Genetically Modified Organisms

Local Code of Practice

University of Glasgow
Garscube Estate :
Faculty of Veterinary Medicine
Wellcome Surgical Institute

Local GM web site :
http://info.vet.gla.ac.uk/operations/committees/gmsc

In compliance with :
Genetically Modified Organisms (Contained Use) Regulations
Risk assessment requirements of Environmental Protection Act

Revised 06/05/06
1. Introduction

Genetically modified organisms (GMOs)
GMOs are defined as organisms ‘in which the genetic material has been altered in a way that does not occur naturally’.

The main types of GMOs used at Garscube include:

- Laboratory bacterial strains carrying cloning/expression vectors with inserted nucleic acid
- Genetically modified viruses and bacteria
- Transgenic animals

Exemptions from adherence to the Contained Use Regulations are granted to the following: hybridomas, DNA vaccines, organisms where genetic exchange has occurred by a natural route such as mating or bacterial recombination, chemically mutated viruses, under certain circumstances (see [http://www.hse.gov.uk/biosafety/gmo/acgm/acgmcomp/index.htm](http://www.hse.gov.uk/biosafety/gmo/acgm/acgmcomp/index.htm) for more information).

Research involving the generation, utilisation, storage and transportation of genetically modified organisms (GMOs) requires an assessment of potential risk to human/animal health and the environment according to the following legislature:

<table>
<thead>
<tr>
<th>Type of genetically modified organism/use</th>
<th>Legislature</th>
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<tbody>
<tr>
<td>GMOs - deliberate release</td>
<td>GMO (Deliberate Release) Regulations 2002</td>
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</table>

This code of practice focuses on compliance with Genetically Modified Organisms (Contained Use) Regulations 2000 and amendments 2002, 2005 legislature which covers genetically modified microorganism (GMM) work and assessments of risk to human health associated with any GM animal work. Compliance essentially comprises 4 elements:

1) the production of risk assessments for GM projects
2) the formation of a local genetic modification safety committee (GMSC) to advise on and review risk assessments
3) the notification to the Competent Authorities (via Health and Safety Executive) of a) premises where GM work is conducted and b) Class 2 and higher status projects
4) the application, and maintenance, of appropriate control measures to contain GMOs.
Formal permission from the HSE may be required prior to initiation of certain programmes of work. COSHH regulations (2002) apply to genetically modified organisms which present a hazard to human health – where these risks are assessed in a GM risk assessment this meets COSHH requirements. These regulations do not apply to any GMOs for which consent has been obtained under the Environmental Protection Act, Deliberate Release Regulations or as a component of a medicinal product for veterinary or human use. Personnel working with genetically modified animals should also comply with the Deliberate Release Regulations as detailed above – local risk assessment forms fulfil the requirements for risk assessment to human health and the environment (under Contained Use and EPA).

2. Garscube Local GM Guidance

2.1 Genetic Modification Safety Committee

A local Genetic Modification Safety Committee (GMSC) [Appendix 1], chaired by a Genetic Modification Biological Safety Officer (GMBSO), acts as a source of advice on GM work, reviews risk assessments [Genetically Modified Organisms (Contained Use) Regulations 2000] and liaises with the Health and Safety Executive (HSE). The GMSC designated within this Code of Practice considers risk assessments for all units within the Veterinary School and the Wellcome Surgical Institute (Medical Faculty) and includes scientific representatives from each unit. Ancillary staff are represented at Research Unit Safety Committee meetings at which general GM safety issues are raised. The GMSC meets several times a year to consider amendments to existing assessments and to review new project assessments. Laboratories and animal facilities on campus (Vet School and Wellcome Surgical Institute) have been notified to the HSE by GMSC and are designated as premises GM223.

2.2 Local Risk Assessment Guidelines

Risk assessments are required for all work carried out using genetically modified microorganisms and non-microorganisms (e.g. naked DNA). See Appendix 2 for summary of procedures.

- **Group leaders are responsible** for ensuring risk assessments are submitted to GMSC for all GM work in their group.

- All staff members involved in the work must read the risk assessment.

- Risk assessments for new projects must be submitted to committee for review **prior to the project start date. Failure to do so may lead to delay of the work programme.** Dates of GMSC meetings and deadlines for submission of risk assessments are circulated in advance by e.mail and are available on request from GMBSO.

