Standard Operating Procedure **SOP048**

Title: PRODUCTION AND CONTROL OF RISK ASSESSMENTS

Location: CBE Laboratories

1. PURPOSE

To describe the process for the generation, review and approval of risk assessment documentation; in line with Health and Safety legislation and University Health & Safety Policy.

2. SCOPE

The SOP applies to CBE personnel and work activities in the Containment Level 2 CBE Laboratory Unit located at Holywell Park or the Tissue Engineering Laboratory (T208B) located in the Wolfson School involving identified biological hazards (Hazard Group 1 & 2 biological agents and Class 1 Genetically Modified Organisms (GMO)), chemical hazards and/or physical hazards.

Special Note: Please read in conjunction with **Bio- labs Risk Assessment Process Guidance note**.

3. RESPONSIBILITIES

CBE Laboratory Users (Risk Assessment Proposer/Submitter)

3.1. Ensure that the appropriate risk assessments described in this SOP are carried out, recorded and approved and that appropriate control measures are in place BEFORE commencing any work activity that may expose themselves or others to hazardous or potentially hazardous materials, equipment or work activity.

3.2. Ensure that they have read and understood all risk assessments relevant to their work activity BEFORE they start work and maintain a record of this in their training file.

3.3. Ensure Risk Assessment is reviewed annually or sooner if there are any changes to the work.

3.4. Ensure Risk Assessment has been reviewed and signed by Supervisor(s)

Supervisors/Principal Investigators

3.5. Review risk assessments and identify the training requirements relevant to the work activity of the persons under their direction.

3.6. Review the risk assessment for accuracy and ensure all risks have been identified and controls put in place to mitigate these risks.

3.7. Ensure that all the requirements identified in the assessment are complied with and that risk assessments remain valid.

3.8. Ensure that a risk assessment is reviewed immediately following a serious incident or where there is reason to suspect it is no longer valid.

3.9. Ensures that any work which entails a risk of serious personal injury or fire by persons working alone in the evenings or at weekends is prohibited, irrespective of the status and experience of the worker.

3.10. Check the Risk Assessment is being reviewed regularly as appropriate.

Document Controller

3.11. Receives approved Risk Assessments from proposers/submitters

3.12. Ensures the approved risk assessment is filed centrally and maintains an up to date record of Risk Assessments.

3.13. Ensures copies of approved risk assessment forms are readily available to CBE Laboratory personnel in a place where the physical, chemical or biological hazard is presented i.e. located in the CBE Laboratory Unit Office .

Peer Reviewer/Approver (Excluding HG2 and GMO Risk Assessments)

3.16 Reviews the risk assessment for accuracy and ensure that all risks have been assessed and adequate controls have been identified.

3.17 Ensures they approve or request changes by liaising directly with the submitter.

3.18 Ensures they return the approved signed Risk Assessment to the submitter and Document Controller .

Approver (HG2 and GMO Risk Assessments)

3.19 Reviews the risk assessment for accuracy and ensure that all risks have been assessed and adequate controls have been identified.

3.20 Ensures they approve or request changes by liaising directly with the submitter.

3.21 Ensures the Risk Assessment gets forwarded to a peer reviewer of the relevant committee as appropriate.

3.22 Ensures they return the approved signed Risk Assessment to the submitter and Document Controller .

4. EQUIPMENT AND MATERIALS

None

5. PROCEDURE

5.1 CBE Risk Assessment Process

i)Proposer checks appropriate CBE Risk Assessment spreadsheets (in CBE-QUAL Workspace). for existing Risk Assessments.

ii)If there is an existing Risk Assessment similar to your proposed work write a **Risk Assessment Review Record** to detail your intended work.

iii)If the Risk Assessment is similar but has *MINOR* differences write a Risk Assessment Review Record to document the changes and list all additional hazards/control measures.

iv)If Risk Assessment does not exist for your proposed work or an existing Risk Assessment requires *MAJOR* changes – write a new one and include the process and all chemicals associated with the process.

v)Please refer to section 5.4 for more information about risk assessment review process.

