Queen Mary University of London

Health & Safety Directorate

Genetic Modification (GM) Activities - Health and Safety Policy, Guidance and Arrangements for QMUL

(Ref: QMUL_HS_192)

Table of Contents

Page

1. Executive Summary

This Health and Safety Policy establishes the framework for the risk assessment, the risk controls and the health & safety measures to be adopted and implemented for working safely with Genetically Modified Organisms (GMOs) by Queen Mary University of London (QMUL) staff and students on QMUL Premises; for Partner Organisations with a written agreement for peer review of GM activities and also for others who may be affected by QMUL activities. The objective of the Policy is to eliminate or where not reasonable practicable, reduce the arising risks to a negligible level and to ensure compliance with the Regulations governing work with GMOs.

The policy defines safe working requirements for GMOs in the context of QMUL's activities; identifies the roles and responsibilities for Heads/Managers/Supervisors of Schools / Institutes / Directorates conducting work with GMOs, for QMUL staff, students and others who may be affected, and notes the key legal and compliance (including notifications to the regulatory authority) requirements specified in the relevant health and safety legislation and guidance.

Guidance on practical measures (including Containment measures, safe working procedures, dealing with accidents and emergencies, inspections, training, supervision and competencies) for QMUL and resources for the risk assessment of Genetically Modified activities are provided or linked. The Policy has been issued following approval by the QMUL Biological & Genetic Modification Safety Committee.

2. Queen Mary University of London - Statement of Policy on Genetically Modified Organisms and Objective of the Policy

The Policy of Queen Mary University of London (QMUL) is to ensure that the risks arising from working with Genetically Modified Organisms (GMOs) are eliminated or reduced to a negligible level as far as is reasonably practicable. The objective of the Policy is to ensure the continued health, safety and welfare of employees (staff), students and others who may be affected by the risks, the protection of the environment and to ensure compliance with the Regulations governing work with GMOs.

It is QMUL policy that the procedures for risk assessment and safety management (including facilities and infrastructure) set out in current legislation (noted below) and in the Scientific Advisory Committee on Genetic Modification's (SACGM) 'Compendium of Guidance' and other statutory guidance, shall be in place **before** commencing the work (activity) that falls within the official definition of Genetic Modification (GM, see below). Risk control and safety management measures should be maintained throughout the duration of the activity, to ensure risks from the GM activity to humans and the environment are minimised to a negligible level.

3. Definitions and Glossary

Genetic Modification (GM): in relation to an organism*, means the **altering** of the genetic material (DNA or RNA) in that organism in a way that does not occur naturally by mating or natural recombination. If the introduced genetic material is capable of **stable incorporation** and/or **continued propagation** in the recipient organism, the work involving it is likely to fall under the GM Regulations listed below.

GM Activities involve organisms* (animals, plants, micro-organisms) which are genetically modified by 'listed techniques' noted in the GM Regulations (see Appendix 1 for definitions, 'listed techniques' and examples) and where Genetically Modified Organisms (GMOs) or Genetically Modified Micro-organisms (GMMs) are received, cultured, stored, transported, destroyed, disposed of or used in any other way.

***Organism:** The term covers biological entities capable of replication or of transferring genetic material, including multi-cellular organisms (animals, plants, insects, nematodes) and single cell organisms (micro-organisms). In relation to the GM Regulations, the term *excludes* humans, human embryos and human admixed embryos.

***Micro-organism:** The term covers bacteria, fungi, viruses, and biological agents such as prions, as well as cell and tissue cultures from plants, animals or humans.

Contained Use: Any activity involving GMOs / GMMs where barriers (physical, chemical and/or biological) are used to limit contact with the GMOs / GMMs, and provide a high level of protection to humans and the environment.

Deliberate Release: A GMO / GMM under a person's control is 'released' if s/he deliberately causes or permits the GMO / GMM to cease to be under control of a person and enter the environment.

4. Legislation

This QMUL Policy sets out the framework to achieve compliance with, and for the safety management of, GM work that is subject to the requirements of the Genetically Modified Organisms (Contained Use) Regulations 2014 (as amended) (SI 2014 No. 1663).

Other legislation covering the environmental risks posed by Genetically Modified Organisms (GMO and GMMs) are: The Genetically Modified Organisms (Risk Assessment) (Records and Exemptions) Regulations 1996 (as amended), the Genetically Modified Organisms (Deliberate Release) Regulations 2002 (as

amended) and relevant sections of the Environmental Protection Act 1990.

The general requirements of the Health and Safety at Work Act 1974, the Management of Health and Safety at Work Regulations 1999, and the Carriage of Dangerous Goods legislation also apply to work with GMOs. The Control of Substances Hazardous to Health Regulations (2002) with aspects regarding biological agents may also apply to work with parental organisms and/or GMO / GMMs.

5. Scope and Application of the Policy

This Policy applies to all QMUL staff, postgraduate and undergraduate students and others (e.g. contractors, academic visitors) who are to conduct activities with GMOs and to all others who may be affected by QMUL GM activities. Where Partner Organisations (clinical / research) enter into a written agreement for peer review of GM activities, this Policy applies to the extent of the written agreement.

6. QMUL Roles and Responsibilities- Head of School or Directorate / Director of Institute and/or Centre Lead*

It is the responsibility of the Head of School / Directorate or Director of Institute and/or Centre Lead in which GM work (activity) is planned to be undertaken for the first time (including higher risk level GM work planned for the first time) to notify the relevant Faculty Vice-Principal at the earliest possible date. A written summary of the intended work sent to the Secretary *(contact details available below)* of the QMUL Biological & Genetic Modification Safety Committee (BGMSC) will constitute such notification. The BGMSC Secretary will facilitate the appropriate Regulatory Authority notification/s (premises and other required notification/s) and inform Senior QMUL Management. *These responsibilities also apply to the Head of a Partner Organisation with a written agreement with the QMUL BGMSC for peer review of GM activities.

It is the responsibility** of the Head of School / Directorate or Institute Director and/or Centre Lead to ensure that;

1. Staff with supervisory ('GM Project Supervisor/s') and other safety responsibilities (e.g. local GM / biological safety officer, lab manager with GM Safety responsibilities) are appointed, trained and are competent for the GM activity planned.
2. Appropriate risk assessment/s for the first and **ALL** subsequent individual GM Contained Use activities are made by the GM Project Supervisor and laid before the QMUL GMSC for approval **BEFORE** any GM Contained Use activity commences.

3. Where required, notification and payment of the appropriate notification fee to the Regulatory Authority from funds held by the School / Directorate or Institute / Centre and that Regulatory Authority approval / consent is obtained and held.
4. Appropriate GM risk assessment/s (and as appropriate local / national study / research ethics approvals) are submitted to the appropriate Regulatory Authority for **ALL** Deliberate Release Activities and consent obtained **BEFORE** the Deliberate Release Activity commences.
5. Appropriate laboratory and/or other facilities (e.g. clinical, environmental control) and other required infrastructure (e.g. hazardous waste collection, storage facilities) are provided for the work to minimise risks to humans and the environment to a negligible level.
6. Safe systems of work are established to ensure risks from the GM activity to humans and the environment are minimised to a negligible level.

**Responsibilities cannot be delegated, although tasks associated with a particular responsibility can be delegated to a competent person.

