University of Essex

School of Biological Sciences

LOCAL RULES FOR GENETIC MODIFICATION SAFETY

September 2017
(To be reviewed annually)

Contents

Abbreviations

ACDP	Advisory Committee on Dangerous Pathogens
ACoP	Approved Code of Practice
BH&GMSC	Biological Hazard and Genetic Modification Safety Committee
BS	Biological Sciences
CL	Containment level
CoP	Code of Practice
COSHH	Control of Substances Hazardous to Health Regulations
DBSO	Department Biological Safety Officer
DHSO	Department Health & Safety Officer
DUBSA	Deputy University Biological Safety Adviser
GM	Genetically modified
GMM	Genetically modified micro-organism
GMO	Genetically modified organism
GLP	Good Laboratory Practice
GOSH	Good Occupational Safety and Hygiene
HoS	Head of School
HSAS	Health and Safety Advisory Service
HSE	Health and Safety Executive
LR	Local Rules
MHSW	Management of Health and Safety at Work Regulations 1999
OHA	Occupational Health Adviser
OHS	Occupational Health Service
PGs	Post-graduates

PPE	Personal protective equipment
RA	Risk assessment
SACGM	Scientific Advisory Committee on Genetic Modification
UBSA	University Biological Safety Adviser

1 Definitions

Local Rules (LR) are a set of arrangements for safe working and organisational structure to be applied throughout a School.

A **Code of Practice** (CoP) is a procedure that applies to a specific laboratory or School. Its purpose is to describe the procedures used in a laboratory for a safe system of work. It states how risk is to be controlled and is therefore a significant part of the risk assessment. Risk assessments should refer to relevant parts of the code of practice and does not need to re-state them.

Genetic Modification is defined as any alteration of the genetic material (DNA or RNA) of an organism using a method that does not occur naturally by mating and/or natural recombination. As a result of this modification a novel product will be formed that may confer additional phenotypic properties to that cell or organism. The creation of a GMO does not necessarily mean the direct alteration of nucleic acids. It could be the addition of another genome into a cell, e.g. the creation of a novel hybrid virus by two viral genomes fusing within a cell could constitute the formation of a genetically modified organism (GMO). (Genetically Modified Organisms (Contained Use) Regulations 2014 as amended; Regulation 2).

> *Genetic modification:*
> *Means any alteration of the genetic material of an organism (ie DNA or RNA), which does not occur naturally (by mating or recombination) and which has been achieved through one of the techniques set out in Part 1 of Schedule 2.*
> *The techniques listed are examples and are indicative of the types of alterations that fall within the Regulations. The requirements of the Regulations (eg risk assessment, application of control measures) apply to the activity in which GMOs are created, used or disposed of rather than the techniques themselves. Guidance 2 Regulation 2 Health and Safety Executive The Genetically Modified Organisms (Contained Use) Regulations 2014*
> *These techniques involve introducing and incorporating new combinations of genetic material (whether derived from an existing organism or synthetically made) into a recipient organism in which they do not naturally occur. The introduced genetic material must be capable of stable incorporation and/or continued propagation in the recipient organism. Techniques considered to be genetic modification include:*
> *(a) any technique which alters the genetic material in an organism using a method that does not occur by natural mating or recombination (eg synthetic generation of artificial chromosomes in yeast);*
> *(b) introduction of foreign or synthetic genetic material into an organism via transfection, recombinant bacteriophage transduction (eg to make gene libraries), transformation, particle bombardment or other gene delivery systems (eg liposomes);*
> *(c) gene deletions or the insertion of multiple copies of a gene in an organism count as genetic modification if they are brought about using any listed technique or other artificial method;*
> *(d) stable introduction of synthetically generated DNA or RNA (eg 'biobricks') into an organism;*

(e) techniques that involve directly introducing heritable genetic material (eg particle bombardment of plant tissues, directly injecting naked DNA into an animal and liposomes) only where the introduced genetic material is intended to be incorporated into the organism's genetic material in a stable way.

Genetic modification of larger GMOs includes not only their generation but also their breeding on (even if one of the parents was not itself a GMO and the cross was by natural means). This also includes situations where only some of the cells contain the modification (ie mosaics).

Part 2 of Schedule 2 lists techniques that are not considered to fall within the definition of genetic modification but only where these techniques do not involve using recombinant or synthetic DNA or RNA or organisms that are themselves GMOs. Techniques that are not considered to be genetic modification include:

(a) organisms generated using methods based on natural mating or recombination;

(b) somatic cell nuclear transfer ('cloning') provided no GM material is present and the donor/recipient organisms are able to interbreed;

(c) artificial transfer of pollen from one flower to another (considered to be natural fertilisation);

(d) hybrid or reassortant viruses generated by natural recombination or transencapsidation during co-infection of a cell;

(e) DNA vaccination, where naked or synthetic DNA is introduced into animals to elicit an immune response against antigens encoded by that material, with no intention of stable integration.

Although not listed, DNA synthesis is not considered to be a contained use. It only falls within the Regulations, where the synthesised DNA is incorporated into an organism.

A genetically modified organism is one that has been altered in this way and can include micro-organisms (GMMs) or multicellular animals or plants (GMOs).

Contained Use covers any activity in which organisms are genetically modified or in which GMOs 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 people and the environment (Regulation 2).

Class: Contained uses are classified into one of four classes, as described in Schedule 1, based on the risk that the contained use presents to human health and the environment. These are referred to as class 1 (no or negligible risk), class 2 (low risk), class 3 (moderate risk) and class 4 (high risk). The contained use class is derived from the outcome of the risk assessment and is only applicable to GMMs and is not used for larger GMOs. (see Levels of Containment within Biological Sciences (BS) below).