Class 2 Projects - Class 2 projects must be notified to HSE (HSE notification form should be submitted with risk assessment to GMSC) - work can start as soon as HSE acknowledgement is received (allow 2 weeks).
Class 3 Projects must be notified to the HSE **45 days in advance of project start** (this involves sending risk assessment and further information to the HSE) - **active** consent is required from HSE before project can start.

**Guidance**

Preparation of an assessment requires reference to the regulations and associated HSE guidance notes [see web site/GMBSO]. Specific queries regarding any aspect of risk assessment and handling of GMOs should be referred in the first instance to a member of the GM safety committee. Guidance may be sought from the following sources, all obtainable from GMBSO and deputies and/or on the local GM web site:

<table>
<thead>
<tr>
<th>Local web site</th>
<th><a href="http://info.vet.gla.ac.uk/operations/committees/gmsc">http://info.vet.gla.ac.uk/operations/committees/gmsc</a></th>
</tr>
</thead>
<tbody>
<tr>
<td>Guidance notes for completion of the Garscube Risk Assessment forms</td>
<td>local web site</td>
</tr>
<tr>
<td>A guide to the Genetically Modified Organisms (Contained Use) Regulations 2000</td>
<td>GMBSO</td>
</tr>
<tr>
<td>Advisory Committee on Dangerous Pathogens The Approved List of Biological Agents HSE 2004</td>
<td>local web site or <a href="http://www.hse.gov.uk/pubns/misc208.pdf">http://www.hse.gov.uk/pubns/misc208.pdf</a></td>
</tr>
<tr>
<td>HSE Compendium of Guidance from the Health and Safety Commission's advisory committee on genetic modification</td>
<td>local web site or <a href="http://www.hse.gov.uk/biosafety/gmo/acgm/acgmcomp/index.htm">http://www.hse.gov.uk/biosafety/gmo/acgm/acgmcomp/index.htm</a></td>
</tr>
<tr>
<td>HSE Newsletters</td>
<td>local web site or <a href="http://www.hse.gov.uk/biosafety/gmo/information.htm">http://www.hse.gov.uk/biosafety/gmo/information.htm</a></td>
</tr>
<tr>
<td>HSE overview of GM issues</td>
<td>local web site or <a href="http://www.hse.gov.uk/biosafety/gmo/index.htm">http://www.hse.gov.uk/biosafety/gmo/index.htm</a></td>
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</tbody>
</table>

**Containment Level**

Classes are applied to activities on the basis of the highest level of containment required to protect human health and the environment from exposure to a particular GMO. In practice a higher containment level may be applied for reasons of convenience or COSHH legislation (e.g. using a Level 2 class II microbiological safety cabinet to protect class 1 GMO-infected cells from contamination or to protect the operator from possible presence of adventitious agents). Thus a Risk Assessment may classify a GM activity as Class 1 but include some procedures conducted at Level 2 – for each procedure state the containment level which will be applied and where this exceeds the level dictated by the GM activity class, indicate the reason for application of the higher containment level: COSHH risk assessment requirements can be fulfilled within a GM risk assessment.
In general, it is not good laboratory practice to use a containment level higher than Level 2 if this is not necessary for safety reasons, and advice should be sought from the HOD and GMSC as required.

Work undertaken in designated areas such as the vaccinia laboratory, LRF containment suite, cat3 suite and MRC cat2 bacterial room must adhere to the relevant Code of Practice. Users of GMOs or GMAs in animal facilities should adhere to local rules for work in these facilities.

**Confidentiality**

Notification of projects to the HSE (not necessary for Class 1 projects) may have implications with respect to confidentiality. If confidentiality of project is important for intellectual property rights or harm to competitive position, please seek advice from GMBSO. Amendments to the 2000 regulations [the Genetically Modified Organisms (Contained Use)(Amendment) Regulations 2002 (The Amending Regulations)] permit some activities to be excluded from the Public Register in the interests of national security.

**Submission of risk assessments**

Assessments should be submitted in electronic form to the GMBSO. The Risk Assessment form, guidance notes and HSE notification form are available on the local web site or from Lesley Nicolson [L.Nicolson@vet.gla.ac.uk] or Paul Everest [phe3d@udcf.gla.ac.uk].

