Biological Agents: Health and Safety Policy and Arrangements for QMUL
(Ref: QMUL_HS_118)
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Biological agents: Health & Safety Policy and Arrangements for QMUL

1. Executive Summary

This Health and Safety Policy establishes the framework for the effective risk assessment, health & safety risk controls and measures to be adopted and implemented for work with biological agents by Queen Mary University of London (QMUL) staff, students; and others or the environment who/which may be affected by QMUL activities. The objective of the Policy is to control and reduce and where significant, eliminate the risks, and to ensure compliance with the legislation governing work with biological agents.

The Policy defines the management of biological agents and safe working arrangements in the context of QMUL’s activities; identifies the roles and responsibilities for Heads / Managers / Supervisors of Schools / Institutes / Directorates conducting the work and for QMUL staff, students and others or the environment who/which may be affected by the work, and notes the key legal and compliance requirements specified in the relevant health and safety legislation and supporting guidance. Specific notification requirements to the regulators are identified along with enabling QMUL procedures.

This version of the Policy has been issued following QMUL wide consultation and approval by the QMUL Health & Safety Advisory Group in June 2017 (updated Nov 2018).

2. Policy Objective and Statement

2.1 The Policy Objective of Queen Mary University of London (QMUL) is to ensure, so far as is reasonably practicable, the health, safety and welfare of employees, students and others involved by effectively controlling and reducing or where significant, eliminating the risks arising from working with biological agents. The Policy also seeks to ensure that the risks to the environment from work with biological agents are controlled and reduced or where significant, eliminated.

2.2 It is the QMUL Statement of Policy that risk assessment/s for work with biological agents are conducted before commencing the work and are continuously reviewed and updated in line with work and technology changes, upon incidents and other significant variables. The appropriate biological control measures identified shall be implemented and maintained throughout the duration of the work, until removal of the risk.

3. Legislation

3.1 Enacted under the Health and Safety at Work etc Act 1974, The Control of Substances Hazardous to Health (COSHH) Regulations 2002 (as amended) requires the use of biological agents in the workplace to be controlled. The control depends on the level of hazard that biological agent poses. Biological agents are divided into 4 Hazard Groups (HG) according to the classification assigned by the Advisory Committee on Dangerous Pathogens (ACDP).

COSHH also requires control of exposure to allergenic biological materials that may cause respiratory or skin sensitisation. COSHH also requires control of exposure to
materials (cell cultures, tissue, blood and other human or animal products) that may contain biological agents.

3.3 Microorganisms or material containing microorganisms which represent a risk to the environment are also covered by this Policy:

*Animal Pathogens*: noted animal pathogens under the Specified Animal Pathogens Order (SAPO) 2008 (as amended) and the Importation of Animal Pathogens Order 1980 (as amended). This legislation aims to prevent the introduction and spread of specified animal pathogens which are not endemic to Great Britain.

*Animal Products or By-products*: There are also regulations covering the importation of animal products or by products into the United Kingdom and subsequent use, including animal tissue or cell cultures, bodily fluids, feathers, hides, manure etc. Importation of any such material is likely to require an Animal Health Importation Licence and use of them under a premises permit under the Animal By-Products (Enforcement) (England) Regulations 2011.

*Plant, fish and bee pathogens*: This Policy includes work involving plant, bee and fish pathogens which are covered by the Plant Health Order 2005, the Bees Act 1980, and Diseases of Fish (Control) Regulations 1994, respectively, and overall by the Environment Act 1995.

3.4 Certain work with biological agents is covered by Schedule 5 ‘Pathogens and Toxins’ of the Anti-Terrorism, Crime and Security Act 2001. This Act requires that adequate security of dangerous substances that may be targeted by unauthorised persons is put in place.

4. **Application and Scope of the Policy**

This Policy applies to all QMUL staff, postgraduate and undergraduate students and others (e.g. academic or teaching visitors and contractors) who are to conduct activities at QMUL with biological agents, and to all others who may be affected by QMUL activities involving such agents.

This Policy document does not deal with the following activities, which are addressed in separate QMUL Health & Safety Policy or Guidance documents:

- Genetic Modified Organisms (GMOs)
- Control of Legionella bacteria in water sources
- Work with live animals or insects which are *not* infected with biological agents
- Final disposal of wastes arising from work with biological agents

QMUL is not licensed and does not contain the facilities or resources to receive, send, handle, store or use any biological agent that is classified as ACDP Hazard Group 4 or SAPO Group 4. The inadvertent receipt and handling of any biological sample suspected of containing ACDP Hazard Group 4 or SAPO Group 4 agents must be notified to the Head of School or Institute and the QMUL Biological Safety Adviser immediately so that appropriate ‘holding’ safety measures can be applied.

5. **Definitions**

5.1 **Biological agent:**
In the context of this Policy document, ‘biological agent’ means any micro-organism (bacterium, fungus, protozoan, virus), cell culture, or endoparasite, including any which have been genetically modified, that may cause any infection, allergic reaction, toxicity or otherwise create a risk to human health or to the environment.

The term also apply to the use of human or animal tissues and products - such as blood, other body fluids or animal parts (which by themselves fall outside the definition of “biological agent”), because of the possibility of their contamination by biological agents which may present a risk to human health or to the environment.

5.2 Biological Containment:

Biological Containment is the set of measures taken to manage biological agents in the laboratory environment so as to prevent, or control, the exposure of laboratory workers, other people and the outside environment to the agent(s) in question.

Biological Containment can be achieved by measures designed to protect the worker and immediate environment (termed primary containment) and those designed to protect other people and the environment external to the laboratory (secondary containment).

Certain minimum containment measures are required for laboratories handling particular hazard groups of biological agents (see below) and are designated Containment Levels 1 through to 4 (see Appendix 1).

5.3 Hazard Group Classification:

Biological agents are classified into four Hazard Groups (HG) according to their ability to cause human infection, the severity of the disease that may result, the risk that infection may spread into the community, and the availability of vaccines and effective treatment. For the purposes of these definitions, “disease” refers to disease caused by infection. Any biological agent that appears in a classification list issued by the Health & Safety Executive (referred to as an “approved classification”) falls into the HG specified there.