2 Duties and responsibilities

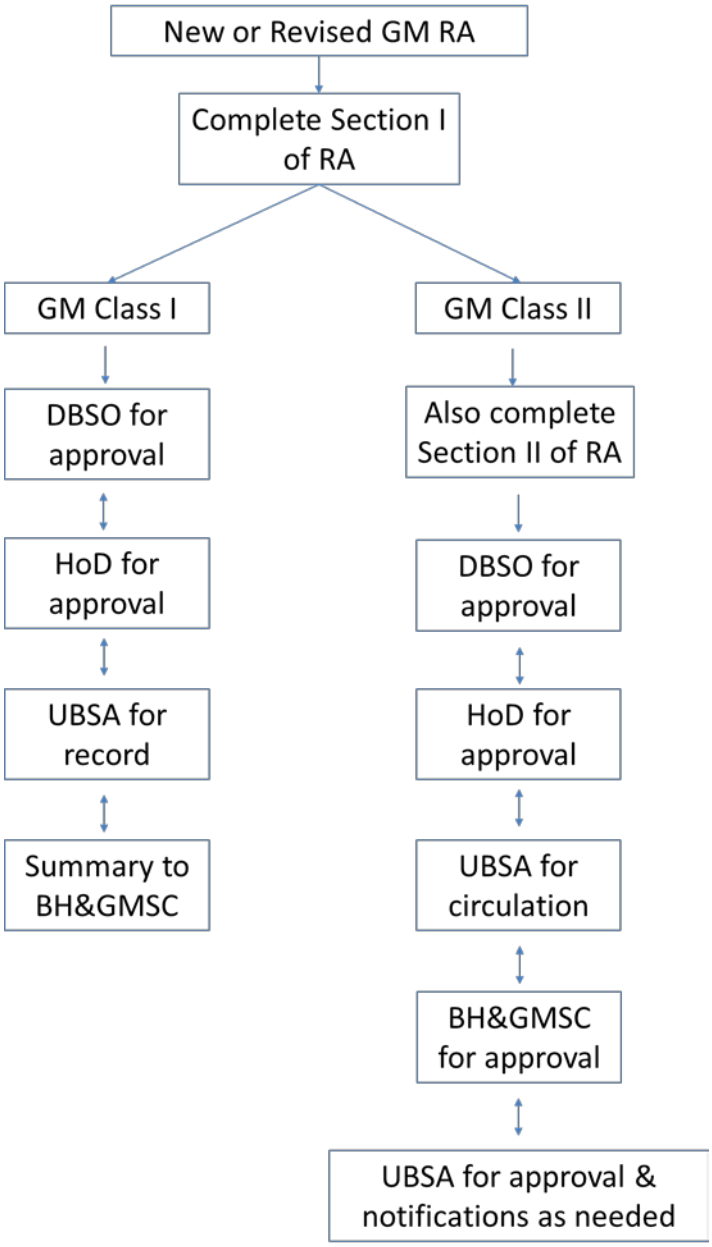
Anyone carrying out contained use work must comply with the Genetically Modified Organisms (Contained Use) Regulations 2014. The main duties under these Regulations are in particular:

- notify the authorities of their intention to use their premises for contained use for the first time;
- carry out an assessment of the risks to human health and the environment of every contained use activity before it begins, reviewing and revising the assessment as necessary and keeping records;
- establish a genetic modification safety committee to advise on risk assessments

designated at Class II or higher;

- classify all activities and notify them where required;
- apply the necessary containment and control measures indicated by the risk assessment;
- draw up emergency plans for riskier activities, and notify any accidents that occur.

Summary flow chart showing the process for approving GM risk assessments:



Head of School (HoS)

The duties of the HoS for ensuring the safe management of genetically modified (GM) work are the same as those for all other aspects of safety within the School as described in the Health and Safety Policy. The responsibility for ensuring compliance with health and safety law has been delegated to the HoS by the University. He/she has appointed various members of staff within the School to act on his/her behalf. The HoS must sign all new risk assessments.

GM Class I

Since Class I work is by definition low risk, so approval is by the HoS, after which the signed risk assessment should be forwarded to the UBSA for the BH&GMSC's records. The BH&GMSC will look at new Class I risk assessments at their next meeting, and the risk assessment signed off by the UBSA if approved. Work can commence once the signature of the HoS has been obtained.

GM Class II

This work carries a higher risk, so required more detailed approval. Work cannot commence until **all** approvals are in place. All Class II risk assessments will be appraised by the DBSO before forwarding to the HoS for signature. The signed risk assessment is then forwarded to the UBSA to be considered at the next BH&GMSC meeting. If the work is approved, then the UBSA will make the relevant notifications to the HSE. Work can commence once an acknowledgement has been received from the HSE.

Department Health & Safety Officer (DHSO)

The DHSO coordinates safety matters within the School with the HSAS and HoS, and monitors compliance with University and School safety policies within the School.

Department Biological Safety Officer (DBSO)

The DBSO is appointed by the HoS and advises the Head on all matters relating to biological and genetic hazards and oversees the day-to-day operational activities related to GM work within the School. The DBSO is the first point of contact in the event of GM-related emergencies within the School.

All schemes of work should be submitted to the DBSO for appraisal before being sent to HoS for final approval (Class I only) and the University Biological Safety Advisor (UBSA) for submission to the BH&GMSC (Class II or above).