**Amendment of Assessments**

Modifications to assessments should be notified to the GMBSO who may refer the assessment to committee for further review. Examples of modifications which may be required include:

- Notification of personnel changes
- New safety information on GMO derived from ongoing work or from published work of others e.g assessment of pathogenicity of mutant deleted in suspected virulence gene
- Termination of programme of work
- Change in disposal procedures (unless covered by changes to departmental safety policy referred to in assessment)
- Assessment of risk associated with transportation to another facility

**Access to Risk Assessments**

Risk assessments, local GM and safety codes of practice should be available, and accessible, by all lab workers. Where GM organisms are used in animals or transgenic animals are used, Biological Services must be provided with a copy of the GM risk assessment so that animal technicians are fully informed of the hazards/risks/consequences to themselves and the environment associated with the work. GMSC will forward relevant risk assessments to Biological Services once they have been passed by committee. Those involved in GM work should have read the associated risk assessment(s) and signed the RA or alternate record, to register their understanding of the risks involved and the containment measures applicable.
2.3 Local GM Practice Guidelines

Safety

Work with GMOs should adhere to Good Laboratory/Microbiological Practice and guidance in accordance with local and University health and safety guidelines.

Training

Any staff member who is undertaking GM work for the first time should be instructed in general GMO handling and disposal procedures. A record should be made that such training has occurred and archived by the local safety officer. Training in particular experimental protocols is required, but does not have to be recorded, for Class 1 and 2 GMO work. More detailed training records may be necessary for Class 3 GMO work and/or where stipulated by the code of practice for Class 2/3 facilities on campus.

Disposal Procedures

The Regulations place emphasis on inactivation of GMOs prior to disposal. In addition to treatment of laboratory GMOs, this applies to treatment of litter waste, or other material associated with animals, if contaminated with GMOs. Disposal of GMOs is conducted according to research unit procedures. As a general guide some local disposal practices are outlined in Appendix 3. Reference to the Codes of Practice for Handling of Recombinant Vaccinia Virus/VSV, the Code of Practice for the LRF Containment Suite, and the Code of Practice for the Category 3 Containment Laboratory is required for procedures conducted in the Vaccinia laboratory, LRF and Cat 3 containment facilities. These outline specific operating procedures for all work conducted in these facilities and disposal and spill procedures. Inactivation, disposal and spill handling procedures for GMOs should be displayed in the laboratory.

Transportation of GMOs

Where transportation of GMOs from one laboratory to another requires passage through general corridor/office areas, double containment is advisable. A robust container which will prevent dispersal of spills should be used (such as a sealed plastic box). Animal cages should be secondarily contained or fully sealed during transportation to further minimise the risk of escape.

To avoid contamination of non-laboratory areas, wherever possible gloves should not be worn outwith laboratories. If a glove must be used to handle transported material, the other hand should be ungloved and the ungloved hand used to open doors.

Where GMOs are to be transported to a laboratory off-campus, an assessment of risk should be made for transportation. This can be included in the original Risk Assessment or can be added as an amendment, notified to GMBSO at a later date, prior to despatch of reagents. Materials should be transported under double containment.
**Class 2 activities**

Where not covered by a specific code of practice, all work with Class 2 viral, bacterial or parasitic organisms should adhere to the following:

- transportation between CL2 laboratories under double containment
- storage in a locked freezer/freezer room facility
- notification on orbital incubators/centrifuges that Class 2 GMOs are in use indicating a) Class 2 GMOs present and b) contact details of person responsible in event of a spill
- spill and disposal procedures on display in laboratory

**Storage of GMOs**

Ideally GMOs should be stored in areas which cannot be accessed by the general public. Most laboratory areas have fully controlled entry preventing access of unauthorised personnel. For those areas which, for reasons of student, client or delivery access, have a point of open entry, the following is advised:

- Class 1 GMOs – where possible, restricted access to storage areas (e.g. freezers, liq N2)
- Class 2 GMOs – restricted access to stored GMOs through lock on freezer or freezer room
- Class 3 GMOs – storage restricted to CL3 facility

**Decontamination of equipment**

Equipment should be appropriately decontaminated prior to servicing or despatch for repair. Procedures for decontamination following a spill should be posted adjacent to bacterial incubators.

**Naked DNA**

The risk of exposure to naked DNA will be minimised by the wearing of gloves and lab coats (and glasses where appropriate) and the covering of open cuts or abrasions. Handling of naked oncogenic DNA or potentially infectious viral nucleic acid will be subject to additional measures such as avoidance of use of sharps and glassware, wherever possible, and limiting exposure to aerosols.