7. Roles and Responsibilities - GM Project Supervisors

It is the responsibility** of a GM Project Supervisor to ensure that:

1. Appropriate risk assessments for individual GM Contained Use Activities are made and recorded, that they are laid before the QMUL GMSC, and that work does not start until the Committee has classified the GM activity according to its risk level and made its recommendations, and where required, Regulatory Authority notification, approval or consent is received.
2. Where required, payment of the appropriate notification fee to the Regulatory Authority.
3. Working practices throughout the duration of the project comply with GM regulations and other relevant legislation (e.g. COSHH), written laboratory rules and within the terms of the risk assessment approved by the GMSC, and where applicable, the notification to the Regulatory Authority.
4. Safety control (Containment) measures identified in GM risk assessment/s and protocols are correctly installed, maintained and tested and that these control measures are locally checked and inspected periodically for effectiveness. Where failure is identified, to remedy safety equipment or safety deficiencies in work practices to the required safety standard. Where remedial action for any safety measure is not in their control, to report defects to the appropriate QMUL department as soon as possible for action.
5. GM workers receive appropriate information, instruction, mandatory and other training and supervision both in specific techniques and in the principles of good laboratory practice and safety, including hazardous waste disposal and emergency procedures applicable to the work, and that any necessary health surveillance (see section 13 below) is instituted for those involved in, or affected by, a GM activity. Mandatory training is detailed at http://www.hsd.qmul.ac.uk/training/ and course schedules are at http://www.hsd.qmul.ac.uk/training/course-calendar/

6. All accidents and incidents (e.g. uncontrolled release of a GM Agent) involving GM materials in their remit are reported to the QMUL Health and Safety Directorate as soon as possible by the prescribed route (http://www.hsd.qmul.ac.uk/accident-reporting/). Partner organisations must also report into their own accident and incident reporting system.

**Responsibilities cannot be delegated, although tasks associated with a particular responsibility can be delegated to a competent person.

8. Roles and Responsibilities - GM Project Workers

It is the responsibility of GM project workers to ensure that they

1. Take reasonable care of their own health and safety, and that of others who may be affected by their work. This is achieved by following the relevant local instructions and safety rules, attending mandatory and other appropriate training for the work and complying with the QMUL Standard and other applicable GM requirements, in line with the relevant legislation. Mandatory training is detailed at http://www.hsd.qmul.ac.uk/training/ and course schedules are at http://www.hsd.qmul.ac.uk/training/course-calendar/
2. Report all accidents (e.g. exposure to a GMO / GMM) and incidents (e.g. an uncontrolled release of a GM Agent) involving GM materials in their work immediately to their GM Project Supervisor and to the QMUL Occupational Health and Safety Directorate by the prescribed route (hhttp://www.hsd.qmul.ac.uk/accident-reporting/).
3. Report any defects with safety equipment or safety deficiencies in work practices to their GM Project Supervisor as soon as possible for remedial action.

9. The QMUL Biological & Genetic Modification Safety Committee (BGMSC)

The QMUL Biological & Genetic Modification Safety Committee (BGMSC) reports to the QMUL Health and Safety Advisory Group (HSAG). The BGMSC is set up to classify Contained Use GM Activities according to risk level prescribed by the GM legislation, to notify QMUL (or Partner Organisation) senior management on the adequacy of the risk assessment and also to provide advice, independent of project management, on the safety aspects of all GM work undertaken by QMUL Schools / Directorates and Institutes and/or Centres, and to Partner Organisations subject to a written agreement. The membership and terms of reference of the committee must be notified to the Chair of the QMUL Health and Safety Advisory Group by the Chair of the BGMSC and kept under review.

The duties, roles and responsibilities of the QMUL Biological & Genetic Modification Safety Committee (BGMSC) are:

1. To review their own membership in the light of current guidance.
2. To ensure that the premises where the work is to be done are correctly registered with the Regulatory Authority (e.g. HSE for Contained Use Activities) as a centre for genetic modification;
3. To review the micro/biological safety arrangements in each laboratory or clinical / other area to be used for GM work and to determine the Containment Level facilities which are required for the work.
4. To receive proposals for GM Contained Use projects and to review the classifications proposed for GMMs (containment level and class) and review the proposals for containment measures based on safety and environmental risk assessments.
5. To give approval, where the committee is satisfied, regarding the classification and containment proposals for Class 1 activities and in other cases (e.g. Class 2 and 3 activities. *Note - Class 4 activities are not permitted at QMUL*) to forward the proposal to HSE with recommendations and to confirm that payment of the appropriate fee has been made;
6. To advise QMUL (or Partner) Senior Management (e.g. Faculty Vice Principal) if any proposal brought to it appears to be subject to the Genetic Modification (Deliberate Release) Regulations 2002 (as amended) so that appropriate policies, procedures and notifications can be put in place and consent obtained;
7. To verify that where a risk assessment indicates a requirement, the names of GM workers involved in or affected by GM work have been notified to the QMUL Occupational Health Medical Adviser with such project data as may be necessary for any health surveillance and/or the compilation of occupational health records;
8. To make recommendations to individual Schools / Institutes and to QMUL on suitable forms of information, instruction and training for workers performing experiments involving GM Agents;
9. To consider accidents and incidents in any GM laboratory or area, to advise accordingly, and to confirm that appropriate QMUL authorities and the HSE are notified (if necessary), of any significant release of genetically modified organisms which presented a hazard;
10. To ensure that appropriate data are obtained from GM Activity Project Supervisors and that returns are made to statutory authorities at the

required intervals;

11. To send an Executive Summary and Minutes of its meetings and, where necessary, to send copies of all formal proposals, with outcome, to the QMUL Health and Safety Advisory Group.

10. Organisation of the QMUL BGMSC

1. The committee should be of the composition listed below to provide representation for both management and staff, and also be representative of all those having access to GM facilities or those who may be exposed to such work:

A Chair;
A Deputy Chair;
The QMUL Biological Safety Adviser (acting as the statutory GM Biological Safety Officer (GM BSO) and competent adviser) - Secretary;
A molecular biologist, at least at senior lecturer level
A microbiologist and/or an infectious disease specialist
Representatives from each Institute, School or Department with GM activities
A Lay member
Trade Union Representative/s
The QMUL Medical Advisor or a member from the Occupational Health Service

2. Other members such as graduate students, technical staff or appointed safety representatives may be co-opted. Representative/s from Clinical Hospitals / Partner Organisations where QMUL staff are to conduct GM gene therapy trials can be co-opted. Representatives of other commercial / spin off entity GMSC's on QMUL locations / premises are invited to attend as observers.

3. Heads of QMUL (Partner) Schools / Directorates or Director / Centre Leads of Institutes in which genetic modification is taking place and GM Project Supervisors shall receive copies of the minutes of the committee meetings, which is achieved by a placing these minutes on a dedicated QMUL website (http://www.hsd.qmul.ac.uk/a-z/health-and-safety-advisory-group/health-and-safety-adviosry-group/bgmsc/).

4. All records of GM project applications should be kept by the Committee Secretary and when required, copies sent to the Chair of the Health and Safety Advisory Group.

5. The quorum for generating/approving annual reports shall be the Chair,

the Secretary / GM BSO and one other member. The quorum for project review shall include the molecular biologist, microbiologist / infectious disease specialist, the Chair and the GM BSO / Secretary.

6. When new higher risk projects (Class 2 and 3) are reviewed by the Committee, the project proposer shall normally attend in order to answer questions from the BGMSC.

11. Role and Responsibilities of the BGMSC Chair / Deputy

The Chair (and Deputy) should be a permanent Academic staff member of QMUL to at least Senior Lecturer level, experienced in, and knowledgeable of molecular biology, GM technology and the Regulations.

1. The Chair and Deputy of the BGMSC shall be appointed by the Chair of the QMUL Health and Safety Advisory Group, consulting with the Director of Health and Safety Directorate.

2. In addition to ensuring the duties of the BGMSC noted above are fulfilled, the Chair (or Deputy in the Chair's absence) will attend the QMUL Health and Safety Advisory Group to provide GM information and expertise as necessary to senior QMUL management.

3. The Chair will co-ordinate the submission of an annual report on GM activities and any other notifications to the QMUL Health and Safety Advisory Group, and

4. Ensure submission of the required GM notifications to the HSE.

12. Roles and Responsibilities of the QMUL GM Biological Safety Officer (GM BSO)

The GM BSO will:

- fulfil the role of a competent adviser to QMUL and Research / Clinical Partner Organisations (with prior written agreements) on GM topics and will have sufficient knowledge and experience to understand the risks to both human health and the environment arising from a proposed GM activity; and
- be able to provide guidance on the adequacy of the GM risk assessment, in line with the Regulations.

