University Occupational Health and Safety Standard
GENETIC MODIFICATION

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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 genetically modified material.

This document sets out the minimum requirements to control risk associated with work activities involving genetically modified material at the University of Strathclyde in order to comply with relevant legislative obligations and University requirements. This Standard should be implemented in conjunction with the OHS Biological Safety Standard.

2. SCOPE

This Standard applies to all staff, students, post graduate students and visitors (for example visiting academics) who either work with genetically modified material or work in areas where genetically modified material is used, or have managerial responsibilities for work activities involving genetically modified material at the University of Strathclyde.

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

3. ABBREVIATIONS

ACDP	Advisory Committee on Dangerous Pathogens
CL	Containment Level
COSHH	Control of Substances Hazardous to Health Regulations
DBSC	Departmental Biological Safety Co-ordinator
GM	Genetically Modified
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
IATA	International Air Transport Association
OH	Occupational Health
OHS	Occupational Health and Safety
RIDDOR	Reporting of Injuries, Diseases and Dangerous Occurrences Regulations
SHaW	Safety, Health and Wellbeing
PI	Principle Investigator
SACGM	Scientific Advisory Committee on Genetic Modification
SIRIS	Strathclyde Incident Reporting and Investigation System
UBSA	University Biological Safety Adviser

4. DEFINITIONS

4.1 **Accident** – a significant and unintended release. Applicable to GMMs in terms of harm to human health or environment and to larger GMOs in terms of human health only, where immediate or delayed harm could arise. (Accidents involving the escape of larger GMO, which could cause harm to the environment are covered by the Environmental Protection Act 1990)

4.2 **Animal** – used in its broadest sense, and includes vertebrates, invertebrates and complex, free-living multicellular organisms such as nematodes.

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 **Class –** in relation to GM Contained Use means one of 4 classes set out in Schedule 1 of the Genetically Modification (Contained Use) Regulations 2014. Class 1 low risk to Class 4 high risk.

4.5 **Contained Use -** an activity in which organisms are genetically modified or in which genetically modified organisms are cultured, stored, transported, destroyed, disposed of or used in any other way and for which physical, chemical or biological barriers, or any combination of such barriers, are used to limit their contact with, and to provide a high level of protection for, humans and the environment.

4.6 **Genetic Modification** - the altering of the genetic material in that organism in a way that does not occur naturally by mating or natural recombination (or both). Techniques constituting genetic modification, not considered to result in genetic modification and techniques to which the regulations don't apply are set out in Schedule 2 of the Genetically Modification (Contained Use) Regulations 2014.

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

4.8 **Genetically Modified Organism** - any **animal** where their genetic material has been altered using a method that does not occur naturally.

4.9 **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.

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

5. ROLES AND RESPONSIBILITIES

The University OHS Standard for Roles, Responsibilities and Accountabilities 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 OHS Biological Safety Standard defines the roles, responsibilities and accountabilities specific to biological safety and should be referred to in conjunction with the Standard.

The roles and responsibilities specifically in relation to the management of GM activities 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 GM material and ensure that these are regularly reviewed;

- Activities involving work with GM material are identified within the department and have been risk assessed appropriately, including approval by the GMSC prior to work commencing;
- Appropriate emergency plans are 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 GM 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 GM material 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

Named person on the GM risk assessment, being responsible on a day-to-day basis for ensuring that risks associated with GM 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 GM safety;
- An up to date knowledge of the risks associated with the work under their control is maintained;
- GM safety is considered as part of the grant application process, where applicable;
- All personnel carrying out work with GM material:
    - 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 made via the BP system are reviewed and approved;
- GM risk assessments are submitted as part of project planning and are submitted and approved by the GMSC in advance of work commencing;
- GM Risk Assessments are reviewed in a timely manner and upon request as part of the annual return undertaken by the GMSC;
- Changes to the GM risk assessment are notified to the GMSC prior to the change being implemented;
- The GM activities remain within the scope of the GM risk assessment as reviewed and approved by the GMSC;
- Laboratory personnel are referred to the OH Service for Health Surveillance where appropriate;
- The IATA trained member of staff is consulted where GM material and/or dry ice is destined for transport;
- In reference to the Nagoya Protocol:
    - They are familiar with the UK Department for Environment, Food and Rural Affairs (Defra) Guidance on the UK Access and Benefit Sharing (ABS) Regulations (2022) and seek advice from Research and Knowledge Exchange Service (RKES) if required.
    - Conduct due diligence prior to project commencement and the acquisition of any genetic resources (whether from the UK or overseas) to determine if a project is in scope of the UK ABS Regulations.
    - Retain all relevant documentation (including that which proves that a project is out of scope) and submit a copy to the gmcommittee@strath.ac.uk and research-integrity@strath.ac.uk. Relevant documentation is likely to include completed due diligence forms and evidence of the intended use and source of genetic resources