5.2 Review/Approval of New Risk Assessment Procedure

i. Submitter/Proposer writes the risk assessment and passes to supervisor.

ii. The Supervisor reviews and checks the risk assessment ensuring the information is accurate and all safety risks have been assessed . If the risk assessment is not adequate it should be returned to the submitter with appropriate feedback. Once the supervisor is satisfied the risk assessment is complete they should sign it and return it to the submitter.

iii. The submitter forwards the risk assessment (with the supervisors signature) to shared.ws.safety@lboro.ac.uk . They should include all supporting information required (e.g SDS, Certificate of analysis). (Ensure Lab manager is cc'd)

iv. Once approved the submitter should forward signed copy to the Document Controller who files the approved Risk Assessment (and other supporting information) centrally.

v. Approved Risk Assessments will be available to view in electronic risk assessment files , hard copies and as read only on LEARN (unless content is confidential) and will be catalogued in a spreadsheet.

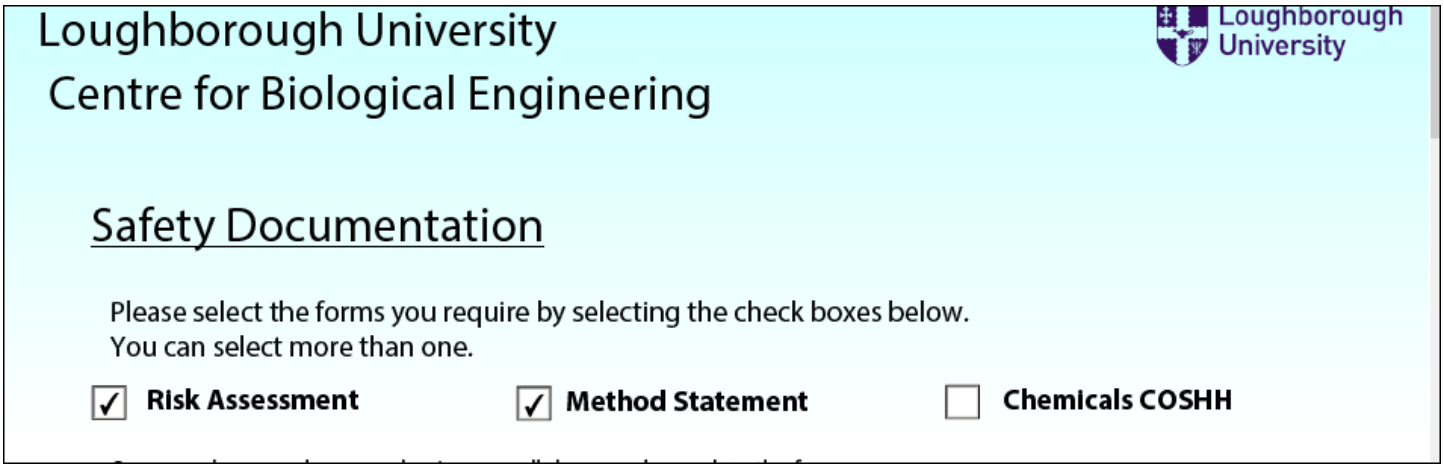
vi. Risk Assessments will be audited periodically.

5.3 Types of Risk Assessment

5.3.1 Physical Hazards

A risk assessment must be carried out, recorded and approved and appropriate control measures implemented BEFORE commencing any work activity that may expose CBE personnel to physical hazards e.g. mechanical or electrical hazards etc associated with the installation and use of new (permanent or temporary) equipment, utilities or infrastructure etc

Complete the CBE Safety Documentation Risk Assessment form. Tick and complete appropriate section(s) and follow section 5.2.


Loughborough University
Centre for Biological Engineering

Loughborough University

Safety Documentation

Please select the forms you require by selecting the check boxes below.
You can select more than one.

☑ Risk Assessment ☑ Method Statement ☐ Chemicals COSHH

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5.3.2 Chemical Hazards

A risk assessment must be carried out, in accordance with the Control of Substances Hazardous to Health Regulations (COSHH), before acquiring, purchasing or using any hazardous chemical agent (including asphyxiants e.g. nitrogen or CO2 gases) for the first time and for all activities where there is a risk of exposure to the chemical agent. An approved COSHH risk assessment and appropriate exposure control measures must be in place before commencing any work activity involving (or producing) a hazardous chemical agent.

NOTE: *For the vast majority of commercial chemicals, the presence (or not) of a warning label will indicate whether a COSHH assessment is required. COSHH applies to virtually all substances hazardous to health except: Asbestos and Lead, which have their own regulations and substances that are hazardous only because they are radioactive, at high pressure, at extreme temperatures or have explosive or flammable properties (other regulations apply to these risks)*

- Complete the **Safety Documentation Risk Assessment Form** (tick COSHH)
- Check that the CBE has the facility to receive and store the chemical agent safely (i.e. in terms of scale and segregation requirements) before acquiring or purchasing the chemical agent.
- Follow procedure in section 5.2 remembering to attach the SDS.

