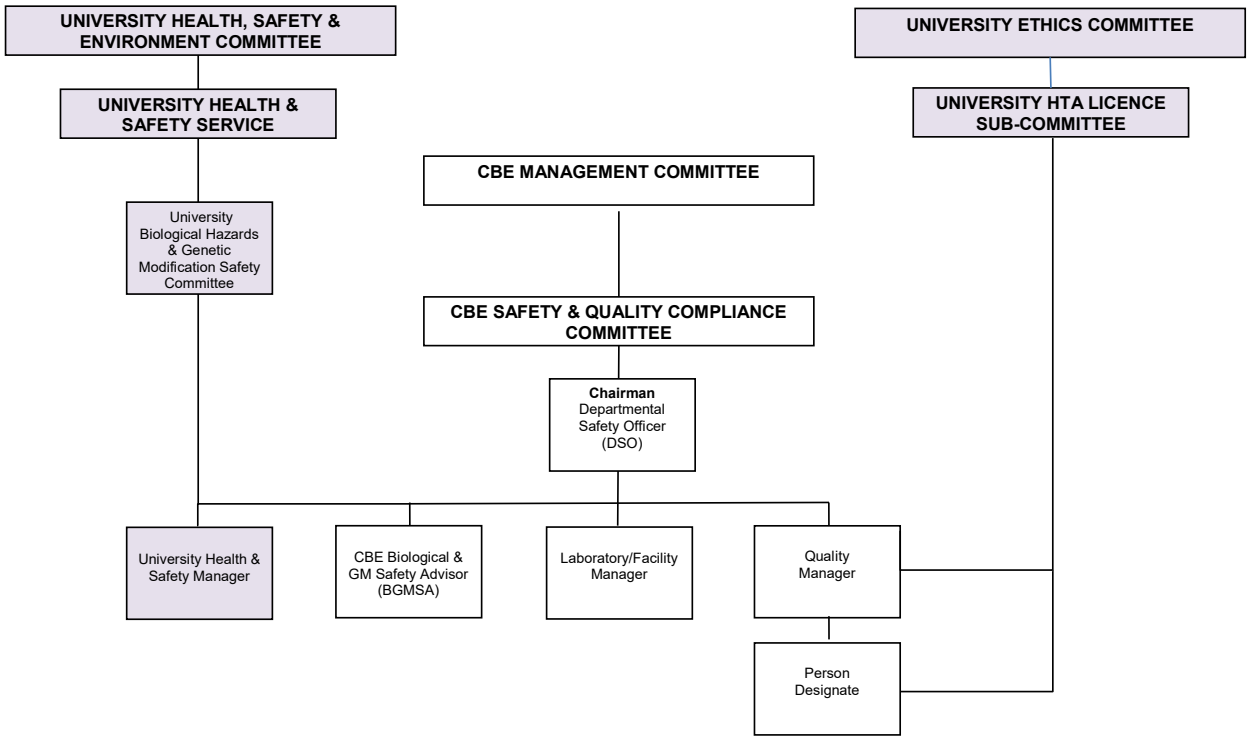
Figure 1. The CBE Organisational Management and Governance Structure



Responsibilities for Research Governance under Health and Safety Legislation

Strategic Scientific Development Officer and Radioactive Waste Advisor and Biological and Chemical Safety Officer(s)

- Radiation Protection and Biological and Chemical Safety Officer(s) carries out the functions of the Biological Safety Officer; providing specialist professional guidance and advice on matters relating to the containment of biological hazards and the safety of staff, and to ensure compliance with the University Biological Safety Policy and relevant legislation. All contact and liaison with

the enforcing authorities (primarily the Health and Safety Executive) on matters relating to biological safety shall be via, or in consultation with, the University Health & Safety Manager. The terms of reference for the function of Biological Safety Officer are provided in the University Biological Safety Policy.

- University Biological Hazards & Genetic Modification Safety Committee (BHGMSC)

  The University BHGMSC is the means by which CBE research staff shall review and approve the risk assessments for work involving Genetically Modified Organisms or Biological Material categorised as Hazard Group 2. The role of the BHGMSC is to ensure consistency in approach and outcome of risk assessments and to help ensure that risk assessments are peer reviewed within a sensible time frame, before work is due to commence. The terms of reference for the BHGM Safety Committee are provided in the University Biological Safety Policy.

- Local (CBE) Biological Agents and Genetic Modification Safety Advisor (BGMSA)

  The local BGMSA shall advise the CBE management and research staff on all matters relating to work involving the acquisition, handling and use of hazardous or potentially hazardous biological material within in the CBE.

- The Departmental (Wolfson School) Safety Officer (DSO)

  The DSO shall advise the CBE management and research staff on all matters relating to work involving the acquisition, handling and use of hazardous chemical substances as well as the installation and use of equipment and/or processes with associated physical hazards.

Responsibilities for Research Governance under the Human Tissue Act (2004)

The role and responsibilities of the Loughborough University Licence Holder, Designated Individual (DI), Person Designated (PD) and Quality Manger are described in the University HTA Licence Compliance Quality Manual.

- Departmental Person Designate (dPD)

Under the HTA licence, an appropriately trained and experienced member of the academic CBE staff shall be appointed as the departmental Person Designate (dPD) to support the University appointed Designated Individual. The dPD shall act at a local level to support the DI and to advise the CBE on procedures and systems agreed by the DI that ensure compliance with the HT Act and the University's HTA Compliance Quality Manual. The dPD will provide support and guidance to CBE staff and students and also in audits and monitoring activities and practices.