(e.g. project proposals, agreements and reports; correspondence with suppliers or research partners, purchase orders and delivery notes).

- In relation to this Standard, report accidents involving a significant and unintended release of genetically modified organisms in the course of a contained use which presents an immediate or delayed hazard to human health or to the environment; and
- Upon suspension or termination of a project, the GMSC is notified and where appropriate all relevant material has been appropriately disposed of and that the process is documented.

5.4 University Biological Safety Advisor

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

- Ensuring that the University's arrangements for GM safety fully meet the statutory requirements;
- Providing competent GM advice in collaboration with the GM Chair to colleagues as necessary;
- Advising the University of any changes to legislation or guidance;
- Liaising with external agencies including the HSE and the Counter-Terrorism Unit on biosafety and biosecurity;
- Revising and/or developing policy, and maintaining up to date guidance;
- Reviewing and analysing 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;
- Investigating incidents involving a significant and unintended release of genetically modified organisms in the course of a contained use which presents an immediate or delayed hazard to human health or to the environment;
- Contributing to committees where specialist understanding of work involving pathogens and GMOs is required; and,
- Convening the University Biological Safety Forum.

5.5 Genetic Modification Safety Committee

The Committee is a statutory requirement under the Genetically Modified Organisms (Contained Use) Regulations 2014. The Committee will ensure that, in relation to matters concerning genetic modification:

- 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;
- They have full oversight of all HSE notifications by means of reviewing all GM risk assessments and subsequently co-ordinating and facilitating the notifications process;
- Activities involving GMMs/GMOs are sufficiently monitored and reviewed;
- The University, its staff and students cooperate and communicate efficiently on GM matters; and,
- Review incidents involving a significant and unintended release of genetically modified organisms in the course of a contained use which presents an immediate or delayed hazard to human health or to the environment, and share the learning outcome where appropriate.

For further information on the role of the GMSC see Information Sheet 'Genetic Modification Safety Committee'.

5.6 All Staff

All staff engaged with work activities involving biological hazards including genetically modified material are responsible for complying with the arrangements put in place to prevent or reduce exposure to those materials. They must:

- Be familiar with and understand all risk assessments for their work activities, including COSHH, general risk assessment and GM risk assessment;
- Register on the BP1 and/or BP2 system;
- Attend any relevant training courses;
- 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; and
- Report any defective equipment to their line manager.

6. WORKING SAFELY WITH GENETICALLY MODIFIED MATERIAL

This Standard and associated information should be used in conjunction with the OHS Biological Safety Standard.

The primary legislation that applies to the use of genetically modified organisms in the workplace is The Genetically Modified Organisms (Contained Use) Regulations 2014. Additional guidance is issued by the Statutory Advisory Committee on Genetic Modification (SACGM). Schedule 2 of the Regulations detail those techniques which (1) Constitute genetic modification; (2) Are not considered to results in genetic modification and (3) The Regulations do not apply.

Note that some GM material may be subject to other legislation e.g. Specified Animal Pathogens (Scotland) Order 2009, The Plant Health (Scotland) Order 2005, or the Anti-Terrorism Crime and Security Act 2001 (ATCSA). Licences and additional security provisions must be arranged prior to acquiring the GM material.

All work activities, including those concerned with genetic modification are covered by the Health and Safety at Work Act 1974 and relevant regulations made under that Act. These include, where appropriate, the COSHH Regulations. Where the provisions of COSHH and The Genetically Modified Organisms (Contained Use) Regulations 2014 both apply, the risk assessment must consider the requirements of both sets of regulations when determining the most appropriate control measures for the work. In circumstances where two sets of regulations differ, the higher standard (i.e. the more stringent control measure) must be applied. Note that GM Risk Assessment considers both human health and environmental protection.