NOTE: *Refer to Section 7.1 of SOP039 'Storage, Handling and Disposal of Hazardous Chemicals' and the CBE Code of Practice for 'Work with chemical carcinogens, mutagens, substances toxic reproduction and cytotoxins' for general guidelines on storage of chemicals and solvents.*

5.3.3 Biological Hazards

A risk assessment must be carried out, recorded and approved, before acquiring, purchasing or using any biological agent for the first time and for all activities where there is a risk of exposure to the biological agent. An approved risk assessment and appropriate exposure control measures must be in place before commencing any work activity involving (or producing) a biological agent.

5.3.3.1Non-GMO Biological Hazards

1)Complete Biological Risk Assessment for Work with Biological Materials Form (BRA) and submit to supervisor for review. Supervisor should review for accuracy and return to submitter with suggested amendments or approval signature.

2**)If the biological agent has been categorised as Hazard Group 1 (HG1) it can be Approved by an experienced CBE member. Please liaise with the Lab Manager.**

3**)If the biological agent has been categorised as Hazard Group 2 (HG2) (**and do not apply to mammalian cells where the HG2 classification is simply due to the potential for adventitious agents) **it should be forwarded to Strategic Scientific Development Office and Radioactive Waste Advisor. (Ensure lab manger is cc'd).**

4)Strategic Scientific Development Office and Radioactive Waste Advisor forwards the approved electronic and or paper copy of the HG2 Biological Risk assessment to the LU GM Safety Committee for final review and approval.

5)Strategic Scientific Development Office and Radioactive Waste Advisor forwards the approved (by the committee) BRA Risk Assessment to the Document Controller and the Proposer/Submitter.

6)The Document Controller places a read only copy onto the CBE LEARN page, updates the risk assessment spreadsheet (including review dates) and files an electronic copy in appropriate folder and places a paper copy in hard copy file .(Confidential material will not be made available to view).

7)The Proposer/Submitter implements the identified exposure control measures before commencing work.

8)Inform the laboratory manager of any incoming biological materials, any associated hazards and provide an expected delivery date.

9)Complete SOP008 Receipt of Biological Materials form when materials arrive

***NOTE:** Refer to SOP008 'Receipt of Hazardous Biological Materials' and SOP005 'Storage and Transport of Biological Materials'.*

NOTE: Please ensure any BRA involving HTA material is flagged with the Person Designate and the Departmental Quality Manager.

5.3.3.2 Genetically Modified (GMO) Biological Hazards

- Proposer/Submitter submits an electronic or paper copy of the completed BRA with the completed **GMO Risk Assessment Form** to their supervisor along with any supporting documentation e.g. written protocol, C of A, Certificates of Authentication etc.
- Supervisor reviews the documentation for accuracy and returns to submitter for amendments as required or with a signature if approved.
- Submitter Forwards the BRA and GMO Risk Assessment Form along with the supporting documentation to the **Strategic Scientific Development Office and Radioactive Waste Advisor** for review and approval**. (Ensure Lab Manager is cc'd)**
- Strategic Scientific Development Office and Radioactive Waste Advisor forwards the approved electronic and or paper copy of the GMO Risk assessment (along with the corresponding BRA) to the LU GM Safety Committee for final review and approval.
- Strategic Scientific Development Office and Radioactive Waste Advisor forwards the approved (by the committee) GMO Risk Assessment to the Document Controller and the Proposer/Submitter.
- The Document Controller places a read only copy onto the CBE LEARN page, updates the risk assessment spreadsheet (including review dates) and files an electronic copy in appropriate folder and places a paper copy in hard copy file .(Confidential material will not be made available to view).
- The Proposer/Submitter implements the identified exposure control measures before commencing work.
- The Proposer/Submitter should communicate expected arrival dates for the material to the Laboratory Manager and complete the SOP008 Receipt of Biological Materials form when the material arrives.

***NOTE:** Refer to SOP008 'Receipt of Hazardous Biological Materials' and SOP005 'Storage and Transport of Biological Materials'.*

5.3.4 Out of Hours and/or Lone Working Hazards

A risk assessment must be carried out, recorded and approved and appropriate control measures implemented BEFORE commencing any work activity alone and/or out of normal hours (8.00 am to 6.00 am weekdays). Guidance on lone and out of hours working is provided in Annex 7 of the local Code of Practice.