The correct group for an unlisted agent must be determined by consideration of the infection criteria listed below, and taking into account the relevant factors used in making the risk assessment required by COSHH.

Hazard Group 1

A biological agent unlikely to cause human disease.

Hazard Group 2

A biological agent that can cause human disease and may be a hazard to employees; it is unlikely to spread to the community and there is usually effective prophylaxis or effective treatment available.

Hazard Group 3

A biological agent that can cause severe human disease and presents a serious hazard to employees: it may present a risk of spreading to the community, but there is usually effective prophylaxis or treatment available.
Hazard Group 4

A biological agent that causes severe human disease and is a serious hazard to employees; it is likely to spread to the community and there is usually no effective prophylaxis or treatment available.

The above categorisation scheme is based on the risks to the health of a "normal" healthy population. It does not take into account the fact that certain individuals may be more at risk, for example, due to a pre-existing medical condition (disease, compromised immunity, the effects of medication, pregnancy, etc).

A biological agent without a classification must not be assumed to be Hazard Group 1. A provisional HG classification must be established by a risk assessment (see below for assessment criteria).

Biological samples, such as human blood or body fluids, animal tissues or products that may contain human disease causing agents also constitute biological hazards and should be handled as such. The provisional HG classification or risk level to which samples should be assigned should be determined by a risk assessment (see below for assessment criteria).

Biological samples may contain biological agents with the ability to detrimentally impact the environment (animals, other wildlife or plant species). The risk level of these samples should be determined by a suitable risk assessment.

6. Risk Assessment

6.1 Heads of Schools, Institutes or Directorates must establish procedures for assessing the hazards and risks associated with biological agents handled. Assessments must take into account the requirements set out in the relevant sections of the Control of Substances Hazardous to Health (COSHH) Regulations 2002 (as amended), the ACDP Approved List of biological agents (2013) and further guidance documents listed in the reference section.

The QMUL Bio-COSHH or equivalent risk assessment templates should be utilised to ensure assessment details are not missed.

Use the QMUL Bio-COSHH templates or equivalent – available at http://www.hsd.qmul.ac.uk/risk-assessment/ or http://www.hsd.qmul.ac.uk/a-z/biological/

6.2 The COSHH Regulations require that:

Exposure to a biological agent must be prevented if this is reasonably practicable;

If it is not reasonably practicable to prevent exposure to biological agents, the biological agent used should be the least harmful that the nature of the activity will permit (for example in teaching and some types of research).

6.3 The risk assessment should be periodically reviewed and updated as necessary over the active life of the project as per QMUL Policy. 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. Significant amendments require consideration and approval by
the BGMSC; and may require HSE approval. Cessation or move of a Project to another Institution requires notification to the QMUL Biological Safety Adviser and if specified, to the HSE (via the QMUL Biological Safety Adviser).

7. **Biological Containment**

The level of biological containment to be applied must be determined by carrying out a risk assessment as required by COSHH. This assessment should include consideration of:

a. the biological agents that may be present;

b. what hazard groups they belong to;

c. what form they are in (including the possibility that they may form spores or cysts that are resistant to disinfection, or go through a developmental cycle in which there are non-infectious forms or dependence on an intermediate host);

d. the diseases they may cause;

e. how and where they are present and how they are transmitted (i.e. routes of exposure);

f. the likelihood of exposure and consequent disease (including the identification of workers who may be particularly susceptible, for example because they are immuno-compromised), drawing on evidence of the prevalence of infection or other ill effect as experienced within a particular type of work or workplace;

g. whether the nature of the activity will permit substitution by a less hazardous agent;

h. the control measures to be applied, and minimisation of the number of people exposed;

i. the need for health and/or environmental monitoring procedures;

j. the need for health surveillance procedures.

Following hazard and risk identification, the minimum biological Containment Level measures required to protect the user and others should be identified from Appendix 1.

Typically, a HG 2 biological agent would require Containment Level 2, a HG 3 biological agent would require Containment Level 3.

Further guidance on derogation of certain measures, circumstances when these would apply, classification of new or unknown biological agents, re-classifying an agent, along with detailed guidance on each Containment Level set of measures is available at [http://www.hsd.qmul.ac.uk/a-z/biological/](http://www.hsd.qmul.ac.uk/a-z/biological/)
8. Roles and Responsibilities

8.1 QMUL Head of School or Directorate / Director of Institute

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

1. Staff with supervisory and allocated health & safety responsibilities are appointed, trained and are competent for the work involving biological agents (e.g. responsible academic or teaching staff member, local biosafety officer, lab manager with biosafety responsibilities).

2. A framework for the School / Directorate / Institute is in place for the drafting, dissemination, implementation and review of risk assessment/s and local procedures (‘safe systems of work’) for handling biological agents and for the facilities / infrastructure, in line with QMUL policy, arrangements and guidance.

3. Notification of intended work with biological agents is made in advance to the QMUL Biological & Genetic Modification Safety Committee via the Biological Safety Adviser (see section 9 below and Appendix 1).

4. Appropriate resources are provided for Containment Laboratories, related infrastructure, equipment and consumables for the work in order to minimise risks to staff, students and others / environment to a negligible level. QMUL planning systems already in place should be utilised – e.g. the QMUL Planning and Accountability Review process.

5. A framework for the training of all users of biological agents is in place and that training is recorded (including training needs assessment, initial and refresher training). QMUL systems for training already in place should be utilised – QMUL staff probation or the PhD student training system / staff appraisal for training needs assessments; training record templates issued by the Health & Safety Directorate; training courses provided by the Health & Safety Directorate.

6. All accidents and incidents involving biological agents are reported as per the QMUL Accident & Incident Policy, and local emergency response procedures are established.

7. Cooperation established with QMUL Estates & Facilities to conduct necessary planned preventative maintenance schemes for Containment Laboratories and equipment.

8. Where Containment Laboratories are installed by an Academic School or Institute (outside the management of an Estates & Facilities (EAF) Capital Project), the School / Institute complies with all of the responsibilities listed for Estates & Facilities - Capital Projects. If maintained by an Academic School or Institute, the School / Institute complies with all of the responsibilities listed for Estates & Facilities - Infrastructure Maintenance below.
9. Where a QMUL School / Institute occupies ‘embedded space’ within another organisation’s premises, to ensure that risks arising from biological agent use and storage are communicated to partner organisations in a suitable format, and actions are completed to minimise the identified risks.