Prior to work commencing using substances that contain or may contain biological agents (including genetically modified material) 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 (including genetically modified). Where additional conditions apply, such as licencing and HSE notifications, UBSA and/or the GMSC must be contacted prior to work commencing. The following sections and associated Information Sheets and Guidance Notes provide information on various practical and administrative aspects of working with GM material to ensure the health and safety of those working with biological hazards at the University of Strathclyde.

6.1 Initiating GM Work Activities

To initiate a GM project the PI must undertake a GM Risk Assessment of the planned work (see Section 6.2). The PI should also notify the DSC and DBSC of their intention to work with GM material. This will ensure that all requirements in relation to working with GM material are met.

On completion, the GM Risk Assessment must be submitted to the GMSC at gmcommitte@strath.ac.uk. The GMSC will review the risk assessment and will either approve the project or will provide feedback. If feedback is provided the PI must consider the feedback and provide a response to the GMSC. Once the GMSC is satisfied that the GM risk assessment is complete, and the classification of the project is appropriate they will either:

1) For Class 1 GMM or non-notifiable GMO projects provide approval for the work to commence. See Section 6.2.1 and 6.2.2
2) For Class 2 GMM or notifiable projects provide assistance with the submission of the HSE GM notification. See Section 6.2.1, 6.2.2 and 6.3.

For further information see the Information Sheet – Flowchart for Initiating GM Projects.

6.2 GM Risk Assessment

No work involving genetic modification should be undertaken until the GMSC has approved the risk assessment. Following approval, the PI will be informed when the work may proceed. Under no circumstances should GM material be brought into the University until a GM Risk Assessment has been completed and approved by the GMSC, and the DSC and DBSC have been informed.

PIs wishing to undertake work activities involving genetic modification must submit a suitable and sufficient GM risk assessment form to the GMSC at gmcommittee@strath.ac.uk in advance of work activities commencing.

The completed risk assessment will be considered and reviewed by the GMSC with a usual turnaround time of 3-4 weeks (excluding any time required for statutory notifications). The GM risk assessment is undertaken in addition to the requirement to complete a general risk assessment and COSHH assessment (and any other relevant risk assessments e.g. DSEAR, manual handling) in relation to the work activity being undertaken.

6.2.1 GMM Risk Assessment

Before any contained use involving GMMs is undertaken, the person responsible for the activity must ensure that a suitable and sufficient assessment of the risks to human health and the environment is carried out. The risk assessment should be proportionate and must take full account of all aspects of the planned work, including handling, transport, work area decontamination, inactivation of GMMs, disposal and waste management including where waste contractors are used.

Projects involving the use of GMMs are split in to one of four classes, only Class 1 and Class 2 projects are permissible at the University of Strathclyde:

- **Class 1** - These projects must be submitted to the GMSC for approval of the risk assessment in advance of the work commencing. Requires GMM Part 1 to be completed. **Class 1 contained use is defined as 'of no or negligible risk', so it is not acceptable to classify any GMM that retains pathogenicity for humans, plants or animals as a Class 1 contained use.**
- **Class 2 -** These projects require notification to the HSE. These projects must be submitted to the GMSC for approval in advance of notification to the HSE in accordance with the statutory requirements. The GMSC will make the notification to the HSE on behalf of the PI in advance of the project starting. The PI is required to the pay the relevant HSE fee. Requires GMM Part 1 **and** 2 to be completed.

For further information on notification to the HSE see Section 6.3.

For further information see the Form GMM Risk Assessment Part 1.

For further information see the Form GMM Risk Assessment Part 2.

For further information see the Guidance Note on Undertaking a Risk Assessment for Genetically Modified Microorganisms

For further information see SACGM Compendium of Guidance Part 2.

6.2.2 GMO Risk Assessment

GMOs (GM animals) are those where their genetic material has been altered using a method that does not occur naturally but excluding chemical or physical mutagenesis. In its broadest sense this includes both vertebrates and invertebrates. The legislation covers the breeding of a genetically modified animal, even when a GM animal is crossed with a non-GM animal the progeny will be considered to be GMOs.

