Working with Microbiological Agents in Biohazard Groups 1 to 2

SHEP 26 A

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Contents

Introduction

This guidance has been produced to provide information relating to the safe use of microbiological agents, toxins and venoms within St. George's University of London for either for research or teaching.

Heads of Institutes are responsible for ensuring that work in the institute is carried out in a safe and healthy manner. They may in certain circumstances delegate the duty for ensuring the adequate monitoring of all work associated with a particular project to the Principal Investigator.

The Control of Substances Hazardous to Health Regulations 2002 as amended (COSHH) require the use of microbiological agents in the workplace to be controlled. The required controls depend on the level of hazard that microbiological agent poses.

In addition the holding and use of certain microbiological agents and toxins is controlled under Schedule 5 to the Anti-terrorism, Crime and Security Act 2007

This document does not deal with the following activities which are covered by other government regulations and St. George's University of London policies

Genetic modification
Agents that are pathogenic to plants
Work with animals

Definitions

Biological agent

"Biological agent" means any micro-organism, cell culture, or human endoparasite, including any which have been genetically modified, which may cause any infection, allergy, toxicity or otherwise create a hazard to human health

Microbiological Hazard Group Classification

Microbiological agents (Bacteria, Parasites, Fungi, Viruses) are divided into 4 biohazard groups according to the classification awarded them by the Advisory Committee on Dangerous Pathogens (ACDP) and the World Health organization (WHO). This is based upon their ability to cause 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.

If an agent is not listed in the ACDP document, it cannot be assumed to be without hazard and the infection criteria listed below should be applied. The method of transmission and the type of work should be taken into account.
While some agents may not pose a risk to a healthy person, products of the organism may pose a risk due to being a toxin or by causing an allergic response.

Biohazard Group 1

A biological agent unlikely to cause human disease in a non immuno-compromised individual.

Biohazard 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.

Biohazard 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. If you are planning on using these organisms you should refer to Shep_26_B.

Containment

Containment is the way in which microbiological agents are managed in order to prevent, or control, the exposure of laboratory workers, other people and the outside environment to the agent in question. This can be a mixture of physical and management controls.

Physical controls are laboratories built to Containment level 1 or Level 2 and include equipment such as microbiological safety cabinets and sealed benches. Under the regulations the doors to containment level 2 laboratories are to be kept closed while work is in progress. If possible bags and coats should not be placed in containment level 2 laboratories.

Management controls include risk assessments, standard operating procedures, training records and maintenance records.

Risk Assessment

It is the responsibility of Heads of Institutes to ensure that procedures for assessing the hazards and risks associated with microbiological agents used in the Institute. Written records of all risk assessments ***must*** be kept. Individuals should be aware that it is important that procedures outlined in the risk assessment are followed as this is a legal document.

COSHH requires that exposure to a microbiological agent be prevented if this is reasonably practicable. This can be through a combination of equipment, procedures and training.

If it is not reasonably practicable to prevent exposure to microbiological agents, the microbiological agent involved in the activity should be the least harmful that the nature of the activity will permit.

The risk assessment should consider

1. The microbiological agents that may be present including those in human or animal

tissues.

2. What biohazard groups they belong to.

3. 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) and the diseases they may cause.

4. How they are transmitted.

5. The likelihood of exposure and consequent disease. The possible effects on immuno-comprised or pregnant workers should be considered

6. Can a less hazardous agent be used e.g. during teaching practicals.

7. The control measures to be applied, and reducing the number of people exposed;

8. The need for monitoring procedures;

9. The need for health surveillance procedures.

10. Any emergencies that may occur and measures to mitigate any effects to the worker or others in the vicinity

The risk assessment should also take into account any chemical, radiological or equipment hazards associated with the work and any need for specialized training.

The risk assessment for the project should be reviewed annually or after any incident that indicates that insufficient risk controls are in place. It should be easily accessible and must be communicated to the relevant staff who must understand the required control measures.

Authorisation of work in Containment Level 2 Laboratories

Heads of Institutes must ensure that:

1. The Safety, Health and Environment Office is informed of plans to work with hazardous microbiological agents in Biohazard Groups 2 or where doubt exists concerning the classification of an agent. The SHE Office will confirm the Hazard Group and required level of containment to both the project proposer and Head of Institute, together with other relevant advice

2. Changes in existing procedures that will, or are likely to result, in enhanced risk from hazardous microbiological agents, are notified to the Safety, Health and Environment Office as soon as possible.

3. All staff must comply with procedures and risk controls stated in the COSHH and General risk assessments and that any changes to work practices are included in

the risk assessments.

