

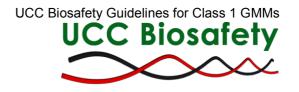
UCC Laboratory Biosafety Class 1 GMM Guidelines

The UCC Biosafety Guidelines aim to provide assistance and guidance to researchers handling biological agents in a safe manner using Good Microbial Practices (GMP) and Good Occupational Safety and Hygiene (GOSH). These guidelines are for a Class 1 Genetically Modified Microorganism (GMM) Laboratory.

Please note that these guidelines do not replace the Environmental Protection Agency (EPA: http://www.epa.ie/) conditions on your GMM consented registry nor do they replace the S.I. No. 73/2001 – Genetically Modified Organisms (Contained Use) Regulations, 2001 (http://www.irishstatutebook.ie/2001/en/si/0073.html).

Checklist		
	Annual Report Submitted? (deadline 31 st March 2011)	
	Limiting Access to GMM facility (e.g. Biohazard sign)	
	Disposal of GMM waste (e.g. Autoclave inactivation record)	
	SOPs – Training of New Staff (e.g. Staff training record)	
	SOPs – Treatment of Spills	
	SOPs – Cleaning & Disinfection of equipment	
	SOPs – Maintenance of Equipment	
	SOPs – Transport of GMMs within Lab/Dept/Building	
	Risk Assessments	
	GM Identification & Characterization	
	Maintenance of records & Log Books: training records/inactivation records/Storage of GMMs	





(A) Access to GMM Class 1 Laboratory

- 1) Access to laboratory working areas should be for authorised personnel only. Visitors should grant access from Principal Investigator or designated responsible person. Children should not be allowed to enter the lab and under no circumstances should vermin/pests and pets be authorised to enter.
- 2) Lab doors should be kept closed and locked when unoccupied.
- 3) A biohazard symbol and sign (e.g. Figure 1 Biohazard Sign) should be placed on the entrance to the laboratory if biological agents are handled in that laboratory including details of the Principal Investigator/Responsible person and phone number.

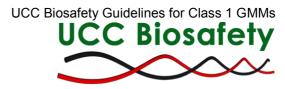
(B) Personal Protection

- 1) Lab coats must be worn at all times when working in the laboratory but removed before leaving the laboratory suite (such as bathroom, offices and canteen).
- 2) Gloves should be worn when handling biological agents and animals but removed when touching door handles, computers, telephone etc. Hands should be washed after gloves are removed.
- 3) Safety glasses/visor or other protective devices should be worn to protect against impacting objects, splashes or UV radiation.

(C) Lab Procedures

- 1) Mouth pipetting is prohibited
- 2) Eating and drinking, applying cosmetics/contact lenses or storage of food and drinks is not permitted in the laboratory.
- 3) Open-toed footwear not permitted in the laboratory.
- 4) Limit the use of hypodermic needles and syringes. The must only be used for injection or aspiration of fluids from laboratory materials/animals.
- 5) Technical procedures should minimize aerosol dissemination.
- 6) **Standard Operating Procedures** should be in place and followed especially in relation to:



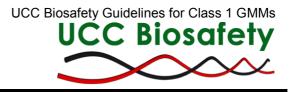


- Accidents and spills of GMM materials
- 7) Inactivation of biological material (e.g. Table 2 Autoclave inactivation record)
- 8) Contaminated waste liquids and solids must be inactivated and/or safely contained, and must not pose a hazard to persons exposed to or handling the material while in the waste management process.
- 9) Packaging and transportation of biological agents outside the University must follow National/International regulations.
- 10) Personnel must wash their hands after touching infectious materials and animals and before leaving the laboratory working area
- 11) Suitable arrangement must be made for the safe handling and transport of biological agents within the workplace.

(D) Class 1 Laboratory

- 1) The Laboratory should be kept clean and tidy.
- 2) Work surfaces should impervious to water and resistant to acids, alkalis, solvents and disinfectants
- 3) Work surfaces must be decontaminated after any spill of potentially hazardous material and at the end of the working day.
- 4) Laboratories should be subject to vermin/pest control where necessary.
- 5) Written documents that are expected to be removed from the laboratory need to be protected from contamination while in the laboratory.
- 6) There must be clearly defined storage areas for biological agents in the laboratory (e.g. Table 3. Example of GMM storage records and Figure 1. Biohazard Sign).

