



Containment Level 3 Derogated Laboratories

1. Containment Laboratories and Control Measures

The effective containment and control of work involving biological materials, biological agents, genetically modified organisms, animals and plants is required to protect people from exposure and prevent any release into the environment. The containment and control measures required for work are determined by a combination of compliance with the relevant minimum legal standards, regulatory guidance, licence requirements and also the outcomes of risk assessments.

2. Containment Levels

There are three containment levels used in university laboratories, animal and plant facilities. The containment level needed depends on the regulatory requirements, the overall nature of the work and the risk assessments. The physical containment level is used to determine which controls are required.

- **Containment level 1** (CL 1) for low risk work involving group 1 biological agents, class 1 genetically modified microorganisms and genetically modified animals or plants.
- **Containment level 2** (CL 2) for medium risk work involving group 2 biological agents, class 2 genetically modified microorganisms and genetically modified animals or plants.
- **Containment level 3** (CL 3) for high risk work involving group 3 biological agents, class 3 genetically modified microorganisms and genetically modified animals or plants.
- **Derogated Containment level 3** (Derogated CL 3) for work involving derogated group 3 biological agents, class 3 genetically modified microorganisms and high risk genetically modified animals or plants but where not all controls normally required as a minimum for full containment level 3 are required.

This guidance provides information on the basic requirements for containment level 3 derogated laboratories together with some typical controls but it is not exhaustive and you will need to do other things as well depending on the specific work and risk assessments. There are many important regulations and guidance sources as well as licence conditions which may have to be complied with depending on the exact nature of the work. The regulations and guidance provides details of the standard containment and control measures for work involving biological agents, genetically modified organisms, specified animal pathogens and plant pathogens and pests, animals and plants. The relevant regulatory guidance must be referred to when making decisions on the containment levels and specific controls required for any work. There are very important containment tables in these documents which summarise the minimum containment conditions and related control measures



which are normally required for each containment level. However in certain circumstances it may be acceptable to use less than the minimum containment and control conditions normally required either subject to application to the regulator for a derogation where the measures are absolutely required for that containment level, or subject to the findings of a suitable and sufficient risk assessment where the measures are conditionally required to comply with a standard so far as reasonably practicable for that containment level. Please note that this guidance is just an overview of typical containment and control measures and is not intended to describe all the necessary controls which will be required for your work. Please contact your School Biological Safety Adviser if you need advice on any aspect of biological safety, risk assessments, containment and control measures.

3. Guidance Sources for Containment Laboratories

There is detailed regulatory guidance on safe working with biological agents and genetically modified organisms, containment and control which is available from the Health and Safety Executive (HSE), Animal Health and Plant Health. Please see the links below to some of the key regulatory guidance documents and website resources. Please see the links below to some important resources.

3.1 Guidance

- [HSE Control of substances hazardous to health](#)
- [HSE Genetically modified organisms \(contained use\)](#)
- [HSE Containment and control of specified animal pathogens](#)
- [HSE ACDP Management and operation of microbiological containment laboratories](#)
- [HSE SACGM Compendium of guidance](#)
- [HSE Sealability of microbiological containment level 3 and 4 facilities](#)

3.2 Websites

- [HSE Biological Safety](#)
- [HSE Biological Agents](#)
- [HSE Genetically Modified Organisms](#)
- [HSE Specified Animal Pathogens](#)
- [Animal Health \(Scotland\)](#)
- [Plant Health \(Scotland\)](#)
- [Animal and Plant Health Agency](#)



4. Good Microbiological Practice and Good Occupational Safety and Hygiene

The general principles of risk control for work involving biological agents and genetically modified organisms to protect people and the environment can be summarised as good microbiological practice (GMP) and good occupational safety and hygiene (GOSH).