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

In the following (sections 9 to 20), where the Head of School, Institute or Directorate responsibilities are noted, typically the tasks would be delegated to an experienced and competent person (e.g. the responsible Research Investigator, the responsible lab manager or the local biosafety officer).

8.2 QMUL Managers / Supervisors

It is the responsibility* of a Manager / Supervisor** to ensure that:

1. Appropriate risk assessment/s for work with biological agents are made and recorded, and kept up to date by periodic review.
   
   Use the QMUL Bio-COSHH templates or equivalent – available at [http://hsd.qmul.ac.uk/Risk%20Assessment/index.html](http://hsd.qmul.ac.uk/Risk%20Assessment/index.html) or [http://hsd.qmul.ac.uk/Lab%20Safety/Biological/index.html](http://hsd.qmul.ac.uk/Lab%20Safety/Biological/index.html)

   Notification of intended work with biological agents is made in advance to the QMUL Biological & Genetic Modification Safety Committee via the Biological Safety Adviser (see section 9 below and Appendices 1 & 2).

2. The risk assessment should be periodically reviewed and updated as necessary over the active life of the work as per QMUL Policy. **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.

3. For notifiable work - the Manager / Supervisor should 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 biological agent material). Significant amendments may require consideration and approval by the BGMSC; and may require HSE approval. Cessation or move of notified work to another Institution requires notification to the QMUL Biological Safety Adviser and if specified, to the HSE (via the QMUL Biological Safety Adviser).

4. Following training needs assessment, all users of biological agents receive appropriate training (initial and refresher).
   
   QMUL Health & Safety Directorate provided Biosafety training is detailed at [http://www.hsd.qmul.ac.uk/training/](http://www.hsd.qmul.ac.uk/training/) or [http://www.hsd.qmul.ac.uk/a-z/biological/](http://www.hsd.qmul.ac.uk/a-z/biological/)

5. Health monitoring and surveillance measures for users of biological agents identified in the risk assessment and/or per HSE or healthcare professional guidance are implemented with QMUL Occupational Health assistance [http://hr.qmul.ac.uk/about-us/](http://hr.qmul.ac.uk/about-us/).

6. Working practices throughout the duration comply with applicable health & safety legislation requirements (e.g. COSHH), QMUL and local written laboratory / facility rules, and where applicable, manufacturer’s operating instructions.
7. All biological containment measures identified in the risk assessment/s and protocols are correctly set up, maintained and tested (where stipulated, via planned preventative maintenance) and that these control measures are locally checked and inspected periodically for effectiveness. These include equipment such as microbiological safety cabinets, an air intake / exhaust ventilation system provided for negative atmosphere and High Efficiency Particulate Absorption (HEPA) filters.

QMUL Biosafety inspection templates are available at http://www.hsd.qmul.ac.uk/a-z/audit-and-inspection/

8. Where statutory planned preventative management tests are required for Containment Laboratories (e.g. microbiological safety cabinets, HEPA filters), to ensure they are conducted within specified timescales, and records are available for QMUL and Regulatory Authority audits and inspections.

9. All accidents and incidents involving biological agents are reported as per the QMUL Accident & Incident Policy.

10. Local emergency and assistance procedures (e.g. appropriate first aid personnel and procedures, spill procedures, rescue procedures) are in place and that these are tested by a simulated exercise periodically for effectiveness.

11. Ensure that all users are fully aware of applicable hazard warning systems (e.g. alarm sounded by a failure of microbiological safety cabinet) and know how to respond safely in an emergency.

12. Maintain operating instructions and other documentation relating to equipment which provides biological containment where it can be readily accessed (electronically or hardcopy).

13. Where a defect / failure is identified with biological containment equipment, to identify remedial or corrective actions and implement without delay. Where remedial action for a safety measure is not in their control, to report defects / failure to the appropriate QMUL department or in the case of embedded space, to the host organisation responsible person as soon as possible for action.

14. Do not use condemned or failed biological containment equipment or systems until full repair and safety checks have been satisfactorily made and that no unsolicited modifications are carried out to biological containment equipment or systems that are likely to render them unsafe.

15. Have a Permit to Work system in place to ensure service engineer / maintenance operative safety during testing / servicing of applicable biological containment equipment and to ensure return of the system to a safe condition.

See details of QMUL permit to work systems here

*Responsibility cannot be delegated, although tasks associated with the responsibility can be delegated to a competent person (e.g. a lab manager).
**IMPORTANT NOTE:** if an individual instructs or issues tasks to another individual or group of individuals, then whether a designated line manager/ supervisor or not, they become responsible for the health and safety of those they have instructed.

### 8.3 Users of biological agents at QMUL

It is the responsibility of users of biological agents 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 local safety rules & instructions, understanding the risk assessment findings, attending mandatory and other appropriate training for the work, in line with QMUL Policy and arrangements.

   QMUL Health & Safety Directorate provided Biosafety training is identified at [http://www.hsd.qmul.ac.uk/a-z/biological/](http://www.hsd.qmul.ac.uk/a-z/biological/)

2. To use all safety and protective equipment (equipment and/or personal protective) appropriately in line with manufacturer’s information and local risk assessment / instructions.

3. Know and understand the limitations for health and safety when working with biological agents, and know and understand safety critical features of equipment, personal protection and hazard warning alarms and emergency procedures.

4. Report all accidents and incidents involving biological agents as per the QMUL Accident & Incident Policy.

5. Report any defects with equipment or deficiencies in work practices to their Manager / Supervisor as soon as possible for remedial action.

6. Do not use failed or condemned equipment until they are repaired and fully fit for use.

7. Do not ignore or misuse anything provided for user health and safety during the work (e.g. not to mute hazard warning alarms of a safety cabinet and then continue to handle biological agents within it).

### 8.4 QMUL Estates & Facilities – Capital Projects and Infrastructure Maintenance

**A.** It is the responsibility* of the Assistant Director of Estates & Facilities for Capital Projects to ensure that they

1. Select and employ competent contractors for the Capital Project in line with applicable QMUL policies for contractors.

