Biological Safety Code of Practice

Guidance for Users of microbiological laboratories and safety cabinets

Document Information

Author	Debbie Robarts, Scientific Safety Advisor, SHEW				
Revised By	Debbie Robarts				
Date	October 2023	Version	3	Status	Live

DOCUMENT CHANGE RECORD

DATE	CHANGE DESCRIPTION	PERSON
14 Mar 2017	First document issue	Debbie Robarts
19 Oct 2021	Minor admin changes	Debbie Robarts
July 2023	Following outcomes of LEV audit, further information included on equirements for Thorough Examination and Test, User Checks and Training to provide further guidance on compliance with COSHH Regs and HSE HSG258. Main sections updated/included are Thorough Examination and Test, User Checks, Routine Testing and Training. Inclusion of Appendices 3 and 4. Sent out for review.	Debbie Robarts
Oct 2023	Minor updates from review	Debbie Robarts

Contents

SUMMARY **4**

SCOPE **4**

INTRODUCTION/BACKGROUND **4**

CLASSIFICATION AND ASSESSMENT **5**

SECURITY AND ACCESS **6**

LABORATORY PRACTICE **6**

Safe Working Practices and Procedures 6

Microbiological Safety Cabinets (MSCs) 7

Thorough Examination and Test *7*

User Checks *7*

Routine Checks/Testing *8*

Use of Equipment 9

Personal Protective Equipment 9

TRAINING, INSTRUCTION AND INFORMATION **10**

ACCIDENT AND EMERGENCY PROCEDURES **11**

Sharps wounds/cuts *11*

Dealing with spillages *11*

Breakage of tubes inside centrifuges *11*

STERILISATION AND DISINFECTION **11**

WORKING WITH HUMAN TISSUE **12**

TRANSPORT **14**

WASTE DISPOSAL **14**

References 15

Appendix 1: Required Containment Measures for Containment Level 2 Laboratories (COSHH Schedule 3 Part II) 16

Appendix 2: Types of Microbiological Safety Cabinet 17

Appendix 3: User Checklist and log 18

Appendix 4: Routine Testing log 19

Appendix 5: Guidance on disinfectant use 20

Summary

The University is committed to ensuring the health, safety and welfare of all staff, students and visitors. To achieve this the University aims to control the risks to human health from micro-organisms and any other biological agents that people may be exposed to as a consequence of University activities.

The principal legislation that applies to biological safety is the Control of Substances Hazardous to Health Regulations 2002 (COSHH). These regulations cover hazardous substances including biological agents (pathogenic micro-organisms) and they contain a schedule of special provisions relating to biological agents. COSHH, together with the associated Approved Codes of Practice (ACOPs), require employers to assess the risks of exposure to biological agents (micro-organisms) and either prevent exposure (where reasonably practicable) or control it adequately.

Scope

This guidance document (code of practice) applies to all microbiological laboratories at the University of Bath. It covers not only deliberate work with biological agents such as in research projects but also incidental exposure such as in the taking of blood or handling of anatomical specimens. However, it does not cover exposure as a result of other routine work such as catching flu from a colleague.

Relevant definitions from COSHH are as follows:

"biological agent" means a micro-organism, cell culture, or human endoparasite, whether or not genetically modified, which may cause infection, allergy, toxicity or otherwise create a hazard to human health

"cell culture" means the in-vitro growth of cells derived from multicellular organisms

"micro-organism" means a microbiological entity, cellular or non-cellular, which is capable of replication or of transferring genetic material

This guidance document addresses the use, handling, transport, storage, disinfection and sterilisation and waste disposal of biological agents in laboratories.

While the general principles within this document will apply to genetically modified organisms, specific SHEW documentation has been produced to cover the additional legislative requirements under the Genetically Modified Organisms (contained use) Regulations 2004.

Introduction/Background

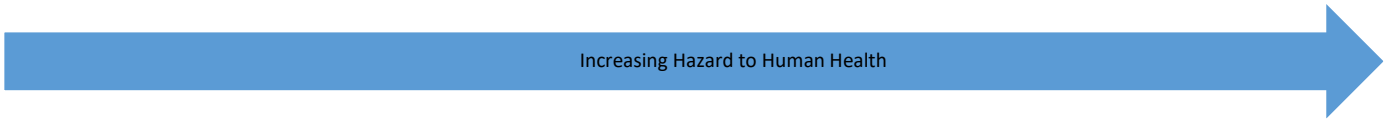
Biological agents are considered to be "substances hazardous to health" in terms of Health and Safety Legislation and so are governed by the Control of Substances Hazardous to Health (COSHH) Regulations 2002. This requires employers to prevent or reduce employees exposure to hazardous substances. Fundamental to this is the production of a COSHH Assessment. Please refer to SHEW Hazardous Substances Standard for more information regarding production of a COSHH Assessment.