The main roles of the BSO are to:

1. Ensure QMUL premises registration with the Regulatory Authority (e.g. HSE) to allow GM work on premises.
2. Advise on draft GM risk assessments prior to their approval by the GMSC.
3. Provide (or arrange) training courses for GM activities and advise on training needs for GM activities.
4. Provide competent / expert advice on:

   The design and layout of Containment Laboratories.

   Appropriate facilities for GM Activities (e.g. GM waste disposal facilities).

   Safe working procedures for GM activities.

5. Maintain detailed QMUL central records based on information (provided by GM Project Supervisors) relating to:

   i. All work involving genetic modification or genetically modified material at QMUL.

   ii. QMUL premises registered with the Regulatory Authority for GM work.

   iii. Personnel involved with GM work.

6. Be responsible for preparing formal minutes of BGMSC meetings.
7. Provide specialist input to investigating the causes and consequences of accidents and incidents and advise on action to be taken following the investigation.

13. Health Surveillance for GM Workers

1. Where required (those working in GM class 3 activities and other activities where a risk assessment indicates), the names of staff and students / academic visitors who will be involved in GM work should be notified by the GM Project Supervisor to the QMUL Occupational Health Service (OHS) with details and the risk level of work in which they will be involved. Details of the process are noted at http://hr.qmul.ac.uk/about-us/ . Partner Organisations should conduct a similar process with their Occupational Health Service.

2. Any GM worker declaring a history of any disorder of the immune system or other serious disease should contact OHS and make an appointment for an interview. Details at http://hr.qmul.ac.uk/about-us/ .
3. Those undertaking low risk work (e.g. class 1 and most class 2 activities) with no identifiable risk to human health will, in general, need no health surveillance. Further guidance on health monitoring can be found in the SACGM Compendium of Guidance (pages 17-20 of Part 1) http://www.hse.gov.uk/biosafety/gmo/acgm/acgmcomp/.
4. The health status of GM workers requiring health surveillance will be reviewed annually by questionnaire administered by OHS and if necessary, will be supplemented by examination and investigation. The OHS will issue two health questionnaires and, if the worker defaults, will inform the Chair of the BGMSC and the worker's line manager.
5. The Occupational Health Service staff will rely heavily on the advice of the BGMSC concerning health surveillance.
6. All staff, students and academic visitors will be provided with advice on those specific conditions which might compromise the health of workers undertaking genetic modification experiments.

14. Guidance on GM Contained Use Activity Risk Assessment, QMUL Arrangements and Procedures

This part of the Standard provides a framework of procedures for GM Contained Use (GMMs and GMOs) work within GM Classes 1, 2 and 3 as laid out in the Genetically Modified Organisms (Contained Use) Regulations 2014 (SI 2014 No. 1663) and incorporating where necessary, procedures from other relevant legislation.

1. The GM Contained Use Regulations and other informative documents such as the Scientific Advisory Committee on Genetic Modification (SACGM) Compendium of Guidance, SACGM newsletters and documents, are available for reference and download from the HSE website (http://www.hse.gov.uk/biosafety/gmo/index.htm).
2. Further Guidance / FAQ documents on GM Risk Assessment and Biological Safety Procedures are also available on the QMUL Intranet in the Health and Safety Directorate web pages (http://www.hsd.qmul.ac.uk/a-z/genetically-modified-organisms/ and http://www.hsd.qmul.ac.uk/a-z/biological/).

15. GM Contained Use Risk Assessment – Key Principles and Requirements

1. Regulation 5 of the GM (Contained Use) Regulations 2014 sets out the duties of the person responsible to ensure that Contained Use activities involving GMMs (which may or may not involve larger GMOs) are assessed before any work starts, that any relevant risks are identified and controls assigned. These include risks (whether immediate or delayed) to the health of humans and the environment arising from the contained use of GMMs.
2. The risk assessment must take full account of all aspects of the planned work, including handling, transport, work area decontamination, inactivation of GMMs, disposal and waste management including where waste contractors are to be used.
3. The key aspects to address in the risk assessment by the GM Project Supervisor (or their nominated competent person) include:
4. Identification of potentially harmful effects to humans and the environment: consider harmful properties of the recipient and donor organisms, vectors and genetic inserts, singularly and in the final construct. Consideration should be made to the wild type pathogen (human and animal) Hazard Group, infectious dose to humans and other affected species, tropism and host range of vector, expression promoters (mammalian / eukaryotic in particular), transmission route/s, pathogenic components, hazardous biological function/s of the organism / vector / insert.
5. Characteristics of the proposed activity: consider how the GMM is being modified and whether it is possible enhancement of function / infectivity / virulence (or conversely attenuation), altered tropism / phenotype / host range, altered drug resistance, allergenic effects, altered survivability or stability and altered routes of transmission could occur. Transfer / mobility of harmful sequences (of insert and also up or downstream effects), particularly sequence mobilisation in bacteria and recombination between related viruses, re-assortment between segmented viruses and oncogene capture events need to be considered.
   As required, consult the SACGM Compendium of Guidance http://www.hse.gov.uk/biosafety/gmo/acgm/acgmcomp/ (Part 2) for guidance on various GM vector systems and inserts. As applicable, consider lenti/retro viruses (section 2.11), routine cloning and expression with attenuated *E.coli* vectors (section 2.3), adenoviruses (section 2.7). There is a section on GM cell lines (section 2.5).
6. How (e.g. culture volumes, use of sharps, inoculation of animal models) and where the activity will be undertaken will need to be considered (including non-standard procedures and/or higher risk environments, e.g. handling outside the normal containment facility in robotic equipment or equipment with potential for uncontrolled dissemination).
7. The severity of any potentially harmful effects to humans and the environment; including baseline information of disease/s, ill health and/or other adverse effect/s that may occur upon exposure, details of the increase of risk if exposed

to the GMO, categories of persons / environmental species who may be more susceptible if exposed to the GMO.

8. The likelihood of them occurring: consider these in relation to the activity, facility, location and also non-standard procedures; and
9. The overall level of risk to humans and the environment. The following risk matrix in the SACGM guidance (4 x 4) is to be used:

		LIKELIHOOD OF HAZARD			
		High	**Medium**	**Low**	**Negligible**
CONSEQUENCE OF HAZARD	**Severe**	High	High	Medium	Effectively Zero
	Modest	High	Medium	Medium / Low	Effectively Zero
	Minor	Medium / Low	Low	Low	Effectively Zero
	Negligible	Effectively Zero	Effectively Zero	Effectively Zero	Effectively Zero

10. Details of inactivation and disposal of waste and effluent.
11. A key requirement to fulfil is to **establish the appropriate Containment to protect humans and the environment from the identified risks**. The risk assessor should select the required Containment measures from the Containment Level Table (see Appendix 2 for small- scale GMMs in a laboratory setting, for other categories see below) and to assign a **provisional Containment Level** for the activity.
12. At QMUL, facilities are in place for Containment Level 1 through to Level 3; Containment Level 4 facilities do not exist and there are no permissions in place for work at that highest risk level.
13. Further information is available on GMMs in a laboratory setting from the SACGM Compendium of Guidance http://www.hse.gov.uk/biosafety/gmo/acgm/acgmcomp/ (Parts 2 on vector systems and inserts and Part 3 on Containment Level measures) and for GMMs in a clinical setting in Part 6.
14. Consideration of other H&S Regulatory requirements (e.g. COSHH, DEFRA animal pathogens, Radiation, Security).
15. Reviewing periodically and reconsidering the containment measures in light of changes to the project, technology, knowledge, location, equipment and also after accidents / incidents.
16. The QMUL GM risk assessment template for Contained Use available on the HSD website http://www.hsd.qmul.ac.uk/a-z/genetically-modified-organisms/ incorporates the relevant prompts and questions to enable the GM risk assessment to be completed. A completed example GM risk assessment is also available for consultation by those drafting a GM risk assessment at http://www.hsd.qmul.ac.uk/a-z/genetically-modified-organisms/ . The SACGM Compendium of Guidance has example risk assessments at http://www.hse.gov.uk/biosafety/gmo/acgm/acgmcomp/part2.pdf (pp 148-157).
17. The QMUL BGMSC will classify the GMM Contained Use Activity into one of three risk classes (GM Class 1 to 3), according to the information in the risk

assessment, overall risk evaluation and per the requirements of the Regulations.

