University Occupational Health and Safety Standard
BIOLOGICAL SAFETY

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1. PURPOSE

The University is committed to meeting its legal obligations by ensuring that it has adequate arrangements, facilities and trained personnel to reduce the risk of injury or ill health from work activities involving biological hazards.

Biological safety can be defined as a group of practices and procedures designed to provide a safe environment for individuals who work with potentially hazardous biological materials. The primary goal of biological safety is to reduce or eliminate exposures to these agents through the use of a range of control measures.

This document sets out the minimum requirements to control risk associated with work activities involving biological hazards at the University of Strathclyde, in order to comply with relevant legislative obligations and University requirements.

2. SCOPE

This document applies to all staff, post graduate students and visitors (for example visiting academics) who either work with biological hazards or work in areas where biological hazards are used, or have managerial responsibilities for biological safety at the University of Strathclyde.

3. ABBREVIATIONS

ACDP	Advisory Committee on Dangerous Pathogens
CL	Containment Level
COSHH	Control of Substances Hazardous to Health Regulations
DEC/UEC	Department/University Ethics Committee
DBSC	Departmental Biological Safety Co-ordinator
GMO	Genetically Modified Organism
GMM	Genetically Modified Micro-organism
GMSC	Genetic Modification Safety Committee
HG	Hazard Group
HoD	Head of Department
HSE	Health and Safety Executive
OH	Occupational Health
OHS	Occupational Health and Safety
SHaW	Safety, Health and Wellbeing
PI	Principal Investigator
SACGM	Scientific Advisory Committee on Genetic Modification
SAPO	Specified Animal Pathogens (Scotland) Order 2009
SIRIS	Strathclyde Incident Reporting and Management System
UBSA	University Biological Safety Adviser

4. DEFINITIONS

4.1 **Biological Agent** - any micro-organism (bacteria, virus, parasite, fungus), cell culture (the in vitro growth of cells derived from multi-cellular organisms) or human endo-parasite, including any which may have been genetically modified, which may cause infection, allergy, toxicity or otherwise create a hazard to human health. In the context of this document 'biological agent' also defines biological material that contains or may contain one or more biological agents.

4.2 **Biological Hazard** - any biological substance originating from a biological source and may include: biological agents; any material which contains or may contain biological agents; or any other biological substances which are not classified as biological agents for example blood, urine, human or animal tissue, semen.

4.3 **Containment Level** - directly related to each equivalent hazard group and describes the level at which biological agents are managed in the laboratory environment to prevent exposure.

4.4 **Genetically Modified Organism** - any micro-organism, plant, or animal in which genetic engineering techniques have been used to introduce, remove, or modify specific parts of its genome.

4.5 **Hazard Group** refers to the classification of biological agents under The Control of Substances Hazardous to Health Regulations 2002 and as listed in the ACDP Approved List of Biological Agents.

4.6 **Micro-organism** - a microbiological entity, cellular or non-cellular, which is capable of replication or of transferring genetic material.

5. SPECIFIC ROLES AND RESPONSIBILITIES

The University OHS Standard for Roles, Responsibilities and Accountabilities (currently under development) document defines the roles, responsibilities and accountabilities necessary to implement the Occupational Health, Safety and Wellbeing Policy statement at each level of the organisation.

The roles and responsibilities specifically in relation to the management of biological safety are detailed as follows:

5.1 Executive Deans

Responsible for performance monitoring of this Standard within their area of responsibility.

5.2 Heads of Department/Heads of School/Professional Services Directors

Responsible for ensuring compliance with this Standard throughout their area of responsibility through provision of adequate resources and performance monitoring. They will be assisted by the DBSC or other nominated person(s) to carry out delegated tasks as deemed appropriate. Specifically, they will ensure:

- Appropriate management, administrative and technical arrangements are in place to effectively control risks arising from activities involving biological hazards and ensure that these are regularly reviewed;
- Activities involving work with biological hazards are identified within the department and have been risk assessed appropriately;
- An up to date inventory or biological material (including pathogens and toxins) is maintained;
- Appropriate emergency plans established, implemented, communicated and practiced if required;
- Mechanisms are in place to monitor (using inspection, health surveillance, incident and accident and work related ill-health report investigations), audit and review OHS performance in relation to biological safety;
- Effective regular health and safety inspections take place and action is taken where inadequate working practices, housekeeping and maintenance standards are found;

- Accidents, incidents and near misses are reported to SHaW and are investigated appropriately with preventative/corrective action taken where required;
- Risk assessments are reviewed at appropriate intervals;
- The appointment of an IATA trained member of staff to facilitate the transport of infectious substances and dry ice where necessary;
- The appointment of a DBSC where necessary;
- The appointment of a COSHH assessor(s); and
- The appointment of a clinical waste co-ordinator.

5.3 Line Managers/Principal Investigators/Academic Supervisors

Responsible on a day-to-day basis for ensuring that risks associated with biological work activities are managed within their area of responsibility. Specifically, they will ensure:

- Departmental safety arrangements are implemented within their area of responsibility as they apply to biological safety;
- An up to date knowledge of the risks associated with the work under their control is maintained;
- Biological safety is considered as part of the grant application process, where applicable;
- All personnel carrying out biological work:
    - are registered as a biological worker on the BP system;
    - are appropriately trained, supervised and competent to carry out their work;
    - comply with all relevant risk assessments and other safety arrangements;
- Biological Worker Registrations are reviewed and approved;
- Risk assessments are undertaken, approved and recorded before commencing work, including the requirement for GM risk assessments;
- Risk assessments are reviewed in a timely manner;
- The UBSA is informed of any intention to work with Schedule 5 material, SAPO agents and any other agents that require notification to the regulatory body/authorities, and comply with any recommendations;
- Laboratory personnel are referred to the OH Service for Health Surveillance where appropriate;
- The IATA trained member of staff is consulted where infectious substance and/or dry ice is destined for transport; and
- Upon termination of a project, all biological material has been appropriately disposed of and that the process is documented.