2. Ensure that a Biological Containment Laboratory or Facility built or re-fitted as part of a Capital Project is installed in accordance with relevant health and safety regulations and appropriate industry/sector standards.

   A summary of key HSE / QMUL / Sector standards and guidance documents are listed in References below (section 22). Further Guidance is available at [http://www.hsd.qmul.ac.uk/a-z/biological/](http://www.hsd.qmul.ac.uk/a-z/biological/)

3. Ensure that suitable commissioning of the Biological Containment Laboratory or Facility is carried out and that the relevant handover documentation is provided to the facility manager or responsible person.

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4. Ensure that the handover documentation is forwarded to Estates Infrastructure Maintenance, and that details of any newly installed biological containment systems (if applicable, e.g. autoclaves, HEPA filters, safety cabinets) are entered on the QMUL insurance register.

5. Ensure that where applicable, that any waste treatment, waste holding station or effluent system commissioning is carried out and that the relevant handover documentation is provided to those noted in points 3 and 4 above.

6. Ensure that users receive appropriate training in the operation of relevant parts of the Containment Laboratory or Facility.

*Responsibility cannot be delegated, although tasks associated with the responsibility can be delegated to a competent person (e.g. Project Manager).

B. It is the responsibility* of the Assistant Director of Estates & Facilities for Infrastructure Maintenance to ensure that they

1. Select and employ competent contractors for maintenance work in line with applicable QMUL policies for contractors.

2. Ensure that the Containment Laboratory under their remit is maintained in accordance with all relevant health and safety regulations and appropriate industry / sector standards.

   A summary of key standards and guidance documents are listed in References below (section 22).

3. Have planned preventative management plans in place for Containment Laboratories within their remit for local inspections and checks, statutory testing and where required, servicing and repairs. That they are conducted within specified timescales, and records are available for QMUL and Regulatory Authority audits and inspections.

4. Have a Permit to Work system in place to ensure service engineer / examiner safety during testing / servicing and to ensure return of the system in a safe condition. Details of QMUL permit to work systems are here.

5. Maintain operating instructions and other documentation relating to Containment Laboratories within their remit where it can be readily accessed (electronically or hardcopy).

   *Responsibility cannot be delegated, although tasks associated with the responsibility can be delegated to a competent person (e.g. Campus Maintenance Manager).

8.5 QMUL Biological Safety Adviser

It is the responsibility of the Biological Safety Adviser to

1. Provide QMUL with Policy and Guidance, tools and templates for the risk assessment, safe handling, use, inactivation, decontamination, safe disposal and transport of biological agents.

2. Provide competent biosafety advice to Heads of Schools or Directorates / Director of Institutes and their nominated duty holders, on legislative requirements and best practice.
3. Establish and co-ordinate registration procedures including the maintenance of a project data base to ensure that existing work, and proposals for new work with biological agents (and genetically modified organisms) is notified to, and reviewed by the QMUL Biological & Genetic Modification Safety Committee, and that any specific regulatory notifications, permits and licences are obtained.

4. Be the point of contact for the national regulators for all biological safety and bio-security matters, and report findings as required by legislation, codes of practice or policy, to the enforcing authorities (in particular the Health and Safety Executive).

5. Be the Secretary of the QMUL Biological & Genetic Modification Safety Committee and ensure meetings, business and operations are conducted effectively.

6. Inspect and monitor QMUL systems and procedures for biosafety in line with the topic and H&S Audit and Inspection Policy, and provide recommendations to improve biosafety.

7. Facilitate and/or provide training for the safe use of biological agents by QMUL staff and students.

8. Liaise with the QMUL Estates & Facilities, and other duty holders with regard to provide competent advice on health and safety legislation and standards for Containment Laboratory and biological facility planning, design, installation, commissioning, maintenance and decommissioning.

9. Liaise with the QMUL Occupational Health Service with regards to occupational health surveillance and monitoring for biological agents where necessary.

10. Keep their own competency, training, knowledge and experience up to date on biosafety.

8.6 QMUL Occupational Health Service

It is the responsibility of the Occupational Health Service to

1. Establish and maintain systematic health surveillance and monitoring activities which involves obtaining information about staff and student’s’ health and which helps protect them at an early stage from use of hazardous biological agents during work or study (see section 12 for expanded details).

2. Collection of data for detecting or evaluating health hazards involving work with biological agents.

3. In conjunction with the Biological Safety Adviser, evaluating biosafety control measures and highlighting defective or insufficient measures for remedial action.

9.0 Notification and authorisation of work with biological agents at QMUL

9.1 Heads of Schools, Institutes or Directorates must ensure that:
a. The QMUL Biological Safety Adviser is informed of plans to work with biological agents in HG 2*** and above. This is achieved by the submission of a Project Summary and Bio-COSHH risk assessment, following the process summarised in Appendix 1 (and detailed in Appendix 2). Peer Review of the Project and Bio-COSHH risk assessment is conducted by the QMUL Biological & Genetic Modification Safety Committee.

***Where manipulation, concentration, amplification or propagation occurs for research and/or teaching purposes:
- ACDP Hazard Group (HG) 2 or 3 wild type Biological Agents listed in [http://www.hse.gov.uk/pubns/misc208.pdf](http://www.hse.gov.uk/pubns/misc208.pdf)
- Biological Agents without an Approved List classification, but fulfilling the classification for HG 2 or 3
- Specified Animal Pathogens Order (SAPO) Group 2 or 3
- Biological Agents or materials needing DEFRA and/or other permit/s for work due to biological / environmental risk and/or import criteria
- Biological materials known or strongly suspected of containing HG 2 or 3.

b. Notification details for the regulatory authorities are communicated to the QMUL Biological Safety Adviser, who will check and forward them to the regulator.

The Health & Safety Executive (HSE) is notified the first time that agents in HG2 and HG3 are used on QMUL premises (CU1 notification). Notification is also required of the subsequent use of certain biological agents in HG2 and HG3.

Agents included in the Specified Animal Pathogens Order 1998 (SAPO), Schedule 5 Pathogens and Toxins List, and other biological agent legislation are notified in advance to the applicable regulator.

c. Changes in existing procedures that result, or are likely to result, in increased risk from biological agents, are notified to the QMUL Biological Safety Adviser. This may entail re-submission of Project Summary and Bio-COSHH risk assessment.

d. Work with ACDP Hazard Group 2 and 3 / SAPO Group 2 and 3 and other high risk agents does not start until written permission to start has been received from the QMUL Biological & Genetic Modification Safety Committee.