All activities involving GM animals must be risk assessed in relation to human health and safety and the environment.

Projects involving the use of GM animals are split into two categories dependent on the requirement to notify the HSE of their use. The risk assessment process will inform the classification:

1) Non-notifiable

- They are incapable of surviving in the environment in the UK; or,
- They have limited ability to transfer genetic material to UK animal species; or,
- The genetic modification does not increase the risk to human health or the environment above that of the non-modified parental organism; and
- The GM animals have either not been inoculated or have been inoculated with Class 1 GM material or other pathogens.

2) Notifiable

- The animals could cause harm to humans or the environment if they escaped from the containment facility, and they have the ability to transfer novel genetic material to UK animal species; or,
- The animals could establish outside the facility; or,
- The GM increases the level of risk to human health or the environment above that of the non-modified parental organism; or
- the animals have been inoculated with a GM material or other pathogen that is above Class 1

For further information on notification to the HSE see Section 6.3.

For further information see the Form GM Animal Risk Assessment.

For further information see the Guidance Note on Undertaking a Risk Assessment for Genetically Modified Animals.

For further information see SACGM Compendium of Guidance Part 5.

6.2.3 Review and Recording of GM Risk Assessments

The GMSC must be notified of any administrative changes or any changes to the GM work activity before the change is implemented. GM risk assessments must be reviewed where there is reason to believe that the contained use has changed or where the assessment is no longer valid. See also Section 6.3.5 for further information on changes to projects notified to the HSE (i.e. Class 2 and above GMM projects and notifiable GMO projects).

PI must notify the GMSC of any changes to the GM project **at any time during the year** and not just during the annual return. Where substantial changes are proposed the GMSC may request that another GMSC project is submitted.

A formal annual GM review is carried out in January by the GMSC. The GMSC must be kept informed of the current status of all projects. Projects are listed under the following statuses:

- Active – Work within the scope of the GM Risk Assessment is active and ongoing.
- Suspended - Propagatable GM Material is stored within the University but not currently in use.
- Archived - No propagatable GM Material remains within the University. Notified projects that are archived will required notification of cessation to the HSE which will trigger the start date for later removal from the public register.

Records of the risk assessment and any review of the risk assessment must be kept for at least 10 years from the date the contained use activity stops. Any records must be made available to the competent authority upon request.

For further information see the Information Sheet – Flowchart for Annual Review of GM Projects.

6.2.4 The Nagoya Protocol

As part of the initial GM risk assessment submission to the GMSC, researchers will be asked about compliance with the Nagoya Protocol on Access to Genetic Resources and the Fair and Equitable Sharing of Benefits Arising from their Utilization. Research utilising non-human genetic resources (defined as "*any material of plant, animal, microbial or other origin containing functional unit of heredity*") or associated traditional knowledge (aTK) is subject to the UK Access and Benefit Sharing Regulations (ABS). This legislation relates to the Nagoya Protocol of the Convention on Biological Diversity which provides a framework to ensure the fair and equitable sharing of benefits arising out of the utilisation of genetic resources. To comply with the regulations, the University is required to seek, keep and transfer all relevant documentation to prove that projects are either a) conducted in compliance with UK ABS compliance measures (as required by Article 4(3) of the UK ABS Regulation), or b) out of scope. To be in scope, genetic resources will have been accessed on or after 12 October 2015 from a country that is party to the Nagoya Protocol and has access and benefit sharing (ABS) legislation (assuming that they are not already governed by a specialised international instrument).

Researchers are requested to undertake and document appropriate due diligence to ensure compliance with the UK Nagoya Protocol (Compliance) Regulations 2015. This can be done using the Office for Product Safety & Standards (OPSS) Self-Assessment Tool which can be downloaded from the UK Government ABS Guidance webpage. This includes a link to the ABS Clearing House which can be used to identify if a country is party to the Nagoya Protocol. A template is provided that should be submitted along with the risk assessment.

For further information please refer to the OPSS guidance on the Nagoya Protocol or contact the Research Policy Team (research-integrity@strath.ac.uk).

