Working with Microbiological Agents in Biohazard Group 3

SHEP 26 B

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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 of biohazard group 3 or from organisms classified as biohazard groups 3 within St. George's University of London for either for research or teaching.

Heads of Research Institute or Research Centre 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.

Work in containment Level 3 laboratories with biohazard group 3 agents poses a greater hazard than that undertaken biohazard group 2 agents. Due to this increased level of risk, it is important that tight control is maintained of the work and the workers involved. In addition there is a requirement that access to the containment level 3 laboratory is restricted to authorised users.

The Control of Substances Hazardous to Health Regulations 2002 as amended (COSHH) and the Specified Animal Pathogen Order 2008 and 2015 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 2001

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. It may also include organisms which primarily infect animals and which can infect both animals and humans and are Zoonoses (HSE).

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. This also applies to organisms that are derived from organisms of the following classes.

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. E.g. *Campylobacter jejun.i*

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 e.g. *Mycobacterium tuberculosis*, or HIV.

Biohazard 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. St. George's University of London does not have facilities to contain these organisms and their use is not permitted on site.

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. The controls are designed to contain both human pathogens and also animal pathogens that require containment under the Specified Animal Pathogen Order (SAPO) 2008 and amendments.

Physical controls are laboratories built to Containment level 3 standards and include equipment such as microbiological safety cabinets and sealed benches, lobbies with negative airflow and monitored airflow in the laboratories. Containment level 3 laboratories must be built to a specific standard and must be authorised before use by the chair of the St. George's University of London Pathogen Management and Genetic Manipulation Safety Committee with appropriate consultation with other members.
Management controls include risk assessments, standard operating procedures, training records and maintenance records.

Risk Assessment

It is the responsibility of Heads of institutes or research centres to ensure that procedures

for assessing the hazards and risks associated with microbiological agents used in the Institutes or research centres.

The risk assessment process should lead to protocols or standard operating procedures that enable the project to proceed safely. The results of the risk assessments for a project should be communicated to the staff or students who will undertake the work.

Written records of all risk assessments must be kept. Individuals should be aware that it is important that procedures outlined in either the general risk assessment or a specific COSHH 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.

The risk assessment should consider

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

2. What biohazard or SAPO 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.

   A separate New and Expectant Mothers Hazard risk assessment (SHEP 19) is available on the portal and should be completed once staff notify their supervisor that they are pregnant

6. Is the available prophylaxis going to be effective.

7. Can a less hazardous agent be used for some parts of the work

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

9. The need for monitoring procedures

10. The need for health surveillance procedures.

11. Any emergencies that may occur and measures to mitigate any effects to the worker or others in the vicinity e.g. interruption of work by a by a fire alarm and the need to leave a laboratory, airflow turning positive within a containment level 3 facility or the failure of a cabinet when handling material whose prime route of infection is inhalation.

The risk assessment must 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 every 2 years 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.

Due to the increased hazard posed by biohazard group 3 organisms, all risk assessments and attached protocols must be completed and discussed with staff members before work starts. Staff members must acknowledge that they fully comprehend the risks, control measures and emergency procedures required.

Authorisation of work in Containment Level 3 Laboratories

Heads of Research Institutes or Research Centres must ensure that:

1. The Safety, Health and Environment Office is informed of plans to work with hazardous microbiological agents in Biohazard Groups 3 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 research centre, 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. New work with biohazard group 3 agents must not commence until the Risk Assessment has been examined by the SHE Office and the Pathogen Management and Genetic Manipulation Safety committee. This may take the form of face to face meetings or communication by e-mail.

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

Training

The Heads of Research Institutes or Research Centres are responsible for establishing procedures ensuring that

1. Individuals wishing to work with any ACDP biohazard group 3 must first contact Occupational Health to obtain clearance prior to starting formal training especially for *M. Tuberculosis*. No individual commences work in a containment level 3 laboratory without formal training in all systems in place for operating the laboratory including waste management.