This is summarised in the Table below:

GMM Contained Use - Final Risk Evaluation	**Containment necessary to control the Risk**	**Risk Classification**
Effectively zero risk to humans and/or the environment	Level 1	Class 1
Low to medium risk to humans and/or the environment	Level 1 with the addition of measures from Level 2 *or* Level 2 (without additional measures)	Class 2
Medium risk to humans and/or the environment	Level 2 with the addition of measures from Level 3 *or* Level 3 (without additional measures)	Class 3
High risk to humans and/or the environment	Level 3 with the addition of measures from Level 4 *or* Level 4 (without additional measures)	This work cannot be conducted at QMUL

18. Where certain Containment Level measures are assessed as not necessary or alternative measures are more appropriate to provide equivalent protection, derogation from applying the higher measure can be requested from the Regulatory Authority. A full justified explanation must be provided.
19. For risk assessment of larger GMOs (e.g. animals, plants) where no GMMs are involved, there is no requirement to consult containment tables but there is a requirement to conduct a risk assessment to establish whether the larger GMO is more hazardous to human health than the non-modified parental species. Similarly, the requirements of the Environmental Protection Act demand that risks to the environment from the GMO are assessed. The most suitable and protective measures should be established and recorded to prevent harm to human health and damage to the environment. Further information is available on larger GMOs from the SACGM Compendium of Guidance http://www.hse.gov.uk/biosafety/gmo/acgm/acgmcomp/ (Parts 4 and 5).
20. QMUL has a generic Environmental Risk Assessment http://www.hsd.qmul.ac.uk/a-z/health-and-safety-advisory-group/health-and-safety-adviosry-group/bgmsc/ that would apply to most low risk (transgenic) rodent model work (where no higher risk GMMs are involved). The GM Project Supervisor must ensure that the minimal requirements stipulated for Environmental Protection are in place and attest by signing it and obtain the BSU manager's attestation before forwarding to the GM BSO.

21. For other larger GMOs, please contact the QMUL Biological Safety Adviser for risk assessment templates.

16. GM Deliberate Release Activities

1. The GMO Deliberate Release Regulations (SI 2443 / 2002 as issued under Directive 2001/18/EC, and the Environmental Protection Act) regulates activities where GMOs are intentionally released from the person's control into the environment.

2. The essential difference between the Contained Use Regulations and the Deliberate Release Regulations, is whether there is intention or an expected action to release a GMO / GMM into the environment (which is then considered Deliberate Release) or whether the intention is to keep the GMO / GMM contained using a combination of barriers (physical, chemical or biological) which is considered to be Contained Use).

3. If a GMM is administered as gene therapy agent or as a vaccine and is expected to be shed by clinical trial volunteer/s in significant numbers into the environment, it is likely that the GM activity would be considered a Deliberate Release activity. Similarly, many plant GM trials would come under the Deliberate Release Regulations as plant material such as pollen, seeds would be expected to be released during a trial and a combination of barriers would not be able to prevent release.

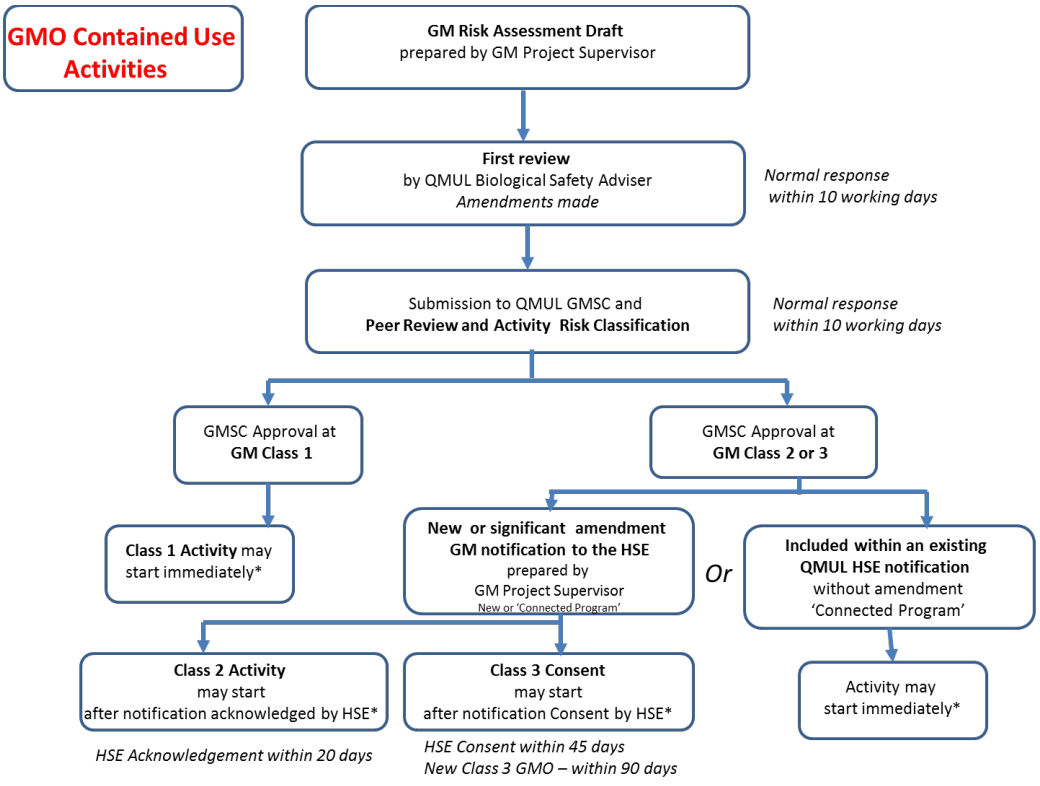
4. All requests (application) to release GMO / GMMs into the environment are referred by the UK Government (enforced by DEFRA) to the Advisory Committee on Releases to the Environment (ACRE). ACRE assesses each request against the possible risks to human health or the environment. If more information is required to review the application then ACRE will request this from the applicant directly. Finally ACRE publishes a report that sets out a summary of its findings in each case. This will recommend that the UK Government either approves or denies the request, and may also contain conditions or monitoring measures that ACRE thinks should be included. Following Government approval (DEFRA), the Deliberate Release activity can commence.

5. A Deliberate Release activity application will need to include a full risk assessment for human health and also a specific Environmental Risk Assessment (ERA). The assessment process for GM release considers potential safety factors such as toxicity, allergenicity, and the fate of any possible transfer of novel genes to other organisms.

6. Further details on the application process is available at https://www.gov.uk/government/collections/genetically-modified-organisms-applications-and-consents

7. Specific guidance for Deliberate Release clinical trials is found in the SACGM Compendium of Guidance Part 6 http://www.hse.gov.uk/biosafety/gmo/acgm/acgmcomp/part6.pdf and for larger GMOs (see Part 4 for plants and Part 5 for animals).
8. Typically, a Deliberate Release Activity will be managed by a sponsor (e.g. clinical trial managing company / entity for a clinical trial) as other regulatory permissions would be involved in the process (research ethics, clinical trials authorisation, food standards, marketing).
9. The B/GMSC of an organisation has no formal role in a Deliberate Release Activity approval process, but can offer advice and recommendations for worker / environment safety, facility and procedure safety and on the risk assessment.
10. The QMUL BGMSC and the GM BSO can offer advice and a local risk assessment template for Deliberate Release clinical trial activities is available at http://www.hsd.qmul.ac.uk/a-z/health-and-safety-advisory-group/health-and-safety-adviosry-group/bgmsc/

17. GM Activity - Risk Assessment and Regulatory Notification Process including Regulatory Inspections



** Facility, procedures and management arrangements must be in place, a QMUL GMSC inspection will be needed for new or altered facilities*

1. Check that the proposed work falls under the definition of 'genetic modification' (GM) – see Appendix 1 below for further details.

