

Loughborough University	Monitoring and Measurement			
The Centre for Biological Engineering				
Document Ref: MI-POL-009	Version No:	1.0	Issue Date:	January 2016

Policy

The Centre for Biological Engineering (CBE) shall apply suitable methods for monitoring and, where applicable, measurement of the Quality Management System (QMS) processes at appropriate stages of the core research product realisation process. These methods shall demonstrate the ability of the processes to achieve planned results and where improvement can be made. When planned results are not achieved, corrective and preventative action shall be taken, as appropriate, to ensure conformity/compliance to specified quality and safety requirements and standards.

Internal Inspection Audit

The CBE shall conduct internal inspection audits at planned intervals to determine whether the QMS, its associated processes and operational procedures are effectively implemented and maintained and to monitor compliance with applicable legislation, standards or guidance.

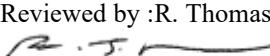
An audit programme shall be planned, taking into consideration the status and importance of the processes and areas to be audited, as well as the results of previous audits. The audit criteria, scope, frequency and methods shall be defined. Selection of auditors and conduct of audits shall ensure objectivity and impartiality of the audit process. Auditors shall not audit their own work.

The responsibilities and requirements for planning and conducting audits, and for reporting results and maintaining records shall be defined in a documented procedure. The management responsible for the area being audited shall ensure that actions are taken without undue delay to eliminate detected non-conformities and their causes.

Change control mechanisms

The CBE shall establish and maintain a change control system that incorporates the requirements to undertake an assessment of the risks associated with changes that relate to CBE systems, processes, facilities and associated equipment, to verify the impact of the changes on the conformity to specified safety and quality requirements and on effectiveness of the QMS before they are introduced and to monitor the potential cumulative effects of multiple minor changes.

Written by: P.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

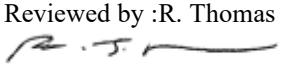
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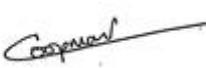
Version History

Version Reviewed	Date Revised/Reviewed	DCN No	Revision Summary	New Version Number
1.0	4 th December 2017 by C.Kavanagh	N/A No changes	No Amendments required Minor Editorial only including review details	1.0 New version not required
1.0	2 nd December 2019 by C.Kavanagh	N/A No changes	No Amendments required Minor Editorial only including review details	1.0 New version not required
1.0	6 th December 2021 by C.Kavanagh	N/A No changes	No Amendments required Minor Editorial only including review details	1.0 New version not required
1.0	4 th December 2023 by C.Kavanagh	N/A no Changes	No Amendments required .New review date only	1.0 New version not required.
1.0	8 th December 2025 by C.Kavanagh	N/A no Changes	No Amendments required .New review date only	1.0 New version not required.

Document Control

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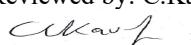
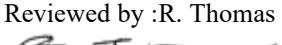
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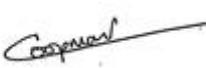
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