4. Female staff are aware of the availability pregnancy risk assessment.

Training

Following the formation of the new institutes, the Heads of Institutes are responsible for establishing procedures ensuring that:

1. Members of an Institute are properly trained in safe working practices including where necessary Good Microbiological Practice and laboratory hygiene. Staff are familiar with the waste disposal policy and disposal of waste correctly.

2. Staff are familiar with the biological transport policy.

3. Signed training records are completed and kept. These should include the name of the person trained and the trainer.
   Alternatively training should be entered recorded on the Yourself system.

4. Undergraduates are trained in safe working practices as required. Under-graduates may handle Group 2 agents only when they are adequately trained and supervised

5. Staff are trained in the selection and use of personal protective equipment (PPE) necessary for their safety

6. Staff are aware of infection control and needlestick policies relating to their work if appropriate.

7. That staff are aware of emergency procedures relating to their work

8. That staff know who to contact in the event of an emergency

Personal Protective Equipment

Heads of Institutes must establish and enforce procedures to ensure that:

1. Appropriate protective clothing and equipment is worn in laboratories where hazardous microbiological agents are handled. These are coats that do up at the front and across the neck and are commonly known as Howie Coats.

2. Staff do not wear laboratory coats in areas where food and drink is consumed.

3. The wearing of protective clothing (including gloves) is minimised in general access areas.

4. Laboratory coats are removed before members of Institutes visit toilets.
5. Laboratory coats worn by members of Institutes using designated Group 2 hazards following the risk assessment are either fumigated or autoclaved before laundering.

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

7. Non-latex gloves are available in all laboratories.

8. Eye protection is available in all containment level 2 laboratories and that it is worn where there is a chance of eye infection, eye splash or other eye damage occurring

9. Only high-necked side or back fastening laboratory coats with elastic cuffs (Howie Coats) are worn in Containment Level 2 areas as identified by the risk assessment.

10. All Personal Protective Equipment (PPE) is checked and cleaned at defined regular intervals and that records are kept. This is particularly important if respiratory protective equipment is used for fumigation.

11. Individuals who may be required to use formaldehyde for laboratory fumigation have been trained in the procedure and are competent.

    Where it is necessary for individuals to wear full face respirators they must be face-fit tested to ensure that the fumigant does not leak into the respirator face piece. Standard Operating Procedures must be in place and these must include checks that the respirator filters are correct for the fumigant used and are in date. Before fumigation with Formaldehyde is undertaken the Safety health and Environment Office should be notified.

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

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

Handwashing and skin care

All staff must wash their hands before leaving laboratories. It is the responsibility of the organisation to provide suitable soap. If individuals are known or suspected to have dermatitis, a suitable perfume free, hypoallergenic soap should be provided.

If individuals have reported problems with their skin following repeated handwashing, individuals should be directed to the HSE information on dermatitis and if necessary arrange an appointment with Occupational Health if they believe the problem is work related.

If necessary a suitable perfume free hypoallergenic hand cream for use after handwashing should be provided.

The HSE has provided information on handwashing

Health Monitoring and Immunisation

Heads of Institutes must establish procedures by which:

1. Details of persons in Institutes working with hazardous microbiological material are notified to the Safety, Health and Environmental Office

2. Appropriate immunisation is offered to these persons, as required by the risk assessment prior to starting the project where possible. If possible staff who are going to work with known biohazard group 2 pathogens for which vaccines exist, should be inoculated prior to commencing the project.

3. Women of childbearing capacity who are planning to start a family should consult with the Occupational Health if they propose to work with teratogenic agents, e.g. rubella, cytomegalovirus, *Toxoplasma gondii*

Members of an Institute who are working with particular microbial and chemical agents may be required to:

1. Undergo medical examination as part of health surveillance

2. Undergo immunisation procedures

3. Provide serum samples for future reference. This is dependent on the agent being used. It will enable staff to be monitored effectively should an untoward incident occur. This should be confirmed with Occupational Health on extension 1661 / 1662.

Security of Microbiological Agents, Toxins and Venoms

Heads of Institutes must establish procedures, which ensure that:

1. Access to laboratories where agents that are listed in Schedule 5 and Schedule 7 of The Anti-terrorism, Crime and Security Act 2001 is controlled and that unauthorised access is not allowed.

2. Mycobacterium Tuberculosis and Cryptococcus neoformans are no longer listed on the on Schedule 5 and Schedule 7 of the Anti-terrorism, Crime and Security Act 2001

3. Microbiological agents including toxins that are listed in Schedule 5 and Schedule 7 of The Anti-terrorism, Crime and Security Act 2001 are stored securely in laboratories.

4. That staff using microbiological agents including toxins that are listed in Schedule 5 and Schedule 7 of The Anti-terrorism, Crime and Security Act 2001 only work in defined laboratories.