5.4 Departmental Biological Safety Co-ordinator

In departments where biological work is undertaken, a person or persons should be nominated by the HoD to liaise with colleagues throughout the department. Specifically, they will:

- Ensure all new staff and students are aware of the requirement to register as a Biological Worker on the BP system;
- Ensure all staff and students have completed the relevant online Biological Safety Training modules;
- Assist in assessing the risks from biological hazards when requested to do so;
- Maintain an inventory of biological material;
- Attend the University of Strathclyde Biological Safety Forum meeting;
- Act as responsible person for the management of microbiological safety cabinets within the department, if nominated by the HoD;
- Act as responsible person for the management of autoclaves within the department, if nominated by the HoD;
- Where health surveillance is required, liaise with the OH Service to establish a surveillance programme;
- Keep an up-to-date record of those staff members who have attended health surveillance and where recommendations are made by the OH Service co-ordinate any action as necessary.

5.5 University Biological Safety Advisor

The UBSA is appointed by the Head of SHaW and is responsible for:

- Ensuring that the University's arrangements for biological safety fully meet the statutory requirements;
- Providing competent biological safety advice to colleagues as necessary;
- Advising the University of any changes to legislation or guidance;
- Liaising with external agencies including the Health and Safety Executive and the Counter-Terrorism Unit on biosafety and biosecurity;
- Revising and/or developing policy, maintaining up to date guidance;
- Reviewing and analysing of biological/GM safety training needs;
- Directing investigations into reported incidents concerning biological and GM agents and make recommendations where necessary;
- Monitoring and auditing health and safety performance;
- Contributing to committees where specialist understanding of work involving pathogens and GMOs is required;
- Convening the University Biological Safety Forum.

5.6 Occupational Health Service

In relation to this OHS Biological Safety Standard, the Occupational Health Service is responsible for:

- Assisting HoDs to meet their statutory obligations by providing health surveillance where identified;
- Liaising with departmental staff to implement a programme of health surveillance where required;
- Providing information on occupational health related issues; and
- Keeping medical records in a suitable form for at least 40 years from the last date of entry.

5.7 Genetic Modification Safety Committee

The Committee is a statutory requirement under the Genetically Modified Organisms (Contained Use) Regulations 2014. The Committee will ensure that:

- The approach to risk assessment is suitable and sufficient and is in accordance with the regulations and takes into account the independent advice provided by the SACGM;
- GM projects are classified appropriately according to the guidelines laid down in relevant legislation and HSE approval given where appropriate;
- Suitable and sufficient assessments have been made of the risk to human health and to the environment;
- Satisfactory decisions on appropriate containment and control measures have been made;
- Activities involving GMMs/GMOs are sufficiently monitored and reviewed; and
- The University, its staff and students cooperate and communicate efficiently on GM matters.

5.8 The University Ethics Committee

The Committee is responsible for the consideration of general ethical issues relating to the teaching and research activities of the University which involves investigations on human beings. The UEC will consider studies submitted for ethical review and will strive to protect the rights, dignity, safety and well-being of all actual and potential participants. In the context of biological safety ethical approval may be required for studies involving the collection and/or use of human biological tissue and/or fluid and the isolation and profiling/typing on an individual's DNA.

5.9 The University Biological Safety Forum

The Forum provides a platform for a collaborative approach to biological safety at the University of Strathclyde. It is expected that the DBSC and/or other departmental

representative attends the forum meetings which are held at least annually. The forum meetings are convened by the UBSA and provide an opportunity for:

- All DBSCs to discuss biological safety issues and exchange professional ideas;
- The dissemination of biological safety information with regard to changes in legislation and guidance;
- DBSAs to raise safety concerns and discuss lessons learned; and
- Consultation on University of Strathclyde OHS Standards and associated documents.

5.10 Estates Services Directorate

Estates Services Operations and nominated staff within the Directorate are responsible for:

- Liaising with departments upon the request of the University's Insurers Engineering Surveyor to carry out statutory thorough examinations of autoclaves under the Written Scheme of Examination;
- Advising departments on the installation, commissioning, and maintenance of microbiological safety cabinets;
- Liaising with departments and the clinical waste contractor to co-ordinate clinical waste uplifts;
- Liaising with departments during lab decommissioning;
- The general maintenance of the fabric of laboratory areas and fixed services (e.g. plumbing and electrics) within each area.

5.11 Tenants

All companies working with biological hazards on the University of Strathclyde's premises must adhere to the University of Strathclyde Estates Services Third Party Policy (contact Estates Services for further information).

5.12 Duties for all Staff

All staff engaged with work activities involving biological hazards are responsible for complying with the arrangements put in place to prevent or reduce exposure to biological agents. They must:

- Be familiar with and understand the risk assessments for their work activities;
- Comply with Standard Operating Procedures and Safe Methods of Work;
- Wear appropriate personal protective equipment;
- Report any incident or accident through the appropriate reporting route;
- Report any defective equipment to their line manager;
- Register on the BP1 and/or BP2 system; and
- Attend any relevant training courses.

6. WORKING SAFELY WITH BIOLOGICAL AGENTS

Prior to work commencing using substances that contain or may contain biological agents (including genetically modified) workers must ensure that biological worker registration, appropriate inductions, training, and risk assessments are complete. The Information Sheet 'Pre-work Process for Biological Work' provides an illustrative overview of the steps required prior to commencing work activities that involve biological hazards. Where additional conditions apply, such as licencing and HSE notifications, the DBSA or UBSA must be contacted prior to work commencing (further details can be found within this Standard).

The following sections and associated Information Sheets and Guidance Notes provide information on various practical and administrative aspects of biological safety to ensure the health and safety of those working with biological hazards at the University of Strathclyde.

PLANNING WORK WITH BIOLOGICAL AGENTS

6.1 Risk assessment

Any work activities involving biological hazards must be subject to suitable and sufficient risk assessment. Principal investigators/academic supervisors/line managers must ensure

that appropriate risk assessments are carried out for all work activities under their control, this will include the completion of:

- A general risk assessment. The Principles and Practice of Risk Assessment training must be completed prior to carrying out a general risk assessment. Further information on the completion of general risk assessments can be found in the Guidance Notes 'Undertaking a Risk Assessment'.
- A COSHH assessment (via the eCOSHH system). See Section 6.1.1-4.
- GM risk assessment for work with GMMs/GMOs. See Section 6.4.4.

6.1.1 Duties under the COSHH Regulations 2002

The University has a legal duty, under the COSHH Regulations 2002, towards those individuals working with biological agents at the University to minimise the risks associated with the hazards to health.