9.2 The appropriate Hazard Group and Level of Containment will be confirmed to the Project Proposer and Head of School, Institute or Directorate, together with relevant advice on biological containment and safe working procedures.

10. Information, Training and Supervision

Heads of Schools, Directorates or Institutes are responsible for establishing and enforcing local rules that:

a. Include:
- Biological agents in use in the area
- Lab rules, such as applicable prohibitions and mandatory PPE requirements
- Disinfectant policy (types of disinfectant in use vs efficacy on organisms), concentration and shelf life
- Waste arrangements for disposal of biologically contaminated solid and liquid waste
- Emergency procedures such as spillage or first aid

Generic Templates for Biological Containment Laboratories are available at http://www.hsd.qmul.ac.uk/a-z/audit-and-inspection/

b. Ensure staff and postgraduate students of a School, Directorate or Institute are properly trained in safe working practices and that this training is documented.

QMUL Health & Safety Directorate provided Biosafety training is detailed at http://www.hsd.qmul.ac.uk/a-z/biological/

c. Ensure training in safe working practices is an integral part of undergraduate courses where potentially hazardous biological materials are handled. Experienced undergraduates may handle HG 2 agents provided they are deemed competent, are adequately trained and supervised.

d. Ensure good microbiological practice is adopted incorporating aseptic techniques together with a high standard of hygiene.

e. Ensure effective and adequate supervision is provided by the Supervisor / Manager or an experienced and competent person.

f. Mouth pipetting is prohibited.

g. Smoking, chewing, application of cosmetics, eating and drinking, wearing of headphones are prohibited in Containment Level 2 and 3 laboratories.

11. **Personal Protective Equipment (PPE)**

Heads of Schools, Directorates or Institutes must establish and enforce procedures, which ensure that:

a. Appropriate protective clothing and equipment is worn in laboratories where biological agents are handled. Only high-necked side or back fastening laboratory coats (Howie-style) or gowns with elastic cuffs are to be worn in Containment Level 2 and 3 laboratories.

b. Wearing laboratory coats or gowns outside of laboratories is prohibited, as far as reasonably practicable, and absolutely prohibited in areas where food and drink is consumed.

c. Wearing of other laboratory protective clothing (including gloves) is minimised in general access areas. Schools / Institutes may identify the need to prohibit the use of gloves in non-laboratory communal areas to prevent spread of any biological contamination.

d. Laboratory coats or gowns are removed before staff and students of biological containment laboratories visit toilets.
e. Laboratory coats or gowns used by members of Schools or Institutes in Containment Level 3 laboratories must be autoclaved before laundering. Frequently used coats or gowns in Containment Level 2 or 3 laboratories should be changed at least once per week.

f. Laundering processes are established in house or with suitable commercial launderers so that students or staff do not take lab coats or gowns home for laundering.

g. Separate, well-defined storage areas are provided for street clothes and for protective clothing (including laboratory coats and gowns).

h. Suitable disposable gloves protecting against biological agents are available in Containment Laboratories (BS EN ISO 374-5:2016; previously BS EN 374-2:2003).

i. Applicable eye and face protection is available and MUST be worn in all biological laboratories. A risk assessment should clearly identify and justify when eye or face protection is not required due to negligible risk of the task and environment.

j. All re-usable PPE is checked and cleaned at suitable intervals.

k. When discovered to be defective, PPE is repaired or replaced before further use.

l. Any PPE that may be contaminated by biological agents must be decontaminated and cleaned or, if necessary, destroyed.

12. **Health Monitoring, Immunisation and Surveillance**

12.1 Heads of Schools, Directorates or Institutes must establish procedures by which:

a. Details of staff or students in QMUL Schools, Directorates or Institutes working with hazardous biological agents (HG 2 or 3) should be notified to the QMUL Occupational Health Service. 
*Details should be forwarded via the QMUL pre-employment medical questionnaire (for staff) or when the student is recruited for the period of study.*

b. Appropriate immunisation is offered to the staff or student, as required by the COSHH Regulations and medical guidance.

c. Female staff or students of child-bearing capacity should consult with the QMUL Occupational Health Service if they propose to work with potentially teratogenic biological agents, e.g. rubella, cytomegalovirus, *Toxoplasma gondii*.
*See New and Expectant Mothers topic page and risk assessment [http://www.hsd.qmul.ac.uk/a-z/new-and-expectant-mothers/](http://www.hsd.qmul.ac.uk/a-z/new-and-expectant-mothers/)*

d. A list of staff working with ACDP HG 3 or SAPO Group 3 agents is recorded and kept for at least 40 years from the date of the last entry made with details of agent, type of work and records of incidents. This may also apply to specified ACDP HG 2 or SAPO Group 2 agents.
QMUL Occupational Health Service maintain a list of all staff notified to them by the School, Directorate or Institute.

12.2 Staff and students of a School, Directorate or Institute working with hazardous biological agents or material may be required to:
   a. undergo medical examination;
   b. undergo immunisation
   c. provide serum samples for future reference.

12.3 Work with blood borne viruses (e.g. Human Immunodeficiency Virus, Hepatitis B or C), and sharps requires specific safe working procedures, health monitoring and where appropriate, procedures for post exposure prophylaxis.

