THE UNIVERSITY OF SHEFFIELD

BIOLOGICAL SAFETY POLICY & PROCEDURES
Statement

This University policy and associated procedures were approved by the Health and Safety Committee on 25 April 2013 on behalf of the University of Sheffield Council and forms part of the Health and Safety Policy of the University of Sheffield.

The use of this management procedure and the incorporation of its requirements into working practices and activities will ensure that the University of Sheffield and its community achieve compliance with its legal duties with regard to health and safety.

The most recent version of the University Policy and Procedures can be found at: -

https://hs.shef.ac.uk/attachments/170?updated=1391525531

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THE UNIVERSITY OF SHEFFIELD
BIOLOGICAL SAFETY POLICY & PROCEDURES

1. Introduction

The University is committed to ensuring that the highest standards of health, safety and environmental protection are achieved for all deliberate laboratory-based work with genetically modified organisms (GMOs) and other biological material which could give rise to a risk of infection, allergy, toxicity or other potential hazards to health. This includes work with micro-organisms, cell cultures, parasites, human or animal tissue (including blood, urine and other body products) or plant material. Compliance with this policy will be achieved through risk assessment and control, appropriate training and the provision of suitable facilities in which to work with biological agents.

Biological hazards that occur from means other than deliberate work such as food safety, Legionella control in water systems or pandemic infections in the workplace, fall outside the scope of this document and are addressed directly within additional specific policies.

2. Legislation

This policy is produced to ensure compliance with the Health and Safety at Work etc Act 1974, the Management of Health and Safety at Work Regulations 1999 and more specifically:

- Control of Substances Hazardous to Health (COSHH) 2002
- The Genetically Modified Organisms (Contained Use) Regulations 2014.

3. Roles and Responsibilities

3.1 President & Vice-Chancellor

The President & Vice-Chancellor is responsible for achieving the objectives of this policy, namely to ensure that Heads of Departments know and undertake their individual responsibilities regarding biological work, and that the requirements of this policy are met.

3.2 Faculty Vice-Presidents

Faculty Vice-Presidents have oversight of resources devolved from the President & Vice-Chancellor. As such, they have a duty for not only the application of these resources, but also its safe application. Faculty Vice-Presidents should satisfy themselves that the departments within their area of responsibility have suitable and sufficient arrangements in place to meet the requirements of this policy.

3.3 Heads of Departments

Heads of Departments are responsible for ensuring that:

- Local rules are produced which state their specific departmental arrangements to comply with this policy. These arrangements shall identify departmental duty holders
and specify the responsibilities placed on each named duty holder. Particular mention must be made of the Biological Safety Officer and any other named person(s) responsible for monitoring adherence to the local rules. The name of this person(s) shall be notified to the University Health & Safety department.

- The local rules are made available to all affected staff and students in the department and shall be incorporated into the local departmental health and safety policy.

- Appropriate measures are provided to eliminate or, where this is not reasonably practicable, reduce risks arising from work with biological agents.

- Risk assessments are carried out in advance of any biological work commencing.

- Risk assessments are reviewed whenever there are significant changes to the work, an adverse incident occurs, or at least annually to ensure that they remain suitable and sufficient.

- All work involving infectious material classified as being of Hazard Group 2 (HG2) or higher in the ADCP document “The Approved List of Biological Agents” is subject to peer review by the members of the Biosafety Committee before the work commences.

- All work involving genetically modified organisms (GMOs) is subject to peer review by the members of the Biosafety Committee before the work commences.

- All work involving plant pathogens that require a DEFRA licence is subject to peer review by members of the Biosafety Committee before the work commences.

- All work involving the holding or use of organisms listed under Schedule 1 of the Specified Animal Pathogen Order 2008 is subject to peer review by members of the Biosafety Committee and that the appropriate licence is obtained from the Health & Safety Executive before the work commences.