The COSHH regulations apply to substances hazardous to health and includes a substance which is defined as a biological agent. The general duties of COSHH apply to incidental exposure to, and deliberate work with, biological agents. However, COSHH does not cover a situation where, for example, one employee catches a respiratory infection from another.

The general risk assessment for a specific work activity will identify the requirement for a COSHH assessment. Work must not be carried out where biological agents are involved until a suitable and sufficient COSHH assessment has been carried out and control measures put in place to reduce the risks so far as reasonably practicable.

It should be noted that whilst COSHH may apply to certain GM work a GM risk assessment must also be completed. Since COSHH only applies to substances hazardous to human health it does not consider environmental risks. Where there is any significant difference in the outcome of the risk assessments, the more stringent conditions must apply.

For further information on working with GM material see Section 6.4.4.

6.1.2 COSHH essentials training

All staff and postgraduate students working with biological hazards must complete the COSHH Essentials online training course.

This course is mandatory for those working with substances hazardous to health who require to understand the need for COSHH assessments and the control measures required when working with such substances. Refresher training should be undertaken every 3 years.

6.1.3 COSHH assessors training

Staff and post-graduate students responsible for carrying out COSHH assessments must complete the COSHH assessors training course prior to carrying out a COSHH assessment. Refresher training should be undertaken every 3 years.

COSHH Essentials and the Principles and Practice of Risk Assessments training must have been completed prior to attending this course.

6.1.4 Review of COSHH assessments

The COSHH assessment must be reviewed at appropriate regular intervals and where a significant change occurs.

Further Information: Visit the University of Strathclyde COSHH Assessment webpages.

6.2 Biological worker registration and approval to work

Individuals planning on working with biological hazards, including genetically modified organisms and micro-organisms; human, animal and plant tissues; bodily fluids and secretions; cell cultures; Schedule 5 pathogens and toxins; soils, samples or other materials from known or suspected high risk sources, must register with SHaW before commencing work. Registrations should be completed on the BP system hosted on the Pegasus system. Registration must take place annually to reflect any changes in work activity. Work must not commence until the registration has been approved by the DSC.

Further information: ‘BP1 Guidance Notes’ and ‘BP2 Guidance Notes’ are available to view within the BP registration system on Pegasus.

The BP systems provide the DSC and the DBSC overview of relevant work activities being undertaken within their area of responsibility. Departments must keep an up to date inventory of relevant material, to include but not exclusively:

- Hazard Group 2 biological agents;
- Hazard Group 3 biological agents;
- Plant materials held under plant health licences;
- Schedule 5 Pathogens and Toxins that are listed on Schedule 5 of the Anti-terrorism, Crime and Security Act;
- Any other relevant material.

6.3 Classification of biological agents and notification to the Health and Safety Executive

The UBSA must be consulted with, prior to work commencing, of any work that requires notification to, and/or licencing from, the regulatory bodies/authorities.

6.3.1 Classification

COSHH classifies biological agents into one of 4 hazard groups. As part of the risk assessment process workers should identify to which HG the biological agent they are working with belongs to and handle the agents at the CL specified for that group as a minimum, e.g. HG2 agents must be handled in a CL2 laboratory.

The ACDP Approved List of Biological Agents lists the HG for a wide range of biological agents and also indicates if the agent has also been assigned a classification under SAPO.

Table 1. Hazard group definitions.

Hazard group	Definition	Permitted at the University of Strathclyde
1	• Unlikely to cause human disease	Yes
2	• Can cause human disease and may be a hazard to employees • Unlikely to spread to the community • Usually an effective prophylaxis or treatment available	Yes, except *Bordetella pertussis*; *Corynebacterium diptheriae*; *Neisseria meningitides* which require notification to the HSE.
3	• Can cause severe human disease and may be a serious hazard to employees • May spread to the community • Usually an effective prophylaxis or treatment available	**No.** Some agents may be used under derogated conditions however notification must be submitted to, and approval gained from, the HSE.
4	• Causes severe human disease and is a serious hazard to employees • Likely to spread to the community • Usually no effective prophylaxis or treatment available	**No.**

If a biological agent does not have a HG classification it should not be assumed that it is HG1. COSHH requires that a provisional HG is determined by considering any available evidence and applying the most appropriate HG definition as defined in Table 1. If there is any doubt between classifications the higher of the two must be used, contact the UBSA for further information.

All viruses that have been isolated from humans but do not have an approved classification must be classified as HG2 as a minimum.

Further information: The ACDP Approved List of Biological Agents.

6.3.2 Notification to the Health and Safety Executive

The University of Strathclyde is permitted to use and hold ACDP HG1 and HG2 biological agents (with the exception of those listed below). The University is not permitted to use, or hold, biological agents from HG3 (except for certain derogated biological agents, see Section 6.12.2) or HG4. Where derogations apply to HG3 biological agents, as detailed in the ACDP Approved List of Biological Agents, notification to the HSE is required and derogation approved as part of the notification. The UBSA must be informed of work with derogated material prior to work commencing.

Additional licencing and notification requirements may apply for other biological agents including SAPO and GM agents. See Section 6.4.

6.4 Biological agents requiring authorisation or licencing

Certain work with biological agents require special authorisation, as detailed in the following sections. The UBSA must be consulted with, prior to work commencing, of any work that requires notification to, and/or licencing from, the regulatory bodies/authorities.

6.4.1 HG2 pathogens listed in COSHH Schedule 3 Part V and HG3 pathogens

The following ACDP HG2 agents require notification to the HSE: *Bordetella pertussis*; *Corynebacterium diptheriae*; *Neisseria meningitides*.

See Section 6.3.2 and Section 6.12.2 for further information on derogations applying to working with HG3 pathogens.

6.4.2 Specified animal pathogens

Specified animal pathogens fall under the Specified Animal Pathogens (Scotland) Order 2009 (SAPO). The purpose SAPO is to prevent the introduction and spread into the United Kingdom of specified animal pathogens which, if introduced, could cause serious disease and economic loss to the British livestock and poultry industries. SAPO prohibits any person from having in their possession any specified animal pathogen listed in Part I of the Schedule to the Order or any carrier in which such a pathogen is known or suspected to be present. It also prohibits the introduction into any animal or bird of any pathogen listed in the Schedule to the Order (Parts I and II).