Specific Occupational Health guidance / procedure documents for health surveillance for blood borne virus work are available from the Occupational Health Service. http://hr.qmul.ac.uk/about-us/

Further guidance on safe working practices including elimination or reduction of sharps with blood borne viruses are available at http://www.hsd.qmul.ac.uk/a-z/biological/

13. **Storage of biological samples**

Heads of Schools, Directorates or Institutes must establish procedures, which ensure, as far as reasonably practical, that:

a. Biological agents are stored and transported in robust leak-proof containers with uncontaminated external surfaces.

b. Biological agents in storage are labelled with the name of the agent, the identity of an appropriate responsible member of the School, Directorate or Institute, the nature of the substance and date of acquisition.

c. Records of stored biological agents and materials are kept and a summary of biological agents holdings (as noted in section 9.1) are communicated to the QMUL Biological Safety Adviser.

d. Periodic stock checks are carried out.

e. Surplus materials are safely discarded.

f. Refrigerators and freezers containing hazardous biological agents (as noted in section 9.1) are locked. During defrosting of a refrigerator, the contents must be stored safely. Discarded material must be thawed before being autoclaved or incinerated.

g. Ampoules must be stored in the vapour phase of liquid nitrogen. Liquid nitrogen banks are kept in areas that can be readily disinfected if an ampoule explodes. All staff, students and other persons nearby must wear full face visors when banks are opened. Ampoules containing HG 2 and 3, SAPO Group 2 and 3 biological agents must be opened in a microbiological safety cabinet, ideally a Class I cabinet or as assessed, a suitable Class II cabinet.
h. Hazardous biological agents should, if possible, be preserved using methods other than freeze drying in view of the risk of implosion and aerosol formation. Class I Microbiological Safety Cabinets must be used for opening ampoules containing desiccated / freeze dried HG 2 and 3 biological agents. Both top and plug of ampoule should be treated as if contaminated.

i. At the end of a research worker’s term of employment, or when the relevant research or teaching is terminated, all hazardous biological agents, including samples that might contain such, are destroyed in an approved and safe manner or stored and accounted for in an approved manner.

j. No hazardous biological materials are taken from the laboratory by a research worker without the written approval of the Head of School, Directorate or Institute.

13. Transporting Biological Agents

a) Heads of Schools, Directorates or Institutes shall establish and enforce procedures, which ensure that biological agents are packaged and transported in accordance with the QMUL Hazardous Materials Transport Policy and Procedures (See Working with Biological Agents QM/H&S/0089 - Guidance Note B15 at http://www.hsd.qmul.ac.uk/a-z/biological/).

b) If a QMUL staff or student is signing the ‘Shipping Form’ as the Responsible Person for sending a shipment containing Category A or B classified biological samples, appropriate training should be obtained in advance. See http://www.hsd.qmul.ac.uk/a-z/transport-of-dangerous-goods/

14. Disinfection, Inactivation and Disposal of Biological Agents

Heads of Schools, Directorates or Institutes must establish and enforce procedures, which state

a. The disinfectants to be used under defined circumstances, ensuring that they have been validated for the biological agents being used.

b. That the use of disinfectants is covered by COSHH assessments.

c. That all material containing biological agents is inactivated or rendered safe before final disposal.

d. That the QMUL Disinfection and Clinical Waste Procedure & Guidance documents should be consulted to establish safe working procedures. Standard Operating Procedure templates are also available from web links below.

Decontamination and Disinfection http://www.hsd.qmul.ac.uk/a-z/decontamination/
Clinical waste http://www.hsd.qmul.ac.uk/a-z/hazardous-waste/

15. Emergency Procedures

15.1 Heads of Schools, Directorates or Institutes must establish appropriate procedures and contingency plans to deal with:

a. A major spillage of biological hazardous material occurring in laboratories.

b. Breakage of tubes containing biological hazards in centrifuges.
c. Arrival in the School, Directorate or Institute of leaking biological hazard containers.

15.2 Heads of Schools, Directorates or Institutes must establish and enforce procedures, which ensure that following an accident:

   a. All debris, contaminated swabs, soiled clothing and equipment, is rendered non-infective before disposal or re-use.

   b. Cleaners, maintenance personnel, visitors and other personnel are prohibited from entering an area until it has been decontaminated.

15.3 Heads of Schools, Directorates or Institutes must establish and enforce procedures, which ensure that QMUL Security have an up-to-date list of staff to be contacted in the event of an accident outside normal working hours.

15.4 Heads of Schools, Directorates or Institutes must ensure that all accidents and dangerous occurrences with biological agents are reported as per the QMUL Accident & Incident Policy and all legally reportable incidents under the Reporting of Incidents, Diseases and Dangerous Occurrences Regulations (RIDDOR) are notified to the HSE via the Health & Safety Directorate.

16. Biohazard Signs

16.1 The standard Biohazard sign must be displayed on the door of all Containment Level 2 and 3 laboratories and facilities. Signs may also be displayed on safety cabinets, refrigerators etc. if the same considerations apply.

16.2 Biohazard signs need not be displayed where there is a negligible risk (at Containment Level 1).

16.3 Biohazard signs must be removed from decontaminated equipment if it is returned to non-hazardous areas.

17. Commissioning of Containment Level 3 Laboratories

17.1 The Head of School or Institute must ensure that the following certificates have been obtained:

   - Room sealability certificate.
   - Microbiological Safety Cabinets commissioning certificate.
   - A Practical Completion Certificate for the building work (if any has been carried out).

17.2 Once the certificates have been obtained the Head of School or Institute or Principal Investigator will contact the QMUL Biological Safety Adviser, to arrange an inspection of the laboratory as it will be used.

17.3 The QMUL Biological Safety Adviser and area Safety Coordinator shall also inspect all protocols for use and management of the facilities. A Code of Practice template for Containment Level 3 is available from the Biological Safety Adviser.
17.4 Containment Level 3 Laboratories for which the Commissioning Certificates have lapsed must not be used until a new certificate is obtained. Certification must be obtained every 12 months.

17.5 The Commissioning Certificates must be displayed on the door to the Containment Level 3 Laboratory at all times.

18. Biosecurity

18.1 The Head of School, Directorate or Institute must ensure that the holding (storage or use) of any micro-organism, toxin or relevant genetic material noted in Schedule 5 of the Anti-terrorism, Crime and Security Act 2001 and subsequent Orders, is notified to the Home Office (Metropolitan Police Counter Terrorism Security Adviser) and that all security requirements, including the selection of personnel with access to these substances, under the Act are fulfilled.

19. Environmental Samples - Risk Assessment and Notifications

19.1 Animal By-Products (ABPs)

ABPs are animal carcasses, parts of animals, or other materials which come from animals but are not meant for humans to eat. ABPs are divided into 3 categories based on the risks they pose. Premises notifications for handling ABPs are approved by and registered with the Animal and Plant Health Agency (APHA). The Biological Safety Adviser holds the details of these registrations for QMUL main campuses. Details are available on request.