Biological agents are classified into four 'hazard groups' according to the following infection criteria:

- their ability to cause infection;
- the severity of the disease that may result;

- the risk that infection will spread to the community;
- the availability of vaccines and effective treatment.

These hazard groups (HG) are:



Hazard Group 1	Hazard Group 2	Hazard Group 3	Hazard Group 4
•*unlikely to cause human disease*	•*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 treatment available*	•*can cause severe human disease and may be a serious hazard to employees* •*it may spread to the community, but there is usually effective prophylaxis or treatment available*	•*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 University of Bath currently only works with Hazard Group 1 and 2 biological agents; the facilities to work with higher class agents are not available, nor is the required regulatory permissions.

Classification and Assessment

COSHH (Schedule 3) requires every employer who is engaged in research, development, teaching or diagnostic work in laboratories which involves working with a Group 2, Group 3 or Group 4 biological agent or material containing such an agent shall ensure that measures taken to control adequately the exposure of employees to biological agents include, in particular, the most suitable combination of containment measures from those listed in the Schedule as appropriate, taking into account:

(a) the nature of the activity;

(b) the minimum containment level;

(c) the risk assessment; and

(d) the nature of the biological agent concerned.

The University of Bath only works with Hazard Group 1 and 2 biological agents and so laboratories are assigned at a maximum of containment level 2. Appendix 1 lists the containment measures required in COSHH for a containment level (CL) 2 microbiological laboratory.

Within the risk or COSHH assessment the heirachy of control (see SHEW Hazardous Substances Standard) should be applied whenever practicable for example:

Eliminating risks: e.g. by substituting a hazardous biological agent with something less/non-hazardous, e.g. using a non-toxigenic strain of a biological agent when carrying out laboratory quality control (QC) tests;

Controlling risks at source: by using engineering controls and giving collective protective measures priority, e.g. using a microbiological safety cabinet when work could create an infectious aerosol, or using needle safety devices to prevent and control needlestick injuries; and

Minimising risks by designing suitable systems of working: e.g. having an effective hand hygiene policy in place. This option also includes the use of personal protective clothing and equipment (PPE), but PPE should only be used as a last resort after considering elimination or tackling at source.

However, there is a slightly different emphasis when working with biological agents. For example, all laboratory workers wear protective clothing in the form of a laboratory coat, but may not always need to use a microbiological safety cabinet. In addition, the physical control measures in place are underpinned by the principles of good microbiological practice, e.g. the use of good aseptic techniques. Such techniques need to be taught and practiced as part of the training for the work to ensure competence, both in terms of scientific technique and safe working practices.

Security and Access

COSHH requires that at CL2, access to the laboratory must be limited to authorised persons only. Restriction of access may be imposed at the entrance to the laboratory itself or else at the entrance to the laboratory suite or unit, depending on the design of the facility and the proximity to non-laboratory areas of the building. The boundary should be established and made clear. A biohazard sign should be posted at the access point to CL2 laboratories, e.g. the main entrance to the laboratory suite, indicating the level of work undertaken. It is recommended that a list of authorised staff is kept and maintained up to date.

In addition to the COSHH Regulation requirements, some biological work will also be 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 or used by terrorists is put in place.

Example biological agents/pathogens that come under this schedule include:

- Ebola virus, yellow fever virus, polio virus;
- Bacillus anthracis, Clostridium botulinum, Salmonella typhi
- Botulinum toxins, Conotoxin, Tetrodotoxin

The full list can be found at the following: http://www.legislation.gov.uk/ukpga/2001/24/schedule/5

Laboratory Practice

Safe Working Practices and Procedures

Safe working practices are essential elements in controlling laboratory risk. Local procedures need to reflect the safe working practices required to control risks. They are most likely to work well if they are prepared in consultation with staff, the local safety committee and safety representatives.

Local rules including basic Good Microbiological Principles (GMP) should be clearly communicated to all lab users. Visitors should also be made aware of these rules and/or be supervised.

Sharp objects may cause cuts, puncture or stab wounds which could result in exposure to hazardous substance or infectious agents. Sharps include unused, disinfected or contaminated needles, syringes with needles, scalpel blades,

lancets, razor blades, also broken vials and slides, or any small broken glass items. An alternative to using a sharp should always be considered and if use cannot be eliminated then a less hazardous alternative should be sought such as plastic or blunt needles. The use of sharps must be justified in the work specific risk assessment.

Safe use procedures should be In place for using sharps. Needles should never be resheathed/capped or pointed at persons. Sharps should never be left lying around. Immediately after use you should dispose of sharps safely in a sharps bin, or make sure that they are cleaned, disinfected and/or sterilised as appropriate and stored securely such as in a beaker or in a cork ring.