Specified animal pathogens can only be held or used by those who have a SAPO licence. Licenses under SAPO must be applied for by the individual PI who will be supervising the project under which the substance will be used. A license or notice issued under this Order must be in writing, may be subject to conditions, and may be amended, suspended or revoked (by notice in writing) by the HSE at any time. The UBSA must be consulted where such work is planned and must be provided with a copy of the licence and any associated documentation.

Further information: Guidance for licence holders on the containment and control of specified animal pathogens.

6.4.3 Schedule 5 pathogens and toxins

The purpose of the Anti-Terrorism, Crime and Security Act (ATCSA) is to build on existing counter-terrorist legislation to ensure that the Government has the necessary powers to counter the threat to the UK. Part 7 of the Act is intended to improve the security of dangerous substances that may be targeted or used by terrorists and a list of substances was identified under Schedule 5. The Schedule 5 list not only covers wild type or intact micro-organisms and toxins but also genetic sequences derived from or coding for such substances.

Prior to acquiring, possessing, using, or disposing of any Schedule 5 pathogens or toxins, notification must be made to the UBSA, the DSC and the DBSA by completion of the Schedule 5 Pathogens and Toxins Notification Form. Notification to the Home Office may also be required prior to work with Schedule 5 agents commencing. The DBSA and UBSA must be consulted with prior to making notifications to the authority.

Departments must ensure that Schedule 5 pathogens and pathogens are securely stored, this would usually be in a lockable container/fridge/freezer in a restricted access area. They

must not be accessible to anyone other than the user. Usage must be logged, with any final inactivation and disposals witnessed and documented using the Schedule 5 Pathogens and Toxins Notification Form.

The University requests a yearly return of its total holdings of any substances on the list. A communication will be sent to departments asking them to declare their holdings, if any, and the quantities held.

Further information: Guidance Notes on 'Working with Schedule 5 Pathogens and Toxins'.

6.4.4 GM work

The primary piece of legislation that applies to the use of GMOs in the workplace is the Genetically Modified Organisms (Contained Use) Regulations 2014. For the purpose of these regulations only, students carrying out activities involving GM material are treated as employees of the educational establishment where they are studying.

In accordance with the GM Regulations, the University of Strathclyde has registered its premises for Class1 and Class 2 work only. PIs wishing to carry out experiments involving genetic modification must submit an appropriate Risk Assessment to the GMSC for approval prior to work commencing. The risk assessment should be carried out using the "The SACGM Compendium of Guidance".

No work involving genetic modification should be carried out on any new project until the GMSC has approved the risk assessment. The completed risk assessment will be considered and reviewed by the GMSC. Following approval, the PI will be informed when the work may proceed.

GM risk assessment is normally carried out in two stages, and in accordance with the relevant parts of "The SACGM Compendium of Guidance" (Parts 1 - 6):

Stage 1 - Identification of harmful properties (hazards) of the genetically modified organism (GMO) or genetically modified micro-organism (GMM)

Stage 2 - Determination of the final classification of risk assessment required i.e. Class 1/Class 2 for GMM or notifiable/non-notifiable for GMOs.

An annual GM risk assessment status review will be carried out in January. The PI will be requested to notify the GMSC of any significant changes to the GM project within the timeline of the annual review and review/resubmit the risk assessment to GMSC.

Further information: Visit the University of Strathclyde's GM webpage.

6.4.5 Plant health licencing

Science and Advice for Scottish Agriculture (SASA) issues plant health licences on behalf of Scottish Ministers for the following activities in Scotland:

- Work with non-indigenous and quarantine plant pests and pathogens;
- For work on certain imported soils and plant material;
- For potato quarantine testing.

Licences are issued following inspection of premises and assessment of the risks associated with the activities, in accordance with EC legislation. Particular attention is given to the containment procedures to be used when handling the licensed material and its disposal on completion of the work.

Further information: Visit the SASA website, Plant Health Licencing guidance notes, Scottish Government website, and contact the UBSA for further information prior to work commencing.

6.5 Information, instruction and training

The training needs of each individual biological worker should be identified according to a Departmental training matrix. The University Induction Checklist (OHS Induction Part 2) can be utilised to aid in establishing initial training. Any additional specific training should be identified and fulfilled as required. Ongoing training and refresher training should be

undertaken to ensure all personnel remain competent. All training should be recorded and readily accessible within departmental files.

6.5.1 Biological safety training

University Biological Safety Training is available online via MyPlace, and comprises 6 video modules with associated quizzes that must be completed and passed prior to work with biological hazards commencing.

Modules 1-3 are mandatory and must be completed by all staff, post graduate students, 4th year undergraduates, and visitors (e.g. visiting academics) working with biological hazards. These modules can be accessed directly via MyPlace.

- Module 1: Basic Biological Safety
- Module 2: Controlling the Risk of Exposure to Infectious Agents
- Module 3: Safe working with Infectious Agents

Additional Biological Safety Training modules 4-6 may be completed dependent on specific requirements. Modules 1-3 must be completed prior to this additional training. Biological Safety Training modules 4-6 should be booked online through via the DAT booking system.

- Module 4: Genetic Modification Risk Assessment
- Module 5: Working with Specific High Risk Biological Agents & Specified Animal Pathogens (SAPO)
- Module 6: Transport of Infectious Substances

Refresher training should be undertaken every 3 years.

6.5.2 Risk assessment training

Training should include the Principles and Practice of Risk Assessment, COSHH Essentials, and when necessary COSHH Assessors training. See SHaW's Training Programme for further information.

Further information: See Section 6.1 'Assessing the risks from work with biological hazards'.

6.5.3 Information and instruction

The University is committed to ensuring that all personnel working with biological material are provided with adequate information, instruction, and training to enable them to work and/or act competently at all times. The fulfilment of this commitment will make an important contribution to reducing accidents and lost time, as well as promoting operational excellence, proactive staff involvement and a positive, sustainable and safe working environment.

Where staff and students are exposed to risks from working with biological agents, then **as a minimum** those who are at risk must be informed about:

- The significant findings of any general risk assessments;
- The significant findings of COSHH assessments;
- The significant findings of any other relevant risk assessments;
- The risks to health from potential exposure;
- The need to identify specific activities where exposure presents a significant risk to the individual;
- How the risks can be reduced and the control measures already in place;
- Emergency procedures including dealing with spillages;
- Arrangements for health surveillance where this is deemed necessary;
- The requirement to report any unexplained health symptoms to their line manager, supervisor and DSC;
- The requirement to report any accidents/incidents to their line manager, supervisor and DSC.