Consult the Genetic Modified Organisms (Contained Use) Regulations 2014 and the Scientific Advisory Committee on Genetic Modification (Contained Use) Compendium of Guidance http://www.hse.gov.uk/biosafety/gmo/acgm/acgmcomp/index.htm for full definitions.

2. Check that the proposed place of work is covered by the QMUL GM Contained Use Premises Notification (see Appendix 2). The three main campus sites of QMUL (Mile End, Whitechapel, and Charterhouse Square), and the main locations of the Barts Health NHS Trust are covered under the notification for GM Centre 774. If the proposed place of work is not covered, contact the QMUL GM BSO to make arrangements to include the new premises.

3. Decide if the proposed work falls under the Contained Use[1] or Deliberate Release[2] Regulations. Most laboratory, clinical research trials, enclosed plant or animal facility based GM work will fall under the Contained Use Regulations. Some non-enclosed plant work and some clinical research trials may fall under the Deliberate Release Regulations. Consult the Compendium of Guidance for further details.

4. Check if other required regulatory approvals have been obtained or are being obtained (e.g. local or multi-centre research ethics committee approval, Medicines and Healthcare Regulatory Authority approval, Home Office approval, ionising radiation work approval, approval for the use of a substance listed under Schedule 5 of the Anti-Terrorism Crime and Security Act etc).

5. **As detailed above, conduct a risk assessment of the proposed GM work for human health and the environment** by identifying the hazards and considering the potential severity, likelihood of occurrence and any considerations of uncertainty. Use the QMUL GM Risk Assessment template/s and consult the Compendium of Guidance and include any relevant scientific citations and supplier information.

6. For GM micro-organisms (GMMO), provisionally set the minimum Containment Level that is necessary to protect human health and the environment from the risks arising from the GM activity. For non-GMMOs (e.g. plants and animals, some clinical trials), state the control measures required to protect from the identified risks. Consult the Compendium of Guidance for information on Containment Levels and control measures.

7. It is permissible to submit risk assessments from more than one QMUL research group in a combined version, as long as the project aims and objectives are cohesive, integrated and attain a defined scientific goal. Project management must be clearly identified so that gaps in either the scientific program, safety requirements or management arrangements do not occur.

8. Submit the draft risk assessment **electronically** to the QMUL GM BSO, who will scrutinise the assessment and if required, will ask for amendments or clarification on the assessment.

9. Once any required amendments are completed, the GM BSO will submit the risk assessment for consideration by the QMUL BGMSC.

10. If using transgenic animal models of negligible risk, complete the generic QMUL Environmental Risk Assessment, available at http://www.hsd.qmul.ac.uk/a-z/health-and-safety-advisory-group/health-and-safety-adviosry-group/bgmsc/. A low risk activity requires the GM Project Supervisor and Biological Services Unit Head or Manager to confirm by signature that the work and containment facilities comply with the specifications laid out in the generic risk assessment. Higher risk activities require the addition of further detail and assessment to ensure that GM Containment measures are sufficient to prevent release of any genetically modified material into the environment. If this is the case, consult with the GM BSO.

11. Risk Assessments of low risk activities (GM Class 1) are considered by the BGMSC via email circulation and response. The BGMSC will normally respond within 10 working days. Any required amendments and the final adjudged Containment Level and GM Class are notified to the Project Supervisor through the QMUL GM BSO. Once a low risk GM activity has been approved by the BGMSC, work may commence, subject to any required amendments.

12. **If the laboratory is new to GM work of any Class, is to be used for a higher risk GM activity than before or has been altered since previous GM work was conducted, it must be inspected by the BGMSC**. The Project Supervisor should arrange a suitable time with the QMUL Biological Safety Adviser to conduct this. The inspection is conducted against the standards required by legislation and detailed in the Compendium of Guidance. Inspection checklists are available with the requirements tailored for QMUL requirements (different settings – GMMs, GMOs and risk levels) at hhttp://www.hsd.qmul.ac.uk/a-z/audit-and-inspection/

13. Higher risk activities (assessed to be GM Class 2 or 3) are considered at a convened BGMSC meeting, which is normally held once a term. GM Project Supervisors should check the scheduled BGMSC meeting dates on the HSD website http://www.hsd.qmul.ac.uk/a-z/health-and-safety-advisory-group/health-and-safety-adviosry-group/bgmsc/ or contact the QMUL Biological Safety Adviser for details. If required, an emergency ad hoc meeting can be held by the BGMSC to consider an urgent risk assessment.

14. GM Class 4 projects are not permitted at QMUL as there are no licensed facilities able to handle such high risk activities.

15. Higher risk QMUL GM Contained Use activities (Class 2 and 3) require notification to the Health and Safety Executive (HSE) through the **CU2 form** https://www.hse.gov.uk/forms/genetic/cu2.doc . See the HSE website for further information (including **the fee payable for new notifications and significant amendments and notification periods** for GM Class 2 and 3 activities at http://www.hse.gov.uk/biosafety/gmo/notifications/fees.htm

    As the three main campus sites of QMUL have already been notified for GM Class 2 and 3 activities, the notification period applicable would be for 'subsequent activities' i.e. GM Class 2 - as soon as the HSE acknowledges receipt of the notification, GM Class 3 - Consent (or a reason for refusal) given within 45 days of the initial acknowledgement.

    Information for the administrative sections of the CU2 notification form (https://www.hse.gov.uk/forms/genetic/index.htm) is in Appendix 2.

16. It is possible for new QMUL Contained Use risk assessments to be included within an existing QMUL notification as a '**Connected Program of Work'**; **ALL** of the Contained Use projects should be coherent and integrated into a programme of work with a common scientific / research goal. Consult with the GM BSO for details and also view the Regulations (Regulation 13).

17. It is also possible for a notification to be submitted for more than one notified premises across the United Kingdom. Consult with the GM BSO for details and also view the Regulations (Regulation 13).

18. Transfer of an existing notified GM activity from another GM Centre should be notified to the HSE through the **CU4** notification form https://www.hse.gov.uk/forms/genetic/cu4.pdf - consult with the QMUL GM BSO for further details.

19. It is necessary to inform the HSE, as part of the notification process under the GMO (Contained Use) Regulations, whether **GM Class 3 GMM/O's** are likely to be subject to any 'trans-boundary movement', entering or leaving the European Union[3]. The HSE is then required to inform the Biological Clearing House and European Commission of such movements. Therefore, the QMUL Biological Safety Adviser must be informed in advance of any intention to export or import Class 3 GMM/Os in order for any necessary notifications to be made to the HSE.

20. **The electronic completed CU2 or CU4 form, along with the approved QMUL GM risk assessment/s, must be submitted through the QMUL GM BSO (Biological Safety Adviser) to the HSE.** The forms will be sent by email to the HSE unless there is sensitive information (see next point), in which case it will be sent by recorded Royal Mail delivery.

21. If sensitive information (e.g. intellectual property, use of animal models, security sensitive information such as use of a Schedule 5 pathogen) is submitted in the notification and non-disclosure to the public register is required, a version of the CU2 and local risk assessment excluding this information must also be submitted. The complete version of the notification must include the justification for any non-disclosure. See http://www.hse.gov.uk/biosafety/gmo/publicregister.htm for details about the public register.

22. **The fee payable to the HSE should be sent by the Project Supervisor or their School / Directorate or Institute**– see Appendix 4 for details of the process (an invoice can be requested from the HSE).

23. The HSE acknowledgement (GM Class 2) or consent (GM Class 3) will be forwarded by the QMUL Biological Safety Adviser to the Project Supervisor upon receipt and work may commence.