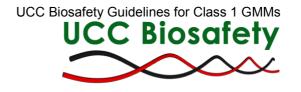




(E) Biosafety Management

- 1) It is the responsibility of the principal investigator to ensure the development and execution of a written biosafety management plan and an operations manual. Such documents may include risk assessments, safety training records, standard operating procedures, licences, and emergency plans (e.g. Table 1. Example of Staff training record, SOPs, Risk Assessments).
- 2) Laboratory personnel, university maintenance, house-keeping staff, and other authorised persons must be trained in, advised of, or consulted by laboratory management of, any special hazards involving biological agents and they must comply with safety procedures that are in place to minimise the risk of exposure to the biological agents.
- 3) Annual reports must be submitted to the EPA.







Authorised Personnel only

Biosafety Level	
Principal Investigator	
Contact Details	

Authorization for visitor access must be obtained from the Principal Investigator listed above

Do not remove items from this lab without prior authorization

Please keep this door locked when not attended

Figure 1 Example of Biohazard symbol for entrance to Laboratory and/or Growth facility/Animal houses.



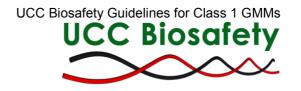


Table 1. Example of Staff training record.

Signature of this record states that I have received full training in appropriate GMP and GLP. I am familiar with all SOPs relevant to Class 1/Class 2 GMOs/GMMs and safe disposal of GMOs/GMMs. I am familiar with the Irish and EU guidelines relevant to the contained use of GMMs

Staff training Record		
Date:	Name:	Principal Investigator



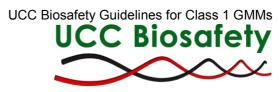


Table 2: Example of Autoclaves Inactivation record

Autoclave GMM/GMO inactivation record		
Date:	Name:	Program settings:
		121°C x 15 min



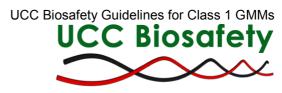
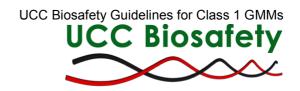


Table 3 Example of GMM storage records.

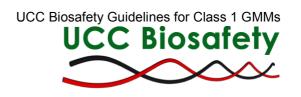
GMM Storage Record			
Date:	Name:	GMM Details	Location





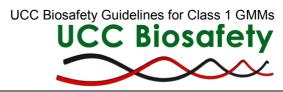
Checklist for UCC Laboratory Biosafety Inspections: 1st Visit





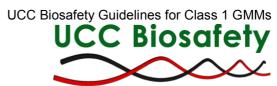
Depar	tment:	Building:	Room: (PI)
Room	: (Lab)	Autoclave Loca	ation:
PI:		Responsible Pe	erson:
Contai	inment Level (GMM):	1□	
Inspec	cted by:		Date://
GMM	Class 1		
Key: X	= no √ = yes N/A = not app	licable	
(examp	ble documents available for i	items in bold)	
(A) Otl	her Requirements		
	Annual Report Submitt	ed (2010)? <i>dead</i>	lline 31 st March 2011
(B) Go	ood Microbiological Prac	ctice (GMP) [GMN	Л Class 1 & 2 & GMO]
	The laboratory shoul	ld be easy to clea	an. Bench surfaces should be acids, alkalis, solvents and
			om clutter & Bench tops
	The laboratory door	should be closed	d when work is in progress
	Biohazard sign at ent	trance to lab, auto	clave area, freezer area
	Minimise the product	tion of aerosols	
	The identity of GMOs culturing of incorrect		larly checked to avoid the
	Appropriate training		aff training record
	Maintenance of equipment Hoods	ment – Autoclave/l	Fume cupboards/Laminar Flow
	Inactivation Record (Autoclave)	
	Washing and decont	amination facilitie	