- Staff are made aware of the requirement to notify certain GMO work to the enforcing authority and to pay the accompanying fee where appropriate. Current fees can be found here: http://www.hse.gov.uk/biosafety/gmo/acgm/acgmwarn.htm

- All persons working with biological materials are competent to do so. Professional qualifications must be scrutinised, induction training completed and authorisation made in writing.

- Records of training and authorisation are kept for anyone working with biological agents at HG2 or higher, or GMO activities at Class 2 or higher.

- Equipment and facilities are regularly tested and maintained to ensure efficient and safe operation and compliance with all relevant legislation.

- Appropriate physical and procedural security measures are adopted prior to work with, or storage of, any biological materials listed under Schedule 5 of the Anti Terrorism Crime and Security Act (ATCSA) 2001.
Heads of Department can employ competent persons to help with this role and delegate the day to day responsibilities in writing to other members of staff. However, the responsibility for the safety of staff, students and visitors remains with the Head of Department.

### 3.4 Director of Health & Safety

The Director of Health & Safety will be responsible for providing assurance on legal compliance to the University Health & Safety Committee. This will be provided through:

- The audit of laboratories working with biological agents and review of departmental inspection reports.
- Reporting on Health and Safety Executive (HSE) and other enforcement agency visits.
- Provision of information, instruction and training relating to the requirements of applicable Regulations and completion of biological risk assessments.
- The investigation of all notifiable accidents, incidents or unintended releases of GMOs or other biological agents.

The Director of Health & Safety will also appoint a University Biological Safety Advisor to assist with fulfilling their responsibilities under this policy. The duties of the University Biological Safety Advisor will include:

- Informing the HSE of all new notifiable GMO projects, and any significant changes to existing notified projects, once approval has been granted by the Biosafety Committee.
- Notifying the HSE of the first use of HG2 agents specifically listed in Schedule 3 (Part V) of COSHH, and all HG3 agents, once approval for these activities have been received from the Biosafety Committee. Note that the use of HG4 agents or Class 4 GMO work is strictly prohibited within the University.
- Notifying the HSE in a timely manner of all other applicable administrative changes to existing GMO risk assessments, including changes to locations of work or where projects are transferred between Principal Investigators.
- Notifying the relevant enforcement agency of reportable accidents, incidents or unintended releases of GMOs.
- Notifying the Home Office of the holding within University premises of any materials listed under Schedule 5 of the Anti Terrorism Crime and Security Act (ATCSA) 2001.

### 3.5 Director of HR and Communications

The Director of HR and Communications has direct management responsibility for the provision of an Occupational Health Service commensurate to the level and variety of work with biological agents conducted across the University.

The University Occupational Health provision will be managed by the Human Resources function.
3.6 University Biosafety Committee

The University Biosafety Committee is responsible for:

- Reviewing and approving all experimental work involving GMOs, and any work involving hazardous biological agents at a classification of HG2 or higher.
- Reviewing and approving all work involving animal or plant pathogens that may have an adverse effect on the wider environment.
- Reviewing and approving all work involving organisms listed under Schedule 1 of SAPO.
- Maintaining Institutional oversight of all direct work with infectious or hazardous biological agents and regularly reporting into UEB Health & Safety Committee.
- Reviewing the Biosafety Committee terms of reference and membership expertise at least on an annual basis.

3.7 Biological Safety Officers

Where work is carried out involving biological agents within a department, a suitable person shall be appointed by the Head of Department to carry out the functions of the Biological Safety Officer (BSO). The duties of the BSO will include:

- Advising on the containment and training aspects of the work.
- Advising on risk assessment and co-ordinating the notification procedures.
- Approving GMO project proposals on behalf of the department, ahead of submission for peer review by the Biosafety Committee.
- Ensuring that local rules for the safety of personnel are drawn up and followed.
- Monitoring to ensure that appropriate training of personnel has been carried out.
- Ensuring accidents/incidents spillages etc. in the laboratory (or other containment facility) are appropriately investigated and followed up.
- Advising on the safe storage, packaging, transport and disposal of GMOs and other harmful or potentially harmful biological material, and ensuring that Principal Investigators keep current and accurate records.
- Ensuring that laboratories are appropriately disinfected/decontaminated at the end of a project or before the entry of maintenance personnel or other authorised non-laboratory workers. Appropriate disinfection could range from swabbing down work surfaces to complete fumigation and will be dependent on the risk assessment.
• Participating in locally organised health & safety inspections of microbiological laboratories.