6.5.4 Supervision

Departments must provide adequate supervision to ensure that risk control measures required to eliminate, reduce or control the risks are being implemented. Supervision should be commensurate with the risk and also the competency of the person(s) being trained.

6.5.5 Record of training and competency

Departments or individual research groups may wish to introduce a Training and Competency Record for workers. This record provides an opportunity for both the academic supervisor/line manager/PI and the trainee to acknowledge that training has been completed and a reasonable level of competency achieved.

The use of the Training and Competency Record is advised for higher risk work, such as that at derogated CL3.

Further information: Template form for 'Training and Competency Record'.

6.6 Emergency procedures

6.6.1 Dealing with spillages

Departments that store or handle biological agents must have in place plans and procedures for dealing with spillages of such material. Risk assessments and COSHH assessments should identify these procedures, and must be reviewed on a regular basis or where significant changes occur. The laboratory should have a clear written procedure for dealing with biological spillages and where necessary this should be displayed as a notice.

Further information: Guidance Notes for 'Dealing with Spillages of Biological Agents'.

6.6.2 Needle stick and other sharps injuries

Sharps are those instruments that are able to cut, prick or cause injury and includes needles, scalpels and other items such as glass. Injuries presenting a high risk are those where the sharp are contaminated with infectious material, including human blood borne viruses such as Hepatitis viruses and HIV. Piercing of the skin or contact with already broken skin will provide a route of potential infection. All biological workers should be aware of the specific hazards and control measures required when working with sharps. Training should be provided locally during supervised induction and training and should include emergency procedures to follow in the event of a needle stick or sharps injury.

The following action must be taken in the event of a needle stick or sharps injury:

- Encourage the puncture site to bleed by applying pressure below the wound, DO NOT suck the wound;
- Rinse the wound under running water for at least 5 minutes whilst encouraging bleeding;
- Dry and cover the puncture site with a plaster;
- Report the injury to the PI/line manager/DSC;
- Dependent on the significant findings of the risk assessment seek medical advice;
- Report the incident through the SIRIS incident reporting webform.

Further information: Information Sheet on 'The Safe Use of Sharps'.

6.6.3 First Aid

Departments are required to undertake a First Aid Needs Assessment to determine the level of provision of First Aid required. The assessment should take into consideration the workplace hazards and risks, including specific hazards requiring special arrangements. Where access to laboratories is restricted it is advisable to make local provisions for First Aid. University of Strathclyde Security Wardens are trained in First Aid to provide assistance in the event of an incident requiring First Aid.

Further information: University OHS First Aid Standard.

6.7 New and expectant workers

A new or expectant worker is a worker who is pregnant or who has given birth within the previous six months, or who is breastfeeding.

Given birth refers to having delivered a living child; or after 24 weeks of pregnancy, a still born child.

Employers are expected to assess risks to all employees and do what is reasonably practicable to control those risks. Risks to new and expectant workers arising from work activities must be thoroughly assessed to comply with legislation. For most workers the risk

of infection is no higher than anyone else, however for those intentionally working with biological material (including animals and animal products) there may be risk of abortion of the foetus or physical and neurological damage. **Work involving potential exposure to pathogens which may cause harm to the foetus should not be permitted.**

Further information: Information Sheet on 'New and Expectant Workers Working with Biological Material'.
Further information: Local Rule 'New and Expectant Mothers'.
Further information: Infection risks to new and expectant mothers in the workplace [ACDP]
Further Information: New and expectant mothers at work; Your health and safety [HSE INDG373]

6.8 Young persons

Risk assessments must take into consideration young persons (defined here as those aged 16-18) prior to any work commencing. Young persons registered as an undergraduate are only permitted to work with biological agents as part of an undergraduate taught practical class where work is usually restricted to handling HG1 biological agents. Exceptions to this may include engagement with high school students who are participating in outreach or other engagement programmes. Such access to laboratories by young persons undertaking learning and development activities must be subject to thorough risk assessment, rigorous control measures implemented, and approval sought from the Departmental Safety Committee before the activity commences.

6.9 Vaccinations

COSHH requires that if the risk assessment shows there to be a risk of exposure to biological agents for which effective vaccines exist, then vaccination should be offered if the employee is not already immune. The pros and cons of immunisation/non-immunisation should be explained when making the offer. Employees may not wish to take up the offer of immunisation, or else do not respond to a vaccine. If so, a risk assessment should be undertaken to determine the likelihood of infection for that particular individual carrying out the work that could result in exposure. If existing controls are not thought to be adequate then adjustments to work must be made to allow them to work safely. Immunisation should only be seen as a useful supplement to reinforce physical and procedural control measures, not the sole protective measure.

The OH service cannot administer vaccinations but they can provide advice. Immunisations may be provided through local GPs or travel clinics at a cost payable by the department.

WORKING WITH CELL CULTURES

6.10 Cell culture

Cell culture is defined in COSHH as *'the* in-vitro *growth of cells derived from multicellular organisms'* and is included in the definition of a biological agent in COSHH as they may be infected (deliberately or adventitiously) with biological agents so they could present a risk of infection and could, in exceptional circumstances, proliferate if inoculated *in vivo*. They may also present other risks such as allergy or toxicity if they are producing biologically active substances.

Where work with cell lines infected with a GMM is undertaken the CL will be determined by both the COSHH and GM risk assessments. The CL should be commensurate with the highest CL determined through these assessments.

Further information: Information Sheet on 'Working with Cell Cultures'.

WORKING WITH BLOOD, BLOOD PRODUCTS AND BODILY FLUIDS

6.11 Working with blood, blood products, and bodily fluids

6.11.1 Biological worker registration

Anyone handling blood/tissue/body fluids (animal or human) must register with SHaW using the BP2 form giving details of samples and sources (See Section 6.2 'Biological Worker Registration'). This requirement includes undergraduate, 4th year Honours and

Postgraduate students when starting their research projects. All persons involved in such work must be made fully aware of the potential risks particularly from blood borne viruses and must receive the appropriate training and supervision. Work must not commence until the registration has been approved by the DSC.

6.11.2 Containment level

All human blood samples must be treated as potentially harmful including blood obtained from the Blood Transfusion Service which, although screened for the presence of HBV, HCV and HIV and also the causal agent of syphilis, must be treated at a minimum, of CL2 and within an appropriate MSC, especially if there is a risk of infectious aerosols being generated.