Microbiological Safety Cabinets (MSCs)

Microbiological safety cabinets are intended to protect the user and environment from the aerosol hazard of infected and other hazardous biological material. To be effective, all microbiological safety cabinets should conform to British Standard BS EN 12469:2000 in terms of type, specification and performance protection provided. Siting and air filtration requirements also need to be considered. BS EN 5726:2005 provides guidance on siting of safety cabinets to ensure operator protection is not compromised by airflow disturbances due to the proximity of benches, doorways, walls and other equipment.

Please refer to Appendix 2 for further information on the types of cabinet available.

Certain operations which may generate an aerosol, such as vigorous shaking, mixing or ultrasonic disruption of any material likely to contain pathogens, must be conducted in a microbiological safety cabinet.

Where microbiological safety cabinets are used to protect the user from an inhalation hazard as a control measure in the risk or coshh assessment for the work being carried out then they are classed as Local Exhaust Ventilation (LEV). Under the COSHH Regulations 2002 they therefore must be subject to a Thorough Examination and Test (TExT) at least every 14 months and other routine checks by users.

Please, refer to SHEW Safe Use of LEV Standard for more information regarding duties and responsibilites.

Thorough Examination and Test

The TExT must be carried out by a competent person and in accordance with the requirements of the COSHH Regulations 2002, BS EN 12469:2000 and HSG 258 Controlling airborne contaminants at work, 2011 where applicable. TExT reports must be kept for at least 5 years. A copy should be available at the workplace containing the LEV system.

Departments and users are responsible for ensuring their microbiolical safety cabinets are in a safe condition for the testing to be carried out and any hazards and controls/lab rules are communicated to those carrying out the testing. Defects should be promplty reported and actioned. Those that have failed the TexT and are awaiting repair should be taken out of service with appropriate signage and communication to users.

User Checks

Users and laboratory supervisors should make regular pre-use and ongoing routine checks to confirm that performance remains satisfactory and that any faults are identified and corrected (BS EN 14175-2:2003). Manufacturers instructions and supplied log books where available should be consulted for appropriate and relevant user checks. These checks should be recorded, this could be in the available log books or alternative record sheet, an example is provided in Appendix 3.

Pre-use checks should be carried out to ensure the safety cabinet is fit for use including:

- Check that the safety cabinet has a test label fixed to the cabinet to confirm that it has been tested/examined within the last 14 months, and has passed the test. Check that the retest date has not been passed.
- Air velocity indicator, where present, is within safe parameters
- No visual or audible alarms
- Internal lighting works
- Work area clean and tidy
- Items not obstructing baffles/grilles

Report failure/defects promptly to your Laboratory Manager/Area Safety Co-ordinator/Technical Staff for remedial action.

Routine Checks/Testing

It is a requirement of the COSHH Regulations and HSG258 that routine checks and/or testing are carried out between TExTs to ensure that the safety cabinet continues to perform to the required standard and there is no variation from that reported in the TExT. Manufacturers instructions and log books provide information on what should be carried out and how frequently. This should be carried out by persons within the department who have been provided with relevant information, instruction and training.

If there are no instructions or logbook, the manufacturer should be asked for assistance. If this is unsuccessful, then an expert should be consulted, e.g., a consultant engineer (such as one who carries out the TExT) or occupational hygienist specialising in LEV to prepare suitable documentation.

BS EN 12469-4:2000 provide guidance on what this should cover if documentation is not available. Routine testing should include the following and should be recorded.

Measurement and Record of Inflow rate

For Class II MSCs:

Measure inflow velocities using a calibrated anemometer. The inflow air velocity measurements should be taken at three positions along the centre line of the aperture, one at each side and one in the middle. The measured airflows at all points must be over 0.4 m/s. Record these readings on a Log Sheet – see Appendix 4 fro an example. It is recommended that this be carried out on a monthly basis.

No individual measurement shall differ from the mean by more than 20%. Record a Fail if:

- any inflow value is less than 0.4 m/s
- if the variation is above 20%

An MSC which fails either or both of these must not be used as it will not offer the protection needed.

Downflow measurements should be taken by the servicing engineers at time of visit, and in accordance with the containment class requirements. These results must be recorded and available. The measured downflows at all points must be between 0.25 and 0.5 m/s. If they are not then they should be included as part of the department routine testing. BS EN 12469-4:2000 Annex G provides guidance on how this should be carried out and what should be recorded.

Air flow pattern visualisation

This should be done with a visible tracer such as smoke or water fog to check if any disturbance in airflow. The direction should be inward over the whole area of the front aperture and downward without undue turbulence over the work

surface. Any observations/disturbances should be recorded. Frequency of checks depends on use and whether there are any concerns regarding performance.