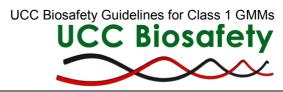
	Hands must be disinfected or washed immediately when
	contamination is suspected, after handling viable materials and also before leaving the laboratory
	Effective disinfectants should be available for immediate use in the
	event of spillage
	Used laboratory glassware and other materials awaiting
Ш	disinfection must be stored in a safe manner
	Use of sharps should be avoided. Contaminated syringes and
<u> </u>	sharps must be disposed of in a "sharps bin" and incinerated
П	Materials for disposal must be transported in robust and leakproof containers without spillage
	Eating, chewing, drinking, taking medication, smoking, storing of
	food and applying cosmetics must not take place in the work area
	, , , ,
Ш	Mouth pipetting must not take place
	Laboratory coats should be worn in the laboratory and removed
<u> </u>	when leaving the laboratory suite
	Personal protective equipment, including protective clothing, must
	be - stored in a well defined place
	- checked and cleaned at suitable intervals
	- when discovered to be defective, repaired or replaced before
	further use
	Personal protective equipment which may be contaminated by
	biological agents must be:
	- removed on leaving the working area
	- kept apart from uncontaminated clothing
	- decontaminated and cleaned, or if necessary, destroyed
	Biosafety Manual with SOPs
	All accidents and incidents should be immediately reported to and
П	recorded by the person responsible for the work or other delegated
	person
	Animals must not be allowed to enter into the laboratory
(C) Phy	sical Control Measures: Facility Design Class 1
(C) Filly	
	process with viable micro-organisms separated from the environment (closed system)
	,
	Accessability of window that opens
LI ontional	biohazard sign on the door
optional	signs at laboratory entrance:
	- special hazard signs if an organism containing rDNA needs
	special provision for persons entering the laboratory





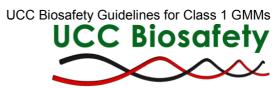
Security 25	University College Cork, Ireland
optional	- names of occupants who have access to the laboratory
	Outward opening of Laboratory doors
Optional	Observation window or alternative to enable occupants to be seen
(D) Phy	sical Control Measures: Containment equipment GMM Class 1
Optional	check the suitability of any chemical disinfectants in use
on site	check position of the autoclave with respect to the GMO installation
	wash hand basin or sink that can be used for hand washing with: - dispenser containing soap - dispenser containing hand disinfectant - paper towels
Optional	check position and design of biological safety hoods
	Check design of the equipment for the safe storage of GMOs. Storage is not allowed in floors as long it is not part of the facility
Optional	check design of waste transport containers
Optional	check design of containers for the transport of GMOs inside the facility
	check design of centrifuge buckets
	Provision of eye wash stations / bottles / equipment
(E) Safe	ety Management – Work Procedures <i>GMM Class 1</i>
	doors closed while working
	workers should be given adequate information on safety matters and be suitably trained. Training should include the following points: a) the existence and application of written work procedures b) the procedures for using particular pieces of equipment c) spillage control and other emergency procedures
Optional	check at which process steps hazardous quantities of aerosols are formed. Any operation that may involve the formation of aerosols (e.g. sonicating, centrifuging, pipetting) shall be performed in such a way as to ensure that these do not find their way into the working





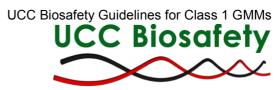
	GMO's are only to be transported within the facility in closed, robust and leakproof containers
	work surfaces must be decontaminated daily and after a spillage
Optional	inactivation of GMOs in contaminated material and waste
	users should ensure that the performance of safety equipment is validated (e.g. autoclaves and safety hoods) - validation of equipment (e.g. autoclaves, safety hoods) - maintenance of the equipment - markers used to verify the efficiency of autoclaves
	skin contact with rDNA material must be avoided
	decontaminate protective clothing before laundering
	protective clothing and street wear must be kept separate
Optional	Gloves (Optional)
Optional	implementation of an insect and rodent control programme
	sample collection, addition of materials to closed system and transfer of viable micro-organisms to another closed system, should be performed as appropriate
	safe storage of biological agents
	Regular identification and confirmation of purity of microbial strains
	Regular identification and confirmation of purity of microbial strains Safe storage of contaminated laboratory equipment
	Safe storage of contaminated laboratory equipment
□ □ □ optional	Safe storage of contaminated laboratory equipment Personnel to remove protective clothing on leaving the facility
(E) Saf	Safe storage of contaminated laboratory equipment Personnel to remove protective clothing on leaving the facility Worker required to wear closed shoes
(E) Saf	Safe storage of contaminated laboratory equipment Personnel to remove protective clothing on leaving the facility Worker required to wear closed shoes Regular maintenance of safety equipment such as safety cabinets ety Management – Organisational matters and documentation