6.3 HSE Notification of Contained Use

The GMSC has full oversight of all notifications by means of reviewing all GM risk assessments and co-ordinating and facilitating the notifications process. Notifications must not be made by researchers, the GMSC will facilitate the process.

6.3.1 Premises Notification

The University of Strathclyde has made premises notification to the HSE. This notification includes the use of Class 1 and non-notifiable GMOs. Further notification to the HSE is required for Class 2 and above GMM activities and notifiable GMO activities.

6.3.2 Class 2 GMM Contained Use Notification

All Class 2 contained uses must be notified to the HSE before the contained use can begin. The GMSC must review the GM risk assessment (Part 1 and Part 2) before advising on the notification process.

The notification is made by completion and submission to the HSE of the CU2 form with the appropriate fee. This submission will include a copy of the risk assessment, details of containment and protective measures (specifically related to waste management arrangements) and any details of expert advice received from the GMSC.

The HSE will send an acknowledgement within 10 working days of receiving a notification. The timescale for starting work will depend on the following:

(a) The first Class 2 contained use with GMMs cannot start until 45 days after the date on which the acknowledgement was sent by HSE; or

(b) The competent authority (the HSE) has agreed in writing that the contained use can start in a shorter period.

(c) For subsequent Class 2 contained uses with GMMs the contained use may start as soon as the HSE acknowledgement has been received.

If the notification includes a derogation request the HSE will confirm in writing the decision on whether or not to allow this derogation. For those class 2 contained uses which may start immediately on receipt of the acknowledgement, the full CL2 requirements must be applied, unless and until the derogation is confirmed.

The University of Strathclyde does not currently permit work at full CL3 or CL4 and therefore Class 3 or 4 projects are not permitted. Certain derogated CL3 projects may be approved by the GMSC and will require HSE notification similar to the above with different conditions applied.

6.3.3 GMO Notification

Notification of GMO use must be made to the competent authority where the GMO presents a greater risk to human health than the non-modified parental organism. Notification will be made to the HSE following review of the GMO Risk Assessment by the GMSC.

The HSE will send an acknowledgement of receipt within 10 working days of receiving the notification. The timescale for starting work will depend on the following:

(a) The contained use involving larger GMOs cannot begin until 45 days after the date on which the acknowledgement was received from HSE;

(b) The competent authority has agreed in writing that the contained use can begin within a shorter period.

6.3.4 Notification in relation to connected programmes of work

A connected programme of work means a series of activities involving contained use which form a coherent and integrated programme. This might involve a programme covering more than one contained use at a single notified premises or more than one contained use carried out by a single person or organisation at more than one notified premises. This might apply, e.g. where an institution or company has several notified premises, which all collaborate on connected work.

A connected programme of work allows submission of a single notification for premises in different geographical locations, e.g. where one premises is in Scotland and the other is in England or Wales. If the contained use is to be carried out by one organisation but in more than one premises, and one or more of the premises is in England or Wales and one or more in Scotland then the application for that contained use must be submitted to the joint competent regulatory authority (although the application will be submitted to HSE, as is the same for any other notification).

Currently the University of Strathclyde does not operate any connected programmes of work. The GMSC should be contacted for information on connected programmes of work.

6.3.5 Changes to notifications (including significant changes affecting risks)

1) Administrative changes

The HSE must be notified about changes to the information supplied as part of either premises or contained use notifications. These changes are concerned with information considered to be administrative and does not relate to changes of a technical nature. Types of changes requiring notification include

- Changes to the details of the person making the notification,
- The person responsible for supervising the contained use,
- The address and description of the premises where the contained use is undertaken,
- Cessation of a contained use,
- Cessation of all contained uses and closure of a facility.
- Notification of additional buildings that are added to those already notified
- New premises to be added to those that are being used for a single contained use (eg this permits the same contained use to be undertaken at more than one premises).

2) Significant changes affecting risk

The descriptive title and purpose of the contained use should be used to help define the scope of the work being notified (i.e. to set boundaries on the work covered). Where the contained use extends beyond these boundaries then the change would be considered to be a new contained use and must be notified as such.