Inspections

Regular inspections should include checking that safety cabinets are being used in accordance with manufacturers instructions and training, that user checks are being carried out and whether there is any damage, suface defects or cracks, etc. These could be included within routine inspections and findings recorded in the inspection report.

Microbioloigcal safety cabinets that have failed the TexT and/or routine tests and are awaiting repair should be taken out of service with appropriate signage (writing on front is not acceptable) and communication to users.

MSC Good Practice

- Before starting work, turn the MSC on, remove the night door, if applicable, and allow the airflows to stabilise for at least 5 minutes
- Keep the amount of equipment in the cabinet to a minimum
- Perform operations as close to the middle of the cabinet as possible (at least 15cm from the front opening)
- Avoid excessive movement of materials and arms through the front of the cabinet
- Whenever remove hands from the MSC then must change gloves or disinfect them before putting them back into the MSC
- When remove/place hands into the cabinet allow the cabinet to stabilize before resuming work
- Keep the work area clean and tidy, both during and after use
- Any spills of viable biological agents within the cabinet must be immediately treated with a suitable disinfectant
- Bunsen burners must not be used in an MSC

Use of Equipment

Typical equipment used in laboratories are centrifuges, shakers, homogensiers, blenders and sonicators. Operation of all of these has the potential to generate aerosols, one of the main sources of infection. Therefore, risk assessments and local procedures should consider how to deal with the risks of contamination from such equipment, for example splashes and/or the generation of aerosols on to surfaces of the equipment or adjacent areas. For example by using shields or carrying out high risk operations in microbioloigcal safety cabinets. Any surfaces that are subject to contamination and to which the operator has access during work should be regularly disinfected.

Machines causing excessive splashing and/or generation of aerosols that cannot be controlled should not be used.

Users should treat any spillage that occurs inside the equipment in accordance with the supplier's instructions for decontamination.

Equipment should be tested regularly and subject to any periodic maintenance requirements in accordance with manufacturers instructions, to ensure its continued safe performance.

Personal Protective Equipment

A suitable laboratory coat must be worn at all times when working in a microbiology laboratory. At containment level 2 this must be side-fastening (Howie style), or backfastening, with elasticated cuffs and should protect the arms, neck and lap, however this type of coat is strongly recommended for all work with biological agents regardless of hazard group at the University.

Laboratory staff should wear disposable gloves where there is a risk of contamination. A supply of suitable disposable gloves in various sizes and materials should be readily available in the laboratory. The risk of latex sensitisation needs to be taken into account when selecting gloves. Gloves should not be re-used or left on a bench, once removed, to minimise the potential for spread of contamination. A punctured glove should be removed immediately and safely disposed of, whether or not there has been an injury. The person should then wash their hands and put on fresh gloves.

Suitable eye protection to British Standard BS EN 166: 1996 is needed where splashing is likely to occur and work cannot be carried out in a microbiological safety cabinet. If contaminated, eye protection should be thoroughly cleaned and disinfected before reuse.

Training, Instruction and Information

All persons working in microbiological laboratories must have a clear understanding of any identifiable risks to their health arising from work and the actions to be taken in dealing with situations in which exposure may occur. The level of training provided should be appropriate to the level of risk and the complexity of work being undertaken and should include:

- information about the risks likely to be encountered in their work;
- the principles and practice of infection control in the laboratory, as a minimum Good Microbiological Practice;
- the safe working practices and procedures for work in a particular laboratory;
- the appropriate procedures in the event of an emergency.

Improper use of sharps and poor technique (i.e., recapping/resheathing) can increase the risk of sustaining a sharps exposure or other injury. Sharps users must be properly trained in safe use, storage and disposal of sharps. This should include disposal of sharps correctly in sharps bins.

Users of microbiological safety cabinets must be trained in correct use, not only in order to understand how they work but also because poor technique can compromise the protection it provides to the user. Manufacturers instructions should be utilised in preparing this training.

Training should cover:

- Principles of how microbiological safety cabinets work, the airflow and limitations of performance
- How to work at microbiological safety cabinets safely including pre-use and ongoing checks
- Operation and function of all controls and indicators
- Actions to be carried out in the event of a system failure/what to do if something goes wrong
- Decontamination of cabinets after use

It is recommended that included in this training is a visual demonstration of how airflow can be affected when a safety cabinet is not used correctly such as with a smoke pen. This could be either through a practical demonstration within the lab or via a video or similar media.

A record of training completed should be made and kept, along with a timeframe (every 3 years is recommended) for refresher training identified in local arrangements.

Accident and Emergency Procedures

All laboratories need to clearly set out the appropriate procedures for dealing with incidents which may result in the release of biological agents. Staff must be instructed and trained in the procedures and spillages should be attended to promptly.