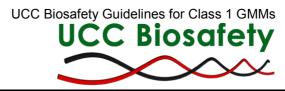
Name and Address of the Owner, where the Owner, which is the Owner, where the Owner, which is the Ow	University College Cork, Ireland
	- a description of the tasks of the BSO a.o. with respect to
	- safety
	- internal control
	- accident/incident response and preparedness
	- internal counselling, advice and education
	- reporting
	a description of the tasks of the project leader a.o. with
	respect to:
	- everyday management
	- drawing-up and executing work-protocol
	a clear description of the separation of responsibilities
	and tasks between the BSO and the project leader
	the discretionary powers/mandate that the BSO has
	received in order to fulfill his duty
	the status of the BSO should be defined. The job description should include
	- mechanisms whereby the BSO can report directly to the licensee
	- instructions that the BSO should hand his function
	over to a deputy in situations where he is involved in carrying out
	the practical work himself.
	- an indication as to the amount of time that the BSO will be
	allocated to undertake their role
	there should be written procedures that cover the
	following:
	- undertaking risk assessments
	- the training of new staff
	- emergency procedures including the treatment of spillages with
	disinfectants
	- cleaning and disinfection of equipment
	- transport of GMOs
	 operation, testing and maintenance of containment equipment measures for limiting access to facilities
	- health surveillance of workers
	written instructions should be in the language of the
	personnel working in the facility
	documents that should be centrally held within an
	institution undertaking GM work:
	a) records indicating working areas and their
	containment levels (these records may include
	plans of buildings)
	b) all of the documents listed in point 8 above
	c) a copy of all risk assessments and notifications
	d) these records should also cover any sites for storage
	of GMOs outside of containment facilities
	e) records of internally organised inspections f) records of incidents and accidents, including
	f) records of incidents and accidents, including evaluation and any remedial action
	g) a list of other data and documents that are held at
L	g/ a list of other data and documents that are neld at





Section 2	University College Cork, Ireland
	other locations within the institution
	examples of documents that can be held separately
	from the main records:
	a) records of staff involved in GM work indicating
	their experience and training and the type of
	projects in which they have been employed
	b) results of procedures for checking the purity and identity of the
	GMOs
	c) results of the testing of containment equipment (e.g. autoclaves
	and safety cabinets)
	d) a list of stored GMOs for each storage facility
	e) work protocols for particular experimental procedures
	Implementation of measures to minimise worker exposure, where
	work with class 1 GMMs with sensitising or toxic properties is being
	carried out (e.g. safety cabinet, provision of inhalation equipment
	when working with sporulating fungi)
(F) Ris	k Assessment
	check that risk assessments have been undertaken for all projects
	and that individual risk assessments contain sufficient information
	and have addressed all relevant issues.
	Ensure accurate descriptions/ characterisations of GMO's or
	groups of GMO's
П	description of the host-organism and name of the GMO
	description of the genetic material used to construct this
	GMO comprising at least the composition and the
	donors it was derived from
	in case of a Class 1 GMMs (requiring only reporting)
	gene functions should be documented
	for GMO's requiring notification the number of notification/licence should also be mentioned
	classification of the micro-organism(s) to be used
	classification of the operation
	check that ongoing projects have not diversified into
	areas of research that were not covered in the original
📙	risk assessment (e.g. by the help of a literature search
	or discussion with other members of staff)
	check that notifications have been made where necessary
	~
	check to see that risk assessments are reviewed by a
	local safety committee, if necessary
	check that people actually handling a particular GMO are aware of the content of the corresponding risk
📙	assessment
<u></u>	สออตออกเตเเ





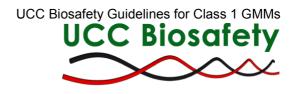
Emergency Responses:		
	check information on accidents (reporting of accidents and near – misses and records of corrective actions that have been taken)	
	provide written procedures for: - a procedure for internal notification of incidents (e.g. spillages) - a procedure for external notification in case of serious risk - a procedure for incident/accident response (measures, reporting, evaluation) - emergency preparedness actions and countermeasures in case of accidents or incidents	

IMPORTANT: Please refer back to your EPA GMO registry to see the conditions that apply to your lab. Some items that are optional for one lab may be required for another. This checklist is for guideline purposes only.

Recommendations/Comments:		
Next Visit Date:/_/_		

Copy to be given to Principal Investigator/Responsible person.





Annex I

Tables adapted from S.I No.73/2001 – Genetically Modified Organisms (Contained Use) Regulations, 2001.