Where ‘significant’ changes are necessary to the ongoing contained use, the HSE must be notified where these changes increase or present different risks from the originally notified work. Risk means risk to human health or the environment in the case of contained uses

involving GMMs, but for contained uses involving larger GMOs it means risk to human health only. Examples of significant changes can be found in (Guidance 15) The Genetically Modified Organisms (Contained Use) Regulations 2014.

The GMSC must be notified of any proposed significant changes in advance of them being implemented in order to assess whether notification to the HSE is required. Notifications of significant changes to an ongoing contained use are charged a fee.

6.4 Information, Instruction and Training

Training must be undertaken in accordance with the OHS Biological Safety Standard, to include COSHH Essentials and Biological Safety Training as a minimum. Where users of GM material are undertaking risk assessments the relevant Assessors training must also be undertaken.

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. Module 4 must be completed by anyone planning to work with GM material.

Modules 1-3 are mandatory and must be completed by all staff, post graduate students, 4th year undergraduates or those assigned to undergraduate research projects (for example) summer projects, 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 and Specified Animal Pathogens (SAPO)
- Module 6: Transport of Infectious Substances

Refresher training should be undertaken every 3 years.

6.5 GM Containment Measures and Derogation

The primary objective for the containment of both GMMs and GMOs is to select physical measures and associated safety procedures appropriate to the level of risk to both human health and the environment. The risk assessment must consider the modified organism, the nature of the activity, or process, and the nature of any product. In some cases the level of containment and control may be dictated by the risk posed by the product or process rather than by the GMO itself.

Where the containment measure differs from that in Schedule 3 of the COSHH regulations the more stringent of the two should be implemented.

For further information see Information Sheet GM Containment Measures.

For further information see Information Sheet Biological Containment Facilities (COSHH requirements)

6.5.1 GMM containment and control measures

The risk assessment process classifies the contained use into one of four risk classes based on the highest containment level selected. The containment tables in Schedule 8 of The Genetically Modified Organisms (Contained Use) Regulations 2014 determine the containment level required dependent on the containment measures identified for contained uses involving micro-organisms in laboratories, in plant growth facilities, and in animal units.

It should be noted that the classification is based on the level of containment required to control the risk, not necessarily the level of containment at which the work is planned to be done. For example, the work may be classified as class 1 based on the containment required

to control the risk, but if the laboratory planned to be used meets CL2 requirements, this does not mean that it becomes risk Class 2. The following table shows containment level with corresponding GM risk classification. Note that Class 3 and Class 4 GM activities are not permissible at the University of Strathclyde.

Containment Level necessary to control the risk	GM Risk Classification
Level 1	Class 1
Level 1 with additional measures from Level 2, or Level 2 without additional control measures.	Class 2
Level 2 with additional measures from Level 3, or *Level 3 without additional control measures.*	*Class 3*
Level 3 with additional measures from Level 4, or *Level 4 without additional control measures.*	*Class 4*

If there is evidence-based justification that a control measure shown in the table in Schedule 8 is not necessary, or alternative measures are more appropriate that provide an equivalent level of protection, users can request a derogation from the HSE where the contained use is notified. Any such request must be supported by appropriate explanation and justification. Note that all measures at the required CL must be applied until written consent for the derogation has been received by the HSE. Applications for derogation must be notified to the GMSC prior to any submissions being made to the HSE.

6.5.2 GMO containment and control measures

A different approach is taken for the containment of GM animals (as opposed to animals infected with GMMs). The Genetically Modified Organisms (Contained Use) Regulations 2014 does not set out detailed containment levels for GM animals. The SACGM guidance takes the approach that a basic level of containment should be applied to all GM animals. This is termed 'not-notifiable' and is suitable for low risk GMOs. The Contained Use Regulations 2014 does not stipulate standards of containment for GM animals in the same way that they set out containment levels for GMMs require the use of any of physical, biological or chemical barriers (or any combination) to effect control. The aim is to apply containment and control measures that any risks to humans or the environment are reduced to either "low" or "effectively zero".

6.6 Principles of Occupational and Environmental Safety

All users undertaking contained use activities involving GMMs must ensure that the risks to human health and the environment arising from the contained use are reduced to the lowest level that is reasonably practicable by using the principles of good microbiological practice as defined in Schedule 7 of The Genetic Modification (Contained Use) Regulations 2014. For contained uses involving GMOs the principles must be applied so far as they are appropriate.