Sharps wounds/cuts

Anyone who sustains a sharps injury such as a needlestick should gently encourage it to bleed and wash with running water, but not scrub. Do not suck the wound. Cover the wound using a clean, dry, waterproof dressing. If it is believed that contamination may have occurred then seek medical advice via the University Occupational Health contamination incident process by calling 01225 821001. This is provided by the Royal United Hospital in Bath. You will be asked for information via a recorded message and will receive a callback. You may be required to attend the hospital for an assessment and blood tests.

An incident report should also be raised as soon as possible, to enable SHEW to aid with the OH process above if required.

Dealing with spillages

All laboratories need clear written procedures for dealing with spillages or other accidental microbial contamination. The risks from a spillage depend on:

- the type of biological agents involved;
- the amount of material spilled;
- the nature of the material, eg blood or culture;
- whether the spilled material easily forms an aerosol.

Breakage of tubes inside centrifuges

If a breakage occurs or is suspected while the machine is running, it should be switched off and the machine left closed (e.g. for 30 min) to allow settling. If a breakage is discovered after the machine has stopped, the lid should be replaced immediately and left closed (e.g. for 30 min).

Cut-proof gloves, covered if necessary with suitable disposable gloves, should be worn for all subsequent operations. Forceps (or simiLar tool) should be used to retrieve glass debris. All broken tubes, glass fragments, buckets, trunnions and the rotor should be placed in an appropriate disinfectant. The centrifuge bowl should be swabbed with the same disinfectant and then swabbed again, washed with water and dried.

Sterilisation and Disinfection

It is important to distinguish between sterilisation and disinfection. Whereas sterilisation results in destruction of all forms of life, disinfection results in destruction of specific organisms. Microorganisms vary in their resistance to destruction by physical or chemical means. A disinfectant that destroys bacteria may be ineffective against viruses, fungi or prions. There are differences in susceptibility between gram-negative and gram-positive bacteria, and sometimes even between strains of the same species. Bacterial spores are more resistant than vegetative forms, and non-enveloped, non-lipid containing viruses respond differently than do viruses which have a lipid coating.

Disinfection is commonly used where sterilisation is considered to be unnecessary, or impractical, e.g. due to the size of the object, or because it may be damaged by sterilisation. Disinfection is not an alternative to sterilisation. Sterilisation processes (e.g. steam sterilisation) are superior to chemical disinfection processes because their effectiveness can be checked.

The main use of disinfectants in the clinical laboratory is to ensure that equipment and the environment are decontaminated and safe to handle. Microbial contaminants on hands are readily removed by washing with soap or detergent. Hand decontamination should be performed after all laboratory work, even when gloves have been worn.

Procedures for dsiinfection should include:

- the wastes and contaminated articles that are to be disinfected, e.g. disposable or reusable articles that are heat sensitive, liquid wastes and effluents other than cultures;
- the disinfectant that is to be used, its use-dilution and how often it should be changed;
- the contact times to ensure inactivation;
- the methods for routine or occasional validation of the disinfection process; and
- the safe disposal of used disinfectants and the need for decontamination of containers.

Disinfectant choice should be determined by:

- the general type or identity of agents for which the disinfectant has demonstrated efficacy;
- the presence of protein or other substances likely to reduce efficacy or be chemically incompatible with the disinfecting agent; and
- the pH and temperature of the contaminated item that are compatible with safe disinfection.

Contaminated items should be completely immersed in liquid disinfectants taking care to prevent air bubbles forming. Intimate contact must be achieved between the disinfectant, whether gaseous or liquid, and the waste or contaminated surface for a sufficient length of time. Organic materials such as oil and grease residues on surfaces may prevent effective contact with the disinfectant.

Only freshly prepared ‘in-use dilutions’ should be used since stored dilutions may lose activity. Different concentrations may be recommended according to the amount of organic matter present. Excessive dilution of the disinfectant agent during use will also reduce its activity.

The table in Appendix 3 provides an overview of the types of disinfectants with their advantages and disadvantges.

In general, the common disinfectants for use at the University will be alcohols and Virkon.

Working with Human Tissue

Human blood, tissue and other biofluids may potentially carry infections. Although occupational transmission of such infections is rare, all blood tissue and secretions should be treated as potentially infectious particularly if they are from an unscreened source and all operations should be performed within containment level 2 laboratory facilities.

The removal, storage and use of human tissue is regulated by the Human Tissue Authority (HTA) under the Human Tissue Act 2004. Human tissue is defined as material that has come from a human body and consists of, or includes, human cells.

The HTA expects human tissue for research to be held under the governance of ethical approval or an HTA licence (unless certain exemptions can be met, see storage below). Where the ethical approval is not by a recognised research ethics committee, human tissue should be held under the governance of both.