Table 4 Containment measures for contained use of GMM in a Class 1 & 2 Laboratory

Measures		Containment Level		
IVICA	suies	Class 1	Class 2	
1	Laboratory suite: isolation	Not required	Not required	
2	Laboratory: sealable for fumigation	Not required	Not required	
Equi	ipment			
3	Surfaces resistant to water, acids, alkalis, solvents, disinfectants, decontamination agents and easy to clean	Required for bench	Required for bench	
4	Entry to laboratory via airlock	Not required	Not required	
5	Negative pressure relative to the pressure of the immediate environment	Not required	Not required	
6	Extract and input air from the laboratory should be HEPA-filtered	Not required	Not required	
7	Microbiological safety cabinet	Not required	Optional	
8	Autoclave	On site	In the building	
Syst	em of work			
9	Restricted access	Not required	Required	
10	Biohazard sign on the door	Not required	Required	
11	Specific measures to control aerosol dissemination	Not required	Required to minimize	
12	Shower	Not required	Not required	
13	Protective clothing	Suitable protective clothing	Suitable protective clothing; footwear optional	
14	Gloves	Not required	Optional	
15	Efficient vector control (e.g. for rodents and insects)	Optional	Required	
Was	te			
16	Inactivation of genetically modified micro- organisms in effluent from hand-washing sinks or drains and showers and similar effluents	Not required	Not required	
17	Inactivation of genetically modified micro- organisms in contaminated material and waste	Optional	Required	
Othe	er measures			
18	Laboratory to contain its own equipment	Not required	Not required	
19	Observation window or alternative to enable occupants to be seen	Optional	Optional	



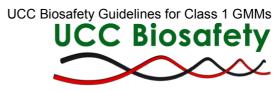


Table 5 Containment measures for contained use of genetically modified microorganisms in plant growth facilities

Measures		Containment Level		
		Class 1	Class 2	
Buil	ding			
1	Permanent structure	Not required	Required	
Equ	Equipment			
2	Entry via a separated room with two interlocking doors	Not required	Optional	
3	Control of contaminated run-off water	Optional	Required to minimise run-off	
Syst	em of work			
4	Measures to control undesired species such as insects, rodents, arthropods	Required	Required	
5	Procedures for transfer of living material between the plant growth facility and laboratory to control dissemination of genetically modified micro-organisms	Required to minimise dissemination	Required to minimise dissemination	

Table 6 Containment measures for contained use of genetically modified microorganisms in animal units

Measures		Containment Level		
		Class 1	Class 2	
Facilities				
1	Isolation of animal unit	Optional	Required	
2	Animal facilities separated by lockable doors	Optional	Required	
3	Animal facilities designed to facilitate decontamination	Optional	Optional	
4	Floor and walls easily washable	Optional	Required for floor	
5	Animals kept in appropriate containment facilities	Optional	Optional	
6	Filters on isolators or isolated room	Not required	Optional	



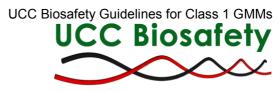


Table 7 Containment measures for contained use of genetically modified microorganisms in facilities other than those covered by tables above

Meas	sures	Containment Level	
		Class 1	Class 2
Gene	eral		
1	Viable micro-organisms contained in a system which separates the process from the environment, i.e. a closed system	Optional	Required
2	Control of exhaust gases from the closed system	Not required	Required to minimise dissemination
3	Control of aerosols during sample collection, addition of material to a closed system or transfer of material to another closed system	Optional	Required to minimise dissemination
4	Inactivation of bulk culture fluids before removal from the closed system	Optional	Required, by validated means
5	Seals designed to minimise or prevent release	No specific requirement	Required to minimise dissemination
6	Designation of controlled area to contain spillage of the entire contents of the closed system	Optional	Optional
7	Controlled area sealable to permit fumigation	Not required	Optional
Equi	pment		
8	Entry via airlock	Not required	Not required
9	Surfaces resistant to water, acid, alkalis, solvents, disinfectants, decontamination agents and easy to clean	Required for bench	Required for benc
10	Specific measures adequately to ventilate the controlled area in order to minimise air contamination	Optional	Optional
11	Controlled area maintained at an air pressure negative to the immediate surroundings	Not required	Not required
12	Extract and input air from the controlled area to be high efficiency particulate air filtered	Not required	Not required
Syst	em of work		
13	Closed systems located within a controlled area	Not required	Optional
14	Access restricted to nominated personnel only	Not required	Required
15	Biohazard signs posted	Not required	Required
16	Personnel to shower before leaving the controlled area	Not required	Not required
17	Personnel to wear protective clothing	Required (work clothing)	Required (work clothing)
Was	te		
18	Inactivation of GMM in effluent from hand- washing sinks or showers or similar effluents	Not required	Not required



UCC Biosafety Guidelines for Class 1 GMMs
UCC Biosafety

19	Inactivation of GMM in contaminated material and waste including those in process effluent before final discharge	Optional	Required, by validated means
----	---	----------	------------------------------