University Biological Safety Advisor (UBSA)

The UBSA

- advises on technical requirements and procedures to enable the University to meet statutory requirements and Codes of Practice
- ensures recording systems meet requirements of statutory bodies
- advises on the technical implications of new and revised legislation and codes of practice
- chairs the Biological Hazards and Genetic Modification Safety Committee (BH&GMSC) and gives final signature for schemes of work on behalf of the committee
- oversees the content of relevant Local Rules and Codes of Practice
- submits documentation as required to the Health and Safety Executive (HSE)
- may obtain expert competent technical advice where appropriate.

Deputy University Biological Safety Adviser (DUBSA)

- deputises for the UBSA in their absence.

- attends the BH&GMSC meetings.

  This role is appointed as required.

Principal Investigators (PIs)

PIs are responsible for

- ensuring that risk associated with their work is fully assessed as required by current legislation
- ensuring that a code of practice is written for their laboratory where required
- maintaining a list of all workers who are currently working or have worked on their GM projects
- ensuring that workers understand and comply with Local Rules and Codes of Practice
- ensuring that adequate training is given (Appendix 2)
- regularly monitoring and reviewing all risks and staff lists and notify of any changes
- ensuring that adequate records are maintained of all GMM/GMO stocks related to their current and previous projects

Biological Hazards and Genetic Modification Safety Committee (BH&GMSC)

The University has established the BH&GMSC to review and comment on new and revised GM projects, and approve or reject proposals to facilitate compliance with regulations. Membership consists of a range of representatives from management, employees and students, in line with information in the H&S Policy

Health and Safety Advisory Service (HSAS)

The HSAS is part of the Human Resources Section and provides impartial technical advice and support to managers and individual members of staff, on all matters relating to the health and safety of employees of the University.

Occupational Health Service

The OHS

- monitors new and existing projects to assess any health screening and/or monitoring requirements
- receives notifications of all new GM workers
- maintains records related to the above as required

Any member of staff with a health concern affecting their work, whether caused or made worse by their work, should arrange to see the OHA.

Visitors

Visitors are defined as non-employees including contractors who may be allowed to enter GM laboratories. Visitors who are not participating in research must be provided with personal protective equipment (PPE), in accordance with codes of practice, and be supervised at all times.

No children under the age of 12 may be admitted to any research laboratories. Children between 12 and 17 may only be admitted with specific approval of the HoS and with an approved risk assessment (RA) covering their visit, and they must be supervised at all times.

3 Arrangements

3.1 General Rules

Supervisors must ensure that workers are aware of all aspects of the local rules and codes of practice. A copy of these must be made available to all workers involved in GM schemes; a proforma acknowledgement of receipt of these may be found in Appendix 5 of this document. A copy of the RA relevant to their particular work must also be shown to the worker who must read it and sign to state that they have understood its content.
RAs must be reviewed at appropriate intervals or if there is material change to the work, equipment used or laboratory.

Supervisors must ensure that all staff and students under their control receive appropriate training to the tasks they are instructed to undertake, and are supervised at a level which is appropriate to their level of competence and experience. A documented record of all training should be kept.

PIs must maintain records relating to work involving genetic modification to include staff lists, RAs, validation tests for waste disposal etc.

All GM work must be conducted in areas accepted by the BH&GMSC as a suitable containment laboratory. The transportation of GMOs between labs is allowed provided an appropriate containment measure is used and a RA has been undertaken.

3.2 Notification to HSE

Notification of activities assessed at level 2 must be sent to the HSE. Revised n otification forms (form CU2) can be accessed at the HSE web site given below. The use of notification forms is not a legal requirement, however, you are advised to do so as they have been designed to make it easier to give the necessary information and to indicate clearly any confidential material. https://www.hse.gov.uk/forms/genetic/index.htm

Section 12 on form CU2 requires information about waste management. This information is important as it is a key way to limit contact between GMMs and the environment and thus provide a high level of safety.

3.3 Levels of Containment within Biological Sciences

Scientific Advisory Committee on Genetic Modification (SACGM) Containment Levels
The four GM activity classes as per Regulation 2(1) are as listed below and are taken from Schedule 1 of A Guide to the Genetically Modified Organisms (Contained Use) Regulations 2014 (HSE Guidance L29), and consider risks to both human health and the environment.

Class	*Description*
1	Contained use of no or negligible risk, for which containment level 1 is appropriate to protect human health and the environment.
2	Contained use of low risk, for which containment level 2 is appropriate to protect human health and the environment.
3	Contained use of moderate risk, for which containment level 3 is appropriate to protect human health and the environment.
4	Contained use of high risk, for which containment level 4 is appropriate to protect human health and the environment.

Where a GM research project is undertaken and has been assessed at more than one level all work must be carried out at the higher level. Similarly, where more than one project is undertaken simultaneously in the same laboratory i.e. shared facilities, all work must be carried out at the higher/highest level.

Class 1

All work carried out at this level must be undertaken in laboratories that conform to the minimum standards described in the Schedule 8 of A Guide to the Genetically Modified Organisms (Contained Use) Regulations 2014 (HSE Guidance L29). You are advised to familiarise yourself with these guidelines which refer to building and equipment, systems of work, waste and other measures.

Class 2

All work carried out at this level must be undertaken in laboratories that conform to the minimum standards described in the Schedule 8 (Part 2) of A Guide to the Genetically Modified Organisms (Contained Use) Regulations 2014 (HSE Guidance L29). You are strongly advised to familiarise yourself with these guidelines which refer to building and equipment, systems of work, waste and other measures. Biohazard signs must be displayed on entrance doors to laboratories carrying out work at this class.

There are currently no laboratory facilities at the University of Essex that conform to CL3 or CL4 standards. No work or storage of materials at these levels is permitted under any circumstances.

3.4 Health Surveillance and Screening

Procedures are in place to monitor the health of those working with Biological Hazards and Genetic Modification follow the guidelines set out in the Control of Substances Hazardous to Health Regulations (COSHH) and by the Advisory Committee on Dangerous Pathogens.