24. A refusal by the HSE to approve Class 2 or issue Class 3 consent will necessitate actions by the Project Supervisor to comply with stipulated

requirements. A re-submission of the CU2 / risk assessment to notify compliance may be required.

25. The HSE may require inspection of any GM laboratory before an acknowledgement or consent is given.

26. GM risk assessments must be kept up to date and reviewed by the Project Supervisor regularly (e.g. annually, when work changes, after an incident involving GM agents). The older version must always be kept on file and the new version submitted to the QMUL GM BSO. The Regulations require that GM risk assessments are kept for 10 years after work ceases (this includes the storage of GM Agents).

27. **'Significant changes' to a GM risk assessment must be considered and approved by the QMUL BGMSC, and for higher risk activities (GM Class 2 and 3), and also by the HSE**. A fee will be payable to the HSE for significant changes to a higher risk activity. The guidance for Regulation 15 of the Contained Use Regulations 2014 states that **significant changes** are those that 'significantly affect the level of risk' – e.g. changes to the GMO, new information to the level of risk, changes to containment and control measures, changes to procedures, requests for derogation.

    See pages 33 and 34 of the Regulations for details on what constitutes 'significant' and 'non-significant' changes at http://www.hse.gov.uk/pubns/priced/l29.pdf and also the ISTR Guidance document http://www.istr.org.uk/docs/ISTR%20BSG%20Significant%20Change%20guidance%20v1.pdf

28. **Cessation of notified risk activities (GM Class 2 and 3) must be notified to the HSE via the QMUL Biological Safety Adviser**. Cessation of a Class 1 activity must also be notified to the QMUL Biological Safety Adviser so that QMUL records can be updated.

29. **GM assessments, notifications and records must be kept for 10 years after work has ceased (which includes storage of any GMO / GMM).** The QMUL Biological Safety Adviser holds copies of all GM assessments and notifications submitted to him by the Project Supervisor.

30. The Project Supervisor must ensure that any project worker requiring health surveillance as indicated by the local risk assessment (e.g. work with animals, hazard group 3 organisms, allergen exposure) registers with the QMUL Occupational Health, **before work commences**. See section above on the topic and consult pages 17-21 of Part 1 of the Compendium of Guidance.

31. **'Exposure records'** for work with Hazard Group (HG) 3 organisms (or cell lines and other biological substances that are classified as equivalent to HG 3) must be kept for 40 years, as required by COSHH. In this context, an 'exposure record' for GM agents is a record of work with a GM agent, not just an accidental exposure to a GM agent. GM Exposure records are different from a 'health record' which details health surveillance and monitoring (held by Occupational Health). A 'GM Exposure record' for a GM project worker for any GM Class (1 – 3) can be generated by the QMUL Biological Safety Adviser upon request. This will note the workers name, GM project and GM agents worked with during their employment at QMUL.

32. **The Project Supervisor should inform the QMUL Biological Safety Adviser of any new GM project workers**. A project worker upon cessation of the project / employment can ask for their 'GM Exposure record' in order to be given to the next employer. Likewise, an employer can ask for previous 'GM Exposure records' from a new project worker.

33. The risk assessment should be periodically reviewed and updated as necessary over the active life of the project as per QMUL Risk Assessment Policy and legislation. **Reviews should be conducted at least once every 3 years**, unless specified otherwise by the BGMSC. Where medium to high residual risk exists, the assessment must be reviewed **annually** as per QMUL Policy. GM Project Supervisors must forward the QMUL Biological Safety Adviser, the new version of the assessment and keep a copy of the old version for **at least 10 years** after work has ceased ('work' includes storage of GM material). Significant amendments require consideration and approval by the BGMSC; GM Class 2 or 3 activities also require HSE approval. Cessation or move of a Project to another Institution requires notification to the QMUL Biological Safety Adviser and for GM Class 2 or 3, also to the HSE (via the QMUL Biological Safety Adviser).

34. 'Significant and unintended release' incidents involving GM agents, both within containment and/or to the environment, must be notified to the HSE using the **CU3** form (https://www.hse.gov.uk/forms/genetic/index.htm) via the QMUL Biological Safety Adviser. The QMUL Accident Report form http://www.hsd.qmul.ac.uk/accident-reporting/ must be completed and submitted to HSD.

18. GM Waste inactivation and disposal

The Genetically Modified Organisms (Contained Use) Regulations 2014, place emphasis on the inactivation and safe disposal of all GM contaminated waste by "validated means". All risk assessments will need to provide evidence of this.

Key validation steps:

1. Validation of disinfectant use: see section 3.5 of the Compendium of Guidance Part 3 http://www.hse.gov.uk/biosafety/gmo/acgm/acgmcomp/part3.pdf and the QMUL Procedures for working with Biological Agents http://www.hsd.qmul.ac.uk/a-z/biological/ - section B12 (Sterilisation and Disinfection) and section B13 (fumigation).
2. Validation of sterilisation equipment and methods: see details as above.
3. Validation of waste contractor: The QMUL Biological Safety Adviser / HSD will check to ensure that the contracted clinical waste contractor has the necessary capability, infrastructure and regulatory permissions to uplift, transport, inactivate and dispose of GMO waste.

QMUL GMM / GMO waste disposal procedure briefing notes are available on the HSD website: http://www.hsd.qmul.ac.uk/a-z/hazardous-waste/

19. Transfer of GMO/GMMs and GM material to and from designated laboratory areas

1. The QMUL Biological Safety Adviser should be consulted before any GM material (GMO / GMM) is removed from the specified laboratory areas other than when it is specifically mentioned in the GM risk assessment. Similarly, any GMO / GMMs brought in from external sources must be reported to the BSO, prior to it arriving. A suitable risk assessment must be submitted and consent from the GMSC must be obtained.
2. See section 17 point 19 above for EU Trans-boundary movements of GM Agents.
3. Guidance on the transport of GM and biological agents is available in the QMUL H&S document 'Procedures for working with Biohazards' http://http://www.hsd.qmul.ac.uk/a-z/biological/ and an online accredited training module is available – details at http://www.hsd.qmul.ac.uk/a-z/transport-of-dangerous-goods/

20. GM Laboratory or other GM facility - Design and Build or Refurbishment

1. **GMMs** - Consult Appendix 2 and the SACGM Compendium of Guidance Part 3 http://www.hse.gov.uk/biosafety/gmo/acgm/acgmcomp/part3.pdf and the QMUL Procedures for working with Biological Agents http:http://http/www.hsd.qmul.ac.uk/a-z/biological/ - in particular, sections B03 – B06 for key ACDP Containment Requirements, B07 for Specified Animal Pathogen Order (SAPO) Containment requirements, and section B09 for microbiological safety cabinets. QMUL Checklist inspection sheets for Containment laboratories are available at hhttp://www.hsd.qmul.ac.uk/a-z/audit-and-inspection/
2. The appropriate HSE / ACDP publications should be consulted and requirements adhered to during the design and build / refurbishment of Containment Laboratories for GMMs. These are listed in section 23 below.
3. **Clinical and animal / plant facilities** should identify and incorporate specific requirements noted in the SACGM Compendium of Guidance and other

relevant ACDP publications for GMO work. QMUL Checklist inspection sheets for GMO clinical and low risk plant containment facilities are available at http://www.hsd.qmul.ac.uk/a-z/audit-and-inspection/

4. Consult the Biological Safety Adviser for further assistance.

21. GM Facility Inspections

1. The BGMSC conducts inspections of new, altered and existing GMO facilities and working procedures, management and arrangements for GMO activities via specific inspections, faculty peer review inspections and QMUL audits. Reports are produced and where actions are necessary to improve standards, procedures and arrangements, these are identified to the responsible person for action and follow up. Inspection / Audit Reports are provided to the BGMSC and higher QMUL (Partner) management bodies and senior management.