1. Design and operate processes and activities to minimise emission, release and spread of hazardous substances.
2. Take into account all relevant routes of exposure including inhalation, ingestion, injection and skin absorption when developing control measures.
3. Control exposure by measures that are proportionate to the risks.
4. Choose the most effective and reliable control options which minimise the escape and spread of hazardous substances.
5. Where adequate control of exposure cannot be achieved by other means, provide in combination with other control measures suitable personal protective equipment.
6. Check and review regularly all elements of control measures for their continuing effectiveness.
7. Inform and train all workers on the hazards and risks from the substances with which they work and the use of control measures developed to minimise the risks.
8. Ensure that the introduction of control measures does not increase the overall risk to health and safety.
9. Keep workplace and environmental exposure to any biological agents or genetically modified organisms to the lowest reasonably practicable level.
10. Block all routes of exposure and release by the consistent application of effective containment and control measures.
11. Exercise engineering control measures at source and supplementing these with appropriate equipment and personal protective clothing where necessary.
12. Test and adequately maintaining control measures and equipment.
13. Test where necessary for the presence of viable process organisms outside the primary physical containment.
14. Provide safe storage for contaminated laboratory equipment and materials where appropriate.
15. Provide effective disinfectants and specified disinfection procedures available in case of spillage.
16. Display biological hazard signs where appropriate.
17. Prohibit in the work area all mouth pipetting, eating, drinking, smoking, applying cosmetics or the storing of food for human consumption.
18. Provide washing and decontamination facilities for personnel.
19. Provide appropriate information, instruction, training and supervision of personnel.



20. Provide and implement local codes of practice and written standard operating procedures to ensure safety.
21. Keep adequate records.

5. Containment Level 3 Derogated Laboratories

Containment level 3 (CL 3) is used for high risk work with hazard group 3 biological agents, class 3 genetically modified organisms, animals and plants. This guidance is a summary of some important controls used for work in containment level 3 laboratories but is not exhaustive and you will need to do other things as well depending on your specific work, local policies, risk assessments, regulatory requirements and licences. Derogated Containment level 3 (Derogated CL 3) is used for work involving derogated work with group 3 biological agents or class 3 genetically modified microorganisms using less than the minimum containment conditions normally required.

5.1 Local Rules and Risk Assessments

- Appropriate safety and security arrangements must be in place to ensure compliance with relevant legal standards and protect people and the environment.
- Managers and principal investigators are responsible for health and safety management, risk assessment and control.
- There must be suitable policies, local rules, risk assessments and effective controls for the work.
- There should be a code of practice and standard operating procedures including emergency procedures.
- A security plan may be required for work involving designated pathogens, toxins or other relevant materials controlled under terrorism laws, which should include site, building, laboratory, personnel, data, transport and emergency requirements.
- All workers and visitors have health and safety responsibilities.
- Risk assessments must be carried out where they are required including general risk assessments, COSHH, BA and GM risk assessments.
- BA and GM risk assessments help you identify the biological hazards, evaluate the risks and decide on appropriate control measures to enable you to do the work safely and reduce the risks of incidents.
- All activities must be covered by written standard operating procedures.
- There must be a list of all authorised persons who have access to the laboratory.
- All workers and visitors must have adequate information, instructions, training and supervision.
- Managers and principal investigators must monitor activities to ensure risk assessments, controls and standard operating procedures are effective and implemented.



- Risk assessments, controls and standard operating procedures must be reviewed and amended where there are significant changes to the activity or risks.
- Managers and principal investigators must keep risk assessments, standard operating procedures and other important records.
- There should be adequate communication and cooperation between users of shared laboratories and facilities in relation to the hazards, risks and control measures required to protect health and safety.
- Important standard operating procedures, emergency procedures and emergency contact information must be visibly displayed where needed in the laboratory.
- School Safety Advisers and School Biological Safety Advisers are available to provide support and advice on health and safety management.

5.2 Laboratory Safety Folders

- There should be a laboratories safety folder which contains the relevant safety information.
- General, COSHH, BA and GM risk assessments.
- Code of practice (CoP).
- Standard operating procedures (SOP) for routine and emergency procedures.
- Safety data sheets.
- Inventories.
- Lists of authorised persons.
- Emergency contact information.