Storage of Samples

Heads of Institutes must establish procedures, which ensure that:

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

2. Stored microbiological agents are labelled with the name of the agent, the identity of an appropriate responsible member of the Institute, and date of acquisition. As part of Good Laboratory Practice all samples should be labelled.

3. Records of stored materials are kept.

4. Periodic stock checks are carried out. This helps prevent freezers becoming full of unwanted material.

5. Surplus materials are safely discarded once projects have ended or other members of the department are notified of the samples location.

6. Refrigerators and freezers containing hazardous microbiological agents should be locked if possible or kept in a locked room. During defrosting of a refrigerator, the contents must be stored safely.
   Discarded material must be thawed before being autoclaved or incinerated to ensure complete killing.

7. Liquid Nitrogen Dewars must be kept in areas that can be readily disinfected if an ampoule explodes. Workers must wear visors when units are opened.

8. When material is being preserved the risks of the chosen method have been analysed.

9. Material is destroyed when the project comes to an end.

10. Workers state that material has either been destroyed or its location when their employment comes to an end.

Transporting Microbiological Agents

Heads of Institutes must establish and enforce procedures, which ensure that

- Staff follow the biological transport policy and consult with the named individuals prior to shipping microbiological agents.

- Staff should also follow the policy when moving items between labs in SGUL.

Disposal of Microbiological Agents

Heads of Institutes must establish and enforce procedures,

1. That the St. George's University of London Clinical waste document is consulted prior to the disposal of any agent.

2. Ensuring that all material containing microbiological agents is rendered safe by either autoclaving or chemical disinfection and that records are kept.

3. That any equipment involved in the disposal is maintained as necessary and that maintenance records are available.

4. Staff should follow the laboratory waste disposal policy and segregate all waste into the correct waste streams.

Disinfection

Heads of Institutes must establish and enforce procedures, which state:

1. The disinfectants to be used for particular organisms, ensuring that they have been validated for the agents being used.

2. How contaminated equipment is to be decontaminated

Emergency Procedures

Heads of Institutes must establish appropriate procedures and contingency plans in the event that:

1. A major spillage of microbiologically hazardous material occurs in laboratories including the release of toxins or venoms.

2. Tubes containing microbiological hazards break in centrifuges.

3. Leaking containers arrive containing microbiological hazards.

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

1. All debris, contaminated swabs, soiled clothing are disposed of safely and without risk to other individuals particularly cleaners and porters

2. Equipment is adequately decontaminated.

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

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

1. Security personnel have an up-to-date list of people to be contacted in the event of an accident outside normal working hours.

Biohazard Signs

The standard Biohazard sign must be displayed on the door of containment level 2 facilities. Signs may also be displayed on safety cabinets, refrigerators etc. if the level of risk warrants the notices.
Biohazard signs must not be displayed where there is a negligible risk.

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

Record Keeping

The Head of Institute must ensure that records of the following are kept

1. Risk Assessments and any modifications to listed work practices

2. Staff training

3. Equipment maintenance

4. Location of microbial agents, toxins and venoms listed in Schedule 7 of The Anti-terrorism, Crime and Security Act 2001

Appendix 1: Hazard groups for materials not listed in the ACDP guidance

Material	Appropriate Hazard Group
Human blood	Group 2 but 3 if Group 3 agent suspected
Human brain	Group 2. Group 3 if Prions suspected, but derogation from full Containment Level 3 can be applied (see ref. 6)
Human sputum and lung	Group 3 if TB possible. Group 2 if TB unlikely on clinical grounds but safety cabinet should be used unless TB eliminated by microbiological tests.

Hazard	Cell type	Containment
Low – uncertain	well characterised /authenticated finite cell lines of human or primate origin non-human, non-primate cell lines which have been authenticated, have a low risk of endogenous infection with a human pathogen and present no apparent hazard to laboratory workers	CL1 and use of microbiological safety cabinet if the risk assessment indicates it to be necessary (e.g. aerosols may be produced).
Medium – uncertain	cell lines/strains not fully authenticated or characterised	CL2 and use of microbiological safety cabinet
High – defined	cells with endogenous pathogens and cells deliberately infected	Containment appropriate to the pathogen
High – uncertain	primary cells from blood, lymphoid cells, neural tissue of human or simian origin	Containment appropriate to the potential risk

Other human material	Normally Group 2. - Group 3 if Group 3 agents are suspected
Non-human primate material	Normally as for human tissues (see above). Group 3 if seropositive for Hepatitis B virus or of unknown status.
Viral nucleic acid	As for the intact virus
Sewage, sludge, polluted water	Normally Group 2.
Other environmental samples	Normally Group 1 or 2 depending on risk, Group 2 for unidentified organisms cultured from samples
Microbial toxins	At least as for source organism. The method of handling and concentration should also be taken into account.