19.2 Animal Pathogens

Any biological agent classified in SAPO Group 2 or 3 by the Department for Environment, Food and Rural Affairs (DEFRA) are required to be registered and appropriate SAPO containment facilities used. Risk assessments should be submitted to BGMSC via the Biological Safety Adviser for approval. Further information can be found at http://www.hsd.qmul.ac.uk/a-z/biological/ and the HSE / DEFRA websites.

Under the Importation of Animal Pathogens Order, a DEFRA import license may be required prior to bringing animal pathogens and carriers (e.g. mites, ticks, fleas, animal samples etc.) into the UK. Further information can be found on the DEFRA website.

The School / Institute Principal Investigator is responsible for applying for the above requisite licence (liaising with the Biological Safety Adviser).

19.3 Fish, Bee and Plant Pathogens

Intentional work involving plant, bee and fish pathogens which are covered by the Plant Health Order 2005, the Bees Act 1980, and Diseases of Fish (Control) Regulations 1994, respectively, could include the need for risk classification, import certification, a quarantine, passport for entry into the UK and/or inspection requirements.
DEFRA and advisory agencies such as the Food and Environment Research Agency (FERA) implement regulations. Further information can be found on the DEFRA and agency websites.

19.4 Contaminated water, soil or other environmental samples

Soils, especially those exposed to or treated with animal manures, can have a high probability of containing spores of hazardous biological agents (e.g. Clostridium tetani). In addition, soils may also contain other viable biological agents or their spores, including bacteria; fungi or parasites.

Note that soils, water or other environmental samples brought back from outside the European Union may contain “exotic” biological agents (viable organisms, and/or their spores or cysts), including Hazard Group 2 or greater species of bacteria, parasites and fungi. Such samples must only be imported under licence (from DEFRA), and any conditions attached to the licence must always be observed.

Where biological agents are propagated from soil, water or other environmental samples and which are likely to contain human or animal pathogens, the requirements of section 9 for risk assessment and authorisation would apply.

20. Allergenic biological materials

Some biological materials or products are known to be respiratory sensitisers, in that exposure by inhalation can lead to the development of an immune response and may lead to the development of asthma. Some materials may also affect the skin - for example, they are classified as irritants or skin sensitisers. Other materials may induce a severe response in the form of anaphylactic shock.

Examples of allergenic biological materials include:

- Enzyme preparations (e.g. subtilisins) as used in enzyme washing powders
- Insect cuticle protein and faecal material (frasse)
- Animal dander (this includes urinary proteins, as well as skin particles and animal fur).

The risk assessment should identify the possibility of sensitisation and appropriate control measures for the materials, involving control of exposure at source.

21. Incidental work with biological agents

There can be work activities at QMUL where exposure to biological agents may occur although there is no deliberate intention to work with them.

For example:
- Cleaning activities in areas / rooms contaminated with infectious moulds
- Gardening work with materials liable to be contaminated with biological agents - e.g., soil (especially if recently manured, or of exotic origin)
- Plumbing activities which may encounter Hepatitis A contaminated water / sewage.

In all cases, the requirements of COSHH apply, i.e., the risks created by the work must be properly assessed, and, where necessary, appropriate control measures put in place before the work is commenced.
22. References

22.1 Regulations


22.2 Websites (QMUL / regulatory / sector)

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


HSE biosafety website http://www.hse.gov.uk/biosafety/

Institute of Safety in Technology and Research (ISTR) http://www.istr.org.uk/biosaf.shtml


22.3 Biosafety publications of interest:


# Appendix 1 – Containment Measures

CONTAINMENT MEASURES FOR HEALTH AND VETERINARY CARE FACILITIES, LABORATORIES AND ANIMAL ROOMS


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<th>Containment measures</th>
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<td>2</td>
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<tr>
<td>1</td>
<td>No</td>
<td>Yes</td>
</tr>
<tr>
<td>2</td>
<td>No</td>
<td>Yes, on extract air</td>
</tr>
<tr>
<td>3</td>
<td>Yes</td>
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</tr>
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<td>4</td>
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<tr>
<td>6</td>
<td>No</td>
<td>Yes</td>
</tr>
<tr>
<td>7</td>
<td>Yes, for animal containment</td>
<td>Yes, for animal containment</td>
</tr>
<tr>
<td>8</td>
<td>Yes, for bench</td>
<td>Yes, for bench and floor (and walls for animal containment)</td>
</tr>
<tr>
<td>9</td>
<td>Yes, for bench</td>
<td>Yes, for bench and floor (and walls for animal containment)</td>
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<th>Containment levels</th>
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<tr>
<td>10  Safe storage of biological agents.</td>
<td>Yes</td>
<td>Yes, secure storage</td>
</tr>
<tr>
<td>11  An observation window, or alternative, is to be present, so that occupants can be seen.</td>
<td>No</td>
<td>Yes</td>
</tr>
<tr>
<td>12  A laboratory is to contain its own equipment.</td>
<td>No</td>
<td>Yes</td>
</tr>
<tr>
<td>13  Infected material, including any animal, is to be handled in a safety cabinet or isolator or other suitable containment.</td>
<td>Yes, where aerosol produced</td>
<td>Yes</td>
</tr>
<tr>
<td>14  Incinerator for disposal of animal carcases.</td>
<td>Accessible</td>
<td>Yes, on site</td>
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Intentional Research or Teaching Work with Hazardous Biological Agents

QMUL Peer Review and Approval Process

Biosafety Risk Assessment Draft (or significant amendment)
Biosafety Project Summary
- Prepared by the Research / Teaching Supervisor

BioCOSHH Risk Assessment Template and Biosafety Project Summary

First Review
by QMUL Biological Safety Adviser
- Email draft and summary to m.r.ariyangagam@qmul.ac.uk
  - Amendments made by Supervisor

Submission to QMUL BGMSC and Peer Review and Work Risk Classification*
- Work is discussed with the Supervisor at the next BGMSC meeting – submit at least 3 weeks before Meeting Dates
  - Final amendments made by Supervisor

Required Regulatory permits / notifications checked / made by QMUL Biological Safety Adviser
(Pathogen CU1, Schedule 5, Import, Animal By Products)

Work can commence †

*QMUL Biological Safety Adviser will email approved risk assessment to Research / Teaching Supervisor