5.3 Security and Signage

- Laboratories and hazardous materials must be secure and properly controlled.
- Laboratories should be locked when not in use or unoccupied.
- Access should be restricted to only authorised persons.
- Visitors and contractors must be adequately supervised.
- Access to laboratories must be controlled using suitable means appropriate for the risks (eg lock and key, swipe card, digital lock).
- Safety signs which are required and should be on laboratory doors for containment level 3 laboratories include (a) authorised persons, (b) biological hazards and (c) containment level 3.



Containment Level 3 (Derogated)

- Relevant safety signs are required for laboratories and equipment (eg biological hazards, chemical hazards, radiation hazards, containment level, flammables and gas cylinders).

5.4 General

- Containment level 3 derogated laboratory consists of a lobby and laboratory or may be single laboratory.
- Containment level 3 derogated laboratory suite may consist of one or more laboratories.
- Laboratory should contain its own equipment (so far as reasonably practicable).
- Laboratory must be sealable to permit fumigation unless this is not required because of derogation.
- Laboratory should be separated from other activities in building.
- Laboratory should have adequate ventilation and temperature control.
- Suitable means of communication should be provided (eg phones and computers).
- Suitable means of detection and warning of emergencies should be provided (eg fire detection/alarms, and gas monitors/alarms).
- Observation windows or alternative (eg CCTV) means of viewing occupants should be provided.
- Surfaces of benches, floors and walls should be impervious to water, easy to clean, resistant to acids, bases, solvents and disinfectants.
- Benches should be constructed of robust material using non-shrink sealants.
- Adequate space and light should be provided for workers and activities.
- Effective inward airflow and negative pressure must be maintained and extracted exhaust air must be HEPA filtered before discharge.



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- Air supply and extract systems should be interlocked and using other means of control to prevent positive pressurisation.
- Air extracts and inputs should not interfere with performance of microbiological safety cabinets or isolators.
- Procedures using hazardous materials or infectious aerosols must be adequately contained (eg equipment, safety cabinets, centrifuges, shakers).
- Microbiological safety cabinets should be used for work where aerosols could be produced.
- Microbiological safety cabinets should be inspected, maintained and tested at least every year but this may be required to be more frequent (eg 6 months).
- Centrifuges should have sealed buckets or rotor which can be opened inside safety cabinets where needed.
- Laboratory ventilation and safety cabinets should be regularly inspected, maintained and tested usually at least every six months.
- Laboratory sealability must usually be validated at least annually unless this is not required because of derogation.
- Validated standard fumigation and emergency fumigation procedures are required unless this is not required because of derogation.
- Lone working should be avoided but if there is no alternative then adequate controls must be used including supervision, active monitoring and the use of lone worker monitor/alarms.
- Avoid use of sharps unless really required and then adequate risk controls should be used.
- Avoid and minimise generation of aerosols.
- Biological materials, biological agents, genetically modified organisms, animals and plants should be safely and securely stored.
- Multiple containment should be used for storage of hazards.
- Biological materials, biological agents, genetically modified organisms, animals and plants should be safely and securely transported.
- Multiple containment should be used for transport of hazards.
- Use suitable robust containers and label accurately for internal transport in and between buildings and where necessary use trolleys and spills kits.
- Use correct packaging containers, labels and protocols for external transport.
- Use the required personal protective equipment (eg lab coat, gowns, gloves, specs, goggles or face shield).
- Disinfect equipment and working surfaces after use where required.
- Disinfect spillages.
- Do not store or consume food or drink in laboratory.
- Do not store outdoor clothes or bags in laboratory.
- Good personal hygiene practices are necessary in laboratories.
- Cover cuts and broken skin with waterproof dressings.
- Handwash sinks preferably with an emergency eyewash hose should be sited near to exit doors.
- Taps should preferably operate without being touched by hand.