• Advising on appropriate methods for testing for the presence of viable process organisms outside the primary containment, if deemed necessary.

• In conjunction with the Departmental Safety Officer, ensuring that control measures and equipment are tested and maintained at appropriate intervals.

• Liaising with the University’s Biosafety Committee on behalf of the department.

• Informing the Health & Safety Department of the addition of new laboratories as well as any decommissioning, change of use or change of Containment Level of any existing laboratories.

• Communicating any changes to relevant Regulations, policies or procedures to all affected members of their department.

• Acting upon on matters relating to biosecurity from Health & Safety and/or Home Office Counter Terrorism Security Advisors, where appropriate.

3.8 Departmental Safety Officers/Facility Managers

Dependent on the local arrangements set by the Head of Department; key duties may be shared with Departmental Safety Officers/Facility Managers, and may include:

• Monitoring that risk assessments are carried out properly, appropriate control measures are in place and their continued effectiveness monitored.

• Ensuring that all dangerous occurrences such as unintended biological release, major spillages and breaches to codes of practice or local rules are reported immediately to both Health & Safety and the departmental Biological Safety Officer.

• Performing and documenting periodic departmental safety inspections.

• Reporting faults identified and documenting completion dates of remedial actions.

• Ensuring records of attendance at safety training are kept centrally or locally as appropriate, to meet statutory requirements of competence for all staff and students.

• Ensuring that all personnel receive, or know where to find local rules and risk assessments which are relevant to their work.

3.9 Principal Investigators

The Principal Investigator on each research project involving biological agents shall:

• Ensure that all work involving GMOs and biological agents at HG2 or higher under their supervision has received prior review and approval by the Biosafety Committee. All risk assessments submitted to the Biosafety Committee must be supported with a statement from the departmental Biological Safety Officer.
• Maintain a register of risk assessments and ensure that the assessments are available to all workers named in the risk assessment.

• Review risk assessments at least annually to ensure they remain suitable and sufficient, and inform the Health & Safety Department of any significant changes to GMO risk assessments via the online BIOS database.

• Ensure that those working under their supervision are aware of the hazards and risks associated with the work and with the control measures in place and the procedure to follow in the event of an accident – this includes ensuring that appropriate disinfectants and/or spillage equipment is readily available at all times during biological work.

• Provide appropriate supervision and monitor compliance with this policy, health surveillance requirements, local rules and their risk assessments.

• Ensure all those working under their supervision undergo health surveillance where appropriate (see later section).

• Assess the competency of all those working under their supervision to carry out work safely, and to arrange appropriate training where necessary.

• Co-operate with the Departmental BSO and/or University Biological Safety Advisor to ensure that appropriate physical and procedural security measures are adopted prior to any work with, or storage of, biological materials listed under Schedule 5 of the Anti Terrorism Crime and Security Act (ATCSA) 2001.

By virtue of this policy, only permanent members of University of Sheffield staff are deemed to have relevant competence to be the Principal Investigator of a GMO project, however in exceptional circumstances the committee will review proposals from long term post-doctoral scientists who are not permanent members of staff.

3.10 Employees/Students

Employees/students must make full and proper use of all measures put in place by the department to control and minimise the risk of exposure to potentially infectious, genetically modified or toxic biological agents. They should, in particular:

• Use control measures in the way intended and as instructed.

• Work to risk assessments and agreed protocols/procedures.