A recognised research ethics committee is one which is established under and operating to the standards set out in the governance arrangements issued by the UK Health Departments, therefore the University ethics committee does not qualify.

Currently the University of Bath does not hold a HTA licence, therefore departments must ensure that any human tissue is not stored on campus within the definitions of the HT Act. Please refer to the link below for the University training requirements.

training-requirements-for-the-human-tissue-act-2004

The HT Act unfortunately does not define the term storage. Neither does it give any minimum or maximum term for storage of human tissue for research. Therefore, the HTA considers storage to be when tissue is kept for any period of time for the purpose of research, subject to the following exceptions:

- It is more than 100 years old;
- Storage is incidental to transportation (and not held for longer than week); or
- Stored with the intent to render acellular.

Blood Sample Collection

Where possible, blood from screened, anonymised sources such as out-of-date or surplus transfusion blood should, where practicable, be used instead of fresh blood from colleagues or students. This is to minimise potential exposure to blood-borne viruses such as HIV and Hepatitis B.

Any person taking blood samples from volunteers must be trained in phlebotomy, this is to ensure good infection control measures are applied. All blood should be treated as potentially infectious. The following precautions are required when taking specimens:

- a separate area should be provided for the taking of blood specimens. Blood should never be taken in any room normally used as a laboratory or office;
- protective clothing should be worn, as specified in the standard operating procedures. Such clothing normally includes a clean laboratory coat or gown and disposable gloves. Staff should never wear the same protection already worn in the laboratory when taking blood;
- when taking blood from people who are known or suspected to carry blood-borne viruses, staff also need to wear a disposable protective apron on top of their laboratory coat;
- care should be taken to avoid spillage or splashing onto the patient, staff, nearby surfaces, the outside of the sample tube, request form etc.;
- if splashing is likely to occur, staff should wear suitable eye protection;
- dispose of items used including PPE in the appropriate waste receptacles.

Persons should not work with (e.g. for research purposes) their own or close colleagues blood. A close colleague is defined as someone who works within the same laboratory. This is to prevent the possibility of alterations to genetic material by viral or other mechanisms which may then be transferred back into the body. The immune system may not recognise these changes as harmful and the person/s may therefore be susceptible to disease.

Medical Research Council guidance note 4 specifically states:

"A donor must not be present in the laboratory at any time when their cells are being handled by others and preferably should not have any access to these laboratories."

Transport

Transport on Campus

The transport of biological agents, including waste, within and between laboratories needs to be managed to minimise the potential for cross-contamination or release from indvertent spills, drops or collision events. The precautions implemented should be proportionate to the inherent hazard associated with the biological material. For example, screw capped tubes are recommended in preference to snap-cap lids. Deep-sided and leak-proof trays or boxes can be employed and where appropriate these may be securely-lidded to minimise potential for spill and/or leakage in the event of a collision or if dropped. They should be made of smooth impervious material (e.g. plastic or metal), which can be effectively cleaned and disinfected.

Transport containers should be suitably labelled to identify their contents and surface-decontaminated, where necessary, before leaving the laboratory.

Spill kits should be readily available for use in the event of an adverse incident during transport, and appropriate personnel trained in their use.

Transport off Campus

The law requires that infectious substances are packaged, labelled, and transported in a manner that minimises the risk of release during transit. The principal UK-applicable legislation with regard to the international and domestic transport of infectious substances by road, rail and air is as follows:

- **Road and Rail**: *The Carriage of Dangerous Goods and Use of Transportable Pressure Equipment Regulations 2009* (CDGR; as amended) apply both to international and domestic transport in the UK.
- **Air**: The *International Civil Aviation Organisation (ICAO) Technical Instructions for the Safe Transport of Dangerous Goods by Air* apply to air transport both within the UK and internationally.

Infectious substances are allocated to UN Class 6.2 and include pathogenic bacteria, viruses, parasites, fungi and any other biological agents that may cause disease in humans or animals. They are then further classified depending on the potential for harm if the substance were to be released during transport.
For more detailed information please refer to the ACDP guidance document Transport of Infectious Substances Appendix 1.2 (Biological agents: Managing the risks in laboratories and healthcare premises). Appendix 4 provides a summary of the classification process. For the biological agents used at the University, they will generally be classed as category B substances requiring packaging complying with UN 3373 specifications.
Also, SHEW have produced a document on Safe Transport of Biological Materials, available on request from SHEW or via the GM wiki.

In addition, there may also be other rules and regulations which need to be taken into account when considering transportation of infectious substances both within the UK and to other countries.

Waste Disposal

The majority of waste from the University microbiological laboratories will be classed as clinical waste and will either require to be rendered safe prior to disposal, e.g. by autoclaving or sent directly for incineration off campus. The procedures for this type of waste are covered in in the SHEW “Hazardous Waste Guidance document”. Therefore, this document should be consulted regarding waste disposal requirements.