**Viral vectors**

Where viral vectors are used sharps and glassware will be avoided wherever possible and every care taken to limit risk of needle-stick injury during inoculation of animals.
Appendix 1

Genetic Modification Safety Committee [GMSC]

See http://info.vet.gla.ac.uk/operations/committees/gmsc/gmsc.htm

Heads of Division, Veterinary Faculty
- Infection and Immunity – E. Devaney
- Pathological Science – R. Jarrett
- Cell Sciences – P. O'Shaugnessy
- Animal Production and Public Health – D. Taylor
- Companion Animal Sciences – J. Anderson

Head of Wellcome Surgical Institute
- M. Macrae

Associate Dean for Research
- I. Morgan

Biological Safety Officers
- D. Mellor [Vet Faculty]
- D. Dewar [Wellcome Surgical Institute]
Appendix 2

Proposed Genetic Modification project

GM bacteria
GM viruses
GM parasites
GMOs in non-GM animals

GM animals e.g. transgenic mice

Guidance available from:
- ACGM guidance + local guidance notes
  Lesley Nicolson (GMSO)
  L.Nicolson@vet.gla.ac.uk
- ACGM guidance part 2E, 3D + local guidance notes
  Paul Everest (dGMSO)
  phe3d@udcf.gla.ac.uk

- determine GM safety committee deadline appropriate to start date of project

Risk assessments:
- complete GMO risk assessment form
  for class 2/3 projects also complete HSE notification form
- complete GMA risk assessment form
- notification of HSE required if GMA more hazardous than wild type

GMSC

Submission to GMSC
send to L.Nicolson@vet.gla.ac.uk
in electronic form before submission deadline

NB a generic risk assessment is available from GMBSO for GMA or GMO in animal work in the Veterinary Research Facility (VRF). Risk assessments for specific projects need only consider the risks presented by the GMOs or GMAs used in the project as the generic risk assessment covers risks pertaining to animal work in general (e.g. prevention of escape, mode of transportation etc., physical barriers within the VRF etc.)
## Appendix 3

### Example of local waste disposal procedures [GMMs]

<table>
<thead>
<tr>
<th>ITEM</th>
<th>STORAGE</th>
<th>TREATMENT</th>
<th>DISPOSAL</th>
</tr>
</thead>
<tbody>
<tr>
<td>Bacterial and yeast waste and other fluid biological waste (where appropriate)</td>
<td></td>
<td>chlorine releasing tablets added e.g. chloros, stericol, covclor, guard or presept (covclor/guard : 1 tablet per 1 litre)</td>
<td>pretreated solution discarded bacteriology suite sink in MRC laboratory</td>
</tr>
<tr>
<td>Contaminated glassware and plastic ware</td>
<td></td>
<td>Soaked in solution containing minimum 1000 ppm chlorine Washed and autoclaved</td>
<td>not applicable</td>
</tr>
<tr>
<td>Biol. contaminated material, flasks, plates, gloves, cultures etc.</td>
<td>Autoclave bags in boxes</td>
<td>Sterilise - Autoclave</td>
<td>Land fill via district council waste uplift</td>
</tr>
<tr>
<td>Needles, Blades, Sharps</td>
<td>Yellow Sharps Boxes</td>
<td>Sterilise - Autoclave</td>
<td>Incineration via Cannon</td>
</tr>
<tr>
<td>Reaction Tubes, Tips, etc.</td>
<td>Unlabelled Cin Bins</td>
<td>Sterilise - Autoclave</td>
<td>Land fill via district council waste uplift</td>
</tr>
<tr>
<td>Clinical Waste</td>
<td>Autoclave bags, drums</td>
<td>Sterilise - Autoclave</td>
<td>Incineration via Cannon</td>
</tr>
</tbody>
</table>

**Recommended hypochlorite concentrations:**

*General laboratory areas*
Pipette Jars and Steeping Baths at a concentration of 500ppm

*Tissue Culture rooms*
Pipette Jars and Steeping Baths at a concentration of 1000ppm

*Clinical Diagnostic Areas*
Pipette Jars and Steeping Baths at a concentration of 1000ppm

*Bacterial Cultures*
Treated at a concentration of 1000ppm

Where these measures are insufficient for a particular GMO, alternative means of disposal should be used as specified in the risk assessment and/or appropriate code of practice.