LONDON METROPOLITAN UNIVERSITY

Biological Safety Policy

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1. Introduction

This Policy sets out the arrangements and requirements for safe working with biological hazards at London Metropolitan University. It provides a framework for protecting staff, students, visitors and the environment from risks associated with biological hazards and to ensure such work is carried out safely.

2. Scope

This policy applies to all work which involves the handling, storage, transport and waste disposal of biological agents at the London Met University.
This includes work[1] involving biological material (e.g. microorganisms, cell cultures, parasites, human or animal tissue) including blood, urine and other body products or plant material that may give rise to a risk of infection, allergy or toxicity.

No-one may commence any activity involving GMOs[2] (including their use; culture; storage; transport; destruction; or disposal) or introduce GMOs into the environment without first consulting the Health & Safety team, undertaking a risk assessment of the activity that has been reviewed by BGMSC and registering with the Health & Safety team. No project involving such work may be started until written authorisation has been obtained from the BGMSC.

Currently there is no license under SAPO, or PHO undertaken within the University. No-one may commence licensed work, including the Human Tissue Act, without obtaining the necessary license, ethical approval and explicit consent from the BSC.

School/Department are required to set up a BGMSC or BSC for GMO or/and licensed work.

For information on the control of Legionella, please refer to Legionella Policy and associated water systems procedures.

[1] Work means work means handling, use, transportation and storage of biological material

[2] The *Genetically Modified Organisms (Contained Use) Regulations 2014* regulates the safe use of genetically modified organisms (GMOs) in containment. The regulations cover both the human health and environmental risks from work involving genetically modified microorganisms which includes modified cell cultures. For larger GMOs (i.e. animals and plants) these regulations only cover the risks to human health with the environmental risks being covered by provisions in the Environmental Protection Act (EPA) and its sub-ordinate regulations, the *Genetically Modified Organisms (Risk Assessment)(Records and Exemptions) Regulations*. Releases to the environment and marketing of GMOs are also covered under the EPA by provisions in the *Genetically Modified Organisms (Deliberate Release) Regulations*. Taken together, all of these Regulations implement, within Great Britain, the EC Directives on the contained use and deliberate release of GMOs.

3. Definitions

- **Biological agents:** means a micro-organism, cell culture, or human endoparasite, whether or not genetically modified, which may cause infection, allergy, toxicity or other wise create a hazard to human health.
  Source: Regulation 2 (1) Control of Substances Hazardous to Health Regulations 2002
- **BSC:** Biological Safety Committee
- **BGMSC:** Biological and Genetic Modification Safety Committee
- **Biohazard:** microorganisms, agents, pathogens, viruses, cell cultures, parasites, human or animal tissue including blood, urine and other body products or plant material which gives rise to a risk of infection, allergy or toxicity
- **GM:** Genetic Modification.
- **GMOs:** Genetically Modified Organisms
- **Organisms:** any individual **living** thing that can react to stimuli, reproduce, grow, and maintain homeostasis. It can be a virus, bacterium, protist, fungus, plant or an animal.
- **SAPO:** Specified Animal Pathogens Order 2008.
- **PHO:** Plant Health (England) Order 2015.
- **UBSO:** University Biological Safety Officer

4. Roles and responsibilities

4.1 Deans of School

Deans of School are responsible for:

- Ensuring that this policy is adhered to within their areas of responsibility
- Ensuring that systems are in place for the review, approval and notification of work at the initial stages, and where appropriate, throughout the project.
- Ensuring that systems in place to meet and review training needs.
- Appointing a School Biological Safety Officer (BSO)

4.2 Health & Safety Team

The H&S Team is responsible for:

- Providing guidance and advice on biological risk management
- Auditing Schools on their holdings.
- Liaising with the National Counter Terrorism Security Office (NaCTSO) and CTSAs regarding work with, and the secure design of, premises holding scheduled material.

4.3 Principal Investigators\ Practical Demonstrators

A principal investigator or practical demonstrator is the initiator of a project or practical

and is the named applicant on the original project application. This person will usually be a member of staff and is directly responsible for the safe execution of the work in progress.

Principal Investigator and Practical Demonstrators are responsible for:

a) Undertaking risk assessments for hazardous activities, including the handling of any hazardous waste and disinfectants used in their laboratory.

- Applying for and securing necessary licenses prior to undertaking any licensed work and including the cost of obtaining such license or regulatory notifications in the project budget.

b) Obtaining the necessary permission from School Management for each new or changed project involving Schedule 5 materials[3] including ethics approval where required.

c) Ensuring that all aspects of the work with any Schedule 5 pathogens, toxins or relevant materials are securely controlled.

d) Classifying all biohazards for which they are responsible in the prescribed manner, and maintaining an up-to-date inventory of biohazards.

e) Ensure that all workers in their groups are familiar with the local rules and the correct use of the laboratory equipment and are trained in the handling of the biohazards involved.