References

Control of Substances Hazardous to Health (COSHH) Approved Code of Practice (ACoP) and guidance L5 Health and Safety Executive (HSE)

HSE Guidance and resources Infections at Work

Biological Agents: Managing the risks in laboratories and healthcare premises. Advisory Committee on Dangerous Pathogens (ACDP) Health and Safety Executive (HSE)

The management, design and operation of microbiological containment laboratories. Advisory Committee on Dangerous Pathogens (ACDP) Health and Safety Executive (HSE)

Safe working and the prevention of infection in clinical laboratories and similar facilities ISBN 978 0 7176 2513 0 HSE Books

The Approved List of Biological Agents. Advisory Committee on Dangerous Pathogens (ACDP) Health and Safety Executive (HSE)

SHEW Hazardous Substance Standard

SHEW Safe Transport of Biological Materials

BS EN 12469:2000 Biotechnology. Performance criteria for microbiological safety cabinets British Standards Institute ISBN 0 5803 4869 5

Code of Practice 9: Research Human Tissue Authority https://content.hta.gov.uk/sites/default/files/2020-11/Code%20E.pdf

Medical Research Council working with biological agents guidance document working-with-biological-agents

HSG258 Controlling airborne contaminants at work: A guide to local exhaust ventilation (LEV)

BS EN 12469-4:2000 Biotechnology – Performance criteria for microbiological safety cabinets

BS EN 5726:2005 Microbioloigcal Safety Cabinets – siting and use of cabinets – recommendations and guidance

Appendix 1: Required Containment Measures for Containment Level 2 Laboratories (COSHH Schedule 3 Part II)

Containment Measures	Why Required
Access is to be restricted to authorised persons only.	Minimise number of persons who could potentially be exposed, particularly those unaware of the risks and without appropriate training and therefore minimise spread of contamination outside the laboratory. This can be achieved by installing a lock and key, card key or digital lock entry system.
Specified disinfection procedure.	Ensures that the correct disinfectant is used for the orgamisms worked with for effective destruction and prevention of infection.
Efficient vector control, e.g. rodents and insects for animal containment.	Prevent spread of contamination to environment.
Bench surfaces impervious to water and easy to clean.	Prevent biological contamination from adhering to work surfaces and transferring to workers.
Bench surfaces resistant to acids, alkalis, solvents, disinfectants.	Bench surfaces must be resistant to damage to prevent biological material adhering to work surfaces and transferring to workers.
Safe storage of biological agents.	Minimises spread of contamination and provides security for material.
Where an aerosol is produced infected material, including any animal, is to be handled in a safety cabinet or isolator or other suitable containment.	Minimises exposure of laboratory workers to airborne biological agents and spread of contamination into rest of lab surfaces etc.

Appendix 2: Types of Microbiological Safety Cabinet

British Standard BS EN 12469:2000 covers three types of microbiological safety cabinet:

Class	Description	Used for
I	Open-fronted cabinets, most potentially infectious airborne particles will be contained within the cabinet. The cabinet must exhaust through a high efficiency particulate absorption (HEPA) filter to the outside air, or to the laboratory air extraction system if used for handling specimens that may contain hazard group 2 or 3 biological agents.	All hazard groups except HG4.
II	Designed to control airborne contamination of the work while at the same time controlling the exposure of the operator. In the simplified form of cabinet these two functions are achieved by a recirculating downward flow of HEPA-filtered air over the work area; part of this airflow is exhausted to the atmosphere through a HEPA filter and makeup air is drawn into the cabinet through the open work front.	All Hazard Groups. They should be used only where protection of the work is essential.
III	A totally enclosed cabinet. The escape of airborne particles is prevented by a HEPA-filtered exhaust system. A HEPA inlet filter supplies sterile air to the interior, but because of the pattern of airflow there is a greater likelihood of contamination of the work after a spill than in a Class I cabinet.	Primarily designed for total containment of work with hazard group 4 pathogens, although their use is advised for work with high titre cultures of some hazard group 3 pathogens or certain hazard group 3 pathogens which are assessed as being highly infective, eg Brucella spp., particularly those infective by inhalation. The use of Class III cabinets demands high standards of maintenance and operator training.