†Containment measures (Facility, Procedures) and management arrangements must be in place; a QMUL BGMSC inspection will be conducted for new or altered work areas

Appendix 2 - QMUL Peer Review and Approval process

Hazardous Biological Agents
Where manipulation, concentration, amplification or propagation occurs for research and teaching purposes
- ACDP Hazard Group (HG) 2 or 3 wild type Biological Agents listed in http://www.hse.gov.uk/pubns/misc208.pdf
- Biological Agents without an Approved List classification, but fulfilling the classification for HG 2 or 3
- Specified Animal Pathogens Order (SAPO) Group 2 or 3
- Biological Agents or materials needing DEFRA and/or other permit/s for work due to biological / environmental risk and/or import criteria
- Biological materials known or strongly suspected of containing HG 2 or 3

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Appendix 3 – Biological Agents: Project Summary

QMUL Biological & Genetic Modification Safety Committee (BGMSC)

Biological Agents – Project Summary for BGMSC Peer Review

The QMUL BGMSC peer reviews Biosafety risk assessments involving intentional* work (research or teaching) with non-genetically modified higher hazard infectious / pathogenic Biological Agents (human and / or environmental) to ensure effective H&S management of the work and to ensure the requirements of the Control of Substances Hazardous to Health (COSHH) Regulations are met.

*Where manipulation, concentration, amplification or propagation occurs.

The (a) project summary sheet (page 2) and the (b) biosafety risk assessment/s (template at http://www.hsd.qmul.ac.uk/a-z/health-and-safety-advisory-group/health-and-safety-advisory-group/bgmsc/) for work with the following biological agents or materials should be submitted to the BGMSC in advance of work commencing:

i. ACDP Hazard Group 2 or 3 wild type (non-genetically modified) Biological Agents - listed in http://www.hse.gov.uk/pubns/misc208.pdf

ii. Biological Agents without an Approved List classification, but fulfilling the classification for ACDP Hazard Group 2 and 3 on page 7 of http://www.hse.gov.uk/pubns/misc208.pdf

iii. Specified Animal Pathogens Order (SAPO) Group 2 or 3

iv. Biological Agents or materials needing Department of the Environment, Food & Rural Affairs (DEFRA) permit/s for work due to biological risk or import criteria

v. Biological materials (cells, tissue, body fluids either from human or animal / other wildlife sources) known or strongly suspected of Biological Agents noted in i – iv. (E.g. work with sputum samples known or strongly suspected to contain Mycobacterium tuberculosis, blood samples known or strongly suspected to contain Human Immunodeficiency Virus and/or Hepatitis B or C viruses).

Note - Biological Agents that are listed or fall under the criteria for ACDP Hazard Group 4 or SAPO Group 4 are not permitted onto QMUL Premises, and therefore will not be considered.

The QMUL Biological Safety Adviser will receive the documents for preparation to the committee:

Email to: m.r.ariyanayagam@qmul.ac.uk
Dr Mark Ariyanayagam (Secretary to BGMSC)
H&S Manager (SMD) and Biological Safety Adviser (QMUL)
Health & Safety Directorate
tel 0207 882 8378

The Project Summary and the Biosafety Risk Assessment/s will be peer reviewed at the next meeting of the BGMSC. The Project proposer should attend the meeting to answer any queries from the committee. The Project will be noted as ‘Approved’ by the BGMSC following any required amendments. The QMUL Biological Safety Adviser will progress or facilitate any regulatory notifications required. BGMSC meeting dates are listed here http://www.hsd.qmul.ac.uk/a-z/health-and-safety-advisory-group/health-and-safety-advisory-group/bgmsc/
(a) Biological Agents – Project Summary

1. Project Supervisor

Title and Name:
Position:
Work Address:

Contact details (email and telephone):

Laboratory / Teaching Facility Location (Campus, Building, Room Number/s):

2. Descriptive Project Title *(No more than one or two sentences)*:

3. Name Biological Agent/s intended to be used *(extend table as required)*:

<table>
<thead>
<tr>
<th>Name of Biological Agent</th>
<th>ACDP / SAPO Group or DEFRA permit</th>
<th>Containment Level Required</th>
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4. Project Summary

Provide a short (one or two paragraphs) summary which describes in terms understandable to a LAY PERSON, the nature and aims of the project, and why the use of hazardous biological agent/s is important for this work. Note which feature(s) of the work produces significant risk(s) to human health and / or the environment. Identify and explain the level of risk posed to human health and / or the environment *(page will extend as text is typed in).*

BGMSC Use Only

--------------------------------------------------------------------------------------------------------------
Project Approval Date: Project Reference: 774/
Signed on behalf of the BGMSC: Name and Position:

Completed Biosafety risk assessment received Y/N
Completed GM risk assessment received (if appropriate): Y/N - Ref: COP / Safety Rules: Y/N
Containment Level Agreed: Y/N Health Surveillance required: Y/N Facility Inspection scheduled: Y/N
Regulatory Notification Required: Y/N – Select: cba1 update, DEFRA permit, ABP update, import / export licence, ATCSA

QMUL/HS/118_Biological Agents_Policy and Arrangements for QMUL_Version 3_June 2017
Document Control

For Version 3 – Ref: QMUL/H&S/118

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<td>Version 1 (QM/H&amp;S/064)</td>
<td>Issued 01/01/2005</td>
<td>-</td>
<td>Author: Dr John Robinson, Director (QMUL H&amp;S Dept)</td>
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<td>Version 3 (QMUL/H&amp;S/118)</td>
<td>June 2017</td>
<td>Legislation Updates. Environmental hazards and risks identified. Roles and responsibilities updated. QMUL Notification and peer review process.</td>
<td>Dr Mark Ariyanayagam (QMUL Biological Safety Adviser and H&amp;S Manager)</td>
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<td>Version 4</td>
<td>26 Nov 2018</td>
<td>Risk Assessment review and updates – to sections 6.2 and 8.2.2 &amp; .3. Eyewear mandatory in biological laboratories noted in 11 (i). Weblinks updated throughout, references updated</td>
<td>Dr Mark Ariyanayagam (QMUL Biological Safety Adviser and H&amp;S Manager). Checked and approved by Rebecca Jones (Acting Head of Health &amp; Safety)</td>
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