- Ensuring that all workers in their groups are registered for the work as identified in the risk assessment, and the list of registered workers is managed by the School and shared with Health & Safety team. The list must be kept accurate and updated regularly.

f) Being responsible for the day-to-day cleanliness of the laboratory, and its physical security and for the safe storage of biohazards in the laboratory.

g) Ensuring that where such organisms[4] are sent outside the University, the Principal Investigator's undertakes a proper assessment and that they are transported appropriately.

h) Ensuring that the local management and Health & Safety team is promptly informed of any accidents in the laboratory.

i) Providing safety information for Permits to Work which are required by maintenance staff and contractors before they may enter any area where work with biological agents is taking place.

[3] Acquisition, storage and use of a specified form of an item on the *Anti-Terrorism, Crime and Security Act 2001* Schedule 5 will require notification to the Home Office, inspection by a police Counter-Terrorism Security Advisor, and compliance with more stringent biosecurity requirements.

[4] Naked DNA is not covered by the Regulations, and it is much easier to send or arrange to receive naked DNA rather than the GMO.

4.4 Lab Users (Staff and Students)

Lab Users are responsible for:

- Adhering to University and local rules.
- Reporting accidents/incidents and near misses to their line-manager/ supervisor/ and via Online reporting form
- Not using any equipment, substance or safety device unless they are deemed competent to do so, having received adequate training and instructions from the appropriate member of staff.
- Being familiar with the actions to take in the event of an emergency.

4.5 Estates

Estates are responsible for:

- Providing adequate and suitable waste disposal
- Providing thorough examination and testing of Microbiological Safety Cabinets
- Sharing relevant maintenance records and reports.

4.6 Occupational Health

Occupational Health is responsible for:

- Delivering the Health Surveillance Programme.
- Providing related health advice upon request.

4.7 Third Party Users

- Third party users of LMU laboratories (e.g. collaborators and visiting researchers) must ensure that they have all of the necessary safety arrangements, notifications and licenses (etc.) in place.
- LMU staff are responsible for reviewing the proposals for work by third parties to ensure that the facilities are suitable for the work to be undertaken.

4.7 Biological Safety Officer (BSO)

- Advises on biological safety matters
- Supports the review and approval of work involving biological hazards.
- Co-ordinates local biological safety arrangements.
- Ensures appropriate risk assessments and control measures are in place.
- Monitors compliance with relevant institutional policies, procedures and statutory requirements.
- Supports the provision of appropriate training, information and guidance to staff and students.
- Monitors and reports biological safety incidents, accidents, near misses and concerns.
- Obtains specialist advice where required.

5. Procedures/ Key Requirements

5.1 Biological Hazards

The degree of containment for microorganisms varies depending on the hazard group to which the microorganisms belong. The Advisory Committee on Dangerous Pathogens (ACDP) produces and periodically updates *The Approved List of Biological Agents*, which classifies many commonly used microorganisms into hazard groups.

This document should be referred to **before** starting any work involving microorganisms. Microorganisms that are not listed are **not automatically assigned to HG1**, these must instead be classified by the person undertaking the work. The ACDP document also lists those biological agents in HG3, which are subject to a partial exemption from the minimum containment level requirements of the Control of Substances Hazardous to Health (COSHH) Regulations when particular activities are being undertaken. If there is any doubt in making an allocation, advice should be sought from the Health & Safety team.

Use of genetically modified organisms is also subject to additional regulations, please contact the Health & Safety team if planning to undertake work with GMOs.

The University does not currently have any containment level 3 or 4 facilities. HG3 and HG4 pathogens, or materials containing them, must not be brought onto University premises.

Further details on hazard groups and related containment requirements and specifications can be found in Appendix IV.

Any person who wishes to work with a pathogen must consult the Health & Safety team, **before commencement**, for the work to be reviewed and approved. This notification must include the names of all workers involved and a list of all rooms which will be used.

5.2 Notification to the authority

In some circumstances, notifications must also be made to the Health and Safety Executive or other regulatory authorities. The Biological Safety Officer will notify the relevant authorities as required. It is the responsibility of the Principal Investigator to provide information set out within this procedure to the Health & Safety team.
For example, under the COSHH Regulations the University may be required to notify to the HSE of:

- the first use of biological agents in Hazard Groups 2, 3 or 4 at a particular premises and
- subsequent use of any of the agents listed in Part V of Schedule 3 to COSHH at particular premises.