- Departmental Quality Manager (dQM)

  The departmental Quality Manager shall be responsible the creation, implementation and day-to-day management of the QMS within the CBE and in conjunction with the CBE Management Committee, promote awareness of regulatory or stakeholder requirements throughout the CBE, including the CBEs commitment to quality. The dQM shall manage the internal monitoring & measurement process and report the efficiency and performance of the QMS to the relevant CBE management committee, including the need for improvement. The dQM shall serve as a liaison with external parties on matters relating to the QMS.

  The dQM, with the support of the CBE Laboratory/Facility Manager and Technical Staff, shall be responsible for the routine operational maintenance of the CBE Laboratory Unit, its equipment and processes. With the dPD, they will ensure that all persons working within the Unit have received and documented the appropriate training and authorisation.

Responsibilities of the CBE Management Committee (CBEMC)

The senior management team for the CBE is responsible for leadership, governance and strategy. It shall implement applicable University's policies within the CBE. It shall ensure that all persons with supervisory or managerial roles, and those appointed to safety or quality related roles, routinely monitor working practices and have a responsibility to identify any instances where the required safety or quality standards are not met and ensure that appropriate corrective action is taken to improve the situation. The CBEM committee shall comprise Principal Investigators and Heads of Group.

Responsibilities of the CBE Safety and Quality Compliance Committee (SQCC)

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The CBE SQC Committee is responsible for the management and maintenance of CBE facilities. This shall include responsibility for ensuring that CBE research facilities and activities conform to and comply with applicable legislation as well as University policy and licences. The SQCC shall comprise internal safety and quality (HTA) representatives and shall be supplemented with external University level representatives as required eg members of the University Health, Safety & Environment Committee or the HTA Licence Sub-Committee.

Responsibilities of Research Personnel and Laboratory Users

- Heads of Group/Principal Investigators

  Each Head of Group/Principal Investigator shall ensure that any current or prospective research or teaching activity involving the acquisition, storage, use and disposal of any material within their area of responsibility is undertaken in accordance with applicable Health and Safety legislation and/or other regulatory, licensing standards or national/local ethical guideline legislation and with the policy and processes described in the CBE Quality Manual.

  Principal Investigators drive the research and have overall responsibility for their projects as well as the governance and management of the research and their team, including responsibility for the use of human samples. This may be delegated to a named, suitably trained colleague (Person Responsible) who will be the custodian of those samples. The Lead Investigator or Person Responsible will be responsible for conducting the research using human samples in accordance with the SOPs, related HTA standards and Codes of Practice and the University's HTA Compliance Quality Manual, and must maintain and make available for internal monitoring and audit by the DI and others, in addition to external audit and inspection requirements, all appropriate and required records and documentation.

- Individual Laboratory Users/Researchers

  It shall be the duty of all CBE employees and students to observe those parts of the University Health and Safety Policy and/or HTA Licence Compliance Quality Manual that are relevant to their own work. Individual workers will observe all risk control measures identified in the risk assessments for their work activity, and take due care for their own safety and that of others. This duty shall also be applied to occupational visitors to the CBE Laboratory Unit.

It is the responsibility of the individual research staff to ensure that all work that they undertake is carried out in accordance with the processes described in the CBE Quality Manual and identify and report all non-compliant practices.

- Designated Responsible Person

  Designated laboratory users (Responsible Person) shall be assigned to selected critical equipment within the CBE. The Responsible Person (RP) shall ensure that appropriate procedures for use and maintenance of the equipment are in place and that all users are adequately trained. The RP shall ensure that the equipment is appropriately decontaminated before maintenance or removal from the CBE Laboratories. The RP, via the CBEMC, shall ensure that an appropriately trained deputy or replacement is available in the event of prolonged absence (> 2 weeks) or before leaving the CBE in the event of their contract of employment ending.

Hierarchy of Governance

The CBE Safety and Quality Compliance Committee (SQCC) are responsible for ensuring the CBE laboratories meet the requirements of staff and the University, including compliance with applicable legislation. The SQC committee reports to the CBE Management Committee, which shall be chaired by one of the Heads of Group/Principal Investigators. The departmental dPD and dQM shall have additional responsibilities associated with membership of the University HTA Licence Sub-Committee.

Internal Communication

The CBE has a policy and process for open communication throughout the CBE organisation, ensuring that data regarding the effectiveness of the QMS is shared through media such as intranet communication, email notification, visual management boards and minuted laboratory user and group meetings. These meetings shall be supported by management review meetings and safety & quality assurance committee meetings to ensure that the QMS processes and arrangements for all work activities within the CBE are effective.

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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 Amendments made. Will be updated when decisions finalised.	1.0 New version not required
1.0	2nd December 2019 by C.Kavanagh	N/A No Changes	Minor Amendments made	1.0 New version not required
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Document Control

The Master Copy of all Controlled Documents is filed by the Departmental Quality Manager. The latest version 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:24.01.2016
Reviewed by: C.Kavanagh Date:04/12/2023

Reviewed by : R. Thomas

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Approved by: Nick Medcalf
Date: 25/01/2016
Review approved by: K Coopman

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