Appendix 3: User Checklist and log

Check	Frequency
Air velocity indicator within safe parameters	Daily
No visual or audible alarms	Daily
Internal lighting works	Daily
Work area clean and tidy	Daily
Items not obstructing baffles / grilles	Daily
Audible noise (of the system)	Daily
In-date and 'Passed' MSC statutory test label	Monthly
Anemometer check record for Inflow (authorised/trained persons carry out the check)	Monthly

User Check Record Log					
Department					
Lab/Room No.					
LEV No.					
Month/Year					
Day	Checked	Issue Y/N	Day	Checked	Issue Y/N
1			17		
2			18		
3			19		
4			20		
5			21		
6			22		
7			23		
8			24		
9			25		
10			26		
11			27		
12			28		
13			29		
14			30		
15			31		
16					
All issues to be reported and recorded					

Appendix 4: Routine Testing log

Class II MSC Routine Testing Logs

Monthly Anemometer Readings Log (Inflow Velocity Check)

Department	
Lab/room No.	
LEV No.	

Date:		Name/Initials:
		
Highest Value	Lowest Value	Average Value
m/s	m/s	m/s
Within 20%	Pass/Fail	

Visualisation (Smoke Test/Water Fog) Test Observations Log

Department	
Lab/room No.	
LEV No.	

Date:	Name/Initials:
Observations:	
Pass/Fail	

Note: It is recommended that the smoke test/water fog test is performed periodically to provide continued assurance that contaminants are captured, or as an additional check if the air flow does not seem to be satisfactory.

Appendix 5: Guidance on disinfectant use

Type/Name	Concentration/Contact time	Effective against	Disadvantages	Additional Information
Hypochlorites e.g. sodium hypochlorite also known as household bleach and NaDCC (tablets) 	<10% Can be used for general wiping so contact time minimal	Highly effective against bacteria, viruses and fungi. They have limited activity against bacterial spores. They are not very effective against Mycobacterium spp.	Corrosive, particularly to skin, eyes and metals. Strong oxidising agent. Reacts with acids to form chlorine gas.	Due to health hazards should **not** be used with the exception of TSE/prions contamination or spill if necessary. NaDCC tablets, if correctly diluted, do not present as significant health hazards and can be used for cleaning up blood spills.
Phenolics: phenol based agents kept in aqueous solution by detergents, e.g. Hycolin, Stericol and Clearsol 	Consult manufacturer's data.	These are effective against bacteria, fungi and have some activity against a limited range of viruses but are poor against non-enveloped viruses. They have no activity against bacterial spores.	Contain Phenol and associated compounds which are corrosive and highly toxic.	Due to the introduction of the Biocidal Product Regulations 2006 phenolic based disinfectants are no longer available on the market. Any existing stocks should not be used and disposed of as soon as practicable. It should be ensured that any similar products are authorised for use.
Peroxygen compounds e.g. Virkon 	1% Virkon in water; minimum contact time 10 minutes, stable for 7 days	Effective against bacteria, viruses and fungi, but can be variable with bacterial spores and Mycobacterium spp.	None apart from effectiveness against some microorganisms.	Low health hazards particularly when dilute, can be disposed of to drain, powder can be used to clean up blood/body fluid spills, compatible with many materials
Alcohols e.g. Ethanol, IPA 	70% ethanol in water; 60% IPA in water minimum contact time 10 minutes	They are active against bacteria, fungi and lipid-containing viruses but not against spores. Their action on nonlipid viruses is variable.	Flammable therefore must be appropriately controlled and stored. Care should be taken when decontaminating electrical equipment.	Do not tend to leave a residue like other products.
Quaternary ammonium compounds e.g. household type products such as Dettol, Flash 	Generally purchased ready diluted or instructions provided. Contact time 10 minutes to allow to dry.	They are active against bacteria, and lipid-containing viruses but not against fungi, spores and non-lipid viruses. They are not very effective against Mycobacterium spp.	Activity of some types can be considerably reduced by organic matter, water hardness and anionic detergents (soap).	Due to their limited range of effectiveness, these are best used on non-critical surfaces such as floors.

Aldehydes e.g. Glutaraldehyde, Formaldehyde 	Formaldehyde is used in gaseous form to fumigate safety cabinets/labs. It is slow acting and needs to right conditions to be effective. Glutaraldehyde is fast acting against most microorganisms with the exception of spores.	Glutaraldehyde effective against whole range of microorganisms. Formaldehyde effective for all microorganisms and spores at temperatures above 20 °C. However, it is not active against prions	Glutaraldehyde has a WEL of 0.05ppm as a respiratory sensitiser. Formaldehyde has a WEL of 2ppm, is toxic and a potential carcinogen.	Neither of these should be used due to their significant health effects.
Iodine and Iodophors, e.g. Evans, VIrophor 	Recommended contact time is 30 minutes, see manufacturers date for concentration to be used depending on use.	Effective against bacteria, viruses and fungi. They have limited activity against bacterial spores.	Iodine can stain surfaces and iodophors are more an antiseptic/sanitiser than a disinfectant.	Approved mainly for agricultural applications, therefore not really suitable reliable laboratory disinfectants.

Appendix 6: Transport Classification Guidance