- Liquid soap and paper towel dispensers should be provided.
- Emergency eyewash hose should be provided which can be used for cleaning eyes, mouth or body in case of personal contamination by any hazards.
- Wash hands after completion of work activities and immediately after any contamination is suspected or handling hazardous materials.
- Laboratory sinks should only be used for work and not used for hygiene and washing hands.

5.5 Safe Use of Sharps

- Avoid the use of sharps unless they are essential since sharps can cause serious injuries and exposure to biological hazards and other hazardous substances.
- Think and plan carefully how the work can be done to reduce the risks of exposure and sharps injuries.
- Use safe techniques when using sharps.
- Use alternative safety sharps where possible if you can (eg syringes with retractable needles and scalpels with retractable blades).
- Use forceps to hold tissues or materials.
- Use blunt instead of sharp needles, scissors and forceps.
- Use core borers instead of scalpels if possible.
- Do not hold materials with hands unless there is really no alternative and it is essential.
- Use forceps or clamps to hold materials when cutting etc.
- Keep the other hand without the sharp as far apart as possible from the hand holding and using the sharp to reduce the risk of stab or cut injuries.
- Generally the further apart your two hands are the less likely you are to injure yourself in a sharps incident.
- Do not pass or transfer used sharps to other people.
- Do not re-sheath needles.
- Store sharps where necessary in solid boxes to prevent contact with them causing injuries.
- Do not leave your sharps lying around since they can injure you and other people and cause incidents.
- Dispose of waste materials carefully and using the correct route.
- Dispose of sharps immediately after use.
- Use puncture resistant sharps bins to dispose of used sharps.
- Take the sharps bin to the sharps not the other way around.
- Put the sharps bin where you are going to use the sharps.
- Lock the lid onto the sharps bin before use and do not overfill sharps bins.
- Do not push objects or fingers into opening of the sharps bin.
- Use personal protective equipment.
- Sharps resistant gloves can offer useful additional protection for some activities.



5.6 Personal Protective Equipment

- Appropriate personal protective equipment (PPE) should be used where required.
- PPE is essential for many aspects of work but generally as additional rather than the main method of protection.
- Suitable laboratory coats or gowns should be used.
- Suitable gloves should be used where required.
- Suitable spectacles, goggles or face shields should be used where required.
- Specialist gloves may be needed for specific biological, chemical and physical hazards.
- Disposable or reusable clothing or PPE (eg overalls, suits, overshoes, caps, gowns and masks) should be used where required.
- Boots, shoes, aprons, visors etc should be used where required.
- Gloves should be worn for work with hazardous or infectious materials.
- Gloves should be used with care to prevent contamination of materials, surfaces and equipment.
- Gloves should be removed and disposed if they become contaminated.
- Gloves must be worn for all work at containment level 3.
- Gowns and coats should be stored in a suitable location in the laboratory or laboratory suite.
- Gowns and coats may need to be autoclaved before laundering or disposal.
- Respiratory protective equipment (RPE) should be used where required but must be properly selected, individually fitted, inspected, maintained and tested.
- RPE may be required in addition, but should not be used as an alternative to more effective control measures like safety cabinets.
- PPE should be removed before leaving the work area and kept apart from normal clothing.
- PPE should be properly stored, kept clean, maintained and cleaned at suitable intervals.

5.7 Waste Inactivation and Disposal

- Waste should be properly labelled, safely handled, stored, transported and disposed.
- Hazardous biological or infectious materials should be properly inactivated using a suitable validated method or combination of methods before waste disposal.
- Waste bags and sharps bins should not be overfilled.
- Dispose of waste safely using appropriate containers and correct waste routes (eg waste bags or bins, sharps bins, hazardous or non-hazardous waste, biological, chemical or radioactive waste).