BS informs HSAS of workers who require health surveillance, by forwarding a copy of the Occupational Health Notification Form. Each newly registered worker is required to complete a health declaration form, to provide a baseline record of his or her health. An annual health questionnaire is then routinely sent out by the HSAS, to monitor any changes to health relevant to the nature of the work.

Following each review, the OHS informs the work Supervisor of the worker's fitness to continue with their work, or offers advice if work restrictions or changes in work practice are required, to protect the worker's health.

3.5 Record Keeping

The HSAS keeps copies of all applications to HSE for GM Class II projects and originals of the RAs for Class I and Class II work. Copies are made and given to Project Supervisors. The School must keep records that are relevant to the School's GM work; these may be in written or electronic format. Such records enable the HoS to provide evidence of compliance with statutory regulations and University duties and to assess the adequacy of the School's arrangements for the management of GM safety.

Record keeping will be devolved to several individuals reflecting their roles within the School and University. The following personnel should keep records as appropriate:

HoS

- Appointment of DHSO
- Appointment of DBSO

DHSO

- A list of laboratory CoPs currently in operation
- A list of all containment laboratories and their category
- Commissioning and maintenance records of autoclaves, microbiological safety cabinets and air-handling systems used in GM laboratories if not kept elsewhere in the University
- Copies of accident and incident reports for the laboratories if not kept elsewhere in the University

DBSO

- A list of currently active GM projects and current copies of local rules
- All records kept by past supervisors who have now left the School

PIs

- All RAs relating to current and past projects
- A list of all workers currently engaged on the project
- Training records for all workers
- Laboratory CoP where applicable

UBSA

- Copies of all RAs and notifications made to HSE for work at Class 2.
- Original applications for all risk assessments or schemes of work
- All agendas and minutes from BH&GMSC meetings
- UP to date BH&GMSC membership list

3.6 Training and Supervision

All those working on a GM project must be familiar with this CoP and with correct procedures for use of laboratory facilities and equipment. In addition, if using micro-organisms they must be trained in good microbiological technique. If this experience has not been gained elsewhere then they must be formally trained in safe techniques for handling micro-organisms, disinfection procedures and the use of microbial safety cabinets. A documented record of all training must be kept. New staff/students should not be allowed to work on any GM scheme or with pathogens or potentially infectious material until they have been correctly trained on a scheme of work and received the

appropriate training in the safe execution of procedures and manipulations involved in that project.

The Project PI is responsible for ensuring that those persons under his/her supervision are instructed in the nature of potential hazards and in the practical use of special procedures, techniques and safety equipment. Inexperienced workers must be closely supervised and alternative supervision arranged in the event of the absence from the University of the principal PI. Such workers must be informed of their alternate supervisor. The closeness of supervision is dependent on the level of training of staff or students working under the project supervisor. Supervisors should not assume competence until it has been demonstrated.

Cleaners and maintenance staff must receive appropriate instructions to ensure the safety of themselves and others. Refresher training should be given to all cleaning and maintenance staff allocated to BS every two years or where a change of usage dictates.

4 Code of Practice

The safety measures and compliance with the Regulations in GM laboratories depend on limited access, the provision of required levels of physical containment and good experimental technique. Doors to the laboratory must be marked with the standard biohazard sign, the current Containment Level and appropriate notices to prohibit unauthorised access.

Only laboratories and other areas listed below are authorised to operate at CL2 with appropriate management standards in place:

Laboratory	PI(s) or Facility
3.07	Graham Underwood, Michael Steinke, Alex Dumbrell, Etienne Low-Decarie, Michelle Taylor
3.21	Antonio Marco
3.25	Leo Schalkwyk, Pradeepa Madapura, Boyd McKew
4.09	Selwa Alsam
4.19	Bioimaging Facility, Philippe Laissue
4.25	Metodi Metodiev, Philip Reeves
4.27	Cell culture facility
5.04	Cell culture facility
5.16	Glyn Stanway, Ralf Zwacka
5.20	Elena Klenova, Greg Brooke
6.19	Chris Cooper, Brandon Reeder

1. No unauthorised access to any laboratory is permitted. Permission to use the facility at any level must be obtained from the PI in charge or their nominee before access is required. This includes postgraduates and undergraduates not usually associated with the laboratory, cleaners, and maintenance staff, visitors, service personnel and contractors.
2. All GM users must be registered on an approved risk assessment and have completed a health monitoring form before commencing work.
3. Keep workplace and environmental exposure to any GMM to the lowest reasonably practicable level.
4. Exercise engineering control measures at source and supplement with appropriate personal protective equipment where necessary.

5 Adequately test and maintain control measures and equipment.

6 Testing, where necessary, for the presence of viable process organisms outside the primary physical containment.

7 All users must ensure that vessels for disposal are available before starting experimental work. Each person is responsible for providing and cleaning their own materials and equipment. Users should be aware of any disinfection policy for their work. This might include

- the efficacy of the disinfectant against the organism
- the correct concentration of the disinfectant
- the methods specified for routine disinfection

8 No equipment may be removed from GM facilities without prior fumigation, sterilisation or disinfection if needed.

9 No unaccompanied or unauthorised visitors or children are allowed within laboratories.

10 Contractors or service engineers must not be allowed to enter laboratories without the knowledge of the Technical Services Manager and PI, and a Permit to Work authorisation where needed. Equipment should be fumigated, sterilised or disinfected as appropriate before work is undertaken.

11 In compliance with other CoP mouth pipetting, eating, drinking, smoking, licking of labels, application of cosmetics (apart from hand/barrier cream) and the storage of food and drink for human consumption are expressly forbidden.