2. QMUL Checklist inspection sheets for GMO / GMM Containment laboratories and other GM areas are available at http://www.hsd.qmul.ac.uk/a-z/audit-and-inspection/

22. United Kingdom GM Regulations

1. **Contained Use:**
   The Genetically Modified Organisms (Contained Use) Regulations 2014
   http://www.legislation.gov.uk/uksi/2014/1663/pdfs/uksi_20141663_en.pdf
2. **Deliberate Release:**
   The Genetically Modified Organisms (Deliberate Release) Regulations 2002
   http://www.legislation.hmso.gov.uk/si/si2002/20022443.htm
   The Genetically Modified Organisms (Risk Assessment) (Records and Exemptions) Regulations 1996
   http://www.legislation.hmso.gov.uk/si/si1996/Uksi_19961106_en_1.htm
   The Genetically Modified Organisms (Deliberate Release and Risk Assessment -Amendment) Regulations 1997
   http://www.legislation.hmso.gov.uk/si/si1997/97190001.htm
3. **Trans-boundary Movement:** Cartegena Protocol and European Regulations on EU-trans-boundary movements of high risk GM material:
   http://europa.eu/legislation_summaries/environment/nature_and_biodiversity/l28119_en.htm

   (See http://www.cbd.int/biosafety/ for further information on the Cartegena protocol and subsequent amendments e.g. the Nagoya-Kuala Lumpur protocoll).

23. GM and Biological Agents Resources and Guidance

1. SACGM Compendium of Guidance
   http://www.hse.gov.uk/biosafety/gmo/acgm/acgmcomp/

2. Significant changes to a GM Contained Use Notification (ISTR guidance document)

   http://www.istr.org.uk/docs/ISTR%20BSG%20Significant%20Change%20guidance%20v1.pdf

3. Additional HSE / SACGM GMO resources
   http://www.hse.gov.uk/biosafety/gmo/information.htm

4. HSE / ACDP biological agents resources
   http://www.hse.gov.uk/biosafety/information.htm

   Key documents

   The Management, Design and Operation of Microbiological Containment Laboratories, ACDP, HSE Books 2018. http://www.hse.gov.uk/biosafety/management-containment-labs.pdf

   Guidance on the use, testing and maintenance of laboratory and animal isolators for the containment of biological agents. HSE, 2006
   http://www.hse.gov.uk/biosafety/isolators.pdf

   Sealability of microbiological Containment Level 3 and 4 facilities, HSE.
   http://www.hse.gov.uk/biosafety/gmo/guidance/sealability.pdf

   Safe working and the prevention of infection in clinical laboratories and similar facilities, HSAC / HSE 2003
   http://www.hse.gov.uk/pubns/priced/clinical-laboratories.pdf

5. DEFRA / ACRE (Deliberate Release)
   https://www.gov.uk/government/policies/making-the-food-and-farming-industry-more-competitive-while-protecting-the-environment/supporting-pages/genetic-modification

   https://www.gov.uk/government/organisations/advisory-committee-on-releases-to-the-environment

6. Bio-security (National Counter Terrorism Security Office, Home Office)

   https://www.gov.uk/secure-hazardous-materials-to-help-prevent-terrorism#chemical-biological-and-radioactive-materials

7. BBSRC / MRC - Containment Facility Design

   Standards for Containment Level 3 facilities - New builds and refurbishments 2014.
   hhttps://mrc.ukri.org/documents/pdf/ssr/standards-for-containment-level-3-facilities/

24. GM and Biosafety QMUL Policy, Procedures / Guidance and Templates

QMUL GMO topic webpage – policy, guidance, procedures and information
http://www.hsd.qmul.ac.uk/a-z/genetically-modified-organisms/

QMUL Biological Safety – policy, guidance, procedures and information
http://www.hsd.qmul.ac.uk/a-z/biological/

QMUL Biological & Genetic Modification Safety Committee
http://www.hsd.qmul.ac.uk/a-z/health-and-safety-advisory-group/health-and-safety-adviosry-group/bgmsc/

Appendix 1: Genetic Modification – 'Listed Techniques'

(A)
Recombinant nucleic acid techniques involving **the formation of new combinations of genetic material** by the insertion of nucleic acid molecules, produced by **whatever means outside an organism**, into any virus, bacterial plasmid or other vector system and **their stable incorporation into a host organism** in which they do not naturally occur but in which they are **capable of continued propagation**.

Techniques involving the **direct introduction** into an organism of heritable genetic material prepared outside the organism, including micro-injection, macro-injection and micro-encapsulation;

Cell fusion or hybridization techniques where live cells with new combinations of heritable genetic material are formed through the fusion of two or more cells by means of ***methods that do not occur naturally.***

Examples:

1. Techniques that alter the genetic material in an organism by a method that does not occur naturally or by mating – e.g. synthetic generation of artificial chromosomes in yeast

2. Mutagenesis - where this is achieved by a series of mutations (e.g. a combination of three or four different mutations designed to introduce a new function) with synthetic DNA or by DNA editing techniques, then the Regulations do apply.

3. Transfection / transduction / transformation of foreign or synthetic genetic material into an organism:
    a. Recombinant bacteriophage transduction to make gene libraries,
    b. Particle bombardment of plant tissues,
    c. Directly injecting naked DNA into an animal *only* where the introduced genetic material is intended to be incorporated into the organism's genetic material in a stable way
    d. RNAi techniques where stable incorporation is achieved

4. 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

5. Stable introduction of synthetically generated DNA or RNA (e.g. 'biobricks') into an organism

6. Genetic modification of larger GMOs (animals, plants) 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 (i.e. mosaics).

(B)
The following techniques are **not** considered to result in genetic modification ***provided*** that they do not involve the use of recombinant nucleic acid molecules or of genetically modified organisms made by techniques other than those listed above

(a) in vitro fertilisation;
(b) natural processes including conjugation, transduction or transformation;
(c) polyploidy induction.

The GM Regulations do not apply to the following techniques of genetic modification, ***provided*** that they do not involve the use of recombinant nucleic acid molecules or of genetically modified organisms other than those made by one or more of the following techniques—

(a) mutagenesis (but see above)
(b) cell fusion (including protoplast fusion) of prokaryotic species which can exchange genetic material through homologous recombination;
(c) cell fusion (including protoplast fusion) of cells of any eukaryotic species, including production of hybridomas and plant cell fusions;
(d) self-cloning, where the resulting organism is unlikely to cause disease or harm to humans, animals or plants.

Note –

a) The GM Contained Use Regulations to do not apply to DNA synthesis itself.

b) Once licensed by the appropriate Regulatory Authority, a medicinal product for human or veterinary use, food product or feed does not fall under the GM Contained Use Regulations.

Appendix 2 – GMMs in Contained Use Laboratories - Containment Level Measures

Part 2 Containment measures

Table 1a Containment measures applicable to contained use involving micro-organisms in laboratories

Containment Measures		*Containment Levels*			
		1	*2*	*3*	*4*
Facilities					
1	Laboratory suite: isolation[1]	not required	not required	required	required
2	Laboratory: sealable for fumigation	not required	not required	required	required
Equipment					
3	Surfaces impervious to water, resistant to acids, alkalis, solvents, disinfectants and decontamination agents and easy to clean	required for any bench	required for any bench	required for any bench and floor	required for any bench, floor ceiling and walls
4	Entry to laboratory via airlock[2]	not required	not required	required where and to extent the risk assessment shows it is required	required
5	Negative pressure relative to the pressure of the immediate surroundings	not required	not required	required except for activities where transmission does not occur by the airborne route	required
6	Extract and input air from the laboratory must be HEPA filtered	not required	not required	HEPA filters required for extract air except for activities where transmission does not occur by the airborne route	HEPA filters required for input and extract air[3]
7	Microbiological safety cabinet/ enclosure	not required	required where and to extent the risk assessment shows it is required	required, and all procedures with infective materials required to be contained within a cabinet/ enclosure	required, and all procedures with infective materials required to be contained within a cabinet/ enclosure