- Local rules must state specific arrangements for waste inactivation and disposal.
- Validation and monitoring of effectiveness is required to prove that an inactivation method works to the required standard.
- Effective disinfectants should be available and used.
- Disinfectants should be suitable for the biological agents, genetically modified organisms, animals and plants used in the work.
- Check manufacturer's instructions and validation of effectiveness of disinfectants.
- Regular cleaning and decontamination of surfaces, safety cabinets and benches etc is required.
- Autoclaves should be located in the laboratory suite unless an alternative location is approved in the derogation.
- Laboratory autoclaves should be inspected, maintained and tested at least every year but this may be required to be more frequent..
- Validation of effectiveness is required for autoclaves using annual thermocouple testing of standard loads.
- Monitoring of effectiveness is required for autoclaves for every run by using either electronic probes and data recorders or printers, or using indicator strips, both of which need to be kept for records.

5.8 Emergency Procedures

- Emergency procedures should be prepared in advance for dealing with safety and security incidents and emergencies.
- Emergency procedures should be determined in risk assessments and set out in standard operating procedures.
- Names and contact details of principal investigators, responsible persons and local safety advisers should be available in laboratory.
- First aid facilities should be provided.
- Workers must understand and be able to implement emergency procedures.
- Assess the incident or emergency before deciding and taking any action.
- Inform others of incidents and isolate the area or evacuate if required.
- Seek assistance and use PPE if required.
- Seek first aid and medical treatment if required.
- Individuals involved in significant incidents should be sent to hospital for clinical assessment and treatment if needed.
- Decontaminate the work area or laboratory after an incident or emergency.
- Obtain assistance from the emergency services where needed (eg Ambulance, Fire, Police and Security).
- Report incidents and emergencies immediately practicable to supervisors, safety officers or managers.



5.9 Spillages and Releases

- Emergency procedures should be prepared in advance for dealing with spillages and releases.
- Emergency spillages and release procedures should be determined in risk assessments and set out in standard operating procedures.
- Minor spillages may be decontaminated using disinfectants.
- Major spillages require evacuation and fumigation of laboratory.
- Instructions, spills kits and PPE should be provided.
- Instructions should be provided on laminated sheet near equipment where required.
- Notify other workers and isolate area if required.
- Evacuate laboratory immediately if significant spillage, contamination or risk of airborne exposure.
- Allow aerosols to settle.
- Contain spillages with tissues or granules where required.
- Cover with suitable disinfectant liquid or granules where required.
- Allow sufficient contact time before clean up.
- Clean up debris gently and do not use a brush.
- Pick up broken glass carefully (eg forceps or swabs).
- Put debris in a suitable waste or sharps container for safe disposal.
- Disinfect contaminated surfaces and equipment.

5.10 Personal Contamination or Injury

- Emergency procedures for dealing with injured or contaminated persons is required.
- Emergency procedure for evacuation of injured persons may be required.
- Remove contaminated clothing as quickly as possible and leave in laboratory.
- Remove contamination from skin, eyes and mouth by thorough washing with water.
- Minor cuts and small puncture wounds should be encouraged to bleed.
- Wash wounds with soap and water.
- Dress wounds.
- Use PPE if required when helping injured persons.
- Seek help where required including where relevant first aid or hospital.
- Emergencies should be sent to hospital and call ambulance if necessary.
- Explain incident and biological agents or genetically modified organisms to medical staff.
- Report all incidents immediately or as soon as practicable.



5.11 Information, Instruction, Training and Supervision

- Information on safety and security should be provided to all workers on hazards, risks, control measures, monitoring, health surveillance and emergency procedures.
- All workers must be given clear written information and training about any significant relevant diseases and infections to which they might potentially be exposed at work or which might pose a potential danger to other people or the environment.
- Instructions should be provided to all workers on controls and actions including safe handling, storage, transport, disinfection, inactivation, disposal and emergency procedures.
- Training should be provided to all workers on detailed and effective application of control measures and emergency procedures.
- All workers must be adequately trained and supervised.
- All workers must be able to recognise how exposure or release can occur and how it can be prevented.
- All workers must be trained and proficient in safe working practices and techniques to protect themselves and other persons in the laboratory as well as the environment.

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