12 Outdoor clothing should be removed before entering the laboratory. Where this is not possible outdoor clothing should be removed before fully entering the laboratory and kept separately from laboratory coats.

13 Laboratory coats are to be worn at all times within laboratories, they should be removed when leaving the laboratory for comfort breaks, or to enter non-laboratory areas. Green laboratory coats are a requirement within plant growth facilities, and standard white laboratory coats within other areas. Safety glasses and other PPE (e.g. disposable gloves) are to be worn except where an RA shows them to be unnecessary. The School has a policy that all workers within labs must not wear open-toed footwear or heavily pierced patterns.

14 All material for autoclaving should be placed into the grey-lidded boxes provided. These should be clearly marked to identify the laboratory of source.

15 On completion of an experiment benches should be washed down with 1% Virkon. Virkon should be changed daily, however it changes colour from pink to clear when it is no longer effective.

16 All operations that are likely to produce aerosols must be carried out in the appropriate microbiological safety cabinet. Such operations should be identified in the RAs associated with the work.

17 Wherever possible use disposable pipettes or automatic pipettes with disposable tips. All pipettes used for handling cultures must be plugged and after use immersed in disinfectant. ABSOLUTELY NO MOUTH PIPETTING. Hypodermic needles should not be used.

18 All cultures must be decontaminated before disposal. This should be done immediately on completion of an experiment.

- Cultures must never be poured down sinks. It is School policy that these be autoclaved before disposal, NOT disinfected
- Waste materials such as paper towels, gloves, plastic petri dishes and other plastics should be collected in an autoclave bag and be autoclaved.
- Contaminated plastic, glassware and other reusable material must first be disinfected or preferably autoclaved before washing up.

19 Wash hands thoroughly before starting and after completing an experiment and

always before leaving the laboratory.

20 Supervisors must ensure safe and secure storage of recombinant organisms and pathogenic material and must maintain an up-to-date inventory. Storage fridges or freezers should be lockable when outside the containment laboratory.

21 All accidents, spillages and breakages must be dealt with immediately. All incidents should be reported to the project supervisor. All accidents should be reported to the DHSO. Spillages of GM material should be dealt with as specified in the RA pertinent to the work undertaken.

22 The School reserves the right to withdraw the right of access to GM laboratories.

Both the GM and Microbiological Laboratory CoP may be adopted for use in the laboratory. If adopted, they may be quoted in RAs; there is no need to re-write them. However, a hard copy must be available in the lab to refer to (preferably attached to the RA) and its whereabouts noted in the RA.

The general principles of good microbiological practice (GMP) and good occupational safety and hygiene (GOSH) are described in the ACGM Compendium of Guidance Part 3 and may be viewed at: http://www.hse.gov.uk/biosafety/gmo/acgm/acgmcomp/part3.pdf

Appendix 1

Emergency procedures

All workers with genetically modified organisms are required to have to deal with accidents, incidents and emergencies that could cause any person to be exposed to a genetically modified organism or an accidental release of genetically modified organisms.

The objective of your emergency procedures is the containment of the genetically modified organisms and the minimisation of risks to health.

You need to consider factors which may include assessing situations, instructions, informing others of accidents, isolation of area, evacuation, seeking assistance, PPE, RPE, preventing spread of contamination or spills, decontamination of work area or laboratory, safe waste disposal, first aid treatment and medical treatment if required.

You should consider all of the relevant factors to establish effective emergency first aid procedures. This may include removing contaminated clothing, removing contamination from skin, eyes and mouth by thorough washing with water, dealing with minor cuts and small puncture wounds, washing wounds with soap and water and dressing wounds. Use PPE if required when helping injured persons. Seek help from first aiders. Emergencies should be taken straight to hospital and call ambulance if necessary (Call Security on their emergency number 2222). Explain the incident and genetically modified organisms and if necessary give them with a copy of the GM risk assessment.

In the event of significant spillage inside the laboratory immediate evacuation may be required. This will depend upon the nature of the organism and should be identified in the risk assessment.

- If feasible a microbiological safety cabinet in the laboratory could be left running to help clear the lab of infectious aerosol, or the laboratory evacuated to allow aerosols to settle. Doors should be secured and signs posted to prevent access.
- Organisms which do not present a risk of aerosol transmission can be mopped up using an appropriate disinfectant (at the correct final concentration). For those which do present a risk of infection via inhalation, appropriate PPE must be worn
- If there is reason to believe a breakage may have occurred in a centrifuge the lid should remain shut to contain the aerosol and left for 30 minutes to allow aerosols to settle. A notice should be left on the lid to alert other users to the problem. The lid should be opened carefully and the interior sprayed with an appropriate disinfectant, followed by a neutral pH detergent and wiped down with 70% alcohol. The rotor /buckets should be inspected, and if intact transferred to a microbiological safety cabinet for opening and disinfection.
- Users of orbital shakers should always check through the observation panel for signs of leaks or spills. If in doubt do not open the lid, turn off and leave at least 30 minutes before opening, following the procedures outlined for centrifuges above.

Appendix 2

Suggested training of staff, postgraduate students and other workers

Understanding of GM Code of Practice and Local Rules

Instruction for use of equipment

Microbial Safety Cabinets
Fume cupboards
Incubators
Autoclaves
Transilluminators
Any equipment where its misuse has safety implications or where loss of materials or information is a risk.