2. Members of staff are properly trained in safe working practices including where necessary Good Microbiological Practice and laboratory hygiene

3. After training has been completed, the trainee will need to undergo and oral test which must be successfully completed prior to access being granted to the Containment Level 3 laboratory. Signed training records are completed and kept. These should include the name of the person trained and the trainer. Additionally training should be entered recorded on the Yourself system. This will include those who are trained to work with particular organisms.

At a minimum staff must be

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

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

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

4. Staff understand how chemically deactivate any organism that they use and understand how to operate the autoclaves within the area.

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

6. Design, use and maintenance of microbiological safety cabinets including airflow testing, alarms and fumigation.

7. Transport and storage of infectious material within and outside the Cat 3 lab.

Personal Protective Equipment

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

1. Appropriate protective clothing and equipment is worn in the laboratories.
2. Any laboratory coat and gloves that had been worn in the containment level 3 lab must be taken off before leaving the lab.

3. Laboratory coats are removed before staff visit toilets.

4. Laboratory coats worn by staff using biohazard group 3 agents autoclave their coats before laundering.

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

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

7. Eye protection is available in all containment level 3 laboratories and that it is worn where there is a chance of eye infection, eye splash or other eye damage occurring

8. Only high-necked side or back fastening laboratory coats with elastic cuffs (Howie Coats) are worn in Containment Level 3 areas as identified by the risk assessment.

9. 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.

10. Laboratory coats must not be hung over other laboratory coats in order to minimise the spread of any possible contamination.

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

12. 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 or that powered respirators are available for use.

13. 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.

14. The Safety, Health and Environment Office must be notified before any fumigation takes place.

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

16. 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 Research Institutes or Research Centres must establish procedures by which:

1. Details of persons 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;

3. Employees / students who are planning to start a family or find they are pregnant should consult with the Safety, Health and Environmental Office and the St. George's University Hospitals NHS Healthcare Trust Occupational Health department if they propose to work with teratogenic agents, e.g. rubella, cytomegalovirus, Toxoplasma. The work should be based on risk assessment on likely and potential for exposure.

Staff 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. The need for this should be confirmed with Occupational Health on 1661 / 1662

Security of Microbiological Agents, Toxins and Venoms

Heads of Research Institutes or Research Centres 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 is 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 (2007) only work in defined laboratories.

Storage of Samples

Heads of Research Institutes or Research Centres 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. If needed for similar future work.

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.

Transportation of Microbiological Agents

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

- That transfer of materials between laboratories takes place in sealed containers e.g. Tupperware sandwich boxes. It is advisable that the box is placed within a Denley tin to provide added protection when moving the organism.

- Material that is to be autoclaved is transferred using sealed metal boxes (Denely tins) if the organism poses an infection risk.

- Material containing microbiological agents are packaged and transported in accordance IATA guidelines for shipping by air or International Carriage of Dangerous Goods by Road (*ADR*) guidelines when shipping by road.

- Staff should follow the biological transport policy.

Disposal of Microbiological Agents

Heads of Research Institutes or Research Centres 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.

Disinfection

Heads of Research Institutes or Research Centres 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. Surfanios is a suggested detergent that has been used to chemically treat HIV, *Mycobacterium tuberculosis*, *Legionella*, *Aspergillus* spp., *Candida albicans*.

2. How contaminated equipment is to be decontaminated with further risks to the workers.

Emergency Procedures

Heads of Research Institutes or Research Centres 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 including human or animal blood break in centrifuges.

3. Leaking containers arrive containing microbiological hazards.

4. Interruption of work due to a fire alarm or other need to evacuate.

5. A person becomes ill during a procedure.

Heads of Research Institutes or Research Centres 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 Research Institutes or Research Centres 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 3 facilities. Signs may also be displayed on safety cabinets, refrigerators etc. if the level of risk warrants the notices.

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 COSSH 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 and also those listed under the Specified Animal Pathogen Order 2015.

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.