Additionally:

- Specified animal pathogen licences for work involving serious animal pathogens.
- Plant health licences are required for work with serious plant pathogens and pests.

Details on the requirement for, and obtaining, ethics approval are available here: https://student.londonmet.ac.uk/your-studies/mphil--phd-professional-doctorates/research-ethics/

6. Risk Assessment/ Control Measures

6.1 Biohazard risk assessment

Any department wishing to use clinical specimens, human material or possible infectious material for the first time must contact the Health & Safety team. The Health & Safety team should inspect the area before work can proceed. A risk assessment and a disinfection and disposal policy must be in place, and disinfectants must be available for use.

Risk assessments are required to be done before any work commences, or for any work involving the possession/use of biological agents, or where there is a risk of exposure to biological agents involved in the work.

The risk assessment must consider the potential risks to humans, animals, plants or other aspects of the environment arising from the work and determine what controls are required to protect humans and the environment.

Managers and Principal Investigators are responsible for ensuring that risk assessments are carried out and the controls are fully implemented, regularly monitored and that the assessment and controls are regularly reviewed and revised where required.

For work involving Biological substances, a Risk Assessment (See Scientific Risk Assessment template in the Risk Assessment Policy tab) form must be used. Follow Risk Assessment Policy for additional guidance.

Risk assessments must be carried out by competent persons and approved by the appropriate manager or principal investigator. The work must be categorised on the basis of risks taking into account the biological agents, the type of activity, hazard group, containment level and all the necessary controls required to ensure that the work can be done safely while protecting people and the environment.
Risk assessments must clearly identify all persons at risk.

The Health & Safety team is available to provide advice on risk assessments and help

ensure that suitable and sufficient assessments have been made of the risks to human health and safety and to the environment, satisfactory decisions are made about appropriate containment and control measures, and the risk assessment and controls are in accordance with the relevant regulations and guidance.

6.2 Risk Assessment Considerations

Risk assessments involving biological hazards must consider:

1. the organism(s), agent, animal, bacterium or virus and whether it has been sourced from reputable suppliers using an approved procurement method.
2. the quantity/ size being sourced.
3. the state of the organism/ animal (i.e. dead or alive).
4. the appropriate hazard group.
5. the appropriate containment level.
6. the control measures necessary to prevent or adequately control exposure and reduce the risks to people, animals, plants and the environment to an acceptable level (controls must be proportionate to the risks).
7. the minimum legal control requirements which must always be used plus any additional controls determined to be necessary in the risk assessment.
8. measures for the safe handling, storage, transport, inactivation and disposal.
9. plans and procedures for incidents and emergencies.
10. the potential consequences of exposure for vulnerable people (i.e. those with pre-existing medical conditions, young workers, new or expectant mothers) and the controls required to manage these exposures.
11. whether any health surveillance is required? Also, consider staff allergies.
12. arrangements for monitoring control measures to ensure that they are effective.

6.3 Biological Safety Committee

Schools which carry out work involving biological agents may be required to establish a Biological Safety Committee (BSC) (i.e. a standing item in the School H&S Committee). This is mandatory if any license is in place. If a BSC is in place it must be involved in the review and approval of biohazard risk assessments.

6.4 Record Keeping

Risk assessments must be held centrally in each School or Department with an appropriate copy being made available to the site where the particular activity is taking place.
Risk assessments must be retained for 40 years as required under COSHH regulations and reviewed from time to time to cater for changes in work activity and whenever new information is available that will affect the assessment. An annual review would be suitable in most cases.

7. Information, Instruction and Training

7.1 Safety Signs

The Biohazard sign should be displayed at access points to warn of infectious hazards and must be placed at the entrance to all Containment facilities.

7.2 Access Restriction

Access to containment facilities must be strictly controlled and only those with a real need should be allowed to enter. Visitors must be supervised and given the appropriate protective clothing and safety instructions before entering the area.

Cleaners and maintenance staff must only be allowed to enter when it is considered safe to do so, for example, when the work situation is such that the possibility of an accident is minimal and may need to be supervised

Unauthorised entry must be prevented. In addition to the displaying of safety signs, doors should be closed when work is in progress and locked when rooms are unoccupied.

7.3 Biosecurity of pathogens and toxins

Acquisition, storage and use of a specified form of an item on the *Anti-Terrorism, Crime and Security Act 2001* Schedule 5 will require notification to the Home Office, inspection by a police Counter-Terrorism Security Advisor, and compliance with more stringent biosecurity requirements. The Health & Safety team audits Schools on their holdings and liaises with the National Counter Terrorism Security Office (NaCTSO) and CTSAs regarding work with and the secure design of premises holding scheduled material.