The principles of good microbiological practice and of good occupational safety and hygiene are detailed in Information Sheet on the Principles of Good Microbiological Practice.

6.7 Transport of GM Material

The risk assessment processes must consider risks associated with transport. This would include the use of appropriate packaging and labelling, supplying appropriate information to the person transporting the GM material, and accounting for possible accidents by putting in place appropriate emergency measures. The duty to control the risks to humans and the environment from GMMs to the lowest reasonably practicable level still remains. Where appropriate an emergency plan should be in place. In the event of an accident during transport, this should be reported to SHaW (see Section 6.9) in order to comply with the requirements of RIDDOR if applicable.

Where any biological material, including GM, is transported between departments there should be adequate exchange of information between the visitor and the host department.

The DSC and the DBSC should be consulted with prior to transporting the material to ensure that safety arrangements are in place. The GM Risk Assessment should be reviewed and the GMSC consulted with where a change of work location is planned.

Where any biological material, including GM, is brought into the University from external organisations (e.g., collaborators at other organisations, or commercial companies), the DSC and the DBSC should be notified in advance. If the GM activity is covered by a GM Risk Assessment at another establishment, this must NOT be taken as GMSC approval at the University of Strathclyde, a new GM Risk Assessment must be submitted to the GMSC prior to the material being brought into the University.

For further information see the Guidance Note on the Transport of GMMs and GM Animals.

6.8 GM Waste

The Genetically Modified Organisms (Contained Use) Regulations 2014 require that GMMs in contaminated material and waste from Class 2 to 4 GM activity are inactivated by validated means. Although the regulations state that inactivation of Class 1 material and waste is only required by validated means where and to the extent the risk assessment shows it to be required, the **University of Strathclyde guidelines are such that ALL contaminated GM material and waste MUST be inactivated by a validated means before disposal.**

Autoclave validation is different to calibration. Validation is carried out by 12-point thermocouple testing using user defined mock loads. This test method is described in The British Standard BS 2646-3: 1993 Autoclaves for Sterilisation in Laboratories. Validation must be carried out annually using a 12-point thermocouple.

For further information on GM waste inactivation see the Guidance Note on GM Waste Inactivation.

For further information on the validation and the safe use of autoclaves see Guidance Note on the Safe Use of Autoclaves.

6.9 Accidents Involving GM Material

In addition to the University's incident reporting process (see Section 6.9.4), under the Genetically Modified Organisms (Contained Use) Regulations 2014 there is also a requirement to notify the HSE of any accident, defined in regulation 2 as '**an incident involving a significant and unintended release of genetically modified organisms in the course of a contained use which presents an immediate or delayed hazard to human health or to the environment'.**

This requirement is in addition to that under the Reporting of Injuries, Diseases and Dangerous Occurrences Regulations 2013 (RIDDOR) to report accidents. Both of these functions fall under the remit of SHaW, and in relation to GM material the UBSA and the GMSC would facilitate the investigation and subsequent submission of the incident report to the HSE. The UBSA must be informed as soon as practicably possible of any such accidents.

6.9.1 Contingency arrangements

The types of accident that might be encountered in the laboratory will vary from low hazard, small-scale releases of biological agents, eg the discharge of aerosol droplets from a pipette to more serious (but less frequent) incidents such as dropping a culture flask or a centrifuge incident. Some accidents have the potential for generating significant aerosols, for example dropping of material from a height. The risk of accidental release may be increased when using particular combinations of equipment, for example the use of glassware in orbital incubators.

Contingency arrangements must be addressed as part of the risk assessment process. Clear written procedures should be displayed as notices if necessary, for dealing with spillages and other forms of contamination, eg aerosol release. All spillages should be dealt with without delay and training on how to deal with spillages should be part of the overall training for personnel.

For further information on spillages see Guidance Note Dealing with spillages of biological agents

For further information on needlestick injury see Information Sheet Safe use of sharps.