Other human sources of blood, blood products or bodily fluids, where the screening status is unknown, must always be handled at CL2, using the appropriate safety measures following the controls identified using a COSHH risk assessment.

Blood, blood products or bodily fluids from animals are potential sources of human infection. Following an assessment of the risk that the source species of animal in question could pose an infection risk, the material should be handled at the appropriate containment level dependent on the hazard group of the biological agent concerned. Advice should be sought form either the DBSC or UBSA should further information be required.

Further information: Information Sheet 'Infection from Animal Sources'.

Further information: Guidance Notes on 'Working with Human Blood, Blood Products and bodily fluids'.

6.11.3 Ethics

The University seeks to ensure that where investigations involving human beings as participants are undertaken within the University in the course of teaching or research standards set by professional bodies are conformed to. The UEC and associated DEC/SECs have been established to consider the ethical issues relating to such investigations. These committees aim to provide impartial advice to participants and investigators and to protect the dignity, rights, safety and wellbeing of all actual and potential participants. They are also responsible for providing ethical approval for investigations involving human participants. Ethical approval is required prior to any such investigations commencing.

Further information: University Ethics Committee.

6.11.4 Undergraduate laboratories

Experiments involving human blood in undergraduate laboratories are rarely justified therefore any project or experiment involving the use of human blood samples taken by skin puncture from volunteer undergraduates or other persons must be approved by the HoD and the UEC prior to commencing work.

6.11.5 Vaccination

Vaccination should be offered to workers whose work activities involve the handling of human blood and blood products. Further information on vaccination can be found in Section 6.9.

FACILITIES AND EQUIPMENT

6.12 Types of biological containment facilities

6.12.1 Containment levels applicable to working with biological agents

Work involving ACDP HG1 and HG2 biological agents, or those suspecting of containing, is permitted at the University of Strathclyde and must be conducted within the laboratories that meet the relevant criteria for the respective containment level as defined by the COSHH regulations, for example:

- HG1 work must be carried out, at a minimum, in a CL1 laboratory
- HG2 work must be carried out, at a minimum, in a CL2 laboratory. CL2 must also be used where there are uncertainties regarding the HG classification.

- HG3 work must be carried out, at a minimum, in a CL3 laboratory. HG3 work is not permitted at the University of Strathclyde unless specific derogations are in place (See Section 6.12.2)

There are no legal minimum containment requirements under COSHH for CL1 laboratories, however it is advised that, where appropriate to follow the containment measures and practices similar to those at CL2. CL1 work is appropriate for undergraduate teaching labs.

Further information: Information Sheet on 'Biological containment facilities'.

In addition to the specific containment requirements defined under the COSHH regulations, more general control measures in the biological agents provisions of COSHH such as displaying the biohazard sign, putting in place procedures for the safe collection, storage and disposal of contaminated waste and the provision of adequate and appropriate washing and toilet facilities must also be addressed.

Further information: Information Sheet on 'General control measures for lab and animal rooms'.

Further information on containment and the required control measures can be found in the ACDP guidance 'Management and Operation of Microbiological Containment Laboratories'

Work involving animal pathogens and GMM/GMOs may require greater containment measures than required solely for the protection of human health. Please refer to Section 6.4 'Biological agents requiring special authorisation'.

6.12.2 Derogation

Certain HG3 biological agents have been identified within 'The Approved List of biological agents' (as published by the HSE) as presenting limited risk of infection for workers because they are not normally infectious by the airborne route. Those intending to work with derogated agents may not need to use all the control measures required at CL3. This **does not** mean that the work can be carried out at CL2, it simply allows for certain physical requirements to be dispensed with, all other aspects of the work should reflect CL3 standards (including management).

Any proposed work involving HG3 biological agents that may be handled under derogated conditions **must** be notified to the HSE prior to work commencing. The UBSA must be consulted with, prior to notification to the HSE, that derogated work is planned.

6.12.3 Access to containment laboratories

For activities such as maintenance and non-routine cleaning in CL2 laboratories and for access to all restricted personnel in the derogated CL3 laboratories at the University of Strathclyde, a formal permit to work (PTW) procedure should be established. This would be applicable to, for example, maintenance staff. The main features of the PTW procedures should be as follows:

- A written PTW, signed by a nominated responsible person, who has carried out a risk assessment for the activity within the work area. This is a formal authorisation to work of which the permit describes. The work should be carried out in the manner described in the permit using the safety measures detailed and by the personnel named on the permit.
- Personnel should have the relevant knowledge, experience and training before being allowed to work under a PTW.
- The PTW must be signed off by both the responsible nominated member of University staff managing the work area and the worker prior to work commencing.

6.13 Signage

Biohazard warning signs must be placed at various locations to indicate the presence of biological hazards, including:

- At the entrance to containment facilities
- On incubators
- On freezers

- Storage equipment

Whilst biohazard signs must be used to indicate the presence of a biological hazard, whether in use or storage, they should be used appropriately but sparingly.

Other signs, e.g. where access is restricted or where authorised access is only permitted, the relevant signage should be used to indicate this is the case.

Further information: Information Sheet on 'Biohazard Signage'.

6.14 Lab decommissioning

Procedures must be in place to ensure the appropriate decommissioning and clearance of laboratory space before handing back to Estates Services, vacating it for refurbishment, or where the space is being handed over to another research group. Individual departments may have departmental lab entry and exit procedures however Estates Services detail requirements for vacating areas where biological work has taken place in Section 4 of the Space Management Policy for Vacating Rooms.

6.15 Microbiological safety cabinets

At CL2 and CL3 (including derogated CL3) procedures that may produce infectious aerosols must be carried out in a microbiological safety cabinet (MSC) or other suitable containment.

Departments are required to appoint a nominated competent person to co-ordinate with Estates Services for all Project Management related activities involving the acquisition of new MSC's, the siting and ventilation of any new MSC's required, reviewing the commissioning requirements if the MSC is re-sited or repaired, and for matters relating to maintenance.

Under COSHH MSC's come under the term 'Local Exhaust Ventilation' and as such must be examined and tested at intervals of not more than 14 months. For ease of organising this maintenance within the required timeframe, it is recommended this is undertaken on an annual basis. The statutory duties regarding maintenance must be performed by a competent contractor. A list of approved technical companies for the University can be supplied by Estates Services. In addition to the statutory testing, airflow monitoring must be undertaken on a monthly basis by the deparmtent.