• Wear personal protective equipment (PPE), including if required respiratory protective equipment (RPE), correctly and as instructed.

• Store PPE when not in use, in the accommodation provided.

• Practice a high standard of laboratory/workplace hygiene.

• Report promptly to their Supervisor any defect discovered in any control measure supplied (including PPE).
They must also co-operate fully with all reasonable requests made by management (through the local Biological Safety Officer/Facility Manager) in relation to compliance with the provisions of this policy.

4. **Provisions of this Policy**

4.1 **Risk Assessment**

No work with any biological agent or genetically modified organism (GMO) shall be carried out until a suitable and sufficient risk assessment has been completed.

Risk assessments for work with GMOs and biological agents of Hazard Group 2 or higher must be reviewed and approved by the Biosafety Committee. Further guidance can be found at the following link: [http://www.sheffield.ac.uk/hs/specialist-information/biosafety](http://www.sheffield.ac.uk/hs/specialist-information/biosafety)

The person(s) directly involved in the work and departmental safety representatives should participate in the risk assessment process.

The risk assessment is subject to annual review to ensure it remains suitable and sufficient. Risk assessments will also be subject to period review as necessary following any update to industry best practice, or Institutional policy decisions arising from the Biosafety Committee.

4.2 **Control Measures**

So far as is reasonably practicable, exposure to biological hazards identified in the risk assessment process shall be in the first instance prevented through the use of non-hazardous alternatives, or reduced by substitution of the hazardous agents with less hazardous alternatives or by using safer procedures/processes.

Where this is not reasonably practicable, suitable protection measures shall be put in place. Work with infectious agents will only take place at the minimum Containment Level required.

These protection measures shall be applied in the following order of priority:

- Design and use of appropriate work processes, systems and engineering controls.
- Use of adequate ventilation systems and organisational measures.
- Restricted access to competent personnel.
- Use of PPE.

Note: The University has no facilities providing adequate protection for work with Hazard Group 4 agents and as such, any work with these agents is prohibited.

4.3 **Use of Control Measures**
The workplace shall be inspected on a regular basis to ensure that the control measures recommended in the risk assessment are in place and are being properly used and/or applied.

Important considerations are:

- The nature of biological agent(s) used or stored in the laboratory.
- The condition of the flooring in Containment Level 2 laboratories and the flooring and walls in Containment Level 3 laboratories.
- The condition and suitability of work surfaces, such as laboratory benching, at all Containment Levels.
- The equipment within the laboratory or laboratory suite, in particular siting and operation of microbiological safety cabinets.
- The security of the laboratory spaces, and restriction of access to authorised persons only.
- Air handling and maintenance of negative pressure where applicable.
- Appropriate and validated disinfection processes, including autoclaving.

### 4.4 Maintenance, Examination and Testing of Control Measures

All control measures (including engineering controls, autoclaves and PPE) shall be maintained in an efficient state, in efficient working order, in good repair and in a clean condition.

The operational performance of all microbiological safety cabinets and re-circulating safety cabinets will be monitored at monthly intervals by a competent member of the department using a recognised technique (such as measuring airflow with a vane anemometer) and the results recorded in a log book. Any incidents of adverse performance should be reported immediately to the departmental nominee with responsibility for arranging maintenance/remedial works, for further investigation.

Under the requirements of the COSHH Regulations, all items of local exhaust ventilation (such as microbiological safety cabinets, fume cupboards etc) shall undergo a scheme of ongoing statutory thorough examination and testing at intervals of not less than 14 months, or as determined by the competent examiner. In addition, all open-fronted cabinets used for microbiological purposes shall be examined for appropriate containment of aerosols (such as KI discus test by a UKAS accredited contractor) at least every 12 months, or more frequent as determined by local risk assessment, or following any significant changes to the laboratory layout or equipment which may have an effect on airflow. Records relating to the monitoring of all safety cabinets shall be kept for 5 years.