All Schedule 5 materials must be kept securely locked, access must be restricted to authorised users only and detailed records must be kept by the Department. Note that pathogens classed as Category A Infectious Substances under carriage of dangerous goods legislation also have elevated biosecurity requirements which will need to be addressed well in advance of transporting this material to or from a University building. Please contact the Health & Safety team for further advice if your work will be affected by these requirements.

7.4 Human tissue and body fluids

Any work involving Human Tissue and body fluids must be conducted in compliance with the requirements of the Human Tissue Act (HTA) 2004. LMU has Guidance on HTA application to use of Human Tissue available here: https://student.londonmet.ac.uk/your-studies/mphil--phd-professional-doctorates/research-ethics/ . Where required, ethics approval must be sought.

7.5 Venepuncture

Any Staff member intending to undertake venepuncture must ensure that suitable and sufficient risk assessment is in place and approved, which will include detailed procedure. School management and local ethics committees should consider this type of work and develop local procedures to be put in place.

7.6 Transport

Some biological samples, cultures and other materials are considered dangerous goods for transport and strict regulations concerning the **packaging**, **labelling** and **transportation** of such materials apply. Even if the biological materials are not classified as dangerous, they should still be transported in a way that prevents leakages in transit in order to avoid security alerts and unnecessary concern to anyone who may come into contact with leaked material.

The Health & Safety team should be contacted well in advance of transporting biological materials so that further guidance can be sought as necessary.

7.7 Immunisation

Effective vaccines are only available for some pathogens. Immunisation is not a substitute for good laboratory or other work practice and is regarded as an additional protective measure against disease and not as the main defence.

Immunisation will be offered to all employees and student groups who are indicated in a risk assessment to be at risk of an occupationally acquired infection for which a safe and effective vaccine is available. The need for immunisations should be identified in job descriptions and individual activity risk assessments.

7.8 Training

Anyone intending to work in areas where there are microbiological hazards must receive adequate training in both the theoretical and practical aspects of the work. Newly trained people must be given supervision initially and it is the responsibility of the Dean or Department to ensure these training needs are met.

The Principal Investigator/Laboratory Manager is to ensure that sufficient instruction is given to those people who only need occasional access to microbiological laboratories (e.g. cleaners and maintenance personnel) to ensure that they do not endanger themselves or their colleagues.

A record of training should be kept by the School/Department. Advice on training may be sought from the Health & Safety team.

8. Records and Monitoring

8.1 Equipment

Equipment in containment facilities must be maintained in a satisfactory working condition. However, before any maintenance or testing is carried out the equipment must be decontaminated (e.g. by disinfection or fumigation and the containment facility made safe).

The Laboratory Manager and laboratory staff should ensure that any maintenance operative is aware of all necessary control measures and ensure that appropriate protective clothing is made available and worn. Only authorised personnel should be allowed into containment facilities. Arrangements for access for maintenance, cleaning etc. needs to be agreed with the Laboratory Manager (following the Control of Works Policy).

Further details on how LMU fulfils its obligations with regards LEV can be found in the Management and Use of LEV Policy.

Autoclaves are required to be inspected **annually** by an external, competent authority and maintained. In addition, the sterilising ability of the autoclave should be validated and measured for each load. These arrangements should be put in place, monitored and recoded by the School.

It should be noted that autoclave tape is not a consistent indication of sterilisation adequacy.

8.2 Emergency response planning

There must be contingency plans in place for dealing with emergencies involving biological hazards. These arrangements must be understood by all undertaking the work and should be included in the training programme for all new workers.
Emergency arrangements should include provision of protective clothing, material for absorbing liquid spills, utensils for clearing up spillages, disinfectants and plastic bags suitable for autoclaving, etc.

This is likely to include arrangements for responding to spillages (including those with a risk of airborne infection), personal contamination and needlestick injuries.

Emergency procedures must be developed by the responsible School and included/referred to in risk assessments.

9. Legislation and Standards

- Health and Safety at Work etc. Act 1974
- Management of Health and Safety at Work Regulations 1999
- Control of Substances Hazardous to Health Regulations 2002 (COSHH)
- Reporting of Injuries, Diseases and Dangerous Occurrences Regulations 2013
- Personal Protective Equipment at Work Regulations 1992
- Provision and Use of Work Equipment Regulations 1998
- Human Tissue Act 2004

10. References

- The Approved List of Biological Agents 2026 https://www.hse.gov.uk/pubns/misc208.htm
- The SACGM Compendium of Guidance
- http://www.hse.gov.uk/biosafety/gmo/acgm/acgmcomp/
- EH76 Control of Laboratory Animal Allergy http://www.hse.gov.uk/pubns/eh76.pdf