Good microbiological technique

Disinfection procedures and waste handling

Storage and access to chemicals and flammable liquids

Storage of GMO and pathogenic organisms

Spillage procedures

Accident and incident reporting procedures

Fault reporting

Packaging for transport

Within the building
Materials sent by public carrier or carried by staff
Receipt of material from other laboratories
Containment of contents
Labelling
Hazard information for carrier
Hazard information and instruction for recipient

Completion of risk and COSHH assessments

Appendix 3

Microbiological Safety Cabinets [MSCs]

A microbiological safety cabinet is a ventilated enclosure intended to offer protection, to the user and the environment, from aerosols generated when handling biological agents or material.

The standard for the design, siting and testing of safety cabinets is specified in British Standards documents:

- BS 5726 1992 2 & 4, dealing with installation and selection, maintenance and use
- BS EN 12469 2000 [replacing BS 5726 parts 1 &3], dealing with performance criteria & testing.

Air discharged from a MSC to the atmosphere must always be HEPA filtered. Microbiological safety cabinets are not designed to protect the user from all hazards, e.g. radioactive, toxic or corrosive hazards, and the exhaust HEPA filters will not remove these types of contaminants from the exhaust air. Particular care must be taken when using materials with such additional hazards to ensure these are not discharged into the laboratory.

There are three types of MSC in common use:

MSC CLASS I - a cabinet with a front aperture through which the operator can carry out manipulations inside the cabinet. It is constructed so that the operator is protected and the escape of airborne particles generated within the cabinet is controlled by means of an inward airflow through the working front aperture with HEPA filtration of the exhaust air. This type of MSC will not provide any protection for the product and is suitable for work with all categories of biological agent, except HG4.

MSC CLASS II - a cabinet with a front aperture through which the operator can carry out manipulations inside the cabinet. It provides both worker and product protection. The escape of airborne particles generated within the cabinet is controlled by means of an inward airflow at the front of the cabinet which is filtered before circulation within it, while the down flow of HEPA filtered air over the working surface protects the work. This type of MSC is also suitable for work with all categories of biological agent, except HG4, though the degree of protection afforded to the operator can be compromised more readily than with a Class I MSC.

MSC CLASS III - a cabinet in which the working area is totally enclosed providing maximum protection for the operator, the work and the environment. Incoming and outgoing air is HEPA filtered. Access to the interior of a Class III cabinet is provided by use of arm- length gloves attached to ports in the front panel of the unit. The use of Class III cabinets is usually confined to work with biological agents in HG4.

The effectiveness of the microbiological safety cabinet depends on:

- good design;
- suitable installation;
- correct use

- ongoing maintenance;

Design
There are numerous manufacturers of MSCs within UK. It is important that the cabinet conforms to British Standard BS EN 12469: 2000.

Installation
Extract systems
The use of cabinets ducted directly to atmosphere via a dedicated extract system is preferred. Ducted cabinets must be fitted with automatic anti-blow back systems downstream of the filters to prevent air flowing back into the cabinet. If it is necessary to have more than one cabinet ducted via the same extract system, then a thimble system will be required to avoid the possibility of any back leakage. Cabinet manufacturers can advise on these

Recirculating cabinets
All of the Class II MScs within the School are of the recirculating type. A recirculating cabinet must be fitted with double HEPA filters on the exhaust, which may be installed in Containment Level 2 facilities providing there are no other hazardous contaminants in the discharged air.

Siting
Cabinets must be sited so as to minimise disturbance of the airflow at the front of the cabinet. Particular care should be taken with recirculating cabinets. Key considerations when siting a cabinet are:

- Doors and windows which open
- Draughts caused by ventilation and air conditioning units.
- Pedestrian traffic routes.
- Location of other MSCs or fume cupboards.

The UBSA must be consulted about any new installation of a Class II cabinet intended to be used at CL2.

Commissioning
When an MSC is installed the following commissioning tests must be carried out after siting.

- HEPA filter aerosol challenge test.
- KI Discus operator protection factor test [OPFT].
- Volumetric airflow rate and airflow patterns.

Correct use
The inward airflow that is drawn through the working aperture of open-front cabinets (Class I and II) can be disturbed by, for example, sudden movements of the arms of the operator and turbulence around the equipment placed inside the cabinet. Therefore observe the following:

- Keep the amount of equipment in the cabinet to a minimum.
- Avoid sudden movement of arms and moving hands in and out of the cabinet.
- Do not obstruct any of the air- intake grills at the front or rear of the cabinet as this will affect the air inflow.
- Work as near to the centre of the work area as possible.

Avoid unnecessary traffic in the vicinity of the cabinet and air disturbance in room. Keep doors

to room closed.

When work is finished the interior of the cabinet should be cleaned with an appropriate disinfectant and the fans left running for 10 minutes before switching of and closing the front cover or fitting the night door. These must be in place when the cabinet is not in use.

Other equipment that affects safe use:
Centrifuges:
Do not place these inside MSCs unless it is totally enclosed or an 'in use' test has been carried out and containment is not affected by use of the centrifuge.

Bunsen burners or similar:
Their use in safety cabinets is strongly discouraged due to disturbance of air flow and reduction of both operator and product protection, along with a greatly increased fire risk.
If these are to be used then an 'in-use' test will be required to establish that protection is not compromised in any way.

Provision of UV light in cabinets
UV is generally ineffective for sterilising the interior of cabinets as radiation is directional and therefore for it to be effective the cabinet must be totally empty. In line with current national and international standards, it is current policy that these NOT be fitted in any Class II cabinets.

If installation is explicitly required by a risk assessment the following requirements must be met:

- UV lighting must be installed in such a manner that it cannot affect performance or durability. Materials of construction must therefore be resistant to the effects of UV.
- There must be an electrical interlock fitted so that the operator cannot be exposed to UV light. Glass fronts to the cabinets MUST be designed to fully block the harmful UV radiation.
- The efficacy of the biocidal activity must be monitored regularly and the lamp changed when efficacy is reduced, or at predetermined frequency that ensures light is still effective

User training
All users of microbiological safety cabinets must receive appropriate training to the standard syllabus defined by the Department concerned.