Further guidance on the use of microbiological safety cabinets can be found in Appendix 2 of the HSE publication ‘Management and Operation of Microbiological Containment Laboratories’ which is available here: https://www.hse.gov.uk/biosafety/management-containment-labs.pdf.

Autoclaves that are used to deactivate biological or GMO waste shall be validated at least annually using a test method defined by BS 2646 (12-point thermocouple) or an equivalent...
standard as appropriate. Validation must be carried out by a reputable and competent service provider using test equipment that is calibrated and traceable to a known national standard.

The use of bench top autoclaves for treating waste is not recommended, as they cannot normally be calibrated to an appropriate standard.

Records of validation shall be kept for a minimum of 5 years.

Where required by local risk assessment, the sealability of laboratories to prevent release of fumigant during full room fumigation will be checked at least annually by smoke pencil test.

In addition, the above control measures shall be visually checked before use and as part of departmental inspections, as per the HSE publication referenced above.

4.5 Health Surveillance

Health surveillance may be necessary when working with certain biological agents. The guidance provided by the Advisory Committee on Dangerous Pathogens (ACDP) makes recommendations where health surveillance is appropriate.

If the risk assessment or ACDP guidelines indicate that health surveillance is required, then advice on the nature of the health surveillance should be obtained from the University Occupational Health Provider.

Details of when health surveillance is required and the process to follow are outlined in Appendix A of this policy.

Women of child bearing age should be made aware that work with certain biological or chemical agents may potentially affect their health or that of their child. The risk assessment should highlight any effects to new or expectant mothers. New, expectant, and breast-feeding mothers should report their condition to their Line Manager so that a personal risk assessment can be performed and the appropriateness of health surveillance considered/reconsidered.

4.6 Information, Instruction and Training

Employees and/or students must be provided with adequate information, instruction and training with regard to any work with material containing potential biohazards. This information, instruction and training at minimum must include:

- Induction training prior to beginning practical work including:
  - Details about the biohazard(s) involved.
  - The findings of any risk assessments undertaken.
  - The control measures required to prevent exposure to this material.
  - Training in good microbiological practice.
  - Familiarisation with the local rules.
  - Training in emergency procedures.
- On-going training commensurate with the tasks required of staff to ensure they are competent to perform their duties.
• Refresher training (where appropriate) to maintain standards.

• Training when a significant change to work, equipment, work environment, work activity or responsibilities takes place, especially where increased or new risks may be involved.

• Biohazard signs should warn of genuine infectious hazards. These must always be placed at the entrance to Containment Level 3 facilities, and should be used at Containment Level 2 - either where a whole room is dedicated for work at that level, or to mark an item of equipment used for storage of biohazards within an otherwise Containment Level 1 area.

• Where laboratories are shared, a list of the species worked with in the laboratory should be displayed at the entrance, unless there is good justification against this, such as biosecurity considerations.

4.7 Emergency Procedures

Arrangements shall be put in place at departmental level to deal with accidents, incidents and emergencies involving biological agents.

These arrangements shall include:

• Needlestick/sharps injury procedure where appropriate.
• Exposure to aerosol or face/eye splash procedures.
• Spillage and decontamination procedures.
• The provision of adequate first-aid facilities.
• Building evacuation procedures.

4.8 Accident and Incident Reporting

All accidents and incidents involving biological agents must be reported as soon as practicable via the University online accident reporting system: https://air.shef.ac.uk/

The requirement to notify accidents and incidents to the HSE or competent authority varies depending on the nature of the biological agent involved:

• For all exposure incidents involving biological agents which have (or could have) resulted in serious human infection, the HSE will need to be notified through the Reporting of Injuries, Diseases and Dangerous Occurrences Regulations (RIDDOR).

• All accidents which are defined as ‘a significant and unintended release of GMOs in the course of their contained use which could present an immediate or delayed hazard to human health or the environment’ must be reported to the HSE via the CU3 – ‘Notification of accidents involving Genetically Modified Organisms’ form.