A planned maintenance programme should be established within departments where MSCs are located to ensure that statutory testing of safety critical equipment does not lapse.

Written assurance must be provided to the engineer, prior to maintenance being carried out, that the cabinet has been decontaminated if it has been used for work with infectious biological agents. Records of maintenance and testing should be kept within close proximity to the MSC. It is useful to indicate on each MSC the type of cabinet and when servicing is next due.

The use of MSCs must be subject to risk assessment, and appropriate pre-use checks carried out. The class of MSC used should be based on the requirement for user protection and product sterility. All staff and students, whose work involves the use of an MSC, must be provided with the relevant information, instruction, training and supervision regarding the safe use of MSCs and the risks of working with biological agents. A record of the training must be kept.

Further information: Guidance Notes on 'The Safe Use of Microbiological Safety Cabinets'.

Further Information: Information Sheet on 'Microbiological Safety Cabinet User Checks'.

6.16 Autoclaves

Autoclave procurement, installation and maintenance must comply with the British Standards set out in BS 2646-3:1993 Autoclaves for Sterilization in Laboratories 1993. A planned maintenance programme should be established within departments where autoclaves are located to ensure that statutory testing of safety critical equipment does not lapse. Where the autoclave is used to make biological waste safe it must also be validated

annually (12 point thermocouple) and the performance monitored through recording of every cycle either electronically or by paper print out.

Further information: Guidance Notes on 'The Safe Use of Autoclaves'.

6.17 Use of mobile phones and other personal electronic devices in laboratories

The use of mobile phones and personal electronic devices in laboratories is prohibited. Exceptions may be allowed for learning and teaching purposes at the discretion of the PI, and must be approved by the Departmental Safety Committee. Any exceptions must be subject to rigorous risk assessment.

6.18 Personal protective equipment

A lab coat and safety glasses must be worn as a minimum requirement when working with biological material. Additional personal protective equipment must be worn as determined by the risk assessment. If a filtered face piece is required this must be individually face fit tested by a trained member of staff.

Reasonable adjustments to the personal protective equipment requirement may be made, on request, on the grounds of religious or medical beliefs. Such requests should be considered on an individual basis and reasonable adjustment made and documented in the risk assessment. Any adjustments made must not increase the level of risk to the individual or others in the area.

Further information: Local Rule on 'Personal Protective Equipment'.

TRANSPORT OF BIOLOGICAL AGENTS

6.19 Classification of infectious substances for transport

The flowchart contained in the Information Sheet 'Classification of infectious substances for transport' should be used to determine the classification of the material to be transported.

6.20 Transport of infectious material and dry ice

In the interest of global public health, human and animal specimens must be transported safely, timely, efficiently and legally from the place where they are collected to the place where they will be received. The transport of infectious material and dry ice is regulated within the UK.

The storage, transport, handling and/or acquiring, of micro-organisms, blood, tissues, body fluids, and secretions, human or animal and any sample likely to contain infectious substances must be managed both internally and externally. Persons packaging Class 6.2 Infectious Substances and/or dry ice for shipment must be trained to do so. Training is online and departments must request an online licence to access and complete the training by contacting SHaW.

In addition and regardless of the presumed infection status of the sample, all biological substances, including those not classified for transport, must be packed using a triple layer system.

Further information: Guidance Notes on 'The Transport of Infectious Substances'.

BIOLOGICAL WASTE MANAGEMENT

6.21 Inactivation and disinfection

The COSHH Regulations 2002 require that specified decontamination and disinfection procedures are in place where work activities involving biological agents are undertaken.

All biological waste generated at the University of Strathclyde must be inactivated by autoclaving or chemical disinfection before being disposed of. GM waste which is covered by the GMO (Contained Use) Regulations 2014, must be inactivated by validated means prior to disposal.

6.21.1 Autoclaves

See Section 6.16.

Further information: Guidance Notes on 'The Safe Use of Autoclaves'.

6.21.2 Selection and use of disinfectants

Disinfection protocols are required for both routine use and for dealing with spillages (see Section 6.6.1 Dealing with Spillages). Disinfection is typically by chemical means and is generally used for surfaces and equipment that cannot be sterilised by autoclaving. Whilst disinfection eliminates nearly all pathogenic micro-organisms it is not an alternative to sterilisation. Where appropriate, disinfection may be followed by autoclave treatment prior to disposal via clinical waste for incineration.

Further information: Guidance Notes on 'The Selection and Use of Disinfectants'. See also Section 6.16 Autoclaves, and Section 6.22 Waste Disposal.

6.22 Waste disposal

All biological waste must be inactivated before leaving the University via the Clinical Waste route. Departments generating biological waste are required to appoint a nominated Clinical Waste Co-Ordinator. It is the responsibility of the waste generator to comply with the departmental procedures for its safe disposal to enable compliance with the COSHH Regulations.

Guidance on the segregation, labelling and packaging of Clinical Waste can be obtained from Estates Services.

Departments are required to keep accurate records on the clinical waste they produce which may be requested for the purposes of auditing. Departments should retain these records for a minimum of 3 years.

A risk assessment should be carried out for the disposal of biological waste, and standard operating procedures written. This is especially relevant for higher risk waste (derogated HG3 material) that must be transported out of the laboratory to a validated autoclave to make safe. Local Codes of Practice and Standard Operating Procedures must be adhered to.

There may be additional requirements for the disposal of GM waste and SAPO waste. For further information see Section 6.4.2 and 6.4.4.

Departments requiring to organise the disposal of clinical waste should email the clinical waste mailbox at clinicalwaste@strath.ac.uk or alternatively contact Estates Services by telephone to discuss their requirements.

Further information: Health Technical Memorandum (HTM) 07-01 provides details of the management of waste from research and laboratory facilities.

MONITORING AND HEALTH SURVEILLANCE

6.23 Health surveillance

The purpose of health surveillance is to protect a person's health and to check the effectiveness of the risk control measures that are in place. In addition to employees, the requirement to undertake health surveillance can also extend to post-graduate students whose activities expose them to certain hazards.