Service & Maintenance
The COSHH Regulations, in relation to local exhaust ventilation require thorough examination and testing as part of routing maintenance at intervals not exceeding 14months. These tests must be carried out by a competent engineer. Cabinets used with HG2 pathogens or unscreened blood MUST be fumigated ahead of servicing.

In addition to the above checks the following checks must be carried out by the operator.

- correct operation of all alarms and indicators
- air velocity inflow readings are within safe limits as set by the manufacturer. For cabinets with digital readout this is normally between 0.7 to 1.0m/second for Class I cabinets and not less than 0.4m/s for Class II cabinets.

Appendix 4

Protocol for the Management of Biological Sciences Containment Glasshouse Facility

Access

Prior to any work commencing in the containment facility, an approved risk assessment (RA) must be completed. The worker must read it and sign to state that they have understood its content. All workers must be aware of this management plan for the glasshouse facility. All workers must receive information, training instruction and supervision relating to work with GM plant material and safe working practices within the GM glasshouse facility and documented records kept. Only when this is satisfied will the worker be allowed access to work. Specifically, a hard copy of the Local Rules and Code of Practice for working with Genetically Modified Organisms is available.

Personal protective equipment (PPE) will be provided within the vestibule of the glasshouse facility and must be worn at all times; at no time should this be worn within other sections of the glasshouse, outside, or removed from this facility unless for removal as contaminated waste or for laundering.

To allow maintenance of this facility, access is allowed to University maintenance personnel and outside contractors. A permit to work must be obtained, PPE must be worn on advice from the management team. Visitors must be accompanied by an approved person who must explain operation of the facility.

The door to each GM unit must be closed at all times and the outer vestibule door locked when unattended. Keys must be returned to the secure key safe in laboratory 6.23. The inner section doors must be closed when workers are in this area. The vestibule area is crucial in maintaining negative pressure inside the glasshouse and ensuring containment of seed and pollen. Before entering the vestibule from the outside, check that the inner section doors are closed. If not, communicate with the workers inside. NEVER OPEN BOTH THE MAIN GLASSHOUSE DOOR TO THE VESTIBULE AND INDIVIDUAL SECTIONS DOORS AT THE SAME TIME.

GM Plant Growth and Husbandry

All GM plant material must be clearly labelled using **ORANGE** tape, identifying owner, GM line, date and lab number. To minimize dissemination of seed and pollen, dispose of any unwanted plants before flowering or bag flowers when seed is required. Plants must be threshed at the seed harvesting station in the GM section of the glasshouse. Seeds are to be stored in the dedicated store in room 4.48. Seed transfer to this room requires containment in a robust sealed container. All GM plant waste must be contained in autoclave bags and stored in the designated bins beneath the right hand bench in section 6 of the glasshouse. The bags will be transferred and contained in grey autoclave boxes prior to being transported to be autoclaved and disposed of. Reusable pots and trays should be washed in the designated sink in the vestibule area. Disposable materials such as canes must be disposed of as GM waste. Sue Corbett (ext 3301) or Phillip Davey (3769) must be notified of heavy loads of washing as this may require higher frequency of pollen and seed filter replacement in the waste water drain.

General practice and maintenance
Within the vestibule there are green dedicated lab coats and disposable overshoes. These must be worn at all times when working in the inner GM sections. Never wear these outside of the facility. Overshoes must be disposed of as GM waste.

A sticky mat inside the outer doorway is designed to trap seed and pollen adhering to footwear. The topmost layer must be regularly removed and disposed of as GM waste.

Unintended dissemination of pollen or seed by invertebrate vectors is a potential risk. The facility has been designed to minimise this risk. However, all staff are encouraged to be vigilant and ensure, as far as possible, that invertebrates do not enter/exit the facility on clothing or equipment. Plant hygiene standards must also be maintained to limit pests that could act as vectors for cross pollination, therefore diseased plants should be disposed of immediately. ANY PLANT OR INVERTEBRATE INFESTATIONS SHOULD BE REPORTED IMMEDIATELY TO THE MANAGEMENT TEAM.

Growing space should be cleaned after completion of each experiment. This ensures removal of all plant debris and soil and prevents infection or infestation of plants from plant pathogens, fungal diseases or pests. Waste water and used cleaning materials must be disposed of as GM waste.

The main floor drain trap should be emptied every month and the filter checked every 3 months. See attached protocol.

After 2 months, lab coats will be double bagged (autoclave bags) and autoclaved before being sent for laundering. Used overshoes will be collected every week, double bagged (autoclave bags) and autoclaved before disposal.

Negative air pressure in the glasshouse facility minimises loss of seed and pollen escape. If there is damage to infra-structure, such as broken glass, phone 2959 or out of hours 2125 for urgent repairs. Air filters are cleaned regularly by Estates Management, by washing in the sink in the containment area.

The area immediately surrounding the glasshouse is monitored monthly for related species that may represent recipients for cross-pollination- these are removed.

Management
Dr Matthew Jones has been appointed as the Director of Glasshouse Facilities. As such, he should receive enquires regarding the containment management of this facility. Technical staff Susan Corbett and Phillip Davey, maintain the facility. As such give training and advice to workers and should be the point of contact for University maintenance personnel and outside contractors requiring access.