All required notifications of qualifying accidents and incidents to the Regulators will be performed by the Health & Safety Department.

For all accidents/incidents involving a specific animal or plant pathogen, in this context an incident is one which has or may have resulted in the release of a specified animal or plant pathogen which could cause serious disease in susceptible species.
4.9 Record Keeping

Records shall be kept for specific intervals for:

- Annual review of relevant risk assessments for a minimum of 10 years.
- Inspection and testing of microbiological safety cabinets and autoclaves for 5 years.
- Health surveillance (health records) for 40 years.
- Instruction and training given in relation to work with biohazards for 40 years.

4.10 Disposal of waste

Waste management and disposal is strictly regulated with complex requirements. As the University generates a substantial quantity of biological waste each year it is critical that the organisation develops robust policies and processes to ensure that both the University and employees meet their legal obligations and manage waste sustainably.

Consequently there is a separate and specific policy relating to the management and disposal of biological waste that all departments and lab workers must comply with. The Biological Waste Policy and Procedures are effectively an annexe of the Biosafety Policy and subject to the same governance processes.

The Biological Waste Policy and Procedures includes the following sections:

- Roles and responsibilities,
- Requirements relating to training and competences,
- Applicable legislative requirements and definitions,
- Our approach to managing risk,
- procedural guidance on how to manage and stream waste.

Further direction on the processes to follow for specific categories of laboratory waste can be found here: [https://www.sheffield.ac.uk/efm/recycling-waste/lab-workshop-waste](https://www.sheffield.ac.uk/efm/recycling-waste/lab-workshop-waste)

4.11 Monitoring/Audit

Compliance with the provisions of this policy shall be monitored by Health & Safety, in line with the agreed Health & Safety Audit Programme. Audits will be conducted at a minimum of every 3 years for departments operating Containment Level 2 laboratories, or more frequently if circumstances dictate. All of the appropriate records shall be made available on request for inspection by the audit team.
Appendix A:

Health Surveillance: Biological Agents & Genetic Modification

The University is committed to ensuring that the highest standards are achieved for all deliberate laboratory-based work with genetically modified organisms (GMOs) and other biological material e.g. micro-organisms, cell cultures, parasites, human or animal tissue (including blood, urine and other body products) or plant material which give rise to a risk of infection, allergy or toxicity or are potentially hazardous to health. This is to safeguard the health and safety of staff and all persons that might be affected by those activities, and to protect the environment.

The Control of Substances Hazardous to Health Regulations (COSHH) 2002 and the University of Sheffield’s Biosafety Policy require all individuals working with certain higher risk biological agents: Hazard Groups 2 - 4 and GMO Classes 2 – 4, are kept under health surveillance. This will mainly consist of a paper health screening form completed prior to starting work.

All staff and Postgraduate students working with unscreened human blood and tissue must also follow this health surveillance process.

All individuals requiring health surveillance are required to complete HM11: Biological Agents & Genetic Modification questionnaire. The agreed process for completion of this form, and the link to download a blank copy, is can be found at the following webpage: http://www.sheffield.ac.uk/hr/wellbeing/healthsurveillance

The process works as follows:

- The Project Supervisor must complete Section A of the form and then forward it to the individual proposed to work with working biological agents and GMO Classes
- The individual will then complete Section B, sign and date the form and forward to it to North02@healthmanltd.com
- HML clinical team will review the questionnaire and a ‘FIT’ certificate will be sent to occupationalhealth@sheffield.ac.uk so that the employees details can be added to the Biosafety database. An electronic copy of the ‘FIT’ certificate will also be sent to the relevant Departmental Safety Officer.

If a Hepatitis B vaccination course, booster or blood test is required:

- The ‘FIT’ certificate will be sent to the University Health Service
- The University Health Service will contact the individual to arrange an appointment

The costs for all vaccinations are charged to the individual’s department.