Statutory health surveillance facilitates early identification of ill health by employing a system of ongoing health checks for employees who may be exposed to certain hazards at work and where there remains a residual risk to health despite appropriate control measures being in place.

Where the risk assessment has identified that individuals are likely to be regularly exposed to substances hazardous to health, at or above the workplace exposure limit or there is a specific requirement for surveillance depending on the substance used, then health surveillance may be required. In the context of biological work this is most likely to involve respiratory health surveillance or skin health surveillance.

For further information on health surveillance visit the Occupational Health webpages.

6.23.1 Animal house workers

Experimental infection: Persons working in animal houses may be exposed to infections normally carried by animals and passed on to man (zoonosis) or work may involve the inoculation of animals with infectious material.

Lab animal allergens: Many people are allergic to animal hair, dander etc. and may be at risk if constantly exposed to the source of their allergy. Before commencing any work involving animals, a pre-placement declaration must be completed. A baseline lung function test must also be carried out and these are available from OH Service.

When a programme of health surveillance is completed, the OH Service will provide the department with an anonymised general report of the results advising whether there are any health issues emerging. Departments must use this information to determine if the current risk control measures are effective or if further action is required.

In addition the OH Service will report to a department or each relevant department on an individual's fitness to continue to work with biological material. Both types of reports must be kept by the department for 40 years, however, only the OH Service will retain records which contain personal medical information.

Further information: Control of laboratory animal allergy (HSE Guidance Note EH76).

6.24 Occupational hygiene monitoring

SHaW currently manage the Occupational Hygiene Monitoring programme. Workplace exposure monitoring should be requested:

- Where there is uncertainty about the levels of airborne contaminants generated by a work activity;
- Where the consequences of exposure are significant; and
- Where there is a need to confirm the effectiveness of the control measures already in place.

Departments should contact SHaW if Occupational Hygiene Monitoring is required.

PERFORMANCE MONITORING

6.25 Monitoring and audit

6.25.1 Departmental Inspections

Routine monitoring of activities involving work with biological hazards is a departmental responsibility.

All facilities are subject to scheduled inspections co-ordinated by the DSC and assisted by the Departmental Safety Committee. Departmental safety inspections should be carried out at least twice per calendar year however more frequent inspections may be required dependent on the findings of the risk assessments, for example derogated CL3 laboratories may be subject to a more frequent formal inspection. A formal inspection report should be produced and resulting actions assigned to the appropriate personnel and followed up to completion.

The UBSA or other representative from SHaW should at request be invited to attend at least one safety inspection per calendar year.

Further information: 'Guidance on Safety Inspections'.

6.25.2 Inspections by regulatory bodies

HSE specialist inspectors ensure legal compliance with secondary legislation made under the Health and Safety at Work etc. Act 1974. Secondary legislation includes regulations such as the COSHH 2002 Regulations, the GM (Contained Use) Regulations 2014, SAPO (Scotland) 2009.

The HSE have extensive powers including the right to enter premises at any time, with or without permission, and with or without warning. HSE inspectors have the authority to take

certain actions and where they consider that there is a breach in health and safety law, or that activities give rise to a serious risk, they can issue notices or proceed with prosecution or caution to the University or individuals.

The HSE specialist inspector routinely visits Higher Education Institutes to inspect high risk activities and those falling within the scope of the GM (Contained Use) Regulations. In most cases this would be a pre-planned visit that would be co-ordinated by the UBSA.

For more information: 'When a health and safety inspector calls'.

6.25.3 Audit

SHaW implements a programme of departmental audits which are independent, in depth, systematic examinations of the health and safety management systems of departments. Audits identify both strengths and weaknesses and make recommendations for improvement. The SHaW audit team contact the department ahead of a scheduled audit and provide information on the process.

7. Documentation and records

7.1 The requirements to meet the standard for Biological Safety are described in this document. Some aspects are covered in more detail in other documents which are referenced throughout.

7.2 Written records must be maintained to comply with this standard.

8. Communication and reporting

8.1 A copy of the latest Standard will be available on the SHaW website.

8.2 Departments are expected to report on compliance with this standard as part of regular OHS performance monitoring, further information can be obtained from SHaW.

8.3 With regard to this Standard departments must report incidents associated with biological work activities without delay. Incident reports should be submitted through the SIRIS Incident Reporting webform. If more than one person is involved in an incident then a separate report should be completed for each individual involved.

8.4 Some incidents may be reportable under the Reporting of Injuries, Diseases and Dangerous Occurrences Regulations 2013 (RIDDOR). These regulations require that certain work related injuries, cases of ill health and dangerous occurrences are reported to the HSE. SHaW manage the reporting of incidents under RIDDOR.

9. Tools

9.1 Guidance notes

- Dealing with spillages of biological agents
- Safe use of autoclaves
- Selection and use of disinfectants
- Safe use of microbiological safety cabinets
- Working with Schedule 5 pathogens and toxins
- Transport of infectious substances
- Working with human blood, blood products and bodily fluids

9.2 Information sheets

- Pre work process for biological work
- Working with cell cultures
- Safe use of sharps
- New and expectant workers working with biological material
- Biohazard signage
- Biological containment facilities
- General control measures for labs and animal rooms
- Infection from animal sources
- Classification of infectious substances for transport

9.3 Forms

- Training and competency record

10. COMPLIANCE

This standard aims to meet the requirements of:

- Control of Substances Hazardous to Health (2002)
- Genetically Modified (Contained Use) Regulations (2014)
- Health and Safety at Work Act (1974)
- Management of Health and Safety at Work Regulations (1999)
- Managing for Health and Safety HSG65 (2013)
- ACDP: Management and Operation of Microbiological Containment Laboratories (2018)
- Personal Protective Equipment at Work Regulations (1992)
- Provision and Use of Work Equipment Regulations (1998)
- Reporting of Injuries, Diseases and Dangerous Occurrences Regulations (2013)
- Plant Health (Scotland) Order (2005)
- Safe Working and the Prevention of Infection in Clinical Laboratories and Similar Facilities (2003)
- The ACDP Approved List of Biological Agents (2013)
- USHA Leadership and Management in Health and Safety in Higher Education Institutions (2015)
- USHA Health and Safety Management Profile (HASMAP) (2015)
- Working Safely with Research Animals: Management of Infection Risks (1997)

11. DOCUMENT HISTORY

Recorded changes to this document are maintained in the SHaW Document Control Register.