Appendix 5

Protocol for the Management of Biological Sciences Controlled Environment Facility

Access

Prior to any work commencing in this facility, an approved risk assessment (RA) must be completed. The worker must read it and sign to state that they have understood its content. All workers must be aware of this management plan for this facility. All workers must receive information, training instruction and supervision relating to work with GM plant material and safe working. Only when this is satisfied will the worker be allowed access to work. Specifically, a hard copy of the Local Rules and Code of Practice for working with Genetically Modified Organisms is available.

Plant Growth and Husbandry

All GM plant material must be clearly labelled using ORANGE tape, identifying owner, GM line, date and lab number. Non GM plants can be labelled with any colour tape, except orange. The controlled environment facilities have no engineered capacity to contain seed or pollen, therefore ABSOLUTELY NO GM PLANTS ARE ALLOWED TO FLOWER OR SET SEED IN THIS FACILITY.

If seed is required, plants must be transferred to the GM glasshouse containment facility before plants flower. Plant transfer to the GM glasshouse requires robust containers that minimise the loss of plant tissue and soil.

All GM plant waste (including non-flowering plants) must be contained in autoclave bags and stored in the designated area next to the sink in the 4.31. The bags will be transferred and contained in grey autoclave boxes prior to being transported to be autoclaved and disposed of. Reusable pots and trays containing soil residue from growing GM plants should be washed in the designated sink in the vestibule area. Disposable materials such as canes must be disposed of as GM waste. Sue Corbett (ext 3301) or Phillip Davey (3769) must be notified of heavy loads of washing as this may require higher frequency of pollen and seed filter replacement in the waste water drain. This protocol is attached to this document.

General practice and maintenance

Plant hygiene standards must also be maintained to limit pests that could act as vectors for cross pollination, therefore diseased plants must be disposed of immediately. ANY PLANT OR INVERTEBRATE INFESTATIONS MUST BE REPORTED IMMEDIATELY TO THE MANAGEMENT TEAM.

Growing space should be cleaned with mild detergent after completion of each experiment. If immediately following the growing of GM plants, waste water and used cleaning materials must be disposed of as GM waste. Cleaning ensures removal of all plant debris and soil and prevents infection or infestation of plants from plant pathogens, fungal diseases or pests. Hygiene is especially important when using the same growing space sequentially for GM and non-GM plants to stop cross contamination of soil and tissue.

Management

Dr Matthew Jones has been appointed as the Director of Glasshouse Facilities. As such, he should receive enquires regarding the containment management of this facility. Technical staff

Susan Corbett and Phillip Davey, maintain the facility. As such give training and advice to workers and should be the point of contact for University maintenance personnel and outside contractors requiring access.

Appendix 6

Protocol for GM Seed Handling in 4.42

Access
Room 4.42 to be locked at all times and keys for individual storage cabinets secured in key safe. Only workers approved for GM work (list available in the glasshouse) are to be given access to the keys.

General practice and maintenance
This facility must be kept tidy and in good order. Seed stocks must be stored within the locked cabinets provided. This facilitates both efficient indexing and minimises experimental errors. All seed must be clearly labelled to enable identification of the GM modification introduced. Any seed transfer to and from this room requires containment in a robust sealed container.

Seed Handling
To avoid cross contamination between seed stocks, only work with one seed line at any one time.

Always dispense and handle seeds in a white shallow tray. This both contains seeds and aids seed detection.

Dispense minimum number of seeds required for each experiment.

After use, mop tray with a damp piece of blue roll which is then disposed of as GM waste.

Spillages of seed on the floor should be contained using a HEPA filtered vacuum cleaner. If there is a seed spill on the floor, lock the room and locate the vacuum cleaner in Biological Sciences stores. Follow the pictorial instructions displayed in the room. The HEPA filter must be treated as GM waste.

Management
Dr Matthew Jones has been appointed as the Director of Glasshouse Facilities. As such, he should receive enquires regarding the containment management of this facility. Technical staff Susan Corbett and Phillip Davey maintain the facility. As such give training and advice to workers and should be the point of contact for University maintenance personnel and outside contractors requiring access.

Appendix 7

Management of waste water from GM containment area of glasshouse

The floor drains and sink waste from this area flow through a large capacity soil trap in the vestibule area of the glasshouse. This trap is emptied regularly (minimum bi-monthly) and contents treated as GM waste.

The waste then passes through a 0.2µm filter located in laboratory 4.31. This filter is replaced regularly (minimum bi-monthly) and contents and replaced filter are treated as GM waste.

Protocol for changing the 0.2µm filter

Materials needed:

- Autoclave box with waste hazard bag
- Paper towel (for splashes and spills)
- Large bin, labelled GM waste
- PPE; protective gloves, safety glasses.

Protocol for emptying the pre filter trap

- Place the large bin (labelled GM waste liquid) under the trap
- Turn off red valves either side of trap to isolate filter
- Remove metal supporting collar from trap
- Loosen trap slowly to drain excess water from pipes
- Empty trap into bin and rinse out with clean water
- Replace trap
- Replace support collar

Protocol for changing 0.2µm filter

- Have the autoclave box ready
- Wear protective gloves & safety glasses
- Remove top of filter housing and place on paper towel.
- Unscrew filter clamp and remove springs holding filters
- Remove filters and place in autoclave box

Protocol for reassembly

- Replace filters, springs and filter clamp
- Replace top of filter housing
- Check pre and post filter taps are closed
- Open red valves
- Check for leaks whilst bin is still in place.

Appendix 8

Acknowledgement of the receipt of School Local Rules and Code of Practice for Genetic Modification

I confirm that I have received a copy of the Local Rules and Code of Practice for work with Genetically Modified Organisms in the School of Biological Sciences and agree to work according to the requirements of the School as set out in these Rules.

Name **…….**

Signature **…….**

Date **…….**

Please return this form to ……by……