- Proposer/Submitter completes the **Out of Hours/Lone Working Risk Assessment Record** shared.ws.safety@lboro.ac.uk route (Document Controller MUST be informed).

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5.3.4.1 Guidance for completing Out of Hours Risk Assessments

- Out of Hours work is for essential work only (time point assays, feeding cell cultures). Out of hours working should not be used for work that could be done during normal working hours or become the norm.
- Ensure you provide detail of exactly what you plan to do out of hours
- Ensure you have identified an out of hours contact who has a good understanding of the CBE Laboratories. Make sure the person you name is aware and is happy to be your emergency contact.
- Out of hours risk assessments must be reviewed every three months or before if there is a change to the work you intend to do. If there are no changes to the work you intend to do within the three months an E-mail to the Document Controller to notify of this must be made.

5.4 Review and Revision of Existing Risk Assessments

Risk assessment should be reviewed at least annually or more frequently if there is any change in the work, or if new information becomes available that indicates the assessment may no longer be valid.

- *No Revision/Minor Revision* - Proposer/Submitter should complete the **Risk Assessment Revision/Review Record** and follow procedure in 5.2.
- If a *MAJOR revision* is required write a new/make amendments to original risk assessment and re-submit for approval following procedure in section 5.2
- Document Controller files a paper copy in the CBE Office by attaching the Revision/Review Record form to the front of the current version of the risk assessment under review or to the new version of the risk assessment if one is issued. A read only copy is placed on LEARN. All reviews are placed in appropriate electronic folder and spreadsheet updated.

Minor Revision

A minor revision is a change to the Risk Assessment which does not affect the risk. This could be a minor change to the location/procedure/materials used or a new person added to the project. If a new person is being added to the risk assessment the Rick Assessment Review form must indicate exactly what the new person will/will not be doing as part of the original risk assessment. It must also detail experience and training provided to justify their addition to the risk assessment.

Major Revision

A significant change to a Risk Assessment will require a new Risk Assessment or major re-write of the Risk Assessment which must be re-submitted and approved.

Significant changes warranting a major revision are (by no means exhaustive) :

- 1)Change to the risk of initial risk assessment
- 2)Change of process/equipment/procedures
- 3)Change/addition of material used if effects the risk (i.e addition of unscreened material)
- 4) Change in the scale of operations
- 5)Change of location if it effects the risk (new facility)
- 6)· Change in the containment conditions or control measures
- 7)Change in the waste treatment procedures
- 8)Changes to people responsible
- 9) Changes to the properties (more virulence, mobility, differences in growth/media, etc)

- E.g With a new strain of bacteria , if the hazard group is the same as the previous strain and the new strain has similar properties to the existing one, then that is fine. If the hazard group changes or the new strain properties are different (potentially increasing the risk) then a new risk assessment would be needed.

6. DOCUMENTATION

Blank templates of the Risk Assessment Forms are available on the CBE website. These forms serve to keep information in a consistent manner and assist the CBE to comply with the detailed requirements for risk assessment and classification as set out in the COSHH and GM (Contained Use) Regulations.

The following records are outputs of this SOP:

- Safety Documentation Risk Assessment Form (Risk Assessment, Method Statement and COSHH)
- Biological Risk Assessment form.

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- Genetically Modified Organism Risk Assessment Form
- Out of Hours/Lone Working Risk Assessment Form.
- Risk Assessment Revision/Review Record

These records shall be filed in the CBE Office in a location that allows easy access and retrieval in emergencies and for future review.

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SOP Version History

Review Number	Version Reviewed	Date Revised/ Reviewed	Revision Summary	New Version Number
1	001	21.08.09	1. Revised to include Risk Assessment procedure for 'Out of Hours' and lone working. 2. Addition of flow charts to clarify the approval process for COSHH, Biological and GMO risk assessments 3. Minor editorial changes and update to reflect new CBE Risk Assessment form.	002
2	002	21.06.11 P.Hourd	Revised procedure for procurement and installation of new equipment; to include impact assessment of room design change	003
3	003	18.01.12	Change to the process for the generation, review and approval of CBE Risk Assessment documentation (documented in CRN 007)	004
4	**004**	**25.06.2018**	**Section 5: Added** ***NOTE***: Please ensure any BRA involving HTA material is flagged with the Person Designate. Section 5.5: Added: Upload onto the internal website alongside original Risk assessment.	**004**
5	**004**	**Sept 2020**	Review Addition of guidance for completing out of hours working risk assessments. Addition of guidance for completing risk assessment review forms.	**005**