6.9.2 Assessing the risk

When drawing up contingency plans as part of the risk assessment process a number of different factors/scenarios should be considered to determine the most appropriate course of action:

- Type of agent - the classification of the GMM, route of transmission, infectious dose (if known), stability in the environment.
- Type of accident - instantaneous or delayed - for example, a dropped flask as compared to a broken centrifuge tube which may be undiscovered until the centrifuge is opened.
- Severity of accident - amount and concentration of material that could potentially be released and form, for example, is aerosol formation likely?
- Numbers of staff potentially exposed - this may depend on location of accident.
- Location within the laboratory - an accident in the open laboratory may require evacuation, as compared to a more 'contained' accident in a microbiological safety cabinet.

It is important when assessing the risk to consider anyone else in the area who might be affected by the work activity, including in the event of emergency that contingency plans are shared.

6.9.3 What to report

The definition of what constitutes an accident (see above and Section 4.1) does not include all unintended incidents, only those which result in a significant and unintended release and which presents an immediate or delayed risk to human health or the environment. Each accident would therefore have to be treated on a case-by-case basis and it will depend on some or all of the following factors:

- GM organism involved;
- Classification of the activity;
- Injury or exposure route;
- Quantity of organism involved;
- Location of accident; and,
- Potential health effects or environmental impact.

Minor spillages of micro-organisms being used in Class 1 activities within the containment laboratory are unlikely to count as significant releases of GMMs, and they will not routinely require reporting to the HSE. This is because they would be highly unlikely to affect people within the facility and will be easily dealt with so that they do not reach the environment. The same may not be true, however, for spillages of GMMs being used in Class 2 activities, or for large scale spillages of GMMs from some Class 1 activities. For large scale Class 1 activities a significant loss of containment (eg 5 - 10% plus of total volume), where there is no agreement that inactivation is not required before disposal, could constitute an accident and require reporting.

6.9.4 How to report

If an accident occurs, the UBSA must be immediately informed by telephoning Ext. 2726 (0141 548 2726 from a mobile). It is the responsibility of the UBSA to facilitate the reporting of the accident to the competent authority, the HSE, under Regulation 22 of the Genetically Modified Organisms (Contained Use) Regulations 2014. The PI/line manager, DBSC,DSC and HoD must also be informed of the incident.

The person reporting the incident should provide the following information:

- The circumstances of the accident;
- The identity and quantity of the GMM/GMO concerned;
- Any information necessary to assess the effects of the accident on the health of the general population and, in the case of a GMM/GMO, on the environment; and
- Any measures taken in response to the accident.

All accidents, including those involving GM material must be reported using the SIRIS Webform, or reported directly to SHaW on Ext. 2726. If more than one person is involved in an incident, then separate forms should be submitted for each individual involved. Where the GMO/GMM presents a risk to human health there may be an additional reporting requirement 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 such incidents under RIDDOR.

7. DOCUMENTATION AND RECORDS

7.1 The requirements to meet the standard for Genetic Modification 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 genetically modified material without delay, and in accordance with Section 6.9 of this Standard. If appropriate an incident report must be completed using the SIRIS 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

- Undertaking a Risk Assessment for Genetically Modified Microorganisms
- Undertaking a Risk Assessment for Genetically Modified Animals
- Transport of GMMs and GM Animals
- GM Waste Inactivation

9.2 Information sheets

- Annual Review of GM Projects Flowchart
- Initiating a GM Project Flowchart
- Genetic Modification Safety Committee
- GM Containment Measures
- The Principles of Good Microbiological Practice

9.3 Forms

- Risk Assessment for Activities involving GMMs Part 1
- Risk Assessment for Activities involving GMMs Part 2
- Risk Assessment for Activities involving GM Animals

10. COMPLIANCE

This Standard aims to meet the requirements of:

- Health and Safety at Work Act (1974)
- The Genetically Modified Organisms (Contained Use) Regulations (2014)
- Management of Health and Safety at Work Regulations (1999)
- Managing for Health and Safety HSG65 (2013)
- The Reporting of Injuries, Diseases and Dangerous Occurrences Regulations (2013)
- ACDP Approved List of Biological Agents

- The British Standard BS 2646-3: 1993 Autoclaves for Sterilisation in Laboratories

11. DOCUMENT HISTORY

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