8	Autoclave	required on site	required in the building	required in the laboratory suite[4]	double ended autoclave required in laboratory

System of work					
9	Access restricted to authorised personnel only	not required	required	required	required (via airlock key procedure)
10	Biohazard sign on door	not required	required	required	required
11	Specific measures to control aerosol dissemination	not required	required so as to minimise	required so as to prevent	required so as to prevent
12	Shower	not required	not required	required where and to extent the risk assessment shows it is required	required
13	Protective clothing	suitable protective clothing required	suitable protective clothing required	suitable protective clothing required; footwear required where and to extent the risk assessment shows it is required	complete change of clothing and footwear required before entry and exit
14	Gloves	not required	required where and to extent the risk assessment shows they are required	required	required
15	Efficient control of disease vectors (eg rodents and insects) which could disseminate GMMs	required where and to extent the risk assessment shows it is required	required	required	required
Waste					
16	Inactivation of GMMs in effluent from hand-washing sinks and showers and similar effluents	not required	not required	required where and to extent the risk assessment shows it is required	required
17	Inactivation of GMMs in contaminated material and waste	required by validated means where and to extent the risk assessment shows it is required	required by validated means	required by validated means, with waste inactivated within the laboratory suite	required by validated means, with waste inactivated within the laboratory

Other measures					
18	Laboratory to contain its own equipment	not required	not required	required, so far as is reasonably practicable	required
19	An observation window or alternative is to be present so that occupants can be seen	required where and to extent the risk assessment shows it is required	required where and to extent the risk assessment shows it is required	required where and to extent the risk assessment shows it is required	required
20	Safe storage of GMMs	required where and to extent the risk assessment shows it is required	required	required	secure storage required
21	Written records of staff training	not required	required where and to extent the risk assessment shows it is required	required	required

1 "isolation" means, in relation to a laboratory, separation of the laboratory from other areas in the same building, or being in a separate building.

2 Entry must be through an airlock which is a chamber isolated from the laboratory. The clean side of the airlock must be separated from the restricted side by changing or showering facilities and preferably by interlocking doors.

3 Where viruses are not retained by the HEPA filters, extra requirements will be necessary for extract air.

4 Where the autoclave is outside the laboratory in which the contained use is being undertaken, but within the laboratory suite, there must be validated procedures for the safe transfer of material into that autoclave, which provide a level of protection equivalent to that which would be achieved by having an autoclave in that laboratory.

Appendix 3- Administrative Details for completing the CU2 Notification Form

QMUL (Centre GM 774) notified premises

Queen Mary University of London
327 Mile End Road, London E1 4NS

Tel 0207 882 5555 fax 0207 882 5556
Email hs-helpdesk@qmul.ac.uk

Date of notification 03/05/2001

Other addresses of QMUL premises where activities are conducted

Barts and The London School of Medicine & Dentistry
Charterhouse Square, London EC1M 6BQ. (notified 03/05/2001)

(this covers the Charterhouse Square campus)

Barts and The London School of Medicine & Dentistry
4 Newark St, London E1 2AT (notified 03/05/2001)

(this covers the Whitechapel campus and includes all projects previously notified under GM Centre 174)

Barts Health NHS Trust Premises

Barts Health NHS Trust
Barts Close, London EC1A 7BE (notified 12/07/2001)

The London Chest Hospital, **Bonner Road, Bethnal Green, London E2 9JX** (notified 26/05/2002)

The Royal London Hospital, Whitechapel
London E1 1BB (notified 2016)

Appendix 4 - Genetically Modified Organisms (GMO) Contained Use - Notification Fee Payments to the Health and Safety Executive

GM Class 2 and 3 Contained Use projects to be conducted at QMUL require a Notification (HSE CU2 form https://www.hse.gov.uk/forms/genetic/) to be completed by the GM Project Supervisor (the Scientific Investigator), with the **payment of a one off fee** from their research grant or Institute / School budget (currently in the region of £900 – 1100) to the Regulatory Authority (Health and Safety Executive, HSE). Significant amendments to existing notifications also attract a fee of approx. £700 – 800.

HSE current list of fees for GM Notifications:
http://www.hse.gov.uk/biosafety/gmo/acgm/acgmwarn.htm

The HSE does now issue invoices for GM project notifications and amendments. This should made at the time of submitting the notification, http://www.hse.gov.uk/biosafety/gmo/notifications/fees.htm for further details.

The HSE will only review the notification once payment is received.

Procedure for GM Notification payments

All completed notifications and significant amendments are approved by the QMUL BGMSC, then coordinated and sent to the HSE by the QMUL Biological Safety Adviser with a request for an invoice **or** with remittance details (see below).

Email / send details to Dr Mark Ariyanayagam, Health and Safety Directorate; m.r.ariyanayagam@qmul.ac.uk).

HSE Payment details

BACS or Agresso

Bank: NatWest Bank, London Corporate Service Centre, CPB Services, 2nd Floor, 280 Bishopsgate, London, EC2M 4RB. Account Name: HSE Main Account, Account Number: 10005889, Sort code: 60-70-80 (when a payment is by BACS, a remittance advice usually accompanies the notification. Payment should be made payable to the Health and Safety Executive).

Cheque

A cheque for the correct amount, made payable to the 'Health and Safety Executive' and sent to The Notifications Officer, Health and Safety Executive, Hazardous Installations Directorate, Biological Agents Unit, 5S2 Redgrave Court, Merton Road, Bootle, Merseyside, L20 7HS

Request an invoice

Invoices can be requested and should be made at the time of submitting the notification.

Procedure

1. GM risk assessment and notification (or amendment) approved by QMUL BGMSC (signed off by Biological Safety Adviser on behalf of the BGMSC).
2. An invoice request to the HSE sent by the Biological Safety Adviser, along with the above documents by email.
3. HSE supply invoice, and payment raised by the GM Project Supervisor with QMUL Accounts Payable as above (BACS / Agresso or Cheque).
4. GM Project Supervisor notifies the Biological Safety Adviser of the BACS or Agresso payment reference and date (or cheque sent date and cheque number).
5. Biological Safety Adviser informs the HSE by email of payment details. HSE will only start review of the documents once the payment is received.

Document Control

Version 3

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Position:	QMUL Biological Safety Adviser and H&S Manager (SMD)
Checked by:	Mrs Marion Richards
Position:	Director of Occupational Health and Safety, QMUL
Checked by:	Dr Martin Carrier / Dr Matthias Dittmar
Position:	Chair / Deputy Chair, QMUL GMSC
Approved by:	QMUL GMSC
Date:	27 January 2015
Status:	ISSUED
Date of Issue:	29 January 2015

Version No.	Date of alteration and re-issue	Details of changes	Changes made by
1	First issued 1/1/2005	-	Dr Martin Carrier
2.1 / 2.2 / 2.3	2008 - 2011	Regulatory and management / arrangements – new and updates (Ref QM/H&S/053,054,093)	Dr Mark Ariyanayagam (QMUL Biological Safety Adviser and GM BSO). Approved by QMUL GMSC and H&S Committee / HSAG.
3	January 2015	QM/H&S/053 (GM Policy), QM/H&S/054 (GM Procedure and QM/H&S/093 (GM Notification Procedure) consolidated, substantial revision to incorporate GM CU 2014 Regulations, DR and QMUL Management arrangements. New reference QM_SE_019.	Dr Mark Ariyanayagam (QMUL Biological Safety Adviser and GM BSO).
4 (New ID: QMUL_HS_192)	26 Nov 2018 Date of next scheduled review: Feb 2022	Risk Assessment review and updates – to section 17.33. Partner organisation peer review and written agreements noted throughout with applicable responsibilities. Web links and terminology updated throughout, Appendices updated, references updated.	Dr Mark Ariyanayagam (QMUL Biological Safety Adviser and H&S Manager). Checked and approved by Rebecca Jones (Acting Head of Health & Safety). To be reviewed by BGMSC Feb 2019.